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

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.

Honeywell 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*	*Expires on 21 July 2031 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 Honeywell'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 Honeywell'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 of 6 years

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 IV-1b- II 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 galvanic Industrial Monitoring and Control sensors and therefore would exclude the critical applications such devices support. Honeywell devices include capillary cells and membrane diffusion cells, both of which rely upon lead anodes to provide unique technical characteristics. Such devices can be

used in portable and fixed installations, with response times (T95 >3secs), rather than <3 seconds outlined in 1b-II. The concentration range of oxygen measurement ranges between 0% to 100%, rather than the 30 ppb of dissolved O2 which is not applicable to gas sensors outlined in 1b-II.

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 devices[3] (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 Honeywell 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?

Honeywell oxygen 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 capillary sensors and membrane diffusions cells and those outlined in 1b-II are substantial. The technical and performance differences of capillary and membrane oxygen sensors permit the measurement of oxygen gas in fixed installations, personal monitoring devices and permeation measurements, all of which are not captured by 1b-II. The criteria are limited and not representational of the requirements of industrial monitoring and control instrumentation for safety, emissions, automotive, biogas, diving gas analysis and environmental applications. These applications do not require T95 <3secs, but rather typically T90 <10-15secs and measuring volumetric oxygen (0-30%O2 or 0-2ppm O2) or oxygen partial pressure (0-100% O2), not dissolved oxygen (<30ppb). If the recommended exemption is not updated to cover lead anodes in electrochemical oxygen sensors for category 9 industrial monitoring and control instruments (IMCI), this will lead to significant social, economic and global impacts and the shutdown of manufacturing and processing sites for energy generation, mining (precious materials), water treatment, petrochemical, chemical, semi-conductor and microchip fabrication.

[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."*

The use of such devices are in both fixed and mobile applications, and end-uses include:

- Water treatment works
- Food packaging
- Refining
- Bio-gas monitoring
- Boiler flue/Emissions analysis
- Ships and military applications such as in submarines and for inspection of fuel storage tanks
- Paper mills
- Semiconductor and photocell manufacture
- For working in confined spaces, such as tunnels, sewers, tanks, etc.
- Building and construction sites, such as in tunnels and trenches
- In mines
- Commercial buildings, medical and laboratories, such as boiler rooms, cryogenic zones such as liquid nitrogen storage.
- Farming
- SCUBA diving gas analysis

The technical requirements of the devices are outlined on page 8 of the exemption renewal request.

4. In the renewal request form, you indicated that your renewal request pertains to RoHS category 9 industrial monitoring and control instruments only. However, the document also makes reference to SCUBA diving gas analysers and medical applications.

    a. Can you please clarify whether your renewal request only pertains to cat. 9 IMCI, or whether the sensors for which you request the renewal are also used in medical applications, which would be RoHS Annex I

EEE category 8, and SCUBA diving equipment, which may be another RoHS Annex I EEE category?

The use of such equipment in medical devices is covered by the proposed derogation 1b-I.

For SCUBA diving equipment, the monitors are used for SCUBA diving gas analysis as part of its generation and monitoring on the quality of the gas. As such it would be classified as an industrial monitoring and control device, designed for exclusively professional use.

b. Can you provide argumentation that justifies SCUBA diving equipment to be categorized as cat. 9 IMCI? If not, which RoHS Annex I EEE category is most appropriate for this type of equipment in your view?

Description in section 'a', design for monitoring and control instruments for exclusive professional use.

5. In the renewal request form, you stated that Honeywell also manufactures capillary oxygen sensors, for which Alphasense submitted a separate renewal request form. Alphasense requested the renewal until January 2027 for general applications and July 2028 for ATEX rated products. Do you, in principle, agree with these requested validity periods for capillary oxygen sensors?

Yes, in principle at the sensor level. Additional time will be required for instrument development and certification as outlined in tables 4, 5 & 6 of the Honeywell derogation.

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. 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.