Consultation Questionnaire Exemption Annex IV n. 14

Exemption for "Lead in single crystal piezoelectric materials for ultrasonic transducers"

Abbreviations and Definitions

RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
EEE	Electrical and Electronic Equipment
Butterfly	Butterfly Network, Inc.
Pb	Lead

Background

The Oeko-Institut has been appointed by the European Commission, within a framework contract[1], for the evaluation of applications for exemption from Directive 2011/65/EU (RoHS), to be listed in Annexes III and IV of the Directive.

Butterfly submitted a request for the revocation of the above-mentioned exemption, which has been subject to an initial evaluation. A summary of the main argumentation for justifying the request is provided below. Additional information supporting this request can be found on the request webpage of the stakeholder consultation (https://rohs.exemptions.oeko.info/exemption-consultations/2025-consultation-1).

For further details, please check the exemption request and additional information submitted by the applicant on the request webpage of the stakeholder consultation.

The objective of this consultation and the review process is to collect and to evaluate information and evidence according to the criteria listed in Art. 5 (1) (a) of Directive 2011/65/EU (RoHS 2), which can be found under:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT

If you would like to contribute to the stakeholder consultation, please review the summary of the argumentation provided and answer the questions that follow.

[1] The contract is implemented through Framework Contract No. ENV.B.3/FRA/2019/0017, led by Ramboll Deutschland GmbH.

1 Summary of argumentation of applicant on the revocation of the exemption

This exemption covers transducers used in medical ultrasound imaging. Medical ultrasound imaging is used to produce images of the interior of the human body. It is also used in minor surgery, for example to guide hypodermic needles to the required sites.

Butterfly is seeking an amendment to exemption 14 in Annex IV to exclude hand-held medical ultrasound devices from the existing exemption. Butterfly justifies its request for revocation as follows: Since 2018, alternative technologies, mainly capacitive micromechanical ultrasonic transducers (cMUT technology), have significantly advanced in ultrasonic transducers as a replacement for piezoelectric crystals. CMUT technology has become a scientifically and technically viable, reliable and effective alternative to lead-containing piezoelectric crystals in portable ultrasound devices. CMUT technology enables comparable durability and equivalent, if not higher, image quality, while also significantly improving the overall user-friendliness of portable ultrasound devices. Devices based on cMUT technology have proven to be resilient, robust and reliable in practice, even under difficult conditions, and are also used in large enterprise-wide healthcare facilities.

2 Questions

- Do you agree with the arguments put forward by the applicant? Are there any additional reasons that support the requested revocation of the exemption?
- In your opinion, what reasons oppose the requested revocation of the exemption?
- 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?
- 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?
- Are there any other aspects that you believe should be taken into account when assessing this application? Please provide relevant documents and evidence.
- 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?
- 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?

Responses submitted electronically will be posted on the RoHS Exemption Website site as they are received unless respondents specifically request that their contribution should not be published. In the latter case, responses should be clearly and visibly marked with the words "Not for publication".