

Questionnaire 1 (Clarification) for Exemption III-6(a) and III-6(a)(I), (TMC)

Current wording of exemptions 6(a) and 6(a)(I)

No.	Exemption	Scope and dates of applicability
III-6(a)	Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight	Applies to categories 8, 9 and 11, and expires on <ul style="list-style-type: none"> - 21 July 2021 for cat. 8 other than in-vitro diagnostic medical devices, and cat. 9 other than 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
III-6(a)(I)	Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight and in batch hot dip galvanised steel components containing up to 0,2 % lead by weight	Expires on 21 July 2021 for categories 1-7 and 10

Acronyms and Definitions

Cat.	Category, referring to the categories of EEE specified in Annex II 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.

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

TMC submitted a request for a five year renewal of exemption III-6(a) for EEE of category 9 industrial monitoring and control instruments (IMCI) in its current wording:

Table 1: Requested exemption renewal

No.	Requested exemption	Requested scope and dates of applicability
III-6(a)	Lead as an alloying element in steel for machining purposes containing up to 0.35 % lead by weight	Applies to category 9 monitoring and control instruments 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 11 September 2023 latest.

2. Questions

1. Could you please confirm that Table 1 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-6(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.

Please find below a table with the correct renewal request, whereas the changes to the consultants' table are marked in **bold**:

No.	Requested exemption	Requested scope and dates of applicability
III-6(a)	Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0.35 % lead by weight.	Applies to category 9 industrial monitoring and control instruments and expires on 21 July 2031.



2. Exemptions 6(a) and 6(a)(I) were reviewed by Baron et al. (2022)² resulting in the below recommendation including also EEE of cat. 9 IMCI:

Table 2: Renewal of current exemptions 6(a) and 6(a)(I) proposed by Baron et al. (2022)

Exemption formulation	Duration
6(a): Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight and in galvanized steel containing up to 0,35 % lead by weight	— 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.
6(a)-I: Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight	Expires on 21 July 2024 for all categories
6(a)-II: Lead in batch hot dip galvanised steel components containing up to 0,2 % lead by weight	Expires on 21 July 2026 for all categories

Source: Baron et al. (2022)

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation. The COM wishes 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.

Would you agree to the recommendation presented in Table 2 for cat. 9 IMCI? If not, please explain your objections taking into account the findings and arguments presented in the report of Baron et al. (2022)² in particular with view of the criticism raised as to lacking information on applications where lead-free alternatives may be viable and where not.

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 **does not** agree with the recommendation presented in Table 2 for cat. 9 IMCI.

Lead as an alloying element in steel containing up to 0.35% lead by weight is intrinsic for machining purposes in niche applications and as such used in numerous product groupings and equipment types of category 9 industrial Test & Measurement instruments.

As further outlined in TMC's submission, alternatives to lead for all type 6 exemptions are in development. However, the manufacturer of Test & Measurement Instruments are not component manufacturers and need to rely on component manufacturer supplies of parts for 75%+ of the components in their instruments. As and when such alternative parts

² C.f. Öko-Institut, https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_22/RoHS_Pack-22_final_report_amended_February_2022.pdf

become available, they will be designed into new equipment that is developed in a cycle of 7-10 years depending on the type of category 9 equipment concerned. The applicants therefore believe a technical solution will be forthcoming and is possibly already available in some cases³, but it needs to be implemented for the specific usage, tried by downstream user (e.g., producer, manufacturer) of the component, and then tested in the full individual piece of equipment.

Given the specific characteristics of category 9 equipment and its long-life span and development cycles, TMC applies for the renewal of exemption III-6(a) for the maximum validity period (i.e., 7 years) to allow for this process to take place.

Based on the above and as further detailed in the application documents, TMC considers the criteria of RoHS art. 5(1)(a) are met and a renewal of exemption III-6(a) with the maximum validity period is warranted. Please also refer to the reply to question 3 regarding the suggested splitting of exemptions.

- In case that the renewal of the current exemption 6(a) beyond 2024 can be justified in line with Art. 5(1)(a), we would like to propose the renewal as exemptions 6(a)(I) and 6(a)(II) like listed in Table 2 to be consistent with the recommendation of Baron et al. (2022).

Table 3: Renewal of current exemptions 6(a) and 6(a)(I) proposed by Baron et al. (2022)

No.	Exemption	Scope and dates of applicability
III-6(a)	Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight	Applies to categories 8, 9 and 11, and expires on <ul style="list-style-type: none"> - 21 July 2021 for cat. 8 other than in-vitro diagnostic medical devices, and cat. 9 other than 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
III-6(a)(I)	Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight	Applies to all categories and expires on <ul style="list-style-type: none"> - 21 July (2024+X) for cat. 9 industrial monitoring and control instruments - 21 July 2024 for all other categories
III-6(a)(I)	Lead in batch hot dip galvanised steel components containing up to 0,2 % lead by weight	Applies to all categories and expires on

³ For those components where alternatives are already available, we still need 7 years to implement the change across our respective portfolios, and where components are not currently available, we may need to submit another renewal request in 5½ years.



		<ul style="list-style-type: none">- 21 July (2026 + Y) for cat. 9 industrial monitoring and control instruments- 21 July 2026 for all other categories
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X and Y can range between 0 and 5 years

Please comment on this proposal explaining clearly any obstacles you see if you do not agree to the proposal.

TMC reply to question 3:

As explained in TMC's official renewal application documents from 20 January 2023, TMC is applying for the renewal of exemption III-6(a) in its current wording and the maximum validity period (*please see answers to question 1 and 2 of this document*).

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 the above table and reiterates the renewal request as outlined in renewal application documents and the answers to question 1 and 2.

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

Baron et al. (2022): Study to assess requests for a renewal of nine (-9-) exemptions 6(a), 6(a)-I, 6(b), 6(b)-I, 6(b)-II, 6(c), 7(a), 7(c)-I and 7 (c)-II of Annex III of Directive 2011/65/EU (Pack 22) – Final Report (Amended Version). 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. Author(s): Yifaat Baron, Carl-Otto Gensch, Andreas Köhler, Ran Liu, Clara Löw, Katja Moch, Oeko-Institut e. V. (Pack 22). retrieved from https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_22/RoHS_Pack-22_final_report_amended_February_2022.pdf.