

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

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	<p>Applies to categories 8 and 9 and expires on</p> <ul style="list-style-type: none"> - 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 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.

AMEKET MOCON (hereafter: MOCON) 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 Hersch cells for oxygen sensors for measurement of permeation	Expires on 21 January 2028 for category 9 industrial monitoring and control instruments (IMCI).

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

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

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)

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



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 MOCON'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 MOCON'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 (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 other than industrial monitoring and control instruments - 21 July [2025 + X*] for cat. 9 industrial monitoring and control instruments

*X can be maximum 3 years and 6 months (until 21 January 2028) as per your request

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.

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

The above proposed derogation would not be suitable as the use of lead is limited to uses with a response time of less than 3 seconds and have a sensitivity of 30ppb. These parameters are not applicable to Hersch sensors and therefore would exclude critical applications.

Specifically, although Hersch sensors are able to detect oxygen below the stated 30 ppb range outlined (it can measure to 200ppt) the sensor response time is not within the <3 seconds as it takes less than 8 minutes to 99% of full reading. Rather, other technical parameters differentiate the unique technical performance of Hersch cells, including the sensor being an absolute method of measurement and thus being able to achieve such low levels of detection. The full list of differentiating technical parameters are outlined in the renewal submission on page 5.

3. According to results of the previous evaluation of exemption 1b, lead is only needed in galvanic oxygen sensors used in instruments designed for the measurement of oxygen in gases with a response time faster than 3 seconds and which are not handheld devices³ (Deubzer et al. 2022). In other words, handheld devices in general and oxygen sensors with a response time slower than 3 seconds can be manufactured without the use of lead, as was explained by the applicant at that time.
 - a. In case you do not agree with the proposal described under question 2: Can you please clarify which technical and performance differences of the MOCON oxygen sensors and their end-uses (applications), compared with oxygen sensors for which the above wording was recommended (Table 4 exemption IV-1b-II), justify a widening of the scope of the recommended exemption in your view?

Hersch sensors were covered under the exemption wording 1b, and it is only due to the latter submission deadline which is applicable to Category 9 Industrial Monitoring and Control Devices that this requirement was not captured during the amendment to 1b-I and 1b-II. Therefore, we believe that this should not be considered a widening of the scope of the exemption, but rather additional information being shared by the relevant deadline.

The technical difference between Hersch sensors and those outlined in 1b-II are substantial. The technical and performance differences of Hersch sensors permit the ultra-low detection of the absolute measurement of oxygen gas in the range of 200ppt to 70 ppm. Such measurements are critical to the production of pharmaceutical products, medical applications, assessment of the integrity of food packaging and solar panel lifespan calculations and improvements. All of these applications are not captured by the currently proposed wording of 1b-II.

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.

³ Handheld devices were defined as following by (Deubzer et al. 2022): “A handheld device is a measuring instrument that is designed to be compact and lightweight as to be held with a single hand and is battery-operated and does not require a direct AC power for measurement.”



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. ReferencesPublication bibliography

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.