Stakeholder Consultation – Request for revocation: Lead in single crystal piezoelectric materials for ultrasonic transducers - Exemption 14, Annex IV

Date: August 1, 2025
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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?

Yes, I generally agree with the arguments presented by the applicant. CMUT technology has reached a level of maturity that makes it a viable alternative to lead-based piezoelectric transducers in handheld ultrasound devices. A key point in support of the revocation is the compatibility of CMUT technology with standard microelectronic processes, such as CMOS, which enables highly integrated and power-efficient ultrasound systems. This feature is especially relevant for handheld applications, where system miniaturization, cost-effectiveness, and power consumption are critical. Integration leads to robust and scalable mass production, further strengthening the sustainability and reliability of CMUT-based systems.

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

While CMUT technology shows significant potential, current limitations remain when comparing with high-end lead-based single crystal transducers, especially in certain application scenarios. CMUTs and PMUTs, in their current industrially-manufacturable implementations, still show lower electromechanical coupling compared to traditional lead based piezoelectric transducers, impacting system efficiency and noise performance. Moreover, linearity in CMUTs is lower than traditional lead based piezoelectric transducers, which negatively affects harmonic imaging, the current gold standard in abdominal, cardiac, and other ultrasound imaging applications. While methods exist to correct nonlinearity (e.g., waveform precompensation), they introduce additional system complexity and power consumption, which may be critical in battery-operated devices. PMUTs are emerging but many of the best performing PMUTs still use lead-based piezoelectrics, which must also be considered in the scope of this discussion if substitution is the goal. Therefore, while CMUTs are suitable for many handheld use cases, some limitations must be acknowledged in terms of overall imaging depth and nonlinear imaging capability.

3. How do you rate CMUT technology in terms of image quality and reliability? What technical parameters are used to evaluate diagnostic procedures?

Image quality in diagnostic ultrasound is assessed using parameters such as axial and lateral resolution, penetration depth, and contrast, which are related to transducer figure of merit such as bandwidth, linearity/harmonic distortion, acoustic pressure output, and signal-to-noise ratio (SNR). CMUTs provide excellent bandwidth, which enables multi-frequency and multi-mode imaging (e.g., whole-body scanning with a single probe) that is a key advantage for handheld platforms. However, for low-to-mid frequency imaging (1–5 MHz), such as in abdominal and cardiac applications, the higher nonlinear distortion of CMUTs compared to traditional lead based piezoelectric transducers may be actively addressed with electronic compensation, but remains a consideration. In terms of reliability, current industrialized CMUT devices have demonstrated satisfactory durability in real-world settings, which confirms their robustness and clinical usability in handheld contexts.

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?

CMUT technology poses no known risks to patient or operator safety and is inherently lead-free, eliminating environmental concerns associated with lead disposal. Furthermore, the possibility to reduce system cost through integration could increase the accessibility of ultrasound imaging in low-resource settings. This is a significant public health benefit.

5. Are there any other aspects that you believe should be taken into account when assessing this application?

Although CMUT technology has reached commercialization and approval in several markets, the field is still evolving rapidly. Significant performance improvements are likely within the next 4 years, driven by both academic and industrial R&D. This ongoing innovation must be considered when assessing the feasibility of long-term substitution. Moreover, PMUTs are also emerging as relevant alternatives, particularly in low-frequency handheld and wearable ultrasound applications. However, many rely on thin-film lead-based piezoelectrics. Their regulatory classification should be clarified in relation to this exemption.

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?

There are no ultrasound applications that CMUT technology is intrinsically unable to address. However, certain applications requiring very high penetration depth, and high acoustic output pressure or linearity (e.g., harmonic imaging, contrast imaging) are more challenging with CMUTs, especially in current implementations optimized for general-purpose handheld use. These limitations could restrict CMUT applicability in certain high-end or specialized diagnostic tasks without appropriate electronic compensation.

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?

The semiconductor and MEMS technologies required to fabricate CMUTs and associated electronics are well established within the EU, both at academic and industrial level. EU-based foundries and packaging facilities can support the production of CMUT transducers. Therefore, a revocation of the exemption would not increase EU dependency on external supply chains for ultrasound probe technology.