COCIR ANALYSIS OF BUTTERFLY NETWORK REVOCATION REQUEST

COCIR has look at the document submitted by Butterfly Network to request a revocation of exemption 14. This document is intended to analyse the request and highlight the claims that are not supported by any evidence or are outright misleading, while a detailed dossier presenting evidence about the comparison of performances between the 2 technologies has been submitted at the same time to the consultant (Oeko).

COCIR would like to note that the "Standard application format and guidance document for RoHS exemption requests on the basis of Article 5(8) Directive 2011/65/EU" document published on the EC website[1] states:

According to the Directive, article 5.1.b, exemptions may also be deleted from the Annexes if the conditions established through applicable criteria are no longer fulfilled. A request for deletion would then ***argue that the various criteria are no longer met.***

As for requesting an exemption or a renewal a minimum of evidence should be provided. According to the same EC guidance, any request should be accompanied by :

- *Test results on the suitability of substitutes and any other technical / scientific documentation supporting your request – If possible and available this documentation should be third party certified.*
- *Third party verified documentation such as life cycle assessment according to ISO 14040, ISO 14044, PCF, CBA etc.*
- *Roadmaps for the further technical development of RoHS 2 compliant substitute applications.*
- *REACH-relevant documentation such as registration, application for authorization etc.*
- *Documentation from suppliers on the availability or non-availability of substitutes*
- *Socio-economic data in as much detail as possible (see application form in Appendix 1 for the necessary categories and level of detail) and if possible and available, with third party certification.*

COCIR has been surprised that the documentation submitted by **Butterfly does not include any evidence other than claims,** most of which goes against what is normally known and accepted about cMUT performances and limitations. No study is linked, no evidence provided, no "*Test results on the suitability of substitutes and any other technical / scientific documentation supporting your request"*.

[1] https://environment.ec.europa.eu/document/download/f1f65e3d-1b90-4dd1-a0d4-797bd6cabe98_en?filename=Guidance_Document.pdf

In the past, similar requests for exemptions or renewals have been discarded due to the lack of any evidence supporting the claims.
Here below COCIR highlights a few of such statements, including ones that are considered highly misleading and factually incorrect.

Text submitted by Butterfly	Comments
Summary of the exemption request / revocation request	
Summary of the exemption request / revocation request Butterfly is kindly requesting the European Commission to set in process and adopt a Decision to amend Exemption 14 of Annex IV of the RoHS Directive by excluding handheld medical ultrasound devices. The current wording of the Exemption 14 Annex IV presumes the use of lead in single crystal piezoelectric materials for ultrasound transducers in all medical ultrasound devices. However, since 2018, alternative technologies, mainly capacitive micromachined ultrasound transducers (cMUT) technology in ultrasound transducers as a substitute to piezoelectric crystals, have evolved significantly. cMUT technology has become a scientifically and technically practical, reliable and effective alternative to lead piezoelectric crystals in handheld ultrasound devices.	Per the EC Guidance, in order to justify the claim that cMUT can replace other technologies, Butterfly must demonstrate, through rigorous and comprehensive evidence, that the cMUT technology performs comparably or better across the full spectrum of intended clinical indications and patient contexts
Thus there is an opportunity to reduce the risk of environmental and consumer exposure to lead which would continue were the exemption to be prolonged as currently worded.	Previous consultations on Annex IV n. 14 have estimated the amount of lead that is placed into the EU market. The revocation request fails to quantify the risk to the environment and consumers versus the benefit to society as analysed by the consultant. If Butterfly has evidence of such risks, such evidence should be presented.
cMUT technology enables comparable durability and equivalent, if not higher imaging quality, in addition to considerably enhancing overall usability of handheld ultrasound devices.	Claiming that cMUT enables higher image quality is a statement contrary to what is commonly known and would require substantial evidence to be proven. Image quality is a very complex concept that depends of several factors including the type of procedure. In addition usability is another vague concept that would need evidence to be supported. COCIR presents in the accompanying dossier an independent study that, even if limited, proves otherwise.

Text submitted by Butterfly	Comments
cMUT technology does not require lead piezoelectric crystals used by traditional handheld ultrasound devices. For example, Butterfly's devices based on cMUT technology have been deployed in war zones such as Ukraine, affirming the resilience, robustness and dependability of our probes under challenging conditions.	Irrelevant.
Additionally, Butterfly's devices have also been deployed in large enterprise-wide healthcare facilities, demonstrating the versatility of handheld ultrasound devices utilizing cMUT technology.	This seems to imply that such healthcare facilities do not have any other PZT/SC based ultrasound and rely only on Butterfly solutions. COCIR does not question the role of cMUT in healthcare environment in certain applications, rather whether it can replace PZT based technology in all applications and indications.
cMUT technology also enables the "one probe" concept, wherein one device can scan the entire body without the use of multiple probes and/or heads, which are a requirement for piezoelectric crystal devices due to technical limitations. In this sense, handheld ultrasound devices using piezoelectric crystals not only can cost significantly more (with resulting implications for public healthcare budgets), but also often require the end user to purchase multiple attachments and/or probes to perform different scans.	Probes and heads exist for very good reasons and are specifically required by several clinical guidance (see COCIR dossier). On the other end cMUT curved arrays cannot be manufactured so the "one probe" is a necessity even when different probes may provide better diagnostic capabilities.
Overall, using the cMUT technology instead of lead piezoelectric crystals is completely feasible in handheld ultrasound devices while also reducing the environmental impact of these devices.	This statement should be supported by rigorous and comprehensive evidence, that the cMUT technology performs comparably or better across the full spectrum of intended clinical indications and patient contexts.
4.c)	
Notwithstanding the fact that lead piezoelectric crystals, contrary to what is implied in the question, is no longer needed or required in handheld medical ultrasound devices, Butterfly would state the following: The lead piezoelectric crystals are commonly used in traditional ultrasound devices to enable medical imaging functionality. However, since 2018, there are scientifically and technically practical as well as effective alternatives to lead piezoelectric crystals in handheld devices – mainly capacitive micromachined ultrasound transducers (cMUT) technology. Butterfly in particular, replaces traditional piezoelectric crystal-based transducers with a single	This entire section is not supported by any evidence, even less rigorous and comprehensive one, that the cMUT technology performs comparably or better across the full spectrum of intended clinical indications and patient contexts.

Text submitted by Butterfly	Comments
silicon chip, or cMUT technology. This chip contains a 2D array of 9000 capacitive micromachined ultrasound transducers (cMUTs). Unlike traditional piezoelectric crystals that are tuned to oscillate at defined frequencies, cMUTs have a much wider bandwidth when applied to biological tissues. This means they can be programmed to emit and detect many different frequencies. The result is a single probe with one head capable of whole-body imaging.	
5.a)	
The currently perceived "gap" between handheld semiconductor-based ultrasound systems and traditional handheld lead-based piezoelectric-based systems, used to justify the RoHS exemption permitting usage of lead-based piezoelectric crystals in ultrasound transducers is according to our experiences nonexistent. Butterfly's semiconductor-based Products offer at least comparable, if not superior capabilities in some instances, to its handheld piezoelectric counterparts.	If cMUT would offer at least comparable if not better capabilities, cMUT would be the preferred choice of the market. The "experience" of Butterfly is not relevant, unless Butterfly can provide some evidence supporting its claims.
cMUT's innovation trajectory is backed by Moore's Law – a guiding principal of the semiconductor industry first observed in 1965 by Intel co-founder, Gordon Moore. Moore's Law states that the number of transistors on an integrated circuit will double every two years – meaning the computer processing power of a chip doubles every two years with minimal rise in cost. The observation still holds true today, supporting Butterfly's commitment to pushing the boundaries of technological advancements in the field of ultrasound. As our chip processing power doubles, our technology becomes greater, among other benefits.	This statement is highly misleading. Moore's Law refers specifically to the doubling of the number of transistors on a silicon chip approximately every two years, which increases computing power per unit cost. It applies to digital logic and semiconductor fabrication scaling, not to analog sensors or physical signal transmission devices like cMUTs. You can't "Moore's Law" your way into better acoustic penetration or Doppler imaging. Improvements in cMUT performance (depth penetration, sensitivity, harmonic response) are bound by acoustic physics, not transistor scaling. For example: • No amount of digital processing will change the acoustic output power of a cMUT membrane. • You can't double ultrasound penetration every two years just because you fabbed your transducer on a smaller node. • Doppler sensitivity and harmonic imaging capabilities depend on

Text submitted by Butterfly	Comments
	physical transducer design, not chip logic.
6.b)	
The entire 6b section is irrelevant for the assessment of cMUT vs SC technology.	
8.b3)	
In comparison with traditional piezoelectric based crystals, which are tuned to oscillate at defined frequencies, CMUTs have a much wider bandwidth when they are applied to biological tissues and, therefore, a single transducer can be programmed to emit and detect many different frequencies. The broadband response of CMUTs allows output of a very short ultrasound pulse, enabling imaging with a high axial resolution and increased clinical utility	This statement is highly misleading, mixing different concepts and not providing any evidence to support such claims. cMUTs *can* offer broader bandwidth compared to some traditional piezoelectric transducers, which in principle can allow shorter pulse lengths and thus better axial resolution. This is particularly useful for superficial or high-frequency imaging. But this advantage comes with trade-offs: lower output pressure, limited penetration, and increased noise. In practice, cMUTs often struggle in deeper imaging or in Doppler modes where signal-to-noise ratio is critical.
By placing the CMUTs in a 2D array, the device can be programmed to emulate scanning patterns and wavefields from any type of transducer – linear, curved, and phased.	This statement is misleading. Linear, curved (convex), and phased arrays have distinct physical geometries designed for different fields of view and use-cases. While 2D matrix arrays can simulate some beam steering and focusing behaviours through electronic phasing, it is not possible to truly "emulate" the wide field of view of a convex probe or the tight steering of a phased array using a flat 2D array—at least not without significant compromises. It is also not possible to cheat aperture and lens physics. A linear array cannot "become" a convex array just through programming—it doesn't have the geometric curvature needed to create the same beam spread naturally. Butterfly should provide some evidence to base such claims.

Text submitted by Butterfly	Comments
Another major future potential for the Product is its interface with artificial intelligence (AI) technology. In fact, the 2D array enables more cost-effective AI development compared to traditional piezoelectric based crystals	This is another misleading statement.AI development depends on data, not the transducer type • AI models for ultrasound (e.g., for image classification, anomaly detection, segmentation) are trained on ultrasound images, not on the internal structure of the transducer. • Whether the image came from a cMUT or a SC probe is irrelevant to the AI algorithm, as long as the image quality and format are suitable. • So saying that cMUTs "enable cost-effective AI development" makes no technical sense. It confuses hardware architecture with data science workflow.
8.d)	
The versatility, durability and high image quality (see table) of the cMUT device compared to that of lead base piezoelectric crystals	We cannot find any table or reference
Moreover, the Product currently has approval for 14+ clinical indications, as such making a significant contribution to the efficiency and sustainability of healthcare systems	Another misleading statement that's also a huge leap in logic. Regulatory clearance for 14 indications, which is the average for handheld devices, **does not in itself prove** that the device: • Improves system-wide efficiency • Reduces costs • Supports sustainability in any measurable way Such claims require: • Real-world outcome studies • Workflow time savings • Resource use comparisons • Clinical accuracy and patient safety evaluations
Comparative Images: Piezoelectric Crystal Handheld Ultrasound Device VS. Butterfly iQ	Considering the images come with no explanation and no data whatsoever to understand what we are looking at, we cannot comment, but the section is void of any value.