Questionnaire 1 (Clarification) for Exemption III-7(c)(I) (Werfen)

NON-CONFIDENTIAL VERSION

Current wording of exemption 7(c)(I)

Table 1: Currently valid exemption wordings

No.	*Exemption*	*Scope and dates of applicability*
III-7(c)(I)	Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound	Applies to categories 1 to 11 (except applications covered under point 34) and expires on - 21 July 2021 for categories 1-7 and 10, and for category 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

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

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.

WERFEN submitted a request the renewal of the above exemption for cat. 9 industrial 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-7(c)(I)	*Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g., piezoelectronic devices, or in a glass or ceramic matrix compound, which are used in in-vitro diagnostic medical devices for the analysis of whole blood.*	Applies to category 8 in-vitro diagnostic medical devices Expires on 21 July 2028 (= 2023 + 5 years)

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 17 September 2023 latest.

2. Questions

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

   Answer from Werfen: In Table 1, Werfen's current exemption is under III-7(c)(I) category 8 which is identified as expiring on 21 July 2023. In this proposal, Section 1, Background, mistakenly identifies Werfen as requesting a renewal for category 9. This is not correct as Werfen's technology falls under category 8: in-vitro diagnostic medical devices. Table 2 is the correct version of the exemption renewal request with the correct wording and categorical identification.

2. Exemption 7(c)(I) was reviewed by Baron et al. (2022)[2]. They recommended specifying exemption 7(c)(I) like listed in Table 3 below.

[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

Table 3: Renewal of current exemption 7(c)(I) recommended by Baron et al. (2022)

Ex. No	Exemption formulation	Duration
7(c)-I	Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound	Expires on 21 July 2024 for all categories
7(c)-V	Electrical and electronic components containing lead in a glass or glass matrix compound that fulfils the following functions: 1) protection and electrical insulation in glass beads of high voltage diodes and glass layers for wafer on the basis of a lead-zinc-borate or a lead-silica-borate glass body,* 2) for hermetic sealings between ceramic, metal and/or glass parts 3) for bonding purposes in a process parameter window for < 500°C combined with a viscosity of $10^{13,3}$ dPas (so called "glass-transition temperature") 4) used as resistance materials such as ink, with a resistivity range from 1 Ohms/square to 1 Mega Ohms/square, excluding trimmer potentiometers** 5) used in chemically modified glass surfaces for Microchannel Plates (MCPs), Channel Electron Multipliers (CEMs) and Resistive Glass Products (RGPs).	Expires on 21 July 2026 for all categories
7(c)-VI	Electrical and electronic components containing lead in a ceramic that fulfils the following functions (excluding items covered under item 7(c)-II, 7(c)-III and 7(c)-IV of this annex): 1) piezoelectric lead zirconium titanate (PZT) ceramics 2) providing ceramics with a positive temperature coefficient (PTC)	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 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 recommendations resulting from previous reviews between 2020 to 2022 for EEE of categories 8, 9 and 11.

If the review shows that WERFEN'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. 11 in the scope of WERFEN's renewal request. **Fejl! Henvisningskilde ikke fundet.** reflects the resulting wordings, scopes and validity periods in consistency

with the state of science and technology assessed by Baron et al. (2022) and with their recommendations.

Table 4: Renewal of current exemption 7(c)(I) like recommended by Baron et al. (2022) (modified)

No.[3]	Recommended Exemption	Recommended scope and dates of applicability
III-7(c)(I)	Lead in high melting temperature type solders (i.e., lead-based alloys containing 85 % by weight or more lead)	Expires on 21 July 2024 for all categories
III-7(c)(V)	Electrical and electronic components containing lead in a glass or glass matrix compound that fulfils the following functions: 1. protection and electrical insulation in glass beads of high voltage diodes and glass layers for wafer on the basis of a lead-zinc-borate or a lead-silica-borate glass body,* 2. for hermetic sealings between ceramic, metal and/or glass parts 3. for bonding purposes in a process parameter window for < 500°C combined with a viscosity of 10 13,3 dPas (so called “glass-transition temperature”) 4. used as resistance materials such as ink, with a resistivity range from 1 Ohms/square to 1 Mega Ohms/square, excluding trimmer potentiometers** 5. used in chemically modified glass surfaces for Microchannel Plates (MCPs), Channel Electron Multipliers (CEMs) and Resistive Glass Products (RGPs).	Applies to all categories from 22 July 2024 on Expires on - 21 July 2026 for categories 1 to 7, 8 other than in-vitro diagnostic medical devices for the analyses of whole blood, and for categories 9, 10 and 11 - 21 July [2026 + **X**] for cat. 8 in-vitro diagnostic medical devices for the analysis of whole blood
III-7(c)(VI)	Electrical and electronic components containing lead in a ceramic that fulfils the following functions (excluding items covered under item 7(c)-II, 7(c)-III and 7(c)-IV of this annex): 1. piezoelectric lead zirconium titanate (PZT) 2. ceramics 3. providing ceramics with a positive 4. temperature coefficient (PTC)	Applies to all categories from 22 July 2024 on Expires on - 21 July 2026 for categories 1 to 7, 8 other than in-vitro diagnostic medical devices for the analyses of whole blood, and for categories 9, 10 and 11 - 21 July [2026 + **X**] for cat. 8 in-vitro diagnostic medical devices for the analysis of whole blood

X is maximum 2 years (2026 + 2 years = 2023 + 5 years)

[3] The numbering is introduced in the current review to facilitate addressing the various exemption parts

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

Answer from Werfen: We agree with the proposal specified in Table 4 and would like to clarify that the Werfen product for which this exemption renewal is being requested falls under category 8: in-vitro diagnostic medical devices for the analysis of whole blood that is listed under III-7(c)(VI). However, see the response to Question 4 below for further detail on timing.

3. In your renewal request you describe the exemption to be required for PZT material used as piezoelectric transducer. Would exemption III-7(c)(VI)(1) in Table 4 cover your application completely? If not, please let us know which other parts of the recommended renewed exemption 7(c)(V) and 7(c)(6) would be required for your application.

   Answer from Werfen: Yes, exemption III-7(c)(VI)(1) for PZT, category 8 for in-vitro diagnostic medical devices for the analysis of whole blood would cover Werfen's exemption renewal application completely. However, see the response to Question 4 below for further detail on timing.

4. You request less than the 7 year maximum validity for the renewal of the exemption. We understand that you develop a lead-free substitute or a possibility to eliminate the use of lead. Could this objective be achieved until 2026 already within the time frame recommended by Baron et al. (2022) in Table 3?

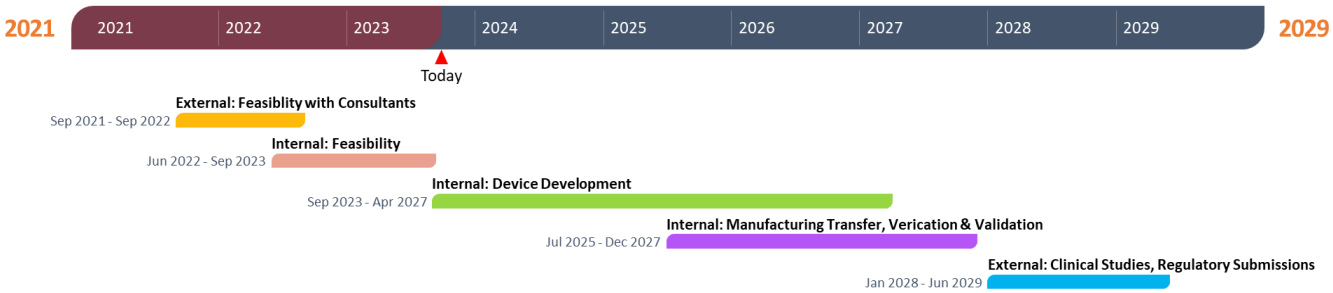
   Answer from Werfen: At the time of filing the original exemption application in January of 2022, 5 years was deemed sufficient time for implementation, based on initial benchtop data from external consultants. Since then, internal feasibility activities have progressed toward developing an alternative lead-free material into the GEM Premier 5000 MARS (commercial product name has been updated to GEM Premier 7000 with iQM3) as described below.

- Additional benchtop studies expanding the scope and sample sizes compared to studies conducted by consultants
- Integration into the full GEM system to evaluate complete functionality
- Assessing impacts on the constraints of the established GEM system

After initial testing, currently available lead-free alternatives have not proven to have the performance that is required to move forward with implementation. The result is that 5 additional years from our proposed exemption extension in the January 2022 application are required for internal development, to the full 7-year maximum validity (also referred to 2026 + 2 or 2028). Testing thus far has shown that the available lead-free alternatives are not a viable solution to implement as all options are accompanied by substantial impact to the existing architecture of the system.

Optimization to achieve equivalent performance would require multiple rounds of high-volume testing in conjunction with modifying the manufacturing process. The goal of additional development is to implement a solution that does not compromise safety, effectiveness, and reliability of the current device utilizing PZT. It is for this reason the application is being updated to request the maximum validity renewal of 7 years. The additional timeline for compliance includes both the internal development required as well as the external regulatory processes with IVDR.

The timeline requested allows for internal timeline completion and factors in time for any external process completion that may follow making any changes to the product once it is on-market. Below is project timeline for compliance with the RoHS directive.



5. You submitted an LCA comparing the current PZT material versus alternatives. The LCA is prepared by Intertek with guidance from ISO 14040 and 14044, and was reviewed by an Intertek expert.

   ISO 14044 states that a critical review is be included in an LCA report if the results of the analysis are to be communicated to any third party, i.e. an interested party other than the commissioner or the practitioner of the study. In case the study is a comparative assertion to be disclosed to the public, ISO 14044 states that "*In order to decrease the likelihood of misunderstandings or negative effects on external interested parties, a panel of interested parties shall conduct critical reviews on LCA studies where the results are intended to be used to support a comparative assertion intended to be disclosed to the public.*" The standard defines a 'comparative assertion' as an "*environmental claim regarding the superiority or equivalence of one product versus a competing product that performs the same function*".

   We consider this review process to be a comparative assertion intended to be disclosed to the public.

   a. Is a critical review report available for the LCA study?

b. Was a panel of interested parties involved into this critical review?

Answer from Werfen: The LCA study is not intended to be disclosed to the public.

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.