Questionnaire 1 (Clarification) for Exemption IV-1a (COCIR)

Current wording of exemption 1a

Table 1: Currently valid exemption wordings

No.	*Exemption*	*Scope and dates of applicability*
IV-1a	Lead and cadmium in ion selective electrodes including glass of pH electrodes	Applies to categories 8 and 9 and expires on - 21 July 2021 for category 8 other than in-vitro diagnostic medical devices (IVD) and for category 9 other than industrial monitoring and control instruments (IMCI); - 21 July 2023 for category 8 in vitro diagnostic medical devices; - 21 July 2024 for category 9 industrial monitoring and control instruments.

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
IVD	In vitro diagnostic medical devices

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.

COCIR submitted a request for renewal of the above exemption for cat. 8 in vitro diagnostic medical devices (IVD) 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*
IV-1a	*Lead and cadmium in thick film pastes in ion selective electrodes used for blood gas systems.*	*Applies to category 8 in vitro diagnostic medical devices and expires on 31 August 2026*

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 25 September 2023 latest.

2. Questions

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

   Yes

2. Exemption 1a was reviewed by (Deubzer et al. 2022)[2]. They recommended specifying exemption 1a as listed in Table 3 below, providing two wording options to the European Commission: Wording option A and wording option B.

[2] C.f. BioIS, https://www.rohs.biois.eu/RoHS-Pack-21_Final-Report_amended.pdf

Table 3: Renewal of current exemption 1a recommended by (Deubzer et al. 2022)

Exemption wording option A

	Exemption	Scope and dates of applicability
1(a)	*Lead and cadmium in ion selective electrodes including glass of pH electrodes*	*Expires on 21 July 2023 for cat. 8 in vitro diagnostic medical devices*
1(a)(I)	*Lead in the stem glass of pH glass electrodes and ion selective electrodes equipped with a pH glass electrode with complex shape as following:* *- Micro type pH glass electrode* *Composite electrode that has a spherical or tube-shaped pH responsive glass membrane with a diameter of 4.0 mm or less and a reference electrode with a liquid junction at a position vertically within 6.5 mm from the tip;* *- Flat type pH glass electrode* *pH glass electrode with a flat pH response membrane at the tip of a glass tube with a diameter of 6.0 mm or more;* *- Needle type pH glass electrode* *Composite electrode that has a conical pH response membrane with a tip angle of 40 ° or less and with a diameter of 10 mm or more."*	*Expires on 21 July 2025 for cat. 9 monitoring and control instruments including industrial monitoring and control instruments.*

Exemption wordings option B

	Exemption	Scope and dates of applicability
1(a)	*Lead and cadmium in ion selective electrodes including glass of pH electrodes*	*Expires on 21 July 2023 for cat. 8 in vitro diagnostic medical devices*
1(a)(I)	*Cadmium in ion selective electrodes including glass of pH electrodes*	*Expires on 21 July 2024 for cat. 9 industrial monitoring and control instruments*
1(a)(II)	*Lead in the stem glass of pH glass electrodes and ion selective electrodes equipped with a pH glass electrode with complex shape as following:* *- Micro type pH glass electrode* *Composite electrode that has a spherical or tube-shaped pH responsive glass membrane with a diameter of 4.0 mm or less and a reference electrode with a liquid junction at a position vertically within 6.5 mm from the tip;* *- Flat type pH glass electrode* *pH glass electrode with a flat pH response membrane at the tip of a glass tube with a diameter of 6.0 mm or more;* *- Needle type pH glass electrode* *Composite electrode that has a conical pH response membrane with a tip angle of 40 ° or less and with a diameter of 10 mm or more."*	*Expires on 21 July 2025 for cat. 9 monitoring and control instruments including 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 COCIR'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. 8 IVD in the scope of COCIR'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 1a as recommended by (Deubzer et al. 2022) reflecting exemption wording option A (modified)

No.	Recommended Exemption	Recommended scope and dates of applicability
IV-1a	Lead and cadmium in ion selective electrodes including glass of pH electrodes	Expires on 21 July 2023
IV-1a(I)	Lead in the stem glass of pH glass electrodes and ion selective electrodes equipped with a pH glass electrode with complex shape as following: - Micro type pH glass electrode Composite electrode that has a spherical or tube-shaped pH responsive glass membrane with a diameter of 4.0 mm or less and a reference electrode with a liquid junction at a position vertically within 6.5 mm from the tip; - Flat type pH glass electrode pH glass electrode with a flat pH response membrane at the tip of a glass tube with a diameter of 6.0 mm or more; - Needle type pH glass electrode Composite electrode that has a conical pH response membrane with a tip angle of 40° or less and with a diameter of 10 mm or more."	Applies to cat. 8 in vitro diagnostic medical devices starting 22 July 2023 and cat. 9 monitoring and control instruments including industrial monitoring and control instruments. Expires on - 21 July [2023 **+ X***] for cat. 8 in vitro diagnostic medical devices - 21 July 2025 for cat. 9 monitoring and control instruments including industrial monitoring and control instruments.

*X can be a maximum of 7 years

Table 5: Renewal of current exemption 1a as recommended by (Deubzer et al. 2022) exemption wording option B (modified)

No.	Recommended Exemption	Recommended scope and dates of applicability
IV-1a	Lead and cadmium in ion selective electrodes including glass of pH electrodes	Expires on 21 July 2023
IV-1a(I)	Cadmium in ion selective electrodes including glass of pH electrodes	Applies to cat. 8 in vitro diagnostic medical devices starting 22 July 2023 and cat. 9 industrial

		monitoring and control instruments. Expires on - 21 July [2023 **+ X***] for cat. 8 in vitro diagnostic medical devices - 21 July 2024 for cat. 9 industrial monitoring and control instruments
IV-1a(II)	Lead in the stem glass of pH glass electrodes and ion selective electrodes equipped with a pH glass electrode with complex shape as following: - Micro type pH glass electrode Composite electrode that has a spherical or tube-shaped pH responsive glass membrane with a diameter of 4.0 mm or less and a reference electrode with a liquid junction at a position vertically within 6.5 mm from the tip; - Flat type pH glass electrode pH glass electrode with a flat pH response membrane at the tip of a glass tube with a diameter of 6.0 mm or more; - Needle type pH glass electrode Composite electrode that has a conical pH response membrane with a tip angle of 40 ° or less and with a diameter of 10 mm or more."	Applies to cat. 8 in vitro diagnostic medical devices starting 22 July 2023 and cat. 9 monitoring and control instruments including industrial monitoring and control instruments. Expires on - 21 July [2023 **+ X***] for cat. 8 in vitro diagnostic medical devices - 21 July 2025 for cat. 9 monitoring and control instruments including industrial monitoring and control instruments.

*X can be a maximum of 7 years

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

The above proposed amendments would not cover all of the uses highlighted in the exemption renewal request and as such we cannot agree to the proposed amendment.

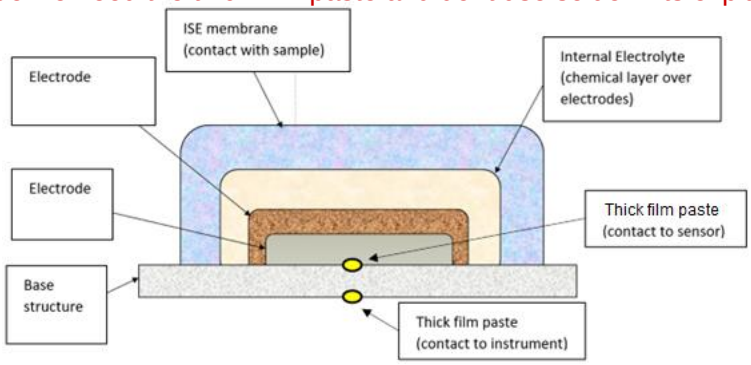
From Table 5, 1a-(I) the proposed amendment would be suitable for the cadmium use if X equates to 7 years. However, 1a-(II) only permits the use of lead in stem glass or in specific geometry types which are not applicable to blood gas systems.

3. Please clarify what the sensitive element of the ISE for which you request the exemption is. Is the thick film paste itself, that is fused onto a ceramic substrate, the sensing element? Or is the thick film paste only the connecting and signal-conducting material between substrate and sensing element? Please provide additional technical illustrations if available.

Request for exemption is for the thick film paste only. The thick film paste is used to create an electrical connection between the sensing element on the substrate and

the signal-processing electronics on the blood gas analyzer. A technical illustration is provided below:

Note for later: Why do we need the thick film paste and dont use solder? Its explained in the request form



4. Are both lead and cadmium needed to achieve the technical parameters required for the thick film paste, including viscosity and resistivity? What is the function of each element in the paste? How are the paste attributes affected if either one or both elements are not added during the production process?

Yes, both lead and cadmium are needed to achieve the technical parameters. The substances contribute to the required viscosity and resistivity which are critical to the current pastes used for manufacturing of existing products. The addition of cadmium oxide and lead oxide lowers the melting temperature of the glass frit which results with a paste that has lower viscosity. With lower viscosity during the firing step, the ink readily moves to the interface between the inks and the substrate. The lower viscosity also helps the ink migrate into substrate pores to fill them. This forms a strong mechanical bond between the metallic inks and the substrate. Defects or pin holes in the fired paste act as air gaps increasing the overall resistivity. Details of technical parameters are outlined in the paper by William S. Rapson on 'The bonding of gold and gold alloys to non-metallic materials'.[3]

Pastes without lead and cadmium are currently being tested for manufacturing of blood gas products:

- The absence of both cadmium and lead in one of the promising alternative thick film paste was trailed. However, upon testing print voids were observed and the conductivity tests undertaken on the samples had a failure rate of 1/3 of the samples. As such, the testing of the thick film paste cannot be pursued further as it does not offer the necessary properties.

- Feasibility testing including printing and functional performance testing with thick film pastes without lead or cadmium from the 2nd supplier is ongoing. Functional data to date is promising. Additional time is needed for assessing scalability and functional testing related to lot to lot variation. The thick film paste also needs to go through formal change control processes to be complaint with Medical Device Regulation requirements.

[3] The bonding of gold and gold alloys to non-metallic materials | Gold Bulletin (springer.com)

5. You stated that among the six main manufacturers of blood gas systems, some do not use planar sensors, but are likely to use macro sensors.

    a. Are macro sensors used to measure the same parameters that are measured by the planar sensors that require the requested exemption?

    Yes

    b. Do macro sensors require the addition of lead and cadmium to function properly, just like the planar sensors in scope of this exemption request?

    No

    c. Are there technical reasons to prefer planar sensors over macro sensors for the application in blood gas systems? Please provide technical reasons and explanations.

A macro sensor in this context is a sensor that is used in large, centralized laboratory systems that need to process a high volume of samples quickly and efficiently. Individual macro sensors that use ion-selective sensor technology can be independently replaced. Ion-selective sensor technology is used for detection of analytes such as sodium, potassium etc. Macro sensors also require regular maintenance by qualified lab personnel.

In comparison, planar sensors are typically cartridge-based sensor arrays. These analyzers use planar sensor-arrays instead of individual macro sensors, which make them maintenance-free and easily replaceable. Cartridge based system are smaller and easier to transport rather than macro-sensor-based systems, making them suitable for both point-of-care and central laboratory settings. While the principle of detection between two systems are ion-selective sensor technology principles, the intrinsic design differences does not allow for inter-compatibility.

The biggest technical advantage of planar over macro sensors is the ability to integrate sensors and reagents into a single consumable cartridge. This makes it possible to develop smaller footprint cartridge-based detection systems. In addition to the smaller footprint, planar detection systems may also offer lower manufacturing costs and reduced overall cost of system ownership due to reduced maintenance.

6. Please define the term glass frit and describe its function in the ISE for which this exemption is requested.

Glass frit is a glass powder which acts as a filler which is typically used for producing the thick film pastes.

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 16 exemptions to Annex IV 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 21. With assistance of Dr. Deubzer, Otmar, Fraunhofer IZM und UNITAR, Saskia Huber, Jana Rückschloss, Fraunhofer IZM, UNITAR Christian Clemm, Bio I. S. Shailendra Mudgal (RoHS 26). Available online at http://rohs.biois.eu/RoHS-Pack-21_Final-Report_amended.pdf.