European Commission

Study to assess requests for renewal of 12 exemptions to Annex III of Directive 2011/65/EU

Under the Framework Contract: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation

Final Report

19 December 2022

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Table of Contents

1. SUMMARY – ENGLISH 13
1.1. Background and objectives 13
1.2. Key findings – Overview of the evaluation results 14
2. NOTE DE SYNTHÈSE : FRANÇAIS 20
2.1. Contexte et objectifs 20
2.2. Principales conclusions - Aperçu des résultats de l'évaluation 21
3. INTRODUCTION 26
3.1. Project scope 26
3.2. Links between the RoHS Directive and the REACH Regulation 29
4. EXEMPTION 4(F) OF ANNEX III: HG IN DISCHARGE LAMPS NOT MENTIONED IN ANNEX III 33
Declaration 33
Acronyms and Definitions 33
4.1. Background and Technical Information 33
4.1.1. Summary of VDMA (2020) exemption request: 34
4.1.2. Summary of LEU (2020) exemption request: 34
4.1.3. History of the Exemption 35
4.1.4. Technical description of the exemption and use of restricted substance 36
4.1.5. Amount of mercury used under the exemption 42
4.2. Applicant's justification for the requested exemption 44
4.2.1. Substitution and elimination of mercury 44
4.2.2. Roadmap towards substitution or elimination of mercury in lamps 51
4.2.3. Environmental arguments and socioeconomic impacts 52
4.3. Critical review 54
4.4. References 54
5. EXEMPTIONS 8(B) AND 8(B)(I) OF ANNEX III: CADMIUM IN ELECTRICAL CONTACTS 58
Declaration 58
Acronyms 59
Definitions 59
5.1. Background and technical information 60
5.1.1. History of the exemption 61
5.1.2. Summary of the requested exemption 62
5.1.3. Technical description of the exemption and use of the restricted substance in electrical switching contacts 63
5.1.4. Cadmium in fixed contacts in oxygen and capnography sensors 67
5.1.5. Amount(s) of restricted substance(s) used under the exemption 69
5.2. Justification of the requested exemption 69

5.2.1. Substitution of cadmium 70
5.2.2. Environmental, health and safety, and socioeconomic impacts 72
5.2.3. Roadmap towards substitution or elimination of cadmium 73
5.3. Critical review 74
5.3.1. REACH compliance – Relation to the REACH Regulation 74
5.3.2. Market situation and delays in announced cadmium substitution in electrical contacts: Protective and other switches 75
5.3.3. Substitution/elimination of cadmium in switching contacts for cat. 8 and 9 EEE (ex. 8(b)) 77
5.3.4. Substitution and elimination of cadmium in "fixed" electrical contacts (ex. 8(b)) 82
5.3.5. Substitution or elimination of cadmium in protective switches (ex. 8(b)(I)) 89
5.3.6. Substitution and elimination of cadmium in other switches (ex. 8(b)(I)) 90
5.3.7. Environmental arguments and socioeconomic impacts 91
5.3.8. Summary and conclusions 92
5.4. Recommendation 96
5.5. References 102
6. EXEMPTION 9 OF ANNEX III: HEXAVALENT CHROMIUM IN ABSORPTION REFRIGERATORS 104
Declaration 104
Acronyms 105
Definitions 105
6.1. Background and Technical Information 105
6.1.1. History of the Exemption 106
6.1.2. Summary of the requested exemption 107
6.1.3. Technical description of the exemption and use of the restricted substance 107
6.1.4. Amount(s) of restricted substance(s) used under the exemption 110
6.2. Justification for the requested exemption 111
6.2.1. Substitution and elimination of Cr-VI in GAHPs 111
6.2.2. Roadmap towards substitution or elimination of Cr-VI 111
6.2.3. Environmental and socioeconomic impacts 112
6.3. Critical review 114
6.3.1. REACH compliance – Relation to the REACH Regulation 114
6.3.2. Scientific and technical practicability of substitution or elimination of Cr-VI 116
6.3.3. Environmental arguments and socioeconomic impacts 121
6.3.4. Summary and conclusions 127
6.4. Recommendation 130
6.5. References 131

7. EXEMPTION 9(A)-II OF ANNEX III: HEXAVALENT CHROMIUM IN ABSORPTION REFRIGERATORS 134
Declaration 134
Acronyms and Definitions..... 134
7.1. Background and Technical Information 134
7.1.1. History of the Exemption 135
7.1.2. Summary of the requested exemption 136
7.1.3. Technical description of the exemption and use of the restricted substance 136
7.1.4. Amount(s) of restricted substance(s) used under the exemption 136
7.2. Justification for the requested exemption 137
7.2.1. Substitution of Cr-VI in absorption refrigerators 137
7.2.2. Roadmap towards substitution or elimination of Cr-VI 137
7.2.3. Environmental and socioeconomic impacts 137
7.3. Critical review 138
7.3.1. REACH compliance – Relation to the REACH Regulation 138
7.3.2. Scientific and technical practicability of substitution or elimination of Cr-VI 139
7.3.3. Environmental arguments and socioeconomic impacts 140
7.3.4. Summary and conclusions 141
7.4. Recommendation 141
7.5. References 142
8. EXEMPTION 13(A) OF ANNEX III: LEAD IN WHITE GLASSES USED FOR OPTICAL APPLICATIONS 144
Declaration 144
Acronyms and Definitions 144
8.1. Background and Technical Information 145
8.1.1. History of the Exemption 145
8.1.2. Summary of the renewal request and stakeholder contributions..... 146
8.1.3. Technical description of the exemption and use of restricted substance 147
8.1.4. Amount(s) of restricted substance(s) used under the exemption 152
8.2. Justification for the requested exemption 152
8.2.1. Substitution and elimination of lead 152
8.2.2. Roadmap towards substitution or elimination of lead 159
8.2.3. Environmental and socioeconomic impacts 162
8.3. Critical review 163
8.3.1. REACH compliance – Relation to the REACH Regulation 163
8.3.2. Scope Clarification 164
8.3.3. Scientific and technical practicability of substitution or elimination of lead 168
8.3.4. Environmental arguments and socioeconomic impacts 174

8.3.5. Summary and conclusions 174
8.4. Recommendation 175
8.5. References 177
9. EXEMPTION SERIES 13(B) OF ANNEX III: CADMIUM AND LEAD IN FILTER GLASSES AND GLASSES USED FOR REFLECTANCE STANDARDS 179
Declaration 179
Acronyms and Definitions 179
9.1. Background and Technical Information 180
9.1.1. History of the Exemption 181
9.1.2. Summary of the requested exemptions 182
9.1.3. Technical description of the exemption and use of restricted substance 183
9.1.4. Amount(s) of restricted substance(s) used under the exemption 195
9.2. Justification for the requested exemption 196
9.2.1. Substitution and elimination of cadmium and lead 196
9.2.2. Roadmap towards substitution or elimination of cadmium and lead 206
9.2.3. Environmental and socioeconomic impacts 208
9.3. Critical review 210
9.3.1. REACH compliance – Relation to the REACH Regulation 210
9.3.2. Scientific and technical practicability of substitution or elimination of lead 213
9.3.3. Environmental arguments and socioeconomic impacts 224
9.3.4. Summary and conclusions 224
9.4. Recommendation 229
9.5. References 231
10. EXEMPTIONS 15 AND 15(A) OF ANNEX III: LEAD IN FLIP CHIP PACKAGES 234
Declaration 234
Acronyms and Definitions 235
10.1. Background and technical information 235
10.1.1. History of the exemption 236
10.1.2. Summary of the requested exemption and stakeholder contributions 236
10.1.3. Technical description of the exemption and use of the restricted substance 237
10.1.4. Amount(s) of restricted substance(s) used under the exemption 240
10.2. Justification for the requested exemption 242
10.2.1. Substitution of lead in FCPs with semiconductor technology nodes of 90 nm or greater 242
10.2.2. Substitution of lead in FCPs with a single die of 300 mm^2 or larger in any semiconductor technology node 243
10.2.3. Substitution of lead in FCPs with stacked die packages 243

10.2.4. Substitution of lead in FCPs with bonds to CZT for cat. 8 medical devices other than IVDs (ex. 15) 244
10.2.5. Roadmap towards substitution or elimination of lead 245
10.2.6. Environmental and socioeconomic impacts 246
10.3. Critical review 246
10.3.1. REACH compliance – Relation to the REACH Regulation 246
10.3.2. Scope and numbering of the renewed exemption 15 248
10.3.3. Scope of exemption 15(a) 249
10.3.4. Substitution and elimination of lead in CZT detectors in medical devices other than IVDs (renewal of ex. 15) 251
10.3.5. Substitution or elimination of lead uses in FCPs in scope of exemption 15(a) 253
10.3.6. Request for general exclusion of legacy products from substance restrictions 263
10.3.7. Environmental arguments and socioeconomic impacts 264
10.3.8. Summary and conclusions 265
10.4. Recommendation 267
10.5. References 268
ANNEX TO THE EXEMPTION 13(B) SERIES 271

List of Figures

Figure 3-1: Relation of REACH categories and lists to other chemical substances 30

Figure 4-1: Chart on the hierarchy of lamps and exemptions 37

Figure 4-2: Standard mercury lamp and UV LED intensity as a function of spectra 38

Figure 4-3: UV spectra of Mercury medium and low-pressure lamps 39

Figure 4-4: examples of projection lamps 39

Figure 5-1: Outline of an oxygen sensor 67

Figure 5-2: Cadmium in fixed electrical contacts 68

Figure 6-1: Functional principle of a GAHP 108

Figure 6-2: Simplified gas absorption heat pump process 109

Figure 6-3: Environmental impacts (CB impacts subtracted from GAHP) 125

Figure 6-4: Environmental impacts (HS subtracted from GAHP) 125

Figure 8-1: Selected devices and their users 151

Figure 8-2: Characteristics of optical glass and plastic types in Abbe diagram 153

Figure 8-3: Graph of light transmission versus wavelength of light 154

Figure 8-4: Graph of stress optical constant and refractive index for optical glass 155

Figure 8-5: Example for the correction of chromatic aberration via the combination of a lens with low and a lens with high Abbe number 168

Figure 8-6: Schematic depiction of the dependency of resolution on Numerical Aperture 170

Figure 8-7: Transmission of optical fibres, quotient spectrum before irradiation 171

Figure 9-1: Idealised shapes of transmission / wavelength curves for light passing through optical filters 185

Figure 9-2: Light transmission / wavelength curve for VG9 optical filters 187

Figure 9-3: Visualization of the long pass filter definition 188

Figure 9-4: Difference in electronic structure of metals, semiconductors and insulators 188

Figure 9-5: Absorption and transmission diagram of an optical striking glass filter 189

Figure 9-6: Optical transmission spectra of cadmium-based glass filters........................190

Figure 9-7: Position of lamp and yellow filter in Humphrey Field Analyser 191

Figure 9-8: Exemplary product examples for reflectance standards...............................192

Figure 9-9: Comparison of cadmium reflectance curve (in blue) and an alternative without cadmium (in red) 193

Figure 9-10: Infrared gas analysis using lead-containing optical filters 194

Figure 9-11: Optical transmission spectra of coloured filter glass (25 mm thickness) comparing slope shapes of CdS, CuInS and CuInSe 199

Figure 9-12: Spectra of ionically coloured glass (top) compared with cadmium glass (bottom)..199

Figure 9-13: Spectra of interference coated filters with coloured glass filters 200

Figure 9-14: Spectra of light transmission for commercial plastic filters........................202

Figure 9-15: Transmission spectra of lead telluride (blue) and germanium (red) coatings 205

Figure 9-16: Transmittance of the filter glass VG9 as a function of the wavelength 218

Figure 9-17: Transmittance of Cd-containing versus Cd-free filter glass........................220

Figure 10-1: Outline of a flip chip package 238

Figure 10-2: Thermomechanical deformation of level 1 solder bumps in FCPs 238

Figure 10-3: Increased thermomechanical stress in larger die FCPs 239

Figure 10-4: Circuit board with carrier circuit onto which the CZT semiconductor crystal is flip-chip bonded 240

Figure 10-5: Example of a stacked die package with a large silicon interposer 243

Figure 10-6: FCP technologies and years of market introduction 255

List of Tables

Table 1-1: Overview of exemption requests, recommendations and expiry dates............15

Tableau 2-1: Aperçu des demandes d'exemption, des recommandations et des dates d'expiration. 22

Table 3-1: Overview of exemptions on Annex III to be reviewed..........26

Table 4-1: Estimated amount of mercury placed on EU market per lamp type..........43

Table 5-1: Disadvantages of lamps vs. resistive emitters..........72

Table 5-2: Comparison of current and requested new wording of exemption 8(b)-I..........89

Table 6-1: Gas and electricity consumption and related CO_2 emissions of the GAHP, the CB and the HS for generation of 25 MWh of annual heating energy..........124

Table 6-2: ELR per 100,000 persons related to GAHP with 38 g initial Cr-VI content..126

Table 6-3: Environmental and health impacts of CBs and HS compared to GAHPs..........128

Table 8-1: Illustrative uses of lead in white optical glass with essential properties..........150

Table 8-2: Properties of two lead-based and three lead-free optical glass types..........154

Table 8-3: Dependence of overall transmission of visible light through a 10-element lens due to transmission of individual lenses..........154

Table 8-4: Comparison of properties of glass and plastic lenses..........156

Table 8-5: SCHOTT Material hardness..........158

Table 8-6: Properties of optical glass based on heavy elements with atomic number ≥ 56 159

Table 8-7: Refractive index and Abbe number of recently patented optical glass..........161

Table 9-1: Comparison of yellow 101 plastic filter with SCHOTT glass filter GG495..202

Table 9-2: Comparison of glass and plastic materials for filters..........203

Table 9-3: Knoop hardness of selected plastics and of optical glasses for optical filters 204

Table 9-4: Sideband wavelengths of lead telluride and germanium coatings..........206

Table 10-1: Lead in flip chip packages (FCPs) in the scope of the exemptions..........241

Table 10-2: Total amount of lead placed on the EU market..........241

1. Summary – English

Under Framework Contract no. ENV.B.3/FRA/2019/0017, a consortium coordinated by Bio Innovation Service was requested by DG Environment of the European Commission to provide technical and scientific support for the evaluation of the renewal request of 12 exemptions to Annex III of Directive 2011/65/EU. The work has been undertaken by the Bio Innovation Service, UNITAR and Fraunhofer Institute IZM, and has been peer reviewed by experts from the three organisations.

1.1. Background and objectives

Directive 2011/65/EU (hereafter "the Directive") on the restriction of the use of certain hazardous substances in electrical and electronic equipment provides "*that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II*" (i.e. lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers and starting July 2019 bis (2-ethylhexyl) phthalate, butyl benzyl phthalate, dibutyl phthalate and diisobutyl phthalate). Article 5(1)(a) provides a basis for excluding certain applications from these provisions through the inclusion of materials and components of EEE for specific applications in the lists in Annexes III and IV. This article further specifies the criteria on which such exemptions can be justified: in cases where the environmental and health protection afforded by Regulation 1907/2006/EC (REACH) is not weakened, exemptions can be justified in cases where at least one of the following criteria is fulfilled:

- "Their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable;
- The reliability of substitutes is not ensured; and
- The total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof."

Furthermore, the availability of substitutes; the socio-economic impacts of substitution; any potential adverse impacts on innovation and life cycle thinking information can also be considered to determine the duration of exemptions.

Article 5(2) of the RoHS Directive stipulates that exemptions listed in Annexes III and Annex IV shall have an expiration date. Where a specific date is not specified, this article lists provisions to clarify the validity. Article 5(3) requires stakeholders to submit applications for granting, renewing or revoking exemptions to the European Commission. Such applications provide the basis for the Commission to initiate evaluations of the exemptions listed in the annexes (or evaluations of requests for new exemptions).

1.2. Key findings – Overview of the evaluation results

The exemption requests covered in this project and the applicants concerned, as well as the final recommendation and proposed expiry date are presented in Table 1-1 below.

The reader is referred to the corresponding section of this report for more details on the evaluation result. For better readability of the table, the following acronyms are used:

Cat. category, referring to categories of EEE in scope of the RoHS Directive (Annex I)

MCI monitoring and control instrument

MD medical device

IMCI industrial monitoring and control instrument

Incl. including

IVD in-vitro diagnostic medical device

Table 1-1: Overview of exemption requests, recommendations and expiry dates

#	Current exemptions	Applicants	Recommendation	Scope and expiry date
4(f)	*Mercury in other discharge lamps for special purposes not specifically mentioned in this Annex*	*Lighting Europe, VDMA*	**Renewal requests withdrawn** due to exemption renewal by COM based on earlier renewal request, c.f. ex. 4(f)(I to IV) of Annex III of RoHS Directive	
8(b)	*Cadmium and its compounds in electrical contacts*	Sensata et al.	**Renew with restricted scope** as exemption 8(b)(II): *Cadmium and its compounds in electrical contacts in* - *circuit breakers* - *thermal sensing controls* - *thermal motor protectors (excluding hermetic thermal motor protectors)* - *AC switches* - *DC switches*	*Expires on* - *31 December 2023 for circuit breakers in rotating parts of computer tomography (CT) MDs (cat. 8 MDs others than IVDs)* - *31 December 2025 for portable emergency defibrillators (cat. 8 MDs others than IVDs) with a Declaration of Conformity (DOC) issued for the first time before 1 January 2015* - *31 December 2025 for other cat. 8 MDs incl. IVDs, and cat. 9 MCIs incl. IMCIs, and for cat. 11.*
			Renew for "fixed" contacts as new exemption 8(c) with specified scope: *Cadmium and its compounds in electrical contacts that are not covered by exemption 8(b)(II), and excluding* - *resistive inks of infrared emitters in medical capnography sensors used with lung ventilators* - *gold-containing pastes for coating electrodes for connections to electrical sensing and signal processing circuits via gold wires in*	*Applies, from [date of the official publication of the COM decision in the Official Journal + 18 months + 1 day] on, to categories 8 and 9.* *Expires on 21 July 2025 for cat. 8 medical devices including in-vitro diagnostic medical devices and cat. 9 monitoring and control instruments including industrial monitoring and control instruments*

#	Current exemptions	Applicants	Recommendation	Scope and expiry date
			sensors for detection of low-level oxygen concentrations at elevated temperatures	
8(b)(I)	*Cadmium and its compounds in electrical contacts used in:* - *circuit breakers,* - *thermal sensing controls,* - *thermal motor protectors (excluding hermetic thermal motor protectors)* - *AC switches rated at:* - *6 A and more at 250 V AC and more, or* - *12 A and more at 125 V AC and more* - *DC switches rated at 20 A and more at 18 V DC and more, and* - *switches for use at voltage supply frequency ≥ 200 Hz*	Sensata et al.	**Renew with below wording** for circuit breakers, thermal sensing controls and thermal motor protectors: *Cadmium and its compounds in electrical contacts in*	
			- *circuit breakers,* - *thermal sensing controls* - *thermal motor protectors (excluding hermetic thermal motor protectors)*	*Expires on 31 December 2023 for cat. 1-7, 10 and 11*
			- *AC switches rated at:* - *6 A and more at 250 V AC and more, or* - *12 A and more at 125 V AC and more* - *DC switches rated at 20 A and more at 18 V DC and more, and* - *switches for use at voltage supply frequency ≥ 200 Hz*	*Expires on [date of the official publication of the COM decision in the Official Journal + 12 months]*
			Renew as exemption 8(b)(III) for other switches in scope of current exemption 8(b)(I): *Cadmium and its compounds in electrical contacts of* - *AC switches rated at* - *10 A and more at 250 V AC and more, or* - *15 A and more at 125 V AC and more,*	*Expires on 31 December 2025 for cat. 1-7, 10 and 11*

#	Current exemptions	Applicants	Recommendation	Scope and expiry date
			- *DC switches rated at 25 A and more at 18 V DC and more.*	
9	*Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75 % by weight in the cooling solution*	*Ariston Thermo SpA*	**Grant exemption** as separate ex. 9(a)(III) if COM deems negative impacts of substitution likely to outweigh benefits thereof: *Up to 0.7 % by weight of hexavalent chromium as an anticorrosion agent in the working fluid of the carbon steel sealed circuit of gas absorption heat pumps for space and water heating.*	*Expires on 31 December 2026 for cat. 1 gas absorption heat pumps.*
9(a)(II)	*Up to 0,75 % hexavalent chromium by weight, used as an anticorrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators:* - *designed to operate fully or partly with electrical heater, having an average utilised power input ≥ 75 W at constant running conditions,* - *designed to fully operate with non-electrical heater.*	*Dometic*	**Renew with current wording.**	*Expires on 21 July 2021 for cat. 1-7 and 10.*
13(a)	*Lead in white glasses used for optical applications*	*Spectaris et al.*	**Renew exemption with new wording:** *Lead in glasses used for optical applications excluding applications falling under points 13(b), 13(b)(I), 13(b)(II), 13(b)(III), 13(b)(IV) of this Annex*	*Expires on:* - *21 July 2025 for categories 1, 2, 5, and 10;* - *21 July 2026 for categories 3, 4, 6, 7, 8, 9, and 11;* - *21 July 2028 for category 8 in vitro diagnostic medical devices and category 9 industrial monitoring and control*

#	Current exemptions	Applicants	Recommendation	Scope and expiry date
13(b)	*Cadmium and lead in filter glasses and glasses used for reflectance standards*	*Spectaris et al.*	**Renew exemption with restricted scope** for reflectance standards as new exemption 13(b)(IV): *Cadmium in glazes used for reflectance standards*	*Expires on 21 July 2026 for cat. 8 MDs incl. IVDs and cat. 9 MCIs incl. IMCIs.*
			Renew exemption with restricted scope for filter glasses as new exemption 13(b)(V): *Lead compound coatings in infrared interference filters used in infrared gas analysis and mid-far-infrared spectroscopy*	*Expires on 21 July 2028 for cat. 9 IMCIs*
13(b)(I)	*Lead in ion coloured optical filter glass types*	*Spectaris et al.*	**Renew with same wording:** *Lead in ion coloured optical filter glass types*	*Expires on* - *21 July 2025 for cat. 1 and 4;* - *21 July 2026 for cat. 2, 3, 5, 6, 7, 10 and 11;* - *21 July 2028 for cat. 8 MDs incl. IVDs, and cat. 9 MCIs incl. IMCIs.*
13(b)(II)	*Cadmium in striking optical filter glass types; excluding applications falling under point 39 of Annex III*	*Spectaris et al.*	**Renew with same wording:** *Cadmium in striking optical filter glass types; excluding applications falling under point 39(a) of Annex III*	
13(b)(III)	*Cadmium and lead in glazes used for reflectance standards*	*Spectaris et al.*	**No renewal, introduce new exemption** 13(b)(IV) with restricted scope: *Cadmium in glazes used for reflectance standards*	*Expires on 21 July 2028 for cat. 8 MDs incl. IVDs and cat. 9 MCIs incl. IMCIs.*
15	*Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages*	*Texas Instruments et al.*	**No renewal recommendation possible** due to lack of substantiated evidence required by Art. 5(1)(a).	

#	Current exemptions	Applicants	Recommendation	Scope and expiry date
15(a)	*Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages where at least one of the following criteria applies:* - *a semiconductor technology node of 90 nm or larger;* - *a single die of 300 mm^2 or larger in any semiconductor technology node;* - *stacked die packages with die of 300 mm2 or larger, or silicon interposers of 300 mm^2 or larger.*	*Texas Instruments et al.*	**No renewal recommendation possible** due to lack of substantiated evidence required by Art. 5(1)(a).	

Note: Like in the RoHS legal text, commas are used as a decimal separator for exemption formulations appearing in this table, in contrast to the decimal point used throughout the rest of the report as a separator.

2. Note De Synthèse : Français

Au titre du contrat-cadre n°. ENV.B.3/FRA/2019/0017, un consortium coordonné par Bio Innovation Service a été sollicité par la DG Environnement de la Commission Européenne pour fournir un soutien technique et scientifique pour l'évaluation de la demande de renouvellement de 12 exemptions à l'annexe III de la directive 2011/65/UE. Le travail a été entrepris par le Bio Innovation Service, UNITAR et le Fraunhofer Institute IZM, et a été revu par des experts des trois organisations.

2.1. Contexte et objectifs

La Directive 2011/65/UE (ci-après « la Directive ») relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques prévoit « que les EEE mis sur le marché, y compris les câbles et les pièces détachées destinées à leur réparation, à leur réemploi, à la mise à jour de leurs fonctionnalités ou au renforcement de leur capacité, ne contiennent aucune des substances énumérées à l'annexe II » (à savoir le plomb, le mercure, le cadmium, le chrome hexavalent, les polybromobiphényles, les polybromodiphényléthers et, à partir de juillet 2019, le phtalate de bis(2-éthylhexyle), le phtalate de butylbenzyle, le phtalate de dibutyle et le phtalate de diisobutyle). L'article 5(1)(a), fournit une base pour exclure certaines applications de ces dispositions par l'inclusion de matériaux et de composants d'EEE destinés à des applications spécifiques dans les listes des annexes III et IV. Cet article précise en outre les critères sur lesquels ces exemptions peuvent être justifiées : dans les cas où la protection de l'environnement et de la santé assurée par le règlement 1907/2006/CE (REACH) n'est pas affaiblie, les exemptions peuvent être justifiées dans les cas où au moins un des critères suivants est rempli :

- « leur élimination ou leur remplacement sur la base de modifications de la conception, ou par des matériaux et composants ne nécessitant aucun des matériaux ou substances énumérés à l'annexe II, est scientifiquement ou techniquement impraticable,
- la fiabilité des produits de substitution n'est pas garantie,
- il est probable que l'ensemble des incidences négatives sur l'environnement, sur la santé et sur la sécurité du consommateur liées à la substitution l'emportent sur l'ensemble des bénéfices qui en découlent pour l'environnement, la santé et la sécurité du consommateur. »

En outre, la disponibilité des substituts, les impacts socio-économiques de la substitution, tout impact négatif potentiel sur l'innovation et les informations sur le cycle de vie peuvent également être pris en compte pour déterminer la durée des exemptions.

L'article 5(2), de la Directive RoHS stipule que les exemptions énumérées à l'annexe III et à l'annexe IV ont une date d'expiration. Lorsqu'aucune date spécifique n'est spécifiée, cet article énumère les dispositions permettant d'en clarifier la validité. L'article 5(3), exige que les parties prenantes soumettent à la Commission européenne des demandes d'octroi, de renouvellement ou de révocation des exemptions. Ces demandes servent de base à la Commission pour lancer les évaluations des exemptions énumérées dans les annexes (ou les évaluations des demandes de nouvelles exemptions).

2.2. Principales conclusions - Aperçu des résultats de l'évaluation

La demande d'exemption couverte par ce projet et le demandeur concerné, ainsi que la recommandation finale et la date d'expiration proposée sont présentés dans le Tableau 2-1 ci-dessous. Plus de détail sur le résultat de l'évaluation est présenté dans le chapitre correspondant à chaque évaluation. Pour une meilleure lisibilité du tableau, les acronymes suivants sont utilisés :

Cat. catégorie de produit électriques et électronique tel que c'est défini dans l'annex I de la directive RoHS

MCI instrument de contrôle et de surveillance

MD dispositifs médicaux

IMCI instrument de contrôle et de surveillance industriel

Incl. inclus

IVD appareil médical de diagnostic in vitro

Tableau 2-1: Aperçu des demandes d'exemption, des recommandations et des dates d'expiration.

Ex. no	Formulation actuelle de l'exemption	Candi-dats	Recommendation	Date d'expiration et champ d'application
4(f)	*Mercure dans d'autres lampes à décharge à usage spécial non spécifiquement mentionnés dans la présente annexe*	Lighting Europe, VDMA	**Demandes de renouvellement retirées** en raison d'un renouvellement d'exemption par la COM sur la base d'une demande de renouvellement antérieure, cf. ex. 4(f)(I à IV) de l'annexe III de la directive RoHS	
8(b)	*Cadmium et ses composés dans les contacts électriques*	Sensata et al.	**Renouveler avec un champ d'application restrient comme pour l'exemption 8(b)(II) :** *Le cadmium et ses composés dans les contacts électriques de* - *disjoncteurs* - *contrôles de captage thermique* - *dispositifs thermiques de protection des moteurs (sauf protecteurs thermiques des moteurs type hermétique)* - *Interrupteurs CA* - *Interrupteurs CC*	*Expire le* *- 31 décembre 2023 pour les disjoncteurs des parties tournantes des DM de tomodensitométrie (CT) (cat. 8 MD autres que les IVDs)* *- 31 décembre 2025 pour les défibrillateurs portables d'urgence (cat. 8 MD autres que IVDs) avec une déclaration de conformité (DOC) émise pour la première fois avant le 1er janvier 2015* *- 31 décembre 2025 pour les autres cat. 8 MDs incl. IVDs et cat. 9 MCI incl. IMCI, et pour le cat. 11.*
			Renouveler pour les contacts « fixes » en tant que nouvelle exemption 8(c) avec une portée spécifiée : *Le cadmium et ses composés dans les contacts électriques qui ne sont pas couverts par l'exemption 8(b)(II), et à l'exclusion* *- encres résistives des émetteurs infrarouges dans les capteurs de capnographie médicale utilisés avec les ventilateurs pulmonaires* *- pâtes contenant de l'or pour le revêtement des électrodes pour les connexions aux circuits de détection électrique et de traitement du signal via des fils d'or dans les capteurs pour la détection de faibles concentrations d'oxygène à des températures élevées*	*Applique, à compter du [date de la publication officielle de la décision COM au Journal officiel + 18 mois + 1 jour], aux catégories 8 et 9.* *Expire le 21 juillet 2025 pour cat. 8 dispositifs médicaux dont dispositifs médicaux de diagnostic in vitro et cat. 9 instruments de surveillance et de contrôle, y compris des instruments de surveillance et de contrôle industriels*

Ex. no	Formulation actuelle de l'exemption	Candi-dats	Recommendation	Date d'expiration et champ d'application
8(b)(I)	*Le cadmium et ses composés dans les contacts électriques utilisés dans :* - *disjoncteurs,* - *contrôles de captage thermique,* - *dispositifs thermiques de protection des moteurs (sauf protecteurs thermiques des moteurs type hermétique)* - *Interrupteurs CA évalués à :* ○ *6 A et > 250 V CA et plus, ou* ○ *12 A et > 125 V CA et plus* - *interrupteurs CC de 20 A et > 18 V CC et plus, et* - *interrupteurs pour utilisation à fréquence d'alimentation voltage ≥ 200 Hz*	Sensata et al.	**Renouveler avec la formulation ci-dessous pour les disjoncteurs, les contrôles de captage thermique et les protecteurs thermiques de moteur :** *Le cadmium et ses composés dans les contacts électriques pour*	
			- *disjoncteurs,* - *contrôles de captage thermique,* - *dispositifs thermiques de protection des moteurs (sauf protecteurs thermiques des moteurs type hermétique)*	*Expire le 31 décembre 2023 pour cat. 1-7, 10 et 11*
			- *Interrupteurs CA évalués à :* ○ *6 A et > 250 V CA et plus, ou* ○ *12 A et > 125 V CA et plus* - *interrupteurs CC de 20 A et > 18 V CC et plus, et* - *interrupteurs pour utilisation à fréquence d'alimentation voltage ≥ 200 Hz*	*Expire le [date de publication officielle de la décision COM au Journal officiel + 12 mois]*
			Renouveler en tant qu'exemption 8(b)(III) pour les autres interrupteurs dans le champ d'application de l'exemption actuelle 8(b)(I) : *Le cadmium et ses composés dans les contacts électriques de* *- interrupteurs CA évalués à* *- 10 A et > 250 V CA et plus, ou* *- 15 A et > 125 V CA et plus,* *- interrupteurs CC de 25 A et > 18 V CC et plus.*	*Expire le 31 décembre 2025 pour cat. 1-7, 10 et 11*

Ex. no	Formulation actuelle de l'exemption	Candi-dats	Recommendation	Date d'expiration et champ d'application
9	*Chrome hexavalent comme agent anticorrosion du système de refroidissement en acier au carbone dans les réfrigérateurs à absorption jusqu'à 0,75 % en poids dans la solution de refroidissement*	Ariston Thermo SpA	**Accorder une exemption en tant qu'ex. 9(a)(III)** si la COM estime que les impacts négatifs de la substitution sont susceptibles d'être plus important que des bénéfices : *Jusqu'à 0,7 % en poids de chrome hexavalent comme agent anticorrosion dans le fluide de travail du circuit étanche en acier au carbone des pompes à chaleur à absorption de gaz pour le chauffage et chaudière.*	*Expire le 31 décembre 2026 pour cat. 1 pompes à chaleur à absorption gaz.*
9(a) (II)	*Jusqu'à 0,75 % de chrome hexavalent en poids, utilisé comme agent anticorrosion dans la solution de refroidissement des systèmes de refroidissement en acier au carbone des réfrigérateurs à absorption : - conçus pour fonctionner totalement ou partiellement avec un chauffage électrique, ayant une puissance absorbée moyenne utilisée ≥ 75 W dans des conditions de fonctionnement constantes, - conçu pour fonctionner pleinement avec un radiateur non électrique.*	Dometic	**Renouveler avec la formulation actuelle**	*Expire le 21 juillet 2021 pour cat. 1-7 et 10*
13(a)	*Plomb dans les verres blancs utilisés pour les applications optiques*	Spectaris et al.	**Renouveler avec une nouvelle formulation :** *Plomb dans les verres utilisés pour des applications optiques à l'exclusion des applications relevant des points 13(b), 13(b)(I), 13(b)(II), 13(b)(III), 13(b)(IV) du présent Annexe*	*Expire le : - 21 juillet 2025 pour les catégories 1, 2, 5 et 10 ; - 21 juillet 2026 pour les catégories 3, 4, 6, 7, 8, 9 et 11 ; - 21 juillet 2028 pour les dispositifs médicaux de diagnostic in vitro de catégorie 8 et la surveillance et le contrôle industriels de catégorie 9*
13(b)	*Cadmium et plomb dans les verres filtrants et les verres utilisés pour les normes de réflectance*	Spectaris et al.	**Renouveler l'exemption avec un champ d'application restreint pour les normes de réflectance en tant que nouvelle exemption 13(b)(IV) :** *Cadmium dans les émaux utilisés pour les normes de réflectance*	*Expire le 21 juillet 2026 pour cat. 8 MD incl. DIV et cat. 9 MCI incl. IMCI.*
			Renouveler l'exemption avec un champ d'application restreint pour les verres filtrants en tant que nouvelle exemption 13(b)(V) :	*Expire le 21 juillet 2028 pour cat. 9 IMCIs*

Ex. no	Formulation actuelle de l'exemption	Candi-dats	Recommendation	Date d'expiration et champ d'application
			Revêtements composés de plomb dans les filtres interférentiels infrarouges utilisés dans l'analyse des gaz infrarouges et la spectroscopie infrarouge moyen et lointain	
13(b) (I)	*Plomb dans les types de verres filtrants optiques colorés aux ions*	Spectaris et al.	**Renouveler avec la même formulation :** *Plomb dans les types de verres filtrants optiques colorés aux ions*	*Expire le - 21 juillet 2025 pour cat. 1 et 4 ; - 21 juillet 2026 pour cat. 2, 3, 5, 6, 7, 10 et 11 ; - 21 juillet 2028 pour cat. 8 MD incl. DIV et cat. 9 MCI incl. IMCI.*
13(b) (II)	*Le cadmium dans les types de verres filtrants optiques de traitement thermique secondaire ; à l'exclusion des demandes relevant du point 39 de l'annexe III*	Spectaris et al.	**Renouveler avec la même formulation :** *Le cadmium dans les types de verres filtrants optiques de traitement thermique secondaire ; à l'exclusion des demandes relevant du point 39 de l'annexe III*	
13(b) (III)	*Cadmium et plomb dans les émaux utilisés pour les normes de réflectance*	Spectaris et al.	**Pas de renouvellement, introduction d'une nouvelle exemption 13(b)(IV) avec un champ d'application restreint :** *Cadmium et plomb dans les émaux utilisés pour les normes de réflectance*	*Expire le 21 juillet 2028 pour cat. 8 MD incl. DIV et cat. 9 MCI incl. IMCI.*
15	*Plomb dans les soudures pour réaliser une connexion électrique viable entre la puce semi-conductrice et le support dans les boîtiers de puces retournées de circuits intégrés*	Texas Instruments et al.	**Aucune recommandation de renouvellement en absence d'éléments nécessaires requises par l'art. 5(1)(a).**	
15(a)	*Plomb dans les soudures pour réaliser une connexion électrique viable entre la puce semi-conductrice et le support dans les boîtiers de puces retournées de circuits intégrés où au moins l'un des critères suivants s'applique : - un nœud de technologie semi-conductrice de 90 nm ou plus ; - une seule puce de 300 mm^2 ou plus dans n'importe quel nœud de technologie des semi-conducteurs ; - boîtiers de puces empilées avec puce de 300 mm2 ou plus, ou interposeurs en silicone de 300 mm2 ou plus.*	Texas Instruments et al.	**Aucune recommandation de renouvellement en absence d'éléments nécessaires requises par l'art. 5(1)(a).**	

3. Introduction

The consortium for the Framework Contract Assistance to the Commission on technological, socio-economic and cost benefit assessments related to the implementation and further development of EU waste legislation (ENV.B.3/FRA/2019/0017) coordinated by Bio Innovation Service (B'Innov) was mandated by the European Commission with the "Study to assess requests for a renewal of eleven exemptions of Annex III of Directive 2011/65/EU" performed under the study request No 07.0201/2020/840152/ENV.B.3.

3.1. Project scope

The Commission needs clear technical and scientific evidence and an assessment of these requests for granting, renewing or revoking exemptions in the light of the criteria listed in the Directive, notably the provisions cited above, taking into consideration the differing validity periods and expiry dates for the various product categories 1-11 of Annex I of the RoHS Directive. During the evaluation, a public online stakeholder consultation was also organized.

This study will provide the Commission required technical and scientific support for the evaluation of the requests for renewal and amendment of the exemptions displayed in the below table.

Table 3-1: Overview of exemptions on Annex III to be reviewed

No.	Exemption wording	Current expiry dates of the exemptions
4(f)	Mercury in other discharge lamps for special purposes not specifically mentioned in this Annex	- [Date of publication of pending Commission decision (+ 12 to 18 months in case of revocation)] for cat. 1-7, cat. 8 medical devices others than in-vitro medical devices, cat. 9 monitoring and control instruments others than industrial monitoring and control instruments, and 10 - 21 July 2023 for category 8 in-vitro diagnostic medical devices - 21 July 2024 category 9 industrial monitoring and control instruments, and for category 11
8(b)	Cadmium and its compounds in electrical contacts	21 July 2021 for categories 8 medical devices others than in-vitro diagnostic medical devices, and 9 monitoring and control instruments others than industrial monitoring and control instruments
8(b)-I	Cadmium and its compounds in electrical contacts used in:	21 July 2021 for categories 1 to 7 and 10

No.	Exemption wording	Current expiry dates of the exemptions
	- circuit breakers, - thermal sensing controls, - thermal motor protectors (excluding hermetic thermal motor protectors) - AC switches rated at: - 6 A and more at 250 V AC and more, or - 12 A and more at 125 V AC and more, - DC switches rated at 20 A and more at 18 V DC and more, and - switches for use at voltage supply frequency ≥ 200 Hz.	
9	Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75 % by weight in the cooling solution.	- 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments, - 21 July 2023 for category 8 in vitro diagnostic medical devices, - 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.
9(a)-II	Up to 0,75 % hexavalent chromium by weight, used as an anticorrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators: - designed to operate fully or partly with electrical heater, having an average utilised power input ≥ 75 W at constant running conditions, - designed to fully operate with non-electrical heater.	21 July 2021 for categories 1-7 and 10
13(a)	Lead in white glasses used for optical applications	Expires on - 21 July 2023 for category 8 in-vitro diagnostic medical devices - 21 July 2024 for category 9 industrial monitoring and control instruments - 21 July 2021 for all other categories including their sub-categories

No.	Exemption wording	Current expiry dates of the exemptions
13(b)	Cadmium and lead in filter glasses and glasses used for reflectance standards	Expires on - 21 July 2023 for category 8 in-vitro diagnostic medical devices - 21 July 2024 for category 9 industrial monitoring and control instruments - 21 July 2021 for other subcategories of categories 8 and 9
13(b)(I)	Lead in ion coloured optical filter glass types	21 July 2021 for categories 1-7 and 10
13(b)(II)	Cadmium in striking optical filter glass types; excluding applications falling under point 39 of Annex III	
13(b)(III)	Cadmium and lead in glazes used for reflectance standards	
15	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages	Applies to categories 8, 9 and 11 and expires on: - 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments; - 21 July 2023 for category 8 in vitro diagnostic medical devices; - 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.
15(a)	Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages where at least one of the following criteria applies: - a semiconductor technology node of 90 nm or larger; - a single die of 300 mm^2 or larger in any semiconductor technology node; - stacked die packages with die of 300 mm^2 or larger, or silicon interposers of 300 mm^2 or larger.	Applies to categories 1 to 7 and 10 and expires on 21 July 2021.

3.2. Links between the RoHS Directive and the REACH Regulation

Article 5 of the RoHS 2 Directive 2011/65/EU on “Adaptation of the Annexes to scientific and technical progress” provides for that:

> “*Inclusion of materials and components of EEE for specific applications in the lists in Annexes III and IV, provided that such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006*”.

Regulation (EC) No 1907/2006 on the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals (REACH) regulates the manufacturing, use or placing on the market of chemical substances on the Union market. REACH, for its part, addresses hazardous substances through processes of authorisation (substances of very high concern) and restriction (substances of any concern):

- Substances that may have serious and often irreversible effects on human health and the environment can be added to the candidate list to be identified as Substances of Very High Concern (SVHCs). Following the identification as SVHC, a substance may be included in Annex XIV of the REACH Regulation (Authorisation list): “List of Substances Subject to Authorisation”. If a SVHC is placed on the Authorisation list, companies (manufacturers and importers) that wish to continue using it, or continue placing it on the market, must apply for an authorisation for a specified use. Article 22 of the REACH Regulation states that:
  “Authorisations for the placing on the market and use should be granted by the Commission only if the risks arising from their use are adequately controlled, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable.”
- If a Member States or the European Chemicals Agency (ECHA) upon request of the Commission considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that it is not adequately controlled, it shall prepare a restriction dossier. ECHA has also the initiative to prepare a restriction dossier for any substance in the authorisation list if the use of that substance in articles poses a risk to human health and the environment that is not adequately controlled. The provisions of the restriction may be made subject to total or partial bans, or conditions for restrictions, based on an assessment of the risks and the assessment of the socio-economic elements.

The approach adopted in this report is that once a substance has been included into the Annexes related to authorisation or restriction of substances and articles under the REACH Regulation, the environmental and health protection afforded by REACH may be weakened in cases where an exemption would be granted for these uses under the provisions of RoHS.

Substances for which an authorisation or restriction process is underway may be discussed in some cases in relation to a specific exemption, to check possible overlaps in the scope of such processes and of requested RoHS exemptions and to identify the need for possible alignments of these two legislations.[1]

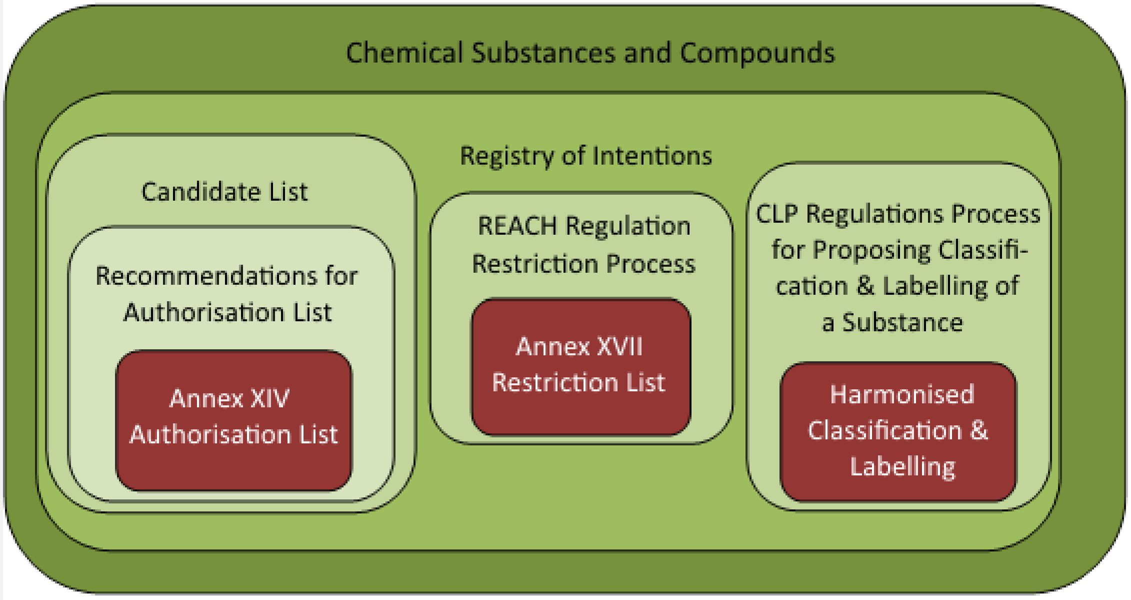
When evaluating the exemption requests, with regard to REACH compliance, we have checked whether the substance / or its substitutes are:

- on the list of substances of very high concern (SVHCs- the Candidate List);
- in the recommendations of substances for Annex XIV (recommended to be added to the Authorisation List);
- listed in REACH Annex XIV itself (the Authorisation List); or
- listed in REACH Annex XVII (the List of Restrictions).

As ECHA is *"the driving force among regulatory authorities in implementing the EU's chemicals legislation"*, the ECHA website has been used as the reference point for the aforementioned lists, as well as for the register of the amendments to the REACH legal text.

The figure below shows the relationship between the two processes under REACH as well as the process on harmonized classification and labelling under the CLP regulation (Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging). Substances included in the red areas may only be used when certain specifications and or conditions are fulfilled.

Figure 3-1: Relation of REACH categories and lists to other chemical substances



Before reaching the "Registry of Intentions" as shown in the figure above, there are additional activities and processes in order to identify substances of potential concern

[1] In 2014, the European Commission has prepared a Common Understanding Paper regarding the REACH and RoHS relationship in 2014 with a view to achieving coherence in relation to risk management measures, adopted under REACH and under RoHS:

REACH AND DIRECTIVE 2011/65/EU (RoHS) A Common Understanding; Ref. Ares(2014)2334574 - 14/07/2014 at http://ec.europa.eu/DocsRoom/documents/5804/attachments/1/translations conducted by the ECHA together with the Member States and different ECHA Expert Groups.[2] If a Member State evaluates certain substance to clarify whether its use poses a risk to human health or the environment, the substance is subject to a Substance Evaluation. The objective is to request further information from the registrants of the substance to verify the suspected concern. Those selected substances are listed by ECHA in the community rolling action plan (CoRAP).[3] If the Substance Evaluation concludes that the risks are not sufficiently under control with the measures already in place and if a Risk Management Option (RMO) analyses does not conclude that there are appropriate instruments by other legislation / actions, the substance will be notified in the Registry of Intentions.

The following bullet points explain in detail the above-mentioned lists and where they can be accessed:

- Member States Competent Authorities (MSCAs) / ECHA, on request by the Commission, may prepare Annex XV dossiers for identification of SVHCs, Annex XV dossiers for proposing a harmonised Classification and Labelling, or Annex XV dossiers proposing restrictions. The aim of the public Registry of Intentions is to inform interested parties of the substances for which the authorities intend to submit Annex XV dossiers and, therefore, to facilitate timely preparation of the interested parties for commenting later in the process. It is also important to avoid duplication of work and encourage co-operation between Member States when preparing dossiers. Note that the Registry of Intentions is divided into three separate sections: listing new intentions; intentions still subject to the decision-making process; and withdrawn intentions. The registry of intentions is available at the ECHA website at: https://echa.europa.eu/registry-of-intentions;
- The identification of a substance as a Substance of Very High Concern and its inclusion in the Candidate List is the first step in the authorisation procedure. The Candidate List is available at the ECHA website at https://echa.europa.eu/candidate-list-table;
- The last step of the procedure, prior to inclusion of a substance into Annex XIV (the Authorisation list), involves ECHA issuing a Recommendation of substances for Annex XIV. The previous ECHA recommendations for inclusion in the Authorisation List are available at the ECHA website at https://echa.europa.eu/previous-recommendations;
- Once a decision is made, substances may be added to the Authorisation List available under Annex XIV of the REACH Regulation. The use of substances appearing on this list is prohibited unless an Authorisation for use in a specific application has been approved. The Annex can be found in the consolidated version of the REACH legal text;
- In parallel, if a decision is made concerning the restriction on the use of a substance in a specific article or concerning the restriction of its provision on the European market,

[2] For an overview in these activities and processes see the ECHA webpage at: https://echa.europa.eu/substances-of-potential-concern

[3] Updates and general information can be found under: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances. The list can be found on the following page: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

then a restriction is formulated to address the specific terms, and this shall be added to Annex XVII of the REACH Regulation. The Annex can be found in the consolidated version of the REACH legal text; and

As of June 2020, the consolidated version of the REACH legal text, dated 28.04.2020, was used to reference Annexes XIV and XVII: The consolidated version is available at the EUR-Lex website: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1907-20200428. Relevant annexes and processes related to the REACH Regulation have been cross-checked to clarify:

- In what cases granting an exemption could "weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006" (Article 5(1)(a) of the RoHS Directive).
- Where processes related to the REACH Regulation should be followed to understand where such cases may become relevant in the future.

In this respect, restrictions and authorisations as well as processes that may lead to their initiation, have been reviewed, in respect of where RoHS Annex II substances are mentioned (i.e. lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) as well as bis (2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DiBP).[4]

[4] The four phthalates, DEHP, BBP, DBP and DIBP have been added to the Annex according to Commission Delegated Directive (EU) 2015/863 of 31 March 2015.

4. Exemption 4(f) of Annex III: Hg in discharge lamps not mentioned in Annex III

The complete wording of the current exemption (status before February 2022) was as follows:

No.	Current exemption wording	Current scope and dates of applicability
4(f)	Mercury in other discharge lamps for special purposes not specifically mentioned in this Annex	Expires on: - 21 July 2021 for medical devices of category 8 other than in-vitro diagnostic medical devices, and for cat. 9 monitoring and control instruments other than industrial monitoring and control instruments - 21 July 2023 for cat. 8 in-vitro diagnostic medical devices - 21 July 2024 for cat. 9 industrial monitoring and control instruments.

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. Information directly taken from information provided by applicants, stakeholders or other sources is described in *italics*. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Acronyms and Definitions

Hg	Mercury
LEU	Lighting Europe
VDMA	Verband Deutscher Maschinen- und Anlagenbau
VskE	German Association for Label and Narrow Web Converters
ANSI	American National Standard Institute

4.1. Background and Technical Information

LEU (2020) and VDMA (2020) submitted requests for the renewal of exemption 4(f) of Annex III for the maximum validity period of five years for all categories except categories 8 and 9, for which the maximum validity period is seven years. An additional 173 stakeholders contributed to the online consultation supporting the renewal request and highlighting the importance of the exemption for their specific uses[5] of lamps in the scope of exemption 4(f).

4.1.1. Summary of VDMA (2020) exemption request:

"The application for prolongation of the existing exemption refers to mercury-containing UV discharge lamps which are used for curing (e.g., of layers of inks and coatings, adhesives, and sealants), for disinfection (e.g., of water, surfaces and air) and for other industrial applications (surface modification, surface activation) The application includes the following lamp types:

UV medium-pressure discharge lamps (MPL) for curing, disinfection, and other industrial applications (internal operating pressure > 100 mbar). The UV medium-pressure lamps can be doped with iron, gallium or lead in addition to the mercury they contain.

UV low-pressure discharge lamps for special purposes in the high-power range. […]

Typical applications to be covered by this application include curing, e.g., of inks and coatings, disinfection of water etc., and other industrial applications like surface activation and cleaning.

It is technically not possible to replace mercury in special UV lamps with other materials/chemicals in order to achieve the same widespread radiation distribution. LED-based technologies are increasingly being used, which in certain applications (e.g., curing) also offer many advantages over mercury-containing UV lamps. Nevertheless, LED technologies cannot be used as an equivalent replacement in many applications."

4.1.2. Summary of LEU (2020) exemption request:

The renewal application concerns lamps and UV light sources defined as:

- *High Pressure Sodium (vapour) lamps (HPS) for horticulture lighting,*
- *Medium and high-pressure UV lamps for curing, disinfection of water and surfaces, day simulation for zoo animals, etc…*
- *Short-arc Hg lamps for projection, studio, stage lighting, microlithography for semiconductor production, etc.*

According to LEU, the replacement of mercury and mercury containing lamps is impracticable so that the lamps covered by exemption 4(f) must remain available on the EU market for new equipment where no functionally suitable alternatives are available and for spare parts for in-use equipment as replacing end-of-life lamps avoids having equipment become electronic waste before due time.

[5] The stakeholder contributions are accessible on the consultation web page: http://rohs.biois.eu/requests3.html

4.1.3. History of the Exemption

Exemption 4(f) was added to the Annex of Directive 2002/95/EC (RoHS I) in September 2010. The exemption series 1 to 4 and exemption 18(b) and 18(b)-I of Annex III allow the use of mercury in discharge lamps of different electrical, optical and geometric properties.

In the review by Gensch et al. (2016) following the renewal request of Lighting Europe (LEU), VDMA and VskE, the consultants recommended specifying the scope of the exemption to avoid misuse, and to ensure effective market surveillance. They recommended granting different exemption durations depending on the category and application of lamp type as displayed below.

No.	Recommended exemption wording	Recommended scope and dates of applicability
4(f)	(I) Mercury in other discharge lamps for special purposes not specifically mentioned in this Annex	Expires on - 21 July 2021 for categories 8 medical devices others then in-vitro diagnostic medical devices, and 9 monitoring and control instruments others then industrial monitoring and control instruments; - 21 July 2023 for cat. 8 in-vitro diagnostic medical devices; - 21 July 2024 for category 9 industrial monitoring and control instruments.
	(II) Mercury in high pressure mercury vapour lamps used in projectors where an output ≥2000 lumen ANSI is required	Expires on 21 July 2021 for category 5;
	(III) Mercury in high pressure sodium vapour lamps used for horticulture lighting	Expires on 21 July 2021 for category 5;
	(IV) Mercury in lamps emitting light in the ultraviolet spectrum for curing and disinfection	Expires on 21 July 2021 for category 5.

Source: Gensch et al. (2016)

After the above review, and prior to the official publication of the renewed exemption, LEU (2020) and VDMA (2020) applied for the renewal of exemption 4(f) in two separate applications in January 2020 to ensure that the renewed exemption with the recommended expiry dates in 2021 would be renewed again. On 24 February 2022, the Commission published officially the renewed exemption 4(f) with a similar wording proposed by Gensch et al. (2016), but with a broader scope and updated expiry dates as shown below.

No.	Exemption	Scope and dates of applicability
4(f)	(I) Mercury in other discharge lamps for special purposes not specifically mentioned in this Annex	Expires on 24 February 2025
	(II) Mercury in high pressure mercury vapour lamps used in projectors where an output ≥ 2000 lumen ANSI is required	Expires on 24 February 2027
	(III) Mercury in high pressure sodium vapour lamps used for horticulture lighting	Expires on 24 February 2027
	(IV) Mercury in lamps emitting light in the ultraviolet spectrum	Expires on 24 February 2027'

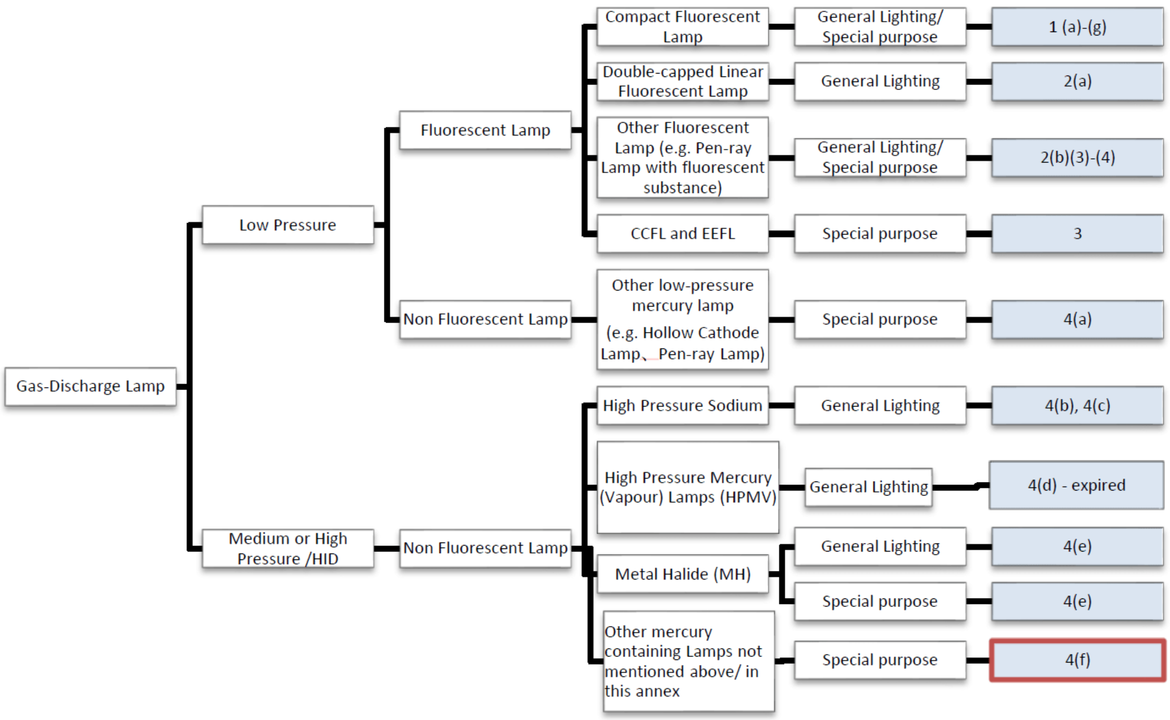
Source: EUR-Lex

The applicants thereupon withdrew their exemption requests on 3 May 2022. The applicants' main arguments for the renewal of the exemption are nevertheless presented in the below report to reflect the development of the scientific and technical status since the last review. The critical review had become obsolete after the withdrawal of the request.

4.1.4. Technical description of the exemption and use of restricted substance

LEU (2020) Mercury is used in special purpose lamps for its intrinsic properties. Due to them, it can emit light at specific wavelength with a high-power output, making it key in certain lighting applications where specific light spectrum and power need to be achieved. It is inserted into the discharge tube or burner for converting electrical energy into light.

Figure 4-1: Chart on the hierarchy of lamps and exemptions



Source: LEU (2020)

According to LEU (2020), mercury's key intrinsic properties are:

- *Relatively low boiling point so in vapour form at low pressures*
- *Its electronic structure enables generation of UV light very efficiently and a tuning of the wavelength emitted depending on the lamp structure and technology to achieve UVA, UVB, UVC, UVV or only visible light.*

Mercury is used to tune the resistance of the plasma in such a way that the efficiency of the combination lamp and driver functions in an optimal way LEU (2020).

High Intensity Discharge lamps generate light in a compact plasma arc with high brightness. After the lamp is started by a voltage pulse, the initial noble gas discharge heats the lamp and evaporates part of the sodium/mercury amalgam pill. At first it is mainly the mercury that goes into the vapour phase. The increasing mercury vapour pressure increases the electrical resistance in the discharge, which allows more power to be put into the discharge. As a consequence of more power coupled into the discharge, the discharge tube wall heats up and sodium and mercury evaporate further until a state of thermal equilibrium is established between the electrical power supplied to the discharge, the heat conducted to the surroundings, and the radiation emitted from the discharge. The lamps are designed in such a way that the optimal efficiency is reached at this equilibrium LEU (2020).

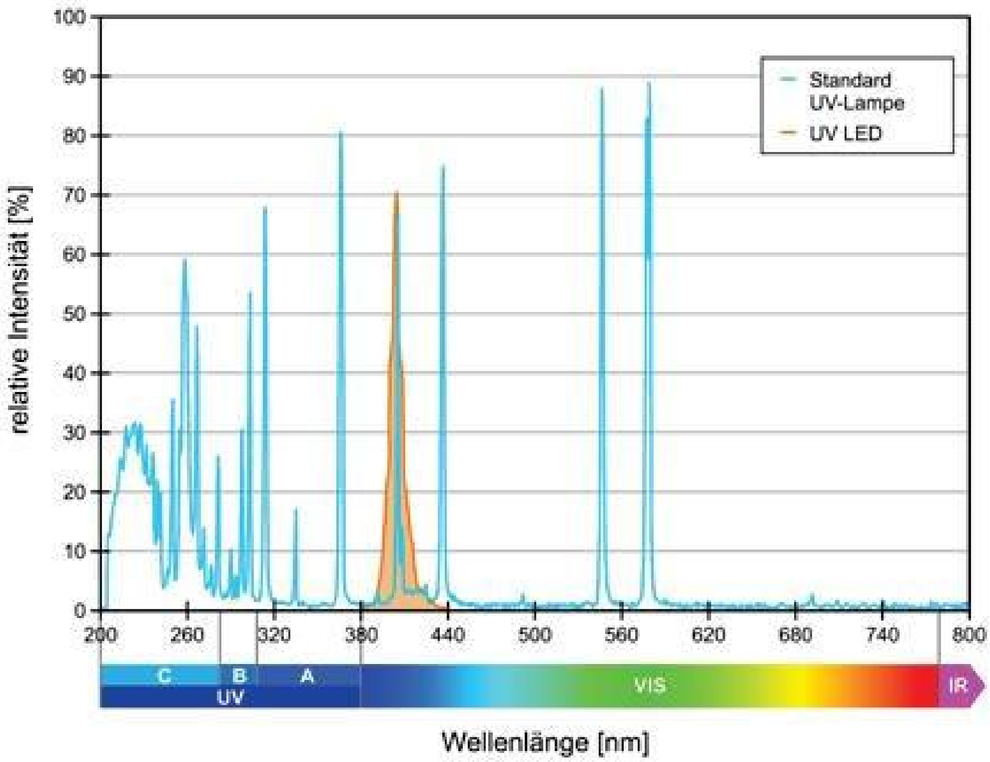
Although the mercury is not consumed over life, the sodium in the discharge tube does chemically react with the PCA wall (Polycrystalline alumina, ceramic discharge tube) and the electrode emitter (Luijks et al. (1992), Itoh et al. (1992)). As a result, the fraction of mercury in the amalgam becomes higher, which raises the lamp's voltage. At a certain point in time, the lamp voltage becomes so high that the main voltage can no longer sustain the arc and the lamp extinguishes. This is the end of the lamp's life. For a given sodium *consumption, a certain amalgam dose is required to reach the specified life. If the dose is too small, the ratio of mercury in the amalgam rises rapidly, as does the lamp's voltage, leading to a premature end of life LEU (2020).*

The mercury also has several additional essential functions to fulfil LEU (2020):

- *The mercury in the plasma of a High-Pressure Sodium lamp does not directly contribute to the spectrum of the lamp because the arc temperature is too low to excite the interesting (optical) energy levels of the mercury atom. However, there is a very significant indirect contribution of the mercury atoms: the proximity of mercury atoms shifts the energy levels of sodium and allows for a substantial broadening of the sodium resonance line (Woerdman et al. (1985), Groot und van Vliet[1] (1986)). This broadening shifts the emission of the lamp to the red and, by tuning the amalgam composition, the optimum radiation for growing plants can be obtained.*
- *The presence of the mercury vapor also greatly reduces the thermal conduction of the sodium-mercury-xenon plasma (Groot und van Vliet[2] (1986)). Therefore, there is less heat loss from the plasma to the discharge tube wall. The efficiency of the lamp is thereby greatly improved by the presence of mercury (Groot und van Vliet[3] (1986))*
- *The high pressure of mercury limits evaporation of the hot tungsten electrode. The low evaporation helps maintain the light flux over the lamp's lifetime. A high evaporation rate of tungsten would lead to a blackening of the arc tube, reducing the transmission of light and thus lowering lumen maintenance.*

Due to its specific energy levels, mercury allows emission of light at characteristic spectral lines which supply the necessary photons for curing and disinfection VDMA (2020).

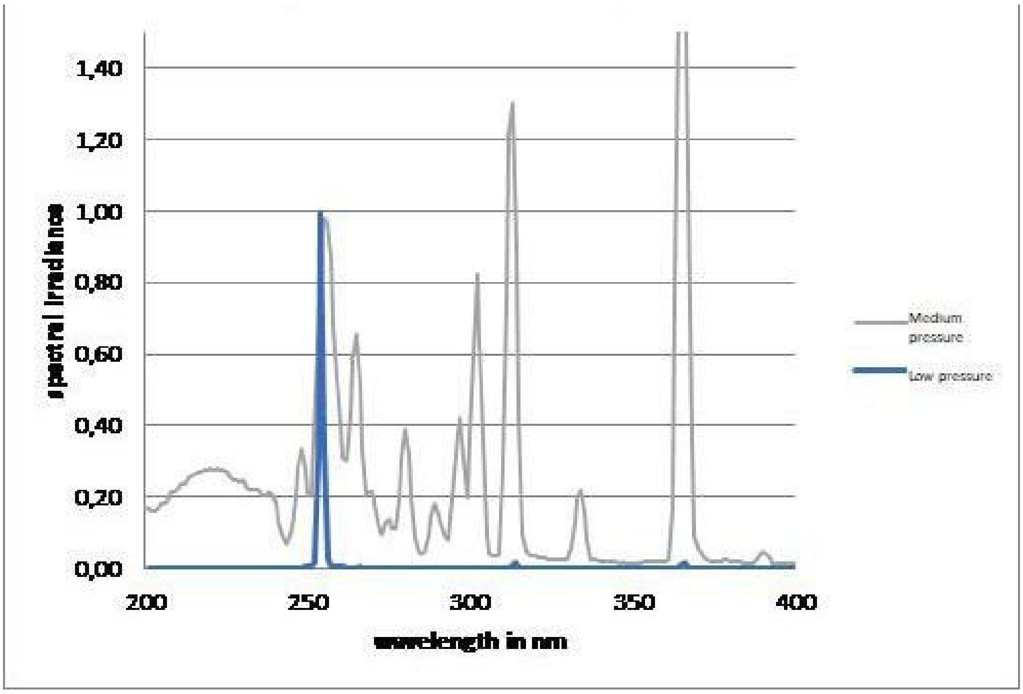
Figure 4-2: Standard mercury lamp and UV LED intensity as a function of spectra



Source: VDMA (2020) (Wellenlänge: wave length)

In Figure 4-2, the different peaks present in the UVC, UVB, UVA and visible range come from the use of mercury in the discharge lamp VDMA (2020). In Figure 4-3, the influence of pressure on the behaviour of mercury-containing lamps on their emission spectra is shown VDMA (2020).

Figure 4-3: UV spectra of Mercury medium and low-pressure lamps



Source: VDMA (2020)

The different lamps under exemption 4(f) which owe their properties to the use of mercury are presented below as discussed in the application from LEU and VDMA.

Lamps for projection

Projection applications are very demanding about the light source. To reach sufficient brightness, the light of the lamp has to be efficiently collected onto the imaging display. This can only be achieved with a lamp that resembles a point source (i.e., a lamp with a high luminance and a short arc). LEU (2020)

Figure 4-4: examples of projection lamps

Source: LEU (2020)

For these UHP (Ultra High Pressure) lamps, the high luminance of the plasma is reached using pure mercury (1) at a very high pressure (2).

(1) Using only mercury results in the best luminance arc. Compared to lamps with spectrum additives (high-performance metal halides), the luminance in a mercury-based lamp is higher by a factor of two. Furthermore, in a pure mercury gas it is possible to design a halogen cycle that keeps the wall clean. This is necessary to obtain a long lifespan small lamp. Mainstream projector lamps currently have a lifespan of 5 000 to 20 000 hours, whereas typical high performance metal halide lamps (with lower pressure and less mercury) typically expire around 1 000 hours LEU (2020).

(2) By reducing the current, the high-pressure reduces the load on the electrodes and serves as a buffer gas to insulate the arc from heat loss. The high-pressure also limits the diffusion of tungsten atoms away from the hot electrode. In addition to the halogen cycle, these properties also enable the long lifespan of UHP lamps compared to other high luminance lamps. The high-pressure also improves the lamp's spectrum, allowing it to match the required output spectrum for quality picture imaging (according REC709 standards). The good colour quality is due to the extreme pressure and the Bremsstrahlung (i.e., deceleration radiation) generated by the collision of electrons with mercury atoms (Lawler (2004), LEU (2020)).

Lamps for stage lighting and other cultural and entertainment purposes:

LEU (2020): Lamps for projection under exemption 4(f) include not only lamps used in projectors, but also those used for studio and stage lighting. These lamps are essential to concerts, shows, theatre, studios, and film sets. Discharge lamps are used by the entertainment industry for high-powered, automated fixtures (moving lights) and follow spots (high-powered lights specifically used for 'following' a performer from a long distance away and operated by a human operator). For theatrical performances, there is an artistic requirement to have a very bright light source, and touring shows tend to use a lot of small discharge lamps, which are very efficient. The lamp power of these kinds of lamps varies between 100W and 650W. Luminous flux goes up to 33 000 lm (depending on lamp wattage and the aperture size of the measurement device). The very small arc distance of 0.7mm towards 1.5mm enables a very high beam intensity

LEU (2020): Within the entertainment sector, three different fixture types can be distinguished: beam, spot, and wash. The difference between these fixture types is in the beam angle:

- *Beam: < 4°*
- *Spot: between 5° and 50°*
- *Wash: > 50°*

Lamps for horticulture applications (High-pressure sodium lamps):

LEU (2020): In lamps used for horticulture applications, mercury broadens the sodium radiation from yellow light towards the red part of the spectrum. It also increases the efficiency of the lamp to stimulate the growth of plants. Currently, there is no available substitute technology that meets all the functional requirements of lamps used in this application.

Research by universities and applied agricultural research stations has demonstrated that the rate of photosynthesis is related to the number of photons (typically between 400– 700 *nm). This photosynthetic flux (Photosynthetic Photon Flux, or PPF) measures the total stream of light available for the plants. This is expressed as the micromole of photons per second (µmol / s) Barnes et al. (1993). A recently discovered secondary effect of these lamps is their ability to provide irradiation with infra-red light. Many crops benefit from infrared radiation from above (from the direction of the sun), especially during the winter. The flux depends on the plant, but for tomatoes it is about 25-30 W/m^2, which is easily provided by HPS lighting. In LED lighting, this radiation is absent. Modern greenhouses typically combine HPS and LED lamps so as to benefit from both LEU (2020).*

HPS lamps are characterised by a very long lifespan (30,000 to 50,000 hours) and a very high luminous efficiency (from 80 lm/W to 150 lm/W). LEU (2020)

Medium-pressure UV lamps for curing

LEU (2020): These lamps contain a mixture of mercury and argon gas inside a sealed quartz tube. When in operation, this mixture is heated to create a stable, mercury plasma that emits radiation at specific wavelengths within the UV range (100-400nm) and which are characteristic of mercury. These lamps are favoured where fast and reliable curing of coatings, inks, and adhesives is required and where a durable, scratch-, abrasion-, and/or chemical-resistant surface is required.

Medium-pressure UV lamps for disinfection

VDMA (2021): These lamp types do not significantly differ in design from lamps used in UV curing. They are used to disinfect water, surfaces, and air. The difference resides in the lamps' spectra, indeed by emitting light at small wavelengths (265nm) because it can destroy cell structures such as DNA or cell walls.

Jelosil UV Technology (2021): Low pressure mercury and amalgam lamps are the most efficient light sources suited for UV disinfection applications due to their efficiency (up to 40 %) of generation for 254 nm resonance line of mercury in arc discharge which is very close to the maximum of microorganism's sensitivity for UV light. It provides technical possibility of constructing powerful light sources with power up to 1500 W and lamp length up to 3 m. Other important application is using 185 nm resonance line of mercury. This used for ozone generation and critical processes in photo reactions during harmful organic substances decomposing including water, air, and surfaces cleaning from industrial contaminations.

Technigraf (2021): According to Technigraf an alternative to a mercury/amalgam UV lamp (185 nm) is theoretically an excimer lamp (Xe2, 172 nm). The practical usage of an excimer lamp in the industry is limited by following factors:*

- *it requires an inert atmosphere to prevent the radiation absorption in air.*
- *the cost efficiency of an excimer system is by a factor 1000 lower in comparison to a mercury/amalgam lamp.*

Depending on the R&D of UVC-LED, they expect that the situation will be more and more improved in the next 3 to 6 years for UV-LED based equipment.

Optimarin (2021): Optimarin`s systems are delivered with a range of UV Chambers from 1 to 18 UV chambers which includes 1 UV lamp per UV chamber with a capacity of 167 m²/h. So, the range of the capacity of one system goes from 167 to 3000m³/hour. During the cleaning process, the water flows through a fine masked filter before it is being radiated with UV light in UV chambers up to 35 kW lamps.

Short Arc mercury lamps

LEU (2020): Short-arc lamps contain a mixture of mercury and xenon gas inside a sealed quartz tube. These discharge lamps are available in wattages ranging from 50 W to 35000 W for DC or AC operation, depending on the type. When high-wattage lamps are at room temperature, the mercury is generally found in the discharge vessel (i.e., bulb) as small metallic droplets. When the lamp is started, the temperature in the bulb rises and heats up in the arc between the electrodes to around 10 000 °C, causing the mercury to vaporise. The temperature on the inside wall of the bulb is around 800 °C. When thermal equilibrium is reached (which may take from 1 to 10 minutes after the lamp is switched on, depending on the type of lamp), the mercury vapour exerts a pressure of about 30 to 70 bar on the bulb (depending on the type of lamp).

4.1.5. Amount of mercury used under the exemption

The amount of mercury placed on the EU market through lamps can be broken down into different contributing sectors:

- *High Pressure sodium lamps*
- *Lamps for projection purposes*
- *Lamps for stage lighting, studios, and entertainment*
- *Medium pressure UV lamps (for curing and disinfection applications)*
- *High pressure short-arc Mercury lamps*

LEU (2020) and VDMA (2020) provided details regarding the amounts of mercury reaching the European market annually. Their answers are gathered in the below table.

Table 4-1: Estimated amount of mercury placed on EU market per lamp type

Lamp type	***LightingEurope estimate LEU (2020)***	***VDMA estimate*** VDMA (2020)
High pressure sodium lamps for horticulture lighting	***30 kg** (figure obtained using the Melisa model, data from manufacturers being confidential)* *Expected to decrease to **22 kg** five years after due to a 6 % market share decrease estimated with the Melisa model*	*No information*
Lamps for projection purposes	***28 kg** total (in 2019):* • ***22 kg** maximum in new lamps* • ***6 kg** maximum in spare part/replacement lamps* *Expected to drop to **13 kg** by 2023.*	*No information*
Lamps for stage lighting, studios, and entertainment	***6 kg** maximum*	*No information*
High pressure short-arc Mercury lamps	***6,1 kg**:* • *1,1 kg total EU medical* • *5 kg total semi-conductor production*	*No information*
Medium pressure UV lamps	*Curing:* • ***108 kg** in 2018* • ***158 kg** in 2021* *Disinfection: less than **100 kg** per year*	*Curing:* • ***75 kg** in 2015* • ***108 kg** in 2018* • ***158 kg** in 2021* *Disinfection: less than **100 kg** per year*
	*In total, approximately **250 kg** of mercury are used in UV lamps for disinfection and curing annually in Europe*	
Other High-pressure lamps	*No information*	*No information*
Total	***Around 320 kg per year, plus the mercury contained in other high-pressure lamps***	

Sources: VDMA (2020), LEU (2020)

The data in the above table illustrate that the lamps accounting for the biggest share of mercury (used for curing applications) are in an upward trend as shown by the amount of mercury increasing from 75 kg in 2015 to 158 kg in 2021. This trend is due to two main factors:

- *More UV machines placed on the EU market than leaving the market (VDMA (2020))*
- *The increase in UV demand in printing presses caused an increase in the length of the lamps, which in turn augmented their mercury content from 0.5 g Hg/per lamp in 2015 to 0.66 g of Hg/per lamp in 2018. VDMA (2020)*

LEU (2020) mentioned in their application that the Melisa model they used to determine the amounts of mercury reaching the EU market for High pressure sodium lamps expects a yearly 6 % decrease for the next five years. They also expect a yearly 17,5 % decrease is expected for lamps for projection purposes up to 2023. This projection since this market grew substantially with the demand for education and offices equipment and that most rooms and offices are now equipped with devices.

IKEA (2021) highlighted that they have 35 coating lines, containing 500 UV curing units. These UV units consume 2 000 UV lamps annually. Sterilair AG (2021): with an annual quantity of ~10'000 emitters/year (before sanitary crisis) and with an amount of 5 mg Hg/ lamp, the total amount of mercury is 50 g annually at the company. Besides, mercury containing lamps are dismantled and the mercury is recycled. Technigraf (2021) elaborated that the UVC-disinfection market consumes about 2 Mio UVC-lamps per year (the sum of the production volumes of main lamp manufacturers). UV-Technik Speziallampen (2021) produces 100 000 UV low pressure lamps and 50 000 UV medium pressure lamps annually.

4.2. Applicant's justification for the requested exemption

4.2.1. Substitution and elimination of mercury

There are three elements which according to the applicants justify the exemption requests; first, the fact that mercury as a chemical element has no substitutes (neither pure elements nor alloys) regarding its light discharge properties, second, there is no mature enough technology to replace mercury-based lamps, and third, even if alternatives existed, it would be impossible to retrofit them in current equipment.

VDMA (2020): There is no alternative chemistry for mercury for the creation of a typical UV spectrum, especially in the UVC range, that is known of. UV LED lamps, which are made up of a large number of LED chips, are an alternative to UV medium-pressure mercury discharge lamps. The state of development of UV LEDs, associated UV reactive materials and process designs allows the use of UV LEDs only in certain applications and often only under certain restrictions. The commercially available UV LED technology is mainly effective in the UVA range.

Both exemption applications discuss alternatives for existing Hg-lamps, below is a collation of their arguments.

Horticulture lighting

LEU (2020): High-intensity discharge lamps are compact and, in general, are high-power lamps. Horticulture applications require that HID lamps operate in closed luminaires. Since over 90 % of the power supplied to the HID lamp leaves the burner as radiation (visible light, infrared radiation, and some UV) the temperature of the luminaire and the lamp is stabilised without the need for heat sinking.

Regarding the most efficient LED lamps currently on the market, the power that is transformed into light is about 40 %, and there is no IR or UV. 60 % of the electrical power is transformed into heat and must be removed by convection/radiation to the surrounding air in the closed luminaire. This makes the design of the luminaire difficult, especially since the environment temperature in the greenhouse is high and the size of the luminaire is limited due to the need to minimize the bulb blocking direct sunlight.

It is not possible to replace the mercury containing lamps used in existing equipment with alternative technology. Lamps used in greenhouses must be replaced almost every year, and these replacement lamps must fit into the existing fixture and deliver the same performance, safety, and reliability that the equipment was originally designed and tested for.

As luminaires, LED solutions for top lighting started entering the market in 2019. This demonstrates that the industry is working on alternatives to HPS systems. These systems are in the early stage of development and currently require end users to have adequate budgets.

Ushio Europe (2021) declared that for some applications like horticultural lighting, there are mercury-free alternatives available to the widely used HPS and MH lamps, e.g. based on LED. However, these LED light sources do not simply replace the mercury containing lamp but instead require a new luminaire. The existing systems were designed for mercury containing HPS lamps and there is no alternative chemistry capable of producing a suitable spectral output and photosynthetic efficiency required for high greenhouse productivity. A greenhouse is usually equipped with 1.000 light points per 10.000 m². An average greenhouse may have 5.000 light points in operation. The need for HPS end-of-life replacement lamps is massive (millions of lamps per year). For a similar application - "tanning/sunbeds" - Ushio Europe (2021) has developed lamps using zinc instead of mercury with quite promising results. However, zinc lamps require a much higher ignition voltage than mercury-based lamps, meaning that simple 1:1 re-lamping for existing sunbeds or tanning systems is not possible. Even a change of control gears will not be possible in most cases, as different air and creeping distances need to be considered.

Venture Lighting Europe (2021) reported that the necessary overall range of wavelengths required for plant growth is not available from mainstream LEDs used in general lighting, especially UV LEDs and Far-Red LEDs. Although, LED light sources are available, they are large and very costly.

Projection lighting

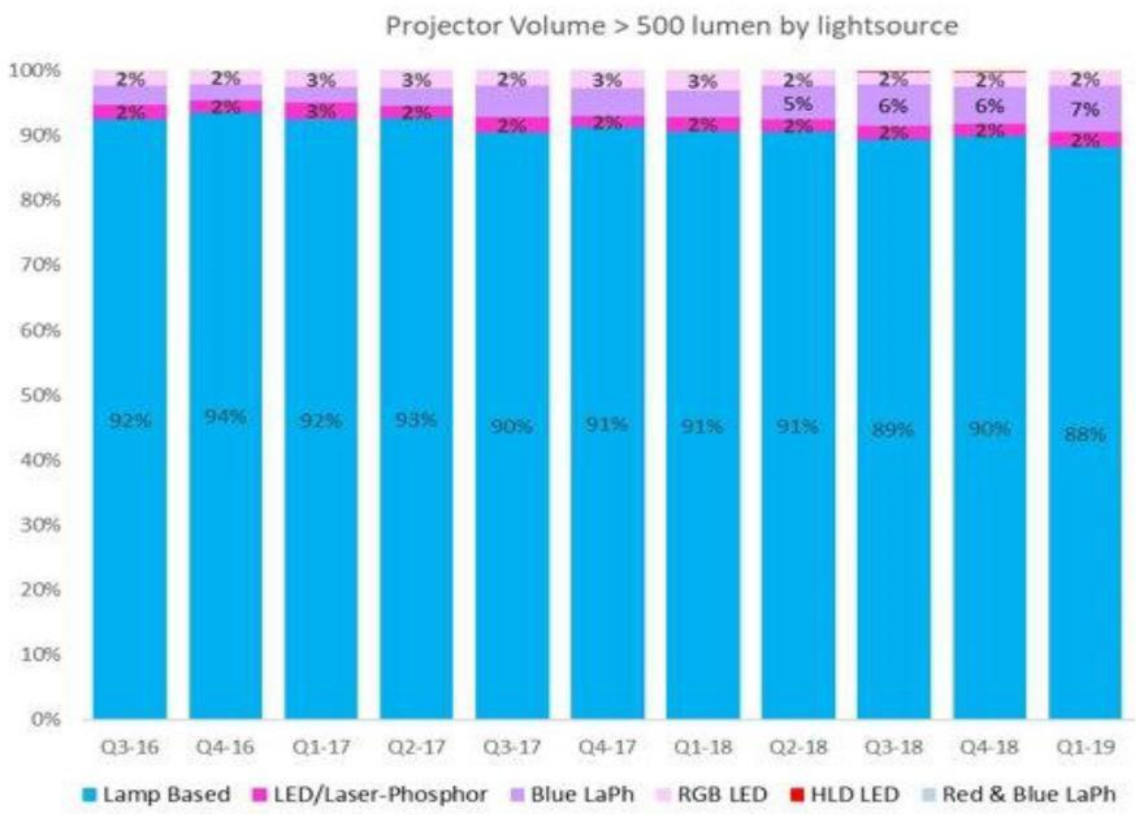
LEU (2020): Hg-free discharge technology based on Zn has been developed (Mönch (2006)). However, this technology is not suitable for projection applications – a result of the metal gas pressure being too low and thus producing a low lamp voltage. This results in low energy efficiency. Although efforts have been made to develop a high-pressure Zn *discharge lamp capable of achieving reasonable energy efficiency in a projection application, these efforts have been terminated due to a lack of technical solution capable of coping with the required extreme high operating temperatures. Furthermore, zinc atoms react violently with the quartz, damaging the transparency.*

Although xenon-lamps can offer the required high luminance needed for projection purposes, they suffer from very low energy efficiency. Because xenon-lamps are about four times less efficient than Ultra High-pressure lamps, they tend to be much larger. As a result, they can only be used in a very limited number of projection applications (Ming (2005)).

LEU (2020): Some projector manufacturers started using solid state light sources within a limited area. These can be categorised as: White LED (1), Scanning Laser (2), RGB LEDs (3), LED/Laser (-phosphor) Hybrid (4), Laser-phosphor (5) or RGB Laser (6), RGBB LEDs (7), or HLD (LED) (8).

In the figure below, the market penetration rate of these alternatives is shown.

Figure 4-5: Market penetration rate of different projection alternatives to mercury-based projectors (2019 data)



Sources: LEU (2020)

Retrofit solutions are neither possible nor available according to LEU (2020):

The mercury-containing lamps used for projection in existing equipment (projectors) are tailor-made to an application/projector in terms of form, fit, and function. Consequently, no replacement light source (besides mercury-based lamps) can fit in that projector. This is the opposite of general lighting, where LED replacement bulbs are widely available. There are several reasons for this:

- *Difference in projector architecture because mercury lamps emit white light while solid state light needs to combine multiple sources to create white light*
- *Different cooling requirement*
- *Different size of light source*

Stage lighting, studio or entertainment:

LEU (2020): Within the entertainment sector, three different fixture types can be distinguished: beam, spot, and wash. The difference between these fixture types is in the beam angle:

- *Beam: < 4°*
- *Spot: between 5° and 50°*
- *Wash: > 50°*

For wash and spot applications, LED is becoming more widely used.

Most manufacturers of stage, studio, and entertainment lighting equipment make a combination of two or three types, the so-called hybrid fixtures: beam/wash (2-in-1) or beam/spot/wash (3-in-1). According to commercial end-users of lamps used for studio and stage lighting, it is generally believed that it will be several years before an alternative light source will be found for the fixtures used in large arena and stadium events, as LED technology is just now reaching its theoretical peak. While the general trend is to replace mercury lamps (new moving lights are typically equipped with LED source and bright profile spotlights will most likely be replaced in the course of the next years), there are still applications used to achieve certain artistic design objectives that do not have acceptable replacements.

Additionally, these LED solutions are not backwards compatible with fixtures mounted with mercury containing lamps, due to following reasons:

- *Different cooling requirements*
- *Different size of light source*
- *Operation on the existing control gear suited for short arc mercury lamps only*
- *Mercury lamps emit white light while solid state lamps need to combine multiple sources to create white light*

Only very recently (April 2019) was a first fixture based on laser technology been commercially released to the market. However, the technology is still very new within the entertainment sector and market penetration is expected to be rather low LEU (2020).

UV curing applications

LEU (2020): The inks, coatings, and adhesives developed for these processes have been designed to respond very efficiently to the broad emission spectrum of medium-pressure mercury lamps to deliver a finished product that meets a wide range of very demanding product specifications.

UV LEDs are a potential alternative technology that has been introduced into UV curing applications. However, to date, their commercial success has been limited to specific niche applications, such as new inks being developed that are optimized for the emission spectrum of UV LED lamps. Nevertheless, after curing, the ink surfaces are not as robust and scratch resistant as what is achieved with mercury lamp-based systems – the result of a limited availability of photo initiators that can be cured with UV LED.

Examples of where the use UV LEDs is already possible include: adhesives in assembly operations such as PCBs in consumer goods; ink jet printing on labels or in wide format printing for point-of-sale displays; and flexographic printing on heat sensitive films. They can also be used in some coating applications in wood finishing, sometimes in combination with medium-pressure mercury lamps.

Replacement/retrofit of UV LED lamps is not possible as the mercury lamps are used in special purpose equipment with existing controls, fixtures, and cooling systems that would not be compatible with an LED lamp. Furthermore, the process ink and chemistry are designed to work with the polychromatic mercury light source and would not be compatible with the LED lamp spectrum currently available. In addition, UV curing lamps must be replaced several times over the life of the equipment. Hence, even if a new technology becomes available, there will be a need for UV curing lamps as spare parts for legacy capital equipment for a considerable period.

VDMA (2021): The problem with all printing applications is that there are currently no high-performance UVC LEDs with a long service life available that are necessary, among other things, for sufficient surface curing (scratch resistance, chemical resistance).

In digital printing, e.g., for large-format inkjet printing systems, UV LED units have been used successfully for the so-called pinning[6]) for some years already. The UV LED units are mainly integrated in the printing heads. The radiation dose of UV LED modules is lower compared to the conventional medium-pressure mercury lamps. If printing is done in several passes (multi-pass technology), polymerisation is ensured by moving the UV-LED modules over the same spot several times. In single-pass digital printing systems, in addition UV mercury discharge lamps are often used in end-of-press drying in order to guarantee sufficient curing of the layers.

GEW (2021) argued that UVC LEDs do not yet provide outputs, price points, and lifetimes that make them commercially viable for UV curing. Even when UV LED formulations and curing lamps provide suitable performance for a given application the cost of the UV LED formulation is to GEW's knowledge at least 10 % more expensive and sometimes up to 300 % more costly than equivalent formulations designed for mercury containing lamps. Most, but not all, ink and coating manufacturers provide a UV LED compatible formulation for sale. Often these are only available for a subset of their full product range. Significant R&D efforts are underway to rapidly expand ink and coating ranges, improve their performance and reduce their costs. A complete universal shift to LED UV curing requires ongoing collaboration throughout the supply chain for at least another 10 to 15 years or more.

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[6] A process in which the ink is partially cured immediately after being jetted to reduce dot gain and provide a sharper, more vibrant image on an inkjet printer. Through-curing is then carried out in a final dryer, usually with conventional UV dryers based on medium-pressure mercury discharge lamps.

<u>Packaging printing applications</u> VDMA (2021): a large number of formulations are used to create the coating effects, which essentially require UVC light in order to meet the requirements reliably. Since high-performance UV LED dryers for the UVC range are currently not feasible, UV medium-pressure mercury discharge lamps still have to be used for these applications.

<u>For printing products with low migration requirements</u> VDMA (2021): reliable curing is also needed for compliance with the European requirements for low migration of substances from food packaging materials (Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food). Since ink layers act as filters for UV light depending on the colour, ink formulations that react very broad band to UV light are necessary. Only UV medium-pressure mercury discharge lamps provide the necessary radiation spectrum.

In order to replace UV medium-pressure mercury discharge lamps in further printing applications by UV LEDs as well, much more durable, powerful and cost-effective UVC LEDs are required. At the same time, appropriate ink formulations must be developed, tested and approved.

The state of the art of UVC LEDs compared to UVA LEDs currently is as follows VDMA (2021):

- *Efficiency approx. 15 times lower.*
- *Power approx. 40 times lower.*
- *Service life (L80 value) approx. 20 to 30 times lower.*
- *Costs per mW approx. 1000 times higher.*

VDMA (2021)There is currently no UVC LED technology available to economically produce and run a UVC LED system for the curing. Thus, the UV LED use is limited to a few applications with UVA LED systems, typically in the commercial sector with printing of 4 process colours, Black, Cyan, Magenta, Yellow. There is also a lot of development work still to be done on spot colour inks, special inks and coatings.

Although there has been progress in the use of UV LED dryers in printing in recent years, the CMR classification of photoinitiators has hampered the LED ink development. Photoinitiators such as pi 369, tpo or thx, which have been frequently used so far, can no longer be used and alternatives must be found VDMA (2021).

Disinfection applications

<u>Water disinfection</u>: according to VDMA (2021), UV-LEDs cannot be used for disinfection because powerful UVC LEDs are currently not available. Chemicals such as chlorine, chlorine dioxide and ozone are widely accepted disinfectants and might be an alternative disinfection method to UV treatment. However, the chemical disinfection methods do have limitations and cannot be used for all water sources. There are some water relevant pathogens (for example parasites such as Cryptosporidium and Giardia Cysts) which cannot be effectively inactivated within the maximum allowable dose rates. Additionally, the chemicals can react with water constituents (for example organic matter) to form disinfection by-products such as THMs (tri halogen methanes), chlorate or bromate. These by-products are a health concern and can provoke chronic diseases. There are maximum contaminant

levels in the drinking water directive defined. Depending on the composition of the raw water, a safe disinfection cannot be reached with chemicals without violating the maximum contaminant levels.

UV LED reactors in drinking water treatment require different designs than conventional UV systems (e.g. flow paths) to increase the efficiency of the reactors. A simple replacement of the existing UV lamps would therefore not be possible. It was not until mid-2019 that the world's first test system with UVC LEDs was installed in a municipal water supply in England (i-Micronews (2019)).

LEU (2020): A possible mercury-free solution could be an XeBr- excimer lamp emitting at 282nm or an XeI*- excimer lamp emitting 253 nm photons. In both cases, the wall-plug efficiency is below 10 %, meaning neither are a realistic alternative given the power consumption comparison with Hg lamps and their poor efficiency. Furthermore, the power supply technology is by far more complex and significantly more expensive compared to conventional ones used to drive Hg-based lamps.*

Another alternative might be a Xe2- excimer lamp emitting 172nm photons with an efficiency of up to 40 %. A phosphor might convert the radiation into the germicidal range around 265nm. Assuming a quantum efficiency for the phosphor of 90 % and the Stokes shift being ~65 %, the total electrical lamp efficiency will come down to ~23 %. This low value might only be partly compensated by a larger germicidal action due to the wavelength. However, lifetime values for the Hg-based conventional lamps easily exceed 10 000h – a number that is very hard to achieve using a 172 nm based Hg-free version.*

With an efficiency of only 3-5 %, the UVC LEDs currently on the market simply cannot compete the 50 % efficiency offered by conventional mercury vapor lamps. Moreover, with an output of 50mW, a huge number of LEDs are needed to achieve the necessary intensity. Although UVC LED technology might suit small consumer applications like toothbrush disinfection containers, their efficiency/performance to milli Watt ratio is far too low to provide the high-power and high turnover demanded by the professional market. This results in higher energy consumption compared to what an application using conventional mercury vapor lamps can achieve. With a lifespan that is 30 % shorter than that of a mercury vapor lamp, UVC LEDs need to be replaced more often, resulting in higher costs for the operator. Despite what is often advertised by LED manufactures, the performance of UVC LEDs isn't independent of temperature. In fact, increased temperatures and ageing of shortwave LEDs have a negative effect on their performance.

According to Xylem Service (2021), LED UV lamps do not function properly with warm liquids, so the food industry cannot work with it. Chlorination is an alternative to UV disinfection; however, it may produce harmful chemicals and does not treat well pathogens such as cryptosporidium and giardia which are very resistant to chlorine but not to UV.

<u>Disinfection of packaging and machine parts</u>: VDMA (2020): The replacement of UV lamps by UV LED modules is currently not possible, as the performance, cost and service life of the necessary UVC LEDs would be contrary to their economical utilisation. UV lamps with mercury discharge lamps are still in demand in the retrofit sector. The long-term availability of UV mercury discharge lamps as spare parts is necessary for installed machines, some of which are in production for 20 years or more.

High-pressure short arc mercury lamps

LEU (2020): Short arc mercury lamps are mainly used for microlithography in the semiconductor industry. This industry is fully dependent on the availability of these lamp types. Currently, there is no available alternative for high-pressure short arc mercury lamps, and mercury cannot be replaced in short arc lamps. There are no other suitable chemical elements that can be used as a substitute to mercury. Retrofit solutions are not available

Other high-pressure lamps for special purposes

LEU (2020) Mercury vapor lamps for medical and industrial research and development applications are used for qualitative and quantitative analysis, colour comparison, observation, and inspection. Carrying out these applications requires multiple specific wavelengths, high-intensity, and a spotlight source. At present, only mercury (or combinations of mercury and other elements/substances) in a single light source are able to meet these requirements. As these lamps are manufactured in various sizes and power consumptions corresponding to equipment, it is impossible to determine the definite amount of mercury limit value. Mercury xenon lamps have a point source of light, which makes it possible to lead light to the optical equipment with high efficiency and maximum intensity on the end of the cathode. On the other hand, because LED has different features, such as surface emission and diffusion light, they are not suitable for the applications mentioned above.

4.2.2. Roadmap towards substitution or elimination of mercury in lamps

VDMA (2021) Printing: The synthesis, approval and registration (REACH) of new suitable photo-initiators requires substantial research efforts and tests which, now, are disproportionate considering the amounts of ink produced. Furthermore, the ink manufacturers state that the development of new UV LED printing inks, their CMR (CMR=Carcinogenic, Mutagenic and toxic to Reproduction) testing and approval takes 5 to 7 years and, therefore, is not economically reasonable considering the present market volume.

Disinfection: Due to the high market potential, the focus of UVC LED development is on the wavelengths between 260 and 285 nm. Now they are in the research and development stage. For example, the power output could be improved[7] from 10 mW in 2014 to 100 mW in 2017 at 280 nm. At present, the efficiency (wall plug) is between 2 and 6 %, but commercial use is not possible for the reasons mentioned above.

LEU (2020) Medical research and R&D: LED must become a larger point source of light than what mercury containing lamp has. As the light emission intensity of a single LED is much lower, it would be necessary to array the LEDs to achieve higher intensity. However, there is a limit to reducing the diameter of the light spot of arrayed LEDs. Point source of high intensity is required for a variety fields, including medical and research and development, and LED is thus not a substitute alternative to a mercury-containing lamp at point source.

[7] Source: https://www.i-micronews.com/water-disinfection-applications-will-be-worth-650m-in-2023/; source as referenced by the applicant

Purion (2021) reported that LG has stopped further research/production of UVC LEDs because of material problems to establish reliable production processes.

DVGW (2021) currently supports the development of a DIN standard for UV LED based water disinfection devices. A first draft standard can be estimated to be published in 2024 as the starting point to establish a new technique.

Hanovia LTD (2021), manufacturing both lamps and systems for curing and for water, air and surface disinfection applications, invested alongside the EU in our Horizon 2020 project ECO UV to commercialise a mercury free lamp with DVGW, Karlsruhe Institute of Technology and the Swedish Institute of Environmental Studies (IVL). ZEROHg UV project, a follow on from ECO UV, with the objective of bringing to market a highly innovative mercury-free ultraviolet (UV) lamp capable of purifying water for critical applications in the food & beverage and drinking water disinfection industries but efficiencies are too low and no guarantee of success

A.C.K. aqua concept (2021) are in UV-sanitation of machinery and tested LEDs since about 20 years. They faced limitations of the LED-technology for all wavelengths below 330 nm.

IKEA (2021) has evaluated UV-LED lamps for their lines. Several production lines have been partly converted to UV-LED. Their intention is to move away from mercury containing UV lamps, however the existing alternatives are not able to fully replace them yet. Klumpp Coatings GmbH upgraded their R&D department with a UV excimer system, with an investment of approximately € 250,000.

Remmers Industrielacke (2021), producer of wood-coating materials, applies a combination of UV-LED´s and Hg-lamps at several finishing lines. UV-LED´s cannot be considered as an overall replacement for Hg-lamps but using this combined curing technology has proven to be a reasonable way to work. In addition, Remmers Industrielacke (2021) provides a list of alternative equipment and producers (EBC: Crosslinking AB; Energy Sciences Inc; PCT and UV-LED: AMS Baldwin; Efsen; Heraeus; Hoenle; IST Metz; Phoseon; Uviterno).

ProMinent (2021) also discusses alternatives (LEDs and Excimer lamps) for disinfection properties.

4.2.3. Environmental arguments and socioeconomic impacts

LEU and VDMA provided generic arguments regarding the environmental impact of mercury in lamps and the social impacts of a possible ban of these lamps. Indeed, the lamps being part of a well organised recycling process involving deposits and regular collection by recycling organisations, there are very few losses as described by VDMA (2020) in their application:

UV lamp manufacturers offer users the redemption of their mercury discharge lamps for recycling purposes. Worn-out lamps are handed over to a certified waste management company which takes over the responsibility for the recycling of the mercury lamps.

Users who do not return their lamps are instructed (mandatory part of the instruction handbook, duty for marking with symbol for separate collection, see Annex III) to have the used mercury lamps disposed of by a certified waste management company. ISO 14001 and EMAS (Eco-Management and Audit Scheme) certified users will ensure this recycling process.

Moreover, these lamps are all intended to be used by professionals and so are part of the collection systems. Only a few of these specialised lamps can find their way into the hands of private users, almost exclusively as projector lamps. These lamps contain on average 20mg of mercury and in total amounted to a 28 kg mercury input in the EU in 2019 (22 kg for new lamps and 6 for replacement/spare part lamps) (LEU (2020)), hence the fraction of these lamps that may end up uncollected through the recycling systems is very small and so will account for very limited quantities of mercury pollution. Recycling was often mentioned during the Open Public Consultation as a potential improvement on which the Commission should focus its efforts instead of banning mercury from being used in lamps. The consultants believe that there is no need to be concerned with lamp recycling in the EU since the system is well put in place for professional users of lamps targeted by exemption 4(f).

A DVGW (2021) survey conducted in 2008 (1094 German Drinking Water suppliers replied) revealed UV-disinfection, using mercury-vapor discharge lamps, as the most relevant disinfection method – especially for small suppliers (< 0.3 Mio m³ per year). Beside this, large water utilities are using more and more UV-disinfection since the last 10 years, e. g. drinking water operators in Berlin (3.5 million residents), in Munich (1.5 million residents) and in the highly populated Ruhr region (approx. 2 million residents).

According to the reports of Optimarin (2021) and BEMA (2021), UV-filters are used for treatment of ballast water in ships, which is one of the (if not the) most effective ways to prevent the transport of invasive species. Optimarin (2021) is dependent on UV lamps to fulfil the obligation to neutralize alien species without using dangerous substances, according to the Type Approvals (TA) issued by IMO and US Coast Guard. Other kinds of technologies have been proven inadequate under some specific marine conditions, hence suboptimal for the removal of the invasive species.

Hanovia Ltd (2021) reported that in 2018 Boston Consulting Group(BCG) estimated the global market just for UV disinfection equipment at $2bn per annum exhibiting a rapid CAGR of 16 %, driven by population growth, urbanisation, industrialisation, water scarcity, pollution, and a desire to move away from chemical disinfection. We know disinfection of Covid significantly increased quantities above and beyond this reported value.

A.C.K. Aqua Concept (2021)'s concerns: (1) Reliable sanitation cannot be warranted by LEDs, (2) LED-sources below 330 nm decompose the LEDs' structure and lead to very low life time and generation of waste and CO_2. (3) Chinese companies would take over if the ban was enforced in Europe and (4) if UV-lamps become unavailable, API destruction and production of dydrogesterone (female hormone 100 % mercury based) would cease.

Ushio Europe (2021) argued that if - due to a ban of mercury containing HPS lamps - greenhouses were forced to switch their entire lighting installations to LED, many of them would go out of business instantly because they simply could not afford the investment. In addition, it would produce a huge amount of pre-mature electronic waste of control gears etc. which is in contrast to the environmental goals of the European Union.

ESIA (2021) argued that due to mercury containing lamps used in specific semiconductor manufacturing equipment, not renewing the exemption would undermine the European Union's commitment to reinforce the EU's semiconductor manufacturing capacity. (In March 2021, the European Commission President responding to European Council of Member states call for action proposed a 'Digital Compass' goal that by 2030, the production of semiconductors in Europe should be 20 % of world production.) Semi Europe (2021) *highlighted that without I-line technology more expensive technology (248 nm) will be used with the need to recertify processes to this new technology. Changing to different wavelengths also increases related costs. The lamps are not generating much waste since typically semiconductor machines are using 6 to 10 lamps per year and after service life the lamps are returned to the lamp manufacturers.*

4.3. Critical review

The exemption request was withdrawn when the COM published the renewed exemption 4(f) (see section 4.1.3 on page 35 for details). The consultants did therefore not conduct a full critical review and assessment of the stakeholders' arguments against the current scientific and technological practicability of mercury substitution or elimination in fluorescent lamps.

The provided technical information and the applicants' justification of their renewal requests suggest, while LED lamps generally are a technology that can eliminate the use of mercury in lighting, that fluorescent lamps in the scope of exemption 4(f) are still required for two reasons:

- Specific qualities of light technically can not yet be achieved with LED lamps, or are not commercially available as LED lamps.
- EEE using these fluorescent lamps – "legacy products" - would require a redesign to accommodate the geometries and electrical/electronic specifications of LED alternatives. This EEE is often characterized by long redesign cycles (long model lives) and long technical life times, and the exchange of the fluroescent lamps by LED lamps may entail further changes in the process environment. Overall, the redesign and subsequent use of devices applying LED lamps would be costly and/or, due to limited numbers of devices produced, may commercially be impracticable, and it may cause additional waste if equipment has to be exchanged prematurely.

The scientific and technical progress of the LED technology may enable further elimination of mercury in fluorescent lamps in the coming years which users of fluorescent lamps should observe and take into account for a potential next renewal request. With time passing and LED technology maturing, applicants should carefully justify continued uses of fluorescent lamps in applications where design changes would facilitate using mercury-free lighting solutions.

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5. Exemptions 8(b) and 8(b)(I) of Annex III: Cadmium in electrical contacts

The current wording and expiry dates of the exemptions are:

No.	Current exemption wording	Current scope and dates of applicability
8(b)	Cadmium and its compounds in electrical contacts	Applies to categories 8, 9 and 11 and expires on - 21 July 2021 for categories 8 and 9 others than in-vitro diagnostic medical devices and industrial monitoring and control instruments; - 21 July 2023 for category 8 in-vitro diagnostic medical devices; - 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11
8(b)(I)	Cadmium and its compounds in electrical contacts used in: - circuit breakers, - thermal sensing controls, - thermal motor protectors (excluding hermetic thermal motor protectors) - AC switches rated at: - 6 A and more at 250 V AC and more, or - 12 A and more at 125 V AC and more - DC switches rated at 20 A and more at 18 V DC and more, and - switches for use at voltage supply frequency ≥ 200 Hz	Applies to categories 1 to 7 and 10 and expires on 21 July 2021

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

A	Ampere
AC	Alternate current
Cat.	category, referring to EEE categories of RoHS Annex I
CB	Circuit breaker
Cd	Cadmium
CT	Computed tomography
DC	Direct current
DoC	Declaration of conformity
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instrument
IVD	In-vitro diagnostic medical device
TMP	Thermal motor protector
TSC	Thermal sensing control
V	Volt

Definitions

AED	Automatic external defibrillator, a portable defibrillator designed to be automated such that it can be used by persons without substantial medical training who are responding to a cardiac emergency[8]
Defibrillator	Medical device delivering a dose of electric current (often called a counter-shock) to the heart as treatment for life-threatening cardiac arrhythmias, specifically ventricular fibrillation (V-Fib) and non-perfusing ventricular tachycardia (V-Tach) [9]

[8] Source: https://medical-dictionary.thefreedictionary.com/AED

[9] Ong, ME; Lim, S; Venkataraman, A (2016). "Defibrillation and cardioversion". In Tintinalli JE; et al. (eds.). Tintinalli's Emergency Medicine: A Comprehensive Study Guide, 8e. McGraw-Hill (New York, NY); Kerber, RE (2011). "Chapter 46. Indications and Techniques of Electrical Defibrillation and Cardioversion". In Fuster V; Walsh RA; Harrington RA (eds.). Hurst's The Heart (13th ed.). New York, NY: McGraw-Hill – via AccessMedicine; Werman, Howard A.; Karren, K; Mistovich, Joseph (2014). "Automated External Defibrillation and Cardiopulmonary Resuscitation". In Werman A. Howard; Mistovich J; Karren K (eds.). Prehospital Emergency Care, 10e. Pearson Education, Inc. p. 425; in Wikiipedia (https://en.wikipedia.org/wiki/Defibrillation)

Fixed contacts	Contacts consisting of two conductive parts that are joined together with a contact material as part of an assembly and are intended to stay securely connected during operation. (Definition introduced by the applicants)
Capnography	Monitoring of carbon dioxide (CO2) concentration or partial pressure in respiratory gases[10]
Protective switches	Switches like circuit breakers, thermal sensing controls and thermal motor protectors with the main function to protect users and EEE in case of emergencies or other potentially dangerous out-of-the-norm events.
Switches	Protective switches and other switches
Other Switches	Other switches than protective switches, i.e. switches for starting and ending operations (on/off functionalities) of electrical and electronic equipment by the user
Switching contacts	Switching electrical contacts consist of a contact pair that can be physically closed or opened with the main function to make or break an electrical current: circuit breaker, thermal sensing controls, thermal motor protectors, and other switches; counterpart to the "fixed" contacts

5.1. Background and technical information

Sensata et al. (2020a) request[11] the renewals of exemptions III-8(b) and III-8(b)-I for EEE of categories 1-10 with the below wordings, scopes and expiry dates. Sensata et al. (2020b) amended the renewal request to include cat. 11 for both exemptions while currently it is covered by exemption 8(b) only. Sensata et al. (2022b) later decided that cat. 11 covering equipment like engine generators and engine welders shall be included into the scope of exemption 8(b)(I).

The below table shows the requested exemption renewals. Changes of the current exemption status are underlined.

No.	*Requested Exemption*	*Requested scope and dates of applicability*
8(b)	Cadmium and its compounds in electrical contacts	Expires on - 21 July 2028 for cat. 8 medical devices including in-vitro diagnostic medical devices, and

[10] Bhavani-Shankar, Kodali; Philip, James (October 2000): Defining segments and phases of a time capnogram. Anesth Analg. **91** (4): 973–977 in Wikipedia (https://en.wikipedia.org/wiki/Capnography)

[11] The contact/switch manufacturers or users providing specific information in the renewal request are Sensata Technologies, Marquardt, NEMA (National Electrical Manufacturers Association, USA) and COCIR for the RoHS Umbrella Industry Project ("the Umbrella Project"). No other producers or users of cadmium in contacts are mentioned in the renewal request.

		for cat. 9 monitoring and control instruments including industrial monitoring and control instruments
8(b)-I	Cadmium and its compounds in electrical contacts used in - circuit breakers rated at - 10 A and more at 250 V AC and more, or - 15 A and more at 125 V AC and more, - thermal sensing controls rated at - 10 A and more at 250 V AC and more, or - 15 A and more at 125 V AC and more, - thermal motor protectors (excluding hermetic thermal motor protectors) - AC switches rated at: - 10 A and more at 250 V AC and more, or - 15 A and more at 125 V AC and more, - DC switches rated at 25 A and more at 18 V DC and more, and - switches rated at 300 V and more for use at voltage supply frequency ≥ 200 Hz	Expiry on - 21 July 2026 for cat. 1-7, 10 and 11

TMC (2020) contributed to the stakeholder consultation stating that their members intend submitting applications for renewal of certain exemptions [here 8(b) and 8(b)-I] *within the legally foreseen deadlines of 18 months prior to their expiries for industrial monitoring and control instruments. They request the European Commission to schedule the evaluation of the Annex III exemptions relevant to category 9 industrial applications in due time, i.e., 18 months prior to 21 July 2024. However, the COM had already clarified with representation of TMC in written correspondence, pertaining to a previous exemption renewal request, that the Commission considers it justified for the technical assessment to start at the same time for all categories as requested by the applicants.*

5.1.1. History of the exemption

The use of cadmium in electrical contacts was already exempted under exemption no. 8 in the Annex of Directive 2002/95/EC (RoHS 1) when RoHS 1 entered into force in 2003:

> *8. Cadmium plating except for applications banned under Directive 91/338/EEC amending Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations.*

With the Commission Decision 2005/747/EC in October 2005, the exemption wording was changed to:

> *8. Cadmium and its compounds in electrical contacts and cadmium plating except for applications banned under Directive 91/338/EEC amending*

Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations.

The exemption was first reviewed by Gensch et al. (2006), later again by Gensch e al. (2009) and thus gradually transferred into the below status with a split into exemption 8a and 8b:

8(a) Cadmium and its compounds in one shot pellet type thermal cut-offs

Expires on 1 January 2012 and after that date may be used in spare parts for EEE placed on the market before 1 January 2012

8(b) Cadmium and its compounds in electrical contacts"

Gensch e al. (2009) recommended the expiry date 31 July 2014 for exemption 8(b), which was the maximum duration (i.e., 4 years) under RoHS Directive 2002/95/EC (RoHS 1). Cadmium-free contact materials were available for applications under exemption 8(b), but industry required time to adapt and test their use to their applications to make sure the cadmium-free contacts suffice in terms of safety and other requirements. The COM adopted the exemption with a validity period of four years.

The exemptions in the Annex of RoHS 1 including exemptions 8(a) and 8(b) were transferred into the recast RoHS Directive 2011/65/EU (RoHS 2). During that process, the expiry dates of all exemptions with maximum validity of four years were systematically extended to five years starting from July 2011 on. This gave industry a total of seven years since 2009 to substitute or eliminate cadmium in contacts.

Sensata (2015) nevertheless requested the renewal of exemption 8(b) for another five years in 2015. The review by Gensch et al. (2016) resulted in the split into two exemptions 8(b) and 8(b)(I) with the current wordings and scopes. Sensata et al. (2020a) submitted another request on 16 January 2020 for another renewal of the exemption so that the two exemptions have become due for review again. On 9 October 2020, Sensata et al. (2020b) amended their renewal request to include EEE of cat. 11 into their exemption request.

5.1.2. Summary of the requested exemption

Sensata et al. (2020a) report that cadmium is used in switching[12] electrical contact systems in the form of silver cadmium oxide (AgCdO), which is one of many categories of metal alloys commercially available for use in switching electrical contacts. Electrical arcs occurring at the opening and closing of the contacts alter the surface layer of the contacts during cycling, which affects the contact system properties and consequently its performance. Surface damage resulting from arcing can lead to contact failure, compromising the reliability of the equipment and creating potential safety hazards for humans, animals and property. As explained further within this dossier, AgCdO remains far superior to most alternatives at "quenching" electrical arcs - switching off electrical current quickly and cleanly and avoiding contact welding and premature failure.

[12] In this document, a distinction is made between switching and fixed electrical contacts. Switching contacts consist of a contact pair that can be physically closed or opened with the main function to make or break an electrical current Sensata et al. 2020a.

Where suitable cadmium-free alternatives have been found to provide required cycle reliability and product performance/safety, the contact system is converted to a cadmium-free alternative. The suitability of alternative materials is affected by a range of factors such as, but not limited to, voltage, current range, size, opening and closing speed, contact force, frequency and required number of operating cycles and other complex conditions in the application; such as continuously changing electromagnetic fields in electric motors.

This multiplicity of factors leads to a substantial amount of "trial-and-error" by manufacturers, their customers and suppliers during product development. It also makes it highly impractical to specify, with any precision, the conditions under which alternative formulations offered by material suppliers are suitable for specific applications. Differing formulations within each major category of metal alloys result in literally hundreds of possible choices.

In addition to switching electrical contacts, cadmium is also being used in fixed[13] *electrical contacts under special conditions for category 8 and 9 applications. Use of cadmium in fixed contacts is needed in highly sensitive applications, such as oxygen and capnography sensors. These applications require very low "drift" during continuous operating periods spanning many years, along with the ability to withstand electro-migration whilst providing suitable conductivity and adhesion properties.*

In line with the current state of the business to replace cadmium in electrical contacts by reliable and safe alternatives, Sensata et al. (2020a) apply for an extension of the exemption for the maximum validity period, based on a partly narrowed scope as proposed by this application.

5.1.3. Technical description of the exemption and use of the restricted substance in electrical switching contacts

The technical background of cadmium uses and requirements for electrical contacts of this kind was described in the review reports of Gensch et al. (2016) and Gensch e al. (2009). The following describes the most important technical aspects and new information of relevance for the requested exemption renewal.

Sensata et al. (2020a) report that cadmium in the form of the silver cadmium oxide alloy (AgCdO) is used in electrical switching (switching: open and close) contacts in various products and end-applications. The technical function of cadmium in switching contacts is to resist the arc energy that is created when the contacts open and "bounce" when closing, as well as helping to prevent contact weld.

Given the high temperatures generated under arcing conditions, the cadmium oxide helps to:

- *Minimize heat concentrations as higher thermal conductivity allows heat to go through the contact layer faster, thereby reducing the temperature rise;*

[13] A fixed contact is where two conductive parts are joined together as part of an assembly and are intended to stay securely connected during operation. (Sensata et al. (2020a))

- *Resist welding of contacts so that the function of opening and closing occurs reliably;*
- *Minimize contact surface erosion;*[14]
- *Prevent contact "sticking" (partial/momentary welding or hooking by rough surface).*

During one breaking operation of electrical contacts, arc erosion results from the combination of:

- *Material removal due to vaporization of the contact material;*
- *Material removal because of the ejection of contact material particles; and*
- *Redepositing of vaporized or ejected contact material.*

The amount of layer change and material erosion (failure mode) induced by the electrical arc at each contact opening and closing defines the product performance, reliability and product safety (failure effect). Surface damages by arcing lead ultimately to contact failure such as, but not limited to, contact welding and contact destruction. When this occurs, the switching device can no longer fulfil its designed functions at the required conditions, resulting in impaired safety function or dangerous failures.

During cycling, the size and distribution of cadmium oxide clusters become smaller, more homogeneously and finely dispersed. This results in good contact stability and anti-welding properties, due to:

- *High viscosity (preventing contact material from splash erosion);*
- *High thermal conductivity (fast heat distribution and reduced temperature elevation);*
- *High electrical conductivity/low contact resistance over long periods (good electrical features and limited heating up of the contact) which is particularly important to long life products such as MRI's which have product lifetimes up to 25 years.*

Sensata et al. (2020a) list the below applications/products of cadmium-containing electrical contacts which they currently know of:

- *Electrical contacts (fixed) used in sensors for detection of low oxygen levels at elevated temperatures;*
- *Electrical contacts (fixed) used in capnography sensors that are used to measure carbon dioxide in inhaled and exhaled air of patients who are undergoing surgery, are being ventilated to assist their breathing or to diagnose medical conditions;*

[14] Reference to: F. Pons, "Electrical contact material arc erosion: experiments and modeling towards the design of an AgCdO substitute", PhD Thesis, May 2010, Georgia Institute of Technology, https://smartechKlicken oder tippen Sie hier, um Text einzugeben..gatech.edu/bitstream/handle/1853/33816/pons_frederic_201005_phd.pdf 8; source as referenced by Sensata et al. (2020a)

- *Electrical contacts (switching) used in switches above certain current and voltage ratings and/or frequency of supply voltage;*
- *Electrical contacts (switching) used in control devices for improving safety of various applications, such as:*
- *Circuit breakers;*
- *Thermal sensing controls;*
- *Thermal motor protectors.*
- *Electrical contacts used in monitoring and control devices that include safety-related products (e.g. overload relays, transfer switches, bypass contactors, fire pump controllers); power switching products (e.g. motor starters, contactors, pilot devices); as well as replacement contacts for these applications.*
- *Electrical contacts used to extinguish arc flash in Solenoid- Actuator and Relay-Power (DC24V) in engines.*

Sensata et al. (2020a) say that many applications of the electrical contacts require high reliability and long lifetimes: therefore, component design and material choice are critical to maintain the required function. Some of the variables that determine the component design and materials choice include:

- *Switching current and voltage;*
- *Number of switch cycles required;*
- *Inductive effects;*
- *Inrush and breaking current*[156]*;*
- *Space available for the contact and for cooling the contactor;*
- *Available "open" gap between contacts for reliable arc suppression;*
- *Frequency of switching;*
- *Heating effect of the surface material;*
- *Type of voltage supply (AC or DC); and*
- *Contactor design, e.g. how this affects "bounce" when contacts close.*

Sensata et al. (2020a) claim that electrical arc erosion plays a crucial role in the reliability and lifespan of switching devices, affecting functionality or preventing fails that can lead to safety issues. Depending on the contact material's behaviour in response to an electrical arc, surface damage can induce severe changes in contact material properties that will adversely impact the device's functionality. Consequently, electrical arc effects and consequences on the contact material surface are highly important.

[15] Explained on page 1 of http://www.te.com/commerce/DocumentDelivery/DDEController?Action=srchrtrv&DocNm=13C3236_AppNote&DocType=CS&DocLang=EN; source as referenced by Sensata et al. 2020a.

According to Sensata et al. (2020a), for category 8 devices cadmium-based electrical contacts are used in a variety of applications, which require the full scope of the 8b exemption. Many types of medical devices use high power circuits that require relays and contactors, both of which have switching contacts to switch power on and off. One such example is as relays in automated external defibrillators (AED) which require stand-off voltage while the relay is open, and high current pulse conduction while closed. Cadmium-based relays ensure that the contact resistance remains low (< 50 mOhm). Without this function the self-tests undertaken by the AED daily, weekly, and monthly might fail, posing a risk of product failure at a critical time for a person experiencing a heart attack.

Sensata et al. (2021) report that switches in AEDs may be DC switches rated at 10 A and more at 150 V DC/400 V AC in defibrillator and AED (class 3 medical devices), which require a single, Dual Pole, Single Throw (DPST) Miniature Power Relay to transfer therapeutic shock energy to a patient. The cadmium containing relay has been tested extensively at millisecond pulse durations, at current and voltage levels far exceeding published "continuous" specifications in order to provide an appropriate therapeutic dose of electrical energy to a patient. The biphasic energy waveform delivered through the closed relay contacts has a very specific profile and duration in order to provide a successful therapeutic outcome. In addition, the device implements a daily self-test by measuring the circuit impedance (milliohms) through closed relay contacts in order to guarantee a safe and efficacious therapeutic patient outcome during use.

Sensata et al. (2021) say that this application type may be considered exotic in that the published "continuous" power rating of the relay is deliberately violated for very short, pulsed application of therapeutic energy through the closed contacts. Both the application of therapeutic energy and the diagnostic impedance measurement are implemented using a "cold switching" method, i.e. the circuit design ensures that the contacts in the relay are fully closed before the switch load is applied[16], so that no signal arcs and metal migration occur, differently from hot switching. A cold-switching use case may be significantly different in impedance drift over time from a hot-switching use case. Cadmium is well known in the industry for low contact resistance.

Another example is the use of cadmium-based circuit breakers mounted on the rotating unit of the Computerised Tomography (CT) system. The circuit breaker operates under high speeds (0.35 sec/rot) and high centrifugal force (about 30 G), so the size and weight of the circuit breaker is critical in order to obtain high centrifugal force resistance characteristics. Failures of the circuit breaker would lead to concerns over electrical safety and reliability.

Cadmium based electrical contacts are also used in power switching of electric motors, specifically as thermal protectors and line-break switches. Electric motors are used in many types of X-ray systems including CT, MRI, PET and SPECT.[17] These types of devices require high levels of reliability over a long lifetime, which can be more than 20 years.

For example, in the medical imaging (RoHS Category 8) sector, cadmium-based electrical contacts are used as a power switch in X-ray tubes, which are characterized by high

[16] Pickering, https://www.pickeringtest.com/de-de/kb/hardware-topics/switching-system-specifications/cold-switching

[17] CT = Computed Tomography, MRI = Magnetic Resonance Imaging, PET = Positron Emission Tomography and SPECT = single-photon emission computerised tomography

voltages and high current, as well as to power MRI wherein electromagnets may consume 800 Ampere (A).

Sensata et al. (2020a) put forward two specific examples of how cadmium-based compounds function in fixed electrical contacts.

5.1.4. Cadmium in fixed contacts in oxygen and capnography sensors

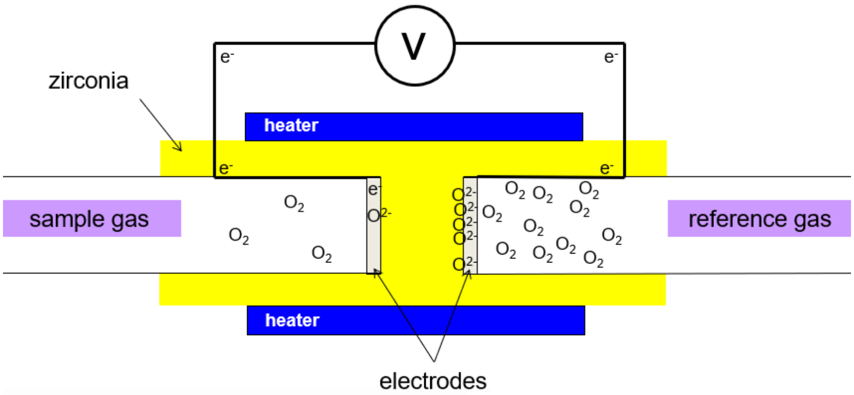
Sensata et al. (2020a) describe the use of cadmium in "fixed" electrical contacts, which they see to be covered by exemption 8(b), but not by 8(b)(I) because they are neither switches nor circuit breakers or thermal sensors. These fixed contacts are applied in oxygen and capnography sensors. *Sensata et al. (2022b) add that fixed contacts are also used in defibrillators and AED high voltage therapy delivery switching.*

For the use of cadmium uses in oxygen and capnography sensors, the applicants provided more detailed information:

Cadmium in fixed contacts of oxygen sensors

Sensata et al. (2022d) provide the below figure illustrating the outline of an oxygen sensor.

Figure 5-1: Outline of an oxygen sensor

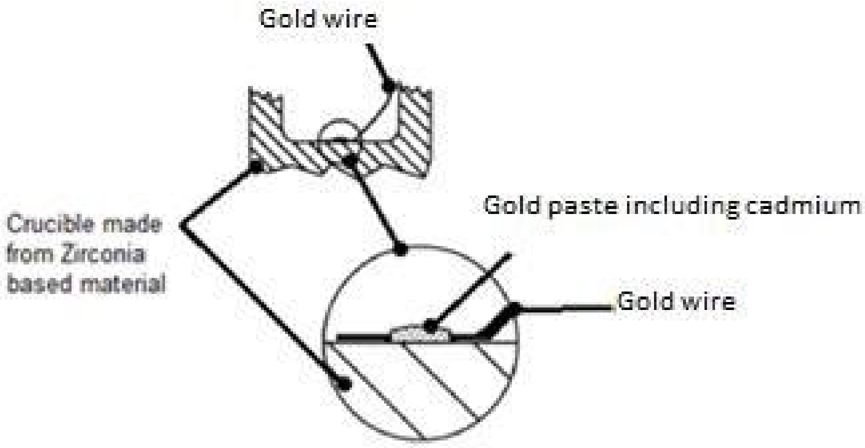


Source: Sensata et al. (2022d)

According to Sensata et al. (2022d), (2020a), the yellow block in the above figure is the crucible made from zirconia. The "crucible" is a hot sensing element used to isolate the measurement gas and the reference gas within a gas measuring device, generally referred to as a "transducer". The heater is a small resistive wire placed around the crucible (measurement cell).The zirconia crucible at room temperature has an impedance ~1014 Ω, but when heated to operating temperature, the resistance falls to ~100-1,000 Ω. The zirconia crucible, when heated to its operational temperature, becomes electrically conductive and produces a voltage across the electrodes when O_2 ions pass by which were generated before in a catalytic process. Zirconia has an ability to conduct oxygen ions between the reference gas and the sample gas. This ionic conduction follows a well-established equation, and the voltage is measured by a voltmeter. The voltage is related to the difference in oxygen concentration in the sample compared to the reference gas in the cell. From the measured voltage, the oxygen concentration can be calculated whose magnitude is a logarithmic function of the ratio of the O_2 partial pressures of the sample and reference gas.

Sensata et al. (2020a) (COCIR) explain that the oxygen sensors' electrical contacts are produced by coating conductive electrodes and 'tacking' gold wire electrodes which in turn are connected to additional electrical sensing and signal processing circuits as illustrated in the below figure.

Figure 5-2: Cadmium in fixed electrical contacts



Source: Sensata et al. (2020a)

Sensata et al. (2022d) further inform that the electrodes and coating material depend on the supplier specifications and can vary between suppliers. However, it can be generally stated that electrodes are made from a good electrically conducting metal, such as gold or platinum. For one manufacturer, the coating used to attach a very small gold wire to the crucible contains a small amount of cadmium.

Sensata et al. (2020a) see the following properties of cadmium for electrical contacts used in oxygen sensors:

- *Very low sensor measurement drift required, when the device is used continuously for multiple years; and*
- *Safe operation under high continuous operating temperature (> 500 °C).*

Cadmium in fixed contacts of capnography sensors

According to Sensata et al. (2020a), capnography sensors are used in patients' breathing monitoring, usually located close to the patient's mouth or nose and therefore must be small and light. Infrared energy from the source is absorbed as it passes through carbon dioxide in the air to measure its concentration. RoHS exemption 8(b) is utilised for the electrical contacts that supply electricity to the heater resistors that generate infrared light.

The electrical contact used in this application is made by printing a special thick film ink to create a contact that connects the heater to the power supply. The ink contains a gold/platinum alloy as the electrical conductor, a glass binder and cadmium oxide. The ink is printed on a fragile surface where good adhesion is essential, therefore precluding the use of metallic wires. The ink is fired at high temperature to melt the glass to form a matrix. Then a thick-film resistor is printed onto the gold/platinum alloy contacts and then heated to create a resistor which is electrically heated to emit infrared radiation.

According to Sensata et al. (2020a), for capnography sensors cadmium and its compounds fulfil the following requirements:

- *Reliable for at least ten years in use;*
- *Does not cause electro-migration;*
- *Withstands being dropped from 1.5 m onto a hard surface;*
- *Conductivity of 60-100 mΩ/square; and*
- *Adhesion > 50 N (initial pull, 90° pull, 2.0 x 2.0 mm pads).*

5.1.5. Amount(s) of restricted substance(s) used under the exemption

According to Sensata et al. (2020a), contacts in electrical switching devices typically contain 10-25 % cadmium in the homogeneous material of the contact face layer. The contact itself will typically be copper or copper alloy.

Sensata et al. (2020a) further report that Sensata Technologies reduced their global cadmium use from 950 kg down to 140 kg during the 2010-2020 period. 780 kg of these 810 kg reduction could be achieved in the period from 2014 to 2020 according to Sensata et al. (2021). They say that they cannot specify the reduction in the EU. For 2022, Sensata target using less than 90 kg of cadmium in their products which would be a further reduction of more than 50 kg compared to 2020.

Sensata et al. (2020a) point out that Marquardt follows a similar trend by reducing cadmium use from 6.9 kg in 2010 down to 2.9 kg in 2020. Sensata et al. (2021) detail that in 2014 Marquardt sold 1.8 % of their power tool switches with AgCdO contacts, resulting in 4.7 kg CdO corresponding to 3.2 kg of cadmium. In 2020, only 0.8 % of power tool switches sold still had AgCdO contacts containing 2.9 kg of CdO (around 2 kg of cadmium). Marquardt thus decreased their annual cadmium consumption for around 1.2 kg between 2014 and 2020. Marquardt highlight that they achieved the main reductions of cadmium use between 2007 (from 16.4 kg of cadmium) and 2014 (down to 4.7 kg of cadmium). Like for Sensata, these figures represent the global use of cadmium and cannot be specified for the European Union.

Fixed electrical contacts[18] contain typically 0.1-2 % cadmium in the homogeneous material of the paste/ink. According to Sensata et al. (2022f), a zirconia oxygen sensor contains around 3 µg of cadmium resulting at around 30 mg of cadmium being placed on the market whereby it is not clear whether this refers to the EU/EEA or world market. The applicants did not provide information on the annual volumes of cadmium in capnography sensors used under the exemption.

5.2. Justification of the requested exemption

Sensata et al. (2020a) put forward that, since the RoHS directive was adopted, electric contact and switch manufacturers have researched substitute materials. This work showed

[18] See section "Definitions" on page 59

that although cadmium performed well in a wide range of applications, each substitute that was evaluated had differing characteristics and no single drop-in replacement exists. Although there are many different contact materials on the market, each type is used only for certain uses and current ratings.

5.2.1. Substitution of cadmium

Technical constraints of cadmium-free materials in switching contacts

According to Sensata et al. (2020a), welding of contacts presents a safety concern because the actuating part cannot open the circuit. Cadmium effectively prevents tack welding, both under severe operating conditions and when the product nears end-of-life. The following characteristics have made cadmium an essential element for contact materials:

- Provides superior performance over longer time periods, which for medical devices and other applications may exceed 20 years;
- Quenches arcs – resists contact welding;
- Produces higher conductivity – i.e. smaller size of contacts; • Leads to less contact erosion – demanded by critical and safety applications;
- Easily manufactured compared to alternatives – i.e., methods for manufacturing alternatives to cadmium vary significantly among suppliers, and these methods influence such properties as arc erosion, contact resistance, and tendency to weld in service. (ASTM B844)[19]. Extensive testing is therefore necessary for each supplier as compared to AgCdO.

Potential alternatives may be found in fine silver, silver nickel alloys, silver zinc oxide (AgZnO), or silver tin oxide ($AgSnO_2$), which potentially offers superior corrosion resistance and better anti-welding properties compared to the other cadmium-free ones. In general, the 10, 12 and 15 % (weight) cadmium oxide grades are replaced with 8, 10 and 12 % (weight) tin oxide. To improve the electrical characteristics of the $AgSnO_2$, a range of additional oxides (dopants) can be added such as tungsten oxide, molybdenum oxide or bismuth oxide. These additives improve the arc-quenching characteristics and prevent the formation of high resistance oxide layers on the surface of the contacts. There are many variants, and their selection is dependent on the type of switching application of the electrical contact. As there is no standard composition, $AgSnO_2$ alternatives are more challenging to manufacture.[20]

However, while $AgSnO_2$-based contact materials offer certain advantages over other cadmium-free ones, they have important deficiencies in comparison with AgCdO. These include higher contact erosion, contact resistance and bulk resistance as well as greater

[19] ASTM B844 Standard Guide for Silver-Tin-Oxide Contact Material, c.f. https://www.astm.org/Standards/B844.htm

[20] Reference, see Wiki https://www.electrical-contacts-wiki.com/index.php?title=Silver_Based_Materials#Silver-Metal_Oxide_Materials_Ag.2FCdO.2C_Ag.2FSnO2.2C_Ag.2FZnO; source as referenced by Sensata et al. 2020a.

temperature rise. Overall, AgCdO contacts last longer and have properties that make them ideal for safety-related applications where device failure must be minimized. Products made with substitute contacts may be more susceptible to failure in the dangerous welded-closed state than are AgCdO contacts.

Sensata et al. (2020a) highlight again that choice of contact material is application-specific. Where substitution activities have indicated that an alternative is suitable, the transition by industry has either already happened or is well underway. However, each application has its own technical requirements. Life-testing "in-situ" is often a requirement to ascertain if the alternative is suitable. While a single protector solution with AgCdO contacts today serves many different applications that see many different electrical and environmental conditions with different life expectancies, the need for testing with alternate contacts is extensive. Many products have undergone testing of alternatives where substitute materials have so far proven unsuitable.

As an example for an application where Cd-free contacts have failed, Sensata et al. (2020a) put forward AED manufacturers having tested alternatives to cadmium, including AgNi, $AgSnO_2$ and gold-nickel in their products to determine their suitability. Due to the alternatives having contact resistance which builds up over time the product fails the self-test function of the AED. Without the self-test function, the AED, which needs to meet stringent requirements of reliability due to the products' function, could cause failures during the product life.

Use of cadmium in fixed contacts of CO_2-sensors

Sensata et al. (2022d) explicate that all capnography sensors require an IR (infrared) source and detector to operate, however the source of IR depends on the application. When the source is continuous, as with an incandescent lamp, it requires additional components to be able to function, these includes an electric motor, control circuitry and a chopper. To avoid the use of such components, and therefore decrease the size, which is essential for capnography, a non-continuous light source is used. Capnography sensors use a cadmium containing gold ink to form strong contacts and a thick-film resistor is printed upon it. The resistor which is formed from this is electrically heated, which produces the non-continuous light source of IR.

Sensata et al. (2020a) also report about alternative inks and light sources for cadmium-free alternatives for medical capnography sensors.

Inks

According to Sensata et al. (2020a), a capnography manufacturer evaluated an alternative thick-film ink that is both cadmium-free and lead-free. Tests showed that on firing the resistive ink, it caused it to interact with the contact ink so that electromigration occurred. During electromigration, thin metallic filaments grow from one conductor to nearby conductors under the influence of an electric field. When two contacts are connected by a filament, this causes a short circuit failure which significantly shortens the product's lifetime. The manufacturer is now testing other alternative inks.

Lamps

Sensata et al. (2020a) report that some capnography manufacturers use lamps as the infrared source. These have several disadvantages compared to resistive emitters, as shown in the table below.

Table 5-1: Disadvantages of lamps vs. resistive emitters

Issue	Lamp	Resistive emitters
Incandescent lamps are much larger that resistive sources	Incandescent lamp is typically a few mm long and a few mm thick. It usually operate in continuous wave mode and thus requires the use of a chopper and an electric motor and control circuit further increasing the size	Our emitter is 0.5 x 0.5mm sitting on a substrate of 6.25 x 1mm in length and width and 0.125mm thick.
Energy consumption	800 – 1000mW on 100% of time	400mW on 35% of time
Lifetime	Incandescent lamps typically last only two years. Motors and bearings can wear out. The chopper is a moving part in the sensor that will negativley impacts its robustness.	At least 10 years
Durability	If product is dropped in the course of its lifetime product failure is common	Increased durability with ability to withstand shocks

Source: Sensata et al. (2020a)

Sensata et al. (2020a) point out that larger size is an issue for patients where the capnography device should ideally be as small as possible so that it does not interfere with hospital staff's access to the patient. Light weight is also very important to prevent the ventilator pulling off the patient. Energy consumption is an issue as hot surfaces are potentially a safety hazard.

5.2.2. Environmental, health and safety, and socioeconomic impacts

Sensata et al. (2020a), (2020b) point out that failures and limited lifetime of electrical contacts in critical applications are subject to safety standards and sector specific requirements such as notified body approval for medical devices. In the applicants' rating, the current alternative material alloys have the potential to fail more often, resulting in increased volume of products disposed into the waste stream. Renewal of the exemption will only result in very limited release of cadmium into the waste stream.

The applicants highlight that cadmium in contact material is normally contained within a mechanical housing, which offers minimal or zero risk of exposure when used as intended during the working life of the device.

Current alternative materials will cause the safety of the equipment to be compromised, which especially in the safety-critical applications in the scope of exemptions 8(b) and 8(b)(I) can lead to injuries or fatalities.

5.2.3. Roadmap towards substitution or elimination of cadmium

*Sensata et al. (2020a) report considerable resources to be invested in the search for **cadmium-free silver metal oxide materials for switching contacts** by:*

- manufacturers such as AMI/Doduco, Brainin, Checon, Chugai, Danco, Deringer-Ney, Loxwood, Metalor, Naeco, Umicore; General Electric, Westinghouse, Siemens, Square-D, and Eaton Electrical;
- academic institutions such as Carnegie-Mellon University, University of Virginia, the University of Technology - Vienna, University of Wales, Osaka University, University of Braunschweig, University of Southampton;
- and private research firms such as the Electric Power Research Institute and the Battelle Institute.

The number of material formulations, product applications and test conditions are undoubtedly large according to Sensata et al. (2020a). This work is often of a proprietary nature, with manufacturers reluctant or unwilling to expose the results of their efforts to competitors. Findings from test efforts, however, can be seen in the proceedings of the IEEE Holm Conference on Electrical Contacts (53 editions), the Technical University of Lodz International Conference on Switching Arc Performance (10 editions), the RSIA International Relay and Switch Technology Conference (54 editions), and others.

Sensata et al. (2020a) recognised that the number of published articles in recent years has decreased. The underlying technical properties which cadmium based electrical contacts are uniquely able to offer are well understood and therefore might be a cause for reduced scientific experimentation. One general finding from this research is that cadmium-free contact materials may be suitable for use in products that tend to have short life expectancies and are disposed rather than repaired at end-of-life – examples would include household appliances, toys/leisure/sports equipment, and automatic dispensers.

Sensata et al. (2020a) insist that cadmium-based contacts must remain available for use in permanently-installed electrical power control equipment and safety- and health- related products, where maintaining public safety is the overriding objective.

For capnography sensors, the next step is to obtain and test alternative cadmium-free inks. Inks that are also lead-free will be tested first but if these are unsuitable, then cadmium-free inks that contain lead will be assessed. If a suitable ink is found in the future, then after testing is complete and the material proven to be suitable, a further two years is required for qualification testing in capnography sensors and to obtain global medical device approvals.

5.3. Critical review

The consultants use the terms “switches”, “protective switches” and “other switches”, or “other than protective switches” where misinterpretations might arise otherwise. Protective switches in this context are circuit breakers, thermal sensing controls and thermal motor protectors, while other switches are for starting and ending operations (on/off functionalities) of electrical and electronic equipment by the user. The term “switches” addresses both the protective as well as the other switches.

5.3.1. REACH compliance – Relation to the REACH Regulation

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV “provided that such inclusion does not weaken the environmental and health protection afforded by“ the REACH Regulation. The article details further criteria which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Annex XIV

Cadmium and several of its compounds are substances of very high concern but so far are not adopted to Annex XIV as substances that require an authorisation for use.

Annex XVII

With regards to Annex XVII, cadmium is mentioned in a few of the listed restrictions.

Paragraph 1 of entry 23 of Annex XVII refers to cadmium and several of its compounds including cadmium telluride. Under this entry, several restrictions are mentioned for cadmium and the compounds, among others:

1. A list of various polymers in which Cd may not be used unless required in colour for safety reasons.
2. Shall not be used for cadmium plating[21] metallic articles or components of articles used in equipment and machinery in certain branches and applications, e.g. cooling and freezing, food production, etc.
3. Shall not be used in brazing fillers unless used for safety reasons
4. Shall not be used or placed on the market if the concentration is equal to or greater than 0.01 % by weight of the metal in metal beads and other metal components for jewellery making, or metal parts of jewellery and imitation jewellery articles and hair accessories, e.g. in wristwatches.

[21] ‘Cadmium plating’ means any deposit or coating of metallic cadmium on a metallic surface

In the scope of the requested exemption, Cd is not used in polymers or jewellery. Its use could, however, be understood as a deposit on a metallic surface according to point 2 above. Since cadmium is applied as silver cadmium-oxide and hence as an alloy, not in metallic form as cadmium, the use of cadmium in in the scope of the exemption is not a "plating" and the restriction does not apply. As to point 3, cadmium in the scope of the requested exemption is not used as brazing filler.

The above stipulations are therefore not applicable to the use of cadmium in the requested exemption.

Due to their carcinogenicity, entry 28 of Annex XVII does not allow the placing on the market, or use of various substances as such, as constituents of other substances, or in mixtures. Various compounds are mentioned in this respect, including among others cadmium sulphide and cadmium nitrate. The use of cadmium in the scope of the requested exemption cannot be considered as placing on the market cadmium or cadmium compounds in the sense of the above since cadmium is used in an article.

Entry 72 lists substances which are classified as carcinogenic, mutagenic or toxic for reproduction. It stipulates that the substances listed in column 1 of the table in Appendix 12 shall not be used in textiles, clothing and footwear. The table lists cadmium and its compounds as listed under entries 28, 29 and 30. Like entry 28, this entry does not address the use of cadmium in the scope of the requested exemption.

To conclude, none of the entries currently listed under REACH would apply to the case at hand. The use of Cd in the scope of the requested exemption cannot be considered to weaken the protection afforded by REACH. The exemption can therefore be renewed if the relevant stipulations of Art. 5(1)(a) apply.

5.3.2. Market situation and delays in announced cadmium substitution in electrical contacts: Protective and other switches

Situation of cadmium substitution and elimination at other manufacturers

The applicants' renewal request and the replies to the consultants' questions are based mainly or exclusively on the situation of cadmium substitution/elimination at Sensata and Marquardt. Stakeholders who contributed to the previous review after the consultation were informed about the review but did not get involved this time. The consultants therefore contacted three manufacturers that seem to produce products with electrical contacts, to inquire the status of cadmium substitution at other manufacturers.

One of them replied stating that they do not manufacture contacts with cadmium and its compounds themselves but that they are exclusively used in purchased components and articles. The other contacted companies did not reply.

It remains unclear whether and how far the situation reported by the applicants actually represents the cadmium-phaseout status in the market, which, however, the consultants assumed in the absence of evidence indicating otherwise.

Reasons for delays of cadmium substitution or elimination at Marquardt and Sensata

Marquardt and Sensata had announced to have their product portfolios changed to cadmium-free contacts until 2020/2021 in the last review in 2015/2016 by Gensch et al. (2016). At that time, Sensata had indicated that only 15 % (11 products) are remaining for conversion until 2020/2021. Marquardt had achieved 98.5 % of cadmium-free contacts for power tools already and had announced to be 99.9 % cadmium-free in 2020. The applicants were therefore requested to explain what happened to these plans and which activities Sensata, Marquardt and members of the umbrella project have been undertaking to achieve the above cadmium substitution targets.

Sensata et al. (2021) stated that Marquardt's activities have been permanently continued, but delayed by internal reorganizations and relocations, time consuming test programs including test failures, late responses from customers and finally by the Corona crisis. Also the corresponding standards IEC/EN/UL61058 (for appliance switches) and IEC/EN/UL62841 (for tools) have changed, which further increased the work load for the transition process. The MQ AgCdO replacement team has been reorganized 6 months ago and is holding weekly meetings to discuss and promote progress. Based on their current progress and prognosis, they believe to reach the 99.9 % target in 2022, resulting in 0.6 kg CdO usage (target for 2020 was 0.9 kg), while the vast majority of this will be used for spare parts.

The applicants were asked which changes in these standards caused the delays. Sensata et al. (2022a) explain that for power tool switches today the main relevant harmonized international approval certification standards are EN61058 and UL61058 under the roof of IEC. Before these two standards were harmonized, UL1054 applied for the US and EN61058 for the EU. Under UL1054, a 10 A 125 V AC switch was tested with 10 A switching on and off. Per UL61058, a 10 A switch is tested with 10(10) A rating, which includes inrush current while switching on. So, the switch will see 60 A (6 x 10 A) when switching on and 10 A when switching off, which means higher electrical load on the switch. So, some of the switches had to be technically upgraded to pass the requirements of the new standards. The transition phase including re-certification from old to new standard has required a lot of testing, certification and engineering capacity over the last years. These capacities are usually limited in companies and cannot be increased easily. So, this slowed down the process of AgCdO elimination, doing both in parallel.

The applicants were requested to explain in more detail how this harmonization of these standards affected their transition to cadmium-free switches.

Sensata et al. (2022b) explain that the approvals according to the previous standard EN61058 focused on 250 V applications, while UL1054 approvals were focused mainly on 125 V applications. The additional challenge arose from upgrading the switches from UL1054 to the harmonized UL61058 – equivalent to EN61058 in the EU - and at the same time to replace AgCdO contacts. It would have been much easier to replace the AgCdO contacts while staying within the old UL1054 standard.

The consultants assumed that 125 V switches are only used outside the EU, for example in the USA where the RoHS Directive is not applicable, which arises the question why this upgrade of switches approved under the old UL1054 to UL61058 could have delayed the phaseout of cadmium in the EU.

Sensata et al. (2022b) point out that, as a clear market request, the ON/OFF switches carry both approvals (UL and EN), so the new UL standard requirements for 125 V applications has to be fulfilled as well with cadmium-free solutions.

Sensata et al. (2022a) highlighted that similar developments apply to the relevant international tool standards (change from EN/UL60746 to EN/UL62841) which created in the transition phase a lot of work load for the switch producers' customers, the power tool manufacturers. These new tool standards are focusing much more on functional safety aspects, which further increased the workload in testing and certification, slowing down the progress in AgCdO elimination process due to limited available testing capacities. Sensata et al. (2022b) elaborate that replacing in their switches AgCdO contacts by other materials, the modified switches need to be tested and released on switch manufacturers' as well as on the power tool manufacturers' side. While the power tool manufacturer's test labs were busy testing their upgrades for the new tool standard (60745->62841), they were not able to perform in parallel the release tests for the AgCdO elimination. So, there were also waiting lines in the customers' test labs. That's the second part of the explanation why the AgCdO elimination takes longer than expected with the previous applications of the exemptions.

In the consultants' point of view, the above arguments explain plausibly the deviation from the original planning to have substituted cadmium in switches until July 2021.

For the other devices in the scope of exemption 8(b)(I), i.e. protective switches (circuit breakers, thermal sensing controls, thermal motor protectors, Sensata et al. (2022a) *put forward that safety reliability is a concern and in some cases causes delay in the planning. The implementation is defined by getting possible alternatives of suppliers, internal testing (quality/safety), customer release testing and agency testing for updating product (safety) certifications.*

Sensata et al. (2022a) declared that Sensata will achieve the phaseout of cadmium in 2023 and Marquardt end of 2025. Therefore, even though Sensata's explanation for the delay is inconclusive, the consultants did not follow up on this and focused on clarifying the scope and the expiry dates of the renewed exemptions.

5.3.3. Substitution/elimination of cadmium in switching contacts for cat. 8 and 9 EEE (ex. 8(b))

Sensata et al. (2020a) request the renewal of exemption 8(b) in its current wording for EEE of categories 8 medical devices including in-vitro diagnostic medical devices (IVDs) and 9 monitoring and control instruments including industrial monitoring and control instruments ((IMCI). Generally, Sensata et al. (2022c) consider long lifetime of products a key criterion why cadmium-free contacts cannot be used, besides other technical reasons. So far, the identified cadmium-free alternatives do not offer the required technical performance to allow their use.

Sensata et al. (2020a) put forward that many types of medical devices use high power circuits that require relays and contactors, both of which have switching contacts to switch power on and off. Sensata et al. (2021) specify "high power circuits" explaining that the voltages and currents are application specific and can range between 5 A and 30 A at 250 V AC, depending on the specific application in devices that may be used for 20 years. They provide the below examples:

- *Small and light weight safety critical circuit breakers in high-speed rotating parts of CT systems;*
- *AED applications: 10-70 A and 150 V DC/400 V AC, with some applications requiring between 2,200 V and 0 V over several milliseconds ("cold-switching").*

The review was focused on the above-mentioned examples to understand whether and how far substitution and elimination of cadmium are actually scientifically and technically impracticable currently and in the coming years.

Substitution and elimination of cadmium in switching contacts of AEDs and other defibrillators

Sensata et al. (2021) elaborate that DC switches rated at 10 A and more at 150 V DC/ 400 V AC in defibrillators and AEDs (class 3 medical devices) require a single, Dual Pole, Single Throw (DPST) Miniature Power Relay to transfer therapeutic shock energy to a patient. The cadmium containing relay has been tested extensively at millisecond pulse durations, at current and voltage levels far exceeding published "continuous" specifications. in order to provide an appropriate therapeutic dose of electrical energy to a patient. The biphasic energy waveform delivered through the closed relay contacts has a very specific profile and duration in order to provide a successful therapeutic outcome. In addition, the device implements a daily self-test by measuring the circuit impedance (milliohms) through closed relay contacts in order to guarantee a safe and efficacious therapeutic patient outcome during use. Both the application of therapeutic energy and the diagnostic impedance measurement are implemented using a "cold switching" method, where no load is present at the contacts during switching. A cold-switching use case may have significant differences in impedance drift over time than a hot-switching use case. Cadmium is well known in the industry for low contact resistance.

It seems that the applicants want to express specific challenges for cadmium-free contacts with cold switching in the context of AEDs. Generally, however, cold switching does not produce signal arcs and metal migrations that pose a problem in hot switching. Cold switching may even be used to achieve a longer lifetime of switches[22] whereas one reason for the use of cadmium in switches is to prevent the arcing and the consequences thereof. The applicants were asked to explain how without arcing and metal migration in cold switches the contact resistance could build up over time in cadmium-free switches so that the AED self-tests failed.

Sensata et al. (2022c) answered repeating the above information provided by Sensata et al. (2021). The question thus remained unanswered. Since the further review showed that the use of cadmium in AEDs and other defibrillators is scientifically and technically practicable but requires the redesign of the devices, the consultants did not follow up on the above question which is related to the principal practicability of cadmium substitution.

The consultants followed up on the failing self-tests in the AEDs which Sensata et al. (2021) presented as one example for many cat. 8 and 9 devices where Cd-free contacts failed. They report that AED manufacturers tested alternatives to cadmium, including AgNi, $AgSnO_2$ and gold-nickel that, however, built up contact resistances over time so that the

[22] Pickering, https://www.pickeringtest.com/de-de/kb/hardware-topics/switching-system-specifications/cold-switching

product fails the self-test function once the resistance exceeds 50 mΩ. Without the self-test function, the AED, which needs to meet stringent requirements of reliability due to the products' function, could cause failures during the product life.

The applicants were asked why the self-test cannot accommodate the increasing contact resistance of Cd-free contacts, e.g. by allowing the tested threshold to increase over time beyond the current 50 mΩ as far as technically acceptable to still ensure the reliable functioning. If this is technically not practicable, the question arises why the 50 mΩ are an absolute threshold which cannot even be overcome after a redesign of the electrical part of the AED so that it can handle higher thresholds in the self-test while still maintaining the devices' reliable functionality.

Sensata et al. (2022a) agree that the self-test threshold could be overcome via redesign and/or software change, however, to undertake this, multiple steps of testing are required to ensure that the safety, efficacy and reliability of the AED's are not compromised. Efforts to move away from Cd-contacts are already underway but a suitable length of time is still required to allow these activities to be undertaken.

The applicants were asked when these tests started and to provide more details on these trials such as testing conditions, sample numbers, results and the time that is still required.

Sensata et al. (2022c) explain that one COCIR company undertook testing in 2010 of $AgSnO_2$*, AgNi and gold-nickel for contact resistance. The testing for* $AgSnO_2$ *was undertaken on 200 samples for both 4-wire 3 /4 pin and 4-wire 5/6 min at a maximum of 100 mΩ. The testing identified that contact resistance was increasing after multiple attempts with the average contact resistance being close to double that of the initial contact resistance by the end of the series of tests. In addition to this burn marks were being observed on the contact surface. No further testing was undertaken by this company due to the criticality of the findings. Similar testing was also undertaken on silver-nickel and gold-nickel with the same findings observed.*

As to next steps and timelines, Sensata et al. (2022a) point out that the inherent differences in performance that alternatives offer, AED manufacturers have paused their testing of alternatives at this point for the substitution of cadmium-free alternative in current designs of products. Instead efforts are focused on ensuring new designed products qualify and design their systems to inherently consider the various performance differences. The point at which each AED manufacturer will discontinue the sales of all devices still relying on cadmium will be different, as their design and qualification timescales are different.

It seems that the above tests were focused on exchanging cadmium-switches by cadmium-free switches in current models that were otherwise not redesigned to accommodate the properties of cadmium-free contacts. Differently from the applicants' argumentation in the renewal request, there is thus no evidence that substitution of cadmium is scientifically and technically impracticable unless the producers' redesign efforts of the AEDs still do not facilitate the use of cadmium-free electrical contacts. The fact that AED manufacturers put efforts into redesigning AEDs to enable the use of cadmium-free contacts at least is an indication that they do not consider these efforts to be deemed for failure from the beginning. The way to RoHS compliance therefore first of all is a matter of redesigning AEDs to facilitate the use of cadmium-free contacts.

This situation resembles the conditions during the review of exemption IV-17 (*Lead in solders of portable emergency defibrillators*) by Deubzer et al. (2022) where COCIR declared that portable emergency defibrillators for which the declaration of conformity (DoC) was issued for the first time after 31 December 2015 do not require the exemption because they were redesigned to avoid the use of lead in solders. The consultants therefore inquired with the applicants whether the redesign for lead substitution included the adaptations necessary to enable the use of cadmium-free contacts. *Sensata et al. (2022e) confirmed that emergency defibrillators, which include AEDs, with a DoC after 31 December 2015 apply cadmium-free electrical contacts and agreed to exclude these medical devices from the scope of exemption 8(b). The applicants agreed to apply the same wording for this exemption like for exemption IV-17 (a), which is the renewed exemption IV-17 as proposed by Deubzer et al. (2022):*

> *Cadmium in electrical contacts of portable emergency defibrillators for which the Declaration of Conformity is issued for the first time before 1 January 2015*

Sensata et al. (2022f) request the exemption to remain valid until 21 July 2028. This expiry date is, however, not plausible considering that exemption IV-17(a) is recommended to expire on 31 December 2025 and that the redesigns enabling the substitution of lead and of cadmium are achieved in the same redesign process.

Substitution and elimination of cadmium in circuit breakers applied in rotating parts of CT devices

As a further example for obstacles for the deployment of cadmium-free contacts, Sensata et al. (2020a) present the case of a cadmium-based circuit breaker in a Computerised Tomography (CT) system that rotates with high speeds (0.35 seconds per rotation, 2.86 rotations per second) generating around 30 G centrifugal force. They state that size and weight of the circuit breaker are critical to resist this centrifugal force, and that failures of the circuit breaker would lead to concerns over electrical safety and reliability.

The applicants were requested to explain why they assume that the resistance against centrifugal forces cannot be achieved with cadmium-free alternatives. Sensata et al. (2021) replied that CT manufacturers are able to evaluate and use only the types of circuit breakers that are currently available on the market, and that only a few very small and lightweight circuit breakers suitable in CT *have been identified, which all use cadmium. They further on claim that currently the number of circuit breakers used in CT annually is too few to persuade circuit breaker manufacturers to redesign and develop cadmium-free versions that CT manufacturers could test. Sensata et al. (2021) point out that once a cadmium alternative is developed which meets the technical criteria of the application, it will be reviewed to determine its safety and reliability.*

The applicants were asked to provide more details about the weight and electrical properties of the cadmium-containing circuit breaker, and to confirm that Sensata, Marquardt and/or other suppliers cannot provide such circuit breakers which would be appropriate for use in applications like the above CT system.

Sensata et al. (2022a) did not answer these questions. *When the consultants insisted, Sensata et al. (2022c) reported their significant progress since 2019 to identify and qualify a Cd-free alternative, and as such the qualification is nearing completion.*

Substitution and elimination of cadmium are therefore scientifically and technically practicable, differently from the claim of Sensata et al. (2020a) which among others used this application as an example to substantiate their request to renew exemption 8(b) for another seven years.

Sensata et al. (2022e) agreed to the below wording and expiry date:

Cadmium in circuit breakers in rotating parts of computer tomography (CT) medical devices *(cat. 8 others than in-vitro diagnostic medical devices); expiry on 31 December 2023*

Substitution and elimination of cadmium in cat. 8 EEE with long life times and in general

Sensata et al. (2020a) inform that cadmium based electrical contacts are also used in power switching of electric motors, specifically as thermal protectors and line-break switches[23]. Such electric motors are used in CT, MRI, PET and SPECT[24] which require high levels of reliability over a long lifetime, which can be more than 20 years.

The above statement raises the question whether the applicants consider cadmium-free contacts to be basically inappropriate for use in cat. 8 and 9 EEE with longer life times. They were therefore requested to provide information such as minimum life times which they consider as long enough to justify in their point of view their statement that cadmium-free contacts are not eligible.

Sensata et al. (2022a) answer that although long lifetimes are a key criterion for Cd-free switches, high reliability and measurement sensitivity contribute to the list of requirements that may preclude their current use. Efforts are still being undertaken to qualify Cd-free switches with all of these requirements but as yet none has demonstrated the required technical performance.

The applicants where further asked for a confirmation from Sensata, Marquardt or other producers of Cd-free switches that cadmium-free switches are principally not appropriate for long life uses.

Sensata et al. (2022a) stated that cadmium has indeed a positive effect on the lifetime of the contact system, but that certain application conditions also play an important role.

Given the safety relevance of switching contacts, long time reliability is a key criterion. Producers have gathered positive experiences with cadmium contacts in the past decades while cadmium-free contacts are a comparably recent phenomenon whose reliability needs to be ensured prior to their broad use. The applicants' above answers are, however, inconclusive as to the long-term reliability of cadmium-free contacts in cat. 8 and cat. 9 EEE.

Adding to this, the specific examples which the applicants put forward to justify the renewal of exemption 8(b) for cat. 8 medical devices for another seven years on closer inspection turned out to be examples for missing redesigns rather than illustrating the impracticability of substitution or elimination of cadmium or the basically lacking reliability of cadmium-free contacts.

The consultants conclude from this situation and the applicants' above answers that there is no evidence that long life times as they may occur with some EEE of cat. 8 are a fundamental obstacle to phase out the use of cadmium in electrical contacts. Concerning

[23] According to Sensata et al. 2022e, line break switches are specific types of AC and DC switches.

[24] CT = Computed Tomography, MRI = Magnetic Resonance Imaging, PET = Positron Emission Tomography and SPECT = single-photon emission computerised tomography

the renewal of exemption 8(b), it should be taken into account that producers of switches will have phased out the last cadmium-containing contacts in their portfolios until end of 2025 latest[25] since their cadmium-free replacements will be qualified for use in all their customers' products, and the applicants did not provide substantiated reasons why this should not include producers of cat. 8 and cat. 9 EEE. In the light of the above, Art. 5(1)(a) in the consultant's opinion would justify renewing exemption 8(b) until end of 2025. Producers of cat. 8 and cat. 9 EEE can still request another renewal of the exemption in case substitution or elimination of cadmium still would be scientifically and technically impracticable in specific cases.

The above approach - linking the expiry date to the phaseout of cadmium-contacts – could be applied specifically to circuit breakers, thermal sensing controls and thermal motor protectors resulting in a 2023 expiry for use of these cadmium switches in cat. 8 and cat. 9 EEE. Since the use of these cadmium-free switches requires a redesign of the EEE, an expiry date in 2023 may require another premature redesign in 2025 in cases where cadmium-free protective switches become available in 2025 only.

5.3.4. Substitution and elimination of cadmium in "fixed" electrical contacts (ex. 8(b))

The applicants claim that exemption 8(b), besides the switching contacts discussed above, also covers what they call "fixed contacts", i.e. contacts without switching functions used in oxygen and capnography sensors and in other devices which the applicants did not specify further.

Substitution and elimination of cadmium in oxygen sensors

Cadmium is used in specific oxygen sensors for low-level oxygen measurements at elevated temperatures. The applicants did not mention any cadmium-free alternatives to cadmium-containing oxygen sensors in their renewal request.

When asked for such information, Sensata et al. (2022a) *stated that they requested the information to answer this question but could not share further information yet at that time. Upon further requests, Sensata et al. (2022d), (2022c) explain that <u>one COCIR member</u> specified their application to rely on the ability to split the oxygen molecules into oxygen ions and this process requires a high precision electrochemical cell (c.f. Figure 5-1 on page 67). The specific design also requires that there is a small catalytic effect on any hydrocarbons and their research has only been able to successfully do this by adding very small amounts of cadmium and lead. COCIR members have trialled alternative variants of the transducer including titanium, zirconium, vanadium, chromium and tantalum. These transducers have been tested fully, configured and powered as they would be used in an instrument, they have been exposed to various gas compositions within the lab environment. None of above variants have met the necessary technical requirements. Testing of alternative materials is still underway into other metals and metal-oxides, including bismuth, tin and zinc.*

[25] C.f. sections 5.3.3 and 5.3.6 on page 28 and 30

The consultants assume, based on the above statement referring to one COCIR member's sensor design that this use of cadmium in oxygen sensors may be a proprietary solution of one manufacturer so that substitution or elimination of cadmium in oxygen sensors may be scientifically and technically practicable.

This assumption is supported by another statement of Sensata et al. (2022d) who mention in their description of the functional principle of oxygen sensors (c.f. page 67) that generally electrodes in oxygen sensors are made from a good electrically conducting metal, such as gold or platinum. The coating can vary from supplier to supplier. "For one manufacturer, the coating used to attach a very small gold wire to the crucible contains a small amount of cadmium."

To avoid misunderstandings, the applicants were requested to confirm this interpretation or otherwise put into perspective their above statement.

Sensata et al. (2022f) explain that the cadmium-containing oxygen sensor offers the unique technical advantage of oxygen measurement at trace levels (parts per million).Generally, customers use the sensors to measure oxygen impurities in the range zero to 10 parts per million (ppm), other applications can be used in the range zero to 1000 ppm. The sensors are heated to elevated levels between 550 °C and 750 °. Their properties are very temperature dependent leading to higher sensitivity at higher temperatures.

Sensata et al. (2022f) put forward that cadmium-free zirconia sensors can be used for percent level measurements which are less stringent. The measurement of oxygen at trace levels is a very difficult application and cryogenic air separation plants rely on the properties of this unique technology. Coulometric technology sensors are also used to measure ppm levels of oxygen, however, the accuracy of this measurement is affected by the presence of carbon dioxide. The zirconia sensor remains unaffected by these conditions.

Substitution of cadmium in zirconia oxygen sensors

Sensata et al. (2022h) point out that the manufacturer is currently working on a cadmium-free zirconia sensor which, however, is not yet in production. Sensata et al. (2022f) had already indicated that the exemption would still be required until July 2026 for cat.8 and 9.

An investigation on the internet showed that zirconia-based oxygen sensors are offered for measurements in the percentage range, but also yielded information about zirconia- oxygen sensors produced by different manufacturers[26] for oxygen detection in the range of parts per millions. These producers were contacted to inquire whether they use cadmium in their zirconia-based oxygen sensors for measurements in the ppm level. Only one manufacturer reacted to the request but did not confirm publicly that zirconia oxygen sensors in his product portfolio are cadmium-free.

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[26] C.f. https://sensorsandpower.angst-pfister.com/en/news/news/article/zirconia-oxygen-sensor-portfolio-covering-ranges-from-ppm-to-95/; https://industrialphysics.com/knowledgebase/articles/zirconia-oxygen-analysis/ and https://industrialphysics.com/product/zr800-oxygen-analyzers/; https://web-material3.yokogawa.com/TI11A03A01-01E.pdf; https://www.mzd-analytik.com/productsdetail_1647.html; https://www.mybacharach.com/wp-content/uploads/2021/02/3100-4100-Technical-Bulletin-Zirconium-oxide-sensor-024-5.ZR100.pdf and http://cesstech.com/products/gas-analyzers-detectors/oxygen-analyzers-from-neutronics-inc-ntron-range/

In the assessment of exemption IV-1(b)[27] by Deubzer et al. (2022), applicants had presented zirconia oxygen sensors as a potential alternative sensor for oxygen measurements to eliminate the use of lead. The applicants did not mention that these sensors use cadmium, which would have been a strong argument to disqualify them as an alternative to a lead-containing sensor. Eliminating one restricted substance by another restricted substance would be questionable. This situation can, however, be considered as circumstantial evidence at best and is no evidence that substitution of cadmium in zirconia oxygen sensors for ppm-level oxygen measurements is scientifically and technically practicable.

In the absence of sound contrary information, the consultants therefore follow the applicants claim that substitution of cadmium in zirconia sensors for ppm-level oxygen measurements is scientifically and technically still impracticable.

Elimination of cadmium by coulometric and other cadmium-free oxygen sensors

Coulometric oxygen sensors as potential technology to eliminate the use of cadmium in oxygen sensors were also investigated. Such sensors are offered, among others for use in air separation[28], which the applicants point out as the most relevant use for zirconia sensors stating that coulometric sensors cannot be used due to the presence of carbon dioxide. The applicants were requested to explain this situation and to communicate the producer of the zirconia oxygen sensors for which the exemption was requested.

Sensata et al. (2022h) revealed that the producer of the zirconia oxygen sensors is Servomex, the producer of the coulometric oxygen sensors identified during the internet investigation. The applicants explain that in many applications both zirconia and coulometric sensors are equivalent and both work very well. There are, however, a few applications where the zirconia has significant advantages, including fast recovery from air shock, where zirconia is not affected at all, but the coulometric measurement may take hours or even days to come back down to measurement range.

Sensata et al. (2022h) further elaborate on the full cycle of gas production to gas use including separation, storage, filling onto trucks (possibly as a liquid), back into storage at new site, bottling and end use. At all these processes the gas quality gets checked as increased oxygen contents can be detrimental to the user's process. In many of these process steps the oxygen sensors can be exposed to air whilst not in use. The zirconia has the significant advantage of fast recovery from air compared to coulometric measurements, which can take hours or even days to come back down to trace level range. The measurements in most of the above steps are not continuous and filling may only take a few minutes and hence the zirconia sensor is extremely well suited for these applications. Other applications include oxygen measurement in carbon dioxide: here the zirconia transducer is generally not affected much, however, the coulometric sensor is not well suited to these applications.

The applicants, in the consultants understanding, specify non-continuous oxygen measurements and oxygen measurements in carbon dioxide as analytical tasks where coulometric oxygen sensors cannot be used. The consultants asked the applicants whether

[27] Exemption IV-1(b): Lead anodes in electrochemical oxygen sensors

[28] C.f. https://www.servomex.com/gas-analyzers/finder/df-550e/?tab=resources---downloads-tab#

the use of zirconia oxygen sensors be restricted to non-continuous oxygen measurements and to measurements of oxygen in the presence of carbon dioxide.

Sensata et al. (2022i) reject the above proposal stating that zirconia sensors need to be used for both continuous and non-continuous measurements in a variety of inert and acidic gases. They put forward multiple applications where the sensor is measuring at low oxygen levels, where, under fault conditions, it can see percent-levels of oxygen. Hence, the sensor needs to be used in both continuous and non-continuous use. The other technologies change from percent-level oxygen to low trace level in a much longer time period and hence the use of zirconia is advantageous. Generally, most of these applications are in a background of nitrogen and other inert gases.

Sensata et al. (2022i) further elaborate that coulometric sensors are sensitive to all acidic gases so that the exemption cannot be limited to carbon dioxide only. Carbon dioxide levels typically should remain below 0.2 % for a 0-100 ppm coulometric sensor. Many applications in air-separation are often measuring oxygen around 0.1 ppm, so the level of carbon dioxide might need to be significantly lower.

The tolerable carbon dioxide level for the use of coulometric sensors thus depends on the oxygen content to be measured – the lower the more sensitive - and on the content of other acidic gases, i.e. gases that generate acids when dissolved in water, e.g. nitrogen and sulphur oxides. It can be taken from the applicants‘ above answers, that continuity of measurements cannot be applied either to describe the field where coulometric sensors could be used instead of zirconia sensors for ppm-level measurements.

The applicants stated in the beginning that for many applications, zirconia and coulometric sensors are equivalent and work both very well in many applications. Coulometric sensors are advertised for measuring ppm-level oxygen in ultra-high pure gases produced from air separation for industrial and medical applications. The applicants' above elaborations raise the question, however, where coulometric sensors can be used at all in air separation to produce ultra-high purity gases. The answers do not provide insights as to uses where, as the applicants stated above, both zirconia and coulometric sensors operate well, which would demarcate the application field where cadmium in zirconia sensors potentially could be eliminated by coulometric sensors.

The consultants searched the applicant's web pages for ppm-level oxygen sensors with main application field in air separation[29] and found, besides a coulometric and a zirconia sensor, another type of sensor equipped with a plasma emission detector, a flame ionization detector, and a thermal conductivity detector (TCD).[30] It is not clear whether and how far this detector type could contribute to eliminate cadmium in zirconia oxygen sensors. Sensors for ppm-level oxygen measurements are also used in other applications – the applicants mention that air separation is just the main application of zirconia sensors – which the consultants did not check after their findings for air separation.

The consultants wish to clarify that it is the applicants' task to provide substantiated, comprehensive and complete information proving that substitution or elimination of restricted substances is scientifically and technically impracticable. In the case at hand, this

[29] C.f. Servomex, https://www.servomex.com/gas-analyzers/finder/#.g-oxygen,.m-trace,.a-air-separation-units

[30] C.f.https://appliedinstruments.co.nz/app/uploads/2022/02/SERVOPRO-Chroma-Datasheet-Apr-2020.pdf, also retrievable from Servomex via search of product type (Chroma): https://www.servomex.com/resources/

would have implied detailed information about alternative oxygen sensors including coulometric and sensors and the alternative one which the consultants found – there may be others as well – and whether and how far they can replace zirconia sensors containing cadmium.

The consultants are of the opinion that the applicants had several possibilities to show that elimination of cadmium is scientifically and practically impracticable. They missed, however, to describe any cadmium-free alternatives to zirconia oxygen sensors in their renewal requests. Sensata et al. (2020a), (2020b) did, however, not provide any such information. Sensata et al. (2022a) did not respond to the consultants' questions related to cadmium-free alternatives. Sensata et al. (2022f) finally mentioned coulometric oxygen sensors as a potential cadmium-free alternative only stating that the presence of carbon dioxide affects their accuracy. Finally, Sensata et al. (2022h) could have been expected to explain in detail where coulometric sensors can be used instead of zirconia oxygen sensors. Finally, there is a third type of sensor which, according to the applicants' web pages, can be used for ppm-level oxygen detection e.g. in air separation which the applicant had not mentioned.

In the light of the above, the consultants conclude that the applicants did not substantiate their renewal request sufficiently to allow the consultants concluding that elimination of cadmium in zirconia oxygen sensors is scientifically and technically impracticable. In the consultants' opinion, the information provided does not allow the consultants to recommend the renewal of the exemption in line with the conditions of Art. 5(1)(a).

Substitution and elimination of cadmium in "fixed contacts" in capnography sensors used with respirators

Functional principle of capnography sensors

While the applicants describe the functional principle of oxygen sensors, there is no such description available for capnography sensors. As the "fixed contact" use of cadmium seems to be very specific, the consultants deem important to understand the details and asked the applicants to provide an outline/figure showing the construction/most important components, and where the cadmium is used, also to see whether the resistive ink can actually be considered an electrical contact. *Sensata et al. (2022d) replied that this cannot be shared at this time.*

According to Sensata et al. (2022a)*, the cadmium-based solution is utilised by multiple different companies, with the specific details of one company's solution shared within the exemption renewal request as it is indicative of the industry requirements.*

In the light of this statement, the consultants assumed that the functional principle must be the same regardless of the manufacturers' specific designs so that there is no reason why such principle information relevant for the review of the applicants' request should not be made available.

Further on, looking at the verbal technical description of the functional principle of capnography sensors and the use of cadmium in the ink (c.f. pages 68 and 71), the consultants wonder why this very general explanation should represent one producer's solution, raising the question how other producers' solution could be different from this technical principle without being another technology. The applicants were requested to answer the above question, and again to provide an outline of the functional principle of the capnography sensors.

Sensata et al. (2022f) *stated that they were not able to gather any further information on capnography sensors from COCIR members.*

Substitution of cadmium in capnography sensors

Sensata et al. (2020a) report about tests with cadmium-free inks in which the resistive ink interacted with the contact ink so that electromigration occurred which can cause short circuits. The manufacturer is now testing other alternative inks.

Upon request to explain the status and prospects of these tests, *Sensata et al. (2022d) explain that they can only share at this time that alternative inks are still be tested to the same standards and requirements as outlined in the exemption renewal request.*

In their roadmap (c.f. section 5.2.3 on page 73), the applicants point out that once a suitable ink is found in the future, further two years would be required after testing is complete and the material proven to be suitable for qualification testing in capnography sensors and to obtain global medical device approvals.

Since the applicants do not reveal any further details of the current status of cadmium substitution, the consultants conclude that at the earliest cadmium-free solutions might become available in around two years from now (status October 2022), i.e. around end of 2024.

Elimination of cadmium in capnography sensors by alternative technologies

In their renewal request, the applicants compare an incandescent lamp solution with the current resistive IR emitter technique (c.f. Table *5-1* on page 72) that they address as "our emitter", which raises the question whether this cadmium-based solution is a proprietary solution of one producer.

Sensata et al. (2022a) highlight that to their best knowledge they are not aware of any other ways of substituting or eliminating cadmium in the CO_2 sensors and that such Cd-free sensors are used in EEE of cat. 8 and 9.

As only alternative technology to eliminate cadmium, the applicants mention incandescent lamps as an IR source. They point out the higher energy consumption of incandescent IR sources and their larger size, which comes on the one hand from the larger size of the lamp and on the other hand from the motor, bearings, control circuitry and a chopper because lamps operate in a continuous mode whereas resistive IR emitters do not. *Sensata et al. (2022d) explain the need for these additional components with the fact that when the source is continuous, as with an incandescent lamp it requires these components. To avoid the use of such components to decrease the size, which is essential for capnography sensor in this application, a non-continuous light source needs to be used. Capnography sensors use a cadmium containing gold ink to form strong contacts and a thick-film resistor is printed upon it. The resistor which is formed from this is electrically heated, which produces the non-continuous light source of IR.*

The applicants were asked why a capnography sensor requires a non-continuous IR source, and what makes an IR source a continuous or non-continuous one.

Sensata et al. (2022f) replied that they were not able to gather any further information on capnography sensors from COCIR members.

Instead of incandescent lamps, the consultants asked why LEDs were not considered as an alternative enabling a cadmium-free IR emitter to replace the resistive emitter technique.

Sensata et al. (2022d) point out that LED in general require more complex electronic and signal processing solutions so have been investigated less by manufacturers due to their confidence of success in finding a suitable solution. There are indications from publications (Chowdhury et al. 2016) that LED power consumption is relatively high (~ 100 mW) and output power can change as much as 1.2 %/ºC of ambient temperature variation. Although this maybe overcome by the addition of microelectromechanical systems, the complexity of the solution introduces a number of additional factors which increase the chance of failure and also additional qualification time. As such, other solutions have been investigated as a priority.

Table 5-1 on page 72 provided by the applicants shows that resistive heaters require 400 mW electrical performance, which is four times the electrical performance of the LED-based solution. As to the size, (Chowdhury et al. 2016), the source referenced by the applicants, indicates the dimensions of the LED-based solution with 10 mm x 10 mm x 16 mm, while the resistive emitter's size is 6.25 mm x 1 mm x 0.125 mm, and the incandescent lamp solution would be a few millimetres long and a few millimetres thick. The resistive emitter is thus clearly smaller than the incandescent lamp solution and still smaller than the LED-based solution but seems to refer to the IR light source only.

The applicants were therefore requested to explain how the larger size – and possibly additional mechanical and electronical elements - of LED emitters would translate into the overall size of capnography sensors as used with lung ventilators. They were also asked to explain why they believe that 100 mW electrical performance of LEDs cause a high energy consumption while their resistive emitter solution operates with 400 mW electrical performance.

Sensata et al. (2022f) replied that they were not able to gather any further information on capnography sensors from COCIR members.

The above answer leaves open questions which in the consultants' opinion are crucial to answer for justifying that scientifically and technically elimination of cadmium is impracticable. The consultants can therefore not recommend renewing the exemption for the above applications of cadmium without infringing Art. 5(1)(a).

Substitution and elimination of cadmium in fixed contacts in other applications

The applicants mention that there are more uses of cadmium in "fixed contacts" beyond those in oxygen and capnography sensors without, however, specifying the applications. *Upon request, Sensata et al. (2022c) state that such contacts are also used in defibrillator and AED high voltage therapy delivery switching.*

The applicants did not provide any further information. The examples of the oxygen and capnography sensors show that the cadmium uses in the fixed contacts are very specific and that detailed insights are crucial to understand the actual need for cadmium uses as well as the status and prospects of its substitution and elimination. The applicants were therefor requested again to provide detailed information describing and justifying in detail the use of cadmium in fixed contacts of these devices. It was pointed out to the applicants that without such information, Art. 5(1)(a) does not allow the consultants recommending the respective exemption(s).

Concerning the AED high voltage therapy delivery switching, Sensata et al. (2022f) explain that a relay with cadmium present in its electrical contact material is used to enable and *disable therapeutic energy from reaching external delivery mechanisms (pads, paddles). Therapeutic voltage is as high as 2200 Volts. The applicants also state that "The cadmium is used in the same way as outlined in Questionnaire 1 and 2 responses" without providing further details.*

Questionnaires 1 and 2 do not contain information as to the use of cadmium in fixed electrical contacts in AEDs or other defbrillators. Further on, in the consultants' understanding, "relays" are switches and not "fixed contacts" in the sense of the applicants' definition. Even in the case that relays actually contain cadmium in fixed contacts, the consultants would have expected a detailed explanation of the technical situation and a justification of cadmium use. To avoid misunderstandings, the applicants were asked to confirm that they actually aspire an exemption for cadmium in fixed contacts in AEDs and other defibrillators.

The applicants were therefore contacted to exclude misunderstandings, and Sensata et al. (2022g) declared that cadmium is actually used in a switching relay and not in fixed contacts of AEDs and other defibrillators.

The request to renew exemption 8(b) for the use of cadmium other than switching contacts in AEDs and other defibrillators lapses with the applicants' above statement as it is technically irrelevant.

5.3.5. Substitution or elimination of cadmium in protective switches (ex. 8(b)(I))

In their request to renew exemption 8(b)(I) for EEE of cat. 1-7, 10 and 11, Sensata et al. (2020a), (2020b), (2021) propose introducing voltage and current limits for circuit breakers and thermal sensing controls while renewing the exemption without scope restrictions for thermal motor protectors. The proposed changes compared to the current exemption 8(b)(I) are <u>underlined</u> in the below table.

Table 5-2: Comparison of current and requested new wording of exemption 8(b)-I

Current Wording	Proposed new wording:
Cadmium and its compounds in electrical contacts used in:	Cadmium and its compounds in electrical contacts used in:
- circuit breakers	- circuit breakers rated at - <u>10 A and more at 250 V AC and more, or</u> - <u>15 A and more at 125 V AC and more;</u>
- thermal sensing controls	- thermal sensing controls rated at - <u>10 A and more at 250 V AC and more, or</u> - <u>15 A and more at 125 V AC and more;</u>
- thermal motor protectors (excluding hermetic thermal motor protectors)	- thermal motor protectors (excluding hermetic thermal motor protectors)

For thermal motor protectors, the applicants request the renewal in its current wording without scope restrictions. It was, however, debated in the last review conducted by Gensch et al. (2016) with Ubukata whether cadmium-free alternatives are available, which arises the question why the exemption is still required another five years later and should be continued even without scope restrictions. *When they were asked why no progress had been achieved for motor protectors, Sensata et al. (2022a) pointed out that they have almost achieved the phaseout of cadmium in motor protectors. Sensata et al. (2022b) further specify this statement reporting that all thermal controls, motor protectors and circuit breakers with Cadmium free electrical contacts can be completely approved internally, by agencies and customers during the fourth quarter of 2022. Additional time till the end of 2023 is needed to cover any unforeseen issues and for cleaning the supply pipeline.*

To avoid misunderstandings, the consultants pressed the point further and proposed to set the expiry date for circuit breakers, thermal sensing controls and thermal motor protectors on 31 December 2023*. Sensata et al. (2022b) replied that there might be other manufacturers affected, except of Sensata, but that they are not aware of. They do not see any issues related to Cd free solutions in the Sensata Technologies portfolio anymore. The complex release process has been nearly completed with good results and phasing out one low volume circuit breaker product. They need some time to empty stock of already produced parts including cleaning the supply pipeline and using up of existing stock of contacts, distribution and sale of the final appliances.*

The above information indicates that reliable cadmium-free substitutes will be available from end of 2022 on for the full spectrum of electrical contacts in circuit breakers, thermal sensing controls and thermal motor protectors, and following the applicants above statement, the exemption could expire end of 2023.

The applicants' argument that other manufacturers might be affected by the exemption expiry would, in the consultants' opinion, not justify the renewal of the exemption for a longer period than required for this transition. Manufacturers of electrical contact devices could have participated in the exemption review to express their needs, which, however, did not happen during the review of this exemption. Further on, Art. 5(1)(a) would not justify renewing the exemption in the light of the above developments because there might be manufacturers that have not yet substituted cadmium in their products, unless such manufacturers would offer specific, indispensable uses of cadmium contacts for which reliable cadmium-free solutions could not yet be achieved. Producers of such applications could have requested the exemption renewal for these cases. Besides the renewal request of Sensata et al. (2020a), neither specific requests nor specific stakeholder contributions were received.

5.3.6. Substitution and elimination of cadmium in other switches (ex. 8(b)(I))

The below table shows the current and the proposed new wordings for the renewed exemption 8(b)(I) for cadmium in contacts of switches.

Current Wording	Proposed new wording:
Cadmium and its compounds in electrical contacts used in:	8(b)-I Cadmium and its compounds in electrical contacts used in:
AC switches rated at: - 6 A and more at 250 V AC and more, or - 12 A and more at 125 V AC and more,	AC switches rated at: - <u>10</u> A and more at 250 V AC and more, or - <u>15</u> A and more at 125 V AC and more,
DC switches rated at 20 A and more at 18 V DC and more, and	DC switches rated at <u>25</u> A and more at 18 V DC and more, and
Switches for use at voltage supply frequency ≥ 200 Hz.	Switches <u>rated at 300 V and more</u> for use at voltage supply frequency ≥ 200 Hz

Like for circuit breakers, thermal sensing controls and thermal motor protectors, Sensata et al. (2020a) had requested the renewal of the switches using cadmium contacts for the maximum validity period of five years. *Sensata et al. (2022a)* revealed in the course of the review that Marquardt will have substituted cadmium in all electrical contacts until end of 2025. The consultants thereupon proposed setting an expiry date on 31 December 2025 for AC switches, DC switches, and switches for use at voltage supply frequencies of 200 Hz and more.

Sensata et al. (2022b) announced that the exemption clause for switches used at voltage supply frequency ≥ 200 Hz is no longer required so that its renewal has become obsolete. As to the 2025 expiry date, they replied that there might be other manufacturers affected, except of Marquardt, but that they are not aware of. Also, this exemption should cover the full supply chain including use up of existing stock of contacts, switch assembly, distribution and sale of the final appliances.

From 2026 on latest, cadmium-free solutions will thus be available for all switches in the scope of exemption 8(b)(I). The applicants did not specify whether the time period required for a smooth transition of the entire supply chain would be included in the 2025 expiry date. As the applicants were explicitly asked for their feedback on the 2025 expiry date, the consultants propose the exemption to expire in 2025 in the absence of more detailed information.

Like for the circuit breakers, thermal sensing controls and thermal motor protectors, other manufacturers of products with electrical contacts being affected by the exemption expiry cannot be considered a sufficient justification in line with Art. 5(1)(a) for a renewal of the exemption for a longer period than required for the above transition.

5.3.7. Environmental arguments and socioeconomic impacts

The applicants put forward that cadmium-free electrical contacts in protective switches in general, and in EEE requiring notified body approval like medical devices and other sector specific approvals, potentially fail more often and may lead to life, health and safety risks *and to more e-waste. They also highlight the limited release of cadmium into the waste stream.*

The consultants do not agree to this general argument. There is no reason to assume that test and qualification requirements in place (see for example section 5.3.2 on page 75) do not correspond to the importance for health and safety of protective and other switches in the scope of exemption 8(a)(I) at least to a degree that the reliability of cadmium-free contacts can be ensured for each respective type of EEE. The main reasons why the phaseout of cadmium from all switches takes until end of 2023 and 2025 respectively are the qualification procedures at switch and EEE level. By then all switches are cadmium-free and are qualified for use in all EEE that apply such switches which is placed on the EU/EEA market. Redesigns of the respective EEE is, however, necessary.

Minor amounts of use of restricted substances do not justify and exemption. Neither Art. 5(1)(a) nor the RoHS Directive set any lower mass limit for restricted substances, but only concentration limits in the homogeneous materials, which is 0.01 %. The argument of minor volumes of cadmium used under the exemption, or of minor cadmium releases into waste or environment per se do not justify an exemption in line with Art. 5(1)(a) unless applicants provide evidence that the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof. The applicants did not provide such information.

5.3.8. Summary and conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria is fulfilled:

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II **is scientifically or technically impracticable**;
- the **reliability** of substitutes is not ensured;
- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

Exemption 8(b): Cadmium in switching contacts of cat. 8 and cat. 9 EEE

The applicants request the renewal of exemption 8(b) in its current wording for seven years. They argue that cat. 8 and cat. 9 equipment uses switches that are out of scope of exemption 8(b)(I) with its voltage and current restrictions. Additionally, exemption 8(b)(I) is recommended to expire in 2023 (protective switches) and 2025 (other switches).

They put forward, as examples that scientifically and technically substitution and elimination are not practicable, light weight safety critical circuit breakers in rotating parts of CT imaging equipment, and switches used in AEDs with high voltages (up to 2,200 V) and high currents (up to 70 A). During the review, it appeared in both cases that scientifically and technically substitution and elimination are practicable, but that the applicants need time to redesign the devices to ensure the reliability of cadmium-free switching contacts in these products.

The applicants agreed to the below wording and expiry date for cadmium in circuit breakers for rotating parts of CT imaging systems:

Cadmium in circuit breakers in rotating parts of computer tomography (CT) medical devices *(cat. 8 others than in-vitro diagnostic medical devices); expiry on 31 December 2023*

For AEDs, the consultants proposed to align the exemption wording and expiry with the recommendation for exemption IV-17 (Lead in solders of portable emergency defibrillators) by Deubzer et al. (2022) assuming that the redesign of portable emergency defibrillators to substitute lead would in parallel take into account the use of cadmium-free switches. The applicants agreed to this approach resulting in the below wording:

Cadmium in electrical contacts of portable emergency defibrillators for which the Declaration of Conformity is issued for the first time before 1 January 2015; expiry on 31 December 2025

While the applicants wanted to maintain their request for a seven-year renewal of the exemption until 2028, the consultants recommend aligning the expiry date with exemption IV-17 (2025). The applicants did not mention any reason why the redesign of the defibrillators should be finalized in 2025 to enable the substitution of lead while the use of cadmium in switches should be continued after that date.

Beyond the above specific examples, the applicants generally claim that exemption 8(b) should remain available for cat. 8 and cat. 9 EEE and they are concerned about the (long-term) reliability of cadmium-free contacts in particular in long-life EEE like for example CT, MRI, PET and SPECT imaging equipment.

The consultants could, however, not obtain any clear statements from the applicants that cadmium-free contacts would be generally inappropriate for any specific cat. 8 and cat. 9 EEE. The above specific devices that the applicants put forward to justify the exemption renewal for another seven years turned out to be examples for not yet completed redesigns. They do not prove any basic impracticability of substitution or elimination of cadmium or the basically lacking reliability of cadmium-free contacts.

The consultants therefore recommend renewing the current exemption 8(b) until end of 2025 considering that latest by then producers of switches will have phased out all cadmium-containing switches and instead will have qualified with their customers cadmium-free switches for use in their cat. 8 and cat. 9 products.

Exemption 8(b): Cadmium in "fixed contacts" of cat. 8 and cat. 9 EEE

The applicants introduce "fixed contacts" as a specific type of electrical contact which, differently from the other contacts, have no switching functionality. These contacts contain cadmium and, according to the applicants, are used in medical capnography sensors as well as in AEDs and other defibrillators (cat. 8 other than IVD), and in oxygen sensors for trace level oxygen measurements (cat. 8 including IVDs and 9 IMCI). The applicants point out that these fixed contacts are not covered by exemption 8(b)(I) and therefore request a seven years' renewal of exemption 8(b) for these fixed contacts.

Cadmium in zirconia oxygen sensors

The applicants requested the renewal of exemption 8(b) for the use of cadmium in oxygen sensors for trace level (parts per million) measurement of oxygen used mainly in air separation plants.

The applicants did not provide information as to cadmium-free alternatives to zirconia oxygen sensors in their renewal request and in follow-up communication. Further exchange with the applicants showed that coulometric oxygen sensors can be used instead of zirconia oxygen sensors, but not in all applications. The applicants did, however, not sufficiently specify the applications of the zirconia oxygen sensors where they cannot be replaced by coulometric sensors. Additionally, the consultants identified a third type of sensor on the applicant's web pages which is listed as appropriate for oxygen measurements in, among others, air separation plants.

The applicants had several possibilities to substantiate the exemption renewal request with comprehensive and detailed information which, however, they did not provide. There is thus not sufficient evidence that the elimination of cadmium in zirconia oxygen sensors is scientifically and technically impracticable in all applications of these sensors.

Cadmium in capnography sensors

Capnography sensors are infrared sensors measuring carbon dioxide levels in air, in this case in exhalation air of patients that are ventilated artificially. The applicants describe cadmium being contained in a resistive ink that connects the power supply to the heater (resistive heater) generating the infrared light for the measurement. The applicants claim that so far, no cadmium-free ink could be qualified for this use. Elimination by alternative technologies, i.e. by other infrared light sources, would result in larger and heavier sensors, which would be cumbersome for patients and medical staff.

The applicants did not provide an outline of the functional principle of a capnography sensor, in particular of the heater, to illustrate how and where the resistive ink is applied, and to understand whether the resistive ink can actually be understood as an electrical contact.

The applicants reported ongoing substitution tests with cadmium-free inks but do not reveal details about the past and ongoing activities. As to the elimination of lead, they only mention incandescent lamps as a potential cadmium-free light source, which, however, they exclude as alternative due to its higher energy consumption and larger dimensions. Incandescent lamps being, according to the applicants, a continuous light source while their resistive heaters are a non-continuous one would require additional electromechanical components to turn the continuous into a discontinuous light source and electronic circuitry for its control. The applicants did not answer questions as to what makes a light source a continuous one in the context of these sensors, and why the sensor requires a non-continuous light source.

The applicants did not answer either questions concerning the energy consumption of LED infrared-emitters compared to their resistive emitters, and how size differences of the various emitter solutions would translate into the overall size and weight of the sensor device as it is used with ventilated patients.

Given the above unclear situation concerning the potential elimination of cadmium in the capnography sensors and the lacking details of the construction due to the applicants' missing substantiated information, the consultants cannot recommend the renewal of the exemption for the capnography sensors. Art. 5(1)(a) would allow the exemption if substitution or elimination of cadmium are scientifically and technically impracticable. The applicants did not provide the respective evidence.

Cadmium in fixed contacts of AEDs and other defibrillators

The applicants requested the renewal of exemption 8(b) for cadmium in fixed contacts of AEDs and other defibrillators for high voltage therapy delivery switching. The submitted information, however, neither substantiates the technical background nor does it explain why the use of cadmium would be justified. The applicants had been pointed out that exemptions cannot be recommend being granted without a detailed technical description and justification. The applicants' answer addresses, e.g. relays, which, in the consultants' understanding, are switches and not fixed contacts in the sense of the applicants' definition. To avoid misunderstandings, the applicants were asked to confirm that AEDs and other defibrillators actually contain cadmium in fixed contacts.

The applicants agreed that relays actually are switching contacts so that this part of the renewal request became technically obsolete. The use of cadmium in switching contacts of AEDs and other defibrillators was reviewed under the renewal of exemption 8(b)(I), c.f. section "Substitution and elimination of cadmium in switching contacts of AEDs and other defibrillators" on page 78.

Exemption 8(b)(I): Cadmium in electrical contacts of switches

The last review of this exemption by Gensch et al. (2016) showed that substitution of cadmium in electrical contacts of circuit breakers, thermal sensing controls and thermal motor protectors, and AC and DC switches is scientifically and technically practicable. The reliability of the substitutes, however, needs to be ensured for all types of technical application cases, which requires efforts and time for redesign, testing and qualification on the switch manufacturers' side, but also on their customers' side, the producers of EEE.

The stakeholders had announced in the last review in 2016 that the substitution of cadmium would be accomplished in 2021, which, however, was not achieved due to, among other reasons, the SARS-CoV2 pandemic, and changes in crucial standards which required additional adaptation, testing and qualification work.

During the review, the applicants conceded that they can achieve RoHS compliance prior to the requested maximum validity periods for the renewed exemption 8(b)(I) until end of 2023 already for circuit breakers, thermal sensing controls and thermal motor protectors. The phaseout of cadmium in the AC and DC switches will be achieved end of 2025, which is considerably beyond 2022, where the applicant, however, was more affected by changes of applicable standards that complicated and delayed the transition progress towards cadmium-free switches. Additionally, the applicants announced that the exemption clause for the specific switches operated at voltage supply frequency ≥ 200 Hz is no longer required so that its renewal is obsolete.

Substitution of cadmium in switches is thus scientifically and technically practicable for EEE in the scope of exemption 8(b)(I) and the reliability of substitutes will be ensured end of 2023 and 2025, respectively. The consultants recommend in line with Art. 5(1)(a) the expiry of exemption 8(b)(I) for these dates.

5.4. Recommendation

Exemption 8(b): Cadmium in electrical contacts of cat. 8 and 9 EEE

Substitution or elimination of cadmium are scientifically and technically practicable after a redesign of the EEE enabling the reliability of the cadmium-free solutions. Given the fact that the full portfolio of cadmium-free switches will be qualified for use by switch producers and in their customers' products by end of 2025, Art. 5(1)(a) in the consultants' understanding would allow granting an exemption to ensure the reliability of cadmium-free switches.

The consultants therefore recommend renewing exemption 8(b) with the below (exemption 8(b)(II)) wording and scopes agreed with the applicants, and the below expiry dates.

No.	Exemption	Scope and dates of applicability
8(b)	Cadmium and its compounds in electrical contacts	Applies to categories 8, 9 and 11 Expires on [date of the official publication of the COM decision in the Official Journal + 18 months] for - category 8 medical devices including in-vitro diagnostic medical devices - category 9 monitoring and control instruments including industrial monitoring and control instruments - category 11
8(b)(II)	Cadmium and its compounds in electrical contacts of - circuit breakers - thermal sensing controls - thermal motor protectors (excluding hermetic thermal motor protectors) - AC switches - DC switches	Applies, from [date of the official publication of the COM decision in the Official Journal + 12 months + 1 day] on, to categories 8 and 9. Expires on - 31 December 2023 for circuit breakers in rotating parts of computer tomography (CT) medical devices (category 8 medical devices others than in-vitro diagnostic medical devices) - 31 December 2025 for portable emergency defibrillators (cat. 8 medical devices others than in-vitro diagnostic medical devices) with a Declaration of Conformity (DOC) issued for the first time before 1 January 2015 - 31 December 2025 for other cat. 8 medical devices including in-vitro diagnostic medical devices, and for category 9 monitoring and control instruments including industrial monitoring and control instruments, and for category 11.

While the current wording of exemption 8(b) does not specify the types of electrical contacts, it is recommended restricting the exemption to switching contacts to prevent uncontrolled uses of cadmium in other contacts like e.g. in “fixed contacts” (see next section).

During the review, substitution of cadmium in CT medical devices proved to be scientifically and technically practicable with ensured reliability until end of 2023. The phaseout of lead in portable emergency defibrillators including AEDs and professional defibrillators requires a redesign of devices with first declarations of conformity (DOC) issued prior to 2015. The 2025 expiry date was aligned with the renewed exemption[31] IV-17 as recommended by Deubzer et al. (2022), and with the phaseout of cadmium in switching contacts as detailed below.

The 2025 expiry date for other cat. 8 EEE and cat. 9 EEE also reflects the time from which on the reliability of cadmium-free switches can be ensured. End of 2025 latest, the manufacturers of switching contacts will have phased out cadmium from their switch portfolios and will have qualified cadmium-free alternatives with their customers. Should cases arise where the reliability proves to still be compromised in specific application cases, the 2025 expiry date would still allow timely renewal requests.

If the COM follows the above recommendation, EEE of cat. 8, 9 and 11 will be covered by exemption 8(b)(II) in future, and exemption 8(b) can expire. Since this transfer from exemption 8(b) with a broad scope to exemption 8(b)(II) with a narrower scope can be considered a partial revocation of the exemption, Art. 5(6) requires a 12 to 18 months transition period. Exemption 8(b) has been covering the use of cadmium in fixed contacts of capnography and in oxygen sensors. The applicants had requested the renewal of the exemption for these sensors, which the consultants cannot recommend ((c.f. section “Exemption 8(b): Cadmium in “fixed contacts” of cat. 8 and 9 EEE” on page 97). Since the expiry of the exemption for these sensors may cause adverse socioeconomic impacts, the consultants recommend granting 18 months transition time.

Exemption 8(b): Cadmium in “fixed contacts” of cat. 8 and 9 EEE

The applicants introduced “fixed contacts” which they describe as electrical contacts containing cadmium but without switching functions. They claim that these contacts have been covered by the current exemption 8(b). Since these contacts are technically different from switching contacts, the consultants recommend establishing a new exemption 8(c) for these types of contacts. Applicants specifically requested the renewal of the current exemption 8(b) for cadmium in fixed contacts of capnography and zirconia oxygen sensors.

The consultants cannot recommend renewing the exemption for zirconia oxygen sensors. The applicant did not provide sufficient evidence that the elimination of cadmium by cadmium-free oxygen sensors based on other technologies is scientifically and technically impracticable in all uses of these sensors. The same applies to the capnography sensors. The applicants did not substantiate that the elimination of cadmium by LED technology is scientifically and technically impracticable so that Art. 5(1)(a) would not allow granting an exemption.

[31] Exemption IV-17: Lead in solders of portable emergency defibrillators

For both above cases, Art. 5(6) requires a transition period of 12 to 18 months since the exemptions are revoked after a renewal request. Since the revocation of the exemptions may have more implications than entailing administrative adaptations, the consultants recommend 18 months transition time. Even though the applicants do not provide specific information on socioeconomic impacts if the exemption is not renewed for capnography and zirconia oxygen sensors, the consultants cannot exclude that adverse impacts might arise, like at least temporary non-availability of RoHS-compliant sensors. The recommended transition period for the sensors is taken into account with the proposed 18 months transition time for exemption 8(b) prior to expiry (c.f. section "Exemption 8(b): Cadmium in electrical contacts of cat. 8 and 9 EEE" on page 96).

The consultants recommend the below wording and scope for the exemption:

No.	Exemption	Scope and dates of applicability
8(c)	Cadmium and its compounds in electrical contacts that are not covered by exemption 8(b)(II), and excluding - resistive inks of infrared emitters in medical capnography sensors used with lung ventilators - gold-containing pastes for coating electrodes for connections to electrical sensing and signal processing circuits via gold wires in sensors for detection of low-level oxygen concentrations at elevated temperatures	Applies, from [date of the official publication of the COM decision in the Official Journal + 18 months + 1 day] on, to categories 8 and 9. Expires on 21 July 2025 for cat. 8 medical devices including in-vitro diagnostic medical devices and cat. 9 monitoring and control instruments including industrial monitoring and control instruments

Besides the use of cadmium in the above sensors, there may be other uses in fixed contacts which so far have been covered by exemption 8(b). Users of cadmium in such contacts may have expected that the exemption would be renewed with the current wording instead of creating a new exemption for these "fixed" contacts. The consultants therefore recommend 31 July 2025 as expiry date for the exemption to allow sufficient time for exemption requests.

In case the COM decides to renew the exemption for the sensors, the consultants recommend the below architecture and the wording that was agreed with the applicants:

No.	Exemption	Scope and dates of applicability
8(c)	Cadmium and its compounds in	Applies, from [date of the official publication of the COM decision in the Official Journal + 18 months + 1 day] on, to categories 8 and 9.
	(I) resistive inks of infrared emitters in medical capnography sensors used with lung ventilators	Expires on [DATE] for cat. 8 medical devices others than in-vitro diagnostic medical devices

	(II) gold-containing pastes for coating electrodes for connections to electrical sensing and signal processing circuits via gold wires in sensors for detection of low-level oxygen concentrations at elevated temperatures	Expires on [DATE] for cat. 9 industrial monitoring and control instruments.
	(III) other electrical contacts that are not covered by exemptions 8(b)(II), 8(c)(I) and 8(c)(II).	Expires on 21 July 2025 for cat. 8 medical devices including in-vitro diagnostic medical devices and cat. 9 monitoring and control instruments including industrial monitoring and control instruments.

While the applicants had requested the maximum validity period of seven years for the capnography sensors, Sensata et al. (2022e) had proposed an expiry on 21 July 2026 for the oxygen sensors. Further on, Sensata et al. (2022i) agreed that the zirconia oxygen sensors, even though used to measure “medical grade gases”, are not used in medical devices. They are therefore considered cat. 9 industrial monitoring and control instruments.

If the COM grants one of the sensor exemptions only, the COM might use the following wording illustrating the case that the exemption is renewed for the capnography sensors.

No.	Exemption	Scope and dates of applicability
8(c)	Cadmium and its compounds in	Applies, from [date of the official publication of the COM decision in the Official Journal + 18 months + 1 day] on, to categories 8 and 9.
	(I) resistive inks of infrared emitters in medical capnography sensors used with lung ventilators	Expires on [DATE] for cat. 8 medical devices others than in-vitro diagnostic medical devices
	(II) other electrical contacts that are not covered by exemptions 8(b)(II), 8(c)(I) and 8(c)(II), and excluding gold-containing pastes for coating electrodes for connections to electrical sensing and signal processing circuits via gold wires in sensors for detection of low-level oxygen concentrations at elevated temperatures	Expires on 21 July 2025 for cat. 8 medical devices including in-vitro diagnostic medical devices and cat. 9 monitoring and control instruments including industrial monitoring and control instruments.

Exemption 8(b)(I)

Substitution of cadmium has been scientifically and technically practicable for years already. The reliability of cadmium-free contacts in EEE of categories 1-11 can, however, only be ensured from 2024 on for all protective switches (circuit breakers, thermal sensing controls and thermal motor protectors), and from 2026 on for other switches respectively. Granting an exemption would therefore be justified by Art. 5(1)(a).

The consultants recommend renewing the exemption with the below wordings, scopes and expiry dates.

No.	*Exemption*	*Scope and dates of applicability*
8(b)(I)	Cadmium and its compounds in electrical contacts of - circuit breakers, - thermal sensing controls, - thermal motor protectors (excluding hermetic thermal motor protectors) - AC switches rated at: - 6 A and more at 250 V AC and more, or - 12 A and more at 125 V AC and more - DC switches rated at 20 A and more at 18 V DC and more, and - switches for use at voltage supply frequency ≥ 200 Hz	Applies to categories 1 to 7 and 10 Expires on [date of the official publication of the COM decision in the Official Journal + 12 months]
8(b)(III)	Cadmium and its compounds in electrical contacts of	Applies to categories 1-7, 10 and 11 from [date of the official publication of the COM decision in the Official Journal + 12 months + 1 day] on
	- circuit breakers rated at - 10 A and more at 250 V AC and more, or - 15 A and more at 125 V AC and more, - thermal sensing controls rated at - 10 A and more at 250 V AC and more, or - 15 A and more at 125 V AC and more, - thermal motor protectors (excluding hermetic thermal motor protectors)	Expires on 31 December 2023 for cat. 1-7, 10 and 11
	- AC switches rated at - 10 A and more at 250 V AC and more, or - 15 A and more at 125 V AC and more, - DC switches rated at 25 A and more at 18 V DC and more,	Expires on 31 December 2025 for cat. 1-7, 10 and 11

The current exemption 8(b)(I) has a wider scope than the renewed exemption 8(b)(III), which in the consultants' understanding is equivalent to a partial revocation of exemption

8(b)(I). Art. 5(6) becomes applicable requiring a transition period of 12 to 18 months. The consultants recommend 12 months to allow for administrative adaptations in industry.

For the switches rated for use at voltage supply frequencies of 200 Hz and more, the applicants stated that the exemption is no longer required and can therefore expire, resulting in the revocation of the exemption. In this case, Art. 5(6) is applicable, and a transition period of 12 to 18 months is to be granted. The consultants recommend 12 months to allow sufficient time for administrative adaptations.

Due to the already advanced time beyond the original expiry date in July 2021, the COM might consider renewing the exemption clauses referring to the protective switches in their current wording. Otherwise, the revised wording of these exemption clauses may enter into force shortly before or even after the manufacturer will have phased out cadmium in these switches. This situation would cause administrative burdens in industry without benefits from the additionally avoided amounts of cadmium due to the restricted exemption scope. If the COM decides to follow this approach, the exemption for the protective switches can be renewed with the current numbering.

The consultants recommend the below exemption wording:

	Exemption	Scope and dates of applicability
8(b)(I)	Cadmium and its compounds in electrical contacts of	Applies to categories 1-7 and 10
	- circuit breakers, - thermal sensing controls, - thermal motor protectors (excluding hermetic thermal motor protectors)	Expires on 31 December 2023 for cat. 1-7 and 10
	- AC switches rated at: - 6 A and more at 250 V AC and more, or - 12 A and more at 125 V AC and more - DC switches rated at 20 A and more at 18 V DC and more, and - switches for use at voltage supply frequency ≥ 200 Hz	Expires on [date of the official publication of the COM decision in the Official Journal + 12 months] for cat. 1-7 and 10
8(b)(III)	Cadmium and its compounds in electrical contacts of - AC switches rated at - 10 A and more at 250 V AC and more, or - 15 A and more at 125 V AC and more, - DC switches rated at 25 A and more at 18 V DC and more.	Applies, from [date of the official publication of the COM decision in the Official Journal + 12 months + 1 day] on, to categories 1-7, 10 and 11 Expires on 31 December 2025 for cat. 1-7, 10 and 11

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6. Exemption 9 of Annex III: Hexavalent chromium in absorption refrigerators

Exemption 9 is one of three exemptions related to gas absorption refrigerators as illustrated in the below table.

No.	Current exemption wording	Current scope and dates of applicability
9	Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75 % by weight in the cooling solution.	Applies to categories 8, 9 and 11 and expires on: - 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments, - 21 July 2023 for category 8 in vitro diagnostic medical devices, - 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.
9(a)(I)	Up to 0,75 % hexavalent chromium by weight, used as an anticorrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators (including minibars) designed to operate fully or partly with electrical heater, having an average utilized power input < 75 W at constant running conditions	Applies to categories 1-7 and 10 and expires on 5 March 2021.
9(a)(II)	Up to 0,75 % hexavalent chromium by weight, used as an anticorrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators: - designed to operate fully or partly with electrical heater, having an average utilised power input ≥ 75 W at constant running conditions, - designed to fully operate with non-electrical heater.	Applies to categories 1-7 and 10 and expires on 21 July 2021.

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described *in italics*.

Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

Ariston	Ariston Thermo SpA
CB	Condensing boiler
Cr-VI	Hexavalent chromium
EEA	European Economic Area
EEE	Electrical and electronic equipment
ELR	Excess life risk (in the context of this review the risk to contract cancer)
GAHP	Gas absorption heat pump
GWP	Global Warming Potential
HS	Hybrid system consisting of a CB and an electrical heat pump
IMCI	Industrial monitoring and control instrument
IVD	In-vitro diagnostic medical device
ODP	Ozone Depletion Potential
RoHS 1	Directive 2002/95/EC (2003b)
RoHS 2, RoHS	Directive 2011/65/EU (2011a)
W	Watt

Definitions

Gross calorific value	amount of heat released by the complete combustion of a unit of an energy carrier
Primary seasonal energy efficiency	Ratio of heat output over the year divided by the Gross Calorific Value of the energy input (Ariston (2022b))

6.1. Background and Technical Information

On 23 December 2020, Ariston (2020) requested the amendment of exemption III-9 to include gas absorption heat pumps (GAHPs) into the exemption scope as EEE of category 1 (large household appliances). They proposed a wording that would cover both absorption refrigerators and GAHPs. The applicant applies for a five year validity period for EEE of cat. 1 under the amended exemption.

No.	Requested Exemption (Ariston)	Requested scope and dates of applicability
9	Hexavalent chromium as an anticorrosion agent of the carbon steel sealed circuit in gas absorption driven appliances up to 0.75 % by weight in the refrigerant solution	Applies to categories 1, 8, 9 and 11 and expires on: - 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments, - 21 July 2023 for category 8 in vitro diagnostic medical devices, - 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11. - 31 December 2026 for category 1 gas absorption heat pumps.

Absorption refrigerators are based on the same physical principles like GAHPs. Dometic (2020), a producer of absorption refrigerators, applied for the renewal of exemption 9(a)(II). Since the requests target different exemptions, and due to differences in the operation conditions that may affect the suitability of substitutes, the two exemption requests are treated separately. The review result of Dometic's renewal request for absorption refrigerators can be found in section 7 on page 134 et sqq.

TMC (2020) contributed to the stakeholder consultation stating that their members intend submitting applications for renewal of certain exemptions [here 9] *within the legally foreseen deadlines of 18 months prior to their expiries for industrial monitoring and control instruments. They request the European Commission to schedule the evaluation of the Annex III exemptions relevant to category 9 industrial applications in due time, i.e., 18 months prior to 21 July 2024. However, the COM had already clarified with representation of TMC in written correspondence, pertaining to a previous exemption renewal request, that the Commission considers it justified for the technical assessment to start at the same time for all categories as requested by the applicants.*

6.1.1. History of the Exemption

The use of Cr-VI in absorption refrigerators was already covered by an exemption 9 when Directive 2002/95/EC (2003a) (RoHS 1) was enacted in 2003. In the revision of this exemption 9 under Directive 2002/95/EC (2003a) by Gensch et al. (2009) it was recommended to renew the exemption. The COM renewed the exemption until 2014, resulting in the wording still reflected in the current exemption entry 9. In the course of the transition from RoHS 1 to RoHS 2, the expiry date was shifted to 21 July 2016.

In the review by Gensch et al. (2016) following the renewal request of Dometic, the consultants recommended to maintain exemption 9 for EEE of cat. 8, 9 and 11 with the same wording resulting in the current scope of this exemption (status October 2021). Ariston (2020) requested the amendment of exemption 9 to include GAHPs into its scope.

6.1.2. Summary of the requested exemption

Ariston (2020) apply for an amendment / change of the wording and the extension of "Exemption 9" in RoHS Annex III.

Gas Absorption Heat Pumps (GAHP) and refrigerators use scientifically and technologically the same thermodynamic principles as absorption refrigerators. More precisely, refrigerators and GAHPs are:

- *Identical from the operating principle*
- *Extremely similar from the operating conditions*
- *Identical from the metallurgy/corrosion/construction point of view*

Therefore, Ariston Thermo SpA is requesting within this application to change the wording of the current exemption to additionally cover gas absorption heat pumps. According to Ariston (2020), GAHPs are the most promising thermally driven heat pump category. It is perceived as the technology to replace the conventional gas boiler technology in support of the energy transition and therefore it is instrumental to accelerate the energy transition toward hydrogen.

Therefore, in place of the current wording:

> *"Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0.75 % by weight in the cooling solution"*

The following wording is proposed:

> *"Hexavalent chromium as an anticorrosion agent of the carbon steel sealed circuit in gas absorption driven appliances up to 0.75 % by weight in the refrigerant solution"*

Cr-VI (hexavalent chromium) is listed on REACh Annex XIV as entry 22. *Ariston (2019) applied for an authorisation under Regulation (EC) 1907/2006 for the "Use of sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 0.70 % by weight (as Cr-VI) in the refrigerant solution".*

6.1.3. Technical description of the exemption and use of the restricted substance

Ariston (2020) describe absorption heat pumps as heat pumps driven not by electricity, but by a heat source such as natural gas, propane, solar-heated water, or geothermally heated water. Because natural gas is the most common heat source for absorption heat pumps, they are also referred to as gas-fired heat pumps.[32]

According to Ariston (2021d), the GAHPs in the scope of the requested exemption are nevertheless EEE (cat. 1) because they require electricity for the following auxiliary functions:

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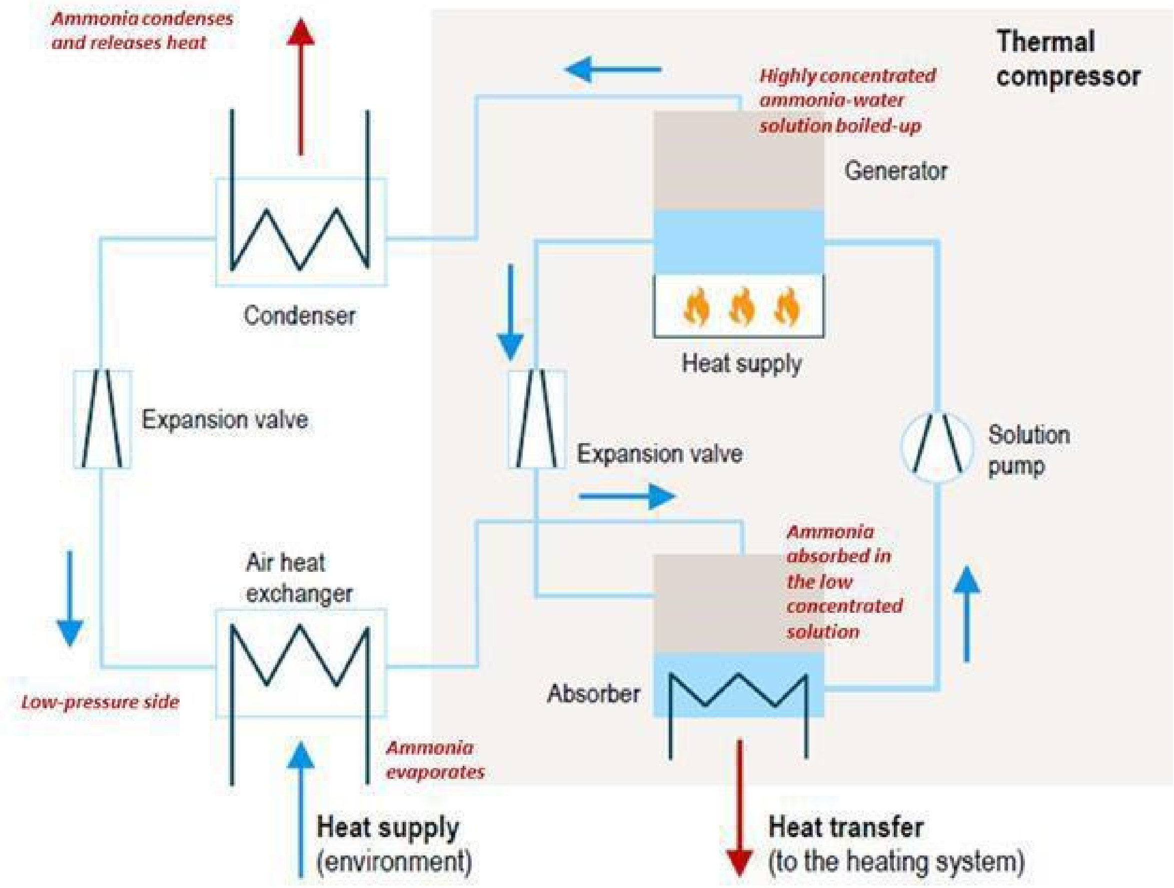
[32] Energy Saver, https://www.energy.gov/energysaver/absorption-heat-pumps

- *Overall appliance control*
- *Activation of the combustion*
- *Pumping of refrigerant solution*
- *Ventilation fan (for air sourced units)*

Usually the total power needed for these auxiliary functions is a very minor portion of total power output (approx. 1-3 % of nominal power).

Ariston (2020) illustrate the functional principle of GAHPs with the below figure.

Figure 6-1: Functional principle of a GAHP



Source: Ariston (2020)

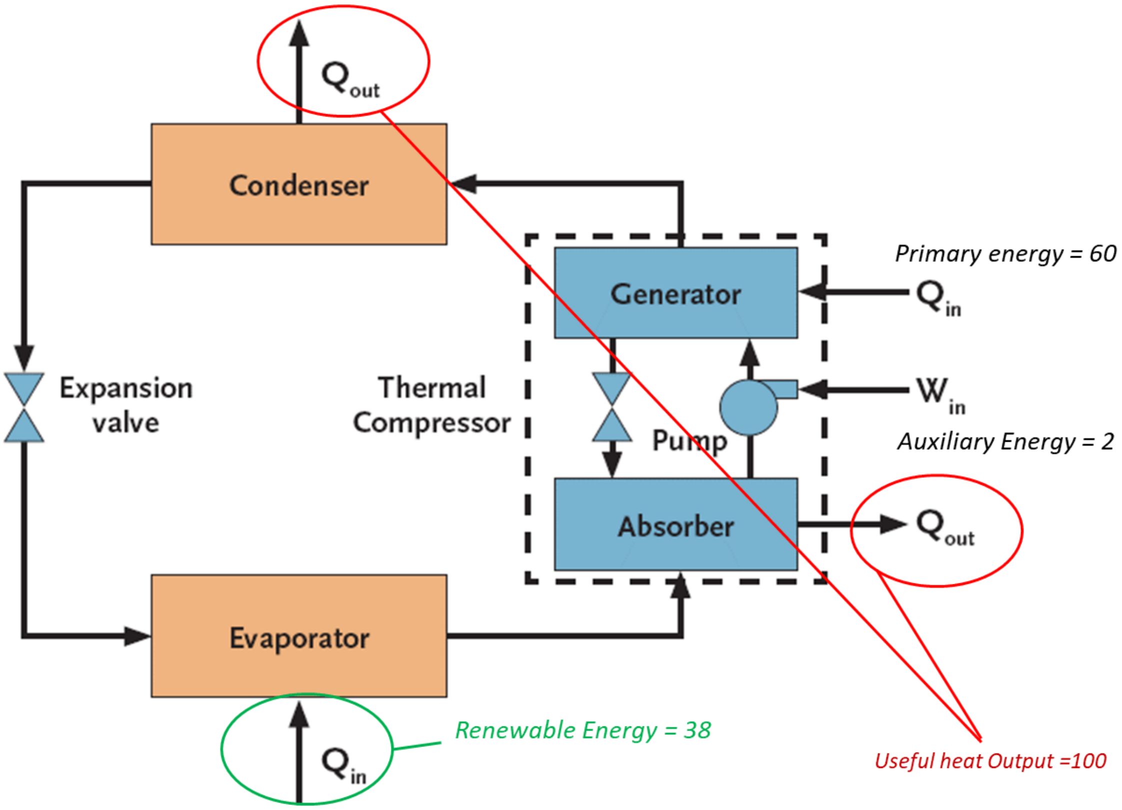
Ariston (2021d) describe the process in more detail:

- ***HEAT SUPPLY**. The combustion of the energy carrier (natural gas, LPG, H_2, etc.) starts the "chemical engine" of the absorption cycle.*
- ***GENERATOR**. Thanks to the thermal input of the burner, ammonia evaporates and separates from the water (desorption process, a sort of "distillation").*
- ***CONDENSER**. The heating energy accumulated in the refrigerant (ammonia) is transferred to the water of the hydraulic loop of the end user.*

- ***EXPANSION VALVE****. Valve (orifice) that separates high pressure side from low pressure side. In the absorption cycle there are a minimum of 2 valves (one on the "refrigerant" and one on the "solution").*
- ***EVAPORATOR with air heat exchanger.** Air heat exchanger where renewable free energy is recovered from the outdoor air and heat the ammonia causing its evaporation.*
- ***ABSORBER.** Vapor of ammonia coming from the evaporator is absorbed into the water coming from the generator. The energy produced by absorption process pre-heats the solution that goes back to the generator, it is recovered and transferred to the hydraulic loop (in parallel to the condenser). This increases the efficiency of the system.*
- ***SOLUTION PUMP****. The water-ammonia solution is pumped back into generator.*

Figure 6-2 displays a simplified gas absorption heat pump thermodynamic process, including some approximate ratios of energy input and output.

Figure 6-2: Simplified gas absorption heat pump process



Source: Ariston (2021d)

In the above figure, the GAHP extracts 38 % of the primary heating energy (Q_{out}, 100 %) from the environment (Q_{in}, renewable energy), 60 % of the heating energy are generated from the combustion of gas, and 2 % from auxiliary energy (primary energy for generation of electricity). Ariston (2020) describe that an ammonia/water mixture (R717) with zero ozone depletion and zero global warming potential is used as refrigerant. The sealed circuit is made of steel, which requires the use of a corrosion inhibitor Cr-VI which currently is the only commercially available material to withstand the demanding environment in terms of temperature, pressure, cavitation erosion and chemical reactions.

Ariston (2021d) highlight the favourable properties of water/ammonia compared to other working fluids:

- *Can be used where the renewable energy (heat supply, Q_{in}) is taken from lower temperature media, e.g. cold air below 0 °C;*
- *Excellent thermodynamic performance of ammonia as refrigerant;*
- *Extremely good quality of water as absorbent;*
- *Absence of crystallization effect;*
- *Wide availability of both;*
- *Ozone Depletion Potential (ODP) of zero;*
- *Greenhouse effect (Global Warming Potential (GWP) of zero);*
- *Limited cost;*

Ariston (2020) explain that chromium VI is used as anticorrosion agent in the refrigerant solution. The inhibitor function is proved and tested for GAHP. In basic media Cr-VI oxidises iron on the steel surface and forms a protective layer which contains iron oxide and chromium (III) oxide. Cr-VI itself is reduced to Cr-III to build the protective layer.

$$9\ Fe + 8\ Na_2CrO_4 + 8\ H_2O \rightarrow 3\ Fe_3O_4 + 4\ Cr_2O_3 + 16\ Na\ OH$$

Equation 6-1: Corrosion inhibition reaction of sodium chromate with iron/steel

This passivating film builds a very effective protection for the carbon steel against corrosive processes and possesses self-healing ability.

A maximum amount of 0.7 % (weight) Cr-VI in the homogenous refrigerant solution is introduced into the sealed system of the GAHP appliances. Before placing on the market, the gas absorption heat pumps are fully tested (mandatory for compliance with Gas Appliance Regulation).

During testing significant amount of Cr-VI will be reduced to chromium oxide (Cr_2O_3) and adhere to the inner surface of the sealed circuit. Consequently, the concentration of Cr-VI in the homogenous material (refrigerant solution) will be significantly lower than the introduced 0.7 % when placed on the market.

Further reduction of concentration is expected in the following operation of the appliance in application. Currently measurements are planned to determine the exact trend of Cr-VI concentration after testing.

6.1.4. Amount(s) of restricted substance(s) used under the exemption

As a worst case, Ariston (2020) estimate around 1,400 kg of Cr-VI to be placed on the EU market under this exemption every year. As the product is not yet placed on the market, exact numbers cannot be currently measured and stated. The amount mentioned in the Chemical Safety Report (CSR) of the application for Authorisation of 1,400 kg/year can be considered as worst case assumption. This value reflects the maximum production capacity.

6.2. Justification for the requested exemption

6.2.1. Substitution and elimination of Cr-VI in GAHPs

Ariston (2020) performed an extensive research on possible alternatives and has come to the conclusion that currently no alternative exists, which could deal with the requirements set by the GAHP. Detailed information on the assessment of alternatives are presented in the application for Authorisation and in the answers submitted to RAC and SEAC during the opinion making process. Ariston Thermo SpA is investing in testing programs to progressively decrease the concentration of Cr-VI in the refrigerant solution to the minimum possible concentration.

GAHPs are considered as replacement technology for condensing boilers. Electrical heat pumps cannot deliver the required high thermal lift. The technology was also supported in a project funded by the European Commission.[33]

6.2.2. Roadmap towards substitution or elimination of Cr-VI

Ariston (2020) collaborate with European universities in monitoring and research of new substitutes. Ariston Thermo Innovative Technologies (Aristonthermo R&D center for innovative / renewable technologies) has invested in creating an endurance test area to perform validation testing of future potential substitutes.

In the roadmap of substitution in the application for Authorisation five stages have been identified to establish a possible future substitute:

1. Monitoring/ Research
2. Identification
3. Validation
4. Product development
5. Market implementation

Overall, Ariston (2020) expect a period of around 20 years from the detection of a possible alternative to the replacement of the corrosion inhibitor. Even with an already identified substitute the replacement is expected to take not less than 12-15 years. Corrosion in GAHPs is a very slow process. Effects of corrosion can materialise after 5 to 10 years without precognition.

Therefore, extensive real appliance testing under ALT (Accelerated Life Test) and / or HALT (High Accelerated Life Test) conditions are required. These tests are by far the longest and most expensive activities in establishing a possible substitute.

[33] The European Commission supported a project to develop the GAHP technology, already available in the EU for the light commercial segment, to allow its cost-effective application in existing residential buildings, c.f. HEAT4YOU, https://cordis.europa.eu/project/id/285158/reporting

6.2.3. Environmental and socioeconomic impacts

GAHPs are only one of several technical options for domestic room and water heating from which only the GAHPs rely on the use of toxic Cr-VI. *Ariston (2021b) provide a condensed summary of fundamental reasons for the use of GAHP technology. The EU Commission roadmap for energy transition anticipates that by 2050 still* ***66 % of buildings*** *("hard to decarbonize")* ***require fossil energy technologies for space and water heating****. These buildings will have the following characteristic: high specific thermal load (= poor insulation), high temperature emission system (radiators).* ***Primary/possible alternatives*** *are heat generators based on combustion technology (boiler) or heat-pump technology (today primarily "electrical heat pump"), hybrid systems, district heating and biomass boilers.*

- ***Combustion technology*** *is a well proven, reliable, high temperature (compatible with the radiators), cost optimized solution that represents by large the dominant solution in Europe. Nevertheless, its energy conversion efficiency is limited by the absence of a renewable fraction and* ***cannot exceed 100 % on primary energy****.*
- *Compression* ***heat pump systems*** *(i.e. electrically driven heat pumps) are particularly efficient when applied with limited "thermal lifts" (difference between "source" and "sink" of the heat), tend to* ***suffer of decreased performance (efficiency and power output) when the thermal lifts increase*** *(cold winter conditions, high output power and temperature for radiators). These behaviours are unavoidably associated with Carnot principle and efficiency losses due to compression.*
- ***Hybrid systems*** *tend to merge the strengths of the two above mentioned technologies: performance of compression heat pump in mild operating conditions and power and high temperature output when thermal lift increases. The development of this technology* ***demonstrates the need for a solution*** *and the existence of limitations of the two technologies used for creating the hybrid. Hybrid systems are therefore capable of achieving high temperature, but only with boiler technology efficiency and enjoy high energy efficiencies but only when thermal lift is reduced.*
- ***District heating*** *will clearly be part of the future scenario, but its use will be* ***limited to those areas where the population density*** *technically and economically enables the solution (large urban areas).*
- ***Biomass****: This technology will be used primarily in* ***areas where the emissions*** *of particulate and other contaminants* ***can be tolerated*** *(not in highly populated areas).*

Ariston (2021b) highlight the unique advantages of GAHPs for addressing those buildings that are not planned to be electrified by 2050:

- *Ability to achieve* ***high efficiency on primary energy and high output power*** *despite radiators that imply high thermal lifts;*
- ***Use of renewable energy:*** *35 % to 40 % of energy delivered to end user comes from the environment;*
- ***Use of a high density energy vector*** *(gas molecules) that allow both for* ***transport and seasonal storage of energy*** *by means of the current gas grid infrastructure;*

- ***Use of green gases*** *(biomethane, bioLPG, hydrogen) as an alternative to fossil natural gas;*
- ***Reduced operating cost for end user:*** *35 % to 40 % lower energy bills compared to traditional condensing technologies;*

Use of a working fluid (ammonia/water) with no global warming and ozone depletion potential *compared to other heating systems which use HFCs refrigerant solutions with extensively higher GWP.*

Ariston (2020) report about a simplified Life Cycle Assessment (LCA) which was performed for their Authorisation application and present the below key findings.

- *Manufacturing*

  The raw materials for a gas absorption heat pump are comparable to the ones for a condensing boiler. The sealed circuit of the gas absorption heat pumps is made of carbon steel and the refrigerant solution consists of the natural refrigerant water and ammonia. Cr-VI is added as corrosion inhibitor. The ammonium-water solution is the most environmentally friendly refrigerant solution featuring a Global warming potential (GWP) of zero and an Ozone Depletion Potential (ODP) of zero. GAHP technology has no fluorinated gas (F-Gas) emissions, and it is therefore exempt from the F-Gas Directive.

  All raw materials for the refrigerant solution are bought from EU based suppliers. Currently, the GAHP manufacturing imposes a 100 % vertical integration at the manufacturing site, which is very atypical for the heating sector.

- *Use stage*

  Ariston (2020) explain that GAHPs are low maintenance products with an expected lifetime of 24 years without any refilling requirements of the refrigerant solution containing Cr-VI.

  According to Ariston (2019), Cr-VI as part of the refrigerant works in the sealed circuit, which cannot be opened after the initial filling anymore. After a short period of time most of the Chromium (VI) will be passivated to Chromium (III) and welded to the inner surface of the sealed circuit.

  Ariston (2020) point out that the technology meets the criteria for the EU Ecolabel and the Energy labelling A++ set by the European Commission (2013). When the primary energy used by the GAHP is “natural gas”, GAHP appliances currently show the lowest CO_2 emission of all fuels (burning oil, fuel oil and gas).

  Ariston (2020) put forward that GAHPs achieve a seasonal space heating efficiency on primary energy (on high temperature applications) in excess of 125 % (measured on “radiator” according to EN12309, and including auxiliary electrical consumption). This means that to cover the energy 25,000 kWh demand of a household per year, a GAHP requires 20,000 kWh of gas per year. Taking into account the CO_2 emissions of gas (0.184 kg of CO_2/kWh)[34], the use of GAHP results in 3,682 kg CO_2 per year.

[34] Treasury, H. M. (2018): The Green Book. CENTRAL GOVERNMENT GUIDANCE ON APPRAISAL AND EVALUATION; source as referenced by the applicant

For comparison, the condensing boiler technology reaches an efficiency between 90 and 95 %. Compared to the 125 % efficiency of GAHPs, the CO_2 emissions are around 30 % – 35 % lower. When the primary energy source is a "green gas" (Bio-gas, Green Hydrogen), the resulting CO_2 emissions will be virtually zero.

The European energy transition will imply large use of green gases by 2050, which will cause substantially higher operating costs for end users with traditional technologies (condensing boilers). The high energy efficiency of the GAHP technology will contribute to lower the heating costs for end users resulting from a more expensive energy sector (green gases, e.g. gases like hydrogen or methane generated with use of renewable energies that could be incinerated with high efficiency in GAHPs). RAC/SEAC (2020) indicate the expected socio-economic benefits of continued use of sodium chromate in the requested authorized use with at least € 3.6 million per year.

- *End of life*

  Dedicated dismantling infrastructure is in place. After end of service, the GAHP will be picked up by authorised installers and replaced by a new one. The sealed circuit containing the refrigerant solution (NH3 and the remaining portion of Cr-VI) will be emptied and collected by installers / workers with specific training. The refrigerant is disposed as hazardous waste according to national laws.

6.3. Critical review

6.3.1. REACH compliance – Relation to the REACH Regulation[35]

REACH Annex XVII

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV "*provided that such inclusion does not weaken the environmental and health protection afforded by*" the REACH Regulation. The article details further criteria, which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the consultants as a threshold criteria: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

REACH Annex XVII (2021) contains entries restricting the use of sodium chromate:

- Entry 28 addresses substances which are classified as carcinogen category 1A or 1B listed in REACH Appendices 1 or 2, respectively.
- Entry 29 addresses substances which are classified as germ cell mutagen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 3 or Appendix 4, respectively.

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[35] REACH 2021.

- Entry 30 addresses substances which are classified as reproductive toxicant category 1A listed in REACH Appendices 1 or 2.

According to the above entries, sodium chromate *shall not be placed on the market, or used,*

- *as substances,*
- *as constituents of other substances, or,*
- *in mixtures,*

for supply to the general public when the individual concentration in the substance or mixture exceeds certain threshold limits.

In the consultants' understanding of the above, the use of sodium chromate in GAHPs is not a supply of sodium chromate to the general public. Sodium chromate is contained in an article from which its liberation and release into the environment, or the access of consumers to the substance, is not intended and is to be prevented. According to Ariston (2020), refilling of the working fluid over the 24 years of foreseen operation time is not necessary. There is thus no necessity to place the substance - sodium chromate, or the working fluid containing Cr-VI - on the EU market for refilling installed GAHPs, which could be interpreted as a supply of Cr-VI/sodium chromate to the general public.

Entry 47 addresses chromium VI compounds, however in cement and leather. The entry is thus not applicable to the uses of Cr-VI in absorption refrigerators and GAHPs.

Entries of REACH Annex XIV

Sodium chromate is a substance of very high concern and is listed as entry 22 on REACH Annex XIV (2021) due to its mutagenicity, carcinogenicity and toxicity for reproduction.[36] Manufacturers, importers or downstream users shall not place a substance listed on Annex XIV on the market for a use or use it themselves[37], unless the use(s) of that substance on its own or in a mixture, or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorized.[38]

On 20 February 2019, Ariston (2019) requested a 20 years authorization for the "*Use of sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 0.70 % by weight (as Cr6+) in the refrigerant solution*". The Commission's decision is pending (c.f. ECHA (2021)), but RAC/SEAC (2020) gave a positive opinion related to the requested authorization.

No other entries of relevance for the use of sodium chromate in the requested exemption could be identified in Annex XIV and Annex XVII (status November 2021).

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[36] C. f. ECHA, Annex XIV, sodium chromate: https://www.echa.europa.eu/web/guest/authorisation-list?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

[37] REACH Art. 56(1)

[38] REACH Art. 56(1)(a)

Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation provided the authorization for the use of Cr-VI in the form of sodium chromate as requested by Ariston (2019) does not speak against it.

6.3.2. Scientific and technical practicability of substitution or elimination of Cr-VI

Use of sodium chromate (Cr-VI) in GAHPs of other manufacturers

GAHPs have been placed on the EU/EEA market for several years already and it is assumed that they contained Cr-VI as an inhibitor. The use of Cr-VI is restricted under the RoHS Directive since 2006, which raises the question how RoHS compliance has been achieved in the past without an exemption for the use of Cr-VI in GAHPs. *In the understanding of Ariston (2021a), only light commercial/large industrial appliances that might fall under the exclusion for large-scale fixed installations (Art. 3(4) of the RoHS Directive) using GAHP's thermodynamic principle have been sold so far on the EU/EEA market[39] starting approximately in 2005. Ariston (2019) are apparently the first company to ask for REACH authorisation and a RoHS exemption for the use of sodium chromate (Cr-VI) in GAHPs for the small residential applications which Ariston classify as EEE of category 1 (large household appliances). Theoretically, manufacturers may also interpret that the GAHP tube system with the Cr-VI solution is not part of the GAHP itself and is thus not an EEE so that a RoHS exemption would not be required.* Since the classification of products is the manufacturers' responsibility, the consultants did not invest time and efforts to follow up on this issue.

Ariston is the only applicant requesting this exemption and no other GAHP manufacturers supported or objected Aristons' exemption request. This arises the question whether other manufacturers may not require Cr-VI in their products. Only Ariston's authorization request was found on the Ariston (2019) webpage and on the list of ECHA (2021) authorisation decisions. Ariston (2021a) *understand that they are currently the company closest to a commercial launch of GAHP for the residential market (cat. 1) and therefore might be considered as a "pioneer". They are aware of several other companies that are investigating GAHPs, but none of these programs have yet reached the commercialization stage and no technical details are currently available. Therefore, they foresee that other manufacturers might take advantage of the requested exemption.*

The consultants contacted three producers who produce smaller GAHPs for residential use[40] to inquire whether they have Cr-VI-free alternatives for their GAHPs and whether they would support Ariston's exemption request. All of them reacted, but did not agree to publish their statements in the context with their names. In the absence of contrary evidence, the consultants therefore follow the applicant's statement that the use of sodium chromate is the current state of the art technology for GAHPs.

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[39] In the consultants' opinion, the use of Cr-VI in commercial/large scale fixed appliances would require an authorization under REACh.

[40] Gas heat pump manufacturers, https://gasairconditioning.com/technologies/heat-pumps/resources/

Potential of the Dometic Cr-VI-free substitute for use in GAHPs

Ariston (2020) highlight that GAHPs are based on the same physical principles and techniques like absorption refrigerators operated with gas. Dometic, a manufacturer of absorption refrigerators, has developed a substitute (corrosion “Inhibitor 7”) for sodium chromate (Cr-VI) which has been implemented almost across their entire product lines. Only the higher power absorption refrigerators covered by exemption 9(a)(II) still use Cr-VI. This exemption is currently under review. Until end of 2025, when Dometic wants to have accomplished the phaseout of Cr-VI in these models as well (c.f. review of renewal request of exemption III-9(a)-II). To obtain some insights into potential scientifical and technical practicability of a future substitution of Cr-VI in GAHPs, the consultants investigated the similarities and differences which may enable or hinder the substitution in GAHPs.

Ariston (2021a) *state that the composition of Dometic’s Inhibitor 7 is not made publicly available and thus cannot be used by other manufacturers. The GAHP technology has two aspects that make the environment of the corrosion inhibitor more demanding.*

1) *Compared to absorption refrigerators, GAHPs require a higher operating temperature as consequence of the higher thermal lift. Their operating temperatures can reach or even exceed 200 °C. In the application for authorisation by Dometic (2015) a reduced corrosion protection of inhibitor 7 at high temperatures (> 180 °C) was reported. At such temperatures, even a minor increase in temperature can drive a substantially higher corrosion rate.*
2) *The expected lifetime of the product combined with the annual operating hour is an additional crucial point. GAHPs are designed for a 24 year duration. In addition, the number of operating hours in a year of a heating appliance is significantly larger than corresponding hours of the “thermal compressor” of an absorption refrigerator.*

Dometic (2021b) inform that most of their absorption refrigerators are taken out of service after 10 to 15 years depending on the specific product, but that at that time most of the products are still functional because products are taken out of service for other reasons than failures. The actual time in operation will vary greatly. It can be expected that a minibar in a hotel is under operation continuously whereas a refrigerator in a recreational vehicle – Dometic also produce absorption refrigerators for such vehicles - *in particular in Europe, has a considerably shorter time in operation given the seasonal use of recreational vehicles. That said, any inhibitor system needs to be designed to maintain function of the cooling system beyond the actual life time of the product and of course it needs to be ensured that the integrity of the cooling system is not compromised during the technical life.*

In the consultants’ opinion, GAHPs on average may have a longer use time supposing that heating systems are more often exchanged closer to the end of their technical life time, and on average are operated for more hours than absorption refrigerators even though this depends on the specific use of these devices. However, the fact that the technical life time of absorption refrigerators exceeds 10 to 15 years may reduce the differences in use and operating hours between these fridges and the GAHPs so that a solution like Inhibitor 7 may still be useable for GAHPs. Ariston was requested to explain further the influence of other parameters, i.e. the input power (gas) and pressure.

Ariston (2021b) explain that while there are no theoretical limitations to input power for the application of GAHP technology, from the business point of view the most attractive market appears to be the one of heat generators for stationary heating application (primarily *residential and light commercial). This market is served by appliances with gas inputs up to 70 kW (subject to EN12309)*[41].

Concerning the influence of operating pressures up to 26 bars of GAHPs on substitution, *Ariston (2021b) explain that primary drivers for the need of a corrosion inhibitor are material (steel), temperature, pressure and life expectancy. The operating pressure is a function of the working fluid (ammonia-water solution), the application conditions (temperatures of sink and source) and the load. The factors influencing the pressure are not expected to change (are given by the application) and therefore are not expected to influence substitution options.*

Ariston (2021a) conclude that, as described in the request for authorization to ECHA, currently no solutions are available to replace Cr-VI in GAHPs. As the GAHP products developed by Ariston are not yet on the market, intensive testing on replacement solutions was not yet possible. Therefore, Ariston relies in a first step on the proven capability of Cr-VI in form of sodium chromate as corrosion inhibitor not to jeopardise the overall reliability and safety of the GAHP technology.

Given the above operating conditions of GAHPs, Dometic was asked for their opinion whether these conditions would principally exclude the successful use of their Cr-VI-free solution for refrigerators in GAHPs. *Dometic (2021a) state that their products covered by exemption 9(a)-II have a boiler temperature of 190-200 °C and operate with a system pressure of 23 to 26 bars. Their electrical heaters typically have an input power between 85 W and 100 W. Other products having gas and electrical heaters and covered by ELV could have an electrical input power of 80 - 250 W.*

Dometic (2021a) conclude that the Ariston application appears to operate under similar conditions like their products with higher boiler temperatures. Therefore, they see no obvious reason why their Cr-VI-free "Inhibitor 7" should not work for GAHP, but highlight that their statement is limited by the fact that they do not have detailed knowledge of the products' designs.

The Dometic solution might thus possibly be applicable to GAHPs as well as a potential future option to substitute Cr-VI in GAHPs, which would, however, require testing, design adaptations and validation taking more than five years looking at the time scales for the substitution of Cr-VI in the absorption refrigerators and those indicated by the applicant for substitution efforts. At the time being, Inhibitor 7 is a Dometic solution for absorption refrigerators and thus not readily available for use by other manufacturers.

Substitution of Cr-VI in GAHPs by lithium bromide/water and other working fluids

Soluble silicon compounds and rare earth metal salts, according to Ariston (2019), may have some potential as substitutes after a thorough testing. Ariston (2021c) mention lithium bromide/water as a potential working fluid instead of ammonia/water and makes Cr-IV unnecessary. Ariston (2021d) explain that in absorption systems using the pair "water - lithium bromide", water works as the refrigerant that is absorbed in the lithium bromide. In this condition, the water in the working fluid crystalizes (forms ice) at around 0 °C. An appliance that operates with such pair will therefore be able to operate as a heat pump only

[41] C.f. European Standards, EN 12309-series, https://www.en-standard.eu/search/?q=EN+12309

when the source of heat is at temperature above zero Celsius (for technical reasons this is usually translated in a minimum operating temperature of 5 °C). This is no problem for air conditioning applications where the "cold source" of heat is the indoor temperature (example 24 °C) and the "hot sink" is the outside ambient (example 35 °C). In case of heat pump applications, the "cold source" is expected to be at -10 °C and the hot sink at 35 °C to 70 °C. The refrigerant (water) will not be able to evaporate at such low temperature since it is already crystalized. Therefore, the thermodynamic cycle of acquiring heat at low temperature and transferring it at high temperature will not be possible. Hence the application of "water-lithium bromide" appliance cannot fulfil the typical operating environment of a heat pump application.

Ariston (2021c) point out that there are other working fluids which are, however, not commercialized.[42] Ariston (2021d) conclude that the search for a pair better than ammonia-water is not expected to end anytime soon, despite the significant research effort ongoing.

According to Shahad et al. (2018) referenced by Ariston (2021d), the ammonia/water mixture as a working fluid for refrigeration systems has been used since the mid of 19th century. Many working fluids are suggested in literature, some 40 refrigerant compounds and 200 absorbent compounds available. Shahad et al. (2018) assessed several of these, in parts by thermodynamic modelling. Actual devices operating with any of these working fluids are not available.

In the consultant's view, the ammonia/water working fluid appears to be the best option in the context of the operating conditions of GAHPs. The lithium bromide/water working fluid cannot be used in GAHPs where the working fluid can be exposed to temperatures below 0 °C. Whether any of the other potential options may be a viable substitute for the NH3/water system should be subject to the applicant's substitution research of the coming years, but the practical implementation of an alternative, if any. According to the applicant's roadmap, no GAHPs with Cr-VI-free working liquids can be expected to be placed on the market in the coming five years.

Ariston's roadmap towards substitution or elimination of Cr-VI

The scope of exemptions 9(a)-I and 9(a)-II related to Cr-VI in absorption refrigerators could be restricted in the past years reflecting the scientific and technical progress. The applicant was therefore asked whether the use of Cr-VI is actually required in all configurations of GAHPs, or whether its use can at least be reduced in certain configurations of GAHPs with specific operating conditions. *Ariston (2021a) state that all GAHP configurations/uses that Ariston can currently envisage do imply the presence of an inhibitor with performance equal or better than Cr6+. No other inhibitor is currently available which could provide the same performance in protection against corrosion under the operating conditions of the GAHP.*

Ariston was asked when they had started their RoHS compliance activities. *Ariston (2021b) explain that their GAHPs are not yet commercialized since it is a new development for residential buildings. Intensive and extended testing on replacement solutions was not possible. Testing lower levels of sodium chromate or alternative inhibitors require the use of real appliances. The operating conditions of the appliance cannot be replicated in lab environments. The inhibitor tests require long time proportional to the life expectancy and a*

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[42] Shahad et al. 2018.

statistically meaningful number of units under test to confirm measurements. Ariston (2021c) substantiate the statistically meaningful number of units with "[…] a minimum of few tens […]". Ariston (2021b) state that these conditions can be met only once volume production is available.

Upon request, the applicant revealed some more details on the current and future substitution efforts. With a newly installed Ariston testing facility, the applicant is confident to be able to progressively reduce the Cr-VI in the product and possibly getting to its full elimination. Ariston (2021a) state that they started a program with Politecnico di Milano (PoliMi, Technical University of Milano in Italy) in 2020 to study in depth the corrosion issue in GAHPs. Ariston (2021b) detail that the program focuses on the specific research on corrosion dynamics, and the inhibitor and its possible substitution are part of the strategic agreement signed between Ariston and Politecnico of Milano. The task includes literature research, analysis of options, test planning, analysis of samples, review of results, identification of strategy to reduce concentration, and identification of possible substitutes.

Ariston (2021b) explain that testing will be performed by means of monitoring inhibitor behaviour (consumption) in a set of GAHP units operating in different conditions for extended duration. These testing facilities have been designed, installed and are currently operated under responsibility of Ariston. Samples of working fluid are measured at PoliMi laboratories, where the rest of the above mentioned research activity will be performed. Further details of this cooperation are covered by a non-disclosure agreement between the university and the applicant.

The GAHPs falling under RoHS cat. 1 (large household appliances) are a new development. For the consultants it is plausible that in the absence of a readily available substitute the product was developed with the state of the art technology which implies the use of Cr-VI in the form of sodium chromate. The applicant's above explications show that Ariston is organizationally and technically prepared to undertake efforts to reduce and substitute Cr-VI in their GAHPs once volume production could be started.

Elimination of Cr-VI

The information provided by the applicant suggests that GAHPs are the most efficient heating technology for residential use so that its elimination would require the use of other heating technologies with higher emissions of carbon dioxide and possibly other contaminants. RAC/SEAC (2020) support the applicant's view stating "[…] *that currently there are no technically and economically feasible alternatives available for the applicant with the same function and similar level of performance."* RAC/SEAC (2020) therefore did not assess alternative technologies, which would be condensing boiler and hybrid systems as described in section 6.2.3 on page 112.

Under the RoHS Directive, the approach towards elimination of Cr-VI is different from the REACH approach above. *Art. 1 of Directive 2011/65/EU (2011b) explains that the RoHS Directive contributes to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE.* Following this objective implies that environment-related product properties, e.g. a lower energy consumption per service provided compared to an alternative technology, cannot be considered as unique functional assets of this product which per se would justify granting an exemption in the presence of products with otherwise comparable functions and properties. Clause (III) of Art. 5(1)(a) [43] would be obsolete if this approach was followed. In this context, it should be mentioned that, while both substitution and elimination are addressed in clause (I) of Art. 5(1)(a) as approaches to avoid the use of restricted substances, clause (III) only mentions substitution. With respect to the above-mentioned objective of the RoHS Directive and taking into account that the RoHS Directive does not clearly define and demarcate substitution and elimination in the legal text, the consultants assume that clause (III) is applicable to elimination cases as well.

In the case at hand, it needs to be considered, according to Art. 5(1)(a) clause (III), whether the positive impacts of the avoided emissions enabled by GAHPs compared to condensing boilers and hybrid systems – c.f. section 6.2.3 on page 112 - are likely to outweigh the adverse impacts arising from the use of Cr-VI in the GAHPs. Since environmental aspects are at the core of this assessment, the elimination case is further discussed in the next section.

6.3.3. Environmental arguments and socioeconomic impacts

If the exemption is not granted, carbon dioxide emissions from domestic heating will be higher compared to a situation where GAHPs can be placed on the market due to the exemption allowing the use of sodium chromate. RAC/SEAC (2020) *indicate related surplus costs for consumers of 3.6 million Euro per year to heat their homes and water with less efficient heating technologies.*

End-of-life of GAHPs

Since workers and the environment can potentially be exposed to Cr-VI when the sealed circuit is opened, the applicant was asked to describe in more detail the fate of the GAHPs once they are going out of operation and need to be treated. Ariston (2019), (2020) did not provide a detailed EoL scenario in their REACh authorization and RoHS exemption request. In the published opinion of RAC/SEAC (2020) as to the authorization request, it seems that the EoL phase was not considered in the risk assessment.

The potential exposure to Cr-VI at EoL also depends on the amount of Cr-VI still available in the system. The content of Cr-VI in the sealed system will be reduced (c.f. Equation 6-1 on page 110) over the use time of the GAHP compared to the time when the GAHP system is placed on the market. The remaining Cr-VI enables a self-healing process when the steel surface becomes exposed to the ammonia/water working fluid during operation so that corrosion is prevented. *Ariston (2021e) have not acquired yet accurate/specific information about the speed of the reaction toward Chromium (III) and how much Chromium (VI) is left at the end of life in GAHP appliances. They expect their ongoing research activities on*

[43] An exemption can be justified if the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

inhibitors for GAHP to provide more information about the topic. Ariston (2021e) reference the last review report of Gensch et al. (2016) when exemption 9 was reviewed for absorption refrigerators which also use sodium chromate (Cr-VI). Dometic, the applicant, estimated at that time that at the end of the product lifetime it can be safely assumed that more than 75 % of the Cr(VI) has been consumed." Ariston (2021e) point out the similarities between their GAHPs and absorption refrigerators and therefore expect that behaviour of the inhibitor in the GAHP will be substantially similar to the one in the refrigerators.

There is thus no exact information available as to the amount of Cr-VI in GAHPs at their EoL. In the above example, around 38 g of Cr-VI are filled into the GAHP system. It can be expected that the Cr-VI content is much lower when the GAHP goes out of operation after 20 years. Following the applicant's above arguments, the remaining Cr-VI in the GAHP system should not exceed around 38 g x 25 % ≈ 10 g.

As to the fate of GAHPs at EoL, Ariston (2021e) state that a dedicated recollection procedure is required. The working fluid will be drained from the sealed circuit to be treated as hazardous waste. The presence of ammonia will impose the use of the first step by means of a specialized company and disposed as hazardous waste according to national laws. This process is in any case a standard procedure for substantially all types of refrigerating appliances sold in Europe since almost all refrigerating gases used in the industry are either subject to F-Gas Regulation[44] or are toxic/flammable gases. Once the refrigerant solution is removed, the GAHP will be treated by authorized recycling companies. GAHP material (primarily steel, copper and aluminium) can be easily recycled (material separation and shredding) and handled under the WEEE as equipment similar to electrical heat pumps or gas boilers.

The F-Gas Regulation addresses fluorinated gases and thus does not apply to GAHPs. Actually, GAHPs at EoL fall under Directive 2012/19/EU (WEEE Directive) as EEE of Cat. 1 (Temperature Exchange Equipment). Waste EEE has to be collected separately and treated achieving the recovery and recycling rates (85 % / 80 %) stipulated in Annex V Part 3. While Annex VII requires the specific treatment for fridges containing fluorinated gases, temperature exchange equipment containing ammonia and Cr-VI like GAHPs is not mentioned as requiring selective treatment.

According to Ariston (2022c) there are no specific labels to applied to the GAHPs to warn that it contains toxic substances, and there is no organized takeback of such systems by the producers. So, it is important that the GAHP is deinstalled by trained personnel who shall be able to identify and treat accordingly the GAHP, which can reasonably be assumed in cases where a GAHP is replaced by another heating system.

Ariston (2022c) highlight in this context that the working fluid containing the ammonia and the sodium chromate does not leave the GAHP but transfers the heat to a secondary tube system to transport it to the radiators. If the GAHP is removed, no working fluid remains at the installation place. It can thus be expected that the GAHPs are removed and treated professionally even though alternative proceedings cannot be completely excluded.

GAHPs have been in use for a while in larger scale applications that are excluded from the scope of the RoHS Directive, and absorption refrigerators using Cr-VI as well have been placed on the market for years as well. It can thus be expected that adequate sites for

[44] REGULATION (EU) No 517/2014.

professional treatment and disposal should be available. This was mentioned by EERA[45] for the absorption refrigerators, and this infrastructure and the related expertise could be used for the sound treatment of GAHPs as well.

Condensing boilers and hybrid systems as potential Cr-VI-free alternatives to GAHPs

Condensing boilers (CB) and hybrid systems (HS) as Cr-VI free alternative heating systems could be used instead of a GAHP in the example household with 25 MWh of annual space heating demand mentioned by Ariston (2020). To obtain insights into the environmental impacts of these three heating systems, the gas and electricity consumption was calculated for the above example household assuming a 20 year life time[46] for each of the heating systems. The primary seasonal efficiency[47] was used to compare the systems since it allows, according to VHK (2019a), the comparison of different heating systems.

For the manufacturing phase of the GAHP, Ariston (2020) claim that the raw materials for a gas absorption heat pump are comparable to the ones for a condensing boiler. The applicant does not make any statements concerning HS in this context. *An LCA performed in the course of an EU research project[48] referenced by the applicant shows that the utilization phase contributes more than 95 % to most environmental impacts.*

In case of differences in the environmental impacts related to the manufacturing of GAHPs, CBs and HS, it can be assumed that they are of low influence on the overall outcome since the use phase dominates the impacts.

VHK (2019b)[49] provide information on required gas and electricity inputs among others for the three above heating systems (appliances for less than 70 kW). The data for these three heating systems were scaled to 25 MWh of heating demand. Table 6-1 shows the heat generated from gas assuming that 90 % of the energy contained in the input gas are converted into heat like in the condensing boiler system in VHK (2019b).

[45] European Electronics Recyclers‘ Association, e-mail exchange with Dr Otmar Deubzer, Fraunhofer IZM.

[46] Ariston 2020 mention up to 24 years for the GAHP

[47] Ratio of heat output over the year divided by the Gross Calorific Value of the energy input per year (Ariston 2022b)

[48] HEAT4YOU, https://cordis.europa.eu/project/id/285158/reporting, deliverable D7.3 Life Cycle Assessment and Life Cycle Cost Analysis

[49] See table 7 on page 14

Table 6-1: Gas and electricity consumption and related CO_2 emissions of the GAHP, the CB and the HS for generation of 25 MWh of annual heating energy

Heating systems (seasonal efficiency)	Heat generated from gas (MWh/a)	Electricity consumption MWh/a	Heat generated from gas (MWh, 20 a)	Electricity consumption (MWh, 20 a)	CO_2 (t, 20 a)[50]
GAHP (138 %)	16.0	0.15	320 MWh	3	76
Condensing boiler (86 %)	25.0	0.12	500 MWh	2.4	118
Hybrid system (104 %)	14.3	3.2	286 MWh	64	91

Source: Values calculated from VHK (2019b), table 7 on page 14

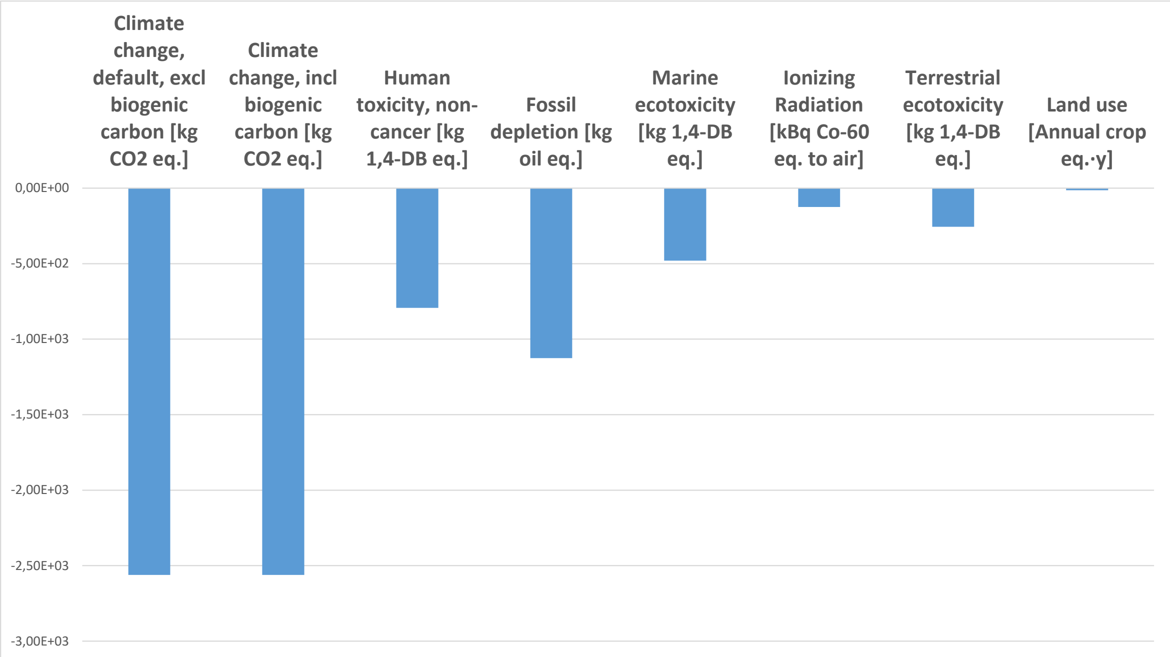
The GAHP saves 15 t of CO_2 emissions over 20 years compared to the HS and even 42 t compared to the CB.

The above data for heat generated from gas and electricity consumption were used to calculate the emissions and related impacts with an LCA software tool.[51] The heating efficiency of the gas condensing boiler modelled in the software was scaled to 86 % seasonal efficiency. Figure 6-3 shows the environmental impacts for the gas condensing boiler system versus the GAHP. The impacts of the condensing boiler system were subtracted from those of the GAHP. The negative values thus indicate that the GAHP's impacts are smaller than those of the condensing boiler system.

[50] Calculated with Sphera GABI Software

[51] Spherea GABI database, https://gabi.sphera.com/international/software/gabi-software/

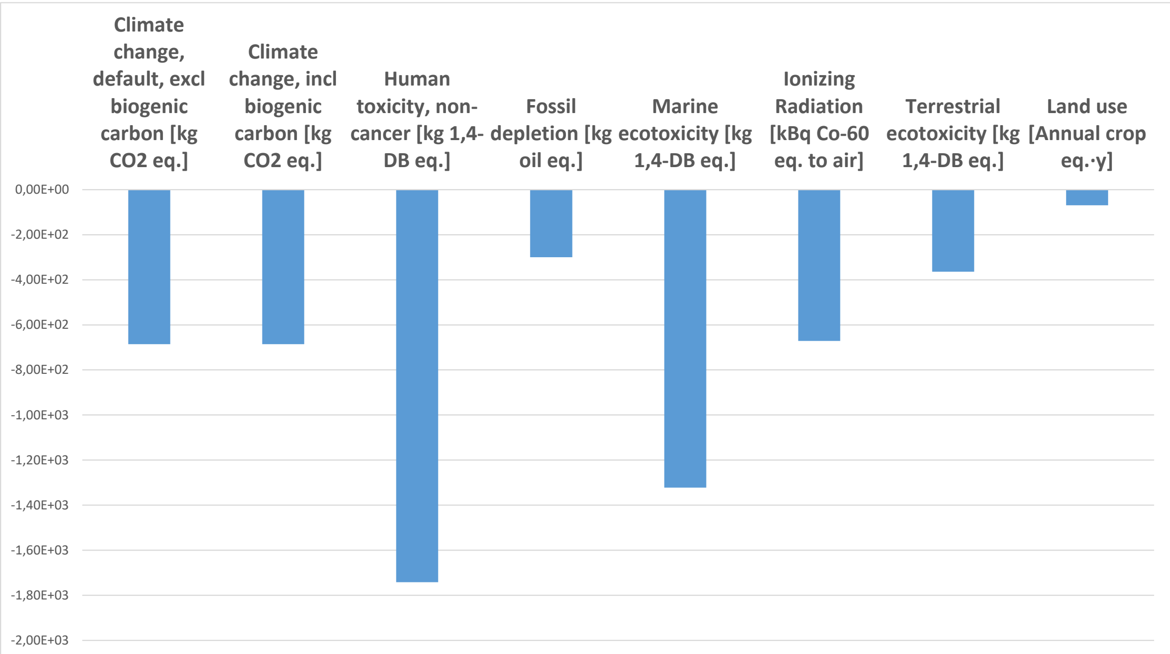
Figure 6-3: Environmental impacts (CB impacts subtracted from GAHP[52])



Impact assessment method: ReCiPE; further impacts are not displayed as they are not visible in the above figure.

Figure 6-4 is based on the same approach, i.e. the impacts of the hybrid system (HS) were subtracted from those of the GAHP. The GAHP has lower impacts in all categories.[52]

Figure 6-4: Environmental impacts (HS subtracted from GAHP)



52 The impact assessment followed the ReCiPE model. Not all impacts of this model are indicated since they would not be visible in the above figure. All of them are, however, negative.

The above figure shows that the GAHP causes less environmental impacts compared to the hybrid system (HS). The results are influenced by the share of renewable energy in the electricity mix. As the renewables' share is expected to increase in the coming years, the advantages of the GAHP over the HS will decrease as the electricity generation from non-renewable sources causes the main environmental impacts of the hybrid system.

As an additional impact, the toxic effects of Cr-VI have to be considered. For methodical reasons, they could not be integrated into the above impact assessment. *As to the amount of Cr-VI used in the above 12.5 kW GAHP, Ariston (2021e) highlight that the volume of refrigerant solution could be affected by many design specific parameters. Nevertheless, for the above example calculation, it could be considered as approximately proportional to the nominal size of the appliance, while the concentration (as % of inhibitor by weight in the refrigerant solution) is be independent from size. Ariston (2021e) assume a Cr-VI content of around 3 g per kW of nominal heating power. Ariston (2021f) roughly estimate that a 25,000 kWh building will require a space heat generator with a nominal heating power of around 12.5 kW., resulting in around 38 g of CrVI in the GAHP.*

For the authorization request the applicant had calculated the ELR[53] for workers and the public arising from the use of Cr-VI in the production of GAHPs. Ariston had requested an authorization for 20 years, but RAC/SEAC (2020) recommended a 12 year period only. *Ariston (2022d) recalculated the ELR for this 12 year period.* Based on these data, the below excess lifetime risks (ELR) were calculated for the above 12.5 kW GAHP containing 38 g of Cr-VI. For the production, it was assumed that the 1,400 kg of Cr-VI which the applicant indicated to process every year in the production plant for GAHPs corresponds to the yearly exposition time of the workers so that 38 g represent $\frac{0{,}038}{1{,}400} = 0.0027$ % of the exposition time and of the total ELR in the GAHP production.

Table 6-2: ELR per 100,000 persons related to GAHP with 38 g initial Cr-VI content

Life cycle stage	Lung cancer (ELR)	Intestinal cancer (ELR)
GAHP manufacturing	3,19E-05	2,28E-07
Production of sodium chromate	3,19E-05	2,28E-07
End-of-life of GAHP	3,19E-05	2,28E-07
Total	**9,58E-05**	**6,84E-07**

No ELR data were available for the production of the sodium chromate and for the end-of-life (EoL) phase of the GAHP. Ariston (2020) claim that all components of the GAHP are manufactured in the EU. It was therefore assumed that the sodium chromate production and storage is similarly well controlled like the GAHP production, and the same ELR was assumed.

[53] Excess lifetime risk: risk that a person contracts cancer in her/his lifetime of 70 years

The EoL phase can be assumed to be the least controlled life cycle phase. For the case that the GAHP is deinstalled, handled and treated by qualified operators with adequate equipment, the consultants adopted the same ELR for the EoL phase like for the production of the GAHP. On the one hand, this assumption represents a best case scenario since it cannot be excluded that each and every GAHP will be handled and treated according to the state of the art. On the other hand, the content of Cr-VI in the GAHP is considerably lower than 38 g - *Ariston (2021e) believe less than 10 g to be plausible* - since it is converted to Cr-III over time which would reduce the related ELR. There is a remaining uncertainty as to the actual situation.

According to Ariston (2020), the tube system in the GAHP is sealed and no working fluid needs to be refilled during the use period. An exposition to Cr-VI during the GAHP use time is therefore not to be expected, and the related ELR is zero.

6.3.4. Summary and conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria[54] is fulfilled:

(I) their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II **is scientifically or technically impracticable**;

(II) the **reliability** of substitutes is not ensured;

(III) the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

Ariston (2020) request the amendment of exemption III-9 with an amended wording to include GAHPs as EEE of category 1 into the exemption scope. The applicant claims that GAHPs are more energy-efficient than alternative technologies for residential space heating. They use, however, sodium chromate as a protectant against corrosion in the circuit in which the ammonia/water working fluid circulates.

The information at hand suggests that substitution of the Cr-VI corrosion inhibitor in GAHPs will remain scientifically and technically impracticable within the next five years. Therefore, it is unlikely that an exemption could have adverse effects on innovation. There is no information from or about other manufacturers of GAHPs that would disprove the applicant's claim that Cr-VI corrosion inhibitors are state of the art for GAHPs and cannot be substituted. A Cr-VI substitute used in the technically similar absorption refrigerators might be applicable in GAHPs as well, but is a proprietary solution of an absorption refrigerator manufacturer and in any case require profound testing and validation for its use in GAHPs.

Elimination of Cr-VI

Cr-VI can in principle be eliminated by condensing boiler or hybrid systems. Compared to these systems, GAHPs cause less carbon dioxide emissions and reduce the overall

[54] Differently from Art. 5(1)(a) in the RoHS Directive, the criteria are numbered so that they can be addressed in the below text.

environmental impacts (c.f. Figure 6-3 and Figure 6-4 page 125) in the reference use scenario (20 years operation time of each of the heating systems). The Cr-VI in the GAHP causes an additional risk for lung and intestinal cancer in the production phase of the sodium chromate (Cr-VI), as well as in the manufacturing and end-of life phase of the GAHP (Table 6-2 page 126). The below table displays the impacts including the human toxicity (cancer) which was too small to be visible in Figure 6-3 and Figure 6-4, and the ELR calculated according to the REACH approach. Negative values indicate lower impacts of the GAHP compared to CBs and HS and vice versa.

Table 6-3: Environmental and health impacts of CBs and HS compared to GAHPs

Environmental impact	GAHP - CB	GAHP - HS
Climate change, excl biogenic carbon [kg CO2 eq.]	-2,56E+03	-6,86E+02
Climate change, incl biogenic carbon [kg CO2 eq.]	-2,56E+03	-6,86E+02
Human toxicity, non-cancer [kg 1,4-DB eq.]	-7,93E+02	-1,74E+03
Fossil depletion [kg oil eq.]	-1,13E+03	-3,00E+02
Marine ecotoxicity [kg 1,4-DB eq.]	-4,80E+02	-1,32E+03
Ionizing Radiation [kBq Co-60 eq. to air]	-1,24E+02	-6,71E+02
Terrestrial ecotoxicity [kg 1,4-DB eq.]	-2,56E+02	-3,64E+02
Land use [Annual crop eq.·y]	-1,36E+01	-6,92E+01
Freshwater Consumption [m3]	-1,90E+00	-9,54E+00
Human toxicity, cancer [kg 1,4-DB eq.]	-1,71E+00	-3,52E+00
ELR per 100,000 persons (lung cancer), (REACH) ELR per 100,000 persons (intestinal cancer), (REACH)	+9.58E-5 +6.84E-7	+9.58E-5 +6.84E-7

The excess lifetime risk emerging from the use of Cr-VI in the GAHP was quantified as 9.58E-5 for lung cancer and 6.84E-7 for intestinal cancer per 100,000 persons. The above table shows that CB systems and in particular HS are related to an excess cancer risk as well in the use phase. The risk is indicated in kilograms of 1,4-DB equivalents and can therefore NOT be compared to the calculated ELR.

As to the overall risk of cancer, it can be concluded that the GAHPs avoids the risk of cancer arising from CBs and HS related to the use phase while it adds a certain risk for lung and intestinal cancer from the sodium chromate and the GAHP production, and from the EoL phase of the GAHP.

Looking at the overall situation, it may not be too far-fetched to conclude that the overall benefits of Cr-VI use in the GAHPs are likely to outweigh the negative impacts of its use. Should the COM arrive at this conclusion, it would be justified to grant the exemption in line with Art. 5(1)(a) provided the authorization for Cr-VI use requested by Ariston (2019) does not speak against it.

Wording of the exemption

Ariston (2021b) point out that their GAHPs in the scope of the requested exemption can be operated with a Cr-VI concentration of 0.7 % instead of 0.75 % allowed in the current exemption 9 which the applicant requests to amend to include GAHPs. Further, the REACH authorization request of Ariston (2019) proposes a 0.7 % Cr-VI concentration for the authorized use in GAHPs so that this threshold cannot be exceeded in a potential exemption under RoHS.

As to the wording of the exemption, Ariston (2021c) had agreed to the below proposal for amending the current exemption III-9:

Up to 0.7 % by weight of hexavalent chromium as an anticorrosion agent in the working fluid of the carbon steel sealed circuit of absorption refrigerators and gas absorption heat pumps.

Ariston (2022a) later raised that some manufacturers currently produce absorption appliances (using Cr-VI as corrosion inhibitor) that are:

- *Heat pumps (thermodynamic principle) which are reversible (they could deliver both space heating and cooling service and domestic hot water) and*
- *Heat pumps (thermodynamic principle) which are dedicated to space cooling/refrigeration application.*

Ariston (2022a) explain that in their role as Chair of the TDHP Working Group of European Heating industries[55] they should raise an objection against the proposed wording. The above two applications are included in "Rohs Category 1" and are described in EN12309, but the proposed wording might not clearly define if they are included. They therefore recommend the following exemption:

Up to 0.7 % by weight of hexavalent chromium as an anticorrosion agent in the working fluid of the carbon steel sealed circuit in gas absorption appliances as defined by EN12309.

The applicant's RoHS exemption request addressed only space heating, and water heating as an integral part of GAHPs. The potential technical alternatives for the assessment of environmental and health impacts, i.e. CB systems and HS, were selected accordingly. For cooling, other alternatives might have had to be considered as well, and it is not clear whether the efficiencies of absorption heat pumps mentioned above for heating would be the same as that of the GAHPs that were subject to this review. There is thus no information whether GAHPs with cooling functions have the same or similar environmental and health properties like the ones for space and hot water heating. The consultants therefore recommend including only the latter devices into the scope of the exemption and to adopt the below exemption wording with a clearer scope:

Up to 0.7 % by weight of hexavalent chromium as an anticorrosion agent in the working fluid of the carbon steel sealed circuit of absorption refrigerators, and of gas absorption heat pumps for space and water heating.

It should be considered that the above wording implies a scope restriction due to the reduced maximum Cr-VI content from 0.75 % to 0.7 % for absorption refrigerators which are in the scope of the current exemption 9. Even though Dometic (2021c), the producer who has requested the current exemption 9, agreed to this revised wording, it cannot be excluded that potential other manufacturers are affected since there was no consultation including absorption refrigerators preceding this amendment to 0.7 % Cr-VI.

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[55] Thermally Driven Heat Pumps (TDHP), EHI, https://ehi.eu/

In case the COM shares the consultants' above concerns, it is recommended to grant a separate exemption with the below wording:

Up to 0.7 % by weight of hexavalent chromium as an anticorrosion agent in the working fluid of the carbon steel sealed circuit of gas absorption heat pumps for space and water heating.

6.4. Recommendation

Cr-VI is listed as entry 22 on RoHS Annex XIV. Ariston (2019) applied for an authorization of their Cr-VI use. If the authorization does not speak against an exemption under RoHS and the COM concludes from the available information that the total negative environmental, health and consumer safety impacts caused by substitution of Cr-VI are likely to outweigh the total environmental, health and consumer safety benefits thereof, the consultants recommend granting the exemption. Substitution of Cr-VI or elimination of Cr-VI by alternative technologies without Cr-VI and lower environmental and health impacts than the current condensing boiler and hybrid systems will foreseeable not become available in the next five years so that the maximum validity period would be justified.

The exemption could be granted as amendment of the current exemption III-9 as requested by the applicant:

No.	Exemption	Scope and dates of applicability
9	Up to 0,7 % by weight of hexavalent chromium as an anticorrosion agent in the working fluid of the carbon steel sealed circuit of absorption refrigerators, and of gas absorption heat pumps for space and water heating.	Applies to categories 1, 8, 9 and 11 Expires on: - 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments, - 21 July 2023 for category 8 in vitro diagnostic medical devices, - 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11. - 31 December 2026 for cat. 1 gas absorption heat pumps

The above reduction of the maximum Cr-VI content from the current 0.75 % down to 0.7 % affects, however, the absorption refrigerators as well. There was neither a request for such an amendment nor a stakeholder consultation addressing this scope restriction for absorption refrigerators. To avoid adverse consequences of this situation, as an alternative the exemption could be granted as a separate exemption, e.g. as 9(a)(III):

	Exemption	Scope and dates of applicability
9(a)(III)	Up to 0.7 % by weight of hexavalent chromium as an anticorrosion agent in the working fluid of the carbon steel sealed circuit of gas absorption heat pumps for space and water heating.	Applies to category 1 and expires on 31 December 2026

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7. Exemption 9(a)-II of Annex III: Hexavalent chromium in absorption refrigerators

The current wording and expiry date of the exemption are:

No.	Current exemption wording	Current scope and dates of applicability
9(a)(II)	Up to 0.75 % hexavalent chromium by weight, used as an anticorrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators: - designed to operate fully or partly with electrical heater, having an average utilised power input ≥ 75 W at constant running conditions, - designed to fully operate with non-electrical heater.	Applies to categories 1-7 and 10 and expires on 21 July 2021

Declaration

In the sections preceding the "Critical review", the phrasings and wordings of applicants' and stakeholders' explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described *in italics*. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

Cr-VI	hexavalent chromium
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instrument
IVD	In-vitro diagnostic medical device
RoHS 1	Directive 2002/95/EC (2003a)
RoHS 2	Directive 2011/65/EU (2011a)
W	Watt

7.1. Background and Technical Information

On 16 January 2020, Dometic (2020) submitted a request for the renewal of exemption 9(a)(II) with the current wording, but only for EEE of category 1 (large household appliances) until 31 December 2025, which is less than the maximum possible five years.

No.	Requested Exemption (Dometic)	Requested scope and dates of applicability
9(a)(II)	Up to 0.75 % hexavalent chromium by weight, used as an anticorrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators: - designed to operate fully or partly with electrical heater, having an average utilised power input ≥ 75 W at constant running conditions, - designed to fully operate with non-electrical heater.	Expiry on 31 December 2025 for cat. 1

No contributions with relevance for exemption 9(a)(II) were received during the stakeholder consultation. Technically, the use of Cr-VI in absorption refrigerators is related to gas absorption heat pumps, see section 4 on page 33 et sqq. for the respective exemption request.

7.1.1. History of the Exemption

An exemption for Cr-VI in absorption refrigerators was already listed on the Annex of Directive 2002/95/EC (2003b) (RoHS 1) when it was published in 2003. In the revision of this exemption (exemption 9) still under Directive 2002/95/EC (2003b) by Gensch et al. (2009), it was recommended to renew the exemption. The COM renewed the exemption until 2014, resulting in the wording still reflected in the current exemption 9. In the course of the transition from RoHS 1 to Directive 2011/65/EU (2011b) (RoHS 2), the expiry date was shifted to 21 July 2016.

In the next review of the exemption by Gensch et al. (2016) under RoHS 2 following Dometic's renewal request, the consultants recommended to maintain exemption 9 for EEE of cat. 8, 9 and 11 with the same wording resulting in the current scope of this exemption (status February 2022). For the other categories of EEE, it was recommended to split the exemption. Prior to the official decision of the COM as to the renewal of exemption 9, *Gensch et al. (2018) revised the initial recommendation made for the RoHS exemption in the 2016 report and propose a change to the formulation of this exemption to align the recommended dates of the formulated exemption with the relevant dates of the REACH authorisation. The average utilised heat input of 75 W during constant running conditions, is understood by Dometic to comprise a possible threshold for separating between low and high boiler temperatures.* The revised exemption wording thus was amended to reflect the differentiation in the authorization into low- and high-temperature boiler products.

The COM (2020) adopted the renewed exemption splitting the original exemption 9 into the three sub-exemptions 9, 9(a)(I) and 9(a)(II) which are currently listed[56] on RoHS Annex III. Exemption 9(a)(I) for lower power absorption refrigerators expired in March 2021 already. Dometic had already pointed out in the last review by Gensch et al. (2016) that they will require exemption 9(a)(II) for the higher power absorption fridges and those operating with

[56] For an overview, see the table on page 12

gas heaters until 2025. Dometic (2020) applied for the renewal of exemption 9(a)(II) in 2020 until end of 2025.

7.1.2. Summary of the requested exemption

Dometic (2020) apply for a renewal of exemption 9(a)-II in the RoHS Directive. They feel confident in substituting the existing corrosion inhibitor containing hexavalent chromium (Cr-VI) in all its absorption refrigerators. Dometic have already started the substitution process for their absorption refrigerators with low boiling temperatures such as hotel minibars covered by exemption III-9(a)(I) with expiry in March 2021. For products with higher boiling temperature in the scope of exemption 9(a)-II they claim to need additional time to finalise the task related to the substitution. Such tasks include redesign of the cooling units, development of a safety monitoring system and extensive testing internally as well as by customers. Therefore, they ask for a renewal of exemption 9(a)-II until 31 December 2025 with the current wording.

This timeline is fully harmonised with the ELV Directive. The products relevant for exemption 9(a)(II) in RoHS are technically similar to products covered by the ELV Directive.

7.1.3. Technical description of the exemption and use of the restricted substance

Like gas absorption heat pumps (c.f. section 4 of page 33), absorption refrigerators use ammonia/water in the steel circuit so that sodium chromate needs to be added as corrosion inhibitor. The technical background of absorption refrigerators was described in detail in the reports of earlier reviews of the exemption by Gensch et al. (2009) and Gensch et al. (2016).

7.1.4. Amount(s) of restricted substance(s) used under the exemption

According to Dometic (2020), the average amount of Cr-VI used for an average absorption refrigerator model concerned is approximately 2 g. The total refrigerant charge is 300 g for this average model with a total weight of the product of 18 kg. Hence:

- *the concentration of Cr-VI in the homogenous material (the refrigerant) is approximately 0.6 % by weight.*
- *the concentration of Cr-VI in the application (the refrigerator) is less than 0.012 % by weight.*

The amount of substance entering the EU market annually through the application for which the exemption is requested is around 100 kg for units produced by Dometic. The applicant did not provide a publicly available substantiation of this figure.

7.2. Justification for the requested exemption

7.2.1. Substitution of Cr-VI in absorption refrigerators

Dometic (2020) have for a very long time put high attention in finding an alternative to Cr-VI as corrosion inhibitor. This work has been ongoing for decades studying not only inhibitor alternatives but also other materials. They now feel confident that a new inhibitor (hereafter named Inhibitor #7) can replace CR-VI in all their products with an acceptable expected lifetime, performance and safety level.

After the industrialisation of this system for products with low boiling temperature in the scope of exemption 9(a)(I), Dometic (2020) now continue the work on the remaining products with higher boiling temperature in the scope of exemption 9(a)(II) for which the challenges are bigger. The work is proceeding according to plan, and they target to have all products with Cr-VI inhibitor phased out during 2025.

Dometic (2020) therefore suggest that exemption 9(a)(II) for these products could expire in December 2025 in line with the suggested timeline for products covered by the ELV Directive.

7.2.2. Roadmap towards substitution or elimination of Cr-VI

Dometic (2020) have to finalize the following tasks before a full substitution of CR-VI is achieved.

- *Finalising and extension of field tests and increased internal testing of some specific models.*
- *Redesign of the cooling units to decrease the boiling temperature and minimising the risk for corrosion inside the tubes. This is an extensive work as we have close to100 different models of cooling units in production.*
- *Update of the control parameters for the safeguard system monitoring the boiler temperature.*

Dometic (2020) state that most of the above activities are the same like for the absorption refrigerators specifically designed for recreational vehicles covered by exemption 14(II) of Annex II of Directive 2000/53/EC (2020) (ELV Directive).

7.2.3. Environmental and socioeconomic impacts

According to Dometic (2020), a loop exists for the product and the refrigerant. The products are covered by the WEEE Directive which requires to reclaim the refrigerant before other treatment steps. Reclaimed refrigerant is considered hazardous waste and sent for separate treatment. Basically, the whole refrigerator is recycled apart from the refrigerant and the insulation blowing agent that is treated as hazardous waste.

7.3. Critical review

7.3.1. REACH compliance – Relation to the REACH Regulation[57]

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV "*provided that such inclusion does not weaken the environmental and health protection afforded by*" the REACH Regulation. The article details further criteria which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

REACH Annex XVII

REACH Annex XVII (2021) contains entries restricting the use of sodium chromate:

- Entry 28 addresses substances which are classified as carcinogen category 1A or 1B listed in REACH Appendices 1 or 2, respectively.
- Entry 29 addresses substances which are classified as germ cell mutagen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 3 or Appendix 4, respectively.
- Entry 30 addresses substances which are classified as reproductive toxicant category 1A listed in REACH Appendices 1 or 2, respectively.

According to the above entries, sodium chromate *shall not be placed on the market, or used,*

- *as substances,*
- *as constituents of other substances, or,*
- *in mixtures,*

for supply to the general public when the individual concentration in the substance or mixture exceeds certain threshold limits.

In the consultants' understanding of the above, the use of sodium chromate in sealed systems of absorption refrigerators is not a supply of sodium chromate to the general public. Sodium chromate is contained in an article from which its liberation and release into the environment, or the access of consumers to the substance, is not intended and is to be prevented. Refilling of the working fluid over the foreseen operation time is not necessary. There is thus no necessity to place the substance - sodium chromate, or the working fluid containing Cr-VI - on the EU market for refilling absorption refrigerators, which could be interpreted as a supply of Cr-VI/sodium chromate to the general public.

[57] REACH 2021.

Entry 47 addresses chromium VI compounds, however in cement and leather. The entry is thus not applicable to the uses of Cr-VI in absorption refrigerators. No other entries with relevance for the use of Cr-VI in the requested exemption could be identified in Annex XVII.

REACH Annex XIV

Sodium chromate is a substance of very high concern and as such is listed on REACH Annex XIV (2021) as entry 22 due to its mutagenicity, carcinogenicity and toxicity for reproduction. [58] Manufacturers, importers or downstream users shall not place a substance listed on Annex XIV on the market for a use or use it themselves[59], unless the use(s) of that substance on its own or in a mixture, or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorized.[60]

The COM (2017) authorized the *"Use of sodium chromate as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75 % by weight (Cr(VI)+) in the cooling solution. This covers the use in 'high boiler temperature products' (recreational vehicles refrigerators and medical cold equipment)."* The authorization expires on 21 September 2029.

The renewed exemption 9(a)(II) as requested by Dometic (2020) implies the use of Cr-VI in EEE of cat. 1 (large household appliances) and shall expire in December 2025, well in advance of the authorization's expiry. The COM (2020) granted the current exemption 9(a)(II) three years after the publication of the authorization with the amended wording proposed by Gensch et al. (2018), which was approximated to the authorization wording.[61] Based on the above situation, the consultants conclude that the renewal of the exemption is considered not to weaken the protection afforded by the REACH regulation.

7.3.2. Scientific and technical practicability of substitution or elimination of Cr-VI

Dometic has been working on the substitution of Cr-VI by the proprietary Inhibitor 7 in their absorption refrigerators for some years already. Absorption refrigerators with lower boiler temperatures covered by exemption 9(a)(I) must be Cr-IV-free since 5 March 2021 when exemption 9(a)(I) expired.

In the previous review of the exemption by Gensch et al. (2016)*, Dometic stated that the products with higher boiler temperatures* – those covered by exemption 9(a)(II) - *need more work before the new inhibitor can replace sodium chromate because the cooling units need to be redesigned and new safety equipment has to be included. Products with higher boiler*

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[58] C. f. ECHA, Annex XIV, sodium chromate: https://www.echa.europa.eu/web/guest/authorisation-list?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

[59] REACH Art. 56(1)

[60] REACH Art. 56(1)(a)

[61] For details also see section 7.1.1 History of the Exemption on page 23.

temperatures were planned to be phased out from 2025 on, and Dometic had envisaged the complete phase-out until 2029.

The applicant's current exemption request to renew the exemption until end of 2025 thus means an expiry clearly before 2029, until when Dometic had originally planned the phase-out. The phaseout time until 2025 is also consistent with the expiry of the corresponding exemption 14(II) of Annex II of Directive 2000/53/EC (2020) (ELV Directive) which covers technically identical products, however for use in vehicles in the scope of the ELV Directive.

Dometic (2015) explain that Inhibitor 7 substituting hexavalent chromium is an inorganic salt with stabilizers. The substance can already be used reliably in absorption refrigerators with lower boiling temperatures but is more difficult to use with the higher boiling temperature refrigerators in the scope of exemption 9(a)-II. The applicant puts forward that redesigns of the boiling units are required to reduce and monitor the boiling temperatures thus avoiding critical operation conditions that might damage the substitute inhibitor. The reliability of the Cr-VI-free absorption fridges must be tested on a statistically relevant number of fridges representing the around 100 models of absorption fridges which the applicant sees to be in the scope of the exemption at hand.

The consultants can follow the argument that these works require time to ensure the reliability of the Cr-VI-free solution under the more challenging operation conditions in absorption refrigerators with higher boiler temperatures. The applicant has followed a long-term development and phaseout program over the past years where such long time periods had been specified and now can achieve the full substitution prior to the originally indicated deadline in 2029.

7.3.3. Environmental arguments and socioeconomic impacts

According to Dometic (2020), a loop exists for the product and the refrigerant. The products are covered by the WEEE Directive. Reclaimed refrigerant is considered hazardous waste and sent for separate treatment. Basically, the whole refrigerator is recycled apart from the refrigerant and the insulation blowing agent that is treated as hazardous waste.

It can be assumed that absorption refrigerators (cat. 1) follow the same collection and transport routes like conventional refrigerators. Both are EEE of cat. 1. The treatment should, however, be different. Since absorption refrigerators have been placed on the market for decades already – the use of Cr-VI in absorption refrigerators has been exempted since the enforcement of the first RoHS Directive in 2003 already – the treatment of these devices should be well established. Operators with respective expertise and equipment for absorption refrigerators are available as mentioned by EERA.[62] It can therefore be assumed that waste absorption refrigerators can be treated according to the state of the art so that the risk arising from the end-of-life treatment of absorption refrigerators should be sufficiently controlled to prevent hazardous impacts from Cr-VI.

[62] European Electronics Recyclers' Association, e-mail exchange with Dr Otmar Deubzer, Fraunhofer IZM.

7.3.4. Summary and conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria is fulfilled:

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II **is scientifically or technically impracticable**;
- the **reliability** of substitutes is not ensured;
- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

Dometic (2020) applied for the renewal of exemption 9(a)(II) which covers the use of Cr-VI in absorption refrigerators with high boiling temperatures. While the applicant substituted Cr-VI already in the models with low boiling temperatures, its substitution in products in the scope of exemption 9(a)(II) is more challenging due to the higher boiling temperatures which create harsher conditions for maintaining the stability and effectiveness of the substitute “Inhibitor 7” over the required refrigerator lifetime. More time is thus required to achieve the substitution, which the applicant wants to have completed by end of 2025. This schedule is in line with the planning the applicant presented in earlier reviews of exemptions related to absorption refrigerators.

Based on the available information, it can be concluded that exemption 9(a)(II) is still required in refrigerators of cat. 1 until end of 2025 to enable the cat. 1 refrigerators in the scope of this exemption to operate reliably without Cr-VI as corrosion inhibitor.

Scientifically and technically, substitution of Cr-VI in refrigerators in the scope of exemption 9(III) is thus feasible but requires more time to ensure the reliability of the substitute in all models of these absorption refrigerators. The COM (2020) granted the current exemption 9(a)(II) based on the authorization decision of COM (2017) for the use of Cr-VI in absorption refrigerators valid until 2029.

The consultants therefore conclude that the renewed exemption is considered not to weaken the protection afforded by REACH, and that granting the renewal of the exemption as requested would be justified by Art. 5(1)(a).

7.4. Recommendation

Substitution of Cr-VI as corrosion inhibitor in category 1 (large household appliances) absorption refrigerators in the scope of the requested renewed exemption 9(a)(II) is scientifically and technically practicable. The applicant however plausibly explains that the testing and implementation of the Cr-VI-free substitute “Inhibitor 7” in these refrigerators still requires four years until end of 2025 to ensure their reliable operation.

Cr-VI is listed as sodium chromate in entry 22 of Annex XIV REACH. The COM authorized its use in the absorption refrigerators with high boiling temperatures until 2029, so that renewing the exemption 9(a)-II in this framework does not weaken the protection afforded by REACH.

In the light of the above, granting the renewal of the exemption would be justified to ensure the reliability of the substitute as stipulated in Art. (5)(1)(a).

The consultants recommend the below wording for the exemption:

No.	Exemption	Scope and dates of applicability
9(a)(II)	Up to 0,75 % hexavalent chromium by weight, used as an anticorrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators: - designed to operate fully or partly with electrical heater, having an average utilised power input ≥ 75 W at constant running conditions, - designed to fully operate with non-electrical heater.	Applies to categories 1-7 and 10 Expires on - 21 July 2021 for categories 2-7 and 10 - 31 December 2025 for cat. 1

7.5. References

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8. Exemption 13(a) of Annex III: Lead in white glasses used for optical applications

The current wording and expiry dates of the exemption are:

No.	Current exemption wording	Current scope and dates of applicability
13(a)	Lead in white glasses used for optical applications	Applies to all categories; expires on: - 21 July 2023 for category 8 in vitro diagnostic medical devices; - 21 July 2024 for category 9 industrial monitoring and control instruments and for category 11; - 21 July 2021 for all other categories and subcategories.

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described *in italics*. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

COM	European Commission
CTE	coefficients of thermal expansion
EEE	electrical and electronic equipment
IMCI	industrial monitoring and control instrument
IVD	in-vitro diagnostic medical device
LCoS	liquid crystal on silicon
Pb	lead [chem.]
RoHS 1	Directive 2002/95/EC
RoHS 2, RoHS	Directive 2011/65/EU
Spectaris	German industry association for Optics, Photonics, Analytical and Medical Technologies

TMC Test & Measurement Coalition

WEEE waste electrical and electronic equipment

8.1. Background and Technical Information

The applicants request the renewal of the exemption with the below wording, scope and expiry dates:

No.	Requested Exemption	Requested scope and dates of applicability
13(a)	Lead in white glasses used for optical applications	Expiry on - 21 July 2028 for category 8 in vitro diagnostic medical devices and category 9 industrial monitoring and control instruments; - 21 July 2026 for all other categories and subcategories.

Stakeholder contributions were received from Christie (2021) and TMC (2021).

TMC (2021) contributed to the stakeholder consultation stating that their members intend submitting applications for renewal of certain exemptions [here 13(a)] *within the legally foreseen deadlines of 18 months prior to their expiries for industrial monitoring and control instruments. They request the European Commission to schedule the evaluation of the Annex III exemptions relevant to category 9 industrial applications in due time, i.e., 18 months prior to 21 July 2024. However, the COM had already clarified with representation of TMC in written correspondence, pertaining to a previous exemption renewal request, that the Commission considers it justified for the technical assessment to start at the same time for all categories as requested by the applicants.*

For the Christie (2021) contribution, please refer to section 8.1.2 on page 146

8.1.1. History of the Exemption

Exemption 13 was added to the Annex of RoHS 1[63] in October 2005 as "Lead and cadmium in optical and filter glass." Exemption 13(a) with the current wording "Lead in white glasses used for optical applications" was published in the Official Journal of the European Union on 25. September 2010[64].

Exemption 13(a) was last reviewed by Gensch et al. (2016a), concluding that the elimination and the substitution of lead in white optical glasses was at the time not practical for the full range of applications, stating that a large part of the potential for substitution had already

[63] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32005D0747

[64] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010D0571

been realised and that the development of further alternatives and their implementation was likely more challenging and more time-consuming.

Gensch et al. (2016a) discussed the possibility to exclude consumer products from the scope of the exemption in order to narrow the scope to equipment used by professionals, which tends to be associated with higher requirements, however, SPECTARIS et al. explained that even consumer equipment required the exemption, such as for sophisticated photographic lenses, binoculars or digital projectors. Differentiating between consumer and professional-grade equipment was also said to be not feasible, as many products may be used by professionals and consumers alike.

Gensch et al. (2016a) also discussed the specification of a refractive index threshold to narrow the scope to only include such types of glasses in scope of the exemption that cannot be manufactured without the addition of lead. However, adjustment of the scope to include only a specified part of the refractive index range from the Abbe diagram was also found to be impractical. Performance thresholds for different properties of glass could also not be set due to the complexity of interdependent variables (refractive index, dispersion, temperature dependent dispersion, transmission of different light wave lengths, birefringence, etc.).

Gensch et al. (2016a) recommended the exemption to be renewed with the following expiry dates:

- For Cat. 1 – 7 & 10 to expire on 21 July 2021
- For Cat. 8 and Cat. 9 to expire on 21 July 2021
- For Cat. 8 in vitro diagnostic medical devices to expire on 21 July 2023
- For Cat. 9 industrial monitoring and control instruments to expire 21 July 2024

The European Commission renewed the exemption accordingly, published in the Official Journal[65] on 16. June 2017.

8.1.2. Summary of the renewal request and stakeholder contributions

Renewal application

SPECTARIS et al. (2019) provided the following summary of their renewal request: *"This exemption renewal request is for the use of lead in optical glass that is used in electrical and electronic equipment. Optical glass containing lead is used in a very wide variety of applications and in many types of equipment. Lead based glass types are used because they have unique combinations of properties and characteristics that cannot be achieved by lead-free optical glass or by different designs. As a result, the technical requirements of the glass and the equipment in which it is used can only be achieved with lead-based optical glass."*

[65] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017L1011&from=EN

Stakeholder contributions

Christie (2021) provided the following statement in response to the consultation questionnaire: *"Christie, being a downstream user of optical glass lenses, supports Spectaris e.V. request on the wording, scope and duration of the exemption 13a. As explained in the exemption request form "digital projectors and rear projection televisions (category 4). Lead glass lenses and prisms are used because these are the only types of glass that have high % transmission at shorter wavelengths and do not cause distortion of the image when the glass temperature increases by heating from the intense light source. This is because the refractive index is less affected by temperature changes than lead-free glass. Heating the glass also affects focusing of the image causing distortion but lead glass lenses can compensate for temperature changes to avoid distortion."*

8.1.3. Technical description of the exemption and use of restricted substance

Function of lead in optical glasses

SPECTARIS et al. (2019) provided the following explanations of what glass is and which function lead fulfils in optical glasses:

Glass usually is a transparent solid material that can be made with many different compositions. Glass is traditionally known as clear non-crystalline inorganic materials based on silicates that are used for windows, drinking vessels and decorative objects. Glass is also used for optical components such as lenses, which are used in cameras, microscopes, projectors and many other different applications. The composition of glass is very variable, and it is controlled to achieve the desired combination of properties. For most technical applications, it is necessary that the glass has a combination of several specific characteristics. Traditional inorganic soda glass types that are used for windows in buildings are relatively inert and so remain transparent for hundreds of years, but these are not suitable for all optical applications. Various additives are used to control the combination of properties that is required for each application and colourless transparent glass types may contain, apart from sodium and silica, also potassium, boron (e.g. borosilicate glass), arsenic, antimony, calcium, barium and lead. Some amorphous (non-crystalline) polymeric materials that are hard and optically transparent are referred to as "glass polymers" and have unique combinations of properties, although these are different to traditional silicate-based glass.

Each batch-ingredient for a glass is added to achieve specific combinations of properties although each individual optical property, such as high refractive index, can be obtained by several different glass formulations. There are, however, certain combinations of optical properties which can be achieved by only one or a few formulations and some combinations of characteristics are only possible in glass formulations that contain lead. Lead based glass has disadvantages such as higher density, which makes the optics heavier, and it is softer than lead-free glass and so it is more easily scratched. However, the combination of optical properties cannot be achieved by any lead-free glass.

Lead is added to types of optical glass that are used in a wide variety of electrical equipment to achieve the following characteristics. Usually more than one of these properties are needed for a specific application and often many are necessary:

- ***Medium to high refractive index** – important for optics used in microscopes, camera lenses, etc.*
- ***Specific Abbe number** – Abbe number is a measure of the variation of refractive index with wavelength so that the refractive index of a glass with a high Abbe number varies across the visible spectrum less than a glass with a low Abbe number. Lead based glass can be formulated to have high Abbe numbers which reduces chromatic aberration […] in parallel to having a high refractive index. It is important to be able to control Abbe number so that by using combinations of lenses of different materials with different characteristics, very precise optical effects can be obtained. Professional camera lenses and microscopes include several lenses made of several different glass formulations to achieve the required high performance.*
- ***Colour aberration** – There are two types of colour aberration that are affected by glass composition; lateral and axial. Axial chromatic aberration is due to differences in focal length of different colours whereas lateral chromatic aberration is affected by image size. Axial chromatic aberration is resolved by combining lenses of two different types of glass, one having a larger refractive index than the other. High refractive index lenses are made of lead-based glass for the best optical quality. Chromatic aberration occurs because all optical glass types that are used for lenses have a refractive index that varies with the wavelength of transmitted light (this property is related to the Abbe number). As a result, each colour focuses at a different convergence point, so that colour images appear with coloured fringes and this effect is more pronounced with high refractive index materials.*
- ***Transmission of light with a high proportion of blue / indigo / violet light** – most types of lead-free glass tend to absorb a high proportion of light having shorter wavelengths (<450nm) whereas lead-based glass types transmit a high proportion of short wavelength visible light to achieve accurate colour reproduction which is important for many applications […].*
- ***Low stress birefringence (low stress optical constant)** – birefringence is a property of transparent materials where light travelling in one axis is refracted differently to light travelling in an axis at 90˚ to the other axis and this is due to the material having different refractive indices in perpendicular directions. Some types of calcite crystals (e.g. "Iceland Spar") clearly show this effect; if a crystal is placed onto a printed page, two distinct images can be seen, one being shifted sideways from the other. Clear plastics such as polycarbonate and acrylics are very susceptible to birefringence. This can be seen as rainbow colours when the plastic items are stressed when viewed by polarised light (each wavelength is refracted differently so that incident white light is transmitted as separated colours).*
- ***Partial dispersion** – Glass types having identical refractive index and Abbe number can have different partial dispersion properties and this can significantly affect image quality. Modulation transfer function (MTF) of a lens is a measure of image quality where a MTF of 1 is perfect quality with no loss of contrast (see additional information for a more detailed explanation of why partial dispersion is an essential criterion).*
- *[…] [here, achromatism and Petzval number were listed by the applicants but lacking explanation, the consultants]*

- ***Abnormal dispersion*** *– this is a quality used to compensate for chromatic aberration.*
- ***Low photoelastic constant (β)*** *– important to minimise distortion due to birefringence when stress is imposed on the glass optics. Related to low stress birefringence, described above.*
- ***Press moulding characteristics*** *– aspherical lenses are made by forming in moulds before grinding and polishing. The moulded shape needs to be as close to the required dimensions as possible to minimise grinding wastes and this is easier with leaded glass because the melting temperature is lower than with lead-free glass. This has a positive effect by using less energy in such press moulding processes due to up to the 200˚C lower process temperature. Aspheres that are sanded and/or polished after pressing are referred to as “preformed mouldings”.*
- ***Thermal properties*** *– Some optical systems require the use of two lens elements that are cemented together (cemented doublets). It is important that both lenses have similar thermal coefficient of expansion to allow for any temperature changes. This is sometimes impossible without lead-based optical glass. Some lens systems are required to maintain focus when the temperature changes (such as due to hot lamps) and this is sometimes possible only with lead-based glass.*
- ***Ionising radiation resistance and blocking*** *– Lead has a high atomic weight and density so is very effective as a barrier to ionising radiation. Such optical systems are used in equipment utilising or measuring ionising radiation. The use of lead as shielding for ionising radiation is however covered by RoHS exemption 5 of Annex IV.*

SPECTARIS et al. (2019) further state that applications usually need many of the above characteristics. Some examples need a combination of high refractive index, a high percentage of short wavelength light transmission and low stress birefringence and these are all achievable only with optical glass containing lead. Lead-free glass types are available which exhibit one or two of these properties only, but none exhibit all three. Furthermore, excellent colour correction as well as other specific combinations of optical characteristics cannot always be achieved with lead-free optical glass. High performance lens systems often consist of many different lenses (some with lead, others lead-free) with each lens required to have a combination of specific properties and many combinations are achievable only with glass containing lead.

Table 8-1: Illustrative uses of lead in white optical glass with essential properties

	High refractive index	Special Dispersion charac-teristics	High change of refractive index with tempera-ture	High trans-mission in blue to UV range	Very low birefrin-gence at high tempera-ture gradients	Produci-bility in large sizes (> 250 mm)	Extremely high homo-geneity in large items	High Faraday effect (Verdet-constant)	High density	Thermal expansion coefficient
Fluorescence microscopy	x	x		xx						
Surgical microscopes	x	x		xx						
Laserscanning microscopy	x	x		xx						
Digital projection	x			xx	xx					
Binoculars, telescopes	x	x		xx						
Temperature stabilized lenses (printing machines)	x	x	x	xx	xx	xx	x			x
Photographic lenses	x	x		xx						
Cinematographic lenses television lenses	x	x		xx						
Photolab equipment	x	x		xx	x					
i-line microlithography	x	xx		xx		xx	xx			
x-ray imaging optics	x	x		xx					X	

Source: SPECTARIS et al. (2019)

Applications of lead-containing white optical glass

SPECTARIS et al. (2019) stated optical glass containing lead is used in very many different types of EEE and provided a number of illustrative examples, some of which are reproduced in the following (including their most appropriate RoHS Annex I EEE category):

- *Optical systems designed for telecom applications in the near IR spectral range from 1000 to 1500 nm (category 3)*
- *Lenses for video and television cameras, camcorders, movie projectors and for photo-laboratory equipment (category 4). As there is a significant thickness of glass that light must pass, the transmission performance in the entire visible spectrum of all glass types used must be as high as possible.*
- *Temperature compensated high end optical imaging systems for printing and photolithography applications used for industrial tools (category 6)*
- *Optical lenses made of lead-glass are used in medical devices to manipulate and focus the laser light onto tissue to create incisions in the eye with very high accuracy for eye surgery (category 8)*
- *CNC video measuring systems, used to measure the dimensions of very small objects such as engineered parts such as for aircraft, e.g. precision made fuel valves and small watch components, silicon wafers for semiconductor and Microelectrical Mechanical System (MEMS) devices. These use high brightness lamps with prisms and lenses which need to have a high internal transmittance at all visible wavelengths and a very low (near zero) photoelastic constant (β) to avoid distortion that would give less accurate measurements. The optical properties of the glass must be affected by temperature as little as possible (i.e. low birefringence), and the glass should have a high thermal conductivity to avoid distortion due to temperature gradients in the lens or prism (category 9).*

- *Laser optics for commercial printers. Large cylindrical lenses are used which must be lead-glass for optimum temperature stabilisation (category 11)*

SPECTARIS et al. (2021a) added examples indicative of category 7:

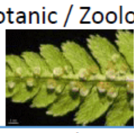
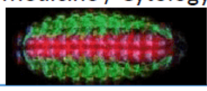
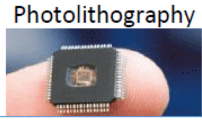
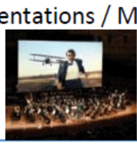
- *Video and television cameras, camcorders and projectors specifically designed for sporting applications*

Regarding the use of leaded optical glasses in professional and non-professional devices, SPECTARIS et al. (2019) stated: *"There are two reasons why a differentiation between professional and non-professional devices would not be productive:*

- *Although certain types of products are intended solely for the professional market, these products are sometimes also bought and used by non-professional users, such as stereo-microscopes or high performance photographic lenses. It is their personal interest to buy and use such high-performance devices.*
- *There are still some consumer products which need the properties of lead containing glass types. One example is projection systems which become very hot during use. For these, the special thermal behaviour of some lead containing glass is needed."*

SPECTARIS et al. (2019) provided select examples and their users in a list, reproduced in Figure *8-1*.

Figure 8-1: Selected devices and their users

Device	Professional users	Non-professional users	Typical Application
Stereo-Microscope	X	X	Botanic / Zoology 
Laserscanning-Microscope	X		Medicine / Cytology 
Photographic lenses	X	X	Architecture 
Binoculars and Telescopes	X	X	Ornithology 
Lithographic lenses	X		Photolithography 
Projectors	X	X	Presentations / Movies 

Source: SPECTARIS et al. (2019)

8.1.4. Amount(s) of restricted substance(s) used under the exemption

SPECTARIS et al. (2019) explained that "The family of lead containing optical glass typically contain 40 – 70% by weight of lead oxide, thus 37 - 65% of lead by weight. The complete range over all known optical glass types is 0.5 – 75% wt. (excluding lead in glass used for radiation shielding and covered by Annex IV exemption 5)."

According to SPECTARIS et al. (2019), the amount of lead entering the EU market annually through applications for which the exemption is requested is 275 tonnes lead per year.

SPECTARIS et al. (2019) provided the following rationale for the above estimations: *"The market demand for lead-containing glass types has been stable since 2014. Based on this stability, we estimate that global production of lead based optical glass used in EEE to be 1,250 tons per year. About 40% of EEE is placed on the EU market so this will contain 500 tons of lead based optical glass. Calculated with the average lead content of approximately 55% lead that would be 275 tons of lead p.a."*

The consultants note that this is the same number reported in the previous review of this exemption by Gensch et al. (2016a).

As additional information, SPECTARIS et al. (2019) stated that the ratio between the globally produced lead-free to lead-containing glass is about 20:1 on a mass basis. This is to be considered an educated estimate, as no glass-type specific statistics are available at global scale.

8.2. Justification for the requested exemption

8.2.1. Substitution and elimination of lead

SPECTARIS et al. (2019) stated that there are three options for the potential substitution or elimination of lead from optical glasses:

- Lead-free optical glass
- Plastic lenses
- Alternative equipment designs

Alternative lead-free optical glass

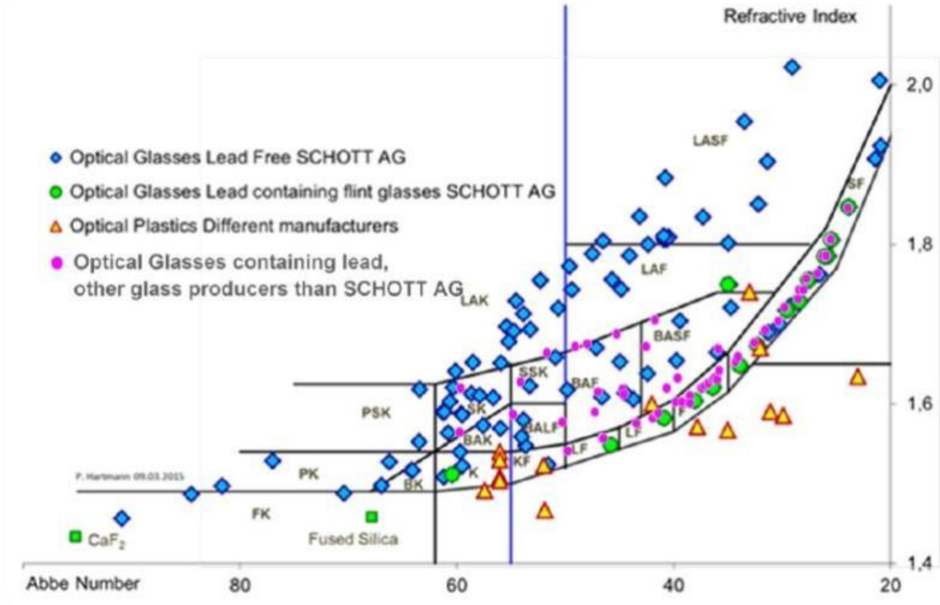
SPECTARIS et al. (2019) provided information intended to show that lead-free glasses cannot be used to achieve the same characteristics of leaded glass. Details provided on three key characteristics (high refractive index, high percentage of short wavelength light transmission, low stress birefringence) are summarized in the following.

Refractive index and Abbe number

The chart in Figure 8-2 below shows the full range of glass types manufactured by SCHOTT, who are the only optical glass manufacturer in Europe, and in addition lead-containing glass types made by all optical glass manufacturers (OHARA, Hoya, CDGM, NHG) as pink dots. According to SPECTARIS et al. (2019), the chart shows "several types of optical glass with high refractive index and low Abbe number. There are a few lead-free glass types with high refractive index and low Abbe number, but their other properties are different to the lead-

based glass and so are not always suitable as substitutes." SPECTARIS et al. (2019) further state that "for most values of refractive index values, the lead-based glass types have the lowest Abbe number; the lead-based glass types mainly being at the right-hand edge of the spread of results."

Figure 8-2: Characteristics of optical glass and plastic types in Abbe diagram

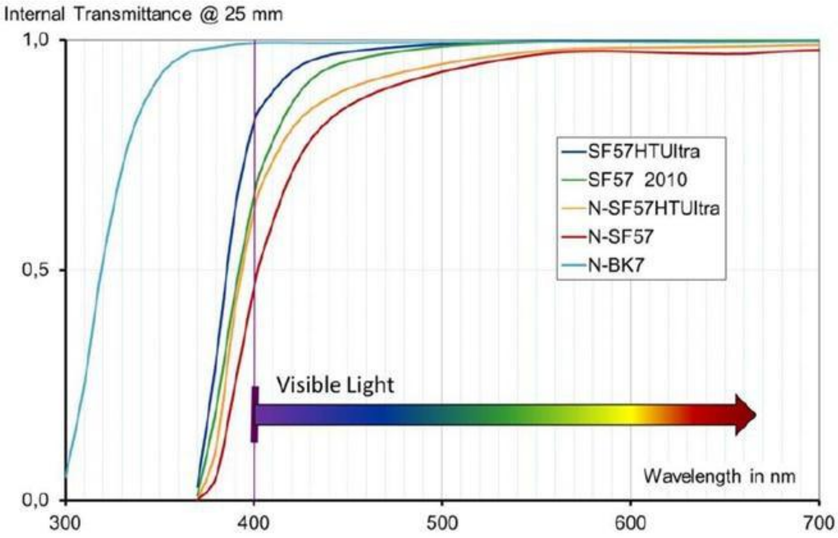


Source: SPECTARIS et al. (2019)

High percentage of light transmission at shorter wavelengths

SPECTARIS et al. (2019) provided the graph reproduced in Figure 8-3, showing the light transmission percentage curve of five examples of leaded and lead-free glass. Arguing that leaded glass needs to be used where high transmission of shorter wavelengths is needed, SPECTARIS et al. (2019) explained that "SF57 and SF57HTUltra are lead glass, whereas N-SF57 and N-SF57HTUltra are the lead free equivalents which have similar refractive index and Abbe number to the SF57 versions, but with inferior blue light transmission. N-BK7 (lead-free) is shown for comparison to demonstrate that even better blue light transmission can be achieved, but the other essential optical characteristics of N-BK7 make this unsuitable for many optical applications." These are displayed in Table 8-2, reproduced from SPECTARIS et al. (2019), showing BK7 has a comparatively lower refractive index and a higher Abbe number.

Figure 8-3: Graph of light transmission versus wavelength of light



Source: SPECTARIS et al. (2019)

Table 8-2: Properties of two lead-based and three lead-free optical glass types

Property	SF57	SF57HTUltra	N-SF57	N-SF57HTUltra	N-BK7
% Light transmission at 400nm	0.847	0.924	0.733	0.830	0.997
Refractive index (589.3nm)	1.8464	1.8464	1.8464	1.8464	1.5167
Abbe number	23.83	23.83	23.78	23.78	64.17

Source: SPECTARIS et al. (2019)

SPECTARIS et al. (2019) provide a fictive example calculation to illustrate why a high percentage of light transmission through a lens is important: An optical system consisting of 10 lens elements (typical of professional camera and video lenses) using optical glasses with poor transmission characteristics leads to a tremendous waste of the light energy fed into the optical system, as is illustrated in Table 8-3.

Table 8-3: Dependence of overall transmission of visible light through a 10-element lens due to transmission of individual lenses

Transmission of individual lens element (Ti)	Overall Transmission (10 lens elements)
73,3%	4,5%
84,7%	19,0%
92,4%	45,4 %

Source: SPECTARIS et al. (2019)

SPECTARIS et al. (2019) provide examples for applications that require high light transmission percentage at shorter wavelengths, two of which are summarized in the following:

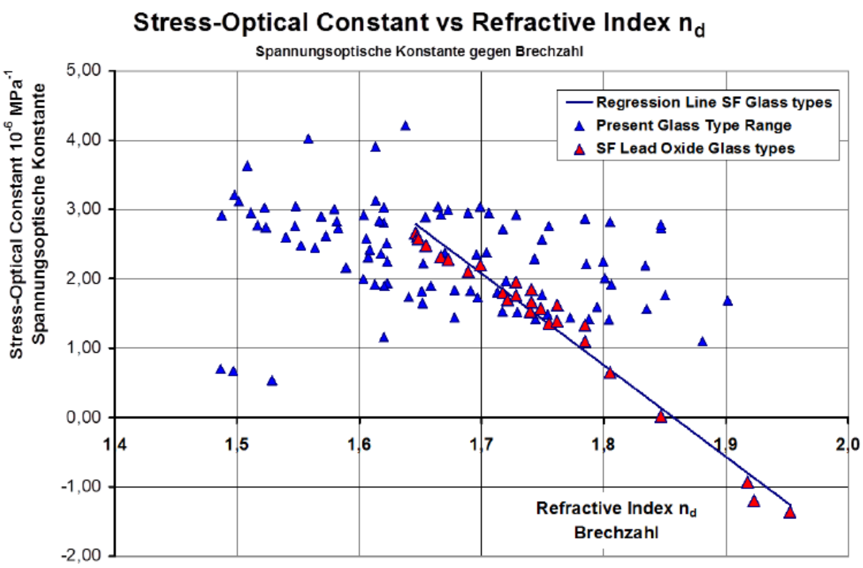
- *Optical microscopes use a series of different lenses to obtain the required magnification and image clarity and it is important that the glass absorbs as little light as possible. Without lead-based glass, very little blue – indigo light will reach the observers eye so that any blue / violet items are not visible and for many* *applications light of wavelengths in the UV/blue range (e.g. 355 or 405nm) is needed. UV wavelengths are also necessary for fluorescence microscopy. Without leaded glass, optical design would need more lens elements to achieve some of the optical characteristics, but other characteristics will be impossible to achieve. Using more lens elements causes a higher level of stray light and reflections and the image quality will be significantly reduced.*

- *Optical fibres for illumination units for operation microscopes in microsurgery. Optical fibres of up to 6 metres in length are used to illuminate patients that are being examined using surgical microscopes during operations. There is significantly higher light transmission with lead-containing optical fibres than with lead-free. To compensate the lower transmission with lead-free optical fibres and the solarisation (this causes the glass to darken and as a result it will absorb more light), a higher light intensity could be fed into the optical fibre, but this would lead to higher heat generation. Heat generation and higher light intensity can threaten patient and user safety so is not acceptable in operating theatres. There is no such safety risk when using a leaded optical fibre in this application.*

Low stress birefringence (low stress optical constant)

SPECTARIS et al. (2019) stated that low stress birefringence is essential for obtaining clear images without distortion and only lead-based glass types have both low stress optical constants and high refractive index. The graph below [Figure 8-4] shows all types of optical glass produced by SCHOTT. Only a very few types, all lead based, have high refractive index (close to 1.8) and very low stress optical constants (<1.0). Birefringence causes poor quality images in cameras and many other types of optical instruments which appears as poor contrast and distorted colours.

Figure 8-4: Graph of stress optical constant and refractive index for optical glass



Source: SPECTARIS et al. (2019)

Plastic lenses

SPECTARIS et al. (2019) listed several disadvantages of plastic lenses compared to glass lenses, these being

- *inferior heat stability,*

- *much higher coefficients of thermal expansion (CTE),*
- *relatively low refractive indices, and*
- *much softer and so are easily scratched.*

On heat stability, SPECTARIS et al. (2019) note that "for example, the temperature inside projectors can reach well over 100˚C and many polymers will distort or melt at these use temperatures. High refractive index (R.I.) spectacle lenses are stable at up to 120˚C although the plastic lens material with the highest refractive index is MR174 (made by Mitsui) with R.I. of 1.74 which has a heat distortion temperature of 78˚C."

Further, SPECTARIS et al. (2019) state that "Polymers also have much higher coefficients of thermal expansion (CTE) than glass so that temperature changes can cause dimensional changes which alter the optical characteristics. Typical linear CTE values are:

- *Glass SF57HT Ultra 9.2 x 10^{-6}/K*
- *Polycarbonate 70 x 10^{-6}/K*

On refractive indices, SPECTARIS et al. (2019) state that "Most clear transparent polymers such as polycarbonate and acrylics have relatively low refractive indices (<1.6) making them unsuitable for high performance magnification applications."

Table 8-4 summarises the main differences between lenses made of glass with plastic lenses.

Table 8-4: Comparison of properties of glass and plastic lenses

Property	Glass	Plastics
Refractive index	1.44 to 2.1 achievable (highest for lead is 2.1)	1.49 to 1.74
Tolerance (i.e. variation in characteristics of commercial lenses)	Low (±0.0001) can be achieved, so variation is very small	Estimated at ±0.001
Abbe number	Broader range (20 to >80) especially to low dispersion values	23 – 58 is possible
Transmittance (through 3mm)	>99% achievable	85 – 91% typically
Birefringence	2 to 10 nm/cm	2 to >40 nm/cm
Density	Lead-based are ca. 5 g/cm3. This offers advantages and disadvantages	1 – 1.2
Water absorption	Zero (so moisture has no effect on performance)	All plastics absorb water causing changes to optical properties (as they swell) and also potentially degradation

		can occur. From 0.01% to 0.3%
Thermal expansion	SF57HT Ultra is 9.2 x 10^{-6}/K, all glass 4.5 to 13 x 10^{-6}/K.	Range is 47 to 80 x 10^{-6}/K. This causes optical changes with temperature and thermal degradation
Refractive index thermal dependence	Smaller range of - 0.7 to + 1.2 10^{-5}/˚C	-8 to -14 10^{-5}/˚C
Resistance to damage	Relatively hard so not easily damaged.	Soft so easily scratched
Exposure to UV light	No effect	Discolours and degraded
Heat resistance	Resistant to temperatures created by lamps and laser light sources	Lamps and lasers can easily cause deformation or even make holes
Medical sterilisation	Completely resistant	May be damaged at sterilisation temperature. Viruses and bacteria can survive within scratches which plastics are more prone to than glass
Thermal conductivity	Lead-glass is relatively high so equilibrates faster than lead-free glass and plastics	Slow to equilibrate so can distort due to uneven heating

Source: SPECTARIS et al. (2019)

The Abbe numbers and refractive indices of optical plastics that are available and all types of optical glass are shown in Figure 8-2 on page 153.

On the material hardness, SPECTARIS et al. (2019) state that "Another significant disadvantage of plastic lenses is that they are much softer than lead-based glass and so are easily scratched and as a result become useless as this distorts images. Although lead-based glass is softer than lead-free glass, it is much harder than plastic and is not easily scratched except by very hard materials whereas plastic lenses are scratched by much softer materials. The methods usually used to measure the hardness of glass and plastic materials are not the same and so comparative data is not published.

However, Spectaris has arranged for three plastics that are used for lenses to be measured for "Knoop hardness" (0.1kg weight and 20 sec indentation, 5 measurements per sample), which is the standard method used for brittle materials such as optical glass. These measured values are compared with the values for glass published by SCHOTT […].

Table 8-5: SCHOTT Material hardness

Material	Knoop hardness (Pascals)
Polycarbonate	Measured at 13.2 ± 0.2
PMMA	Measured at 22.4 ± 0.1
Polydithiourethane (used for spectacle lenses)	Measured at 14.0 ± 0.1
Lead-based glass SF57	350
Lead-based glass SF11	450
Lead-free N-SF57	520
Lead-free N-SF11	615

Source: SPECTARIS et al. (2019)

The larger the Knoop hardness value, the harder the material. Lead-based glass is more than 10 times harder than the hardest plastics."

Alternative equipment design

SPECTARIS et al. (2019) stated that "Different designs of equipment that provides the same function and performance, but without leaded glass would be, if available, viewed as an alternative. However, leaded glass is used in a very wide variety of applications as described here and no alternative designs have been or are likely to be developed with equivalent performance for a very large variety of applications. One example described […] is of LCOS projectors. Alternative designs of projector are widely used but it is acknowledged that LCOS designs give the best optical performance."

Providing more detail, SPECTARIS et al. (2019) explained that "In LCOS projectors, white light from the lamp is split using three polarising glass beam splitters into the three primary colours, red, green and blue. Each coloured light beam passes through different optical pathways to create red, green and blue images which are then recombined to generate the image. It is essential that the light transmission of each colour is equal to achieve accurate colours, but the percentage of blue light transmission through most lead-free glass types is significantly lower than the other colours and so accurate colours can be produced only by attenuating the red and green signals. As a result, more energy (ca. double) is needed to obtain an accurate colour bright image with lead-free glass than with lead-based glass that have high blue light transmission efficiency. If more intense lamps are used, these generate more heat which potentially causes optical distortion due to heating of optical glass."

SPECTARIS et al. (2019) further remark that "Digital compensation software is now available and is used to modify poor quality images. This cannot, however, be used as an alternative to good quality images obtained using lead-based optical glass. This technology can only convert poor or medium optical quality to acceptable limits for amateur users. High end optics such as diffractive limited microscope objectives need the best direct optical imaging. If an image is distorted due to the properties of an inadequate optical system, digital processing software will not make the image better or clearer."

8.2.2. Roadmap towards substitution or elimination of lead

SPECTARIS et al. (2019) stated that "In the last 25 years not one single lead-containing glass type had been developed. Lead-containing glass types had been reduced by 88% by number within this time-frame and now have a share of 12% on the melted tonnage of all optical glass types."

Regarding the further potential to substitute lead in glass with other elements, SPECTARIS et al. (2019) stated that "There are about 90 naturally occurring elements in the periodic table. Those that are toxic such as mercury cannot be used, and radioactive elements are also unsuitable. In the last 100+ years, glass types of every conceivable combination of elements have been made and evaluated. One of the main reasons for use of lead in optical glass is to achieve high refractive index, low Abbe number and good blue wavelengths transmission. These characteristics are generally obtained by use of a high concentration of elements with a high atomic number and lead is one of the heaviest metals that is not radioactive. Table 10 [reproduced in Table 8-6 below, the consultants] describes the behaviour of the metallic elements in the periodic table from atomic number 56 (barium) to 83 (bismuth) in glass, based on past research."

Table 8-6: Properties of optical glass based on heavy elements with atomic number ≥ 56

Heavy elements	Atomic number	Properties in glass
Barium	56	Used in glass, with refractive index typically 1.57 and Abbe number of typically 55 to 60 so properties are very different to lead-glass
Rare earths (Lanthanum to Lutetium)	57 to 71	Most colour glasses. Lanthanum crown glass used as commercial glass types, but have high Abbe number (typically 55 – 60) with refractive index of 1.53 – 1.57 and so are very different to lead-glass.
Hafnium	72	Only suitable as a dopant in glass as tends to cause crystallisation. Used in polycrystalline ceramics.
Tantalum	73	Additive in some special glass types, but only small amounts can be added to avoid crystallisation
Tungsten	74	Additive in some special glass types, but only small amounts can be added to avoid crystallisation. Can also give a blue colour.
Rhenium	75	Inert, does not form glass. US research found that solubility of Re in borosilicate glass is only 0.3%.
Osmium	76	Inert, does not form glass.
Iridium	77	Inert, does not form glass.
Platinum	78	Inert, does not form glass.
Gold	79	Stable only as metal particles. Colloidal gold particles are used to colour glass red.

Mercury	80	Toxic.
Thallium	81	High refractive index glass can be made, but no commercial products exist due to its severe toxicity (<1 gram is fatal).
Lead	82	Stable, ideal combination of properties.
Bismuth	83	High refractive index, but reduction of Bi^{3+} to lower valency states can occur and causes brown / black colouration.
Atomic number higher than Bi	≥84	Radioactive, so unsuitable

Source: SPECTARIS et al. (2019)

There are a limited number of elements in the periodic table available that can be combined to form optical glass. Also, many of the combinations of elements that form optical glass do so within relatively small composition ranges as crystallisation occurs outside of these compositions. A publication on Ba, Ti silicate glass showed that glass without crystalline inclusions is possible only within relatively narrow concentration ranges of each element[66]*. After many decades of research, practically all possible combinations of elements have been prepared and evaluated and this has shown that for the types of applications described in this renewal request, there are no alternatives to the compositions that contain lead.*

A Spectaris member has carried out a keyword-based review of scientific publications since 1990 resulted in 225 hits with a detailed review resulted in 40 hits publications on glass compositions. However, not a single publication referred to substitution of lead, including none of the 23 found hits with date since 2014. While many referred to lead-free glass types with typical lead crystal glass properties and naming typically Barium oxide, Zinc oxide, Bismuth oxide and Titanium oxide and similar substances as ingredients, the published optical properties are analogous to known lead-free optical glass, in some cases for low Tg glass types. None of these publications are applicable for the combination of high index, low refraction and high transmission at short wavelengths, so no content explains new approaches of lead-free optical glass types.

Recent research has included the evaluated of glass combinations with 10 or more constituents and has also evaluated production method variable such as cooling rate. One recent publication describes glass types with up to ten constituent oxides. There are only a few recent patents on complex lead-free glass formulations, but these glass types are not intended to be replacements for lead-containing glass […].

[66] https://nvlpubs.nist.gov/nistpubs/jres/057/jresv57n6p317_A1b.pdf

Table 8-7: Refractive index and Abbe number of recently patented optical glass

Patent and date	Typical component elements	Refractive index	Abbe Number
US1024369B2 2016	Si, Ti, Zr, La, Nb and Ba	1.7	39
US9284216B2 2016	Si, La, B, Ge, Hf and In	1.75 to 1.9	42 to 53

Source: SPECTARIS et al. (2019)

It therefore appears that the only feasible alternative for substitution is to search for alternative designs, but this has not been possible for the types of applications described here, mainly as high-quality imaging requires lenses with suitable performance.

For all applications, research has already been carried out and when lead-free substitutes were found, they are used. Further research into alternative designs is uncertain and may never be successful due to the demanding combinations of essential characteristics. Therefore, it is not possible to predict how long this type of R&D will take or whether substitutes can be found for all of the diverse applications. It is entirely probable that it will never be possible to replace leaded glass in all applications.

In the 1990s all large optical manufacturers introduced lead free glass types with optical properties as close as possible to those of the preceding lead containing glass types. The lead-free glass types were required by the consumer optics market, which asked for eco-friendly cameras. By the end of the 1990s there was very little lead containing glass used for consumer optics, which has the largest share of glass usage by far. Many companies, which could not afford to develop lead-free glass went out of business. Today, lead-containing glass types are used only for cases, where there are no alternatives to achieve the optical performance. This restricts their use to special high- end applications. The production of lead-free glass since the 1990s is much larger than that of lead containing glass.

In the last 20 plus years, all newly developed glass types are lead-free. Before 1998 SCHOTT AG (glass manufacturer in Germany) had a global market share of 35% of lead containing glass, now it is 15%. However, the total number of glass types made by SCHOTT has been reduced by half since then. Related to the original number of types made before 1998 (202 glass types) the present number means a share of only 8%. For the world-wide production SCHOTT estimate the present ratio between lead-free to lead containing optical glass is about 20:1. It appears that the RoHS Directive has not contributed towards the reduction in lead use because most replacement had been achieved before RoHS was adopted in 2002 and further substitution has not been technically feasible (hence the need for exemption 13a). There is a contribution to the reduction due to RoHS to be expected, since optical equipment manufacturers have tried to remove lead glass wherever possible form their designs. However, this contribution is small compared with the yearly fluctuations in total volume and in ratio between lead free to lead containing glass. Consumer cameras no longer use lead-based glass and pocket cameras have been replaced by smartphones with built-in cameras, but this has occurred irrespective of RoHS.

Lead-based glass manufacturers constantly review the published literature for papers on new glass formulations but in recent years, no new glass types have been discovered that could replace lead-based optical glass. Unless a new formulation is discovered, it is difficult to see what else glass manufacturers can do to replace lead.

Equipment manufacturers also regularly review their designs to determine if lead-free glass can be used, but for the reasons explained in sections 4 and 6, this has not been possible. Where substitution was possible, this has already been carried out as lead-free glass is both cheaper and lighter in weight than lead-based glass. Only those applications (examples are described in section 4 (B)) where lead-glass is essential for technical performance reasons remain and as lenses are essential for these applications it is difficult to foresee any alternatives.

8.2.3. Environmental and socioeconomic impacts

SPECTARIS et al. (2019) stated that not renewing this exemption would have negative effects regards to environmental and human health aspects, but emphasizes that this is not used to justify the exemption. They made the following claims:

- *Environmental pollution monitoring would become less accurate without lead-containing glass, increasing likelihood of undetected pollution*
- *The availability of spare parts to repair and refurbish existing equipment depends on a healthy market for new products because optical glass production cannot be scaled down (small scale production is technically impractical due to difficulty to precisely control the process)*
- *Human health would be negatively affected if lead could not be used in optical glass, as the diagnostic and treatment performance of relevant medical devices would be decreased*

Regarding end-of-life treatment of equipment containing leaded glass, SPECTARIS et al. (2019) indicated that no closed loop exists for EEE waste of the applications in scope of this exemption renewal request. SPECTARIS et al. (2019) provided the following statements:

- *On recycling: "Based on WEEE EUROSTAT data for categories 8 and 9 (the categories that have most uses for this exemption), data for Germany indicates about 86% of collected WEEE is recycled."; "Based on WEEE EUROSTAT data for categories 8 and 9 (the categories that have most uses for this exemption), data for Germany indicates about 11% of collected WEEE is incinerated"; "Based on WEEE EUROSTAT data for categories 8 and 9 (the categories that have most uses for this exemption), data for Germany indicates about 2% is not recovered (6 – 8% France), so is probably landfilled, but this does not include unreported WEEE."; "The quantities of lead in each waste stream are not measured. As the quantity of lead optical glass used annually has not changed for many years, the total amount is likely to be the same as the amount used (from section 4.4) of 275 tonnes."*
- *On reuse: "Eurostat data is available for only a few EU States and only for a few WEEE categories. Based on categories 8 and 9 data for France and Germany, reuse is typically 0.1 to 1%"*

As optical glasses containing lead are used in an immense variety of products, the consultants conclude that the implementation of a closed-loop systems is not feasible.

SPECTARIS et al. (2021a) also offer a comment on environmental aspects associated with optical polymers: "The plastics strategy from the EC outlined targets towards tighter control of (single use) plastic material and the associated impacts on the environment, especially the pollution of our maritime environment. We have to assume that this plastic strategy will *have effects also on other polymer materials besides single-use plastics making optical applications with polymer materials unattractive."*

8.3. Critical review

8.3.1. REACH compliance – Relation to the REACH Regulation

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annexes III or Annex IV "*provided that such inclusion does not weaken the environmental and health protection afforded by*" the REACH Regulation. The article details further criteria which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the consultants as a threshold criteria: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Annex XIV

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV as an element. The fact that lead is a candidate substance therefore, at the time being, does not weaken the *environmental and health protection afforded by* the REACH Regulation.

Annex XVII

Annex XIV lists lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:

- Entry 10: Lead chromate;
- Entry 11: Lead sulfochromate yellow;
- Entry 12: Lead chromate molybdate sulphate red;
- Entry 55: Tetraethyllead

None of the above substances is of relevance for the use of lead in the scope of the requested exemption. A renewal of the requested exemption would not weaken the protection afforded by the listing of substances on the REACH Authorisation list (Annex XIV).

Annex XVII contains entries restricting the use of lead compounds:

- Entry 16 restricts the use of lead carbonates in paints;
- Entry 17 restricts the use of lead sulphates in paints;
- Entry 19 refers to arsenic compounds but includes a few lead compounds and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;
- Entry 28 addresses substances which are classified as carcinogens category 1A or 1B listed in REACH Appendices 1 or 2, respectively. In this context, it stipulates that

various lead compounds shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;

- Entry 30 addresses substances which are classified as reproductive toxicant category 1A listed in REACH Appendices 1 or 2, respectively. Like for entry 28, entry 30 stipulates for some lead compounds that they shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;
- Entry 63 restricts the use of lead and its compounds in jewellery and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children;
- Entry 72 lists substances which are classified as carcinogenic, mutagenic or toxic for reproduction. It stipulates that the substances listed in column 1 of the table in Appendix 12 shall not be used in textiles, clothing and foot wear. The table lists lead and its compounds mentioned in entries 28, 29, 30 and Appendices 1-6.

The use of lead within the scope of the requested exemption does not regard paints or jewellery, nor components that could be expected to be placed in the mouth by children under normal or foreseeable use. Furthermore, this use of lead is not a supply of lead compounds as a substance, mixture or constituent of other mixtures to the general public. Lead is part of an article and as such, the above entries of Annex XVII of the REACH Regulation would not apply.

No other entries with relevance for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the current status of these annexes, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

8.3.2. Scope Clarification

Relevant EEE categories

SPECTARIS et al. (2019) requested the renewal of this exemption for all equipment categories listed in RoHS Annex I. However, examples of applications that require the exemption that were provided by the applicants in the exemption renewal request only cover categories 3, 4, 6, 8, 9 and 11. Therefore, the consultants requested the applicants to provide examples for every category. In response, SPECTARIS et al. (2021a) stated:

From our point of view, it cannot be excluded that for special applications in categories 1 and 2 (large household appliances, small household appliances) optical lead glass is used in optical elements like sensors and others. Optical production is a highly fragmented business. There are some big companies but also a lot of small and medium sized companies in this market. It is very likely that such small and medium sized optical manufacturers, which are often very specialised and application driven companies, make use of exemption 13a for the categories 1, 2, 5, 7 and 10 and buy leaded optical glass components from distributors. We are therefore not able to provide examples of uses in all RoHS categories. The correct RoHS category for some types of electrical products is not clear and may depend on their end use application. More information has been provided since writing the exemption renewal request and video and television cameras, camcorders *and projectors specifically designed for sporting applications are indicative examples of category 7 applications.*

When asked for an overview of the most important RoHS categories in terms of quantities for the use of optical glass, SPECTARIS et al. (2021a) stated:

Based on the examples provided in our request for the renewal of RoHS exemption 13a we are aware of, these would be the categories 3, 4, 6, 8, 9 and 11. However leaded optical glass may be also used in other categories. However, the technical function of leaded optical glass – as outlined in detail in our renewal request for exemption 13a – are applicable to all RoHS categories and therefore the use of the exemption may be significant in other categories as well.

When asked to confirm whether leaded optical glass was required for a list of specific application examples compiled by the consultants, including children's' toys, front glass of TV sets, tablets and smartphones, lenses of Blu-ray disc drives, and glass used in imaging equipment, among others, SPECTARIS et al. (2021b) did not provide a specific response. SPECTARIS et al. (2022a) further stated: We have requested additional examples several times from the members of the Umbrella project and did not receive any extra information. We can only reiterate our position that we cannot exclude the possibility that lead containing glasses are contained in categories 1, 2, 5 and 10 but cannot provide examples.

The consultants note that the applicants provided examples of specific equipment where the exemption is known to be needed relevant for categories 3, 4, 6, 7, 8, 9 and 11, while no examples could be provided for categories 1, 2, 5 and 10. With view to potentially different possibilities of substitution of lead in glasses depending on specific requirements of different types of equipment, the consultants consider it necessary that specific examples of applications can be provided as evidence that the exemption is in fact needed in all categories for which the exemption is requested. Speculation that leaded glass may or may not be used in a range product groups in the scope of RoHS without evidence is therefore considered a weak basis for a recommendation to renew the exemption for such categories.

SPECTARIS et al. (2021a) provided some insights into which type of equipment does not require the exemption, stating: "All consumer optics from pocket cameras to DSLRs (digital single lens reflex) use only lead-free glasses. Industrial optical systems without special performance requirements also use lead-free glasses. A large if not the most part of pocket cameras has been replaced by smartphone cameras using mainly plastic optics." As the named equipment does not cover one or several entire equipment categories, an exclusion entire categories from the scope is not considered justified on the basis of this information.

In a virtual meeting, the consultants engaged the applicants in discussions on the potential option for shorter validity periods for equipment categories without documented application examples. SPECTARIS et al. (2022c) supported this approach, as it would send a signal to end-users of the glass to provide evidence where needed for a potential future review. Participants also provided an example for why not all downstream uses are known to them: Lead-containing glass may be used to manufacture sensors (category 9) that may be used in household devices (categories 1 and 2).

Terminology "white glass"

Before the split into 13(a) and 13(b), exemption 13 was phrased "Lead and cadmium in optical and filter glass" and did not use the term "white glass". In the review of exemption 13 that recommended the split into 13(a) and 13(b) and first introduced the term "white glass" (Gensch et al. 2009) did not explicitly describe the rationale behind the introduction of the term. When asked to clarify the physical background to the glasses in scope of this exemption being "white" and to provide a definition of the term "white glass" that clearly differentiates it from other types of glass that are not in scope of exemption 13(a), in particular those covered by exemption 13(b), SPECTARIS et al. (2021b) stated:

With "white" a transparent glass is meant. We recommend for the sake of clarity, please remove the word "white" in the sentence "Lead in white glasses used for optical applications" and have it as "Lead in glasses used for optical applications". Optical glass is glass used in optical systems in order to influence light with respect to its direction (imaging) or to its spectral transmission (filter effect). There is no special definition for 'white glass', however white does not mean that it is white in colour.

In a virtual meeting with the applicants, questions around the term "white glass" were further discussed:

- SPECTARIS et al. (2021c) were not aware of technically valid definitions of the term "white glass". The term tends to be used to describe transparent (colourless) glass, such as window glass.
- The current wording is confusing for downstream users of leaded glass, and compliance questions from downstream users regarding the meaning of "white glasses" are received regularly.
- No appropriate alternative for the word "white" is known that may help distinguish it from other glasses, such as those in scope of exemption 13(b) series. "Transparent" would also be misleading and there is no technically valid definition either.

In the consultants' view, the removal of the term "white" from the wording of exemption 13(a) may potentially widen the scope and may lead to other types of glasses, including ion-coloured filter glasses in scope of exemption 13(b) series, being implicitly included. To clearly differentiate the scope of exemption 13(a) from exemption 13(b) series, the consultants discussed the following wording option with the applicants:

- Lead in glasses used for optical applications excluding applications falling under points 13(b), 13(b)-(I), 13(b)-(II) and 13(b)-(III) of this Annex

SPECTARIS et al. (2021c) initially agreed that this phrasing may be a good way to avoid the term "white glasses" and prevent an overlap between types of glass covered by exemptions 13(a) and 13(b) series, however, also voiced concern over the phrasing as a "double exemption", due to the term "excluding" being used in an exemption wording.

However, the consultants note that similar phrasing has already been implemented in exemption 13(b)-(II) („…excluding applications falling under point 39 of this Annex") and Annex III exemption 42 („Applies to category 11, excluding applications covered by entry 6(c) of this Annex."). The consultants agree, however, that other phrasing would be possible.

When asked whether the above wording captures those glasses that require this application while excluding glasses that do not require it, SPECTARIS et al. (2022a) agreed. However, when asked whether the current wording, using the term "white glass", or the above suggested wording option would be preferable, SPECTARIS et al. (2022a) stated to "prefer the current wording as this would result in less administrative burden explaining the differences and updating documentation. However, both options would be acceptable."

SPECTARIS et al. (2022a) requested the consultants to include an explanation in this report that the terminology of "white optical glass" is equal to transparent optical glass, so that this technical explanation does not have to be revisited in possible future reviews of this exemption.

Requested validity period

Having performed the last review of this exemption, Gensch et al. (2016a) concluded: *"[…] consideration should be given in future reviews to the possibility of aligning exemption durations of all categories with time, to allow the evaluation process to be more efficient and to be carried out less often."*

Therefore, to lower the administrative burden and to maximize efficiency of the next evaluation of this exemption, the consultants asked the applicants whether they would agree to a deviation from the requested maximum validity period for categories 8 and 9 and to apply the maximum validity period for categories 1-7 and 10-11 (5 years) to all categories equally.

However, SPECTARIS et al. (2022a) stated not to agree and provided the following reasons:

- *"Article 5 (2) of the RoHS directive 2011/65/EC states, that the maximum validity period for exemptions for categories 1 – 7, 10 and 11 is five years and 7 years for categories 8 and 9. Category 8 and 9 products are categorized by high reliability and safety requirements, which often require lengthy approval testing and certification, as outlined in the Review of the Directive 2002/95/EC Categories 8 and 9 Report. As such, by reducing the maximum validity period to 5 years the more severe impacts which originally justified a longer maximum validity period will be reintroduced.*
- *With the renewal of the exemption for the categories 1 – 7, 10 and 11 every five years we simultaneously apply for the renewal of the exemption for categories 8 and 9 for the next validity period of seven years. So, there is no additional administrative burden associated with this approach, which was now applied for the last two renewal round for this exemptions."*

The consultants understand that the applicants wished to reflect the maximum validity period foreseen by the RoHS Directive for the above stated reason.

8.3.3. Scientific and technical practicability of substitution or elimination of lead

Alternative lead-free optical glass

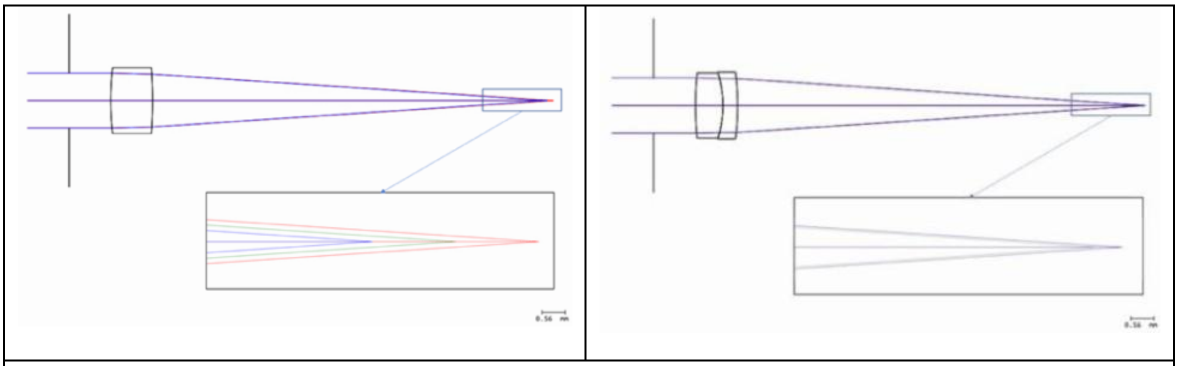
Leaded glasses have lower Abbe number per refractive index

SPECTARIS et al. (2019) provided an Abbe diagram showing lead-containing and lead-free glasses (in addition to optical plastics) according to their respective Abbe number and refractive index (reproduced in Figure 8-2 on p.153).

SPECTARIS et al. (2019) made the argument that for each value of refractive index, leaded glass will have the lowest Abbe number. When asked to describe for which applications a low Abbe number was needed, as low Abbe number generally tends to lead to higher chromatic aberrations, an undesirable effect in many optical applications, SPECTARIS et al. (2022b) stated that *“The main reason to use glasses with low Abbe numbers is to correct colour aberrations of optical systems. Furthermore, the high refractive index of glasses with low Abbe-numbers is of interest to achieve a high power with low curvature on optical surfaces“.*

Providing further detail on the first aspect, SPECTARIS et al. (2022b) explained: *“The most important reason to use glasses with low Abbe number is the correction of chromatic aberrations and thus to enable optical designs. Optical designs are based on combinations of glass types and many parameters. Specifically, the chromatic aberration of a single lens can be compensated by combining it with a second lens with a different Abbe number.”* SPECTARIS further explained that the achromatic condition has to be fulfilled to have the same focal length for two wavelengths in an optical system and illustrates this with an example in Figure 8-5. *“A combination of two lenses with positive and negative power could have the same focal lengths for two wavelengths. This can be achieved with proper combination of glasses with high and low Abbe numbers.” SPECTARIS et al. (2022b) added that this is a simple example and that in microscopic applications, the number of lenses is much larger and the usage of different glass types and with different Abbe numbers is needed.*

Figure 8-5: Example for the correction of chromatic aberration via the combination of a lens with low and a lens with high Abbe number



Left: Single lens of N-BK7 (Abbe number = 64,17) with axial colour: focal points of red, green, and blue light are separated. **Right:** Doublet of N-BK7 (Abbe-number 64,17) and N-SF2 (Abbe-number 36,43) fulfilling achromatic condition: focal points of red and blue light are coincident, focal point of green light is slightly separated (remaining secondary colour).

Source: SPECTARIS et al. (2022b)

On the second aspect, the high refractive index, SPECTARIS et al. (2022b) explained: *"In case of monochromatic aberrations many glasses with a low Abbe number are of interest because their high refractive index. The Abbe-diagram shows that many optical glasses with a high refractive index have a low Abbe number. Typical examples are the SF-types (so called heavy flints, in German language: Schwerflinte). A lens made of a glass with a high refractive index needs much less curvature at its surface to achieve a certain power. This has an impact to aberrations like spherical aberration, coma, astigmatism, field curvature or distortion."*

The consultants can follow that glasses with low Abbe numbers are needed for the reasons described by the applicants. Indeed, judging from the Abbe diagram provided by SPECTARIS et al. (2019) and reproduced in Figure 8-2 on p.153, lead-containing glasses are associated with the lowest Abbe number per value of refractive index. Although some lead-free glasses are also attributed low Abbe numbers and high refractive indices, the applicants' argument that a number of other factors, as discussed below, are also crucial to determine whether a glass can be used in a given application. One such example provided was the inferior blue light transmission of a lead-free glass with similar refractive index and Abbe number compared to a lead-containing glass. In the same diagram, some optical plastics can be observed to have even lower Abbe numbers, but the applicants provided plausible arguments regarding other disadvantages that disqualifies them for various optical applications, such as inferior heat stability, higher coefficients of thermal expansion, and much lower material hardness (discussed in more detail below on p.171ff).

Stress optical constant

When asked which of the glass types displayed in the diagram on stress-optical constant versus refractive index (reproduced in Figure 8-4 on p.155) contain lead, SPECTARIS et al. (2022b) clarified that only the red-marked SF (German: Schwerflint) lead oxide glass types do. SPECTARIS et al. (2022b) reiterated the relevance: *„The stress-optical constant has to be considered, when stress (mechanical or thermal) influences optical performance of optical systems. With the behaviour of the lead-containing glass types, within the design the influences of thermal or mechanical stress can be compensated to stay with constant refractive indexes and accordingly with a constant optical performance. This is only required for high precision optical designs and is also reflected in the stable market demand on lead-containing glass types."*

The consultants can follow the argument that only lead-containing glasses are associated with the highest values of refractive index and low stress optical constant, which may be needed for some high-precision optical designs. None of the lead-free glasses shown in the diagram are located in the same range as some of the lead-containing glasses.

Examples of equipment with lead-free glasses

The consultants produced a short list of examples of commercially available equipment advertised to feature lead-free glasses:

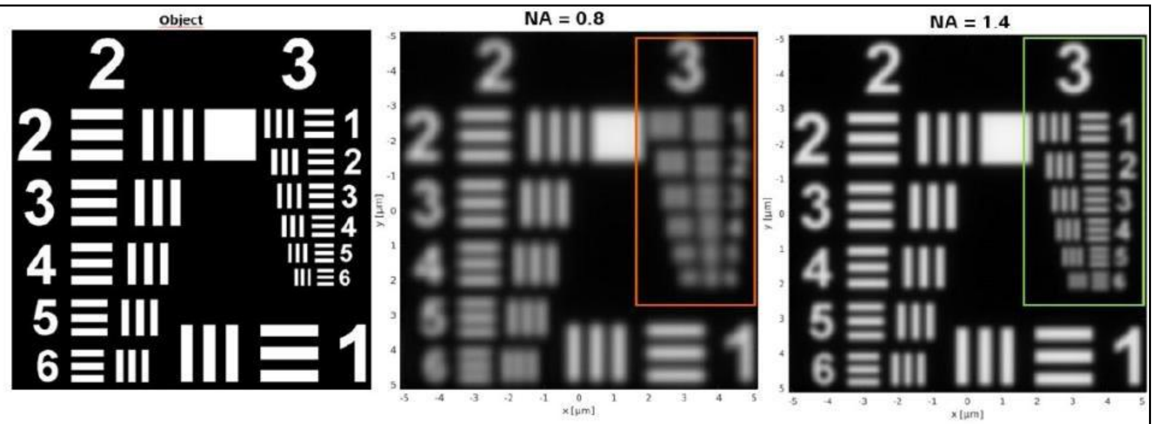
- Microscopes using lead-free glass made by Leica Microsystems (2017)
- Fluorescence microscopes using lead-free glass made by Zeiss (n.d.)
- Fibres for illumination units for medical microscopes made by Schott (n.d.)

When requested to comment on these and to evaluate to which degree these examples can substitute applications using lead-containing glass, SPECTARIS et al. (2022b) provided explanations for each.

Regarding the first example, the light microscope, SPECTARIS et al. (2022b) stated that it is an example of a low-cost microscope that makes no mention of wavelengths (especially blue / UV light; fluorescence) in its technical specifications. Leica provided a statement to SPECTARIS et al. (2022b) stating that the example microscopes are used in the visible wavelength range used for the optical inspection of components, such as on printed circuit boards or specimen selection and preparation. Due to the wavelength and application range, it is not necessary to use glasses within the scope of exemptions 13(a) or 13(b). Leica also emphasizes that "this product group represents only a part of the Leica Microsystems product portfolio and cannot be considered as representative for all product groups. Leica microscopes that work in the UV wavelength range and use fluorescence as an analysis method, for example, still require Pb-containing glasses with regard to their areas of application."

Regarding the second example, the fluorescence microscope, SPECTARIS et al. (2022b) stated that the example microscope (Plan-Apo 20x/0.8) has "been designed for applications mainly in the visible range of the light spectrum at a low to medium magnification of 20x, where it can achieve a comparably good transmittance. One reason for this relatively high transmittance (despite lead-free glass) is that it has only very few lens elements (compared to higher N.A. [Numberical Aperture, the consultants] objectives or objectives that are used for UV-applications). Although it contains only few lenses, it does not achieve any significant transmission at or below 350 nm (which renders some applications like calcium imaging with Fura2, ablation or uncaging impossible)." SPECTARIS et al. further explain that this particular microscope is a "high quality objective, however it does not have the resolution of other research objectives in the portfolio, such as the Plan-Apo 40x/1.4." SPECTARIS et al. (2022b) illustrate this with a schematic depiction of the dependency of image resolution on numerical aperture (Figure 8-6).

Figure 8-6: Schematic depiction of the dependency of resolution on Numerical Aperture



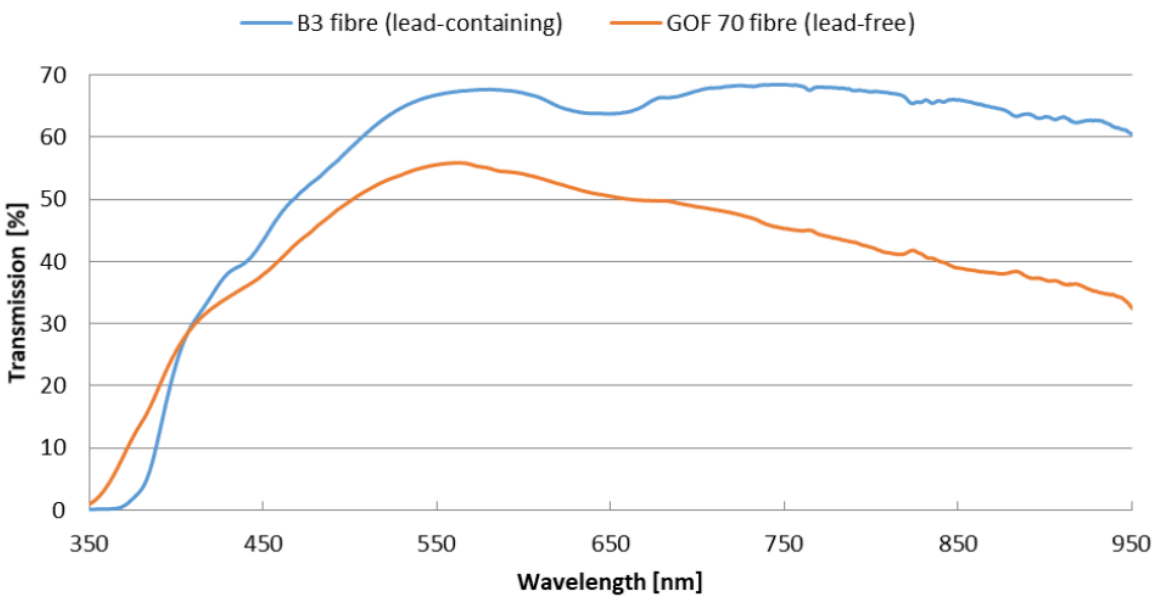
Left: original object; Image transformation by an optical system with numerical aperture (NA) of 0.8 (**centre**) and NA of 1.4 (**right**). With lower NA, a significant amount of information is lost, that cannot be used to draw scientific conclusions.

Source: SPECTARIS et al. (2022b)

The consultants can follow the argument that individual microscopes may be produced without lead-containing glass lenses, but that this does not mean that all optical applications can be covered with those. For other applications, lead-containing glass may still be needed, such as where higher transmittance at lower wavelengths or higher resolution are required.

Regarding the third example, the fibres for illumination units, SPECTARIS et al. (2022b) point out that the difference in the percentage transmission over a wavelength range between lead-containing and lead-free fibres has been shown in the initial exemption renewal application in the diagram produced below in Figure 8-7. According to SPECTARIS et al. (2019), glass fibres that do not contain lead solarize faster than lead-containing fibres, leading to darkening of the glass and thereby higher absorption rate of light. Solarisation would lead to higher required light intensity, which, however, would also lead to higher heat generation, posing a threat to the patient and user safety.

Figure 8-7: Transmission of optical fibres, quotient spectrum before irradiation



Source: SPECTARIS et al. (2019)

The consultants can, in principle, follow the argument made by the applicants that lead-containing glass tends to be less susceptible to solarisation and therefore may result in higher transmission values. The lead-containing glass fibres may therefore be technically superior to their lead-free counterparts. However, the consultants also note that the particular lead-free fibre product is advertised by Schott (n.d.) explicitly for medical diagnostic applications, such as endoscopy, microscopy, spectroscopy and fluorescence technologies. Schott (n.d.) also mention its "*excellent transmission*" properties, however, without providing comparisons to lead-containing products. Therefore, the consultants assume that lead-free fibres are used in practice at least in some applications, but may not necessarily be technically equal to lead-containing fibres in all applications.

Plastic lenses

SPECTARIS et al. (2019) described several disadvantages of plastic lenses compared to glass lenses: inferior heat stability, higher coefficients of thermal expansion (CTE), relatively low refractive indices, and much lower material hardness.

The consultants understand from the applicants' argument that plastics tend to have a lower heat stability compared to glass. However, this is likely only relevant for a subset of those applications in which glass can potentially be substituted by optical plastics lenses. This is not expected to be an issue in applications that are not subject to elevated temperatures. However, it is acknowledged that vicinity to heat sources, including light sources, could be problematic for plastic lenses and that many optical applications rely on light sources in relative vicinity. The consultants can also follow the applicants' argument that plastics tend to be softer than glass and therefore easier scratched. This, again, is not expected to be an issue in all applications, such as lenses inside of measurement instruments without contact to external objects.

SPECTARIS et al. (2019) stated that most clear and transparent polymers have low refractive indices and therefore are not suitable for use as lenses. When asked for transparent polymers that do have higher refractive indices, SPECTARIS et al. (2021a) explained that "A few types have been developed that are used to make spectacle lenses. Spectacle lenses can be thinner if they have high refractive index. Examples include allyl diglycol carbonate (ADC) and polymers manufactured by Mitsui. High-refractive polymer (HRIP) based materials cover a range of refractive indices up to 1.74 with limited applications. […] However, such HRIPs do still have a low dispersion behaviour. For this reason, optical corrections cannot be made by using HRIPs. Especially the following optical corrections are not possible with polymer glasses:

- *Reduction of the chromatic aberration,*
- *Reduction of Petzval field curvatures,*
- *Achromatization,*
- *Reduction of spherical aberrations,*
- *Correction of apochromates and colour correction.*

For the correction of theses parameters optical glasses are necessary which have not only a high refractive index but also a high dispersion, which is fulfilled by optical lead glasses. Additionally, polymer glasses have severe disadvantages as compared to inorganic glasses […]."

SPECTARIS et al. (2021a) further reiterated on the inferior heat stability of polymers compared to glass, pointing out medical sterilization as one application where polymers cannot be used. For instance, medical endoscopes are required to be autoclaved at a temperature of 134°C for sterilization and at such temperatures, polymers tend to deform.

Regarding transmission, SPECTARIS et al. (2021a) stated to have compared high-conductivity polymers from Zeonex and Topas to Schott's F2HT, but transmission was still found to be inadequate.

SPECTARIS et al. (2022c) added that optical polymers are used where this is technically feasible, as they are cheaper in material as well as processing compared to optical glasses. However, optical polymers cannot replace lead-containing mineral glasses in all applications for the technical reasons outlined in the renewal request (cf. section 8.2.1 on p.155ff).

The consultants also note that plastic lenses are already used in a range of applications, including camera modules in smartphones, ophthalmological spectacle lenses (the latter are not in the scope of the RoHS directive, since they do not rely on electrical functions), and possibly in children's toys (SPECTARIS et al. (2021a)). However, given the provided information, the consultants can follow the applicants' arguments that plastic lenses cannot substitute glass lenses in all applications due to the disadvantages in technical properties described above.

Alternative equipment design

SPECTARIS et al. (2019) described the example of LCoS projectors as one example for which alternative, lead-free designs have been developed and are widely used. LCoS projectors are described by the applicants to have several advantages compared to the alternative technologies LCD (liquid crystal display) and DLP (digital light processing). In a limited internet research, the consultants found that DLP projectors are indicated to dominate digital cinemas with a market share of 85 % (Scott Wilkinson (2020)). In a workshop held with the applicants, SPECTARIS et al. (2022c) clarified that DLP projectors for low-end applications can likely be implemented with lead-free glasses, but higher performance devices require lead-containing glass. This would mean that although lead-free alternative designs to high-end projectors are available, high performance devices still require leaded glass.

When asked about other examples of alternative, lead-free designs with a comparable performance to designs using lead-containing glass, SPECTARIS et al. (2021a) provided the following explanations: "In the 1990s all large optical manufacturers globally introduced lead free glass types with optical properties as close as possible to those of the preceding lead glass types. The lead- free glass types were required by the consumer optics market, which asked for eco-friendly cameras. By the end of the 1990s there was hardly any lead glass used for consumer optics, which has the largest share of glass usage by far. Companies which could not afford developing the lead-free glasses went out of business. Nowadays lead glasses are used only for cases, where there are no alternatives to achieve the required optical performance. […] All consumer optics from pocket cameras to DSLRs (digital single lens reflex) use only lead- free glasses. Industrial optical systems without special performance requirements also use lead-free glasses. A large if not the most part of pocket cameras has been replaced by smartphone cameras using mainly plastic optics. Since substitutions were made in the 1990s, we are not aware of new examples of types of products that have replaced lead-glass with lead-free glass types."

The consultants can follow the general line of argument presented by the applicants. It appears plausible that lead-containing glasses would only still be employed in products where lead-free alternatives do not provide the same or better performance.

Roadmap towards substitution or elimination of lead

The applicants explained that lead-containing glass has been substituted with lead-free glass in all applications in which it is technically feasible. The applicants also stated that "*practically all possible combinations of elements have been prepared and evaluated and this has shown that for the types of applications described in this renewal request, there are no alternatives to the compositions that contain lead."* Alternatives, such as optical polymers, cannot replace leaded glass in all applications, and SPECTARIS et al. (2022c) do not expect ground-breaking new developments in the field of optical polymers.

While unsatisfactory from the standpoint of the goals of the RoHS Directive, the consultants have not come across evidence that would contradict the explanations provided by the applicants. Therefore, the consultants understand that the applicants have not provided a specific roadmap for the substitution or elimination of leaded glass types at this time.

8.3.4. Environmental arguments and socioeconomic impacts

SPECTARIS et al. (2019) provided statements on potential negative effects on environmental and human health aspects but emphasizes that this is not used to justify the exemption. It can be followed that the performance of relevant equipment may on some cases be negatively affected in case the use of lead-containing glass was no longer feasible. Regarding the recycling of end-of-life equipment using lead-containing glass, SPECTARIS et al. (2019) only provided generic information on waste electrical and electronic equipment (WEEE) as opposed to specific data on the equipment in scope of this exemption renewal request. No close-loop collection and recycling system is in place. In the consultants' view, given the diversity of equipment potentially using this exemption, a close-loop system would not be feasible. Lead-containing glass can therefore be expected to arrive at a variety of WEEE treatment facilities within the EU and beyond EU borders.

8.3.5. Summary and conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria is fulfilled:

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II **is scientifically or technically impracticable**;
- the **reliability** of substitutes is not ensured;
- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

The consultants understand from the information provided by the applicants that substitution of lead-containing glasses with lead-free glasses or optical polymers has already taken place in applications where it is technically feasible. In recent years, no ground-breaking new developments have been achieved regarding the development of new substitutes. The applicants further made the point that the use of lead oxide in glass is and has been minimized due to work safety and environmental considerations, both of which incur additional costs (workplace safety measures, biomonitoring, etc.) and therefore disincentivise the use of leaded glass. It was stated that only its specific technical properties are reasons for the use of leaded glass. The consultants consider the provided arguments plausible and did not encounter contrary information.

The consultants also understand that translucent polymers ("plastic glass") are not viable substitutes for many applications due to a range of inferior technical properties, being inferior heat stability, higher coefficients of thermal expansion, relatively low refractive indices, and much lower material hardness. No current or recent research and development activities were identified that promise polymer glass which can be expected to replace leaded glass. Therefore, the consultants can follow the applicants' line of argumentation regarding optical polymers.

The applicants stated that redesign of equipment to use lead-free alternatives to leaded optical glass have largely taken place since the 1990s. Such alterative designs also exist regarding equipment that to this day requires leaded glass to provide sufficient performance, but in such cases, variants using leaded glass still outperform variants using lead-free glass. This argumentation is in line with arguments on substitution discussed above and is seen as plausible by the consultants.

The term ‘white glass’ was discussed with the applicants and found that it was likely introduced into the exemption wording to differentiate it from coloured filter glass, such as glass covered in exemption 13(b) series. However, ‘white glass’ is merely used as a term denoting ‘transparent glass’ and is not a precise technical term. Therefore, the applicants requested to remove the term from the exemption wording. The consultants proposed another wording option to delineate glasses in optical applications covered by this exemption from the glasses covered by exemption 13(b) series, in which the latter are explicitly excluded from the scope of exemption 13(a). The applicants agreed to this wording option in principle, but stated to prefer the current wording, as a change in wording would create administrative burden in the relevant value chains.

The applicants requested the exemption to be renewed for all RoHS Annex I equipment categories, however, specific examples for equipment that is known to require the exemption were only provided for a subset of categories (3, 4, 6, 7, 8, 9 and 11) and not for others (1, 2, 5 and 10). Therefore, there is a lack of evidence that the exemption is in fact required to cover all categories. The consultants consider it justified to either exclude the affected categories from the exemption scope or to include them with a reduced validity period. The latter option would give the applicants more time to gather evidence regarding the types of equipment in which the leaded glass is used in practice before a possible next evaluation of the exemption.

8.4. Recommendation

The available information suggests that substitution and elimination of lead in glasses and lead-containing glasses used for optical applications is not yet technically feasible in all cases. Leaded glass has some properties that are needed in a range of applications that cannot be achieved by existing alternatives. In the consultants’ view, Art. 5(1)(a) would therefore allow granting an exemption.

The consultants propose two exemption wording options below. Both are deemed viable and have been discussed with the applicants. The consultants favour option 2 as it removes the term ‘white glasses’, which is not a technically well-defined term, and instead clearly delimitates the types of glasses in scope from those in scope of exemption 13(b) series. The applicants stated to prefer option 1, as keeping the current wording would avoid administrative burdens of adopting a new wording.

Regarding option 1, the consultants follow the applicants’ request to reiterate here that the terminology of ‘white optical glass’ in context of the wording of exemption 13(a) is equal to ‘transparent optical glass’, so that this aspect does not have to be revisited in possible future reviews of this exemption.

Option 1: Renew with current wording

	Exemption	Scope and dates of applicability
13(a)	Lead in white glasses used for optical applications	Applies to categories 1-11.

		Expires on: - 21 July 2025 for categories 1, 2, 5, and 10; - 21 July 2026 for categories 3, 4, 6, 7, 8, 9, and 11; - 21 July 2028 for category 8 in vitro diagnostic medical devices and category 9 industrial monitoring and control instruments.

Option 2: Renew with new wording

	Exemption	Scope and dates of applicability
13(a)	Lead in glasses used for optical applications excluding applications falling under points 13(b), 13(b)(I), 13(b)(II), 13(b)(III), 13(b)(IV) of this Annex	Applies to cat. 1-11 Expires on: - 21 July 2025 for categories 1, 2, 5, and 10; - 21 July 2026 for categories 3, 4, 6, 7, 8 medical devices others than in-vitro diagnostic medical devices, 9 monitoring and control instruments others than industrial monitoring and control instruments, and 11; - 21 July 2028 for category 8 in vitro diagnostic medical devices and category 9 industrial monitoring and control instruments.

It should be noted that mentioning the specific exemptions in 13(b) series results in an interlinkage and potential complications. In the review of exemption 13(b) series, the consultants recommend a new exemption 13(b)-(IV), which would have to be mentioned in the exemption wording of 13(a) in case the Commission decides to follow the consultants' recommendation for a new exemption 13(b)-(IV).

Regarding the equipment categories for which the applicants could not produce examples (categories 1, 2, 5, and 10), it should be noted that both wording options above include those in scope as well but foresee an earlier expiry date. Alternatively, the Commission may decide to remove them from the scope entirely due to a lack of evidence:

Option 3: Renew with current or new wording with narrower scope

	Exemption	Scope and dates of applicability
13(a)	Lead in […]* ** following sentence depending on wording options 1 or 2 above*	Applies to categories 1-11. Expires on: - 21 July 2026 for categories 3, 4, 6, 7, 8, 9, and 11; - 21 July 2028 for category 8 in vitro diagnostic medical devices and category 9 industrial monitoring and control instruments.

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9. Exemption series 13(b) of Annex III: Cadmium and lead in filter glasses and glasses used for reflectance standards

The current wording and expiry dates of the exemptions of this series are:

No.	Current exemption wording	Current scope and dates of applicability
13(b)	Cadmium and lead in filter glasses and glasses used for reflectance standards	Applies to categories 8, 9 and 11. Expires on: - 21 July 2023 for category 8 in vitro diagnostic medical devices; - 21 July 2024 for category 9 industrial monitoring and control instruments and for category 11; - 21 July 2021 for other subcategories of categories 8 and 9
13(b)-I	Lead in ion coloured optical filter glass types	Applies to categories 1 to 7 and 10. Expires on 21 July 2021 for categories 1 to 7 and 10
13(b)-II	Cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex	
13(b)-III	Cadmium and lead in glazes used for reflectance standards	

Declaration

In the sections preceding the "Critical review", the phrasings and wordings of applicants' and stakeholders' explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described *in italics*. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

Cat.	Category, referring to the categories of EEE on RoHS Annex I
Cd	Cadmium
CdS	Cadmium sulphide
CdSe	Cadmium selenide

CdSeS	Cadmium selenide sulphide
Cr	Chromium
Cu	Copper
COM	European Commission
EEE	Electrical and electronic equipment
Fe	Iron
IMCI	industrial monitoring and control instrument
IVD	in-vitro diagnostic medical device
JBCE	Japan Business Council in Europe
Lucideon	Company producing reflectance standards
Mn	Manganese
Ni	Nickel
NIR	Near infrared
Pb	Lead [chem.]
RoHS 1	Directive 2002/95/EC
RoHS 2, RoHS	Directive 2011/65/EU
Sb	Antimony
Spectaris	German industry association for Optics, Photonics, Analytical and Medical Technologies
TMC	Test & Measurement Coalition
VG9	Name for a commercial lead-containing, green-coloured glass filter produced by the German company SCHOTT

9.1. Background and Technical Information

On 27 November 2019, SPECTARIS et al. (2019) requested the renewal of the exemption with the below wording, scopes and the maximum possible durations for the respective categories of EEE in the scopes:

No.	Requested Exemption	Requested scope and dates of applicability
13(b)	Cadmium and lead in filter glasses and glasses used for reflectance standards	Applies to categories 8, 9 and 11.
13(b)-(I)	Lead in ion coloured optical filter glass types	Applies to categories 1 to 7 and 10.
13(b)-(II)	Cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex	
13(b)-(III)	Cadmium and lead in glazes used for reflectance standards	

The stakeholder Lucideon (2021a) provided missing information on Exemption 13(b)-(III). In consultation with the European Commission (2021a), the additional information submitted to complete the original request was accepted.

TMC (2021) contributed to the stakeholder consultation stating that their members intend submitting applications for renewal of certain exemptions [here 13(b)] *within the legally foreseen deadlines of 18 months prior to their expiries for industrial monitoring and control instruments. They request the European Commission to schedule the evaluation of the Annex III exemptions relevant to category 9 industrial applications in due time, i.e., 18 months prior to 21 July 2024. However, the COM had already clarified with representation of TMC in written correspondence, pertaining to a previous exemption renewal request, that the Commission considers it justified for the technical assessment to start at the same time for all categories as requested by the applicants.*

9.1.1. History of the Exemption

Exemption 13 was already included in the RoHS 1 as *"Lead and cadmium in optical and filter glass."* In 2010[67], the exemption was divided into 13(a) and 13(b):

- 13(a) Lead in white glasses used for optical applications
- 13(b) Cadmium and lead in filter glasses and glasses used for reflectance standards

In the reviews of Annex III after 2006 the applications in the scope of this exemption were specified taking into account scientific and technical progress. The last review of, at that time only exemptions 13(a) and 13(b), in 2015/2016 by Gensch et al. (2016) resulted in the current five exemptions[68] under number 13 in 2018. The further split of exemptions was motivated by limiting the use of lead and cadmium to those types of filter glasses where either the one (lead under 13(b)-(I)) or the other (cadmium under 13(b)-(II)) was required at

[67] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002L0095-20100925

[68] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011L0065-20180706

that time, and to limit the use of both lead and cadmium to the glazes of reflectance standards.

Exemption 13(b) has kept the wording before the last review of the exemption by Gensch et al. (2016) lead to a splitting into 13(b)-(I), (II), and (III) and only has categories 8, 9, including their respective subcategories, and 11 in scope, while the other categories are in scope of 13(b)-(I), (II), and (III).

9.1.2. Summary of the requested exemptions

SPECTARIS et al. (2019) provided the following summary pertaining to exemptions 13(b), 13(b)-(I) and 13(b)-(II): *"This exemption renewal request is for the use of cadmium and lead in optical filter glass that is used in electrical and electronic equipment. There are many types of optical filter glass whose batch contains cadmium, but only a few formulations whose batch contains lead with only one filter glass whose batch contains lead being regularly manufactured. These types of optical filters are used in a very wide variety of optical applications and in many different types of equipment. These materials are used because of their unique optical properties, such as "sharp cut-off" in the visible spectrum that is unaffected by viewing angle. They are also very stable in harsh environments. Most of the alternatives to glass with cadmium and/or lead in the batch do not exhibit such sharp wavelength "cut-offs". Interference filters can sometimes be used as they do have sharp cut offs but the wavelength at which this occurs is viewing angle dependent and so these are unsuitable for many applications. Most of the apparent alternatives are detrimentally affected by harsh environmental conditions such as heat, moisture, UV light, etc. which makes them unsuitable for many applications.*

A special type of infrared interference filter is also used that contains lead for analysis of low concentrations of gas. These are a different design to the filters to the types used for visible light wavelengths."

The exemption renewal form provided by SPECTARIS et al. (2019) did not contain any information on exemption 13(b)-(III), stating *"The exemption renewal request covers all types of products that require these exemptions, but excludes information on cadmium and lead in glazes used for reflectance standards as the applicants are not expert in these products."* Upon request, SPECTARIS referred to the company Lucideon, which in turn provided the missing information (Lucideon (2021a)). In consultation with the European Commission (European Commission (2021a)), the additional documents were accepted.

Lucideon (2021a) provided the following summary: *"Ceramic Colour Standards […] are optical reflectance materials that are used to calibrate and check the measurement performance of spectrophotometers and optical devices." and "The Ceramic Colour Standards are physical optical accessories to spectrophotometers, not an integral part of such equipment, and have no electrical parts or contact with electricity. All of the standards are now Lead-free and most of them have eliminated Cadmium. Cadmium has only been used where no suitable alternative is available." Lucideon (2021a) added that "The wording of the new Exemption should be: 13b-III Cadmium in glazes used for reflectance standards".*

9.1.3. Technical description of the exemption and use of restricted substance

SPECTARIS et al. (2021b) explained that optical filter glasses in general serve for separation or selection of light wavelength ranges in a wide variety of applications in research and industry. Ideally separation occurs at a given wavelength with 100 % transmission in the pass band and 0 % in the blocking range with infinitely steep slope. Real filters show residual absorption in the transmittance range band and residual transmittance in the blocking range with transition ranges of differently steep slopes. In production of filters it is important to come as close as possible to the desired ideal filter characteristics.

Addressing the difference between "ion coloured" optical filter glasses, covered by exemption 13(b)-(I), and "striking" optical filter glasses, covered by exemption 13(b)-(II), SPECTARIS et al. (2021b) explained that "Striking filter glasses provide uniquely steep slopes and an extremely high blocking effect but due to their single edge only with a long pass characteristic. Band pass or band blocking filters [cf. Figure 9-1 on p.185, the consultants] require ion-coloured glasses, which have two edges. However, these edges are smooth rendering only a moderate separation capability."

Types and categories of equipment requiring the exemption

SPECTARIS et al. (2019) provided a non-exhaustive list of types of EEE, often indicating the corresponding RoHS Annex I EEE category or categories, an excerpt of which is reproduced as follows (the full list of provided examples, albeit without further descriptions, is reproduced in the "Annex to the exemption 13(b) series " on page 271:

- *Airport runway lamps that indicate the runway location (category 5 or 9) – bright specific coloured light visible from all directions which should not change in colour with viewing direction which would occur with coated filters and interference filters.*
- *Spectrometers; for example, as stray light filters for UV and for near-IR spectrometers, requires high % transmission in the desired wavelength range and a steep cut-off with no transmission outside of the desired range (categories 8 and 9).*
- *Radiation thermometers – (category 9) uses filters containing cadmium to detect light of specific wavelengths without interference from other wavelengths. These determine temperature by measuring the light intensity at a specific wavelength so other wavelengths must be blocked. Cadmium provides the steep edge and lead provides fine adjustment of the transmission limit wavelength.*
- *Filters in medical fibre optic core temperature probes that are used to measure body temperature of patients while undergoing MRI scans (category 8). This filter is used in the optical head of the signal conditioner to reduce/eliminate the unwanted scattered light (noise) in the optical head. Only red cadmium filters give accurate body temperature measurements.*
- *Imaging luminance colorimeters – light measurement to simulate the human eye's light responses. The colour response is simulated by 4 different "stacks" for the so called Xr, Xb, Y and Z response of the "standard observer" as defined by the "International commission of illumination, CIE". The filters are sequentially introduced into the beam path of a camera system. Calibrations and evaluation of the data result in a precise image of luminance and colour. The closest match can only be achieved with filters containing cadmium (category 9).*

- *Spectroradiometers- This type of device has a very high fidelity of colour measurements. The light of different colours (plus infrared and ultraviolet) is dispersed by an optical grating and then analysed by a charge-coupled device sensor. However, optical gratings diffract the so called 'higher orders' of light as well as the required wavelengths. This means that light with half the wavelength will follow the same beam path (e.g. 360 nm will appear as signal at 720 nm). To eliminate these higher order wavelengths, optical filter glass is used. Optical filters containing cadmium have to be used in these measurement devices for light measurement (category 9).*
- *Ingredient meters and thickness meters – use filters containing both cadmium and lead. These devices function by measuring the amount of an ingredient in the test sample to determine either its concentration, or if this is known, it can be used to measure the sample's thickness by making use of the Lambert-Beers law. This is achieved by accurate measurement of transmitted light at a specific wavelength and filters are needed to remove other wavelengths (category 9).*
- *Infrared sensors – these filters contain an evaporated layer of lead compounds which transmit light of wavelengths between up to 15 µm and has a high refractive index. This combination of properties cannot be achieved by any other materials or designs.*
- *IVD analysers (category 8); in-vitro diagnostic medical device (IVD) analysers automatically analyse a variety of materials, and some tests use colour to measure concentrations (using optical absorption spectroscopy). The required colours are selected by blocking other wavelengths using optical filters including some that contain cadmium. These must have sharp-edges to the transmitted spectrum and be stable with no colour change or fading during the life of the equipment for accuracy to be maintained.*
- *Lasers; many types of lasers with fundamental wavelength in visible and near-Infrared (NIR) wavelengths use optical filters containing cadmium. Sharp spectral filtering using cadmium-containing glass is required to achieve spectrally pure signals for power level setting, attenuation, and diagnostics. These filters are used, for example, to separate the fundamental NIR radiation from other wavelengths like pump sources with 808 nm /880 nm / 888 nm and harmonics such as 523 nm / 355 nm /266 nm. The filtered NIR is used for determination of power values for diagnostic reasons, but mainly for power level settings and attenuation by end users of the tool. Ultra-short, pulsed laser sources are used in a growing market segment like e.g. micromachining of glass, in the semiconductor industry and used to produce photovoltaics and display technologies (category 6, 8, 9 and 11).*
- *Lead containing green filter glass such as VG9 has many minor uses. It separates the different colour channels for colour TV cameras (category 4) and is used for colposcopes[69] (category 8).*

[69] Medical device for visual examination of the cervix, the vagina and the vulva

General function of lead and cadmium in glass

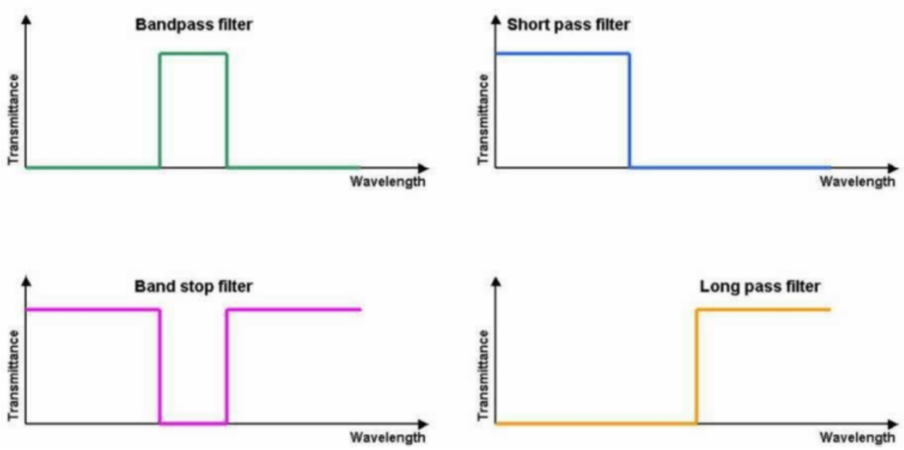
SPECTARIS et al. (2019) explained that optical filter glass types generally are clear, transparent, non-crystalline materials with a variety of compositions. Traditionally "glass" has been understood to consist of complex inorganic silicates based on a variety of ingredients such as sodium, barium, calcium, potassium, boron, arsenic, antimony and lead but there are many diverse compositions of materials that meet the definition of "glass".

Summarizing the role of lead (Pb) and cadmium (Cd) in glasses in scope of exemption 13(b) series, SPECTARIS et al. (2019) stated that lead and cadmium are added to optical glass batches used for the production of light filters where a well-defined slope in the absorption spectrum is required, such as a sharp cut-off within a narrow wavelength range. Both Pb and Cd are needed to ensure that there is a high percentage of light transmission at wavelengths above the "cut off" and close to zero transmission below the cut off wavelength. Ideally, the separation occurs at a certain wavelength with 100 % transmission of the desired wavelength range and 0 % for undesired wavelength side with an infinitely steep slope. In reality, these values are not achieved, but are implemented as far as possible.

SPECTARIS et al. (2019) provided a diagram to illustrate idealised shapes of transmission / wavelength curves for light passing through optical filters, reproduced in Figure 9-1.

Citing the applicants, Gensch et al. (2016) highlighted a key difference between ion coloured filter glasses (ex. 13(b)(I)) and striking filter glasses (ex. 13(b)(II)): Striking filter glasses provide uniquely steep slopes and an extremely high blocking effect, but due to their single edge only with a long pass characteristic. Band pass or band blocking filters require ion-coloured glasses, which have two edges. However, these edges are smooth rendering only a moderate separation capability.

Figure 9-1: Idealised shapes of transmission / wavelength curves for light passing through optical filters



Source: SPECTARIS et al. (2019)

SPECTARIS et al. (2019) summarized required properties of optical filters as follows:

- *Optical filters are required to block light of certain wavelengths and transmit light of other wavelengths. Ideally 100 % of the desired wavelengths are transmitted and 0 % of undesirable wavelengths are blocked. Also, the wavelength range between 100 % and 0 % transmission should be as small as possible.*
- *The function of optical filters needs to be independent of viewing angle.*

- *Optical filters should be robust and not easily damaged, such as by scratching, abrasion, heat or moisture.*
- *Precise control of light wavelength control is essential.*

13(b) Cadmium and lead in filter glasses and glasses used for reflectance standards

A technical description for exemption 13(b) was provided by Gensch et al. (2016).

13(b)-(I) Lead in ion coloured optical filter glass types

According to SPECTARIS et al. (2019) ion coloured optical filter glass makes use of the light absorption of ions of special elements such as iron, nickel, manganese, chromium, vanadium, cobalt and copper. The special absorption characteristic of a given ion in a well-defined glass composition depends not only on the metal ion itself but also on its environment of other ions to which it is bonded in the glass matrix. The environment is given by the base glass composition in the first instance. Secondly it varies considerably due to the amorphous character of glass, which contrary to crystals provides many different bonding distances and angles for the same type of ions. This variable environment causes absorption bands to broaden and hence leads to inferior filter properties with much less steep slopes. In order to obtain the best filter characteristics, the best environmental glass and the optimum ion content has to be found. A further remaining optimization possibility is to use more than one colouring ion as e.g. in the green filter glass VG9[70], where Cu^{1+}/Cu^{2+} and Cr^{3+} ions are used. This, however, puts even more stringent requirements on the base glass composition.

SPECTARIS et al. (2019) further elaborate that the colour of glass depends on the valence of the added metal ion and on its surrounding glass matrix ions. So, there is not much freedom for choice of a metal ion / glass matrix combination for best performing glass filters. The green glass filter VG9 is the last remaining regularly manufactured type of a family of VG glass coloured with chromium III and copper II ions in a lead silicate glass matrix. It is the only green filter glass type in a portfolio of 58 glass types. Its usage is with about 400 kg / year (very low). Chromium III and copper I ions added to lead-free glass matrices do not give the same light filtering properties so are not suitable replacements. One application of lead-based optical filters is in fluorescence microscopes to transmit only the desired wavelengths. This needs to be independent of viewing angle. Although only one type of filter (VG9) is made as a standard product at present, it is conceivable that a use may arise from an equipment manufacturer who has no alternative to using a type of lead glass filter that is not currently produced as a standard product and so this material will need to be covered by this exemption 13b.

Just like all optical filters, band pass filters, such as VG9, should have very steep edges for the separation of the desired transmitted light from the undesired light which is to be strongly blocked. SPECTARIS et al. (2021b) further added that "The lead content is necessary to have sufficient high ratio between blocking and transmittance."

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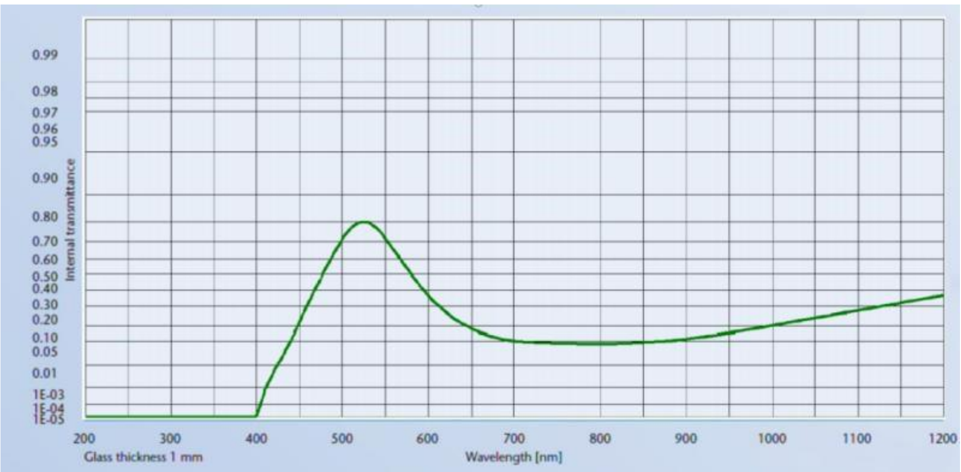
[70] VG9 is the name for a commercial product manufactured by the company SCHOTT, with 'V' denoting 'verde', the greenish colour of the filter glasses. For details see the product page: https://www.schott.com/shop/advanced-optics/en/Matt-Filter-Plates/VG9/c/glass-VG9 [accessed 15 September 2022, the consultants

Figure 9-2: Light transmission / wavelength curve for VG9 optical filters



Source: SPECTARIS et al. (2019)

SPECTARIS et al. (2019) provided further insights as follows: With metrology applications, false light coming from wavelength ranges which should be blocked off but still have some residual intensity due to the smooth edges will reduce signal to noise ratio and thus give inferior accuracy and poor image quality. The task in developing such glass is to find compositions leading to the steepest possible slopes and the highest light transmission. Mineral filter glass consists of a base glass and colouring chemical elements. As stated above, in the case of VG9, only copper II and chromium III in combination with leaded base glass give the required performance. In different base glass, the absorption bands of these colouring agents will shift in position and vary in width. For VG9 the optimized base glass is a silicate glass with 15 % lead oxide in its composition. Other variants will decrease the quality of the filter characteristics.

Application examples of the VG9 glass described by SPECTARIS et al. (2019) include:

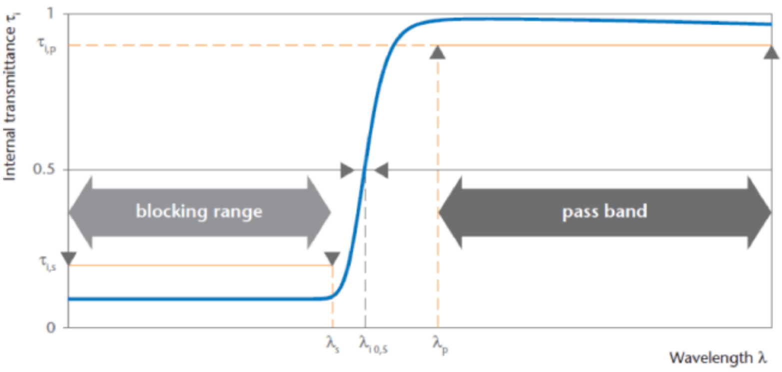
- *Colour image recording: Several of the above examples which record colour images (colour TV) require steep edge filters to split the visible spectrum into several colour channels each of which are recorded separately. This requires that the filters have the steepest edge possible and that they are not affected by viewing angle. This combination of properties is achievable only by optical glass filters based on cadmium and lead.*
- *Colposcopes are used to examine inside the cervix to look for abnormalities. The instrument is essentially a low power binocular microscope, but the illumination light is filtered to use in particular a green colour. This enables blood vessels and any abnormalities to be visualised. Lead glass filters (such as VG9) need to be used to ensure that the transmitted green light wavelengths are stable. Lead has a dual function of providing the required optical properties and of lowering the glass melting point so that the added green pigments are stable.*

13(b)-(II) Cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex[71]

SPECTARIS et al. (2019) explained that striking optical filter glass is made by adding about 1 % of cadmium compounds to molten glass. In the first stage they are colourless clear glass types. By precisely controlled heat treatment (the so-called striking process) cadmium chalcogenide microcrystals are grown. Their semiconductor band gap renders the desired long pass filter characteristic with a very steep slope and high blocking of the short wavelengths. By changing the heat treatment parameters, i.e. temperature and time, it is possible to control the crystals' size and thus the cut-off wavelength. SPECTARIS et al. (2019) further added that as well as giving a steep edge, cadmium compounds give very low transmission at wavelengths shorter than the steep edge and very high transmission at longer wavelengths. This is important for many applications as this prevents image distortion effects such as "flare" (stray light) and "ghosting" (a second feint image).

SPECTARIS et al. (2021b) provided an illustration of the definition of a long pass filter, where longer wavelengths can pass the filter and shorter wavelengths are blocked, reproduced in Figure 9-3.

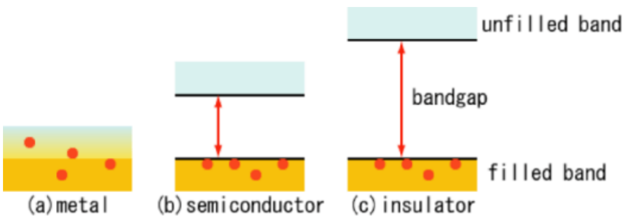
Figure 9-3: Visualization of the long pass filter definition



Source: SPECTARIS et al. (2021b)

Providing further technical detail, SPECTARIS et al. (2019) explain that the steep slope effect is based on the semiconductor electron band gap characteristic of the microcrystals formed by the cadmium compounds, illustrated in Figure 9-4 below.

Figure 9-4: Difference in electronic structure of metals, semiconductors and insulators



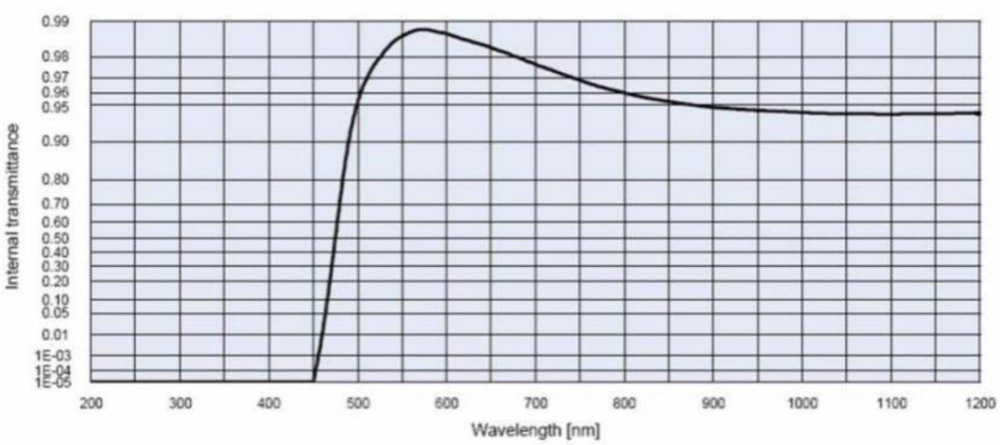
Source: SPECTARIS et al. (2019)

[71] Exemption 39 was replaced by exemption 39(a) as published in the Official Journal of the European Union on 7 August 2017. Exemption 39(a): Cadmium selenide in downshifting cadmium-based semiconductor nanocrystal quantum dots for use in display lighting applications (< 0,2 µg Cd per mm2 of display screen area).

In order to cross the bandgap, electrons must have energy that is higher than the threshold value given by the bandgap's width. For the glass type GG495 for instance, this energy lies at 2.5 eV (electron volts). All light with higher energy will be strongly absorbed. Just below this energy electrons cannot surpass the bandgap and so light will be fully transmitted because the energy of visible light radiation is dependent on its wavelength. The cadmium chalcogenide semiconductor is unique in having the required bandgap energy and bandgap width to achieve the absorption edge wavelengths that are required (in the red/orange range) for the filter. Also, the precise absorption edge wavelength is adjusted by the temper (heat treatment) process that has been found to be unique in that it grows the cadmium chalcogenide particles to the desired particle size, which controls the cut-off wavelength of the filter.

SPECTARIS et al. (2019) further detailed that by adjusting the quantities of other constituents (sulphur, selenium and tellurium), as well as the temper process conditions, red, orange and yellow filters are produced with wavelength separation at well-defined wavelengths. Filter glass produced with cadmium are used to absorb wavelengths from ca. 400 nm. SPECTARIS et al. (2019) provided an example diagram showing the transmission properties of optical striking glass filter over a wavelength range, noting that the nonlinear y-axis scale is used for a better view of residual absorption and transmittance by stretching the extreme parts of the transmission scale, reproduced in Figure 9-5.

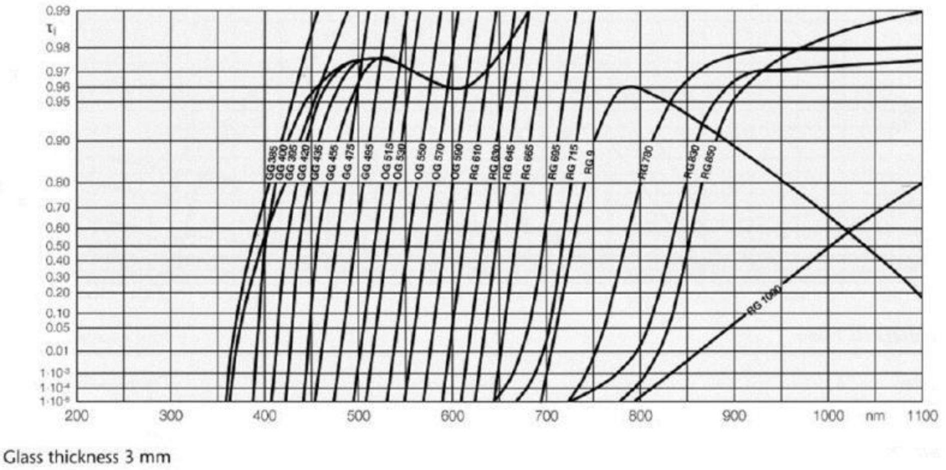
Figure 9-5: Absorption and transmission diagram of an optical striking glass filter



Source: SPECTARIS et al. (2019)

SPECTARIS et al. (2019) further explain that a red filter allows only red light to pass whereas an orange filter allows red and orange light to pass. An important characteristic of cadmium-based optical filters is the difference in optical filtering above and below the cut-off wavelength. Cadmium filters can be designed to absorb almost 100 % of light having wavelengths shorter than the cut-off value and transmit better than 95 % light with longer wavelengths. Furthermore, the range of wavelengths between 95 % transmission and < 1 % transmission can be designed to be relatively small, so that these filters are classified as "steep-edge" filters. Spectra obtained from optical filters that contain cadmium, manufactured by SCHOTT (Germany) are shown in Figure 9-6.

Figure 9-6: Optical transmission spectra of cadmium-based glass filters



Source: SPECTARIS et al. (2019)

SPECTARIS et al. (2019) note that a few of the curves above in Figure 9-6 have different shapes to achieve specific absorption profiles which are produced by adjusting the ingredients, a variety of metallic additives, but a steep cut-off as shown in this section can be obtained only by the use of cadmium compounds.

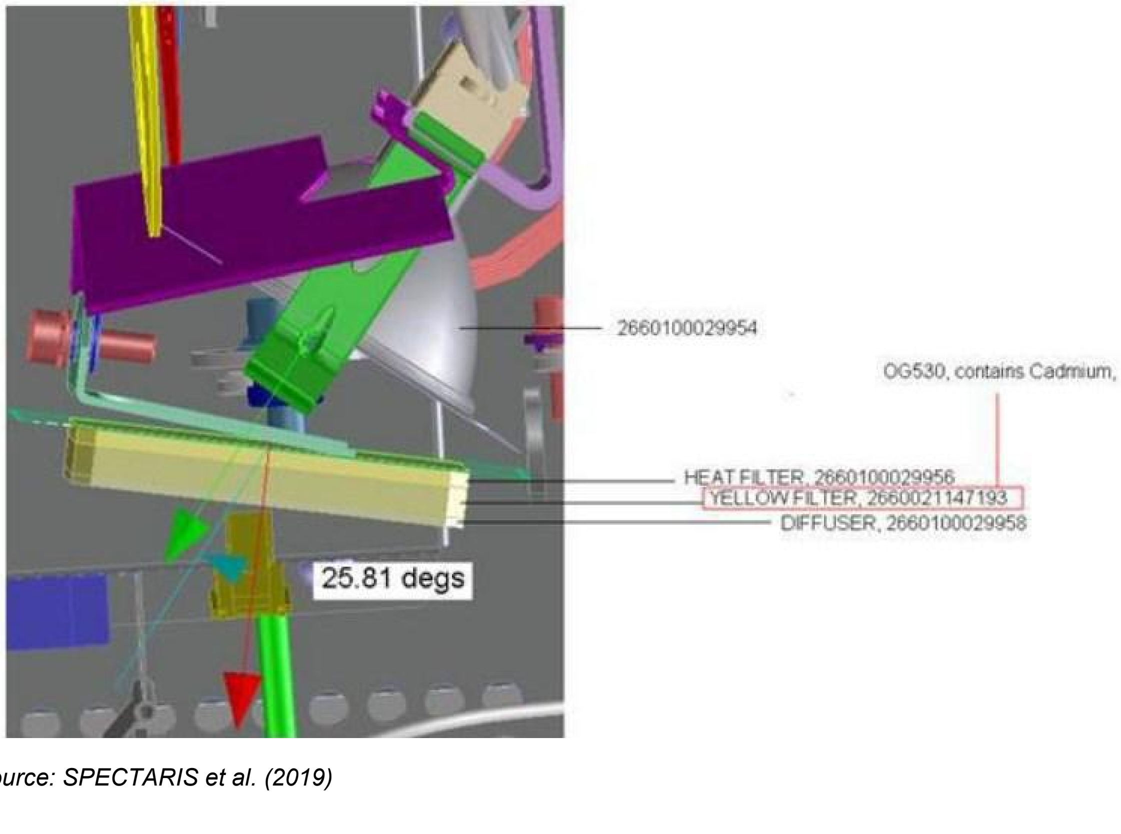
SPECTARIS et al. (2019) provided detailed descriptions of application examples that require cadmium optical filters, which are reproduced in the following.

- ***Colour image recording**: Several of the above examples which record colour images (colour TV) require steep edge filters to split the visible spectrum into several colour channels each of which are recorded separately. This requires that the filters have the steepest edge possible and that they are not affected by viewing angle. This combination of properties is achievable only by optical glass filters based on cadmium and lead.*
- ***Fluorescence spectroscopy** is an analytical technique that is used for analysis of some types of organic substances, molecular biology (e.g. cell and tissue analysis), medical research, cancer detection and other medical diagnostic procedures and industrial applications such as semiconductor analysis. All fluorescence techniques require optical glass with high percentage transmission at short wavelengths and fluorescence microscopes require many high-quality lenses that contain lead as well as optical filters that are independent of viewing angle. Fluorescence spectroscopy operates by exposing the sample to light of a preselected wavelength which can be ultraviolet or visible light. Some materials absorb this light and then emit light of a longer wavelength by fluorescence in all directions. The emitted fluorescence is detected for quantitative analysis, imaging or mapping, depending on the type of instrument used. Medical diagnostics, for example often use near Ultra Violet (UV) or blue/violet light to cause fluorescence and so a high percentage transmission of light at short wavelengths is essential.*
- ***Fluorescence microscopes** can be used to create images in which light is scattered by the object and so the optical filters must have a steep edge and be independent of viewing angle. Images are often made by staining materials with fluorescent dyes. The wavelength of light used to illuminate samples will have a different wavelength to the fluorescent light emitted by the dyes, but these two*

wavelengths are usually similar. If a white light source is used, steep-edge cut off filters are needed to remove light of wavelengths that are not required for inducing fluorescence and filters are also used to remove the input excitation light from the output fluorescent light. Examples of tests carried out with fluorescent dyes shows the small differences in wavelengths that need to be separated, for example, an orange-red dye is excited at 553nm to fluoresce at 569nm. Only cadmium-based filters have sufficiently steep edge filter properties at all viewing angles to separate these wavelengths.

- ***Humphrey field analyser (HFA) SWAP:*** *The patient's retina is illuminated with light of specific wavelengths to determine their response to coloured light. This technique uses two types of optical glass filters that contains cadmium (SCHOTT OG530 and RG850). The OG530 is a yellow filter that provides yellow background illumination. The HFA uses normative databases that are used to compare patient's visual field test results to an age-matched population. To use these databases, the optical spectrum from the optical filters must not change. Figure* 9-7 *below shows how the yellow filter is used. A cadmium-based optical filter is used so that the spectrum is the same irrespective of the angle between the lamp and the patient's eye. The RG850 optical glass filter is used to pass near infrared light from an 880nm light emitting diode (LED) and to block visible light. The purpose of the LED is to generate a reflex from the cornea and to illuminate the pupil to track the gaze of the patient. This filter is critical because it blocks the emission from the LED in the red part of the spectrum that would be visible to the patient and possibly could be mistaken for a stimulus. Cadmium-free dichroic filters cannot be used to reject visible light by reflection, because it would appear as a bright spot in the bowl instead of a dark spot, which could also confuse the patient into thinking a stimulus was presented, when it was not.*

Figure 9-7: Position of lamp and yellow filter in Humphrey Field Analyser



Source: SPECTARIS et al. (2019)

13(b)-(III) Cadmium and lead in glazes used for reflectance standards

According to Lucideon (2021a), ceramic colour standards manufactured and supplied by Lucideon Limited are optical reflectance materials that are used to calibrate and check the measurement performance of spectrophotometers and optical devices. They add that reflectance standards "are not sold by ourselves as a part of any instrument but as an accessory which may be momentarily held against the instruments measuring aperture/in the measurement path, before the instrument is used, and are usually stored in a separate box. The Colour Standards are usually sold as 5 cm or 10 cm squares, sealed into plastic trays with waterproof silicone sealant and are usually stored in protective cases to further protect them and prolong their lifetimes."

Lucideon (2021a) further explained that their reflectance standards do not change colour over time, unlike other materials. Colour standards are used to calibrate instruments at suitable intervals. If the results of the calibration measurements are unchanged between measurements, this proves that the instruments are still performing properly and that the results they give are correct. The colour standards are also used to determine the differences in measurements taken from different instruments so that colour can be communicated between them. In order to perform as colour standards, a range of colours is required that covers the colour gamut. Red and Orange are vital to this as their reflectance curves have steep slopes that are used by the instrument software to check reflectance values at certain wavelength.

Figure 9-8: Exemplary product examples for reflectance standards

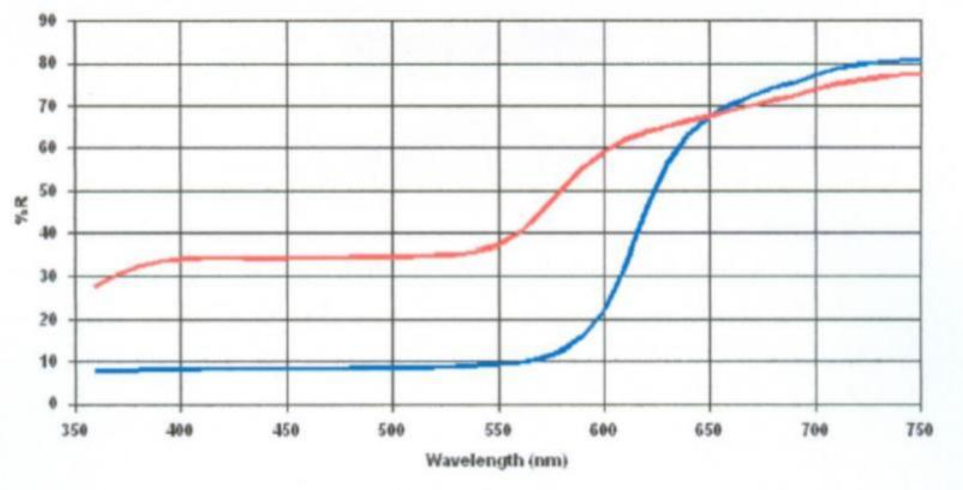
Source: Lucideon (2021b)

Lucideon (2021a) clarified that the glazes that Lucideon Limited uses do not require lead as all of the standards contained in the range of ceramic colour standards have eliminated this material. However, there are two standards which use cadmium-containing pigments to produce colours for which there is no suitable cadmium-free alternative. These two standards are the red and orange ceramic colour standards. The orange and red colour standards contain approximately 0.03 % of cadmium on a weight basis.

Lucideon (2021a) added that the functional part of the standards is a modified glass (glaze) which is bonded to a porous ceramic substrate by high-temperature heat-treatment. The standards have specific colours with the steepest reflectance slopes practically possible to provide a rigorous test of spectrophotometer performance, while remaining stable in colour.

The diagram reproduced in Figure 9-9 was provided by Lucideon (2021a) as illustrative example of reflectance curves with and without cadmium.

Figure 9-9: Comparison of cadmium reflectance curve (in blue) and an alternative without cadmium (in red)



Source: Lucideon (2021a)

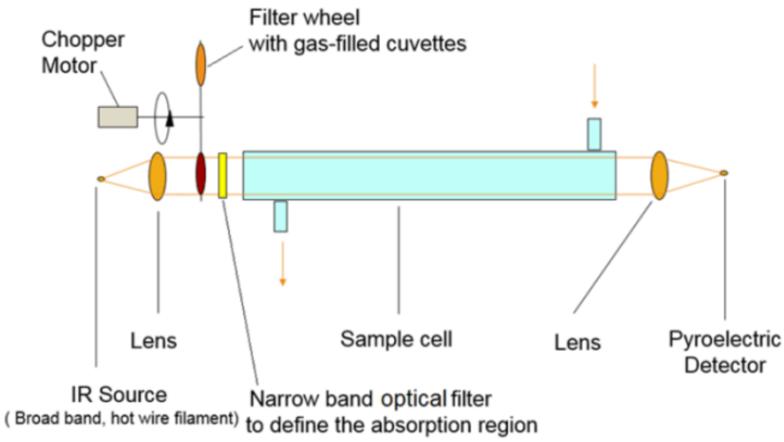
Addressing potential doubts whether reflectance standards are in fact in the scope of RoHS, Lucideon (2021a) stated that "Lucideon does not believe that our Colour Standards are part of an EEE as we supply them simply as Standards. However, some of our customers, who manufacture and sell spectrophotometers, do consider them to be part of an EEE as they supply the Colour Standards along with their spectrophotometers. As this is the case, we require an exemption so that our customers can use our products."

Infrared interference filters with lead compound coatings

SPECTARIS et al. (2019) provided a technical description as follows: Filters made from an infrared transparent material with thin coatings of lead compounds are used in instruments for accurate chemical analysis of trace concentrations (sub-ppm to 100 %) of gases such as sulphur dioxide (SO_2), nitrogen oxide (NO), carbon monoxide (CO), methane (CH_4) and nitrous oxide (N_2O) in air or in flue gases. These instruments analyse flue gases from boilers crematoria and from industrial processes to ensure that the concentrations of toxic gases (such as carbon monoxide) are as low as possible, and these data are used to control the combustion process conditions in real-time. These analysers are also used to analyse gases for trace impurities such as in compressed oxygen that is used for hospital patients. This type of analysis is difficult because analysis results obtained with most methods are affected by the presence of other gases that also respond to the analysis technique, so that the wrong composition information is obtained. For example, analysis of a few parts per million (ppm) of carbon monoxide in a gas containing many percent of carbon dioxide requires a technique that can accurately discriminate between the absorption wavelengths of these two gases.

Infrared spectroscopic analysis of gases is described below, which relies upon the use of lead containing interference filters. The analyser can selectively analyse single compounds in a gas mixture by selecting an appropriate wavelength using infrared filters which block other wavelengths. SPECTARIS et al. (2019) provided an illustration depicting an infrared gas analysis setup, reproduced in Figure 9-10.

Figure 9-10: Infrared gas analysis using lead-containing optical filters



Source: SPECTARIS et al. (2019)

SPECTARIS et al. (2019) added that the filters consist of a thin coating of a lead compound deposited onto an infrared transparent material (e.g. optical glass, silica, calcium fluoride, etc.). The choice of lead compound, substrate and the coating thickness determine the wavelengths where infrared light has a high percentage of transmission and different wavelengths are selected for each gas being analysed. As each gas absorbs infrared light at specific wavelengths, it is possible to design filters that are specific for analysis of one gas in a mixture of different gases, and the analysis results are not affected by other gases that absorb at different wavelengths, even if they are in close vicinity on the wavelength spectrum. Typically, these filters are designed to function in the 4 to 14 µm wavelength range.

SPECTARIS et al. (2019) further clarified that the infrared filters used for gas analysis have a different composition from other filter glass types relevant to exemption 13(b) series, as these are "interference" filters that utilise a thin coating of a lead compound deposited on an infrared transparent substrate. The coating material composition and thickness are chosen to achieve a high percentage of transmission in the desired narrow wavelength range in which infrared light transmission occurs. Various lead compounds are used for different gases being analysed including the oxide, sulphide, selenide, telluride and fluoride, with the compound choice dependent on the ability to transmit infrared light in the wavelength range required for the gases being analysed.

With reference to mid-far-infrared spectrometer using lead-containing optical filters, JBCE (2022a) added: „The filters consist of a thin coating of a lead compound deposited onto an infrared transparent material (e.g. Sapphire, Germanium, Silicon, Zinc selenide, Chalcogenide glass, etc.). The choice of lead compound, substrate and the coating thickness determine the wavelengths where infrared light has a high percentage of transmission and maximizing the required detection sensitivity in the mid-far-infrared band. Typically, these filters are designed to function in the 4 to 25 µm wavelength range." JBCE (2022a) added that these types of analysers are usually tailor-made for specific customers' requirement. The number of the unit place on the EU market is around a few units annually.

9.1.4. Amount(s) of restricted substance(s) used under the exemption

According to SPECTARIS et al. (2021a) "the market demand for lead-containing glass types has been stable since 2014" and from this, the production figures for exemptions 13b series can be derived. SPECTARIS et al. (2019) estimated that 192 kg of cadmium and 46 kg of lead are placed on the EU market annually due to exemptions 13(b) series.

In more detail, SPECTARIS et al. (2019) estimated the total weight of Pb- and Cd-filter glass placed on the global market to be 120 tonnes, of which approximately 40 tonnes annually enter the EU market. The cadmium proportion of filters varies from 0.4 to 1.8 % but on average it is closely to 0.4 %. Based on the global consumption of cadmium filter glass used in EEE in scope of RoHS, an amount of 480 kg Cd per year can be derived. The EU consumption of cadmium filter glass used in EEE in scope of RoHS is about 192 kg Cd per year. The lead proportion of filters varies from 0.3 to 60 % and on average it is about 13 %. Thus, for those lead-based filter glass types the EU consumption of lead used in EEE in scope of RoHS is about only 46 kg Pb per year (globally 115 kg). Filters coated with lead compounds for infrared analysis are used in small numbers in the EU with each filter containing only a few milligrams of lead (the coatings are typically 0.35 µm thick) and so much less than 1 gram of lead is used for this application annually.

When asked to explain how the 46 kg Pb per year were derived, SPECTARIS et al. (2021a) stated that calculations were based on data from SCHOTT and refer to specific data and weighted calculations. While information on the average lead proportion in filters (named 13 %) refers to the average per all related filter glass types, the calculation on the Pb equivalent (46 kg) is based on production data (produced glass, used lead oxide and derived lead equivalent) and assumptions on global production quantities analogously. By calculating based on weighted data, the result of stated Pb equivalent is significantly lower than calculating the 13 % of lead oxide of the glass tonnage (for clarification: lead oxide is used in powder batch preparations and the percentage data had been provided referring on the lead oxide share in %, since this had been the reported data of previous applications on the exemptions). On a global level, no data from glass-specific tonnage and references to applications are available. Accordingly, for the share of globally produced filter glasses the assumptions have been made on catalogue data and market studies as well as on literature about applications and glass research.

SPECTARIS et al. (2021a) explained the considerably smaller amount of lead which enters the EU market annually due to applications making use of exemptions in 13(b) series (46 kg Pb) when compared to exemption 13(a) (275 tons Pb) as follows: Optical glass in scope of exemption 13a is colourless glass used for a very wide variety of applications, some in significant quantities, whereas lead-based glass filters have fewer end uses, none of which require large quantities of these materials. In related technical applications a typical filter has dimensions of a few mm² and a thickness of a few mm, while optical glass applications have much bigger dimensions.

When asked, SPECTARIS et al. (2021a) further confirmed that lead used in infrared interference filters amount to less than 1 gram annually.

9.2. Justification for the requested exemption

9.2.1. Substitution and elimination of cadmium and lead

SPECTARIS et al. (2019) explained that filter glass and optical equipment manufacturers have already phased out filter glass types with cadmium and lead proportion wherever this has been possible. Most equipment manufacturers have already attempted to switch to cadmium and lead-free filter glass wherever possible because cadmium and lead-free substitutes have lower prices. In Japan, almost all glass manufacturers have stopped production of cadmium and lead containing filter glass since consumer optics, which is the by far largest market, does not require the special performance of these filters.

SPECTARIS et al. (2019) further stated that research has been carried out for many decades and alternatives to cadmium and lead are already used where these are suitable. A SPECTARIS member has carried out a keyword literature search of optical glass filter materials. Since the last renewal request, there were no publications referring to substitution. Specifically for the traffic lights, there was one publication with a suitable filter glass type, however, this is based on lead containing glass and/or with an unusually high level of arsenic – thus overcompensating the benefit of cadmium-free filter glass types and also not achieving the high percent transmission.

13(b) Cadmium and lead in filter glasses and glasses used for reflectance standards

The arguments provided by the applicants that justify the exemption for cadmium and lead in filter glasses were not provided separately for exemptions 13(b), 13(b)(I), (II) and (III). Therefore, the consultants separated the provided arguments into the following sections on 13(b)(I), (II), and (III). The sum of arguments provided for individual exemptions 13(b)(I), (II) and (III) are naturally relevant for 13(b).

13(b)-(I) Lead in ion coloured optical filter glass types

According to SPECTARIS et al. (2019), "only one type of filter glass is currently produced that contains lead and is used because of its unique combination of properties."

The following paragraphs reproduce information provided by SPECTARIS et al. (2019) on efforts to develop alternatives to lead in ion coloured filter glass types pertaining to exemption 13(b)-(I) as well as cadmium in striking filter glass types pertaining to exemption 13(b)-(II). As the applicants applied for all exemptions in the 13(b) series of exemptions, and exemption 13(b) itself includes both cadmium and lead in its scope, the applicants did not provide separate information on cadmium and lead in all cases.

According to SPECTARIS et al. (2019), glass manufacturers have in the last 30 years considered the entire periodic table to determine whether substitutes exist:

- *Alkali and alkaline earth metals – give colourless glass.*
- *Transition metals (except zinc, cadmium and mercury, see below) and rare earth metals - if these dissolve to form a glass, they result in coloured or colourless glass, but this depends on the valency state. If the valency changes, the colour also changes. Often, especially at higher concentrations, these metals ions cause crystallisation so that an opaque material is produced. Two transition metal ions are used in VG9 glass, but this unique material has the required performance only with*

lead silicate glass. A recent patent[72] describes red coloured glass that contains copper and neodymium oxides. Figure 2 of this patent shows that this does not give sharp cut-off as provided by cadmium chalcogenides.

- *Zinc, cadmium and mercury form chalcogenides with sulphur, selenium and tellurium. Only cadmium chalcogenides give red/orange/yellow coloured striking glass filters with steep edges (and requires small amounts of zinc to be present).*
- *Most transition metals (e.g. aluminium, indium, tin, bismuth) either do not form glass (so ceramics result) or if they do form glass, these metals dissolve without forming the fine semiconducting particles that give steep edge filtering of cadmium chalcogenides. Ternary chalcogenide glass types have also been investigated as described in Section 6 of the renewal application. Quaternary glass formulations are also being investigated and one recent patent[73] describes $Cu_2ZnSnSe_4$ in silicate glass. This glass appears to be an effective sharp cut-off filter in the as-annealed condition, but the cut-off wavelength is in the ultraviolet region and so is not a substitute for cadmium chalcogenides.*
- *Non-metals – these include sulphur, selenium and tellurium which are used in combination with cadmium. Phosphorous is used in colourless phosphate glass. Phosphides, antimonides and arsenides do not form transparent glass and react with acids to emit very toxic gaseous hydrides. The halogens tend to give materials that are water soluble and are usually colourless.*
- *Gaseous elements: Hydrogen – occurs in hydroxides, these are water sensitive and usually crystalline, oxygen is used in most optical glass, nitrogen occurs as nitrides but these are usually not transparent, and the noble gases are unreactive and do not form glass.*

SPECTARIS et al. (2019) note that the above list only leaves the radioactive elements which are unsuitable and add that combinations of all the elements in the periodic table have been evaluated and only cadmium gives all of the essential characteristics for the applications where these filters are currently used.

13(b)-(II) Cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex

According to SPECTARIS et al. (2019), there are three alternative types of optical filters that are used for some applications, but these cannot replace cadmium-based optical filter glass where the essential characteristics of cadmium filters are required. These substitutes are (i) alternative additives in glass, (ii) coatings on glass and (iii) coloured "plastic" filters. The applicants provided detailed discussions on each option, reproduced in the following sections.

(i) Alternative additives in glass

SPECTARIS et al. (2019) described that cadmium plus sulphur, selenium and tellurium are added to glass to make a material that contains micro particles of cadmium as mixed

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[72] US 9,061,939 B2, June 2015, „Red-dyed glass and method for producing same".

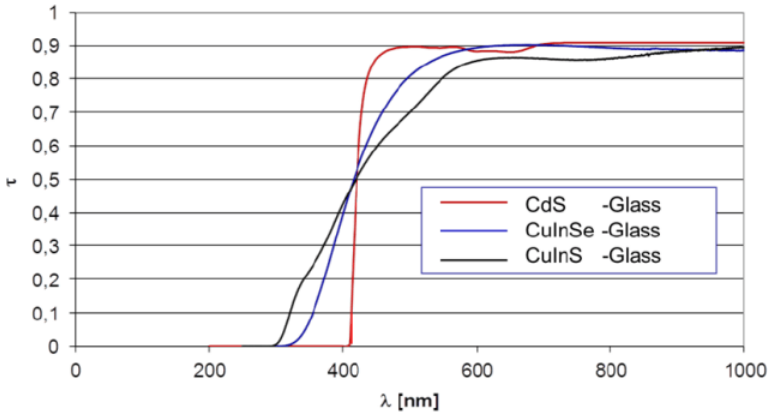
[73] US 9,650,287 B2, May 2017, "Visible light and infrared light transmitting optical colored glass, composition thereof, and preparing method thereof".

sulphide, selenide and telluride (as $CdS_xSe_yTe_z$ where x, y and z range from 0 to 1 and x+y+z =1) in the glass matrix. The cut off wavelength is regulated by the ratio of these elements as well as by the heat treatment conditions. The exact form of the cadmium compound is unclear but can be seen as very small particles in a colourless matrix, so it is not a colloidal dispersion. To obtain the same optical properties, alternative inorganic compounds would be needed that are thermally stable at the melting temperature of the types of glass used (therefore organic pigments cannot be used) and gives the same optical spectrum with the same steep edge. Research has been carried out for many decades to look for alternatives to cadmium, but with no success. The range of elements and their combinations that are suitable is limited as explained here:

- *Industry is limited to the ca. 90 naturally occurring non-radioactive elements of the periodic table. The additive must be a compound with two or more elements which must be at least one metal and to match the performance of cadmium, also at least one non-metal.*
- *The compound must be coloured which eliminates many metallic elements. Many of the transition metals and rare earth metals will colour glass but none give the same optical characteristics (all combinations have been tested, see also the listing provided for ex. 13(b)(I) on p.196).*
- *Non-metals could be O, N, S, Se, Te, P, As or Sb. Halides are unsuitable as they are either water soluble or too unstable and so cannot be combined with molten silicate glass.*
- *The compounds that are suitable must disperse in molten glass without causing crystallisation of the glass (this would destroy the optical properties) and form clear transparent glassy materials. The coloured phase particles that are firmly bound within the glass matrix must be so small (much smaller than 1 micron particle diameter) that the glass is clear and transparent.*
- *Research has found that a few compounds can be used as coloured glass additives which are either combinations of group II metals with group[74] VI non-metals (i.e. II-VI compounds such as CdS) or group III metals with group V non-metals (i.e. III-V compounds such as GaAs). However, very few of these compounds are yellow, orange or bright red with sharp wavelength cut-offs.*
- *Most coloured compounds that can be added to glass give different colours to cadmium. For example, nickel compounds are green, cobalt compounds are blue, iron are dull red or brown, mercury (as sulphide) is pink, etc. Compounds with three or more elements have also been evaluated such as CuInSe (a II-III-VI compound), but these also do not give the required steep edge cut-off, as shown below in Figure* 9-11*. The diagram illustrates that CdS glass has a far better filter effect than CuInS or CuInSe glasses.*

[74] Refering to the groups in the periodic table of the elements.

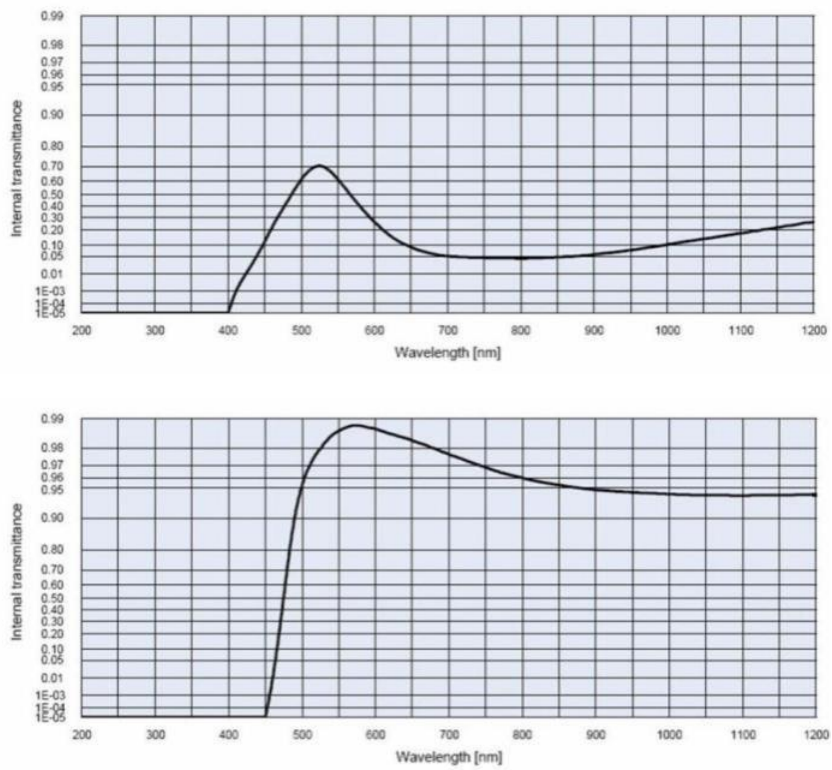
Figure 9-11: Optical transmission spectra of coloured filter glass (25 mm thickness) comparing slope shapes of CdS, CuInS and CuInSe



Source: SPECTARIS et al. (2019)

According to SPECTARIS et al. (2019), metal ion coloured glass is another alternative type of coloured glass filter where metal ions (usually transition metals) are inserted into the glass matrix to colour the glass. In the typical example shown in Figure 9-12, Cu+/Cu2+ and Cr3+ ions are added to the glass, but the spectra are very different to those of cadmium steep edge filters".

Figure 9-12: Spectra of ionically coloured glass (top) compared with cadmium glass (bottom)



Source: SPECTARIS et al. (2019)

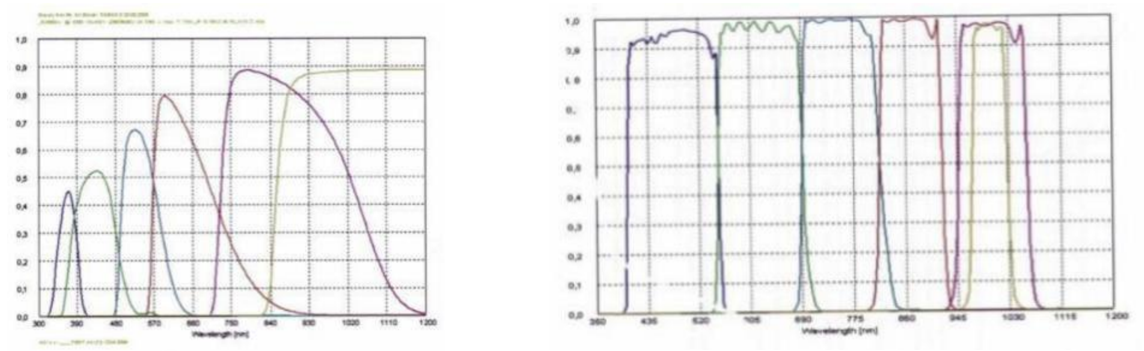
According to SPECTARIS et al. (2019), Figure 9-12 shows that ionically coloured glass types have different shaped spectra to cadmium based glass with lower light transmission at longer wavelengths and the slope of the curve of the metal ion coloured glass is shallower than the steeper slope of the cadmium filter.

Describing another potential alternative, SPECTARIS et al. (2019) refer to colloidal dispersions. Colloids are produced by several metal sulphides such as Pb, Sb, Cu, etc. and also by metals such as gold and silver. Coloured glass including ruby red colours can be obtained by adding substances to glass which form colloidal dispersions. The colloid's particle size controls the colour by light diffraction, but colloids do not give sharp wavelength cut-offs, so are not suitable alternatives to cadmium compounds. Striking glass types with cadmium are not colloidal dispersions and so the colour of the individual particles is important for the optical characteristics. A steep edge cannot be obtained by colloidal dispersions that are red in appearance and research has shown that the steepness of the absorption edge increases during heat treatment, and the steepness is a characteristic of the cadmium chalcogenide particles. Alternative sulphides such as antimony, lead, copper, etc. can give ruby red glass, but these all form dispersions of colloidal particles and the glass does not exhibit the steep edge obtained only by cadmium compounds. 3d metals [transition metals] such as Fe, Mn, Ni, etc., when added to glass dissolve in the glass to form ionic complexes within the matrix. The colour depending on both the metal ion and the structure to which it is bonded. These all however have shallow absorption edges unlike cadmium filters.

(ii) Thin film coatings on transparent substrates for interference filters

SPECTARIS et al. (2019) described that interference, or dichroic filters, are quite widely used for certain applications but their properties are very different to glass filters based on cadmium compounds. Their main characteristic is that they absorb light within a specific but rather narrow wavelength range with sharp cut-offs at both ends of this wavelength range. Spectra of light that have passed through this type of filter are quite different to spectra obtained with cadmium glass filters as shown in Figure 9-13.

Figure 9-13: Spectra of interference coated filters with coloured glass filters



Left: Spectra of coloured glass filters, the two at the right contain cadmium (RG9 and RG850);
Right: Spectra of five types of interference coated filters

Source: SPECTARIS et al. (2019)

According to SPECTARIS et al. (2019), interference filters are also viewing angle dependent and can give "ghost" images. Describing a specific example for an application where this is a problem, SPECTARIS et al. (2019) refer to Humphrey field analysers (HPA), tools commonly used by optometrists, orthoptists and ophthalmologists for measuring the human visual field: Dichroic filters cannot be used instead of the yellow filter because changes in viewing angle affect the transmitted spectrum and any change means that the normative databases cannot be used to determine if the patient is suffering from early stages of glaucoma or other conditions. The light source used is a halogen lamp which gives light with a range of incident angles. The light spectrum transmitted through a cadmium-

based optical filter will always be the same, whereas spectra of light transmitted through dichroic filters varies with angle of incidence. This will be the same if the filter is placed parallel with the lamp's face as the angle of incidence will span 20˚. Dichroic filters cannot be used as alternatives to the RG850 filter to reject visible light by reflection because it would appear to the patient as a bright spot instead of a dark spot, which could confuse the patient into thinking a stimulus was presented when it was not and give erroneous results.

Besides interference or dichroic filters, SPECTARIS et al. (2019) describe coloured coatings as potential alternative: If inorganic compounds are used as coatings onto glass, unless the coatings are based on cadmium compounds, the steep edge properties described above cannot be achieved. Organic pigment coatings are inferior because they fade when exposed to ultraviolet light and all thin coatings are easily lost by abrasion.

(iii) Transparent plastics with organic pigments

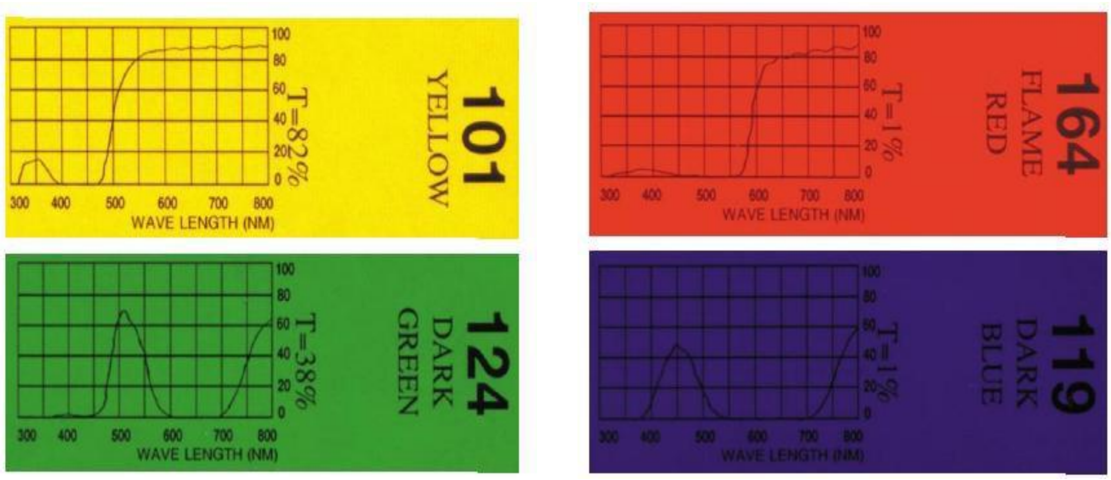
Discussing the third potential alternative to cadmium-containing striking optical filter glass types, SPECTARIS et al. (2019) explain that transparent plastics with organic pigments are used as optical filters and have advantages and disadvantages, but these disadvantages make them unsuitable for many applications. The addition of organic dyes and organic pigments to molten glass is impossible as all are thermally unstable at glass melting temperatures. Only heat stable inorganic compounds such as the cadmium chalcogenides (e.g. CdS/Se) can be used. Coloured organic compounds can, however, be added to a few types of transparent non-crystalline plastics such as acrylics, to give clear coloured transparent plastics without decomposition of the coloured substance. Achieving optical clarity is however not possible for all combinations of coloured compounds and polymers. Most polymers are available only as opaque materials, and most pigments will not dissolve so give opaque dispersions. Optical transparency requires that the pigment either dissolves in the polymer, so is present as discrete molecules, or that the particle size is sub-micron and smaller than the wavelength of visible light, so that they are not visible to the human eye. Coloured transparent plastics are however used for low-end optics (e.g. children's toys) where high performance is not required.

SPECTARIS et al. (2019) list the main disadvantages of optical plastics as follows:

- *Plastics are easily scratched.*
- *They are affected by humidity as all plastics absorb water from humid air.*
- *They are affected by high temperatures (distort, degrade, change colour). Optical filters are used with lamps that can become very hot as well as with laser light sources that heat the filter. Apart from heat transmitted by the lamps, most filters function by absorbing light of certain wavelengths and transferring the absorbed energy into heat.*
- *Organic pigments fade when exposed to ultraviolet light and polymers are also affected causing colour changes. Brittle fracture may also occur when exposed to UV light.*
- *Image quality tends to be poor as the surfaces of plastic filters are easily warped, so are not optically flat.*
- *Some polymer filters with organic pigments have relatively poor maximum transmission percentages at wavelengths of light that should pass through the filter.*
- *Some polymer filters transmit light at wavelengths where light needs to be blocked.*

An example of the spectra of four commercial cadmium-free plastic filters was provided by SPECTARIS et al. (2019), reproduced in Figure 9-14. According to the applicants, the diagrams show that the slope is not as steep as Cd-containing filter glass and transmission is significantly lower. In the red spectrum, the slope is much less steep than with cadmium based optical glass filters as shown in Table 9-1.

Figure 9-14: Spectra of light transmission for commercial plastic filters



Source: SPECTARIS et al. (2019)[75]

Table 9-1: Comparison of yellow 101 plastic filter with SCHOTT glass filter GG495

Transmission %	Yellow plastic (nm)	SCHOTT GG495 (nm)
20	489.6	490
40	500	495
60	510.4	499
80	541.7	505
20 to 80 % range	**Over a range of 52.1 nm**	**Over a range of 15nm**

Source: SPECTARIS et al. (2019)

SPECTARIS et al. (2019) describe another polymer-based alternative: Several types of "gel filters" are used for photography and other applications. These include polyester gel filters and the Kodak Wratten range of coloured filters. These are made of gelatine with organic dyes so will fade in sunlight, they will readily absorb moisture (and distort) at high ambient humidity and as gelatine is a protein, they will be affected by a wide variety of chemicals such as oils, fingerprints, etc. and are prone to degradation by micro-organisms. Gel filters are also heat sensitive so cannot be used with hot lamps or at high ambient temperature and being relatively soft, they are easily damaged.

[75] SPECTARIS et al. provided the following link to the original source of the diarams, which they had accessed in May 2019, but it is no longer accessible at the time of writing: https://www.eventtechnik3000.ch/VARYTEC-Farbfolie-gelb-101

Table 9-2: Comparison of glass and plastic materials for filters

Property	Glass filters	Plastic filters
Tolerance (i.e. variation in characteristics of commercial lenses)	Low (±0.0001) can be achieved, so variation is very small	Estimated at ±0.001
Abbe number	Broader range (20 to >80) especially to low dispersion values	23 – 58 is possible
Transmittance of unfiltered light (through 3mm)	>99 % achievable	85 – 91 % typically
Density	Lead-based are ca. 5 g/cm3. This offers advantages and disadvantages	1 – 1.2
Water absorption	Zero (so moisture has no effect on performance)	All plastics absorb water causing changes to properties (as they swell) and potentially degradation can occur. From 0.01 % to 0.3 %
Thermal expansion	CTE(-30°C; +70°C) = 5.1 - 11.9 x 10^{-6}/K	Range is 47 to 80 x 10^{-6}/K. This causes optical changes with temperature and thermal degradation
Refractive index thermal dependence	Smaller range of - 0.7 to + 1.2 x10-5/˚C	-8 to -14 x 10^{-5}/˚C
Resistance to damage	Relatively hard so not easily damaged	Soft so easily scratched
Exposure to UV light	No effect	Organic pigments fade and plastic discolours and degrades
Heat	Resistant to temperatures created by lamps and laser light sources	Lamps and lasers can easily cause deformation or even make holes

Source: SPECTARIS et al. (2019)

Regarding hardness of the material, SPECTARIS et al. (2019) stated that the methods usually used to measure the hardness of glass and plastic materials are not the same and so comparative data is not published. However, Spectaris has arranged for three plastics that are used for plastic lenses to be measured for "Knoop hardness" (0.1 kg weight and 20 seconds indentation, 5 measurements per sample), which is the standard method used for brittle materials such as optical glass. These measured values are compared with the values for glass published by SCHOTT in Table 9-3.

Table 9-3: Knoop hardness of selected plastics and of optical glasses for optical filters

Material	Knoop hardness (Pascals)
Polycarbonate	Measured at 13.2 ± 0.2
PMMA	Measured at 22.4 ± 0.1
Polydithiourethane (used for spectacle lenses)	Measured at 14.0 ± 0.1
Lead-based glass SF57	350
Lead-based glass SF11	450

Source: SPECTARIS et al. (2019)

SPECTARIS et al. (2019) concluded that it is clear from these results that plastic filters will be much more easily scratched than glass filters. Scratches will cause light scattering which has a detrimental effect on most of the uses of cadmium-optical filters.

13(b)-(III) Cadmium and lead in glazes used for reflectance standards

Lucideon (2021a) stated that all of the standards are now lead-free and most of them have eliminated cadmium. Cadmium has only been used where no suitable alternative is available. The cadmium-containing pigment is encapsulated in an inert zirconium silicate (otherwise known as zircon, which is often used as a replacement for diamonds because it is so inert chemically) crystal. The inert zirconium silicate crystals are encapsulated in the homogeneous glass matrix, which no longer includes lead oxide. The glass surface does not come into contact with people during normal usage.

Lucideon (2021a) further explained that it is possible to produce red or orange coloured glazes or plastic without cadmium. In glaze, the steep reflectance slopes required cannot be achieved without a cadmium-containing pigment. In addition, the alternatives often have complex reflectance curves which make results from such standards hard to interpret in terms of instrument performance. In plastics, the organic dyes used will produce steep reflectance curves, but they are unstable and bleach (lose their colour) under the UV component of the spectrophotometer illuminating light.

Finally, Lucideon (2021a) stated that the Lucideon Ceramic Colour Standards have been proven not to change colour over time (referencing a publication[76]) and many are still being used or stored in laboratories around the world. They are seldom disposed of unless damaged beyond use by mistreatment.

Infrared interference filters with lead compound coatings

According to SPECTARIS et al. (2019), interference filters with thin lead compound coatings are used because the lead compounds have one of the highest refractive index of coating materials and also give very good blocking properties outside of the transmission wavelength range. This means that they allow only a relatively narrow wavelength range to pass and block higher and lower wavelengths. Using a coating material having a high

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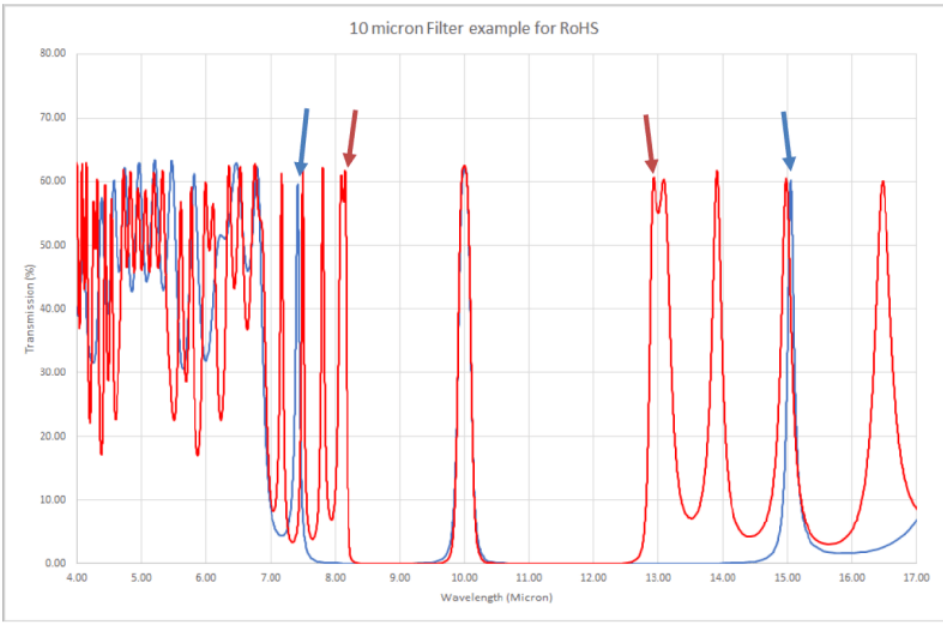
[76] Stability of Ceramic Color Reflectance Standards; Hugh S. Fairman, Henry Hemmendinger, Received: 11 August 1997, 13 May 1998.

refractive index gives the steep cut-off that is required to avoid interference from other gases. Also, this can be achieved by using one coating layer on the substrate. The use of multiple layers has been considered, but this introduces defects such as marks, splits and scratches which reduce transmission and result in poor yields as sub-standard filters become waste. Also, each filter typically allows through 70 – 80 % of light in the required wavelength range and so if more than one filter is used, this significantly reduces the percentage of light passing which reduces the sensitivity and accuracy.

SPECTARIS et al. (2019) further explain that an undesirable property of interference filters is that they also transmit light at wavelengths other than the main transmission wavelength and these are called "sidebands". Ideally the sidebands should be as far away from the main transmission peak as possible because they need to be blocked by other filters. As all filters typically give a "bell-shape" curve, if the sidebands are close to the main peak, the filters can also block some of the required wavelengths, thereby reducing sensitivity. The small signals obtained by spectroscopic analysis methods always experience some signal noise and so it is important that the signal from the transmission wavelengths is as strong as possible, despite the very low gas concentrations being detected. Any change that reduces signal strength will reduce performance because it decreases the signal to noise ratio. Research with lead-free coatings, such as germanium, shows that these sidebands are at wavelengths that are much closer to the desired transmission wavelength than with lead compounds. An example is shown in [Figure 9-15]."

SPECTARIS et al. (2019) explained that Figure 9-15 shows the transmission spectra of lead telluride interference filter (blue line) and a germanium transmission filter (red line). The arrows indicate the closest primary sidebands to the main transmission wavelength.

Figure 9-15: Transmission spectra of lead telluride (blue) and germanium (red) coatings



Source: SPECTARIS et al. (2019)

The applicants provided a data table listing the wavelengths of the closest sidebands in a table reproduced in Table 9-4. According to SPECTARIS et al. (2019), a larger gap is desirable, as well as the refractive index, where a higher value is also desirable.

Table 9-4: Sideband wavelengths of lead telluride and germanium coatings

	Lead telluride coating		**Germanium coating**	
Refractive index at 10µm	5.6		4.25	
First Order Sideband wavelengths	7.4µm	15µm	8.25µm	13µm
Δ from 10µm	2.6µm	5.0µm	1.75µm	3.0µm

Source: SPECTARIS et al. (2019)

Regarding possible substitutes to lead-containing coatings, SPECTARIS et al. (2019) stated that manufacturers have carried out extensive research to obtain the highest sensitivity and accuracy because these analysers are used to detect trace concentrations of toxic gases so that emissions of these can be prevented. Alternative coatings and changes to the analyser design have been considered. Research has found that lead compounds have the highest refractive index of the materials that transmit at the required infrared wavelengths and so because of the sideband issue described above, they give the best sensitivity and can detect lower gas concentrations than other filter materials.

JBCE (2022a) added that, besides interference filters for infrared gas analysis, the above also applies to mid-far-infrared spectrometers. The reason why lead cannot be avoided in mid-far-infrared spectrometers is the same as that of the measurement of gas concentrations described above.

9.2.2. Roadmap towards substitution or elimination of cadmium and lead

According to SPECTARIS et al. (2019), since RoHS took effect in 2006, no candidates for substitution cadmium or lead in steep-slope filter glass has been discovered, even though the search for a cadmium-free and lead-free replacement with the same filter properties was started latest around 1990. The application of these glasses was always restricted to niche uses with especially high-performance requirements. Manufacturers do not publish the quantities of cadmium / lead filter glass produced annually, so it is not possible to determine whether any decrease has occurred with any accuracy. If there has been an influence by RoHS1 on quantities produced, this has not been observable separately from year-to-year fluctuations.

In addition to the descriptions of research into potential substitute elements provided by SPECTARIS et al. (2019) and reproduced under section 9.2.1 starting on p.196, the applicants provided further information reproduced below, with a focus on cadmium and therefore exemptions 13(b) and 13(b)-(II). Information on reflectance standards pertaining to exemption 13(b)-(iii) was provided separately and is reproduced separately further below.

Roadmap

SPECTARIS et al. (2019) mentioned recently patented quaternary $Cu_2ZnSnSe_4$ in silicate glass, which appears to be an effective sharp cut-off filter. When asked where the applicants see applications for this filter glass, SPECTARIS et al. (2021a) stated that *"The patent does not mention possible uses for filters made with this material which is not commercially available. This type of filter could not be used as a substitute for filters in scope of 13b because it does not block 100 % of light at wavelengths above the cut-off value, only 90 % according to the patent."*

Actions to develop further possible alternatives (substitution)

According to SPECTARIS et al. (2019), the cadmium compounds used are semiconductors present as specific size particles. The semiconductor properties, such as band-gap, etc. cannot be matched by different semiconductors, and the ability to form dispersions of the correct particle size in glass is difficult to achieve as most materials either dissolve or remain as colloids. Therefore, it has not been possible to replace cadmium compounds in striking glass with cadmium-free alternatives.

SPECTARIS et al. (2019) add that at this time, the mechanism by which cadmium compounds create the steep edge in glass is not fully understood which makes the development of substitute materials difficult. Ruby red glass can be made using cadmium-sulphide-selenide (chalcogenide glasses) or with colloidal dispersions of many substances with suitable particle size, but only chalcogenides gives the optical steep edge effect. Research has shown that the sharp edge of cadmium filter glasses is due to electronic excitation of electrons in cadmium chalcogenide crystals within the glass and that the edge can be steepened by heat treatment which enhances this effect. Simple light scattering by colloids does not do this. Steep edge light filtration by cadmium chalcogenides therefore depends on the energy levels of the valence and conduction bands of the atoms in the molecule as well as the bandgap. Research with alternatives to cadmium that give similar red colours also does not give steep edges and this appears to be because these are colloidal (their colour is dependent on particle size as this affects light scattering and diffraction). Colloidal substitutes do not form the necessary small semiconducting crystals that are formed by heat treating cadmium chalcogenides in glass. Therefore, so far it has not been possible to identify a substitute to cadmium that has the same steep edge property, and this may never be possible as no alternative metals have the needed combination of energy levels and ability to form the correct size crystals dispersed in a transparent glass.

Potential for elimination

According to SPECTARIS et al. (2019), an example substitution option considered in the past is dichroic filters. These have been used by equipment manufacturers to replace cadmium filters in those applications where this has been technically possible and viewing angle is not an issue. There is a financial incentive for equipment manufacturers to replace cadmium filters with dichroic filters (or coloured glass and plastics) where this is possible because dichroic filters and coloured glass and plastic are cheaper that cadmium filters. However, for the reasons explained in Section 6 of the renewal request form (cf. section on 13(b)-(II) on in section 9.2.1 in this report), this is not always an option.

The only other possible alternatives in these applications would be completely different designs of optical equipment but, so far, alternatives have not been developed for the applications described in this renewal request and other applications that require cadmium and lead filter glass. It is also not possible to envisage alternative designs of equipment that would provide the same function and performance without these filters, so research timescales cannot be planned. Therefore, no substitutes are likely to be developed in the foreseeable future and so at least the maximum validity period is required for this exemption.

Coated filters are also cheaper than coloured glass filters and cadmium glass filters and they can be used in applications where transmissive sidebands and the angular dependence of coated filters are acceptable.

Plastic filters are also much cheaper than coloured filter glasses and are used when filter function tolerances are not stringent and visual colour perception is a more important aspect *than strict wavelength separation. Plastic and coated filters can block unwanted light only to residual transmission of about 1 %. If this is acceptable, they may be used instead of cadmium filter glasses, which block unwanted light to 0.000001 % and below. This very high blocking is needed in applications where safety and reliability is essential. An example where substitution has occurred is for amateur photographic camera filters where it can be expected that image processing software can imitate a filter's effect so that amateur photographers may have bought less yellow orange and red optical glass filters in recent years than previously. However, professional users with higher image quality requirements, this trend may not be the same because if an image is distorted because the cut-off-edge was not sharp enough, digital processing software will not achieve the image quality that would be achieved with cadmium (or lead) optical filters. Cheaper substitutes will already be used where this is possible and so cadmium filters are used only when substitution is not technically possible.*

Timeframe for substitution

Referring to the timeframe for substitution or elimination of cadmium-containing filter glasses, SPECTARIS et al. (2019) explained that during the last 30+ years, research into how striking glass filters function and substitutes for cadmium has been carried out as described above. Substitution by cheaper dichroic filters or coloured glass and plastics has already been carried out where this is possible by equipment manufacturers. Therefore, the current situation is that there do not appear to be any further combinations of elements from the periodic table to evaluate. A variety of alternative composition and production methods have been evaluated by one Spectaris member, but none produced a filter with the essential performance properties achieved by cadmium filter glass. It is therefore very difficult to estimate timescales for substitution. Based on current knowledge, substitutes will not be identified in the next 10 – 20 years.

Reflectance standards

Referring to reflectance standards, Lucideon (2021a) explained that lead has been successfully phased out. Only the orange and red colour standards in their portfolio still require the use of cadmium. Regarding opportunities to phase-out cadmium from reflectance standards, Lucideon (2021a) stated that "Lucideon Limited started life as the British Ceramic Research Association in the late 1940s and keeps abreast of developments in the technical developments in the field of ceramic technology, so if any cadmium-free alternative pigments ever become available we will be aware of them and will be more than willing and able to test them as suitable alternatives." When asked whether Lucideon themselves carry out research into cadmium-free alternatives, Lucideon (2022a) responded that they do not carry out any research into cadmium-free alternatives as they do not have any funding for such research activities. If there was a commercial need for such research they could bid to carry it out.

9.2.3. Environmental and socioeconomic impacts

No environmental assessment was provided by SPECTARIS et al. (2019) and it was indicated that environmental considerations are not relevant for this exemption renewal request. SPECTARIS et al. (2019) stated that *"Emissions from cadmium and lead containing filter glass types are very small and controlled."* However, the following bullet points were provided as negative impacts in case the exemption was not renewed:

- ***"Environmental impacts**: Unable to analyse for environmental pollutants. Gas analysers that use lead compound coated interference filters will be less sensitive if they are not permitted by these exemptions. This would result in higher emissions of toxic gases.*
- ***Health impacts**: Medical research would be much more difficult or impossible without fluorescence microscopes, HFAs and other instruments that use these filters.*
- ***Consumer safety impacts**: Facility security survey at night time without dazzling observer (by use of near infrared imaging). Some types of speed enforcement cameras use these filters."*

SPECTARIS et al. (2019) explained the wide-ranging industry that depends on optical glass, and thus often filter glass: There are an estimated 5,000 manufacturers in the EU that rely on optical glass and many of these use filter glass (most are SMEs), worth €69 billion per annum (not including end users such as the medical sector, aerospace, etc.). The European Photonics industry has a 50 % global market share for production technology, 35 % global market share for Optical Measurement & Image Processing and a 32 % global market share for Optical Components and Systems[77]. The European Photonics Production Growth rate is more than 3.5 higher than the EU's gross domestic product growth rate and has grown with an average compound annual growth rate of 5 % since 2005.

Following this line of reasoning SPECTARIS et al. (2019) described the potential impact of a rejection of the renewal request on the EU market: If exemption 13b series were not renewed, this would have a devastating impact on EU industry affecting up to 5,000 companies in the photonic sector alone with many billions of lost income to the EU and many lost jobs. 300,000 people work directly in the EU photonics sector, but many more in EU industries that rely on photonic equipment. If exemption 13b is not renewed, this would mean that many types of products could not be sold in the EU, making EU industries such as film production and R&D uncompetitive or impossible and the health of EU patients would be negatively affected as equipment that relies on these filters could not be obtained by EU hospitals and clinics.

In addition to the disadvantages for EU industry, SPECTARIS et al. (2019) also cited the negative impact on the film production and health sectors: If exemption 13b (series) is not renewed, this would mean that many types of products could not be sold in the EU, making EU industries such as film production and R&D uncompetitive or impossible and the health of EU patients would be negatively affected as equipment that relies on these filters could not be obtained by EU hospitals and clinics. Without this exemption, hospitals could not replace optical instruments such as "Short Wavelength Automated Perimetery", Fluorescence microscopes and IVD analysers and this would severely harm many thousands of EU patients per year. Also, EU manufacturers of a very wide variety of products ranging from aerospace, automotive, engineering, etc. could not buy the optical instruments they rely on so that many industries would not be able to continue operating in the EU. EU researchers in research establishments would become uncompetitive or be unable to continue in many fields without high performance optical instruments. Many manufacturers and researchers rely on equipment that needs exemption 13b to remain highly competitive.

[77] From Optech Consulting, data at https://www.photonics21.org/ppp-services/photonics-downloads.php

SPECTARIS et al. (2019) stated that a closed loop system for EEE in scope of exemption 13(b) series is not possible. However, based on WEEE EUROSTAT data for categories 8 and 9 (the categories that have most uses for this exemption), data for Germany indicate about 86 % of collected WEEE is recycled. Based on categories 8 and 9 data for France and Germany, reuse is typically 0.1 to 1 %. About 11 % of collected WEEE is incinerated. About 2 % is not recovered (data for Germany, 6 - 8 % France), so is probably landfilled.

With respect to exemption 13(b)-(III), Lucideon (2021a) added that if instrument users are not able to obtain the Orange and Red Colour Standards to check their instruments then this will deny them the ability to use two of the seven Chromic Standards that cover the instruments colour gamut, thus potentially rendering about 28 % of the gamut inaccessible.

9.3. Critical review

9.3.1. REACH compliance – Relation to the REACH Regulation

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV "*provided that such inclusion does not weaken the environmental and health protection afforded by*" the REACH Regulation. The article details further criteria which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Lead

Annex XIV

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV as an element. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by*" the REACH Regulation.

Annex XIV lists lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:

- Entry 10: Lead chromate;
- Entry 11: Lead sulfochromate yellow;
- Entry 12: Lead chromate molybdate sulphate red;
- Entry 55: Tetraethyllead

None of the above substances is of relevance for the use of lead in the scope of the requested exemption. *SPECTARIS et al. (2019) explained that Pb compounds contained in batches for filter glass are present as a complex multi-element mixed oxide in the new substance glass (CAS 65997-17-3) after the melting process, so there is not necessarily an exact stoichiometric chemical formula. SPECTARIS et al. (2022c) and JBCE (2022d) confirmed, however, that the above listed substances relevant under REACH Annex XIV are not contained in glasses relevant for this exemption series.*

A renewal of the requested exemption would not weaken the protection afforded by the listing of substances on the REACH Authorisation list (Annex XIV).

Annex XVII

Annex XVII contains entries restricting the use of lead compounds:

- Entry 16 restricts the use of lead carbonates in paints;
- Entry 17 restricts the use of lead sulphates in paints;
- Entry 19 refers to arsenic compounds but includes a few lead compounds and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;
- Entry 28 addresses substances which are classified as carcinogens category 1A or 1B listed in REACH Appendices 1 or 2, respectively. In this context, it stipulates that various lead compounds shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;
- Entry 30 addresses substances which are classified as reproductive toxicant category 1A listed in REACH Appendices 1 or 2, respectively. Like for entry 28, entry 30 stipulates for some lead compounds that they shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;
- Entry 63 restricts the use of lead and its compounds in jewellery and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children;
- Entry 72 lists substances which are classified as carcinogenic, mutagenic or toxic for reproduction. It stipulates that the substances listed in column 1 of the table in Appendix 12 shall not be used in textiles, clothing and footwear. The table lists lead and its compounds mentioned in entries 28, 29, 30 and Appendices 1-6.

The use of lead within the scope of the requested exemption does not regard paints or jewellery, nor components that could be expected to be placed in the mouth by children under normal or foreseeable use. Furthermore, this use of lead is not a supply of lead compounds as a substance, mixture or constituent of other mixtures to the general public. Lead is part of an article and as such, the above entries of Annex XVII of the REACH Regulation would not apply.

No other entries with relevance for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the current status of these annexes, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

Cadmium

Annex XIV

Cadmium and several of its compounds are substances of very high concern but so far are not adopted to Annex XIV as substances that require authorisation for use. *SPECTARIS et al. (2019) explained that cadmium compounds present in optical filter glass are in the form* *of very small, dispersed particles in the glass matrix, without an exact stoichiometric chemical formula.*

Annex XVII

With regards to Annex XVII, cadmium is mentioned in a few of the listed restrictions.

Paragraph 1 of entry 23 of Annex XVII refers to cadmium and several of its compounds including cadmium telluride. Under this entry, several restrictions are mentioned for cadmium and the compounds, among others:

1. A list of various polymers in which Cd may not be used unless required in colour for safety reasons.
2. Shall not be used for cadmium plating metallic articles or components of articles used in equipment and machinery in certain branches and applications, e.g. cooling and freezing, food production, etc.
3. Shall not be used in brazing fillers unless used for safety reasons
4. Shall not be used or placed on the market if the concentration is equal to or greater than 0.01 % by weight of the metal in metal beads and other metal components for jewellery making, or metal parts of jewellery and imitation jewellery articles and hair accessories, e.g. in wristwatches.

In the scope of the requested exemptions, Cd is not used in polymers or jewellery. It is also not used in plating or brazing fillers in the requested exemptions. The above stipulations are therefore not applicable to the use of cadmium in the requested exemption.

Due to their carcinogenicity, entry 28 of Annex XVII does not allow the placing on the market, or use of various substances as such, as constituents of other substances, or in mixtures. Various compounds are mentioned in this respect, including among others cadmium sulphide and cadmium nitrate.

The use of cadmium in the scope of the requested exemption cannot be considered placing on the market cadmium or cadmium compounds in the sense of the above since cadmium is used in an article.

Entry 72 lists substances which are classified as carcinogenic, mutagenic or toxic for reproduction. It stipulates that the substances listed in column 1 of the table in Appendix 12 shall not be used in textiles, clothing and footwear. The table lists cadmium and its compounds as listed under entries 28, 29 and 30.

Like entry 28, this entry does not address the use of cadmium in the scope of the requested exemption.

To conclude, none of the entries currently listed under REACH would apply to the case at hand. The use of Cd in the scope of the requested exemption cannot be considered to weaken the protection afforded by REACH. The exemption can therefore be renewed if the relevant stipulations of Art. 5(1)(a) apply.

9.3.2. Scientific and technical practicability of substitution or elimination of lead

Scope clarification

Exemption 13(b) maintained the same wording for categories 8, 9 and 11 after the last review by Gensch et al. (2016) split the exemption into 13(b)-(I), (II) and (III), which have the categories 1-7, 10 and 11 in scope. The following table shows the current wording and scope of series 13(b) exemptions:

No.	Current exemption wording	Current scope
13(b)	Cadmium and lead in filter glasses and glasses used for reflectance standards	Applies to categories 8, 9 and 11;
13(b)-I	Lead in ion coloured optical filter glass types	Applies to categories 1 to 7 and 10;
13(b)-II	Cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex	
13(b)-III	Cadmium and lead in glazes used for reflectance standards	

The applicants requested the renewal of exemption 13(b) for equipment falling into categories 8, 9 and 11. When asked whether equipment of these categories could not use the current exemptions of the 13(b) series to reflect the scientific and technical progress, SPECTARIS et al. (2021a) stated that *"It would be possible to include categories 8, 9 and 11 in exemptions 13bI, 13bII and 13bIII only if some changes are made. This is because infrared interference filters with lead would not be covered by the current wording of 13bI which is limited to ion coloured glass."* The applicants proposed the following exemption wording option, specifying that they did not see any reason to keep the terms 'ion coloured' and 'striking' in the wording of 13(b)-I and 13(b)-II, respectively:

No.	Proposed exemption wording	Proposed scope
13(b)-(I)	Lead in optical filter glass types and in infrared interference filters	Applies to categories 1 to 11
13(b)-(II)	Cadmium in optical filter glass types; excluding applications falling under point 39 of this Annex	
13(b)-(III)	Cadmium and lead in glazes used for reflectance standards	

SPECTARIS et al. (2021a) proposed an alternative to the above wording: *"Return to the wording of 13b for all categories 1 to 11. This is the simplest option and the scope would be identical to 13b for 8, 9 and 11 plus 13b-I, 13bII and 13bIII for categories 1 – 7 and 10."* While the consultants agree in principle that a return to the previous version of exemption 13(b), before the split into 13(b), 13(b)-(I), 13(b)-(II) and 13(b)-(III), would indeed be simpler, this would also undo the efforts by Gensch et al. (2016), having carried out the previous review of this exemption, to narrow the scope to only those applications that are known to require lead and/or cadmium. In the consultant's view, returning to the wording of 13(b) for all applications and categories would permit the use of both cadmium and lead in all applications in scope of 13(b) series, including those that do not require the use of cadmium and/or lead, thereby effectively widening the scope of the exemption. Therefore, the consultants did not take this variant into further consideration. Regarding the removal of the terms ‘ion coloured’ and ‘striking’ from the wording of exemptions 13(b)-(I) and 13(b)-(II), respectively, the consultants engaged with further exchange of information with the applicants, discussed further below in the individual sections on exemption 13(b)-(I) (p.217 et sqq.) and 13(b)-(II) (p.219 et sqq.).

According to SPECTARIS et al. (2022a), infrared interference filters would need to be mentioned explicitly in the wording of exemption 13(b)-(I), as they would otherwise not be covered. In response to a consultant questionnaire, JBCE (2022c), presumably representing the manufacturer(s) of such equipment, stated that an exemption of lead for use in infrared interference filters was only required for category 9 subcategory industrial monitoring and control instruments. In contrast, SPECTARIS et al. (2019) had applied for categories 1-7 and 10 for exemption 13(b)-(I) covering the use of lead in ion-coloured filter glass. Due to this difference in the scope of the requested exemptions for lead in ion coloured optical filter glass types and infrared interference filters, as well as other differences discussed further below in the report, the consultants think that a new exemption for infrared interference filters would be more suitable.

The above considerations lead the consultants to consider the following wording option for the series 13(b) exemptions, with the terms ‘ion coloured’ and ‘striking’ only in parentheses to indicate the applicants’ request to remove them from the wording.

No.	Proposed exemption wording	Proposed scope
13(b)-(I)	Lead in (ion coloured) optical filter glass types	Applies to categories 1 to 11
13(b)-(II)	Cadmium in (striking) optical filter glass types; excluding applications falling under point 39 of this Annex	
13(b)-(III)	Cadmium and lead in glazes used for reflectance standards	
13(b)-(IV)	Lead in infrared interference filters	

Relevance to RoHS Annex I EEE categories

In the exemption renewal request, SPECTARIS et al. (2019) marked every equipment category (1 to 11) from RoHS Annex I as relevant. However, the provided list of indicative examples of applications that require exemptions from the 13(b) series did not include examples for every category. When requested to provide examples for every category, SPECTARIS et al. (2021a) responded: *“Optical production is a highly fragmented business. There are some big companies but also a lot of small and medium sized companies in this market. It is very likely that such small and medium sized optical manufacturers, which are often very specialised, and application driven companies make use of exemptions 13b, 13bI, 13bII and 13bIII for other categories, like, 1, 2, 5, 7 and 10 and buy cadmium and/or lead filter glass from distributors and so were not able to provide examples of uses in all RoHS categories.”*

When asked to name the most important categories in terms of quantities for the use of lead, cadmium, and both for each exemption in 13(b) series, SPECTARIS et al. (2021a) stated that *"Based on the examples provided in our request for the renewal of RoHS exemptions 13b, 13bI, 13bII and 13bIII we are aware of, these would be the categories 3, 4, 5, 6, 8, 9 and 11."*

Some examples of applications were described in the renewal request without providing explicit information into which of the 13(b) series exemptions the application would fall. The consultants therefore attempted to clarify the situation by requesting the applicants to assign application examples to their relevant exemptions and categories in a table. Table A-1 in the Annex (p.271 et sqq.) reproduces the results, listing the application examples provided by the applicants in the renewal request in addition to further examples mentioned in the applicants' responses to consultant questionnaires. It should be noted that the validity of assigning application examples to individual exemptions and EEE categories could not be verified by the consultants. In rare cases, the relevance was questioned – for instance, cathode ray tubes are no longer produced and/or imported into the EU market, and are therefore considered irrelevant. In another case, colour channel separation for colour TV cameras was provided as an example for category 4 (consumer equipment), however, it is questionable whether TV cameras count as consumer equipment. In this case, the applicants did not tick category 4 in the table despite mentioning it explicitly in text – here, the consultants added the tick to category 4 on behalf of the applicants.

From the consultant's perspective, the most relevant observations from the information contained in Table A-1 are that application examples provided by the applicants, firstly, frequently appear to correspond to several exemptions at once and, secondly, still do not cover all equipment categories 1 through 11. More specifically, the table does not contain equipment falling into category 1 ('large household appliances'). When asked in a questionnaire whether examples of applications falling into category 1 could ultimately be provided, SPECTARIS et al. (2022a) stated that such information was not available, and *"We can only reiterate our position that we cannot exclude the possibility that cadmium and lead containing filter glasses are contained in category 1 but cannot provide examples." With regard to category 4 ('consumer equipment'), the consultants note that the applicants listed "separation of the different colour channels for colour TV cameras"* and "*high performance cameras, such as television broadcasting, cinematography, medical applications*" as examples of equipment. However, the consultants doubt that the examples actually fall into category 4.

Summarizing the table for exemptions 13(b)-(I) and (II), the consultants note:

- For both exemptions 13(b)-(I) and 13(b)-(II), the applicants provided application examples for categories 2, 3, 5, 6, 7, 8, 9, 10, 11;
- For both exemptions, the applicants did not provide application examples for categories 1 and 4.

In a virtual meeting with the applicants, the consultants described a potential course of action in which the validity period for categories without concrete application examples would be shorter than the requested validity period in order to incentivize to end-users of the glass to provide evidence where needed. This potential approach was stated to be supported by SPECTARIS et al. (2022b).

Regarding reflectance standards in exemption, the consultants engaged with Lucideon on which categories needed to be in scope of exemption 13(b)-(III). Currently, glazes used in reflectance standards make use of exemption 13(b)-(III) addressing EEE categories 1 to 7 and 10, and exemption 13(b) addressing categories 8 and 9 including the subcategories of categories 8 and 9, and 11. A renewal of both exemptions with the same scope was requested by the applicants.

When asked whether the scope could be narrowed to those categories into which equipment using the reflectance standards fall, Lucideon (2021c) stated that their clients "include manufacturers and users of Colorimeters & Spectrophotometers, as well as medical device manufacturers. As part of our Business Development activities we are always looking for new applications for our Colour Standards so they could potentially be used in a wide variety of categories." Upon further inquiry and explanation by the consultants that an exemption can only be recommended for those categories for which evidence exist that the exemption is in fact needed, Lucideon (2021d) specified: "Our Colour Standards are used in equipment which measures the attenuation of a beam or beams of light after being reflected from their surface. The equipment that we are aware of that [use our] Colour Standards includes Colorimeters, spectrophotometers, retro-reflectometers, densitometers and medical diagnostic instruments. We do not have the details of the medical diagnostic equipment as this is held to be commercially confidential by our Clients and they will not share any technical data with us for this reason." Lucideon (2022b) confirmed not to be aware of any use of their reflectance standards outside the above mentioned application examples, which all fall into RoHS Annex I EEE categories 8 and 9. Lucideon (2022b) stated not to be aware of any other categories in which their reflectance standards are used, but as they are always looking for new applications, future needs cannot be ruled out at this stage.

From the above information, the consultants conclude that the exemption covering reflectance standards only requires the inclusion of categories 8 and 9 in scope.

Regarding the type of equipment that needs lead-containing infrared interference filters, the consultants asked whether gas detection and concentration measurement instruments as described in the exemption renewal request were the only application. JBCE (2022a) responded that it was *"not limited to only the gas concentration measurement, but certain mid- far-infrared spectrometers also use this technique".*

Economic perspective

Pertaining to all exemptions in the 13(b) series of exemptions, the consultants engaged the applicants in discussions on the economic perspective. SPECTARIS et al. (2021a) indicated that economics are not a reason to keep using cadmium and lead filters, as they are *a minimum of two to three times as expensive as lead- or cadmium-free filters and mainly in a range of five times and up to ten times more expensive.* SPECTARIS et al. (2021c) stated that wherever possible, the *use of lead oxide is and has been minimized due to work safety and environmental considerations, both of which also incur costs (workplace safety, biomonitoring, etc.) and that only its specific technical properties, and not economic incentives are reasons for the use of leaded glass*. It was clarified that protection from exposure was only relevant during the glass manufacturing, but not further down the value chain (e.g. during integration of the glass into EEE).

13(b): Substitution and elimination of cadmium and lead in filter glasses and glasses used for reflectance standards

As has been discussed above in the section "Scope clarification" (p. 213ff), the applicants stated it to be feasible that applications currently making use of exemption 13(b), i.e.

equipment falling into categories 8 and 9, would in the future make use of exemptions 13(b)-(I), (II), and (III) instead. According to the applicants, infrared interference filters would need to be mentioned explicitly. Therefore, a review of infrared interference filters is accounted for in a separate section on a potential exemption 13(b)-(IV) (p.228 et sqq.).

13(b)-(I) Substitution and elimination of lead in ion coloured optical filter glass types

Glass types in scope of exemption 13(b)-(I)

The consultants note that the applicants based their reasoning for why lead cannot be avoided in ion coloured optical filter glass types on a glass type denoted ‘VG9’, described as the *last remaining regularly manufactured type of VG family glass.* In the renewal form (p.34), the applicants stated that *“Only one type of filter glass is currently produced that contains lead”*. This made the consultants believe that VG9 was the only type of ion coloured optical filter glass type that still required exemption 13(b)-(I). Therefore, during the review process, the consultants engaged the applicants in discussions on how this could be reflected in the exemption wording and scope in order to ensure that the scope could be as narrow as possible and as wide as necessary.

As VG9 is a name for a commercial product by the producer SCHOTT[78], explicitly mentioning VG9 in the exemption wording was not considered an option. The consultant therefore investigated whether the fact that VG9 was a green filter glass could be used to narrow the exemption scope. However, in response to a consultant questionnaire, SPECTARIS et al. (2021b) mentioned another type of filter produced by SCHOTT, named RG1000, as an example for a filter that needs exemption 13(b)-(I): *“As another example RG1000 is a longpass filter that contains Cr and Mn. The strong blocking and transmittance properties can only be achieved, when Cr and Mn are fixed in a lead containing glass matrix. This glass is not green.”*

Responding to further consultant questioning, SPECTARIS et al. (2022c) provided additional clarification, stating that *“VG9 is not the last glass that still requires exception 13b-I. VG9 or the comment on it in the application as "the last remaining standard product [...] of the VG family glass" actually refers only to the product family of VG filter glasses, where only VG9 still contains PbO (V for verde, greenish colour of the filter glasses). Nevertheless, other filter glasses are dependent on 13b-I and cannot be substituted.”*

While RG1000 was mentioned as an example of another type of filter glass needing exemption 13(b)-(I), it was stated by SPECTARIS et al. (2022c) that more optical glass filter types require the exemption, for the same technical reasons described for VG9.

The consultants noted that RG1000 was mentioned in the renewal request as an example for a filter glass containing cadmium (cp. renewal request on p.4, reproduced in this report in Table A-1 in the Annex. SPECTARIS et al. (2022c) rectified this information, clarifying that *RG1000 contains lead oxide, but no cadmium and thus falls into exemption 13(b)-(I). Cr_2O_3 and PbO function here as colouring components and provide the required absorption in the UV range. Other RG filter glass types, however, contain CdO (and no lead oxide), thus 13b-II. This makes RG glass types an exception in that they are assigned to both exceptions.”*

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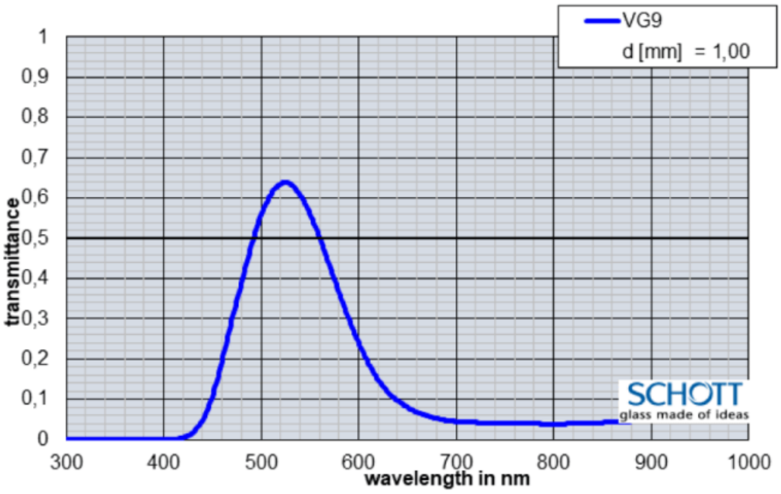
[78] More information on the VG9 product website of SCHOTT here: https://www.schott.com/shop/advanced-optics/en/Matt-Filter-Plates/VG9/c/glass-VG9 [accessed: 15 September 2022, the consultants]

Due to the fact that the applicants had previously only mentioned the glass type VG9 in relation to exemption 13(b)-(I), most of the correspondence regarding 13(b)-(I) was focused on VG9 and its technical properties and potential substitutes. However, as stated above, the applicants argued that other glass types require this exemption for the same technical reasons. While the consultants understand that the applicants presented their arguments based on VG9 as a representative of other ion coloured optical filter glass types and can follow the applicants' argument that these require the addition of lead for the same technical reasons, the consultants also consider that more transparency is needed on other glass types that require the same exemption. Therefore, in case another renewal request for exemption 13(b)-(I) is made in the future, the consultants propose for more information to be made available on other ion coloured glass types than VG9, unless transparent reasoning is provided why the sole focus on VG9 is justified.

Substitution and elimination of lead in VG9

Discussing the role of lead and substitution possibilities, SPECTARIS et al. (2021b)*stated that the VG filter glass types are bandpass filters (relative narrow pass band in the green wavelength range). The colour is determined by Cr and Cu, but the steepness and the blocking properties as the main important characteristics can only be achieved in a lead containing glass matrix. SPECTARIS et al. (2021b) further provided another transmittance diagram of VG9 as a function of wavelength reproduced in Figure 9-16.*

Figure 9-16: Transmittance of the filter glass VG9 as a function of the wavelength



Source: SPECTARIS et al. (2021b)

When asked to provide comparative diagrams that show the technical limitations of lead-free glass in comparison to lead-containing glass, SPECTARIS et al. (2022d) stated to not have such diagrams available. However, SPECTARIS did provide a transmittance graph comparing cadmium-free and cadmium containing glass (cf. Figure 9-17 on p.220), showing the steepness of the absorption edge of cadmium-containing glass, and stating that the comparison would look the same when comparing lead-free and lead-containing glasses.

The consultants therefore note that the evidence provided by the applicant is relatively limited. However, no other stakeholders participated in the review process claiming that lead-free alternatives were available providing the same technical properties. Further, a limited internet-based search for literature carried out by the consultants did not indicate that such substitutes are available. The applicants also stated that the addition of lead to filter glasses in scope of exemption 13(b)-(I) is associated with additional cost due to required additional health and safety measures in the production lines of the glasses, and that the only reason to use lead for relevant glass types is to achieve the technical properties that cannot be achieved without the addition of lead to the base glass.

The consultants understand from the applicants' descriptions that adding lead oxide to the glass matrix of ion coloured optical filter glasses changes the properties in a way that results in steep blocking and transmittance profiles of metal ions that cannot be achieved without the addition of lead. Other elements to substitute lead have so far not been identified. The consultants find the argumentation provided by the applicant plausible and did not encounter contradicting information.

Term "ion coloured" in the exemption wording

In response to the consultation questionnaire, the applicants proposed to omit the term 'ion coloured', stating not to see any reason to specify "ion coloured" in the wording. They deem the impact on removing the term rather low, and inform that the term is not a common designation for the actual users, therefore leading to confusion in the value chain. SPECTARIS et al. (2021c) clarified that it is not a common designation in the sense that downstream users do not request or purchase 'ion coloured' filter glasses per se, but rather by technical specifications. However, it was also stated that the current wording (including 'ion coloured') can be retained in order to keep additional administrative work to a minimum, as downstream users are already accustomed to the current wording.

From the consultants' perspective, an additional factor in this regard is that removing the term from the current wording may potentially widen the scope to other optical glass filter types that are not ion coloured currently or in the future. In the consultants' understanding, lead is added as a matrix element during the glass production that interacts with the positioning of the light absorbing metal ions. Therefore, lead is only needed in case of ion coloured glasses in the consultants' view and keeping the current wording is therefore preferable.

13(b)-(II) Substitution and elimination of cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex

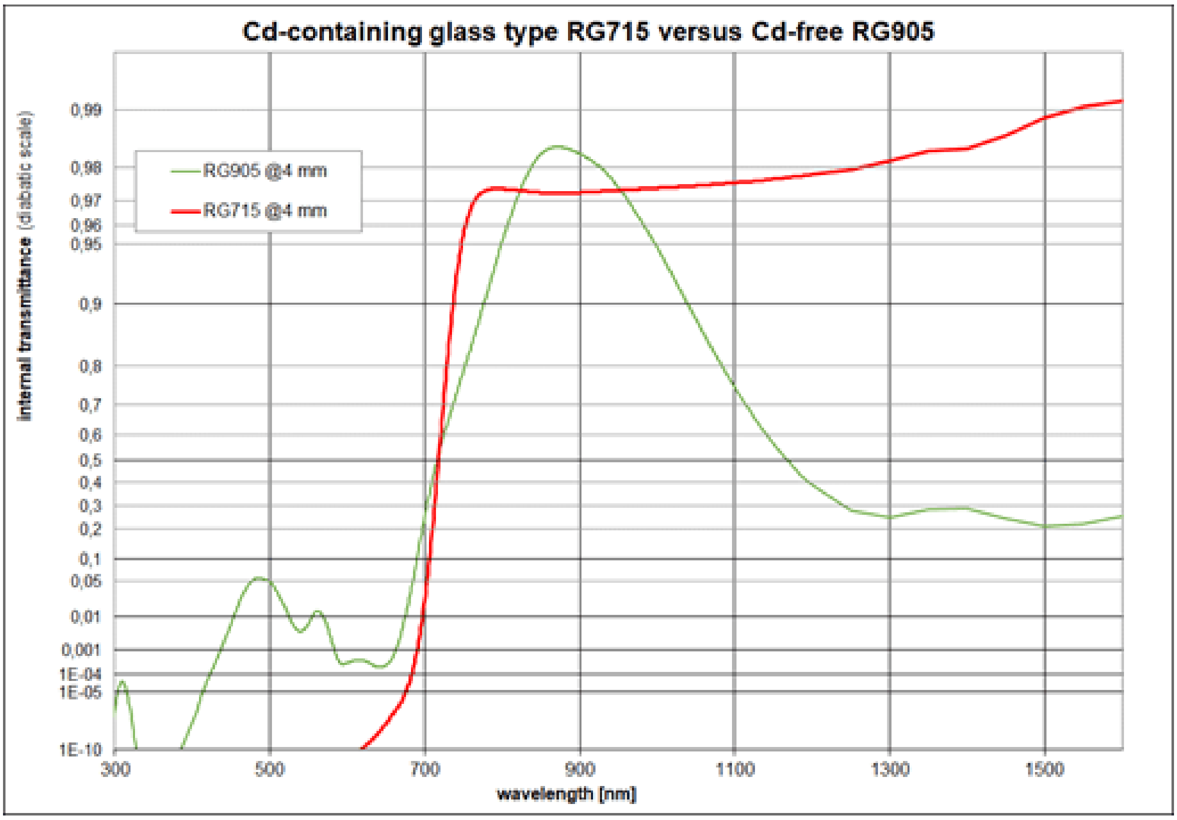
SPECTARIS et al. (2019) provided a detailed technical description of why cadmium is added to specific optical filter glass types and how the addition of cadmium leads to the desired properties of long-pass filters. These properties are a steep edge in the transmission graph going from blocked to transmitted wavelengths and the ability to control specific parameters during the production process to adjust how the wavelength bands to be blocked or transmitted by the final product.

SPECTARIS et al. (2019) described three types of optical filters that could be an alternative for cadmium-containing filter glass and that these alternatives are used for some applications: (i) Additives other than Cd, (ii) thin film coatings on transparent substrates, and (iii) transparent plastics with organic pigments.

Regarding the current application of the alternatives in practice, SPECTARIS et al. (2021a) stated that "These alternatives are used if they provide technical performance that these uses require. There is also a desire by manufacturers to avoid products containing cadmium if this is technically achievable." For instance, one example for using plastics provided by the applicants is in low-end optics in children's' toys.

Discussing alternative additives to cadmium in glass, SPECTARIS et al. (2019) described that very few of II-IV and III-V compounds are yellow, orange or bright red with sharp *wavelength cut-offs. When asked which of them were and for what reasons those were not used to substitute cadmium, SPECTARIS et al. (2021b) responded that they cannot be used: They do not provide a sharp cut-off-wavelength and a strong blocking, which is of higher technical importance than the colour (type of colour and intensity). To illustrate, SPECTARIS et al. (2022d) provided another transmittance graph for a cadmium-containing filter glass compared to a cadmium-free filter glass, showing the steepness of the absorption edge, reproduced in Figure 9-17.*

Figure 9-17: Transmittance of Cd-containing versus Cd-free filter glass



Source: SPECTARIS et al. (2022d)

The consultants find the technical explanations regarding the role of cadmium in ‘striking’ optical filter glasses plausible. No stakeholder provided any information contradicting the information provided by the applicants. Own research carried out by the consultants also did not result in findings that contradict the arguments provided by the applicants. The consultants therefore consider that the use of cadmium in certain filter glass types requiring a steep edge and high blocking and transmittance properties in a longpass filtering function indeed still require the addition of cadmium.

13(b)-(III) Substitution and elimination of cadmium and lead in glazes used for reflectance standards

For this exemption, Lucideon acted as the corresponding stakeholder, while SPECTARIS et al. represent the applicants for all other exemptions of the 13(b) series of exemptions. The correspondence with Lucideon was carried out largely through emails, following up on their initial responses to consultant questionnaires.

The wording of exemption 13(b) uses the term “glasses used for reflectance standards”, while exemption 13(b)-(III) uses the term “glazes used for reflectance standards”. When asked about the discrepancy, SPECTARIS et al. (2021c) clarified that glazes are used for reflectance standards, which are glasses coated on a (ceramic) substrate. Therefore, the term glazes is appropriate and can be maintained in the wording.

Substitution and elimination of lead and cadmium from glazes used in reflectance standards

Lucideon (2021a) stated that "The glazes that Lucideon Limited uses do not require Lead as all of the standards contained in the range of Ceramic Colour Standards have eliminated this material." Other companies did not participate in the stakeholder process. Accordingly, in the consultants' view, lead can be removed from the scope of exemption 13(b)-(III).

Regarding cadmium, Lucideon stated that cadmium was only needed in red and orange reflectance standards. In correspondence with the consultants, Lucideon (2022c) confirmed that cadmium was only ever used in red and orange pigments and that other colour pigments had never used cadmium. Lucideon (2022b) explained that the pigments used for red and orange reflectance standards contain the cadmium compounds cadmium sulphide (CdS) and cadmium selenide (CdSe). Lucideon (2022c) further clarified that both compounds do not exist as discrete compounds in the pigments as they mix in different ratios, e.g. a pigment may have the chemical formula $CdSe_{0.25}S_{0.75}$ *or similar. Lucideon (2022d) further elaborated that these CdSeS (cadmium selenide sulphide) compounds are chromophores encapsulated in a zircon (Zirconium Silicate, ZrSiO4) matrix that prevents the pigment from reacting with the glaze as it melts.*

The main technical reason to use cadmium has been stated to be the steep slope in the wavelength reflected by a given standard that cannot be achieved without the addition of cadmium. Responding to questions from the consultants, Lucideon (2022d) explained that "the slopes need to be as steep as possible to help the users and the analytical software that they use to interpret the reflectance data that they get from their measurements. The shallower the slope, the less useful the Standard is in terms of Precision and Accuracy."

When asked whether other colour shades could be used that would not require cadmium, instead of using red and orange, Lucideon (2022d) responded that "the Colour Standards need to cover as much of the visible spectrum as possible and in order to give the best results and the slopes need to be as steep (well defined) as possible. No suitable Orange or Red colours can be achieved without the use of the pigments that we purchase as their encapsulation in their zircon matrix allows them to survive the firing process at 1000°C + that is needed to produce the stable & durable Colour Standards that they are. Orange & Red are known as primary colours in most industries as two of the seven colours of the rainbow (Red, Orange, Yellow, Green, Blue, Indigo & Violet) so it is unlikely that any other colours would be acceptable in their place." Lucideon (2022e) further explained that the CdSeS pigment has the necessary and discrete gaps in its valence electrons to allow it to absorb and reflect electromagnetic radiation at the required wavelengths.

Reference can be made to Gensch et al. (2013) who evaluated an exemption request for the use of cadmium in the glaze / colouring of ceramic components of luminaires. Here it is stated: "As for using cadmium in ceramic glazes and colours, the applicants [CELMA, an industry association, the consultants] explains that red colours have long been a challenge for the ceramic industry as most red pigments are unstable at high temperatures. The deep red colour produced by cadmium selenium sulphide is prized for its pure deep red colour. Cadmium is also used to increase the vividness of ceramic glaze colours." In their critical review, the consultants at the time stated: "As for the cadmium colours, it has been sufficiently supported that certain hues may only be obtained with cadmium-based colours."

With respect to the potential to eliminate the use of cadmium, Lucideon (2021a) stated that plastics could be used instead of glazes and that the required steep reflectance slopes could be achieved using organic pigments, but that they were unstable and bleach (lose their colour) under the UV component of the spectrometer illuminating light. When asked about the time frames of the degradation process experimentally and in practice in order to gauge the relevance of this technical drawback and whether this applied to all types of instruments using reflectance standards, Lucideon (2022b) stated not to have any comparative laboratory data as it is axiomatic that the degradation will happen.

Regarding other companies that produce reflectance standards, Lucideon (2021a) stated not to be aware of any other manufacturers that have developed useable red and orange colour standards that do not contain lead or cadmium. Lucideon stated that Mount Baker Research in the U.S. and Evers Corporation in Japan also offer reflectance standards, but that Lucideon has no technical information on how they are made. Lucideon also mentioned Labsphere, a U.S. company, producing red and orange standards which are believed to also use cadmium-containing pigments.

The consultants could not identify Mount Baker Research but attempted to establish contact with Every Corporation on the subject. However, no response was received.

Responding to a consultant questionnaire, Lucideon (2022e) stated not to be aware of any alternative methods to calibrate optical measurement equipment besides reflectance standards: "reflectance standards are needed so as to replicate the behaviour of specimens when illuminated by the light generated by the colorimeter or spectrophotometer, no other system is possible to do this."

Judging from the information provided by the applicants, and in the absence of contrary information, it appears that the exemption for lead is no longer needed, while cadmium is still required in reflectance standards to produce the well-defined, steep cut-off towards undesired wavelengths in red and orange reflectance standards. The consultants understand that primary colours need to be covered in order to properly calibrate optical measurement equipment.

Infrared interference filters with lead compound coatings

The applicants argued that the use of lead compound coatings results in unique technical properties of infrared interference filters that cannot be replicated using lead-free alternatives. Main arguments provided by the applicants include:

- Only lead compound coatings, such as lead telluride, have both a high refractive index and the desired blocking properties to enable only a sufficiently narrow wavelength range to pass while blocking other wavelengths. This is needed in applications like flue gas analysis, where individual gases need to be detected with high sensitivity.
- Undesired side bands are farther apart from the desired wavelength in lead-containing filters compared to lead-free filters. As side bands are blocked by other filters, there is a higher risk of signal reduction when side bands are too close to the wavelength band for which transmission is desired.

To support the second argument, the applicants provided a diagram (cf. Figure 9-15 on p.205) comparing transmission spectra of a lead telluride interference filter and a germanium transmission filter, indicating that the side bands are located farther away from the target wavelength in case of the lead-containing filter. When asked to explain the difference between interference and transmission filters, JBCE (2022d) responded:

"Interference filters (bandpass) are a type of transmission filter. Transmission filter is a generic term for optical filters (long-pass, band-pass and short-pass) that are inserted into the optical path to reduce the intensity of the incident light and/or modify its wavelength dispersion characteristics for emission. Each optical filter has different properties depending on the refractive index of the thin film material at wavelength of incident light. There are three types of transmission filters: reflective type, absorptive type and interference type. Interference filters have a structure consisting of alternating layers of thin films of high and low refractive index substances. The incident light is repeatedly reflected and transmitted in the multilayer film structure and is separated into transmitted and reflected light according to wavelength. This allows a specific wavelength range to be selectively extracted and transmission of other wavelengths to be blocked. Interference filters with excellent properties have been achieved by employing lead compounds with a higher refractive index than other substances. For example, [Figure 9-15 on p.205] shows the properties of an interference filter with a centre wavelength of 10.00 µm. The lead telluride interference filter (blue line) has a reject range of 7.5 µm to 14.5 µm, whereas the germanium transmission filter (red line) has a narrow bandwidth of 8.3 µm to 12.6 µm."

When asked once more what type of transmission filter the germanium-based filter was and whether it fulfilled the same function as the lead telluride interference filter, therefore warranting a meaningful comparison, JBCE (2022e) clarified that the diagram in Figure 9-15 shows the comparison of two interference filters - lead telluride interference filter and germanium interference filters - as coating materials, adding that „germanium transmission filters" here means the same as "germanium interference filters". The comparison therefore compares lead-containing with a lead-free filter, demonstrating that the lead-containing filter has a desirable, broader reject range.

When asked to elaborate on research activities and a possible roadmap to a phasing out of lead, JBCE (2022d) responded that "At present, no membrane substance has been found with properties equal to or better than lead compounds, and no alternative plan can be presented. Even if alternative materials are found, more than five years are needed for interference filter design, optical property evaluation, temperature property evaluation, lifetime testing and mass production evaluation before commercialization."

In correspondence with JBCE, the consultants established that known equipment requiring this exemption exclusively falls into category 9 subcategory industrial monitoring and control instruments. As to the types of IMCI, JBCE (2022b) stated: "Infrared interference filters with lead compound coatings are used in infrared gas analysis and mid-far-infrared spectrometers." When asked whether other manufacturers of infrared interference filters may use them in equipment falling into other categories, JBCE (2022b) replied that "It is possible that other manufacturers of such interference filters may produce equipment for other categories. However, we do not know such cases. JBCE (Japan Business Council in Europe) is not a manufacturer, but an industry association. JBCE member companies require the exemption 13(b)-(IV). We do not know other manufacturers requiring this exemption."

The fact that an exemption for infrared interference filters would only be needed for subcategory IMCI of category 9 leads to the conclusion that the option to include these filters in exemption 13(b)-(I) via a change of wording is not the preferred option, as exemption 13(b)-(I) is needed for almost all categories and therefore has a much wider scope. Additionally, SPECTARIS et al. (2021c) explained a technical difference between filters in scope of exemption 13(b)-(I) and infrared interference filters as follows: *„Comparable to the 13b III reflective standards, the interference filters are based on reflection on surfaces and not on absorption of the bulk glass."* Therefore, the consultants conclude that a new exemption would be needed to ensure that infrared interference filters can be covered. The preferred option from the consultant's point of view would be to introduce a new exemption 13(b)-(IV) for infrared interference filters.

Regarding the potential exemption wording, in response to a consultant questionnaire, JBCE (2022b) agreed with the term 'lead compound coating', which, in the consultant's view, would not include metallic lead, stating: "We agree with the phrasing "lead compound coatings". It is not known for us that metallic element lead is used for this purpose."

Further, when asked whether 'infrared gas analysis' and 'mid-far-infrared spectrometers' were in fact the only applications requiring the lead compound coatings, JBCE (2022f) confirmed that these are in fact the only applications known to JBCE, proposing the following wording option: "Lead compound coatings in infrared interference filters used in infrared gas analysis and mid-far-infrared spectroscopy".

The consultants therefore consider the following exemption wording and scope would be appropriate:

Proposed exemption wording	Proposed scope
Lead compound coatings in infrared interference filters used in infrared gas analysis and mid-far-infrared spectroscopy	Applies to category 9 industrial monitoring and control instruments.

Judging from the information provided by the applicants, the consultants understand that the use of lead is indeed still required in this highly specialized application due to the high refractive index afforded by the addition of lead and the desired distance between the target wavelength and sidebands.

9.3.3. Environmental arguments and socioeconomic impacts

When asked about environmental impacts related to the use of cadmium and lead in filter glasses, SPECTARIS et al. (2021a) replied: "We state that environmental impacts are not applicable to our exemption renewal request and this is because it is based only on the first bullet justification of Article 5.1a. of the RoHS-Directive."

The consultants note that the applicants have nevertheless described a range of negative socio-economic impacts in the case that the renewal request is rejected. The consultants find it plausible that if cadmium- and lead-containing glasses and glazes in scope of exemption 13(b) series were no longer available in the EU, some negative consequences would occur, as described by the applicants, including adverse effects on the job market and the healthcare industry.

9.3.4. Summary and conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria is fulfilled:

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II **is scientifically or technically impracticable**;
- the **reliability** of substitutes is not ensured;
- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

A summary and conclusions on each of the 13(b) series of exemptions, referring to the above points, is provided in the following sections.

13(b) Cadmium and lead in filter glasses and glasses used for reflectance standards

Exemption 13(b) was renewed following the last review of the exemption by Gensch et al. (2016), including in its scope only categories 8 and 9 with their sub-categories, and category 11. Therefore, the current review focused on the integration of categories 8, 9 and 11 into the scopes of exemptions 13(b)-(I), 13(b)-(II) and 13(b)-(III) whose scope is more specified and thus narrower than the scope of exemption 13(b). The applicants confirmed the practicability of this approach but highlighted that infrared interference filters would need to be explicitly mentioned in the exemption wording to ensure that they would be within scope. Therefore, the consultants conclude that all applications currently covered under exemption 13(b) can be shifted to exemptions 13(b)-(I) through 13(b)-(III), in addition to a newly proposed exemption 13(b)-(IV) covering infrared interference filters. Consequently, exemption 13(b) will no longer be needed and can expire, which is reflected in more detail in the consultants' recommendation (section 9.4). As prescribed in RoHS Article 5(6), an exemption that is revoked shall expire at the earliest 12 months and at the latest 18 months after the decision has been published. Such a transition period is required in the case at hand since formally, the shift of cat. 8 and 9 EEE from an exemption with a broader scope to an exemption with a narrower scope can be considered a partial revocation of the exemption.

13(b)-(I) Lead in ion coloured optical filter glass types

A number of ions, such as chromium and copper, are used in filter glasses for their special light absorption properties to achieve the desired blocking and transmitting of defined wavelengths. A sharp cut-off ('steep slope') between the blocked and transmitted wavelength range is required in some applications, which can only be achieved when lead is added to the base glass to ensure that the addition of the ions yields the desired filtering properties. Accordingly, lead-free base glass cannot achieve the same technical properties, leading to a situation where ion-coloured filter glass types still require the addition of lead. The applicants stated that there is no other motivation than technical reasons to keep using lead in the production of relevant filter glass types. On the contrary, it was explained that using lead results in higher costs due to additional safety requirements in glass manufacturing facilities.

Judging from the provided information, the consultants can follow the applicants' argument that the described technical properties cannot be achieved without the addition of lead currently and in the coming years. In the consultants' view, RoHS Article 5(1)(a) can be considered fulfilled and would allow granting an exemption.

Regarding the exemption wording, the applicants argued that the term 'ion coloured' can be removed from the exemption wording, as it is not commonly used in the market to designate the filter glass types in scope of this exemption, leading to some confusion in the value chain. However, the applicants also stated that customers are already accustomed to the term at the current time. In the consultants' view, there is a possibility that removing the term would lead to a widening of the scope of exemption 13(b)-(I) to allow lead to be used in all optical filter glass types. Therefore, the consultants consider it the preferred solution to keep the current wording unchanged.

The consultants note that the applicants based their argumentation on an individual, commercial ion coloured filter glass type denoted VG9. In case of another renewal request for exemption 13(b)-(I) in the future, the consultants propose that more information should be made available on other ion coloured glass types beyond VG9, unless transparent reasoning is provided why the sole focus on VG9 is justified.

13(b)-(II) Cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex

Cadmium is added to the base glass of filter glass to enable the striking process, in which the initially clear glass is processed with a secondary heat treatment to produce the cadmium-based filtering substances. The resulting longpass filters block wavelengths below a defined value and transmit those with longer wavelengths through the filter. The one edge on such striking optical filters is particularly sharp (or steep), which can only be achieved by adding cadmium.

The applicants described three types of optical filters that could be considered potential alternatives for cadmium-containing filter glass. Additives other than cadmium, thin film coatings on transparent substrates, and transparent plastics with organic pigments. However, research of several decades has not identified additives other than cadmium to lead to the same results. Thin-film coatings introduce the issue of viewing angle dependency, leading to ghost images and transmission of unwanted side-bands. Transparent plastics with organic pigments have other shortcomings, including their degradation under UV exposure and lower hardness of the material, besides a number of other factors (cf. Table 9-2).

Judging from the provided information, the consultants can follow the applicants' argument that the described technical properties cannot be achieved without the addition of cadmium currently and in the coming years. In the consultants' view, RoHS Article 5(1)(a) can be considered fulfilled and would allow granting an exemption.

Judging from the provided information, the consultants can follow the applicants' argument that the described technical properties cannot be achieved without the addition of lead currently and in the coming years. In the consultants' view, RoHS Article 5(1)(a) can be considered fulfilled and would allow granting an exemption.

Regarding the exemption wording, the applicants argued that the term 'striking' can be removed from the exemption wording, as it is not commonly used in the market to designate the filter glass types in scope of this exemption, leading to some confusion in the value chain. However, the applicants also stated that customers are already accustomed to the term at the current time. In the consultants' view, there is a possibility that removing the term would lead to a widening of the scope of exemption 13(b)-(I) to allow cadmium to be used in all optical filter glass types, separate from the explicit exclusion of applications falling under point 39 of RoHS Annex III. Therefore, the consultants consider it the preferred solution to keep the current wording unchanged.

Exemption 39 was replaced by exemption 39(a) as published in the Official Journal of the European Union on 7 August 2017. This needs to be reflected in the wording of exemption 13(b)-(II).

13(b)-(III) Cadmium and lead in glazes used for reflectance standards

Ceramic colour standards are optical reflectance materials that are used to calibrate and check the measurement performance of spectrophotometers and other optical devices. Reflectance standards are typically not a part of any instrument but an accessory which may be momentarily held against the instruments measuring aperture / in the measurement path, before the instrument is used. The standards are usually 5 cm or 10 cm squares, sealed into plastic trays with waterproof silicone sealant and are usually stored in protective cases to further protect them and prolong their lifetimes. Lead is no longer required in reflectance standards and can therefore be removed from the exemption scope. Cadmium is said to still be needed to produce red and orange glazes, as only the addition of cadmium-based pigments enables steep slopes in the wavelength required to ensure the accuracy of relevant optical equipment. While plastics using organic pigments can produce steep slopes, they have been stated to degrade and lose colour under the influence of UV light while the use for the calibration needs stable conditions over long periods of time. The consultants can follow these arguments, but note that no evidence in the form of measured data to showcase the timeframe in which the degradation takes place has been submitted by the applicants. Nevertheless, the consultants can overall follow the argument that cadmium-free reflectance standards cannot substitute cadmium-containing red and orange reflectance standards currently and in the coming years.

Although only reflectance standards of the colours red and orange require the exemption for cadmium, as all other colours can be produced without, it was not found to be feasible to narrow the wording of the exemption to reflect this, as the colours themselves cannot be described in sufficient technical precision. Besides, the consultants consider that not narrowing the scope to only red and orange will not lead to increased usage of glazes with cadmium in this case, as all other colours do not require its addition or could not even be produced with cadmium.

While the renewal of the exemption was requested for all RoHS Annex I EEE categories, the specific application examples mentioned by Lucideon were devices and instruments falling into categories 8 and 9 only. The applicants were requested to but did not provide application examples for other categories. In the consultants' view, it is the applicants' duty to provide evidence that the exemption is needed in the categories for which the renewal was requested. From the information available during the exemption evaluation period, it appears reasonable to narrow the scope of exemption 13(b)-(III) to only include categories 8 and 9 including their respective sub-categories.

Judging from the provided information, the consultants can follow the applicants' argument that the described technical properties cannot be achieved without the addition of cadmium currently and in the coming years. In the consultants' view, RoHS Article 5(1)(a) can be considered fulfilled and would allow granting an exemption.

The applicant does not carry out research into cadmium-free alternatives due to lack of funding for such research activities. While the progress made in recent years, i.e. outphasing of lead is noteworthy, the consultants consider it expectable that users of the exemption continue to engage in efforts to substitute or eliminate cadmium from the last remaining applications in scope of exemption 13(b)-(III). It may be advisable to emphasize this point in possible future reviews of this exemption.

Infrared interference filters with lead compound coatings

Infrared interference filters consist of a thin coating made from lead compounds deposited onto an infrared transparent substrate. The coating material composition and thickness are chosen to achieve a high percentage of transmission in the desired narrow wavelength range in which infrared light transmission occurs, while rejecting other wavelength bands. The applicants argued that lead compounds have one of the highest refractive index of coating materials while also providing very good blocking properties outside of the transmission wavelength range, thereby only allowing a relatively narrow wavelength range to pass while blocking lower and higher wavelengths. The lead compounds coating also enables a steep cut-off that is required to avoid interferences with infrared emissions from other gases in an analysed sample.

The applicants argued that alternative methods to manufacture such filters that would eliminate lead cannot achieve the same properties. Using multiple layers of lead-free coating material aimed to achieve the same properties of one lead-containing coating, introduced defects and leads to poor yields, while the multiple layers also reduce the percentage of transmitted light. Lead-free coating materials were also described as having side bands that are closer to the transmitted wavelength, thereby increasing the risk of interfering signals from other gases.

In the consultants' view, the applicants have provided detailed technical information illustrating for which purpose lead is used in infrared interference filters and that its substitution and elimination are scientifically and technically impracticable currently and in the coming years. The information is congruent with arguments for using lead in other applications in exemptions 13(a) and 13(b): High refractive index, good blocking properties, and steep wavelength cut-off. The consultants can therefore follow the arguments provided by the applicants and did not encounter contradictory information. No other stakeholders provided information that affected this evaluation.

Judging from the provided information, the consultants can follow the applicants' argument that the described technical properties cannot be achieved without the addition of lead currently and in the coming years. In the consultants' view, RoHS Article 5(1)(a) can be considered fulfilled and would allow granting an exemption.

Due to the application examples provided, the consultants concluded that the exemption is only needed for equipment falling into RoHS category 9 subcategory industrial monitoring and control instruments, which the applicants confirmed.

9.4. Recommendation

The available information suggests that substitution and elimination of lead and/or cadmium in the filter glasses and reflectance standards are scientifically and technically impracticable where their unique properties are needed in a range of applications. In the consultants' view, Art. 5(1)(a) would therefore allow granting an exemption.

Regarding exemptions 13(b)-(I) and (II), for several categories of EEE, concrete applications for the exemptions could not be named. The consultants consider that in the absence of evidence, shorter validity periods for these categories would give applicants time to gather the required information while allowing the exemptions to expire earlier for these categories in case the applicants cannot gather evidence to support another renewal request. Therefore, the consultants recommend a staggered approach:

- Maximum validity periods as requested by the applicants of exemptions for categories with known applications; this applies to categories 2, 3, 5, 6, 7, 8, 9, 10 and 11 for both exemptions 13(b)-(I) and (II);
- Reduced validity periods in case of presumed possible uses of the exemptions where the applicants could not produce evidence, this applies to categories 1 and 4 for both exemptions 13(b)-(I) and (II).

It is noted that SPECTARIS et al. (2022b) argued for a simplified exemption 13(b) series, as too many different expiry dates considerably increase the effort required on the applicants' side. The consultants recommend the below wordings and scopes for the renewed exemptions of the 13(b) series.

<table>
<tr><th></th><th>Exemption</th><th>Scope and dates of applicability</th></tr>
<tr><td>13(b)</td><td>Cadmium and lead in filter glasses and glasses used for reflectance standards</td><td>Applies to categories 8, 9 and 11.
Expires on [date of publication in Official Journal + 12 months] for
- category 8 medical devices including in vitro diagnostic medical devices;
- category 9 monitoring and control instruments including industrial monitoring and control instruments;
- category 11.</td></tr>
<tr><td>13(b)(I)</td><td>Lead in ion coloured optical filter glass types</td><td rowspan="2">Applies
- to categories 1-7 and 10;
- from [date of publication in Official Journal + 12 months + 1 day] on to categories 8, 9 and 11.
Expires on
- 21 July 2025 for categories 1, 4;
- 21 July 2026 for categories 2, 3, 5, 6, 7, 10 and 11;
- 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices and category 9 monitoring and control instruments including industrial monitoring and control instruments.</td></tr>
<tr><td>13(b)(II)</td><td>Cadmium in striking optical filter glass types; excluding applications falling under point 39(a) of this Annex</td></tr>
<tr><td>13(b)(III)</td><td>Cadmium and lead in glazes used for reflectance standards</td><td>Expires on [date of publication in Official Journal + 12 months] for categories 1 to 7 and 10.</td></tr>
<tr><td>13(b)(IV)</td><td>Cadmium in glazes used for reflectance standards</td><td>Applies to cat. 8 and 9 from [date of publication in Official Journal + 12 months+ 1 day] on.
Expires on 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices and category 9 monitoring and control instruments including industrial monitoring and control instruments.</td></tr>
<tr><td>13(b)(V)</td><td>Lead compound coatings in infrared interference filters used in infrared gas analysis and mid-far-infrared spectroscopy</td><td>Applies to category 9 industrial monitoring and control instruments from [date of publication in Official Journal + 12 months + 1 day on].
Expires on 21 July 2028 for category 9 industrial monitoring and control instruments.</td></tr>
</table>

EEE of categories 8, 9 and 11, currently in the scope of exemption 13(b), are recommended to be integrated into the scopes of exemptions 13(b)(I), 13(b)(II), and 13(b)(III) so far only covering EEE of cat. 1-7 and 10. Formally, this is equivalent to narrowing the exemption scopes for these categories of EEE which is considered a partial revocation of the exemption. As prescribed in RoHS Article 5(6), an exemption that is revoked shall expire at the earliest 12 months and at the latest 18 months after the decision has been published. The consultants recommend a 12 month transition period to allow for administrative adaptations. More time should not be required as the scope restriction only reflects the technical development, and the applicants did not request a transition period.

The wordings of exemptions 13(b)(I) and 13(b)(II) should be renewed with the current wording, but cat. 8, 9 and 11 EEE be added to the scopes so far only comprising categories 1-7 and 10. For the newly added cat. 8, 9 and 11 EEE, the exemption should only become applicable once their 12 months transition period under exemption 13(b) will have expired.

The wording for the current exemption 13(b)(III) is recommended to be renewed only for cadmium as exemption 13(b)(IV). Substitution or elimination of lead has become scientifically and technically practicable. The scope of exemption 13(b)(IV) should be narrowed to only include the EEE of categories 8 and 9 transferred from exemption 13(b). The exemption should only become applicable to cat. 8 and 9 EEE once their 12 months transition period under exemption 13(b) will have expired. The exemption is not relevant for other categories of EEE. Exemption 13(b)(III) can expire for categories 1 to 7 and 10 after a 12 month transition period to be granted according to Art. 5(6) if an exemption is revoked.

A new exemption 13(b)(V) is recommended to reflect that infrared interference filters require the exemption but are only covered by exemption 13(b) which shall expire. The scope needs to include category 9 industrial monitoring and control instruments only. There was no evidence that the exemption might be used in other categories of EEE. For cat. 9 industrial monitoring and control instruments, the exemption should only become applicable once their 12 months transition period under exemption 13(b) will have expired.

Finally, it is noted that considerable time and effort was spent by both the consultants and the applicants to untangle technical information and arguments and to which individual exemption and application examples they apply. Therefore, for potential future renewal requests, the consultants recommend that applicants provide separate documents or at least clearly separate chapters for each of the individual exemptions in the exemption 13(b) series.

9.5. References

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JBCE (2022a): Additional answers to SPECTARIS et al. questionnaire 3 for RoHS exemption 13(b) of Annex III. Received from Takuro Koide, JBCE, via email by Christian Clemm (IZM / UNITAR) on 7 January 2022.

JBCE (2022b): Answers to questionnaire 1 for RoHS exemption 13(b) of Annex III. Received from Tetsusaburo Miura, JBCE, via email by Christian Clemm (IZM / UNITAR) on 5 August 2022.

JBCE (2022c): E-Mail correspondence on "RoHS Renewal of Exemption 13(b)-III" from JBCE to the consultants on 15 August 2022. Received from Tetsusaburo Miura, JBCE, via email by Christian Clemm (IZM / UNITAR) on 15 August 2022.

JBCE (2022d): Answers to questionnaire 2 for RoHS exemption 13(b) of Annex III. Received from Tetsusaburo Miura, JBCE, via email by Christian Clemm (IZM / UNITAR) on 21 October 2022. JBCE.

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JBCE (2022f): Answers to questionnaire for RoHS exemption 13(b) of Annex III. Received from Tetsusaburo Miura, JBCE, via email by Christian Clemm (IZM / UNITAR) on 9 December 2022. JBCE.

Lucideon (2021a): Additional information to the application for renewal of exemption 13(b)-(III) cadmium and lead in glazes used for reflectance standards.

Lucideon (2021b): E-Mail correspondence on "RoHS Renewal of Exemption 13(b)-III" from Lucideon to the consultants on 2 November 2021. Received from Sean Hillman, Lucideon, via email by Jana Rückschloss, Fraunhofer IZM, on 2 November 2021.

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Lucideon (2022b): Answers to questonnaire 6 for RoHS exemption 13(b). Received from Sean Hillman, Lucideon, via email by Christian Clemm, Fraunhofer IZM / UNITAR, on 31 August 2022.

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SPECTARIS et al. (2019): Request for renewal of exemption 13(b) of RoHS Annex III. Exemption Request Form. Unter Mitarbeit von Umbrella Project Technical Working Group. SPECTARIS e.V. Online verfügbar unter https://rohs.biois.eu/RoHS_exemption_application_SPECTARIS_13b.pdf, zuletzt geprüft am 21.10.2021.

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SPECTARIS et al. (2022b): Workshop on RoHS Annex III Exemptions 13(a) and 13(b). Meeting minutes for virtual workshop held on 7 July 2022 between representatives of SPECTARIS et al., Fraunhofer IZM and UNITAR; minutes prepared by Fraunhofer IZM and UNITAR and approved by SPECTARIS et al.

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10. Exemptions 15 and 15(a) of Annex III: Lead in flip chip packages

The current wording and expiry dates of the exemptions are:

No.	*Current exemption wording*	*Current scope and dates of applicability*
15	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages	Applies to categories 8, 9 and 11 and expires on - 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments; - 21 July 2023 for category 8 in vitro diagnostic medical devices; - 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11
15(a)	Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages where at least one of the following criteria applies: - a semiconductor technology node of 90 nm or larger; - a single die of 300 mm^2 or larger in any semiconductor technology node; - stacked die packages with die of 300 mm^2 or larger, or silicon interposers of 300 mm^2 or larger.	Applies to categories 1 to 7 and 10 and expires on 21 July 2021

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described *in italics*. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

A	Ampere
AC	Alternate current
ASIC	Application specific integrated circuit
CTE	Coefficient of thermal expansion
DC	Direct current
DoC	Declaration of Conformity
EEE	Electrical and electronic equipment
FCP	Flip chip package
ILD	Interlayer dielectric
IMCI	Industrial monitoring and control instrument
IVD	In vitro diagnostic medical device
IVUS	Intravascular ultrasound
RoHS 1	Directive 2002/95/EC (2003)
RoHS 2, RoHS	Directive 2011/65/EU (2011)
T_g	Glass transition temperature; temperature below which the physical properties of plastics are similar to those of a glassy or crystalline state, and above which they behave like rubbery materials.[79]
TI	Texas Instruments
V	Volt

10.1. Background and technical information

On 16 January 2020, TI et al. (2020a) requested the renewal of the exemptions with the below wordings, scopes and the maximum possible durations for the respective categories of EEE in the scopes:

No.	Requested Exemption	Requested scope

[79] C.f. Introduction to Plastics and Elastomers, https://reader.elsevier.com/reader/sd/pii/B9781455778966000595?token=78C309888840668524A0C179096A065CC5C566F408B4C23BB63835BEDFB5C7A824A0C5FBAD0658223456531881F4DBDF&originRegion=eu-west-1&originCreation=20211022075517

15	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages for bonding to cadmium zinc telluride (CZT)	Does not apply to applications covered by point 15(a) of this Annex. Applies to category 8, other than in vitro diagnostic medical devices.
15(a)	Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages where at least one of the following criteria applies: - a semiconductor technology node of 90 nm or larger; - a single die of 300 mm^2 or larger in any semiconductor technology node; - stacked die packages with a die of 300 mm^2 or larger, or silicon interposers of 300 mm^2 or larger.	Does not apply to applications covered by point 15 of this Annex; Applies to Categories 1 to 7, 8, 9, 10 and 11.

TMC (2021) contributed to the stakeholder consultation stating that their members intend submitting applications for renewal of certain exemptions [here 15] within the legally foreseen deadlines of 18 months prior to their expiries for industrial monitoring and control instruments. They request the European Commission to schedule the evaluation of the Annex III exemptions relevant to category 9 industrial applications in due time, i.e., 18 months prior to 21 July 2024. However, the COM had already clarified with representation of TMC in written correspondence, pertaining to a previous exemption renewal request, that the Commission considers it justified for the technical assessment to start at the same time for all categories as requested by the applicants.

10.1.1. History of the exemption

The exemption was added to the Annex of RoHS 1 in 2005 after a review of the related exemption request by Goodman (2004) with an expiry date in 2010. Zangl et al. (2010) reviewed the exemption in 2008/2009 again under RoHS 1. The consultants recommended to extend the exemption's validity until 2014, the maximum allowed validity period for exemptions under RoHS 1. Exemption 15 was transferred to Annex I of RoHS 2, and the maximum validity period was thereby extended to July 2016. Upon a request for renewal, Gensch et al. (2016) reviewed the exemption under RoHS 2 resulting in the split of the exemption into exemption 15, which maintained the previous status of the exemption for EEE of cat. 8 and cat. 9, and introduced exemption 15(a) with a restricted scope for the other categories of EEE in the scope of RoHS.

10.1.2. Summary of the requested exemption and stakeholder contributions

According to TI et al. (2021b), *lead containing solder bumps are still required to complete a viable electrical connection between the semiconductor die and its package carrier especially when the package type involves older technologies, large dies, or complex stack* *up. This is because for such cases, lead containing solder bumps provide better quality, reliability and life for the product being softer and more ductile than lead-free solders and can therefore withstand stress related reliability issues manifested in various forms such as solder cracking, silicon cracks, delamination, cracks in the low-K dielectric layers, and package warpage.*

Older product technologies are defined as those having transistor gate lengths of 90 nm and longer. Large die and large interposers are defined as being 300 mm^2 or larger.

Since the onset of Covid-19 pandemic, global semiconductor manufacturers have been dealing with challenges as the result of worldwide supply chain shortages. The semiconductor supply shortage is not expected to ease until 2023, trials on new materials will be therefore delayed, as well.

TMC (2021) contributed to the stakeholder consultation stating that their members intend submitting applications for renewal of certain exemptions within the legally foreseen deadlines of 18 months prior to their expiries for industrial monitoring and control instruments. They request the European Commission to schedule the evaluation of the Annex III exemptions relevant to category 9 industrial applications in due time, i.e., 18 months prior to 21 July 2024. However, the COM had already clarified with representation of TMC in written correspondence, pertaining to a previous exemption renewal request, that the Commission considers it justified for the technical assessment to start at the same time for all categories as requested by the applicants. The Commission refers to the fact that Article 5(5) of the RoHS Directive requires an exemption request must be made not later than 18 months before the exemption expires but does not lay down rules on how early before the expiry date an exemption renewal request is to be submitted, or when the COM should start the technical evaluation.

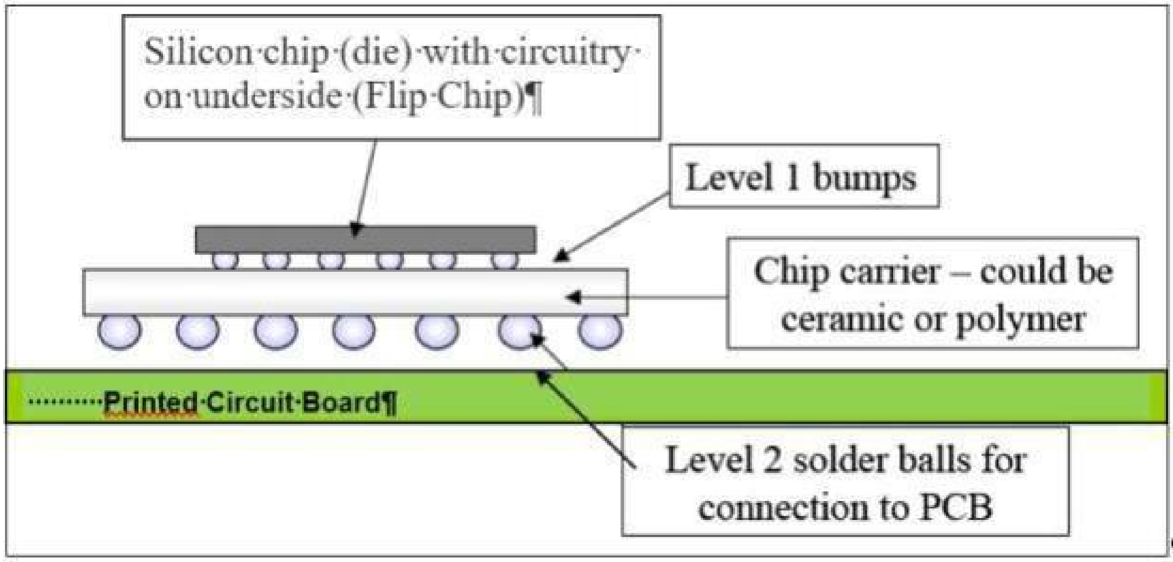
10.1.3. Technical description of the exemption and use of the restricted substance

Thermal mismatch as root cause for the use of lead

The technical background was described in detail in the earlier reviews of the exemption by Zangl et al. (2010) and Gensch et al. (2016). The explanations in this section will therefore be focused on the crucial points which are necessary to follow the technical arguments discussed in the context of this review and any new aspects which the applicants raise.

Figure 10-1 shows the outline of a flip chip package (FCP) with level 1 bumps produced from lead-containing solder according to the exemption scopes.

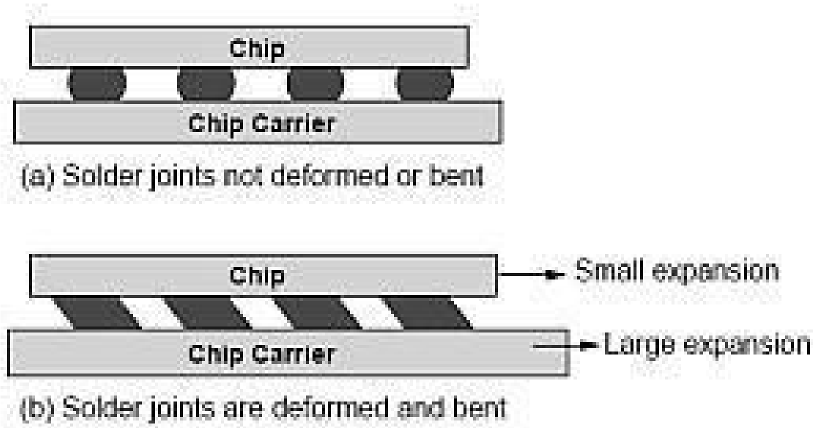
Figure 10-1: Outline of a flip chip package[80]



Source: Goodman (2004)

Differences in the coefficients of thermal expansion (CTEs) between the chip carrier and the chip exert mechanical stress on the level 1 solder bumps resulting in their deformation. Lead-free solders are more brittle than the ductile lead-containing solders so that compensate less thermomechanical stress increasing the strain on the chip and chip carriers. Larger thermomechanical stress may thus result in debonding of the joints or cracks in the bonded materials.

Figure 10-2: Thermomechanical deformation of level 1 solder bumps in FCPs

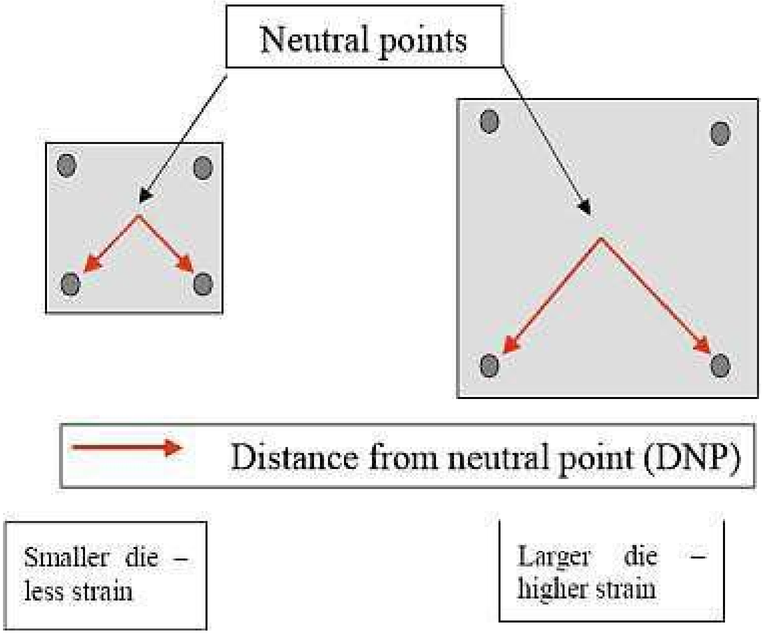


Source: Goodman (2004)

Larger dies (chips) exert larger thermomechanical stress in particular on those bumps with longer distance from the "neutral points" near the centre as displayed in Figure 10-3.

80

Figure 10-3: Increased thermomechanical stress in larger die FCPs



Source: Intel et al. in Zangl et al. (2010).

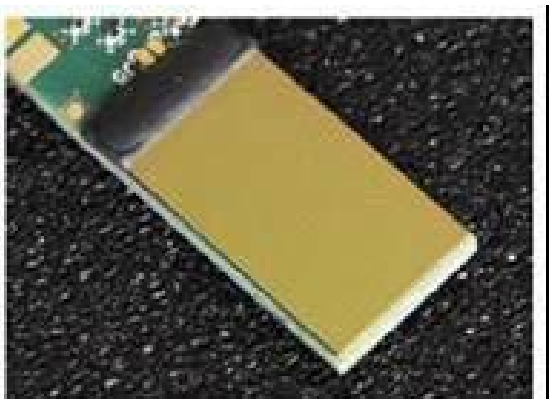
A thorough redesign of FCPs (materials, geometries, sizes, technologies) allows the use of lead-free solders nevertheless within the limits, which TI et al. (2020a) see in the scopes of the renewed exemption as requested. Such redesigns are linked to the technical progress since the materials and technologies used needed to be developed as well.

According to the applicants, the above physical effects, mostly based on thermal mismatches due to differences in the applied materials' coefficient of thermal expansion, still require the use of lead in the applications in the scope of the proposed renewed exemption 15(a). This renewed exemption 15(a) would include, differently from the current exemption 15(a), EEE of categories 8 and 9.

Specific situation of lead use in FCPs with CZT dies

TI et al. (2020a) say that exemption 15(a) is acceptable for category 8 medical devices except for the use of specific flip chip bonding to CZT (cadmium zinc telluride) for ionising radiation detectors. They describe this detector as a specific type of integrated circuit (IC) flip chip package that consists of a CMOS (complementary metal–oxide–semiconductor) die, typically CZT or cadmium telluride that is bonded on the underside CMOS circuit of the crystal using lead alloy "bump bonds" to attach it to the carrier circuit. The image below shows a prototype ASIC (Application-Specific Integrated Circuit) carrier circuit, onto which the CZT crystal will be solder bump-bonded.

Figure 10-4: Circuit board with carrier circuit onto which the CZT semiconductor crystal is flip-chip bonded



Source: Nuclear Instruments and Methods in Physics Research A862 (2017) 18–24), referenced in TI et al. (2020a)

Since the above figure does not provide real insights, the applicants were asked to provide a schematic view of the CZT-FCP similar to Figure 10-1 on page 238. *TI et al. (2021c) could, however, not make this available.*

TI et al. (2020a) report these detectors to be applied in Computed Tomography (CT) machines that are used for 3D X-ray imaging of patients. CZT X-ray detectors give superior image quality with lower radiation doses compared to other types of detectors.[81] *The CZT die is heat and stress sensitive so that the solder used must have a melting point as low as possible and be very ductile. Each die has an area of about 200 mm^2, and the CMOS circuitry will use < 90 nm technology node. To generate high definition images, multiple dies are used to obtain a large area detector for very good image resolution and quality.*

TI et al. (2020a) summarize the requirements for flip chip bonding between CZT ionising radiation detectors to carrier circuits as follows:

- Melting point of < 120 °C
- Must be very ductile
- Constituents of the alloy must not diffuse into direct conversion sensor as they can destroy its function
-

10.1.4. Amount(s) of restricted substance(s) used under the exemption

TI et al. (2020a) consider the flip chip lead (Pb) content as a sum of two parts. The flip chip semiconductor die bumps on the silicon chip vary from the general eutectic 37 % Pb to more than 85 % Pb by weight. The flip chip bumps also require a Pb cladding on the substrate / interposer bonding pads or solder posts on the headframe, generally using the 37 % eutectic Pb, but could range much higher to meet production processing and reliability requirements such as thermal cycling demands. During the integrated package assembly process, the Pb

[81] See also the report of Deubzer et al. 2022 for the review of exemption IV-1

will interact and form a single homogeneous substance. The exact share of lead weight in the solder after assembly will vary according to the bump size, pad size, and lead content in each material type. The final Pb content will likely be less than 85 % by weight.

Table 10-1: Lead in flip chip packages (FCPs) in the scope of the exemptions

Example of F/C Pb Materials	% Pb Content
Silicon Flip Chip Die Bump	37% - 97%
Solder Cladding on Substrate Pad* * May not be used for ceramic	37% - 75%
Combined Flip Chip Materials after Assembly	37% - 97%
Flip chip bumps to CZT	~34%

Source: TI et al. (2020a)

TI et al. (2020a) estimate that 85 kg/year of lead entered the EU in 2019 due to the flip chip exemptions. Table 10-2 below details the amount of lead estimated being shipped into the EU market. The 2008 through 2014 lead usage estimates from previous reports are included for reference.

Table 10-2: Total amount of lead placed on the EU market

Amount of lead (Kg)			
2008	2014	2018	2019
2315	896	112	85

Source: TI et al. (2020a), the 2018 and 2019 figures are derived from table 3 on page 11 of a market report82

[82] TechSearch International: Survey of High Pb and Eutectic Flip Chip Market, Dec 2019; source as referenced by the applicants

10.2. Justification for the requested exemption

10.2.1. Substitution of lead in FCPs with semiconductor technology nodes of 90 nm or greater

TI et al. (2020a) state that these types of FCP semiconductor devices use low–strength F-TEOS as low-K material. As a result, they are especially sensitive and experience low-K dielectric cracking at relatively low stress levels.

Silicon technology nodes with transistor gate lengths longer than 250 nm used aluminium interconnect in the wafer processing backend. Later on, industry had to migrate to copper interconnects due to device performance expectations and increased circuit densities. Devices on the 250 nm to 90 nm technology nodes converted to a common low dielectric constant film (low-k): fluorinated tetraethyl orthosilicate (F-TEOS). F-TEOS made copper interconnects possible. At that time, F-TEOS was a breakthrough in materials engineering and from an electrical perspective reduced the capacitance in the silicon wafer backend dielectric stack. Reducing the resistance of interconnect wiring and reducing the capacitance of the interlayer dielectric (ILD) allow for higher device clock speeds. Dielectric capacitance was significantly reduced with F-TEOS when compared to the dielectrics used earlier in the semiconductor industry. The porous nature of the film is what reduces the capacitance and F-TEOS offered improved electrical performance at the expense of film mechanical strength.

The low mechanical strength of F-TEOS makes it susceptible to dielectric fracturing beneath the under bump metallization (UBM) on the silicon chip (die) with lead-free wafer bumps, due to the increased stresses imposed. This does not occur with leaded C4 (controlled collapse chip connection) wafer bumps. Lead-free wafer bumps are significantly less ductile than those containing lead, and the observed failure mode mechanism is driven by coefficient of thermal expansion mismatch between the silicon die and the carrier which transfers the strain to the less ductile lead-free bump and the fragile F-TEOS dielectric.

Fracturing of the dielectric with Pb-free wafer bumps is commonly referred to as "ghost" or "white" bumps due to the way they appear by acoustic imaging. Not only can the failure mode reduce assembly yields, but it can also adversely impact product reliability. The failure may not be caught when a unit goes through component assembly and final test. Compromised units that ship are at high risk of failing during the customer's board level assembly process or in the field. The failure rates are unacceptably high. This failure mode does not occur with wafer bumps that contain lead because leaded bumps absorb the stress associated with the CTE mismatch between the silicon chip and the substrate to which the solder attaches.

TI et al. (2020a) state that flip chips are commonly used in long life, high reliability applications that remain in the field for over 20 years and require continuous availability as replacement parts. Legacy flip chip devices and many large die devices are older products that have declining volume year-on-year making it difficult to justify an all-layer and material redesign (this is usually not technically possible, as described in this renewal request). Removing these products from the market would create long supply gaps with minimal impact on the amount of lead in the EU market, but prevent the sale of many types of products in the EU.

10.2.2. Substitution of lead in FCPs with a single die of 300 mm^2 or larger in any semiconductor technology node

TI et al. (2020a) explain that packages with Pb-free bumps on silicon up to 300 mm^2 die size has been qualified and are now in production. The shipment volume for legacy devices with Pb bumps will decrease drastically over time in the next several years. New products introduced into the market in the last several years are assembled with Pb-free bumps even though the die size is greater than 300 mm^2.

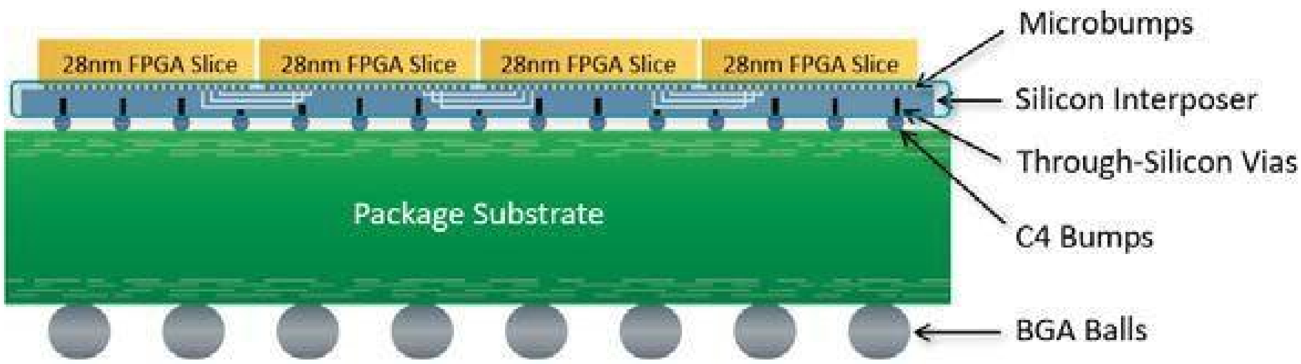
Although the volume of these legacy Pb bump devices with large die (> than 300 mm^2) will be reduced in the next several years, there are many equipment manufacturers that are still using the legacy devices in small volume. Some of these devices are used in networking equipment and telecommunication products that have a long product life cycle. The semiconductor manufacturers have the obligation to continue to supply to these customers that have designed-in these devices with Pb bumps.

Even if a Pb free solution may be available, which for many products is not the case, qualifying a legacy device with a Pb free bumps is economically not feasible for these equipment manufacturers due to the high mix and low volume type of product offering.

10.2.3. Substitution of lead in FCPs with stacked die packages

TI et al. (2020a) state that FCPs applying stacked die packages with dies of 300 mm^2 or larger, or silicon interposers of 300 mm^2 or larger, still require lead. Figure 10-5 represents the schematic side view of a stacked silicon interposer package containing four active silicon dies connected to each other through a passive interposer with through silicon via (TSV) using micro-bumps.

Figure 10-5: Example of a stacked die package with a large silicon interposer



Source: TI et al. (2020a)

According to TI et al. (2020a), in this type of package any number of active dies can be assembled on the interposer and can then be connected to an organic package substrate with C4 (controlled collapse chip connections) bumps. A capillary underfill is used to fill the gap between the micro-bumps and interposer, which helps in reducing the stress in micro-bumps. C4 bumps are created on the interposer backside and are connected to a package substrate. A second layer of C4 bump capillary underfill is used to fill the gap between the interposer, C4 bumps and the organic package.

The warpage of such stacked dies on interposer packages are inherently higher due to presence of multiple underfill material and copper TSV structures in the interposer. Transition to lead free solder would require an alternate underfill with higher glass transition temperature Tg which further makes warpage worse. Higher warpage adds significant stress to the package causing underfill delamination leading to bump cracks and cracking of silicon Low-K. In addition to this, the use of lead-free solders and associated underfill materials also decreases the coplanarity of the device. Insufficient coplanarity causes significant challenges for end users during the board attach process causing non wet and head-in-pillow (HIP) joints, according to TI et al. (2021c) a surface mount defect exhibiting package warpage in large FCPs. Higher package warpage increases oxidation of the BGA & printed solder on PCB as they do not make contact during reflow. So, this cause HIP defects. Hence lead-free solders cannot be used in stacked die FCPs with interposers of 300 mm² size and larger.

10.2.4. Substitution of lead in FCPs with bonds to CZT for cat. 8 medical devices other than IVDs (ex. 15)

TI et al. (2020a) say that cadmium zinc telluride (CZT) dies may be damaged by temperatures of > 120 °C as the properties and performance would be adversely affected. Solders such as eutectic tin/lead solder (melting point 183 °C) and commonly used lead-free solders such as tin-silver copper (around 218 °C melting point) cannot be used as flip chip bonds to the underside of the crystal because melting these solders requires significantly higher temperatures. The solder alloys that have been found to be suitable are bismuth-tin-lead solders with around 34 % of lead and a melting point of around 96 °C to around 105 °C.

The only lead-free solders alloys that have low melting points and are sufficiently ductile are contain indium, e.g. bismuth-indium-tin solders (54 % Bi, 16.3 % In, 16.3 % Sn) with a melting point of 81 °C (eutectic). This melting point is, however, too low as there is a risk of melting due to internally generated heat and if the equipment is used in hot climates. Indium-tin as another potential alloy melts at 125 °C and thus above the 120 °C upper limit.

TI et al. (2020a) further on inform that indium metal electrodes may diffuse into the CZT substrate and would destroy the "blocking contacts" which are used on semiconductors to prevent atoms, e.g. from bonding materials, diffusing into the semiconductors and destroying their function. One publication states that indium dopant in CZT increased electrical resistivity threefold which would be expected to be detrimental to CZT as an X-ray detector.[83] Therefore, alloys containing indium cannot be used as they could cause poor reliability and shorten lifetimes. Alloys containing lead can be used as only these have all of the essential requirements.

Bonding of CZT using anisotropic conducting adhesives according to TI et al. (2020b), initially gives suitable electrical connections. However, with CT, the CZT detector assembly

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[83] .C.f. https://www.researchgate.net/publication/223200104_Effects_of_In_doping_on_the_properties_of_CdZnTe_single_crystals; source as referenced by TI et al. 2020a

is exposed to very intense ionising X-ray radiation used for imaging that will destroy the adhesive, which would cause the electrical bonds to be lost as the adhesive decomposes.

10.2.5. Roadmap towards substitution or elimination of lead

TI et al. (2020a) claim that substitutes for leaded solders are being developed by the industry for new designs. These solutions require implementation of multiple changes in package materials and die design, among others

- *removal of solder bumps from high stress locations;*
- *use of underfill materials with higher glass transition temperature (T_g) which are able to off-load the stress from the solder joint; and*
- *use of lower TCE carrier dielectrics.*

Implementation of the above mentioned solutions to legacy products[84] is not possible, or will require extensive redesign and requalification. The cost of re-designing and re-qualifying these products is extremely high, reaching $1 Million per product at component level only. Such high cost cannot be justified for legacy products manufactured in small quantities and over the prime of their life-cycle. Neither do viable alternatives exist to replace legacy ASICs, as no drop-in pin-compatible replacements, meeting same form fit and function exists. The cost of re-designing and re-qualifying existing systems to operate with alternative solutions is even higher than the cost at component level. Thus, for legacy products not originally designed to meet long-term reliability requirements with lead-free solders, no alternatives exist.

Conversions where possible, require a major change of all materials currently being used. The industry is continuing to research Pb-free solutions using new materials and process techniques. These solutions

- *cannot change product footprint, i.e. must fit into the same electronic environment as the lead-containing FCP*
- *must maintain compatibility with package designs*
- *must meet or exceed current form / fit / function requirements.*

TI et al. (2020a) are of the opinion that the electronics industry has demonstrated a strong commitment to developing new lead free flip chip devices as new technologies with adequate reliability become available. The remaining devices manufactured in leaded flip chip attach have proven to be much more difficult or impossible to substitute. Sales of older designs of components are expected to continue declining as those products are replaced with newer technology, assuming that this research is successful.

[84] Remark of the consultants: In this case, the applicants consider older models of FCPs as legacy products, not the EEE in which they are applied.

10.2.6. Environmental and socioeconomic impacts

TI et al. (2020a) put forward that the total lead amount in solder bumps is extremely small, having a minimal impact on the amount of lead in the EU market. For reference – approximately 216,500 large ASIC devices amounts to 10.0 kg of lead . This equates to approximately 20,000,000 small ASIC devices. Moreover, the lead containing bumps are located at an internal interface of the ASIC package and are encapsulated by a chemically stable polymer (underfill), significantly limiting impact on the environment.

Because of the long life-time of some devices and evolving IC manufacturing processes, devices manufactured in low volumes and used in specialist products that are made in small numbers, such as medical devices and test equipment, may require a "lifetime buy" when the older wafer fabrication processes are retired. In these cases, the manufacturers could be entirely dependent on existing inventory that has been manufactured with design rules that required leaded solders. If these devices are unable to be used in the manufacture of new products, these ICs would have to be disposed of and add to the electronic waste stream without contributing the value in which the products were intended before the product's useful end of life and the types of products that rely on them could not be sold in the EU. In addition, many existing products on which consumers and businesses are now dependent upon would become obsolete/waste due to unavailability of repair parts. Many of these devices with very large monolithic die were developed many years ago and are now sold in relatively small volumes. It would not be worthwhile for IC manufacturers to convert these devices to a Pb free bump package, even if this were technically possible, which as explained in section 6, is not technically possible. Due to the long qualification cycle for new of redesigned devices by IC manufacturers and also by end-users, it is likely that these components would become obsolete before qualification was completed.

Exemption 15(a) is very widely used in medical devices. Medical device manufacturers use the same components as all other sectors of the electronics industry but can be seriously affected by early obsolescence of components (if drop-in replacements are not available) , as redesign of medical devices involves retesting, sometimes clinical trials and they need to gain approval from Notified Bodies before redesigned products can be sold. This can mean that some products are no longer sold in the EU which limits the choice of hospitals, and this can negatively affect healthcare.

10.3. Critical review

10.3.1. REACH compliance – Relation to the REACH Regulation

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV "*provided that such inclusion does not weaken the environmental and health protection afforded by*" the REACH Regulation. The article details further criteria which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the consultants as a threshold criteria: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Annex XIV

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV as an element. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by*" the REACH Regulation.

Annex XVII

Annex XIV lists lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:

- Entry 10: Lead chromate;
- Entry 11: Lead sulfochromate yellow;
- Entry 12: Lead chromate molybdate sulphate red;
- Entry 55: Tetraethyllead

None of the above substances is of relevance for the use of lead in the scope of the requested exemption. A renewal of the requested exemption would not weaken the protection afforded by the listing of substances on the REACH Authorisation list (Annex XIV).

Annex XVII contains entries restricting the use of lead compounds:

- Entry 16 restricts the use of lead carbonates in paints;
- Entry 17 restricts the use of lead sulphates in paints;
- Entry 19 refers to arsenic compounds but includes a few lead compounds and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;
- Entry 28 addresses substances which are classified as carcinogens category 1A or 1B listed in REACH Appendices 1 or 2, respectively. In this context, it stipulates that various lead compounds shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;
- Entry 30 addresses substances which are classified as reproductive toxicant category 1A listed in REACH Appendices 1 or 2, respectively. Like for entry 28, entry 30 stipulates for some lead compounds that they shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;
- Entry 63 restricts the use of lead and its compounds in jewellery and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children;
- Entry 72 lists substances which are classified as carcinogenic, mutagenic or toxic for reproduction. It stipulates that the substances listed in column 1 of the table in Appendix 12 shall not be used in textiles, clothing and foot wear. The table lists lead and its compounds mentioned in entries 28, 29, 30 and Appendices 1-6.

The use of lead within the scope of the requested exemption does not regard paints or jewellery, nor components that could be expected to be placed in the mouth by children under normal or foreseeable use. Furthermore, this use of lead is not a supply of lead compounds as a substance, mixture or constituent of other mixtures to the general public. Lead is part of an article and as such, the above entries of Annex XVII of the REACH Regulation would not apply.

No other entries with relevance for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the current status of these annexes, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

10.3.2. Scope and numbering of the renewed exemption 15

TI et al. (2020a) propose restricting the scope of exemption 15 to FCPs with CZT dies used in EEE of cat. 8 other than IVDs with the below modified wording. The applicants originally requested the renewal of exemption 15 but TI et al. (2022a) later to establish it as a new one and to number it as 15(b).

The consultants followed this approach since exemption 15 has to be maintained anyway in its current wording as reference for Art. 4(4)(f) which stipulates that substance restrictions do not apply to EEE which benefited from an exemption, and which was placed on the market before that exemption expired. The requested exemption thus reads as below:

No.	Requested Exemption	Requested scope
15(b)	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages for bonding to cadmium zinc telluride (CZT)	Applies to category 8, other than in vitro diagnostic medical devices

TI et al. (2020a), (2020b), (2021a), (2021b), (2021c), only mention CT imaging equipment using lead-containing solders in CZT-FCPs for detecting X-rays, but, upon the consultants' suggestion, they were reluctant to restrict the scope to CT devices without providing sound information of other uses that would require the use of lead. Upon the consultants' announcement to restrict the exemption scope to X-ray CZT detectors unless the applicants specify further uses of these X-ray detectors that require lead solders, *TI et al. (2022a) proposed to add positron emission tomography (PET) and single photon emission tomography (SPECT) which are both based on the detection of γ-rays (radioactive, ionizing radiation) and may also be used in combination with CT.*

TI et al. (2021a), however, had already explained earlier that *"The radiation detected by PET and SPECT has a very low intensity as it is from radioisotopes that are inside the patient and so must be at levels that are very low to avoid radiation damage to the patient." It is the new use of CZT for CT imaging that now requires the use of exemption 15." "Research has shown that anisotropic conducting adhesives cannot be used as the polymeric material is destroyed by the intense exposure to X-radiation."*

PET and SPECT imaging CZT-detectors therefore do not require the use of lead solders. The consultants adapted the proposed wording to reflect the technical specifications and to simplify the exemption wording, which TI et al. (2022a) originally did not oppose.

No.	Exemption	Scope and dates of applicability
15(b)	Lead in solders to complete a viable electrical connection between cadmium zinc telluride (CZT) semiconductor dies and carriers within integrated circuit flip chip packages of X-ray detectors used in computed tomography (CT)	Expires on XXX for category 8 other than in vitro diagnostic medical devices.

10.3.3. Scope of exemption 15(a)

Since exemption 15(a) consists of several subclauses, the consultants will use the below numbering which allows to address the individual subclauses in the text:

No.	Exemption
15(a)	Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages where at least one of the following criteria applies: (i) a semiconductor technology node of 90 nm or larger; (ii) a single die of 300 mm^2 or larger in any semiconductor technology node; *(iii)* stacked die packages with a die of 300 mm^2 or larger, or silicon interposers of 300 mm^2 or larger.

The applicants requested the renewal of the exemption for categories 1-11 including in-vitro diagnostic equipment and industrial monitoring and control instruments without giving details about specific types of EEE for which the various clauses of the exemption are relevant.

TI et al. (2021b) put forward that from the Umbrella Project Working Group's point of view, since FCPs are used in multiple end use applications in a highly fragmented business across large OEMs, small to large suppliers, and distributors, it is quite difficult to know exactly in which end use application the final customer places the IC or FCP products in. Therefore, they are not able to provide examples of uses where 15(a)(i), 15(a)(ii), or 15(a)(iii) gets placed in.

From the consultant's point of view, a global industry consortium including producers of different types of EEE manufacturers and their suppliers, i.e. not only producers of FCPs, should have access to information of products in which FCPs are used. Otherwise, the question arises why the umbrella project requests the renewal of the exemption for uses which are unknown to its members. Additionally, the impression arises that the exemption is not supported by users of FCPs who can be assumed to know in which types of equipment they use which FCPs in the scope of the exemption. The applicants were requested again to provide examples – not an exhaustive list – of EEE using the exemption whereupon TI et al. (2021c) provided the below examples.

- *Use of ex. 15(a)(i)*
  - *Network and servers; Internet of Things; ASIC prototyping (Cat 3, 4); Industrial tools (Cat. 6), industrial monitoring (Cat 9), High Side Current Sense Amplifiers (Cat 1-7).*
- *Use of exemption 15(a)(ii)*
  - *Data centre with high volume data, high transmission speed and high frequency applications (cat 11); and CPU, GPU, FPGA & ASICs are examples of end products where Lead (Pb) based FCPs are still being used in all categories 1-7 and 10 and 11.*
- *Use of exemption 15(a)(iii)*
  - *CPU, GPU, FPGA & ASICs are examples of end products where Lead (Pb) based FCPs are still being used being used in all categories 1-7 and 10 and 11.*

TI et al. (2021c) further list EEE for which they are not able to narrow down the use of FCPs to specific exemption clauses.

- *Category 8 (IVD)*
  - *Data processing computers of in vitro diagnostic devices*
- *Category 9 (IMCI)*
  - *Theodolites and tachymeters (Total Station)*
  - *Surveying Instruments (3D Scanner)*
  - *Field programmable gate arrays of analysis and measurement instruments*
  - *Industrial ethernet hubs of analysis and measurement instruments and systems*
  - *Tachometers of analysis and measurement instruments*
  - *Industrial data processing computers of analysis and measurement instruments*
  - *Distributed Control System (DCS)*
  - *Safety Instrumented System (SIS)*
  - *High-content analysis system*
  - *Paper Quality Control System*
  - *Film/Sheet Thickness Gauge*
  - *Electric to Pneumatic Converter*
  - *Pneumatic to Electric Converter*
  - *Power Analyzers*
  - *Oscilloscopes*
- *Category 11*

- *Professional salon equipment used mainly at hair salons for haircut, shampooing, perming, colouring, treatment and the like.*
- *Professional aesthetic equipment used mainly at aesthetic salons for skin care, including facial care and body treatments and the like.*

Since the above information is the result of repeated urgent requests for such information already, the consultants did not ask for more details. The above listing provides at least some insights into uses of FCPs in EEE of various categories which substantiate the plausible assumption and the applicants' claim that FCPs in the scope of exemption 15(a) are used in many types of EEE across all categories.

10.3.4. Substitution and elimination of lead in CZT detectors in medical devices other than IVDs (renewal of ex. 15)

Substitution of lead in CZT-detector FCPs

TI et al. (2020a), (2020b) request the renewal of exemption 15 for FCPs containing CZT semiconductors used as detectors in CT, PET and SPECT medical imaging equipment. For completing a viable electrical connection between the semiconductor die made from CZT and the carrier in the FCPs, bismuth-tin-lead solders are used with around 34 % of lead and a melting point between 96 °C to around 105 °C. The applicants claim that CZT dies may be damaged if exposed to temperatures above 120 °C. An internet investigation produced information confirming this statement.[85]

It is therefore plausible that solders with higher melting points cannot be used which excludes the use of lead-free solders like tin-silver copper (around 218 °C melting point) or indium-tin alloys melting at 125 °C as another potential alternative.

Since CZT is a very brittle material, solders must be ductile, which is either achieved with lead, or alternatively with indium, which at the same time reduces the melting point of solders. The potential alternative to lead-containing solders with low melting point and sufficient ductility are therefore indium-containing solders, e.g. bismuth-indium-tin solders (54 % Bi, 16.3 % In, 16.3 % Sn) with a melting point of 81 °C (eutectic) which the applicants consider as too low because the solder joints may melt due to internally generated heat – detectors may heat up during operation - and if the equipment is used in hot climates. Conductive adhesives as a potential low-temperature alternative decompose if exposed to X-rays or γ-rays, according to the applicants.

The applicants were asked how warm CZT detectors may become during operation. Also, the performance of these detectors seems to be temperature-dependent, i.e. their performance decreases with increasing temperature[86] so that they may have to be cooled, which then might enable the use of lead-free solders like the above bismuth-indium-tin alloy.

TI et al. (2022c) replied that "It has been extremely difficult to find a consensus on detector temperatures during operation due to the differing designs by manufacturers. However, it is

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[85] C.f. for example https://www.qptechnologies.com/wp-content/uploads/2020/12/CSR_2009-OctNov-111309_CZT.pdf

[86] C.f. Washington et al. 2010.

important that the environment of the CT is considered not just during its operation, but also considers the manufacturing of the device which cannot tolerate, even in rapid soldering processes, temperatures in the order of 120 °C as the output response of the CZT is altered by temperatures.

This statement is inconclusive as to the operating temperatures, and TI et al. (2020a) themselves had brought in the bismuth-indium-tin solder as viable solution for reflow soldering below 120 °C.

TI et al. (2022c) raise, as another concern with indium-based solders, the diffusion of indium into the CZT detector which, as indium is a dopant of CZT, modifies the electrical contact and this deteriorates the crystals' performance.

The applicants did not provide publishable evidence that this concern actually materialized in tests with the above-mentioned indium-containing solder. Overall, it remains unclear whether lead-free solders can be used.

Elimination of lead in CZT-detector FCPs

There are other detector technologies for the detection of X-rays, which were discussed during the review of exemption IV-1 (Pb, Cd and Hg in detectors for ionising radiation) by Deubzer et al. (2022). The CZT detectors were found to provide the best image quality and enables reducing patients' X-ray exposition while still achieve image qualities that are adequate for the diagnostic purpose. Other detectors can therefore not eliminate the use of CZT-detectors and the use of lead in the FCPs from which these detectors are built.

Concerning the possibilities for eliminating lead in CZT-detectors via conductive adhesives, TI et al. (2021a) had originally stated that conductive adhesives decompose if exposed to X-rays.

When the consultants announced that they will not include PET and SPECT imaging into the exemption but restrict the scope to X-ray detectors used in CT imaging equipment, *TI et al. (2022c)* reported:

"[…] COCIR companies have been undertaking further investigations into alternatives to lead solder. As such the use of conductive adhesives in currently marketed PET devices and CT devices has now been proven and is no longer required to be included in the exemption renewal request for exemption 15." TI et al. (2022c) add that there is no certainty that lead-free solutions would work for future generations of detectors and that they reserve the right to submit new requests anytime for this use.

While exemption 15 is thus not required for CZT detectors in CT medical imaging equipment, TI et al. (2022c) now suggested including "catheters" into the scope of exemption 15:

No.	Exemption	Scope and dates of applicability
15(b)	Lead in solders to complete a viable electrical connection between cadmium zinc telluride (CZT) semiconductor dies and carriers within integrated circuit flip chip packages of catheters	Expires on XXX for category 8 other than in vitro diagnostic medical devices.

TI et al. (2022c) asked to *„Please note that in the original exemption renewal request (page 31) detailed exemption 15's use in catheters. Given the proposed scope changes to the exemption, this will need to be explicitly listed in the exemption.“*

Page 31 of the original renewal request submitted by TI et al. (2020a) elaborates intravascular ultrasound (IVUS) imaging as example that "[…] explains why not renewing exemption 15a would harm EU citizens." The section in the renewal request is related to exemption 15(a), not exemption 15 (now renumbered as exemption 15(b)). It does not contain technical information as to the use of CZT detectors. It mentions that "Co-registration is possible - This means the IVUS images can be mapped to the angiogram (X-ray image) to facilitate image interpretation and easy length measurements without a mechanical "pullback device". This information without further details cannot be related to the use of CZT detectors in catheters for IVUS imaging itself.

Further on, while the consultants had requested several times to provide evidence of uses for lead-soldered CZT detectors others than in CT imaging equipment, the applicants confirmed that still in October 2022 that PET and SPECT should be included into the exemption scope, but did not mention catheters. Besides these procedural incongruities, adding catheters to the scope of exemption 15(b) moreover raises several questions which to answer would require a sound justification and a thorough critical review, e.g. why catheters used for intravascular ultrasound imaging would require a CZT X-ray detector. In case these detectors are actually used in catheters for IVUS imaging, it would have to be clarified why it cannot be substituted like in the CT X-ray imaging equipment. TI et al. (2022c) did not add any such information but just referenced page 31 of their renewal request where such information is not available.

The consultants are of the opinion that the applicants had several possibilities to bring in the catheters earlier to allow a reasonable review according to the requirements of Art. 5(1)(a). The information submitted is not sufficient to recommend the inclusion of catheters into the scope of exemption 15(b) without infringing Art. 5(1)(a).

Overall, since lead can be substituted in X-ray detectors used in CT imaging equipment, there is no need to adopt a new exemption 15(b) to Annex III.

10.3.5. Substitution or elimination of lead uses in FCPs in scope of exemption 15(a)

Summary of the applicants' justification (exemption 15(a))

For the better overview of the various types of FCPs in the scope of exemption 15(a), and to guide the critical review, the below summarizes the applicants' arguments for each of the exemption clauses:

- FCPs with technology nodes of 90 nm and more ("larger nodes") technically cannot use lead-free solders, and they cannot be redesigned to enable the use of lead-free solders to allow the continued use in legacy products without the exemption. The substitution of lead in FCPs with technology nodes smaller than 90 nm is, however, scientifically and technically practicable. FCPs with smaller technology nodes technically can replace those with larger ones, even though not as drop-in replacement. The EEE which use these FCPs would need to be redesigned to be able to use the FCPs with technology nodes of less than 90 nm. The applicants justify their renewal request for this part of exemption 15(a) with the continued use of FCPs with technology nodes of 90 nm and more in EEE which has not yet been redesigned but is still placed on the market as new EEE ("legacy products").

To put the above information into perspective, the consultants would like to point out that the exemption would not be needed for EEE already placed on the market because Art. 4(4)(f) provides for the continued availability of spare parts for these products.

- The substitution of lead remains scientifically and technically impracticable in FCPs with dies and/or silicon interposers larger than 300 mm² (exemption clauses (ii) and (iii)) .This applies to all FCPs regardless of the technology nodes, i.e. for the old FCP designs with technology nodes of 90 nm and more as well as modern FCPs down to 20 nm.
- The 300 mm² threshold size also applies to stacked die FCPs with silicon interposers (exemption subclause (iii)). Such FCPs require the use of lead solders if they apply silicon interposer of this size or larger ones.

The above aspects were discussed with the applicants during the critical review in four questionnaires which did not enable the consultants to obtain clear insights into the actual technical situation. The applicants' answers were inconsistent, incomplete and partially contradicting other provided information (c.f. subsequent sections). In an online meeting with the applicants, which the consultants requested right after questionnaire 5 was sent out as a last attempt to obtain conclusive, stringent and sufficiently detailed information, the consultants explained their role, the background and essentials of the exemption review process to avoid misunderstandings on the kind of information which Art. 5(1)(a) requires to justify the renewal of the exemption. It was also pointed out to the applicants that exemptions cannot be renewed without applicants providing substantiated evidence. The below sections describe the results of the review including the information provided with questionnaire 5.

Use of larger node FCPs in "legacy products".

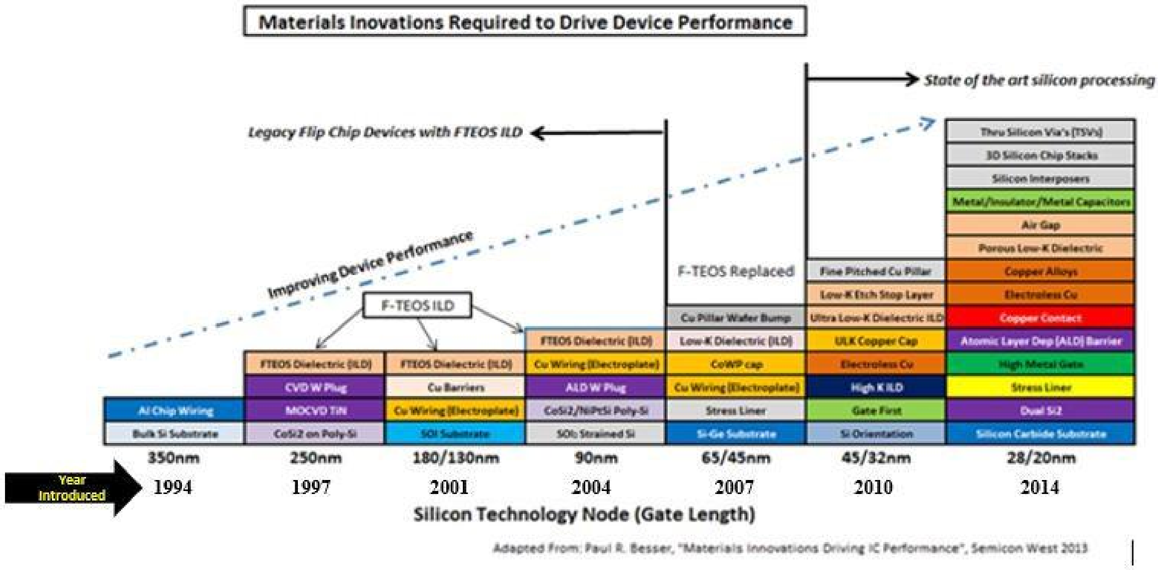
Previous reviews, e.g. by Gensch et al. (2016), already showed that lead cannot be substituted in FCPs with technology nodes of 90 nm or larger. The use of lead can, however, be eliminated using smaller (< 90 nm) technology node FCPs.

TI et al. (2021c) state that they are still *"[…] selling 90 nm products because the product lifecycle is long and necessary to satisfy customer demand. We expect customer demand for older technology nodes will continue to remain for several more years, and current supply chain shortage only retains or intensifies the customer demands." According to TI et al. (2020a) these older technology FCPs are still used in products which they call "legacy products". These are products which were designed in the past with FCPs that are covered by exemption 15(a) and since then have not been redesigned/replaced by more modern products to allow the use of FCPs which do not depend on exemption 15(a), for example lead-free soldered FCPs with technology nodes smaller than 90 nm.*

The RoHS Directive acknowledges the needs of products with longer redesign cycles/model lives by allowing maximum exemption validities of seven years for EEE of cat. 8 and 9 instead of only five years like for the other categories 1-7, 10 and 11. Actually, TI et al. (2020a), (2020b) report that exemption 15(a) is very widely used in medical devices.

TI et al. (2021b) provided the below Figure 10-6 allowing an overview about the FCP technologies and their market introduction. The figure does not include FCP technologies introduced after 2014 with nodes down to 7 nm and less.

Figure 10-6: FCP technologies and years of market introduction



Source: TI et al. (2021b)[87]

The above figure shows that FCPs with technology nodes smaller than 90 nm have been introduced in 2007. These types of FCPs do not require exemption 15(a)(i). According to Art. 5(1)(a), exemptions are only justified if "*[…] elimination or substitution via design changes […] is scientifically or technically impracticable*". In the cases at hand, the design of products still using 90 nm and larger FCPs could have been changed to allow the use of FCPs with smaller nodes after 2007. This aspect was already addressed in the last review of the exemption by Gensch et al. (2016).

TI et al. (2021a) agree that lead-free flip chip packages (FCPs) with technology nodes smaller than 90 nm can provide all electrical/electronic functionalities. This implies that their use may require a redesign of the EEE in which they are used, e.g. the surrounding circuitries and an adaptation to different geometries of these lead-free FCPs. *According to TI et al. (2021b), 250 nm, 130 nm, and 90 nm FCP technologies are still produced and placed on the EU/EEA market. Instead the industry is accelerating to end of life the products where the older FCP technologies are used.*

Lead-free soldered FCPs with nodes smaller than 90 nm introduced in 2007 have been available on the market for around 15 years already. Nevertheless, TI et al. (2020a), (2020b) highlight the continued need of FCPs with 90 nm and larger in "legacy products", which are new EEE still placed on the market with such FCPs, and are intended to be placed on the market further on.

Following the assumption of seven-year redesign cycles - underlying the maximum validity periods for EEE of cat. 8 and 9 – the legacy products could have been redesigned since 2015 latest. In 2021/2022, even the last products that were still produced with large

[87] The figure could not be made available in better quality.

technology nodes would be due for a redesign, around 15 years after the introduction of smaller lead-free technology nodes.

Concerning these aspects, TI et al. (2020a) only state in their renewal request that that flip chips are commonly used in long life, high reliability applications which remain in the field for over 20 years and that legacy flip chip devices and many large die devices are older products that have declining volume year-on-year. Removing these products from the market would create long supply gaps with minimal impact on the amount of lead in the EU market, but prevent the sale of many types of products in the EU.

The applicants were requested to explain why FCPs with technology nodes larger than 90 nm are still used in new, already redesigned products in 2021 and should be used even until 2026/2028. *TI et al. (2022a) stated that they are no longer designing new products with 90 nm technology but are still selling current 90 nm products because the product lifecycle is long and necessary to satisfy customer demand. They expect that the customer demand for older technology nodes will continue to remain for several more years, and current supply chain shortages only retain or intensifies the customer demands.*

The answer focuses on the large node FCPs and does not give more detailed insights as to the specific reasons why these FCPs are still used in new EEE more than 14 years after the introduction of lead-free smaller node FCPs.

The applicants were requested again to justify in the light of the above RoHS stipulations why exemption 15(a)(i) should be continued beyond 2021 at all, and then even with maximum validity periods for all categories of EEE, among which many EEE have shorter model lives. They were also asked whether there possibly were reasons for the renewal request that have not yet been mentioned, possibly related to the FCP producers next to the arguments related to the FCP users.

TI et al. (2022b) provide the below examples of EEE with model lives of 15 years and more.

1) *These products are intended to survive the whole life of end use equipment such as those used in HiRel[88] Industrial instrument and control systems that may range up to 15 to 20 years. Therefore, the model life is expected to be more than 15 years.*

2) *Automotive with replacement spare parts is another area where model lives of more than 15 years. In some cases, we see satellite based communication equipment that require model lives of 15 years or more.*

3) *The medical imaging sector see design cycle of up to 10 years, long production periods and very long life varying from 10 to 20 years, depending on the exact product in question.*

4) *Some of the larger node FCPs are used in networking equipment and telecommunication products that have a long product life cycle. The semiconductor manufacturers have the obligation to continue to supply to these customers that have designed-in these devices with Pb bumps. TI et al. (2020a)*

[88] High reliability; the consultants

Automotive and satellite applications are excluded from the scope of the RoHS Directive. Asked how such "old model" EEE designed 15 or more years ago and still sold nowadays without changes can reflect the technical state of the art, e.g. for cat. 8 medical devices where technological progress improves diagnostic and therapeutic capabilities, TI et al. (2022b) replied:

"Answer to above question is incorporated into question #1. As far as 15(a)(i) is concerned, it applies to other categories 1-7, 9, 10, 11 as well with several older models and spare parts with no end of life seen in the current forecast."

The referenced answer to "question #1" refers to the "Substitution of lead in CZT-detector FCPs" on page 251 addressing the use of CZT detectors in medical imaging equipment and does not address the aspect to which the question relates. To the contrary, CZT detectors are a comparably new technology. The consultants thus do not see how this could answer the question related to cat. 8 EEE and for other EEE with model lives of 15 years and more.

As to the redesign or design of new products to avoid the use of lead in exemption clause 15(a)(i), TI et al. (2022b) *"Agree that 90 nm technology has been in production for several years, however there is no end in sight for products in this technology node to end of life or change to a newer technology with Pb-free bumps for the following reasons:*

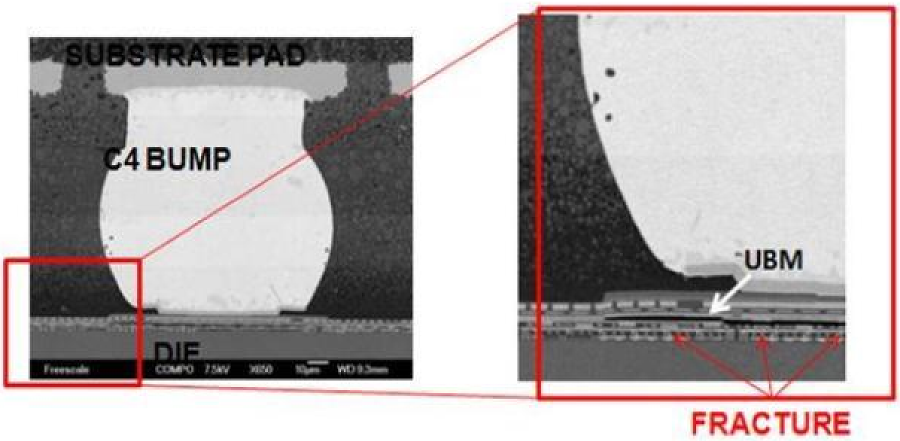
5) *There are 100s of customers still using these products in their production line. Changing these products to Pb-free would require qualifications with reliability data that are not accepted by end users in Automotive and high HiRel* (high reliability) *applications where higher package stresses are encountered.*

6) *As a result of die shear mode failure and cratering issues that are encountered on some specific application that uses Pb-free bumps, we are required to remain in "High-Lead" bump solution.*

7) *Cu-pillar bumps is an option for Pb-Free solution, but due to package solderability issues and temp cycle stresses that we are not able to satisfactorily pass that are associated for reliable interconnection between Cu pillar and lead frame of the package, we have to heavily rely back on SnPb solder bump solution (from 2013 onwards).*

   The picture below was already reported in the initial dossier submission showing a fracture.[89]

[89] The applicants refer to figure 1 of the renewal request submitted by TI et al. 2020a.



8) *Changing these products to Pb-free process would require significant die design work to get them to pass reliability. They cannot pass reliability without overhauling the die design resulting in negative returns that are not feasible. Therefore, the exemption 15(a) for 90nm and larger technology node should continue to remain."*

9) *As further applications, TI et al. (2020a) report that exemption 15(a) is widely used in medical devices. Redesign of medical devices involves retesting, sometimes clinical trials and they need to gain approval from Notified Bodies before redesigned products can be sold.*

The consultants had highlighted several times that they are aware that larger node FCPs cannot be converted to lead-free designs and asked the applicants to focus their arguments for the renewal of the exemption on the redesign aspect or technical or other reasons that would justify that large node FCPs are or still have to be used. The impossibility of this conversion is nevertheless the main part of the above explanation again. The context of the presented figure in the renewal request shows that the failed Cu-pillar bumps were tested in large node (minimum 90 nm) FCPs so that this aspect of the above justification also refers to a lead-free conversion of large node FCPs.

In the consultants' opinion, the above is not a conclusive explanation as to why EEE with large die FCPs are still placed on the market 15 years after lead-free FCPs have become available from 2007 on, and why this should still be continued for another five to seven years, i.e. 20 to 22 years after 2007. It also remains unanswered how products with 20 years of model life can cope with modern technical requirements. The mentioned examples for their application – automotive and HiRel (high reliability), medical devices, do not provide insights beyond the necessity of requalification that would justify in line with Art. 5(1)(a) that they have not been redesigned yet and shall not be redesigned in the coming five to seven years. Since redesigns are inevitable anyway, the consultants do not see why redesign requirements should be a principle obstacle for RoHS compliance.

TI et al. (2020a) mention that devices manufactured in low volumes and used in specialist products that are made in small numbers, such as medical devices and test equipment, may require a "lifetime buy" when the older wafer fabrication processes are retired. In these cases, the manufacturers could be entirely dependent on existing inventory that has been manufactured with design rules that required leaded solders.

This statement describes potential consequences if the exemption would be revoked, but does not justify either why these devices could not be redesigned or be replaced by new design EEE to allow the use of smaller node lead-free FCPs. Adding to this, it should be mentioned that life time buys are not an option if the exemption is revoked since EEE placed on the market after the expiry date of the exemption would not be RoHS-compliant.

The fact that users of large node FCPs seem to refuse a redesign or new design of their products to avoid the use of lead because of required requalifications is not in line with the requirements that arise for producers from the RoHS Directive, where design changes are expected as a mean to achieve compliance. Further on, products have to be redesigned or replaced by newly designed successor products, which implies new qualifications, as otherwise due to the scientific and technological progress products will be outdated and no longer be accepted by customers. In the worst case, a redesign or new design of long model life EEE might be pre-mature, as far as the prematurity aspect can be considered applicable at all 15 years - and more than 20 years including the requested renewal periods - after lead-free alternatives have become available.

TI et al. (2021a) agree that lead-free smaller node FCPs can provide all electrical/electronic functionalities of larger node FCPs. The Umbrella Industry Project as a global consortium of EEE producers, their suppliers and associations, could be expected to be in the position to provide detailed and specific information explaining why their products could not, and in the coming years cannot yet be, redesigned, or why, possibly, smaller node FCPs cannot be used in their products even after a redesign, or whether there are other reasons that might be of relevance for the requested renewal of the exemption for large node FCPs.

Use of large dies in FCPs (exemption clauses 15(a)((ii) and (iii))

TI et al. (2020a), (2020b) *state that the volume of single die legacy lead bump devices with large die (> than 300 mm^2) will be reduced in the next several years but that there are many equipment manufacturers that are still using the legacy devices in small volume.*

The below summarizes the applicants' answers related to the maximum die sizes which still allow the use of lead-free solders, or require the use of lead solders respectively.

(A) TI et al. (2022a) claim that the latest generation FCPs or earlier generations still depend on exemption 15(a)(ii), i.e. the use of lead solders for large die single FCPs, and that for the latest technology FCPs the die size limit for lead-free solder use is still 300 mm². "For newer Si technology nodes, many changes have been made to the BOM [bill of materials; the consultants] & package structure to accommodate package stresses as compared to the older node package BOM while for older technology nodes the situation is unchanged."

(B) TI et al. (2020b) report that "New products introduced into the market in the last several years are assembled with Pb-free bumps even though the die size is greater than 300 mm^2." Upon request, TI et al. (2021b) state that the largest dies which can be manufactured with lead-free solders are 338 mm^2 dies in FCPs that use more advanced technology nodes such as 20 nm and advanced substrate material with low CTE cores and Cu pillar bump. The first of these FCP with lead-free bumps and die size greater than 300 mm² was introduced around 2013/2014. Subsequent to that, FCP packages in smaller technology nodes are designed as lead-free packages.

(C) *The applicants were asked whether "smaller technology nodes" in this context refers to 20 nm and less, or "smaller technology nodes" in the general sense compared to larger nodes like e.g. 90 nm.* TI et al. (2021b), (2021c) replied that "Smaller is intended in the general sense compared to larger nodes e.g. 90 nm", but that "Not all technology and new packages could be converted to lead free. For example, in 2010, 28 nm technology was introduced with leaded FCP because of die size greater than 300 mm² ; currently, manufacturers have achieved leadfree in 20 nm technology with up to 328 mm² dies."

Statements (A) on the one hand, and (B) and (C) on the other hand are incongruent. In (A) the applicants claim that the 300 mm² die size threshold is still relevant for all technology nodes, in (B) TI et al. provide information which speaks of much larger lead-free soldered dies: up to 338 mm² in 20 nm. In (C) they report 328 mm² maximum die size only (not 338 mm² like mentioned before) achieved in 20 nm technology.

In (B) the applicants state that subsequent to 2013/2014, *FCP packages in smaller technology nodes are designed as lead-free packages* - maybe either because they do no longer use larger dies or because they allow lead-free soldering with all dies sizes - *and explain in (C) that "smaller technology nodes" in statement (B) refers to die sizes smaller than 90 nm* – not smaller than 20 nm - from which could be concluded that lead-free solders can be used with all technology nodes < 90 nm regardless of die sizes. *TI et al. put forward the legacy products that require the lead-soldered large die FCPs, and that these large die lead-soldered FCPs will be reduced over time*, which would support the assumption that later generations of FCPs do not need exemption 15(a)(ii) because otherwise this statement would not make sense in the context of exemption 15(a)(ii).

The applicants were requested to explain how the above different statements are plausible in their context and to provide a detailed, stringent and transparent description of the technical situation, i.e. which die sizes can be produced with lead-free solders.

According to TI et al. (2022b), "To enable LF [lead-free] in larger die size products, new assembly & substrate material needs to be applied. The Build of Materials are completely different & assembly process needs to be finetuned to enable it. The process margins are also much narrow."

This explanation does not answer the question.

The consultants requested the applicants to elaborate whether and how far chiplet designs could make the use of large dies obsolete so that lead-free solders could be used and exemption clause 15(a)(iii)) no longer be required for chiplets in general or for specific chiplet constructions. Chiplet designs, among other aspects, are characterized by combinations of smaller dies rather than one large die containing all electronic functionalities. Manufacturing of large chips with highly miniaturized technology nodes below 20 nm may cause overproportioned cost due to the risk of lower yields while at the same time not all functionalities benefit from this extreme miniaturization.

TI et al. (2022b) replied that *"Chiplet will need an interconnect which currently is the Si Interposer, a very large Si die."*

The exemption wording clearly differentiates between dies and interposers. This differentiation was also followed in all previous communications with the applicants and so far has been followed by the applicants as well. The applicants' reply thus does not answer the question since it refers to the interposers, not to the chips which are in the focus of this section, and which had been addressed in the questionnaire. Interposers in stacked die FCPs in the scope of exemption clause 15(a)(iii)) are discussed in the below section.

Silicon versus organic interposers to facilitate substitution of lead (clause 15(a)((iii))

In the previous review of exemption 15(a) – at that time still exemption 15 - by Gensch et al. (2016), the applicants requested the renewal of the exemption part 15(a)(iii) as follows:

"Stacked Die Packages using interposers greater than or equal to 300mm²"

The critical review revealed that the above exemption could be restricted to silicon interposers since FCPs with plastics interposers (organic interposers) do not require the use of lead. This finding is reflected in the current subclause 15(a)(iii) which restricts the exemption to stacked die FCPs with silicon interposers.

For the current review, the applicants were therefore requested whether silicon interposers can be replaced by organic ones to avoid the use of lead. The applicants had not mentioned this aspect in their renewal request. *According to TI et al. (2021a), "At this point UP[90] Exemption #15-15a WG Participants have no evidence that other technologies will be a drop-in replacement to silicon interposers for this application. Silicon interposers provide the best CTE match to interconnect die as well as signal integrity needs to connect multiple dies."*

The above reply insinuates that organic interposers would have to be used as drop-in replacements. As organic interposers exhibit different material properties, the consultants are aware that FCPs have to be designed from the beginning for organic or silicon interposers respectively. The consultants wanted to clarify the conditions which still allow the use of organic interposers and conditions where silicon interposers are indispensable. In the next questionnaire, the consultants referred to the conditions mentioned in the last review and asked the applicants whether these conditions still apply and could be used to specify the scope of subclause 15(a)(iii).

According to Intel et al. in the report of Gensch et al. (2016), silicon interposers are required where high densities of connections are needed, i.e. 200,000 connections across two adjacent dies. Interposers other than silicon may be used to manage the mechanical stress risk from thermal expansion mismatches between a silicon die product and the plastic package. Plastic interposers are not suitable for products that require high bandwidth and extremely large connectivity (> 10,000 connections) between the two adjacent dies, like for example in flip chip grid array products.

TI et al. (2021b) confirmed that the above conditions are still valid and reported that the number of connections since then increased to greater than 200,000 and is still growing.

The above connection densities, e.g. "10,000 interconnects", in the consultants' understanding cannot be interpreted as density of interconnects as this would require the reference for example to a volume. To avoid misunderstandings in the interpretation of these figures, the applicants were asked for clarification.

TI et al. (2022b) explained that *"Unfortunately, its confidential to provide such information."*

[90] UP: Umbrella Project; WG: Working group

The consultants cannot follow what could justify confidentiality in the context of this question and consider the question as unanswered.

The consultants requested more information as to whether the density of more than 10,000 connections between two adjacent dies could be used to restrict the use of silicon interposers in subclause 15(a)(iii).

TI et al. (2021b) answered that *"Current interposer used with active Silicon is primarily Silicon Interposers. There should not be any restriction as it is dependent on product design & applications."* The applicants did not explain these dependencies on product design and applications and where hence asked to do so. *TI et al. (2021c) stated "We believe, plastic interposers that are also known as organic interposer, can also be used with Silicon Die. However, with organic interposers, signal integrity will be a challenge as line/space rules for organic interposer are much bigger. TI et al. (2021c) further claimed that the above should clarify the dependencies between use of plastics or silicon interposers on the one hand, and products and applications on the other hand.*

The consultants did not consider this answer sufficient to explain the dependencies of product design and applications in the context of use of organic interposers. To shed light on these aspects, the consultants tried to pave the way again for a more specific and detailed answer asking whether the number of max. 10,000 interconnects with plastics interposers is to be interpreted as an absolute maximum, or whether it depends on interposer size/thickness, or whether other aspects are to be considered in this context. The applicants were explicitly requested to explain the interdependencies of these various aspects.

TI et al. (2022a) replied that "These are dependent on the product definition. If more interconnects are needed the size will be bigger. The interdependencies are related to total number of interconnect & minimum line/space. There is a balance between these & often defined by overall package/product reliability & application". According to TI et al. (2022a), the line/space dimensions of connections in silicon are 2 µm or less vs 15 µm to 18 µm in organic interposers. TI et al. (2022a) agree to the consultants' conclusion that the bigger line/space requirements of plastics interposers are the reason why the maximum number of connections cannot exceed 10,000 connections between two adjacent dies. A higher connection density would require reducing the line/space sizes to a degree which organic interposers would not allow.

Still the above explanations do not answer the question why 10,000 interconnects cannot be considered a maximum in organic interposers, or otherwise which aspects influence this maximum in a way that silicon interposers may have to be used with less than 10,000 interconnects already. In a final attempt, the consultants asked the applicants again to show in more detail with example FCPs in the scope of exemption 15(a)(iii) which have less than 10,000 interconnects between adjacent dies where silicon interposers still have to be used, and explain the reason(s) for the use of other than organic interposers in this case. If there are different reasons for the use of silicon interposers with FCPs of less than 10,000 interconnects, the applicants were requested to explain each one with an example, including the conditions which require the use of silicon interposers.

TI et al. (2022b) replied that "The interdependencies are very much product related & cannot be disclosed due to confidentiality reason."

The consultants are of the opinion that it should be possible to explain such interdependencies on a level that is sufficiently general to protect proprietary knowledge and specific to the degree that allows following the physical or other relevant factors. With the above answers it remains completely unclear which conditions require the use of large silicon instead of organic interposers and in consequence the use of lead solders.

In the same context, the consultants inquired into the technical concept to interconnect chips based on embedded silicon bridges instead of using large interposers and whether this bridge technology could replace the designs with large interposers and thus the necessity to use lead solders.

TI et al. (2022b) state that "The Si Bridges is an option, but the needs are based on product requirements. In some cases, it can be used to connect 2 dies. In other cases, Si Interposer with higher metal layers can connect more than 2 dies to form a SoC."

The above answer is too vague and general to allow insights into the potential of the silicon bridge technology with regard to the substitution of lead in FCPs in the scope of exemption clause 15(a)(iii).

10.3.6. Request for general exclusion of legacy products from substance restrictions

The applicants submitted a leaflet produced by COCIR (2022) along with questionnaire 5. In this leaflet, COCIR (2022) request the exclusion of "legacy products" from substance restrictions in the context of REACh. Since it was submitted for the review of exemptions 15 and 15(a), the consultants assume that it was meant to substantiate the necessity to continue the exemption for what the applicants call legacy products, i.e. new products placed on the EU/EEA market still using old model of FCPs. For due diligence reasons, the consultants included the document into the critical review.

COCIR (2022) lobby as correct approach the exclusion of legacy models from restrictions, which means that existing models can continue being provided to EU hospitals while the resources of companies are focused on designing the next generation of devices enabling to focus on substituting the restricted substance. As new generation models will be designed SoC[91]-free (where possible), the quantity of restricted substances is going to decrease over time as legacy models are gradually phased out of the market.

COCIR (2022) claim that this approach was introduced in the review of exemption renewal requests under RoHS via the reference to the "Declaration of Conformity" (DoC) as a basis to exempt legacy products (exemption 27 in package 22, Published in the OJ May 12, 2022). Thus, exemption 27 ensures that new models of MRI coils are lead free, while older models can be sold even after the deadline to avoid redesign and a scarcity of critical accessories for imaging departments.

During the review of exemption IV-27, Gensch et al. (2020) actually proposed the DoC approach, however, not in order to generally exempt legacy products from the RoHS substance restrictions. The approach was applied in this and subsequently in other exemption reviews if the alternative without the DoC reference resulted in a broader exemption scope than without the DoC approach. One important precondition for the DoC approach was that specific dates were available related to DoCs from which devices in the

[91] SoC: Substances of (very high) concern

exemption scope do no longer depend on the exemption, while products designed before those dates still depended on the exemption for their RoHS compliance. For details see the review report for exemption 27 in Gensch et al. (2020).

It is also important to note that the RoHS exemptions with DoC reference do not durably exempt any types of EEE in their scope from the RoHS substance restrictions but still expire following the normal RoHS exemption expiry regime. The respective EEE was thus not excluded from the scope of the RoHS Directive, but temporarily exempted from certain substance restrictions like it is usually the case with exemptions.

Overall, the DoC approach applied in past exemption reviews cannot be interpreted as a general exclusion or exemption for legacy products. In the review of exemptions 15 and 15(a), this approach is not applicable as the above-mentioned criteria under which it was applied are not met.

10.3.7. Environmental arguments and socioeconomic impacts[92]

TI et al. (2020a) point out that the total around 10 kg of lead used in ASIC devices are extremely small, and that the lead solder bumps are located at an internal interface of the ASIC package encapsulated by a chemically stable polymer (underfill).

The current RoHS Directive does not allow granting exemptions based on minor quantities of regulated substances. The only criteria are those mentioned in Art. 5(1)(a), where quantities of lead may be justifiable if the total negative environmental, health and consumer safety impacts caused by its substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof. The applicant did not raise arguments in this context to justify the exemption.

With respect in particular to the withdrawal of exemption clause 15(a)(iii), the applicants also point out that life time buys of FCPs may result in unused FCPs which would then add to the e-waste generated in the EU. Also, many existing products on which consumers and businesses are now dependent upon would become obsolete/waste due to unavailability of repair parts.

If the exemption is not renewed, life time buys of FCPs no longer covered by exemption 15(a) would result in incompliance with the RoHS Directive for products placed on the market with such FCPs after the expiry of the exemption. Legally, Art. 4(4)(f) would, however, allow the repair of EEE placed on the market prior to the exemption expiry.

Economically and technically, the situation might be different. Possibly – the applicants had implied this in a web conference with the consultants – the fabrication plants for the older node technologies cannot be operated economically if these FCPs can no longer be used in new EEE placed on the market. The applicants were requested to present in questionnaires such or any other sound arguments for the continued use of these FCPs that are not related to the users of the FCPs but to the producers. The applicants did not elaborate any such arguments in the review process.

TI et al. (2020a) also point out that exemption 15(a) is very widely used in medical devices. Medical device manufacturers use the same components as all other sectors of the

[92] For details of the mentioned arguments, c.f. section 10.2.6 on page 20.

electronics industry but can be seriously affected by early obsolescence of components (if drop-in replacements are not available), as redesign of medical devices involves retesting, sometimes clinical trials and they need to gain approval from Notified Bodies before redesigned products can be sold. This can mean that some products are no longer sold in the EU which limits the choice of hospitals, and this can negatively affect healthcare.

The above statement is not specific as to which devices specifically would be affected if the exemption would be withdrawn after lead-free alternatives, at least for larger node FCPs, have been available since 2007. Like for the other aspects raised, the consultants cannot exclude that the above impacts might arise if the exemption is not renewed.

10.3.8. Summary and conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria is fulfilled:

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II **is scientifically or technically impracticable**;
- the **reliability** of substitutes is not ensured;
- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

The applicants request the renewal of exemption 15(a) for all categories of EEE for the maximum possible five or seven years.

Renewal of exemption 15 for CZT-detector FCPs

The applicants request the renewal of exemption 15 for CZT detectors in EEE of cat. 8 other than in-vitro diagnostic devices. Since X-ray detectors in CT imaging equipment were mentioned as the only use in the renewal request and in subsequent communication, the consultants insisted that the exemption scope should be restricted to this application unless the applicants could provide evidence for other uses. During these discussions in the ongoing review, the applicants declared the exemption to be obsolete for CT imaging equipment because conductive adhesives meanwhile were found to be appropriate to eliminate the use of lead in CZT X-ray detectors. Instead, the applicants suddenly requested catheters to be included into the scope of this exemption, but without further justification and evidence that would allow the consultants to recommend this exemption to be adopted to Annex III in line with the requirements of Art. 5(1)(a). The consultants therefore cannot recommend the COM to grant this exemption.

Renewal of exemption 15(a)(i) for larger node (≥ 90 nm) FCPs

The applicants claim that FCPs with technology nodes larger than 90 nm are used in devices which are still placed on the EU/EEA market as new EEE, and they reiterate on the statement that these older FCP models cannot be redesigned to enable the use of lead-free solders. While the latter aspect has been acknowledged in previous reviews of the exemption already, the applicants could not plausibly explain why these larger node FCPs are still used in new products while lead-free alternatives – smaller node FCPs – have been available since 2007. The applicants mention products with very long model lives as justification but cannot explain how, in the light of rapid technological progress in the EEE sector in the past decades, devices designed 15 years ago can still meet the current market needs and can be expected to meet these requirements for another five to seven years. The use of smaller node (< 90 nm) FCPs would eliminate the use of lead. The applicants failed to provide plausible justifications why these larger node lead-containing FCPs should still be allowed to be used in products placed on the market now and in the coming years until 2026 or 2027.

The above aspect had been contentious already in the last review of this larger node FCP clause of the exemption by Gensch et al. (2016), and at that time there was no clear justification for it either. It should be noted in this context that Art. 4(4)(f) would allow the use of larger node FCPs for the repair and upgrade of EEE placed on the market prior to the exemption expiry so that the renewal cannot be justified with the repair of products placed on the market in the past years.

The consultants wish to highlight that there may be reasons for their continued use. Applicants are, however, obliged to provide the information substantiating their renewal request to a degree that allows consultants to recommend the exemption renewal without infringing Art. 5(1)(a), which expects producers to adapt the design of their devices if this enables the substitution or elimination of restricted substances. The information submitted by the applicants therefore does not allow the consultants to recommend the renewal of the large node clause of exemption 15(a) in line with Art. 5(1)(a).

Due to the above situation, the consultants cannot exclude that some of the socioeconomic impacts discussed in section 10.3.7 (Environmental arguments and socioeconomic impacts) on page 264 may actually arise if this part of the exemption addressing the old larger mode FCPs is not renewed, in particular that some products may no longer be available on the EU/EEA market even though this situation may have been avoidable by a timely redesign of the respective devices.

Renewal of exemption 15(a)(ii) and (iii) for large die and large interposer (≥ 300 mm²) FCPs

The applicants claim that the use of lead is scientifically and technically impracticable for FCPs with dies of 300 mm² or more, independently from the technology nodes. The review process revealed that larger die size FCPs with smaller technology nodes were produced with lead-free solders which in principle may allow restricting the exemption scope. Despite several rounds of questionnaires, the applicants provided, however, inconclusive and contradicting information as to which die sizes in which technology nodes could actually be produced without lead solders. No conclusions are feasible on the scientific and technical practicability of lead-free soldering of FCPs with dies larger than 300 mm² in single die and stacked die FCPs.

Next to large dies, stacked die FCPs are built with silicon interposers that, according to the applicants, still require the use of lead solders for interposer sizes of 300 mm² or more. The previous review of the exemption by Gensch et al. (2016) showed that using plastic/organic interposers instead of silicon interposers enables lead-free soldering of FCPs with interposers of 300 mm² and more. Whether plastics or silicon interposers are used depends on the number of connections between adjacent dies in the FCP. While the applicants acknowledged that generally 10,000 interconnects can be considered as a threshold which, if exceeded, requires the use of silicon interposers, they failed to explain why this threshold either cannot not be used to restrict the exemption scope, or why such a scope restriction does not make sense. The actual scientific and technical practicability of lead-free soldering in the context of technical conditions requiring the use of large silicon interposers remains unclear.

In the absence of sound evidence, the consultants cannot recommend renewing the second and third clause of exemption 15(a).

10.4. Recommendation

Renewal of exemption 15

The applicants requested the renewal of exemption 15 for lead applied in flip chip packages (FCPs) with cadmium-zinc-telluride (CZT) dies which are used for X-ray detectors in computer tomography imaging equipment (cat. 8 medical devices others than IVDs).

After extensive scope discussions, the applicants announced that lead can be substituted in these detectors and instead requested the inclusion of catheters into the scope of this exemption. In the absence of evidence how CZT detectors are used in catheters, and that substitution or elimination of lead are scientifically and technically impracticable, the consultants can, however, not recommend granting this exemption in line with Art. 5(1)(a).

The current exemption 15 still covers the use of CZT detectors in cat. 8 medical devices others than IVD. The applicants requested the renewal of this exemption only for these CZT-detector FCPs for use in cat. 8 medical devices others than IVDs, which the consultants recommend to reject. If the COM follows this recommendation, Art. 5(6) applies stipulating a transition period of 12 to 18 months for the CZT detector FCPs under exemption 15. Since there is no evidence that the substitution or elimination of lead in CZT detector FCPs is scientifically and technically impracticable and in the absence of evidence that other criteria under Art.5(a)(1) are met, the consultants recommend a 12 month transition period only.

The consultants recommend the below wording, scope and expiry date for exemption 15.

No.	Exemption	Scope and dates of applicability
15	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages	Applies to categories 8, 9 and 11. Expires on [date of publication in Official Journal + 12 months] for - cat. 8 medical devices including in-vitro diagnostic medical devices and; - cat. 9 monitoring and control instruments including industrial monitoring and control instruments; - cat. 11.

Renewal of exemption 15(a)

The applicants did not provide substantiated evidence that would allow the consultants to recommend the exemption renewal in line with the conditions for exemptions laid out in Art. 5(1)(a), i.e. it could not be clarified whether and how far substitution or elimination of lead are still scientifically and technically impracticable. It remained unclear why larger node (≥ 90 nm) flip chip packages still are used and intended to be used another five or seven years in new EEE placed on the EU market while smaller node lead-free alternatives have been available since 2007. For the other clauses of exemption 15(a), the applicants did not clarify whether and how far the technological state of the art would allow restricting the scopes of these exemption clauses, i.e. whether, how far and under which conditions dies larger than 300 mm² can be produced without the use of lead solders. For the stacked die FCPs, no conclusion was feasible whether and under which conditions the use of organic/plastics interposers instead of silicon interposers could support the substitution of lead and thus allow restricting the scope of this part of the exemption.

The consultants expect that the expiry of exemption 15(a) results in non-availability of flip chip packages to produce certain EEE and may cause related socioeconomic impacts, see section 10.3.7 on page 264.

In case the COM wishes to renew exemption 15(a), the consultants recommend the current wording and scope of exemption 15(a) and to add cat. 8, 9 and 11 as proposed by the applicants. Formally, cat. 8, 9 and 11 EEE would then be transferred from an exemption with a broad scope (ex. 15) to an exemption with a narrower scope (ex. 15(a)), which is equivalent to a partial revocation of the exemption. Art. 5(6) requires 12 to 18 months transition time. To allow for administrative adaptations in industry, the consultants recommend 12 months, which are taken into account by the expiry date for categories 8, 9 and 11 in exemption 15 (c.f. previous section), after which these categories of EEE are included into the scope of exemption 15(a).

No.	*Exemption*	*Scope and dates of applicability*
15(a)	Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages where at least one of the following criteria applies: - a semiconductor technology node of 90 nm or larger; - a single die of 300 mm^2 or larger in any semi-conductor technology node; - stacked die packages with die of 300 mm^{2}or larger, or silicon interposers of 300 mm^2 or larger.	Applies - to categories 1-7 and 10 - from [date of publication in Official Journal + 12 months + 1 day] on, to cat. 8, 9 and 11 Expires on [DATE] for categories 1-11.

10.5. References

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Annex to the exemption 13(b) series

Table A-1: Assignment of application examples to exemptions and EEE categories

Exemption					EEE category (RoHS Annex I)										
13b	13b-I	13b-II	Application example provided by the applicants		1	2	3	4	5	6	7	8	9	10	11
x	x	x	Security, surveillance and medical applications, e.g. infrared illumination with filters that suppress visible light (category 3, 8 or 9).				x					x	x		
x	x	x	Airport runway lamps that indicate the runway location (category 5 or 9) – bright specific coloured light visible from all directions which should not change in colour with viewing direction which would occur with coated filters and interference filters.						x				x		
x	x	x	Laser eye protection goggles / glass (most types have no electrical function but any designs with an electrical function would be in category 9).										x		
x	x	x	Traffic monitoring - cameras to take pictures of drivers exceeding the speed limit and toll monitoring systems (category 9).										x		
x	x	x	Environmental monitoring equipment, e.g. used to monitor environmental pollutants, waste sorting, waste water analysis, exhaust gas analysis, airborne (from airplanes, satellites) environmental diagnosis photography, etc. (category 9).										x		
x	x		Analysis of ppm levels of gases in air or in flue gases (category 9).										x		
x			Colour channel separation for colour television (category 4).					x							
x		x	Spectral filters for photographic cameras (category 3).				x								
x	x	x	Attenuation or separation of undesired wavelengths in telecommunication by separation of undesired wavelengths transmitted by coated filters (category 3).				x								

Exemption					EEE category (RoHS Annex I)										
13b	13b-I	13b-II	Application example provided by the applicants		1	2	3	4	5	6	7	8	9	10	11
x		x	Light barriers for motion control in electrical machinery (category 6).							x					
x	x	x	Bar code readers (category 6 and IVD category 8 used for identification of samples for IVD analysis).							x		x			
x	x	x	Logistics automation equipment such as letter and parcel sorting machines (category 6 or 9).							x			x		
x	x	x	Industrial measurement as part of or used with machines used for manufacturing – many different applications (category 6 or 9).							x			x		
x	x	x	Industrial displays (category 6).							x		x	x		
x	x	x	Fluorescence microscope (categories 8 and 9); more details below.									x	x		
x	x		Spectrometers; for example, as stray light filters for UV and for near-IR spectrometers, requires high % transmission in the desired wavelength range and a steep cut-off with no transmission outside of the desired range (categories 8 and 9).									x	x		
x			Gas chromatograph detectors – use filters containing lead to detect the spectra of sulphur and phosphorous compounds (category 9).										x		
x		x	Flame photometric detectors used for process gas chromatography- The filters are needed to separate light of 394nm from other wavelengths which is used to measure intensity and calculate the concentration of sulphur compounds in the process gas. Blue filters containing lead are used for this application (category 9).										x		
x	x	x	Infrared cameras (category 9).										x		
x		x	Surveying instruments (category 9).										x		
x	x	x	Radiation thermometer – (category 9) uses filters containing cadmium to detect light of specific wavelengths without interference from other wavelengths. These determine temperature by										x		

Exem-ption					EEE category (RoHS Annex I)										
13b	13b-I	13b-II	Application example provided by the applicants		1	2	3	4	5	6	7	8	9	10	11
			measuring the light intensity at a specific wavelength so other wavelengths must be blocked. Cadmium provides the steep edge and lead provides fine adjustment of the transmission limit wavelength.												
x		x	Filter in medical fibre optic core temperature probes that are used to measure body temperature of patients while undergoing MRI scans (category 8). This filter is used in the optical head of the signal conditioner to reduce/eliminate the unwanted scattered light (noise) in the optical head. Only red cadmium filters give accurate body temperature measurements.									x			
x	x	x	Imaging luminance colorimeter – light measurement to simulate the human eye's light responses. The colour response is simulated by 4 different "stacks" for the so called Xr, Xb, Y and Z response of the "standard observer" as defined by the "International commission of illumination, CIE". The filters are sequentially introduced into the beam path of a camera system. Calibrations and evaluation of the data result in a precise image of luminance and colour. The closest match can only be achieved with filters containing cadmium (category 9).										x		
x	x	x	Spectroradiometer- This type of device has a very high fidelity of colour measurements. The light of different colours (plus infrared and ultraviolet) is dispersed by an optical grating and then analysed by a charge-coupled device sensor. However, optical gratings diffract the so called 'higher orders' of light as well as the required wavelengths. This means that light with half the wavelength will follow the same beam path (e.g. 360nm will appear as signal at 720nm). To eliminate these higher order wavelengths, optical filter glass are used. Optical filters containing cadmium have to be used in these measurement devices for light measurement (category 9).										x		
x	x	x	Ingredient meters and thickness meters – use filters containing both cadmium and lead. These devices function by measuring the amount of an ingredient in the test sample to determine either its concentration, or if this is known, it can be used to measure the sample's thickness by making use of the Lambert-Beers law. This is achieved by accurate measurement of transmitted light at a specific wavelength and filters are needed to remove other wavelengths (category 9).										x		

Exem-ption					EEE category (RoHS Annex I)										
13b	13b-I	13b-II	Application example provided by the applicants		1	2	3	4	5	6	7	8	9	10	11
x	x		Infrared sensors – these filters contain an evaporated layer of lead compounds which transmit light of wavelengths between up to 15µm and has a high refractive index. This combination of properties cannot be achieved by any other materials or designs.												
x	x	x	Light meter for specific wavelength ranges (category 9).										x		
x	x	x	Industrial image processing for quality assurance as part of electrical machines (category 6).							x					
x	x	x	Detection of faked paintings, filters are used in controlled wavelength light sources (category 9).										x		
x		x	High quality scanners used to digitise colour images (category 3).				x								
x		x	High performance cameras, such as television broadcasting, cinematography, medical applications, etc. (category 4).					x							
x	x	x	Light filters for astronomy research (category 9).										x		
x	x		Short Wavelength Automated Perimetery (SWAP) using a Humphrey field analyser (HFA) is a medical technique used to detect eye conditions such as Glaucoma and optic neuritis (category 8, more details below).									x			
x	x	x	IVD analysers (category 8); IVD analysers automatically analyse a variety of materials and some tests use colour to measure concentrations (using optical absorption spectroscopy). The required colours are selected by blocking other wavelengths using optical filters including some that contain cadmium. These must have sharp-edges to the transmitted spectrum and be stable with no colour change or fading during the life of the equipment for accuracy to be maintained.									x			

Exemption					EEE category (RoHS Annex I)										
13b	13b-I	13b-II	Application example provided by the applicants		1	2	3	4	5	6	7	8	9	10	11
x	x	x	Many types of lasers with fundamental wavelength in visible and near-Infrared wavelengths use optical filters containing cadmium (such as RG1000 filters). Sharp spectral filtering using cadmium-containing glass is required to achieve spectrally pure signals for power level setting, attenuation, and diagnostics. These filters are used, for example, to separate the fundamental NIR radiation from other wavelengths like pump sources with 808nm /880nm / 888nm and harmonics such as 523nm / 355nm /266nm. The filtered NIR is used for determination of power values for diagnostic reasons, but mainly for power level settings and attenuation by end users of the tool. Ultra-short pulsed laser sources are used in a growing market segment like e.g. micromachining of glass, in the semiconductor industry and used to produce photovoltaics and display technologies (category 6, 8, 9 and 11).							x		x	x		x
x	x		Lead containing green filter glass such as VG9 has many minor uses. It separates the different colour channels for colour TV cameras (category 4) and is used for medical colposcopes (more details below) (category 8).					x				x			
x	x	x	Optical filters are used with optical microscopes to remove unwanted wavelengths (category 8, 9).									x	x		
x		x	bar code readers (category 10)											x	
x	x	x	logistic sorting equipment such as letter or parcel sorters (category 11)												x
x	x	x	Distance sensors and safety light barriers										x		
x	x	x	distance meters available in hardware stores, speed traps, automatic doors of department stores, toy robots and robot vacuum cleaners			x					x		x		
x	x	x	light for hair removal or skin treatment, either for common household use (as cosmetic treatment) or for medical treatment using the long wavelength radiation			x						x			
x		*x*	In industrial applications, e.g. related to semiconductor technology, handling of UV sensitive glues,							x			x		

Exem-ption					EEE category (RoHS Annex I)										
13b	13b-I	13b-II	Application example provided by the applicants		1	2	3	4	5	6	7	8	9	10	11
x	*x*	*x*	within laboratories handling of sensitive biological specimen or chlorophyll activity monitoring in greenhouses the filter glasses within 13b enable a strong blocking of UV light.										x		
x	*x*	*x*	Within category 11 eye safety can be named: Laser goggles for short wavelength lasers require longpass filter glasses.												x
x	*x*	*x*	'LIDAR' (Light detection and ranging or Light imaging, detection and ranging). Non-automotive LIDAR use NIR Laser and an imaging unit that requires perfect blocking of UV and visible light. Such LIDAR units are used for applications such as crime scene documentation, wind measurement, environmental and agricultural monitoring, as well as all kinds of surveillance.										x		
x	x	x	Cadmium and lead filter glass may also be used in many other types of equipment, such as lighting applications, leisure products, medical devices and automatic dispensers.						x		x	x		x	

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