

Consultation Questionnaire Exemption Request 2016-2

Exemption Request for „Lead in solders used to construct and connect to Peltier thermal cyclers used for in-vitro diagnostic analysers that use polymerase chain reaction“ until 31 December 2020

Background

The Oeko-Institut and Fraunhofer IZM have been appointed by the European Commission, within a framework contract¹, for the evaluation of applications for exemption from Directive 2011/65/EU (RoHS 2), to be listed in Annexes III and IV of the Directive.¹

Roche has submitted a request for the above mentioned exemption, which has been subject to a first completeness and plausibility check. The applicant has been requested to answer additional questions and to provide additional information, available on the request webpage of the stakeholder consultation (<http://rohs.exemptions.oeko.info/index.php?id=272>).

The objective of this consultation and the review process is to collect and to evaluate information and evidence according to the criteria listed in Art. 5 (1) (a) of Directive 2011/65/EU (RoHS II), which can be found under:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT>

If you would like to contribute to the stakeholder consultation, please answer the following questions:

Questions

1. Roche has requested an exemption with the following wording:

“Lead in solders used to construct and connect to Peltier thermal cyclers used for in-vitro diagnostic analysers that use polymerase chain reaction” until 31 December 2020

- a. Do you agree with the scope and formulation of the exemption as proposed by the applicant?
- b. Please suggest an alternative wording and explain your proposal, if you do not agree with the proposed exemption wording.
- c. Please explain why you either support the applicant’s request or object to it. To support your views, please provide detailed technical argumentation / evidence in line with the criteria in Art. 5(1)(a) to support your statement.

¹ The contract is implemented through Framework Contract No. FWC ENV.A.2/FRA/2015/0008 of 27/03/2015, led by Oeko-Institut e.V.

2. Please provide information concerning possible substitutes or developments that may enable reduction, substitution or elimination, at present or in the future, of the use of lead in the requested exemption;
 - a. In this regard, please provide information as to alternatives that may cover part or all of the applicability and/or functionality of the in-vitro diagnostic analysers that use polymerase chain reaction.
 - b. Please provide quantitative data as to application specifications to support your view.
 - c. Please provide a roadmap of such on-going research (phases that are to be carried out), detailing the current status as well as the estimated time needed for further stages.

3. Please provide information as to research initiatives which are currently looking into the development of possible alternatives for some or all of the applications and functionalities of in-vitro diagnostic analysers that use a polymerase chain reaction.

4. There are other manufacturers delivering products based on the same technologies (Peltier elements), e.g. Abbott, Siemens, Beckman, Cepheid, and Qiagen, which have not applied for an exemption. One other device, the Hologic Panther, uses incubators instead of Peltier elements. It is yet to be established if some or all of these other manufacturers support the exemption request.

Please provide information as to why these manufacturers do not need the requested exemption, or alternatively, to clarify why granting the requested exemption is justified for Roche despite there being other similar devices on the market that do not need the exemption.

5. Roche indicates a maximum of around 1.5 kg of lead that would be used annually under the requested exemption. Is this estimation realistic in your point of view?

6. Are there any other aspects you deem to be of importance for the requested exemption?

In case parts of your contribution are confidential, please provide your contribution in two versions which are clearly marked (public /confidential). Please also note, however, that requested exemptions cannot be granted based on confidential information!

Finally, please do not forget to provide your contact details (Name, Organisation, e-mail and phone number) so that Oeko-Institut/Fraunhofer IZM can contact you in case there are questions concerning your contribution.