Questionnaire 1 (Clarification) for Exemption III-13a (TMC)

Current wording of exemption 13a

Table 1: Currently valid exemption wordings

No.	Exemption	Scope and dates of applicability
III-13a	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.

Acronyms and Definitions

Cat.	Category, referring to the categories of EEE specified in Annex I of the current RoHS Directive
COM	European Commission
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instruments

1. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[1] by the European Commission through for the evaluation of applications for the review of requests for new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

TMC submitted a request for renewal of the above exemption for cat. 9 monitoring and control instruments (IMCI) with the wording, scope and validity period shown in the below table:

Table 2: Requested exemption renewal

No.	*Requested exemption*	*Requested scope and dates of applicability*
III-13a	*Lead in white glasses used for optical applications*	*Applies to category 9 industrial monitoring and control instruments (IMCI) and expires on 21 July 2031.*

[1] Implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017

As result of a first review, we identified that some information is missing. Against this background the questions below are intended to clarify some aspects concerning the request at hand.

We ask you to kindly answer the below questions until 3 November 2023 latest.

2. Questions

1. Could you please confirm that Table 2 correctly reflects the requested renewal of the exemption?

> **TMC reply to question 1:**
>
> TMC would like to reiterate that all submitted renewal applications, including the renewal application for RoHS *exemption III-13(a)* request the renewal of the exemption for category 9 industrial monitoring and control instruments in its existing wording with the subsequent maximum renewal period of 7 years.
>
> Table 2 therefore correctly reflects TMC's renewal request.

2. Exemption 13a was reviewed by (Deubzer et al. 2022)[2]. They recommended specifying exemption 13a as listed in Table 3 below, providing 3 wording options to the European Commission (COM).

2 The final report on RoHS Pack 23 is available on the BioIS website: https://www.rohs.biois.eu/RoHS_Pack-23_Report_Final_20221220.pdf

Table 3: Renewal of current exemption 13a recommended by (Deubzer et al. 2022)

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.

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.

Source: (Deubzer et al. 2022)

The COM have not yet officially published their decision as to the adoption of the above recommendation. The COM wish the consultants to assess in this current review round whether there are any substantial reasons in line with Art. 5(1)(a) against the adoption of the above recommendation for EEE of categories 8, 9 and 11.

If the review shows that TMC's arguments justify the renewal of the exemption, the consultants would recommend the below wordings, scopes and expiry dates. These expiry dates may be adapted to the specific situation of cat. 9 IMCI in the scope of TMC's renewal request. Table 4 reflects the resulting wordings, scopes and validity periods in consistency with the state of science and technology assessed by (Deubzer et al. 2022) and with their recommendations.

Table 4: Renewal of current exemption 13a as recommended by (Deubzer et al. 2022) (modified)

No.	Recommended Exemption	Recommended scope and dates of applicability
III-13a	Lead in […]*	Applies to cat. 1-11. Expires on: - 21 July […]**

	** following sentence depending on wording options 1 or 2 from Table 3 above*	- 21 July 2028 for cat. 8 in vitro diagnostic medical devices - 21 July [2028 **+ X**] for cat. 9 industrial monitoring and control instruments *** the following sentence depends on options 1, 2 or 3 from Table 3 above*

X can be maximum of 3 years

a. Please comment on this proposal explaining clearly any obstacles you see if you do not agree to the proposal. Please address the 3 options referenced in Table 3 individually.

TMC reply to question 2:

As outlined in the exemption renewal request and the annexed socio-economic analysis submitted to the European Commission by TMC on 20 January 2023, TMC applies for renewal of exemption III-13(a) in its current wording and for the maximum validity period, i.e., 7 years.

Exemption 13(a) is an exemption to allow the addition of lead into glass for specific optical components. These optical components (glass lenses, filters, and fibres) are highly specialised, individually specified components that perform a key part of the functionality of the instruments in which they reside. Their use within the heart of the measurement system is such that replacement of these components, even if an equivalent fit, form, and function part is available must undergo rigorous and extensive testing and validation.

The addition of lead (typically as PbO) into glass introduces unique properties. As lead is a heavy element, it increases the density of the glass, thereby increasing its refractive index. The typical refractive index of lead glass is ~1.6, compared to 1.46 of typical (soda) glass. In addition to increased refractive index, the addition of lead increases the transmission of light through glass, particularly in the UV spectrum.

As further outlined in the submitted documents, the Test & Measurement Coalition has no knowledge suggesting that there is a substitute available that would be suitable for lead-glass in high accuracy measurement instruments. At this point, eliminating the use of leaded-glass is not possible without the reduction of performance of critical instrumentation.

Whenever an exemption is renewed, TMC would like to emphasise the importance of retaining the initial wording and numbering as published in the original RoHS annexes. Amending the scope of the exemption by changing the application or substance restriction value has a significant administrative burden to industry and negatively impacts the compliance. This includes:

- The data management and ERP Solution re-engineering to segregate existing supplier declarations from those of the new (re-worded) exemption takes time as well as resources and is open to error.

- Separating and managing suppliers' declarations when schemas are in transition adds huge complexity where the same exemption number exists with a different description.

It needs to be kept in mind that industrial monitoring and control instrument manufacturers have to manage suppliers' declarations for hundreds of thousands of items. Additionally, after reviewing the current state of the evolution of technology for the cat. 9 industrial measurement and control instruments, TMC members have difficulty in understanding how the rewording and relisting and/or splits recommended by the consultants will lead to greater protection of human health and the environment compared to the wording in its current form. The recommended rewording/split would only lead to significant unnecessary burden for stakeholders without commensurate benefits.

Therefore, TMC favours and applies for the **wording of option 1** with an extension of the applicability dates for category 9 industrial test and measurement instruments until **21 July 2031.**

Please note that answers to these questions will be published as part of the evaluation of this exemption request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version in which proprietary information is clearly marked.

We ask you to kindly provide the information in formats that allow copying text, figures and tables to be included into the review report.

3. References

Deubzer et al. (2022): 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 Pack 23. With assistance of Dr. Deubzer, Otmar, Fraunhofer IZM and UNITAR, Fraunhofer IZM Jana Rückschloss, UNITAR Christian Clemm, Bio I. S. Shailendra Mudgal (RoHS 28). Available online at https://www.rohs.biois.eu/RoHS_Pack-23_Report_Final_20221220.pdf.