

Questionnaire 6 Exemption 5 of RoHS Annex IV

Acronyms and Definitions

COM	European Commission
Pb	Lead

1. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed¹ 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.

You submitted information to substantiate your request for the renewal of the above-mentioned exemption. This information was reviewed and as a result, we ask you to kindly answer the below questions for further clarification of your request until 29 June 2021 latest.

2. Questions

- At p. 32 of the exemption request it is stated, *“The biggest impact is likely to be with collimators. Hospitals usually buy different types to optimise imaging for different isotopes used for PET and SPECT and for different medical procedures. A lead collimator typically costs \$1500 where a similar tungsten collimator has been estimated to be \$30,000.”*

Could you detail how these costs were calculated (amount and price of material) or if they were based on an existing product price on the market? Does the price for the tungsten collimator cover only higher material prices or also higher manufacturing costs?

\$1500 was the price of a lead PET collimator in 2018. The cost of a tungsten collimator at \$30,000 was estimated as follows: The difference in price is partly due to the difference in metal prices of lead and tungsten as specified in footnote 20 (in 2018, the tungsten price was about 12X the lead price - see <https://www.metalar.com/tungsten-price/>). In addition to the difference in material costs, an estimate was made by collimator manufacturers of the additional production costs that are expected to be incurred, assuming that the technical issues described in page 27 could be overcome, although at present, there is no known method of making a hexagonal tungsten grids commercially and so this estimate is made based on the information available at the time.

The only way a more accurate cost could be calculated would be by a company to enter into technical discussions with potential providers to ensure the engineering requirement specific to each collimator are met. Subsequent to this prototype(s) would then be fabricated and trialed, before production orders would be placed. It would only be at this point that an accurate manufacturing cost could be calculated, and to date no COCIR companies have engaged in such level of activity as the overall environmental and health benefits of substitution do not outweigh the use of tungsten.

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.

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

It would be helpful if you could kindly provide the information in formats that allow copying text, figures and tables to be included into the review report.