Questionnaire 1 (Clarification) Exemption 1 of RoHS Annex IV

Wording of the Requested Exemption:

Lead in solders for bonding to ultrasonic transducers

Requested validity period: *7 years*

1. Acronyms and Definitions

Pb	lead
PIN-PMN-PT	lead indium niobate - lead magnesium niobate – lead titanate
PMN-PT	lead magnesium niobate - lead titanate
US	ultrasonic

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 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 29 August 2020 latest.

3. Questions

1. Overall, it seems that avoiding lead in bonding to US transducers is scientifically and technically feasible, despite of the technical challenges you describe, even though a redesign of (parts of the) devices is necessary.

    a. Is this correct?

    The design of US transducers without lead solder is scientifically and technically feasible only when the initial design of the equipment considers lead free solder as a design consideration. Backwards compatibility of the alternative solutions is not possible with designs which originally used lead solder.

    b. If not, please explain in which cases it is not correct, i.e. where lead-free solutions are scientifically and technically not feasible despite of new designs.

    Redesign of older ultrasound imaging equipment that uses lead solders is not feasible, whereas design of new replacement products is a very lengthy process and so without this exemption, these designs could

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

no longer be placed on the EU market. As explained in our exemption renewal request, this would have a negative impact on the health of patients in the EU.

2. If situation 1.a) above applies, could the exemption scope be restricted to older designs and exclude new designs similar to the approach and the recommendation for exemption 27-IV, c.f. Gensch et al. (2020 c)?

This would be acceptable.

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.

4. References

Gensch et al. (2020 c): Study to assess seven (7) exemption requests relating to Annex III and IV to Directive 2011/65/EU: request for renewal of exemptions 6(a), 6(b), 6(c), 7(a) and 7(c)-I of Annex III; request for renewal of exemption 27 of Annex IV; and request for a new exemption for lead in bismuth lead strontium calcium copper oxide superconductor cables and wire and lead in electrical connections to these wires to be added to Annex IV (Pack 18) – Final Report. 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. Carl-Otto Gensch, Yifaat Baron, Moch, Katja, Öko-Institut e. V. und Dr. Deubzer, Otmar, Fraunhofer IZM, https://circabc.europa.eu/sd/a/9eaaeae6-6dd2-4ab1-9715-d3a4a69fed1b/RoHS_Pack18_final.pdf.