Questionnaire 1 (Clarification) for Exemption IV-1b (Dräger)

Current wording of exemption 1b

Table 1: Currently valid exemption wordings

No.	*Exemption*	*Scope and dates of applicability*
IV-1b	Lead anodes in electrochemical oxygen sensors	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.

Dräger 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*
IV-1b	*Lead anodes in electrochemical oxygen sensors*	*Applies to category 9 industrial monitoring and control instruments (IMCI) and expires on* - *31 December 2025 for new instruments that use electrochemical oxygen sensors;* - *21 July 2031 for oxygen sensors that are spare parts for instruments placed on the market before 1 January 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 30 September 2023 latest.

2. Questions

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

   Yes table 2 correctly reflects the requested renewal for continued use of oxygen sensors that contain lead anodes in new Electrical and Electronic Equipment (EEE) of categories 9 (Industrial Monitoring and Control Instruments) until the end of 2025.

   Exemption 1b was reviewed by (Deubzer et al. 2022)[2]. They recommended specifying exemption 1b as listed in Table 3 below.

2 Please see the amended final report on RoHS Pack 21 on the BioIS website: https://www.rohs.biois.eu/RoHS-Pack-21_Final-Report_amended.pdf

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

	Exemption	Scope and dates of applicability
1(b)	*Lead anodes in electrochemical oxygen sensors.*	*Expires on 21 July 2021 for cat. 8 medical devices others than in-vitro diagnostic medical devices*
1(b)-I	*Lead anodes in electrochemical sensors that measure oxygen concentrations of inhaled and/or exhaled air for patients and that are consumables in medical devices put on the market before 26 May 2024.*	*Expires on 21 July 2025 for cat. 8 medical devices others than in-vitro diagnostic medical devices*
1(b)-II	*Lead in galvanic oxygen sensors in instruments that are* *(a) designed for the measurement of oxygen in gases with a response time < 3 s (t95) and which are not handheld devices, and* *(b) designed for the measurement of dissolved oxygen in concentrations below 30 ppb.*	*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 Dräger'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 Dräger'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 1b as recommended by (Deubzer et al. 2022) (modified)

No.	Recommended Exemption	Recommended scope and dates of applicability
IV-1b	Lead anodes in electrochemical oxygen sensors	Expires on 21 July 2021 for cat. 8 medical devices other than in vitro diagnostic medical devices
IV-1b-I	Lead anodes in electrochemical sensors that measure oxygen concentrations of inhaled and/or exhaled air for patients and that are consumables in medical devices put on the market before 26 May 2024.	Expires on 21 July 2025 for cat. 8 medical devices other than in vitro diagnostic medical devices
IV-1b-II	Lead in galvanic oxygen sensors in instruments that are (a) designed for the measurement of oxygen in gases with a response time < 3 s (t95) and which are not handheld devices, and	Expires on - 21 July 2025 for cat. 9 monitoring and control instruments other than industrial

	(b) designed for the measurement of dissolved oxygen in concentrations below 30 ppb.	monitoring and control instruments - [21 July 2025 **+ X***] for cat. 9 industrial monitoring and control instruments

*X can be maximum of 5 months and 10 days (until the end of 2025, as per your request)

Note 1: Please note that the recommended exemption IV-1b-II is intended to apply to two separate types of galvanic oxygen sensors: (a) for the measurement of oxygen in gases in instruments that are not handheld devices, as specified, and (b) for measurement of dissolved oxygen, as specified.

Note 2: Please note that the explicit inclusion of replacement oxygen sensors is subject to evaluation of missing information requested in question 3 below.

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

The wording of the exemption IV-1b as shown in table 4 is not sufficient for Dräger as it only provides for the use of the lead-containing electro chemical sensors in medical devices or as consumables (spare parts) to service medical devices. As shown in Table 4, this exemption does not cover the use of these electrochemical sensors as consumables/spare parts in industrial monitoring and control instruments that will be put onto the market before the expiry of the current exemption on 21st July 2024 or at the end of the requested exemption on 31st December 2025. We therefore suggest that you include under exemption IV-1b in Table 4 the exact wording, scopes and expiry dates as requested by Dräger in Table 2.

Additionally, our assessment indicates that in theory and if no difficulties are encountered, it would take at least 5.5 years from the time a lead-free sensor is available, until EEE that works with such a lead-free sensor could be put onto the market. This time is necessary to re-design, test and evaluate the reliability and the accuracy of the EEE and to get the necessary approvals. Although these comments pertain to our application for an exemption for category 9 EEE, we would like to appeal that any decisions must also consider that the electrochemical sensors have a wide range of application including the use in medical devices of category 8 to measure oxygen concentrations in inhaled and exhaled air of patients who are being ventilated while undergoing surgery or MRI scans under anesthesia.

Exemption IV-1b-II as shown in Table 4 does not cover Dräger electrochemical sensors and therefore would not be applicable to industrial monitoring and control instruments made by Dräger. As such, Dräger does not agree with the proposal as shown in table 4 because this would mean that Dräger will no longer be able to service industrial monitoring and control instruments that uses the lead-containing electrochemical oxygen sensors after the expiry of the exemption 1b on 21st of July 2024 or in the case that the request is granted, after 31st December 2025.

We therefore recommend that you include in table 4 an additional exemption specifically addressing the use of lead-containing electrochemical sensors as consumables/spare parts in industrial monitoring and control instruments of category 9 as requested in our application (see table 2).

You request the maximum validity period for replacement oxygen sensors. We interpret that you want to ensure that instruments placed on the market before the expiry of the requested validity period (end of 2025), which are still designed to work with lead-containing oxygen sensors, will be able to receive lead-containing replacement sensors beyond the end of 2025. We further interpret that vice versa, instruments placed on the market starting January 2026 will no longer contain leaded oxygen sensors and therefore also will not need leaded replacement oxygen sensors.

a. Can you please clarify whether our understanding is correct?

   Yes, you understood correctly. Dräger would like to be able to continue servicing those devices that were designed to work with this type of a sensor beyond 2025. You also correctly understood that after the end of 2025, Dräger will no longer put onto the market lead containing sensors.

   RoHS Art. 4(4)(f) postulates that the substance restrictions stipulated by RoHS Art. 4(1) do not apply to ‘spare parts’ for EEE which benefited from an exemption and which was placed on the market before that exemption expired.
   Does Dräger consider replacement oxygen sensors to be ‘spare parts‘ in the sense of the definition under RoHS Art. 3(27)? Please substantiate your response.

   Yes, replacement electrochemical sensors are spare parts in the sense of the definition under RoHS Art. 3(27). Electrochemical sensors used in our industrial monitoring and control instruments as well as those used in anesthesia medical devices have a life span of maximum one year. After this period, the sensor must be replaced for the device to continue functioning as intended. In the absence of the replacement sensor, the device will be rendered non-functional.

b. In case Dräger does not consider replacement oxygen sensors as ‘spare parts‘ according to RoHS Art. 3(27), please describe how they are defined and which RoHS Annex I EEE category would be most appropriate in your view.

2. In the renewal request form, you indicated that your renewal request pertains to RoHS category 9 industrial monitoring and control instruments only. However, throughout the request form there are several references to medical

instruments and applications, such as "*the medical device detects that the sensor is consumed and informs the user to replace the sensor with a new one*"; "*For monitoring patients, the following characteristics are essential: […]*"; "*Mass spectrometers can analyse all substances in patients' breath*"; among other examples.

a. Please confirm that your renewal request only pertains to category 9 IMCI as indicated or whether your oxygen sensors are also used in medical devices, which would be category 8.

Apart from the use of the sensors in industrial monitoring and control instruments of category 9, they are also used in medical devices to measure oxygen concentrations in inhaled and exhaled air of patients who are being ventilated, and when undergoing surgery or MRI scans when under anesthesia. However, this renewal request should be understood as covering EEE of category 9.

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. Amended 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.