Questionnaire 2 COCIR Exemption 15 of RoHS Annex IV

Lead in solders for bonding to ultrasonic transducers

Acronyms and Definitions

1. 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.

You submitted information to substantiate your request for the renewal of the above-mentioned exemption. This information was reviewed and as a result, we ask you to kindly answer the below questions for further clarification of your request until 30 August 2021.

2. Questions

1) We understand from your answers to the clarification questionnaire that substitution of lead is scientifically and technically practicable after a redesign of US-transducers accommodating the specific properties of lead-free solders. You state that the time required on the one hand, and the staff and time available on the other hand have not yet allowed to convert all medical devices using US transducers to new design lead-free models. You point out the technical problems related to the conversion, which makes it reasonable in our opinion to assume that simpler models were easier to convert and would have been the first option to start with than more complex ones.

   This is not exact. The choice to redesign models depends on the market needs of clients and it always driven by the need to maintain a differentiated portfolio of products always abe to meet the need of any client. The manufacturer can decide to design a new product as the technological advancements can make it possible to have a better one to substitute the older ones for the same market niche or the manufacturer can decide to redesign an older model, adding some improvement anyway, as there has not been any advancement to justify releasing a new model for such clinical indications. Other older models could have not been redesigned as their useful market life was almost at the end and new models could be used as replacements.

   The lack of staff does not mean that redesign started for all models in parallel and that the simpler ones could be finished in a shorter time. It means that the manufacturer selected a few models based on the consideration reported above and assigned engineering teams to the redesign, while other teams were assigned to the design of new models. As we explained in other exemptions, the design of new models that have better clinical performances must have the priority for the interest of patients and healthcare.

   Could you please technically classify the remaining older design models still depending on exemption 15?

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

As said above, considering industry as a whole, even if it could be possible to define categories, we would have the situation that in each category there would be

- older designes that are still under redesign and others that are now lead free
- others that have not been redesigned and will be discontinued
- new lead free designs

Please note that unlike other products in RoHS, medical devices are not interchangeable. While any mobile phone, from the cheap single core, small screen one to the 8 cores bigger-than-your-pockets one could be used for the same functions, medical devices in a manufacturer portfolio are designed for specific clinical applications and procedures.

2) To avoid misunderstandings and potential gaps in the exemption scope:

   a) Ex. 15 is not required in in-vitro diagnostic medical devices. Is this correct?

We enquired with MTE and it seems exemtpion 15 is not used in IVD applications.

   b) Ex. 15 is only required in industrial monitoring and control instruments. Is this correct? If so, could you please give us examples of such equipment?

COCIR cannot answer this question

3) Most of the justifications provided in the renewal request seem to refer to cat. 8. We are not sure whether the socioeconomic situation described for question 1) above (substitution or elimination of lead are in principle scientifically and technically practicable, but would have required more staff capacity than what you stated to have available to redesign all models of EEE in time) applies to cat. 9 EEE as well.

   a) What is the specific situation in terms of models to be converted, time required, staff capacities, etc. for producers of cat. 9 EEE? Please give reasons that substantiate the claim that despite scientific and technical practicability lead could not yet be substituted or eliminated.

COCIR cannot answer this question

   b) Should the socioeconomic situation not be the root cause of the still enduring need of ex. 15, please explain the other reasons.

COCIR cannot answer this question

Please note that answers to these questions may be published as part of the review 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.

It would be help the review process if you could kindly provide the information in formats that allow copying text, figures and tables to be included into the review report.