JBCE answer to Questionnaire 1 (Clarification)

Exemption 1b of RoHS Annex IV

29th August, 2020

As an applicant, JBCE would like to answer the questions dated on 18th August.

Please kindly find our answers in the attached.

If you have any further questions, please do not hesitate to contact to us.

We are looking forward to continued contribution during the consultation phase of evaluation.

Yours sincerely,

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ABOUT JBCE

Founded in 1999, the Japan Business Council in Europe (JBCE) is a leading European organisation representing the interests of over 85 multinational companies of Japanese parentage active in Europe.

Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, railway, textiles and glass products.

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Questionnaire 1 (Clarification) Exemption 1b of RoHS Annex IV

Wording of the Requested Exemption:

Lead anodes in electrochemical oxygen sensors

Requested validity period: *7 years*

1. Acronyms and Definitions

Pb lead

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.

JBCE submitted a request for the renewal of the above-mentioned exemption, which has been subject to a first review. As a result we have identified that there is some information 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 August 2020 latest.

3. Questions

1. Are there manufacturers of the sensors in the scope of your exemption request which are not represented by JBCE? If so, could you please let us know about such manufacturers?

   Yes. Some of us are manufacturers of the sensors and some are manufacturers of the finished products.

2. COCIR applies for the renewal of the exemption until end of 2025 because a lead-free electrochemical sensor has become available for sensing oxygen in medical respiratory care devices.

   We could not find any information what exact model of the sensor which COCIR mentions in the renewal application.

   Do you know of these sensors, and can they be an alternative for equipment of category 9 as well?

   We believe that COCIR uses the sensors for medical devices. As long as we know, the performance requirements of medical device application and the applications for monitoring and control instruments are

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

different. We assume that the sensor refereed in COCIR's application is not enough performance, especially for the following parameters which are very critical for the equipment of category 9.

- Detecting resolution in lower measurement range.
- Quicker response
- Different type of interfering gases from the medical applications.
- Durability (different operating condition from the medical applications)
- In the case of the dissolved oxygen measurement, water-proof function is required.

3. You list several alternative sensors which are used, but have also disadvantages. Does each oxygen sensor have to cover the full spectrum and all features of the pH glass electrodes, or can parts of the sensing task be excluded from the scope where alternatives are available covering these parts?

   We mentioned our best knowledge on the outlines of various electrochemical oxygen sensors in our exemption renewal application. We do not exclude alternatives available from our exemption renewal application. We do not have any other information on the applications and alternatives.

4. On page 15 of your exemption request you list the various steps for testing and qualifying alternative sensors.

   a. Could you please add the time lines to the various steps?

   We believe that the commercially available lead-free oxygen sensors at present cannot fit the performance requirements of category 9 equipment. If the sensors which can achieve our performance requirements become available, we will be able to proceed the further development applying sensors to our final products according to the table below. For the steps of the timeline, please find the table below.

	1st year				2nd				3rd				4th				5th				6th				7th			
	CQ1	CQ2	CQ3	CQ4	CQ1	CQ2	CQ3	CQ4	CQ1	CQ2	CQ3	CQ4	CQ1	CQ2	CQ3	CQ4	CQ1	CQ2	CQ3	CQ4	CQ1	CQ2	CQ3	CQ4	CQ1	CQ2	CQ3	CQ4
1.Initial feasiblity evaluation (sensor performance)																												
Sensitivity, response time, accuracy, measurement range (low concentration)																												
Adjusting temperature compensation																												
Lifetime, shelf life evaluation																												
Influence of interfering gases in oxygen																												
2.Evaluation of reliability, durability, transportation, evaluation by end users																												
3.Establishment of production lines and evaluation for production.																												
4 Specific approvals																												

   b. Can some of the required tests not be done in parallel, e.g. influence of other gases than oxygen and reliability testing, etc.?

   Please see the answer No. 4.a.

5. We are not quite sure whether and where your exemption request might contain proprietary information. To avoid accidental publication of confidential information, we ask you to kindly provide a version of your renewal request which can be published.

   We do not have any proprietary information in our exemption renewal application.

Please note that answers to these questions will be published as 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.