

First Questionnaire Exemption Request No. 2016-2

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

Abbreviations and Definitions

IVD	in-vitro-diagnostic
IVDA	in-vitro-diagnostic analyzer
PCR	polymerase chain reaction

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 renewal of the above mentioned exemption, which has been subject to a first evaluation. The information you have referred has been reviewed and as a result we have identified that there is some information missing and have formulated a few questions to clarify some aspects concerning your request.

Roche feedback has been included in this response in blue, bold italic font. Roche has also provided a version of this response in which proprietary content has been redacted for public distribution.

Questions

- 1) Roche mentions that it does not know which solders competitors use. Please specify who the competitors are.

Roche response: The competitors are summarized in Table 15 of the Exemption Request and include Abbott, Hologic, Siemens, Beckman, Cepheid, and Qiagen.

- 2) Roche does not mention the total amount of lead that would be used under the requested exemption due to confidentiality reasons. In such cases, maximum values can be indicated to clarify the range of substance used, for example less than X kg. Please indicate a maximum you deem appropriate for the amount of lead in the EU and worldwide.

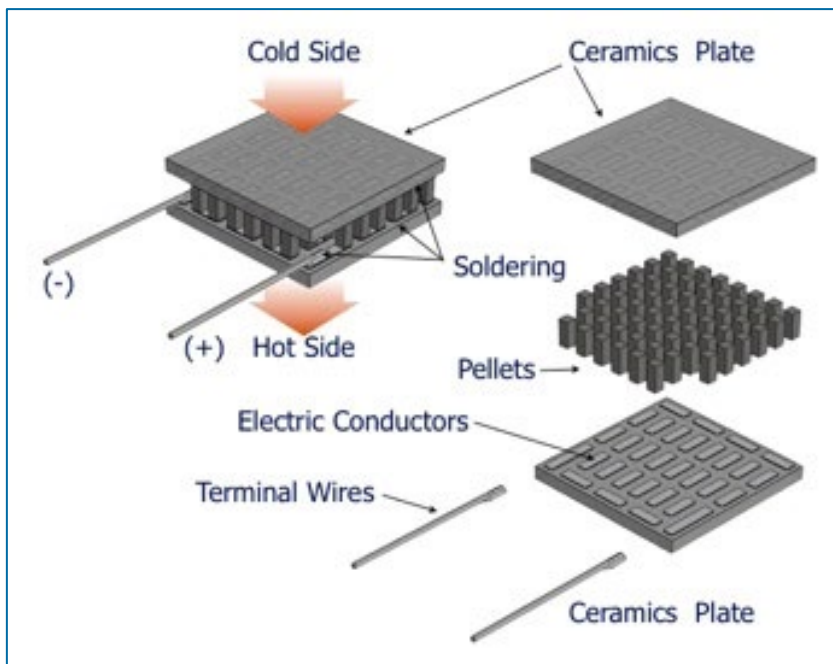
Roche response: Roche wishes to clarify that two versions of the RoHS Exemption Request document were submitted for review; one version was redacted and is intended for public distribution (marked “public” in the filename). The information requested by Oeko is not included in the version intended for public distribution. The un-redacted version intended for review has been included with this response.

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.

At this time, Roche would like to update the figures for the EU market, and present the figures for worldwide distribution (outside of the EU) and total global distribution. Based on these figures, Roche requests that “a maximum of 1.5 kg” total of Pb per year be exempted.

- 3) As Peltier elements are crucial for your exemption request, please provide a description of such elements, including an illustration (photo or drawing) where the lead solder is applied.

Roche response: An illustration of a Peltier element is presented below. The solder is applied on the Electric Conductors (made of copper) on the Ceramic Plate, in order to create an electrical connection between the Conductor and the Pellets (made of bismuth telluride).



- 4) You explain that an additional challenge for lead-free solder use is the brittle bismuth telluride semiconductor material that can fracture and fail under sufficient strain. Are Peltier elements available with alternative semiconductor materials that would be more appropriate for lead-free soldering?

Roche response: The alternative Peltier elements that underwent feasibility testing by Roche were selected because they met fundamental design requirements for application on the COBAS TaqMan instruments, and were thus suitable for further evaluation. These elements all used bismuth telluride semiconductor material.

- 5) Roche conducted experiments (page 5 et sqq. in the exemption request) to test the temperature and ramp specifications, and the endurance of lead-free soldered Peltier elements.
- a) Do you have any explanation why the lead-free soldered Peltier elements did not pass the temperature and ramp specification test?

Roche response: No, Roche cannot confirm the reasons why the lead-free soldered elements did not meet the temperature and ramp performance specifications. Possible factors include the design of the Peltier element and/or the properties of the lead-free solder.

- b) In both tests, some lead-free soldered Peltier elements fulfil the test criteria. We conclude from this, that lead-free solders are not principally inappropriate. The large variation in particular in the endurance test in our opinion may indicate that the root causes of the failures are not the lead-free solders per se, but other reasons like for example insufficiently exact soldering process controls, or variations in the surfaces that are bonded with the lead-free solders. Please comment.

Roche response: Roche agrees that various factors could explain the results observed in both the temperature response and endurance testing studies, including the performance of the lead-free solder and/or other design and manufacturing factors related to the elements.

- 6) In table 3 of your exemption request Roche compares polymerase chain reaction (PCR) analysers of various manufacturers. Do all these analysers use Peltier elements, or are there any alternative technologies that do not depend on the use of such elements and therefore would not require the requested exemption?

Roche response: Based on market intelligence, Roche concludes that all but one of these instruments appears to use Peltier technology for heating and cooling during PCR. One instrument, the Hologic Panther, uses incubators instead of Peltier elements. However, Roche PCR assays are not designed to be used with incubators and therefore such technology is unsuitable for deployment on COBAS TaqMan Instruments.

- 7) Roche explains in the exemption request that it has already PCR analysers on the market which are RoHS compliant, e.g. the cobas 4800 and the next generation cobas 6800/8800 systems. Please explain how Roche achieved the RoHS compliance of these devices, and why this solution cannot be applied to all the other Roche PCR analysers.

Roche response: The cobas 4800 System and the cobas 6800 / 8800 Systems were developed much more recently than the COBAS TaqMan (CTM) and TaqMan48 (CTM48) instruments, and were initially designed with RoHS-compliant Peliter elements. The elements used in the cobas 4800/6800/8800 Systems have significant differences in design and performance requirements versus the elements used in the CTM and CTM48, and could not be deployed on these instruments without significant modifications to the hardware and temperature control firmware.

Roche would like to reiterate that there are stringent regulations associated with the accreditation or licensure of laboratories. After Roche obtains regulatory clearance or approval for a change to an IVD instrument, our customers must subsequently implement the change, which typically requires that the customer perform extensive planning, validation, and often, submissions to regulatory bodies. The costs and effort associated with these requirements can be extensive.

Roche additionally would like to reiterate that the COBAS TaqMan Instruments are older instruments, and that the requested exemption is proposed only through <DATE>. By this time Roche intends to end support for the instruments in the European Union, based on the planned conversion of existing TaqMan customers to the newer cobas 4800 System or cobas 6800/8800 Systems.

Please note that answers to these questions are to be published as part of the available information relevant for the stakeholder consultation to be carried out 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.