Consultation Questionnaire Exemption 1(b) of RoHS Annex IV

Current wording of the exemption:

Lead anodes in electrochemical oxygen sensors

Expires in July 2021 for cat. 8 and 9 equipment other than in-vitro diagnostic devices and monitoring and control instruments in industry

1. Acronyms and Definitions

2. 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 and JBCE submitted requests[2] for the continuation of the above-mentioned exemption. The request has been subject to a first completeness and plausibility check. The applicant has been asked to answer additional questions and to provide additional information, available on the request webpage of the stakeholder consultation.[3]

SUMMARY OF THE EXEMPTION REQUEST

The applicants request the renewal of the exemption[2] with different wordings and scopes (c.f. question 1 below) for the maximum 7 years:

The applicant JBCE[2], *"[…] request the extension of exemption 1b of Annex IV for Lead anodes in electrochemical oxygen sensors used in monitoring and control devices. There is a wide variety of measurement methods for oxygen concentration. Galvanic oxygen sensors with lead anode are one of measurement methods of oxygen concentration. Galvanic oxygen sensors with lead anode are incorporated into analysis and measuring instruments for oxygen concentration measurement to provide rapid and accurate analysis and wide ranges of measurement. The technology is used by a wide variety of industry sectors, researchers and for educational purposes.*

Galvanic sensors with lead anodes are available on the market; however, the technical requirements, such as, measurement range, accuracy and response time are not sufficient for some analysis and measuring instrument for oxygen concentration. The other substitutes are also not feasible technically."

According to COCIR[2], *"This exemption is required to allow the use of electrochemical oxygen sensors for measurement of oxygen concentrations in inhaled and exhaled air of patients who are being ventilated, and when undergoing surgery or MRI scans when under anaesthesia. Electrochemical sensors have many advantages including their very small size and no need for a power supply which provide them with unique functionality critical to patient care.*

Alternative types of oxygen sensor have been assessed, but all alternative types are unsuitable for the aforementioned applications. Lead-free electrochemical sensors have recently become available and have

[1] It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017

[2] Exemption request available at https://rohs.biois.eu/Ex_1b-IV_COCIR_Renewal-Request.pdf, https://rohs.biois.eu/Ex_1b-IV_JBCE_Renewal-Request.pdf

[3] Clarification questionnaire available at https://rohs.biois.eu/Ex_1b-IV_COCIR_Questionnaire-1_Clarification.pdf, https://rohs.biois.eu/Ex_1b-IV_JBCE_Questionnaire-1_Clarification.pdf

been evaluated. Tests have shown that these are not drop-in replacements and cannot be used with the existing oxygen analyser instruments currently in use in EU hospitals and clinics. Analyser instruments that are connected to the sensors and indicate the oxygen concentration are being redesigned to use new lead-free sensors although these cannot be sold in the EU until redesign, testing a qualification is complete and Medical Device Regulation approval is granted which is not expected before 2025. This exemption will be required after 2025 to allow the currently used lead-based sensors to be used as replacements with the current designs of analyser instruments that are in use in EU hospitals and clinics."

The stakeholder consultation is part of the review process for the request at hand. The objective of this consultation and the review process is to collect and to evaluate information and evidence according to the criteria listed in Art. 5(1)(a) of Directive 2011/65/EU.[4]

To contribute to this stakeholder consultation, please answer the questions below by December 2nd, 2020.

3. Questions

1. JBCE requested the continuation of the above exemption with its current wording and scope for 7 years. COCIR requested the renewal of the above exemption of RoHS Annex IV with the same wording, but different validity periods.

   Lead anodes in electrochemical oxygen sensors

   Until the end of 2025 for new instruments that use electrochemical oxygen sensors that contain lead. Maximum validity period for replacement oxygen sensors.

   a. Please let us know whether you support or disagree with the wording, scope and re-quested validity period of the exemption. To support your views, please provide detailed technical argumentation / evidence in line with the criteria4 in Art. 5(1)(a).

      ITG disagree in all respect to the requesters input such as technical requirements (lack of measurement range, accuracy and response times), incompatibilities (as there are, mechanical and electrical interfacing) and the sensor's properties of being a drop-in replacement. Please, find our argumentation / evidence below and in Annex 1.

      Electrochemical sensors have by no means to stand behind other gas measuring technologies even opposite: RoHS and its foreseeable importance as a restrictive ensuring a green, as global, future has given the company an opportunity in creatively playing with alternative possibilities to lead, hence encouraging our development department. Outstanding results are even better performing lead-free sensors than before:

      - Lifetime

      As we tested the new leadfree cell according to lifetime, it has shown that it lasts even longer than its leaded twin (see condition and figure 1 in Annex 2).

      - Output Drift

      The new leadfree sensor has shown to drift less and even have a more stable performance than its leaded forerunner (see condition and figure 2 in Annex 2).

      - Response Time

      The figure shows that new leadfree sensors from ITG responds more than twice as fast than a usual cell (see condition and figure 3 in Annex 2).

      - Linearity Error

[4] Directive 2011/65/EU (RoHS) available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT

In linearity the new unleaded cell has shown unexpected and extraordinary performance: It leaves the leaded cell far behind as its linearity is observably smoother and even lower (see condition and figure 4 in Annex 2).

b. If applicable, please suggest an alternative wording and duration and explain your proposal.

ITG offers and supplies since 2013 a line-up of lead-free (free of any heavy-metals) oxygen sensors as either drop-in replacement or as customised version into the EU as well as outside EU market. When compared to the classical leaded-anode counterpart such sensors are characterised by:

- RoHS is no longer applicable in general to ITG's lead-free sensors;
- no hazardous materials, less risk in case of any damage;
- not considered as toxic waste and therefore easier to dispose off;
- ground and airborne transportation is much easier due to harmless electrolyte;
- noticeable longer lifetime relieving logistics supply chain and stocking time;
- a significant longer operation time;
- considerably less output signal drift and hence longer calibration intervals possible;
- a faster response time;
- a lesser linearity error;
- same geometrical dimensions and for-factor and largely electrically equivalent design;
- no external electrical power needed to operate.

Since the introduction of this lead-free cell, we have seen a considerably increasing demand in the world-wide market. That market can be divided into two sales of channels, firstly device manufacturers using the cells for the initial assembly of their analysers and secondly through distributors to service the demand of the aftermarket. Whereas the later lags thanks to the longer product life of the lead-free cell a bit behind the first. Around 70% of the lead-free sensors go into to the medical field as there are all life-supporting systems (ventilators, anesthesia machines, ECMOs), ergo-spirometry (breath-by-breath analysis) and home-care therapeutic instruments (CPAP-systems). The remaining part is divided into various industrial applications such as flue gas measurement, process technology, oxygen deficiency (gas-blanketing), quality inspection and others.

2. Please provide information concerning possible substitutes or elimination possibilities at pre sent or in the future so that the requested exemption could be restricted or revoked.

a. Please explain substitution and elimination possibilities and for which part of the ap-plications in the scope of the requested exemption they are relevant.

The above mentioned lead-free sensor is still of galvanic type comprising a zinc anode and a counter-electrode consisting of any kind of precious metal. The weak acidic electrolyte (caesium-carbonate as leading constituent) has been designed and tailored in order to withstands impacts of acidic gases i.e. carbon-dioxide, aggressive bromides, anesthesia gases or harsh solvents.

b. Please provide information as to research to find alternatives that do not rely on the exemption under review (substitution or elimination), and which may cover part or all of the applications in the scope of the exemption request.

   Except of the some phthalates commonly used as plasticizer in the sensor housing material no other component of the lead-free sensor is relevant to REACH (Registration, Evaluation, Authorization and Restriction of Chemicals).

c. Please provide a roadmap of such on-going substitution/elimination and research (phases that are to be carried out), detailing the current status as well as the estimated time needed for further stages.

   At present ITG has lead-free galvanic sensors from the very low ppm-range up to 100 Vol.% of oxygen commercially available. With the same technology we see potential to go even further into the sub-ppm range.

   Furthermore, we strive to downsize the sensor's geometrical dimension to make it more suitable for mainstream measurements (i.e. real-time, to be incorporated into a face-mask) and to set new limits with regard to time response down to 100 msec which then allows an accurate time-resolved measurement of a breathing curve.

3. Do you know of other manufacturers producing devices of comparable features and performance like the ones in the scope of this exemption request that do not depend on RoHS-restricted substances, or use smaller amounts of these substances compared to the applications in the scope of this requested exemption?

   By its nature oxygen can be detected with a variety of different techniques. Some of them can be found under Annex 3 where those competitive technologies are compared with regard to the key-features commonly demanded from the market. Even some electrochemical operating principles such as amperometric, potentiometric, conductometric, ChemFETs and not to forget fluorescence quenching technologies are used to detect gas-phase oxygen.

   Next to the galvanic oxygen sensor technique each of the above play an ever-increasing role in environmental monitoring, medical and health applications, industrial safety, security, surveillance, and automotive industry.

4. As part of the evaluation, socio-economic impacts shall also be compiled and evaluated. For this purpose, if you have information on socioeconomic aspects, please provide details in respect of the following:

   a. What are the volumes of EEE in the scope of the requested exemptions which are placed on the market per year?

   b. What are the volumes of additional waste to be generated should the requested ex-emption not be renewed or not be renewed for the requested duration?

   c. What are estimated impacts on employment in total, in the EU and outside the EU, should the requested exemption not be renewed or be renewed for less than the re-quested time period? Please detail the main sectors in which possible impacts are expected – manufacturers of equipment in the scope of the exemption, suppliers, re-tail, users of medical devices, etc.

d. Please estimate additional costs associated should the requested exemption not be renewed, and how this is divided between various sectors (e.g. private, public, industry: manufacturers, suppliers, retailers).

5. Is there any other information you wish to provide?

In summary it can be said that lead-free galvanic oxygen sensors are an affordable option for an extended field of applications. Moreover, it is already well established and market response of OEMs in particular is high.
Their basic advantages when integrated into analysers are size, costs, less expenditure on electronics (processing units, no power supply make them superior for portable use) reasonable gas treatment and head-space.

However, former insufficiencies linked to the classical leaded fuel cells (lifetime, drift, toxic and environmentally hazard) are eliminated by the lead-free alternative. What is more, in some points the lead-free variant has caught up or even overtaken competitive oxygen sensor technologies.

Hence, with the above said we see no reason to continue the exemption currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

Please note that answers to these questions can be published in the stakeholder consultation, which is part of the evaluation of this 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.

Please do not forget to provide your contact details (Name, Organisation, e-mail and phone number) so that the project team can contact you in case there are questions concerning your contribution.

Annex 1.

Leaded versus Lead-free sensor

<table>
<tr><th colspan="2">Characteristics</th><th>LEAD-FREE</th><th>LEADED</th></tr>
<tr><td rowspan="3">4. Compatibility</td><td>mechanical</td><td colspan="2">no change,

Fig. 5: Sensor side view with typical outer housing
(white cap, white thread M16x1) and approximate dimensions.</td></tr>
<tr><td>electrical</td><td>recommended
load resistor : >1 MΩ</td><td>recommended
load resistor : >1 kΩ</td></tr>
<tr><td>chemical</td><td>weak alkaline
electrolyte</td><td>strong alkaline
electrolyte</td></tr>
<tr><td rowspan="4">Handling</td><td>operating temperature</td><td colspan="2">no change,
typically 5-45 °C</td></tr>
<tr><td>operating pressure</td><td colspan="2">no change,
typically 700-1250 hPa</td></tr>
<tr><td>operating humidity</td><td colspan="2">no change,
0-100% RH, non-condensing</td></tr>
<tr><td>storage conditions</td><td colspan="2">no change
typically 5 to 30 °C, 0-98% rH
typically shelf life about 6 months possible</td></tr>
<tr><td rowspan="2">Basic Characteristics</td><td>Initial output voltage @ air</td><td colspan="2">no change
typically 9 – 15 mV</td></tr>
<tr><td>N_2-baseline</td><td colspan="2">no change,
typically < 0.1 Vol. % O_2</td></tr>
</table>

INTERFERENCES	**anaesthetic agents**	according to DIN EN ISO 80601-2-55 *)	
	CO_2	none @ 5 % CO_2 bal. N_2	< 0.25 Vol.% @ 7 % CO_2 bal. N_2

*) Sensor meets clause 201.101 “Interfering gas and vapour effects” of ISO 80601-2-55:2018

Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

Annex 2

.: KEY FEATURES :.

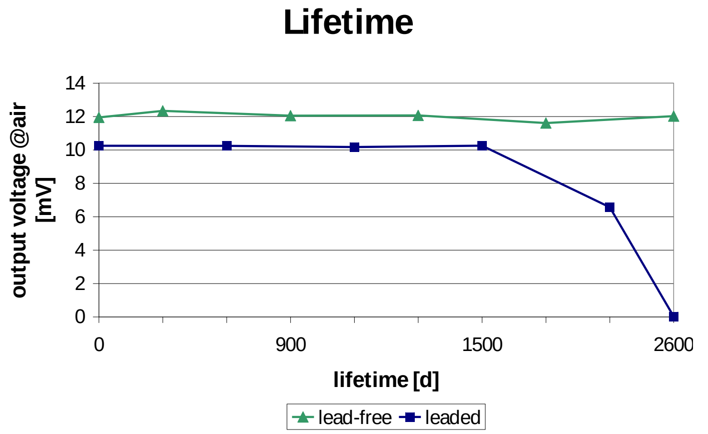

Fig. 1: Conditions According to the assumption of the anode, we set up an accelerated lifetime-test at high pressure and 100% O_2. **Conclusion** Whereas the leaded cell will find its end of life at approximately 2600 days the lead-free cell keeps on going.

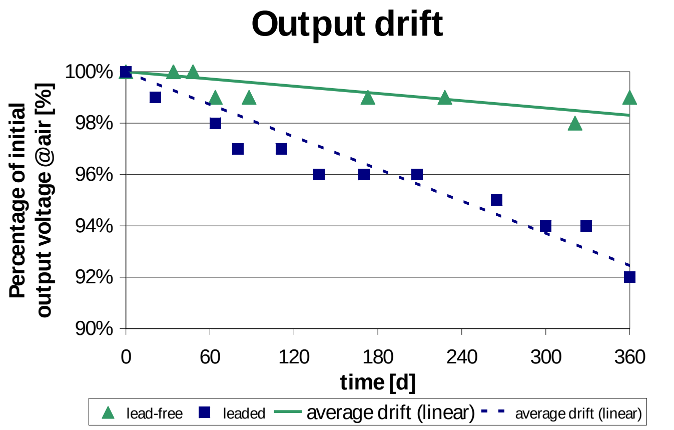

Fig. 2: Conditions Average drift within a time period of 12 month at room ambient conditions. **Conclusion** The lead-free cell is much more stable than the leaded sensor and drifts less by the factor of 4.5.

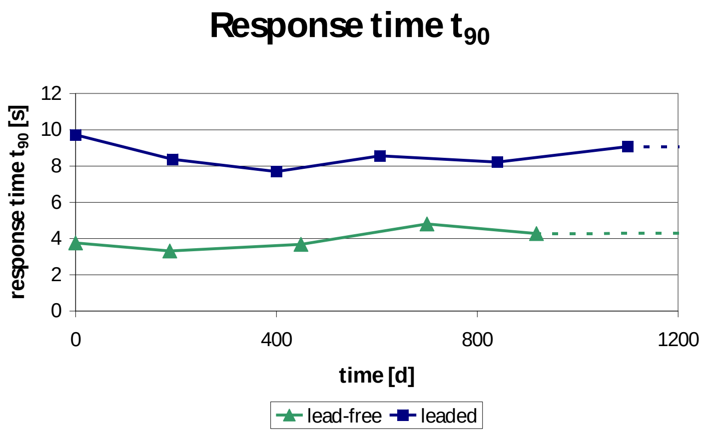

Fig. 3: Conditions Accelerated lifetime test at higher temperature and 100% O_2. Since almost 3 years the response time is constant within a +/- 1.5s interval. **Conclusion** The lead-free sensor is even faster, 2.5 times than the leaded cell.

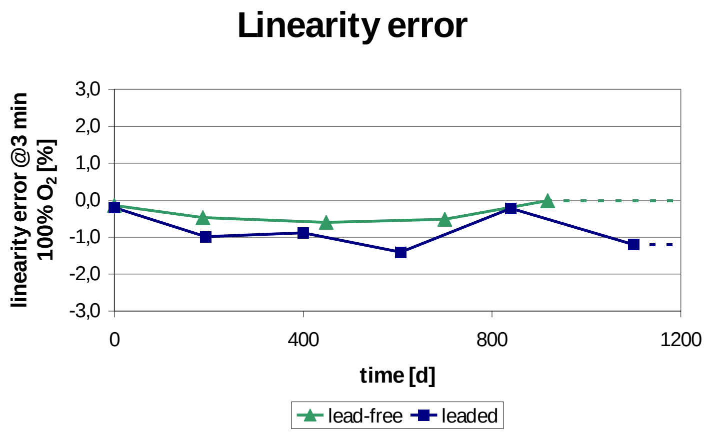

Fig. 4: Conditions Accelerated lifetime test at higher temperature and100% O_2. Since almost 3 years the linearity error is lower than –1.5%. **Conclusion** Tops off the leaded cell as its linearity error is even lower as well as smoother.

Annex 3

A key-feature comparison chart lead-free galvanic fuel cell versus competitive techniques commonly used to measure oxygen in various fields.

Sensor Techniques typical characteristics	lead-free galv. fuel cell	TDL optical sensor	paramagn. Sensor	ultra-sonic sensor
ext. power consumption required	none	yes	yes	yes
motion sensitive	none	none	yes	none
lifetime limitation in medical areas	> 6 years	> 6 years	> 6 years	> 5 years
approximate OEM costs (based on 100 units per month)	60,00 €	2.000,00 €	1.000,00 €	300,00 €
weight	20 grams	3000 grams	50 grams	500 grams
service/ maintenance required after	none	2 years	2 years	none
sample preparation/ pretreatment/ filtering required	none	yes	yes	yes
humidity affected	none	yes	yes	yes
cross-interferences to anaesthesia gases	none	minor	none	for binary gases only
MRI suitable	yes	none	none	none
warm-up time	none	2 min.	120 min.	none
accuracy (% of full scale)	0.1	0.1	< 1	1%
Sensitivity drift	less than 1% per month	+'/- 1% per year	less than or equal 1 % per week	?
Sensor positioning	independent	independent	≤ 0.05 % O2 per 1° change	independent