Questionnaire 3 Exemption 17 of RoHS Annex IV

Lead in solders of portable emergency defibrillators (category 8)

Requested validity: Until the end of 2025

1. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[1] by the European Commission through for the evaluation of applications for the review of requests for new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

COCIR has submitted a request for the renewal of the above-mentioned exemption, which has been subject to a first review. As a result we have identified that some information is missing. Against this background, the questions below are intended to clarify some aspects concerning the request at hand.

We ask you to kindly answer the below questions until 21st of August 2021 latest.

2. Questions

1. In the last questionnaire you answered the following: "*There is subset of defibrillators which are specifically designed for the most demanding of environments, such as emergency responder vehicles. The durability and reliability of defibrillator is always reflective of the environment the equipment is design to be operated within.*" You argue with the high reliability requirements which, next to other reasons, prevented that you achieved compliance in time. Vice versa, it should technically be less challenging to start with the lower requirement mobile defibrillators.

    a. Is it possible to clearly define the defibrillator for harshest environments and for less challenging environments, e.g. by certification? If not, please kindly let us know how mobile defies are certified for the quite different use environments you describe above.

    There is no easy way to define what the harshest of environments are, as it is usually the combination of factors which drive the most demanding of technical requirements. Equipment is qualified to different standards, with the selection of relevant standards driven by the expected operational environment of the equipment, for example RTCA DO-160G (Environmental Conditions and Test Procedures for Airborne Equipment) is known to be used for airborne equipment. However, the standards to which equipment is qualified to is not necessarily disclosed by the manufacturer.

[1] It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017

2. Following the above approach, the exemption could be split as follows to reflect the differences of the uses and related requirements:

17a	Lead in solders of mobile emergency defibrillators	
(I)	Designed for indoor use (e.g. in hospitals, medical practices, companies, public buildings such as schools and authorities, private homes, etc.)	Expires on 21 July 2023
(II)	Designed for outdoor operations such as ambulances, helicopters, military purpose and big events etc.	Expires on 31 December 2025

a. Please kindly comment our proposal.

We would suggest that the wording is clarified to include 'designed for' as outlined above. However, it should be noted COCIR represent just a very small part of the portable defibrillator market. As this proposal to split the exemption has not been publicly shared we cannot judge how this will impact the remaining industry.

Although work is underway to qualify lead free alternatives the timeframes for qualification are currently such that qualification may not be completed for some COCIR members for indoor use by the timeframes outlined. In part this time will be utilised to finalise the testing of alternative, but is also complicated by the current supply chain issues in procuring PCBA which a level of uncertainty as to when it can be completed.

Therefore we conclude that the split will add considerable risks to a sector that may not be aware of the ongoing discussion and could also impact companies that are doing their best to be lead-free in the next 2 years but may meet some unexpected obstacles.

Please note that answers to these questions may be published as part of the evaluation of this request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.