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Statement on the extension of RoHS exemption 14 (Annex IV): EU Commission Questions

Relevant Exemption		Type of request	Applicant(s)
Annex IV n. 14	Lead in single crystal piezoelectric materials for ultrasonic transducers	Revocation	Butterfly Network, Inc.

Dear Sir or Madame,

In Response to the requested revocation of the exemption for “Lead in single crystal piezoelectric materials for ultrasonic transducers” by Butterfly Network, Inc. I answered the questions to the best of my knowledge. Please feel free to contact me, should you require further information on this subject.

1. Do you agree with the arguments put forward by the applicant? Are there any additional reasons that support the requested revocation of the exemption?

I partially agree with the arguments. Butterfly devices are capable of organ imaging in most point-of-care ultrasound (POCUS) scenarios. However, there is a lack of peer-reviewed studies demonstrating the diagnostic reliability of these devices. Available literature suggests inferior image quality of Butterfly devices compared to other handheld ultrasound systems. It remains unclear whether this inferiority has clinical relevance. We conducted three studies, in which Butterfly was rated among the devices with inferior image quality (Herzog et al., 2024; Kampfrath et al., 2024; Merkel et al., 2024). A general response to whether cMUTs are capable of replacing single crystal materials remains open until more suppliers with more scientific data are available.

2. In your opinion, what reasons oppose the requested revocation of the exemption?

a) Butterfly uses handheld ultrasound as a use case. Up to date, this is a relatively new field of Ultrasound with undefined borders. Devices might be totally portable, like the Vscan from GE, require a wired connection, like the Butterfly, or have a small screen, like the Venue Go from GE. All these devices might be considered 'portable' or even 'handheld'. However, without an official definition of the term, revoking the exemption seems imprecise.

b) As one of two providers of MEMS based transducers, Butterfly would gain a significant market advantage, increasing dependence on this non-EU company. The risk of this dependency should be considered carefully.

3. How do you rate cMUT technology in terms of image quality and reliability? What technical parameters are used to evaluate diagnostic procedures? Based on your experience, how would you rate conventional technology based on lead in single crystal piezoelectric materials for ultrasonic transducers compared to cMUT technology?

See point 1 and sources (Herzog et al., 2024; Kampfrath et al., 2024; Merkel et al., 2024). There is no established objective parameter to determine image quality, and it is debatable whether resolution is the most important metric (Herzog et al., 2024). From my own experience, I would rate the image quality of the butterfly devices as clearly inferior to the images of single crystal based transducers. Since Butterfly is the only company currently offering cMUT-based handheld ultrasound devices, generalization is difficult.

4. How do you assess the potential negative effects of substitution on occupational health and consumer safety, reliability of the cMUT technology? How do you assess the overall benefits of cMUT technology for the environment, health and consumer safety?

A forced and rapid substitution could increase the risk to patient safety. The physicians are currently trained on transducers containing single-crystal transducers. Replacing them with Butterfly probes may increase the risk of misdiagnosis.
Usually, the ultrasound transducers are safely encapsulated, providing no risk due to Pb to the patient. Nevertheless, they do have a negative impact on the environment and contradict the ROHS-guideline. cMUTs may be lead-free, but it is questionable whether semiconductor manufacturing processes are more environmentally friendly than those used for single crystal transducers.

5. Are there any other aspects that you believe should be considered when assessing this application? Please provide relevant documents and evidence.

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6. What are the limitations of cMUT technology? Which applications cannot be replaced by cMUT technology but are possible with other handheld ultrasonic transducers or vice versa?

cMUTs suffer from a limited maximum output pressure and strong non-linearities. These limitations restrict their use in advanced signal architectures, such as pulse compression or coded excitation, which are currently being translated into clinical applications.

7. How do you assess the EU's dependency on other countries in this sector? Would a revocation of the exemption increase the EU's dependency? If so, why?

A revocation may not increase dependency at the cMUT technology level, but given that Butterfly is currently the only provider of cMUT-based handheld devices, the EU would become fully dependent on a single non-EU company.

Conclusion:
Reconsidering the exemption 14 is recommended once definitions of “handheld ultrasound” are made and other suppliers of cMUT based handhelds are available. Until then, research on quality metrics to assess ultrasound devices is recommended to objectively assess new devices.

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