Consultation Questionnaire Exemption 1(a) 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

# Acronyms and Definitions

# Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[[1]](#footnote-2) 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]](#footnote-3) 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]](#footnote-4)

SUMMARY OF THE EXEMPTION REQUEST

The applicants request the renewal of the exemption2 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 COCIR2*, “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 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]](#footnote-5)

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

# 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.*

* 1. 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).
	2. If applicable, please suggest an alternative wording and duration and explain your proposal.
1. 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.
	1. Please explain substitution and elimination possibilities and for which part of the ap-plications in the scope of the requested exemption they are relevant.
	2. 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.
	3. 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.
2. 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?
3. 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:
	1. What are the volumes of EEE in the scope of the requested exemptions which are placed on the market per year?
	2. 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?
	3. 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.
	4. 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).
4. Is there any other information you wish to provide?

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.

1. It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017 [↑](#footnote-ref-2)
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> [↑](#footnote-ref-3)
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> [↑](#footnote-ref-4)
4. Directive 2011/65/EU (RoHS) available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT> [↑](#footnote-ref-5)