

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

Current wording of exemption 13b

Table 1: Currently valid exemption wordings

| No. | Exemption | Scope and dates of applicability |
|---------|---|--|
| III-13b | Cadmium and lead in filter glasses and glasses used for reflectance standards | Applies to categories 8, 9 and 11; expires on: <ul style="list-style-type: none"> - 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. |

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 appointed¹ 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:

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

Table 2: Requested exemption renewal

| No. | Requested exemption | Requested scope and dates of applicability |
|---------|---|--|
| III-13b | Cadmium and Lead used in filter glasses and glasses used for reflectance standards. | Applies to category 9 industrial monitoring and control instruments (IMCI) and expires on 21 July 2031 |

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(b) 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 13b was reviewed by (Deubzer et al. 2022)². They recommended specifying exemption 13b as listed in Table 3 below.

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 13b recommended by (Deubzer et al. 2022)

| | Exemption | 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 [date of publication in Official Journal + 12 months] for <ul style="list-style-type: none"> - category 8 medical devices including in vitro diagnostic medical devices; - category 9 monitoring and control instruments including industrial monitoring and control instruments; - category 11. |
| 13(b)(I) | Lead in ion coloured optical filter glass types | Applies <ul style="list-style-type: none"> - 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 <ul style="list-style-type: none"> - 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. |
| 13(b)(II) | Cadmium in striking optical filter glass types; excluding applications falling under point 39(a) of this Annex | <ul style="list-style-type: none"> - 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. |
| 13(b)(III) | Cadmium and lead in glazes used for reflectance standards | Expires on [date of publication in Official Journal + 12 months] for categories 1 to 7 and 10. |
| 13(b)(IV) | Cadmium in glazes used for reflectance standards | 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. |
| 13(b)(V) | 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 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. |

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 13b as recommended by (Deubzer et al. 2022) (modified)

| No. | Recommended Exemption | Recommended scope and dates of applicability |
|---------------|---|---|
| III-13b | Cadmium and lead in filter glasses and glasses used for reflectance standards | <p>Applies to categories 8, 9 and 11.</p> <p>Expires on [date of publication in Official Journal + 12 months] for</p> <ul style="list-style-type: none"> - category 8 medical devices including in vitro diagnostic medical devices; - category 9 monitoring and control instruments including industrial monitoring and control instruments; - category 11. |
| III-13(b)(I) | Lead in ion coloured optical filter glass types | <p>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.</p> <p>Expires on</p> <ul style="list-style-type: none"> - 21 July 2025 for categories 1, 4; - 21 July 2026 for categories 2, 3, 5, 6, 7, 10 and 11; |
| III-13(b)(II) | Cadmium in striking optical filter glass types; excluding applications falling under point 39(a) of this Annex | <ul style="list-style-type: none"> - 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices; - 21 July 2028 for category 9 monitoring and control instruments other than industrial monitoring and control instruments; - 21 July [2028 + X] for category 9 industrial monitoring and control instruments. |
| 13(b)(III) | Cadmium and lead in glazes used for reflectance standards | Expires on [date of publication in Official Journal + 12 months] for categories 1 to 7 and 10. |
| 13(b)(IV) | Cadmium in glazes used for reflectance standards | <p>Applies to cat. 8 and 9 from [date of publication in Official Journal + 12 months+ 1 day] on.</p> <p>Expires on</p> <ul style="list-style-type: none"> - 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices; - 21 July 2028 for category 9 monitoring and control instruments other than industrial monitoring and control instruments; - 21 July [2028 + X] for category 9 industrial monitoring and control instruments. |
| 13(b)(V) | Lead compound coatings in infrared interference filters used in infrared gas analysis and mid-far-infrared spectroscopy | <p>Applies to category 9 industrial monitoring and control instruments from [date of publication in Official Journal + 12 months + 1 day on].</p> <p>Expires on 21 July [2028 + X] for category 9 industrial monitoring and control instruments.</p> |

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.

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(b) in its current wording and for the maximum validity period, i.e., 7 years.

Exemption 13(b) is an exemption to allow the addition of cadmium (Cd) and lead (Pb) into glass specifically for the creation of filters and reflectance standards. Category 9 products use glass filters within the optical design for highly specialist applications. These optical systems are part of sensitive measuring apparatus used throughout a wide variety of applications and industries, where highly sensitive accurate measurements are needed.

As further outlined in submitted documents, to the best of knowledge of the Test & Measurement Coalition there are no alternatives that have been developed for the applications described in this exemption renewal request and other applications that require cadmium and lead filter glasses.

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.

TMC therefore does not agree with the consultants' proposed wording and splitting as outlined in table 4 and reiterates the renewal request as outlined in renewal application documents and the answers to question 1.

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.