Questionnaire 3 Exemption 14 of RoHS Annex IV

Lead in single crystal piezoelectric materials for ultrasonic transducers

Acronyms and Definitions

US ultrasonic

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 201ylj1/65/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 11 May 2021 latest.

2. Questions

1) We checked for ultrasonic devices using the cMUT technology and found the below ones[2].
   a) Medical imaging with CMUT by Butterfly Network: Butterfly Network | Point of care ultrasound solutions
   b) Medical imaging with CMUT by Hitachi: 4G CMUT (hitachi-medical-systems.de)
   c) Medical imaging with PMUT: Exo | Medical Imaging and Technology
   d) CMUT-probes by Verasonics: GE Transducers for Vantage Systems – Verasonics

   In our understanding, the above cMUT-based products cover a broader range of US medical imaging applications for which - and possibly also others - the elimination of lead could be scientifically and technically practicable.

   Please let us know whether you agree or disagree and explain your position.

   The differences of cMUT technology in comparison to lead use in single crystals is discussed in the exemption application request in Section 6(A). Although, it can be seen that applications are developing which utilize the benefits of cMUT technologies, such as wide clinical coverage, many applications cannot be served by these alternatives, such as, because the image quality is inferior. For some applications lower image quality may be acceptable, but for most applications this is not.

   Lifetime is also a significant factor and CMUT technology is still far from reaching an acceptable level.

[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] Further information was found about Philips CMUT (Philips external company presentation 16x9 (position-2.eu)) and an EU project (http://position-2.eu/)

As discussed in the exemption request, there are technical difference between the two technologies. Recent information we received highlights additional elements. To obtain a large acoustic pressure, a large vibration (amplitude) is required- especially for lower frequencies- which in turn requires a large drive voltage. A drive voltage for CMUT for higher frequencies would need to be in the range of 10V, and 1000V for lower frequencies, to be comparable to a single crystal element. From this is can be seen that there are applications still where single crystal elements are unable to be replaced, due to challenges such as safety, due to insulation performance with high voltages, as well as performance requirements.

Due to such limitations, researchers have focused their investigations on applications that play to the strengths of cMUTs namely ability to produce small feature sizes and wide bandwidths. These applications include catheters, endoscopic probes, high frequency linear arrays and probes with wide clinical coverage. Transducers for these applications cannot be fabricated easily using PZT technology and therefore the reduced acoustic output associated with cMUTs can be accepted. Single use catheter devices can accept limited lifetimes.

The technology will keep evolving and more and more applications will make use of CMUT technology in the future. Due to the current limitations of cMUT technology, lead base sensor technology is necessary to achieve the adequate clinical performance in core modes.

We also like to underline that RoHS requires that the alternatives do not involve a negative impact on environment and health (that outweighs the use of the substance). 12 grams of lead are used in EU per year for exemption 14. Extending the use of CMUT technology to applications where it is not actually used, would probably save some fraction of a gram per year. We cannot quantify the impact on health stemming from reduced performances of critical medical devices, but this impact has to be weighted against the environmental benefits stemming from the substitution of milligrams (if not less) of lead.

Please note that answers to these questions may 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.

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