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

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.

Alphasense 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 capillary oxygen sensors*	*Applies to category 9 industrial monitoring and control instruments (IMCI) and expires on* - *21 January 2027 for general applications;* - *21 July for 2028 for ATEX rated products.*

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.

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 Alphasense'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 Alphasense'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 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 also note that the wording in Table 4 is based on the amended final report of RoHS Pack 21 as cited above.

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 capillary sensors and therefore would exclude the critical applications such devices support. Rather capillary sensors are able to measure to 20ppb and have other critical performance characteristics which include the ability to operate at 0% oxygen, minimal response to temperature and pressure and wide operating temperature range. The full list of technical parameters is outlined on page 6 of the renewal request.

3. Can you please confirm whether the capillary oxygen sensors for which you apply for a renewal of this exemption are “galvanic oxygen sensors” that are used in “instruments designed for the measurement of oxygen in gases”?

   This is correct.

4. 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 below 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. Can you please clarify which technical and performance differences of capillary oxygen sensors, compared with oxygen sensor types for which the wording in Table 4 (exemption IV-1b-II) was recommended, justify a widening of the scope in your view?

Capillary 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

[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.”*

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 those outlined in 1b-II are substantial. The technical and performance differences of capillary 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.

b. We believe that answers to our question 4a may be, at least partly, described in the confidential information you provided with your renewal request form. Is it possible that you provide a non-confidential version of that document that carries the same message and information, but leaving out those aspects that you consider confidential?

The which technical and performance differences of capillary oxygen sensors, compared with oxygen sensor types is outlined in the following non-confidential information.

Alphasense capillary lead oxygen sensors have a nominal output of 65 to 200 uA in ambient conditions, with the specific output depending on the lifetime of the sensor in question. Galvanic partial pressure sensors from the three manufactures were disassembled to calculate the current output, as shown in Table 1, showing that the current is at, or under, 10 uA for all three sensors.

Table 5 Measured output, shorting resistance and calculated current of galvanic lead-free partial pressure sensors A, B and C

Sample	Shorting resistance (Ohm)	Output measured in ambient (mV)	Calculated current in ambient (uA)
A	7000	13.5	2
B	1100	11	10
C	1150	10	9

For capillary oxygen sensors, lower output causes the sensor to:

- Have a slower response time to changes in oxygen as shown in Figure 1 below.
- Increases the pressure step response, meaning the time in which the sensor requires to get back to its normal readings after a pressure change, as shown in Figure 2. This is an important parameter for applications such as oxygen monitoring in mine shafts where pressure changes are commonplace.
- Increases the output variance of the sensors when the sensor is used in a pumped method rather than a dispersive method, as shown in Table 2. The greater the output variance the greater the degree of uncertainty of the measurements. Given a significant proportion of these sensors are utilised in via a pumped method, such as applications which the sampling location is hard to reach or in a pipeline where the temperature of toxicity is not suitable e.g., boiler flues, the decrease in sensor performance would be significant.

This shows that, in addition to there being no capillary galvanic lead-free sensor available, the technology employed in partial pressure galvanic lead-free sensors cannot be readily applied to capillary type sensors, if at all.

Pressure galvanic lead-free sensors cannot be readily applied to capillary type sensors, if at all.

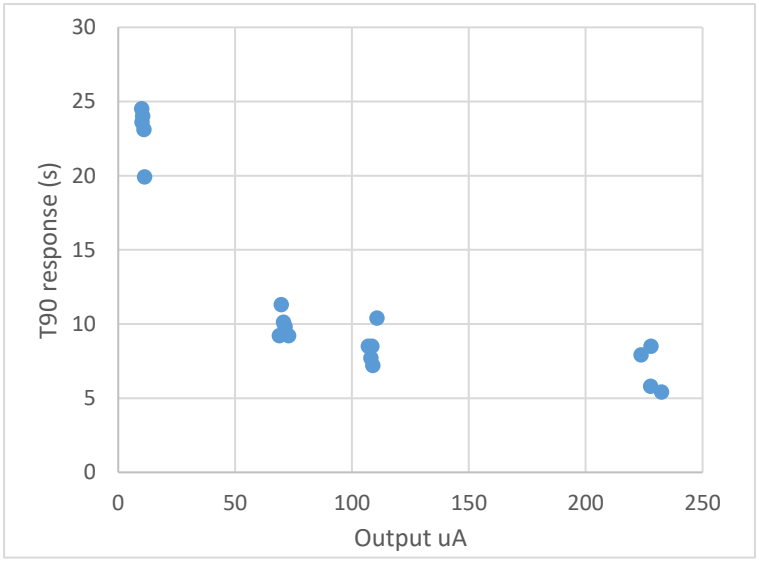

Figure 1 Effect of capillary size on response time 0 – 20.9 % oxygen. Low output sensors are slower to respond to changes in oxygen level.

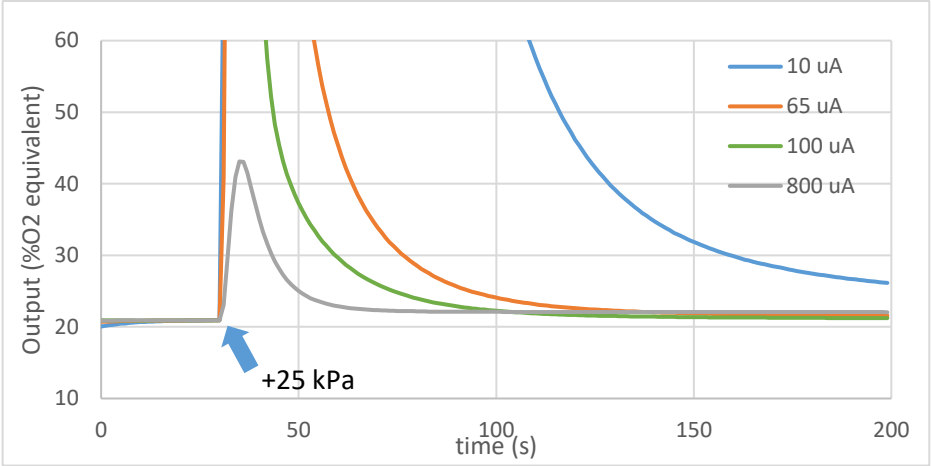

Figure 2 Response of capillary lead oxygen sensors to 25 kPa increase in pressure. Low output sensors take much longer to recover.

Table 6 Response to simulation of pumped sampling, 'aspirator test', showing the range of output as a function of the nominal output. Smallest capillary listed at the top of the table, to the largest capillary listed at the bottom of the table. Low output sensors have a much larger variation in output in response to pumped sampling instrumentation.

Sensor output (µA)	Output variance range (%)
10	15-35
65	19-23
100	19.5-22.5
200	19.8-22.0
800	20.7-21.2

5. You stated that capillary lead oxygen sensors are also used as spare parts for instruments already placed on the market. Could you please clarify whether lead-containing capillary oxygen sensors are still used in new instruments being placed on the market, or whether the exemption renewal request is perhaps only needed for spare parts for instruments already "in the field" (i.e. no longer put on the market)?

   Capillary oxygen sensors are also used in new instruments.

6. You stated that the majority of the capillary industrial market is expected to change to amperometric sensors when the technical issues are resolved. Please clarify whether this means that capillary sensors will no longer be

needed at all at that future point in time, or whether you expect there may still be specific applications or conditions that require capillary sensors.

Due to the technical challenges, such as requiring power and susceptibility to high carbon monoxide and carbon dioxide content, it will only be possible to confirm that all applications are able to utilize amperometric sensors at the end of the qualification testing. However, it is the intention that at this stage that all applications will be attempted to be permitted for the lead-free amperometric sensors being researched.

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.