

31th July 2025

**JBCE's answer to the Consultation Questionnaire Exemption Annex IV n.14
Exemption for "Lead in single crystal piezoelectric materials for ultrasonic
transducers"**

JBCE welcome to comment about the Pack 28 consultation. We would like to feedback about the revocation of exemption under n. 14 (Lead in single crystal piezoelectric) of AnnexIV.

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

Answers to the Questions

Disagree

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

Answers to the Questions

CMUT technology has a short history compared to the conventionally used piezoelectric crystal technology, and we believe it is too early to replace it.

- 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?

Answers to the Questions:

CMUT technology is promising, but it has yet to fully match the performance of high-performance piezoelectric single crystals in certain advanced medical applications that require the highest resolution and sensitivity, such as detailed cardiac diagnostics and intravascular ultrasound (IVUS). There is also still insufficient data on performance and long-term reliability. The technical parameters to evaluate diagnostic methods are generally sensitivity, bandwidth, and quality of diagnostic images. Piezoelectric single crystals (PMN-PT, PIN-PMN-PT, etc.) boast extremely high piezoelectric properties and conversion efficiency, providing high-resolution, high-sensitivity images. In particular, in areas where advanced diagnosis is required, their performance remains the gold standard, and they have a high level of reliability backed by many years of proven use.

- 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?

Answers to the Questions:

Since cMUT technology does not use lead, it is believed that the risk of occupational exposure to lead can be avoided. However, images may be generated by applying high DC voltages, and in such cases, the high voltage may affect consumers if the CMUT device is damaged. Compared to piezoelectric single crystals, there is still insufficient data on long-term reliability.

CMUT technology has both advantages and disadvantages compared to piezoelectric single crystals, and continuing the exemption until alternative technologies can be objectively proven to be equivalent or better in terms of performance, reliability, and cost for all medical needs is an essential measure for a smooth technology transition.

- Are there any other aspects that you believe should be taken into account when assessing this application? Please provide relevant documents and evidence.

Answers to the Questions:

Number of manufacturers capable of commercially producing handheld medical ultrasound devices equivalent to the cMUT ones produced by Butterfly Network, Inc.?

After searching the websites, it appears that there are still very few, if any.

- 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?

Answers to the Questions:

CMUTs may require high bias voltages to operate. Compared to piezoelectric transducers, they may have lower sensitivity, making it difficult to detect weak signals. CMUTs are manufactured using MEMS technology, which can be a complex and expensive manufacturing process.

In certain advanced medical fields that require the highest resolution and sensitivity, such as detailed cardiac diagnosis and intravascular ultrasound (IVUS), as well as high-resolution non-destructive testing, it seems unlikely that high-performance piezoelectric single crystal devices will be able to replace them.

Conversely, applications that can be enabled by cMUT technology but are difficult to achieve with other handheld ultrasonic transducers include ultra-broadband ultrasound imaging and microscale imaging for cellular-level observation.

- 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?

Answers to the Questions:

Handheld medical ultrasound devices are manufactured globally, and the EU is likely to be comparatively dependent on other countries. Since Butterfly Network Inc. is a US company, the revocation of the exemption will likely increase the EU's dependency on other countries.

About JBCE

Created in 1999, the Japan Business Council in Europe (JBCE) is a leading European organisation representing the interests of more than 115 multinational companies of Japanese parentage active in Europe. Our members operate across a wide range of

sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, steel, textiles and glass products. Building a new era of cooperation between the European Union (EU) and Japan is the core of our activities, which we perform under several committees focusing on: Corporate Policy, Corporate Social Responsibility, Digital Innovation, Environment & Energy, Standards and Conformity, and Trade.

JBCE - Japan Business Council in Europe

EU Transparency Register: 68368571120-55

Contact: info@jbce.org, odani@jbce.org