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

Wording of the Requested Exemption:

Lead anodes in electrochemical oxygen sensors

Requested validity period: *31 December 2025 (and 7 years for replacement sensors)*

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.

COCIR 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. Could the exemption scope be specified with the following exemption wording?

   Lead anodes in electrochemical sensors that measure oxygen concentrations of inhaled and exhaled air for patients in respiratory care products.

   For COCIR applications the exemption wording would cover the required applications. However, we believe that these sensors are also used in category 9 applications, but these are not included in the COCIR renewal request.

2. We think the addition of the 7 years validity for replacement sensors is not required. In our opinion, the replacement sensors can be understood as consumables to which the RoHS Directive applies like for example for printer cartridges.[2] Alternatively, they could also be classified as spare parts. In this case, following the logic of the other exemptions, the replacement sensors can used without time limitation in products that were placed on the market prior to the exemption expiry.

   Would you agree to this approach?

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

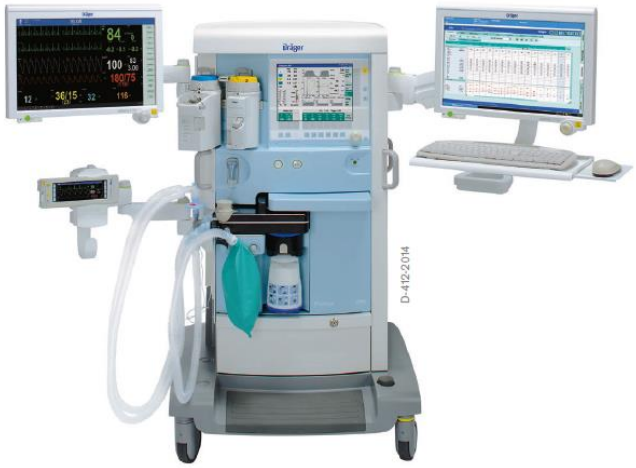
[2] C.f. https://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf, page 21

It is COCIR's interpretation that the sensors are consumable and therefore in the scope of RoHS. The RoHS substance restrictions are not excluded by RoHS Article 4.4 because the replacement sensors are not used for the '*repair, the reuse, the updating of functionalities or upgrading of capacity*', so do not meet the requirements of this exclusion.

If the EC is willing to clarify this topic and support the interpretation officially, we would be happy to support it as well.

3. Could you provide us with an outline of devices containing the oxygen sensors in the scope of this exemption request?

A commonly used example of a use of these sensors is as an integral part of anaesthesia equipment used in hospital operating theatres to ensure that the patient is breathing correctly. An example of these is:



These machines control the flow of anaesthetic to patients who are undergoing surgery and measure the oxygen and other gas concentrations in gas inhaled and exhaled by the patient.

These sensors are also used in intensive care ventilators and ventilators used for other locations such as in ambulances, hospitals wards, etc. Ventilators aid monitor breathing and monitor the oxygen concentration in inhaled and exhaled breath. In some models the sensor is located in the inspiratory gas pathway. An example ventilator is shown below:

4. You state in your exemption application that the sensors are treated to recycle the materials.

    a. Aren't they (potentially) infectious waste and must therefore be safely treated, e.g. in incinerators?

    Some manufacturers operate a full take-back solution for WEEE and as such collect the used sensors. Some models of sensor operate on the inspiratory side of the breathing systems and therefore are not in contact with expiratory breathing air from the patient, however as air is filtered, contamination is very unlikely to occur and so they can be safely recycled. Customers are also asked to confirm proper disinfection of medical equipment prior to return so manufacturers are willing to take back and recycle.

    b. Which materials are recycled from the sensors? The lead is mostly dissolved, so may be costly to be recycled.

    Lead is present in used sensors as a mixture of lead metal and lead oxide. This is treated with other electrical equipment waste for metals recovery, which includes the recovery of lead and platinum (and some also gold) contained within the sensors. The most commonly used recycling process for electrical equipment waste is smelting which is where the material is heated to a high temperature under reducing conditions when any lead oxide will be reduced to lead metal. The process that is used varies but details of one large European recycler's process are available from https://www.researchgate.net/publication/284043293_Recycling_of_Electronic_Scrap_at_Umicore_Precious_Metals_Refining

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.