Consultation Questionnaire Exemption Request 2017-4

Exemption for „ Lead in solder and hexavalent chromium in parts used to make RF detectors in Mass Spectrometers“

Abbreviations and Definitions

SCIEX	AB SCIEX
Cr VI	Hexavalent chromium
MS	Mass spectrometers
Pb	Lead
RF	Radio frequency

Background

The Oeko-Institut and Fraunhofer IZM have been appointed by the European Commission, within a framework contract[1], 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.

SCIEX 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=282).

SCIEX applies for an exemption for "*Lead in solder and hexavalent chromium in parts used to make RF detectors in mass spectrometers*", requesting a duration of 2 years.

SCIEX explains that radio frequency (RF) detectors are used in its mass spectrometers (MS), which are in the scope of RoHS category 8 (medical devices) and category 9 (monitoring and control instruments). "*The RF detectors convert a high voltage RF input to a low voltage DC output signal. The DC output signal is used as the feedback for precision control of the high voltage RF applied to the quadrupole mass filter in our instruments. In order to meet our analytical mass stability and peak width stability requirements, the RF detector is required to be very stable, quite accurate, and highly linear over two orders of magnitude of input voltage. In order to meet these requirements, the RF detector uses special capacitors held within a temperature controlled oven.*"

The applicant explains that lead solders (Sn63Pb37) are used in the RF detectors where lower soldering temperature is required and that CrVI is used in coated parts of the detector capacitor case to ensure the maintenance of its shielding effectiveness. In research into substitutes, lead-free solder alloys were looked into as well as the use of chromium III plated metals for the detector case. Altering the materials was considered a high risk to the performance and reliability of the instrument since the RF detector has to be extremely accurate, very stable, and highly linear over

[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.

two orders of magnitude of input voltage. Alternative substitutes will have to achieve the same level of performance.

SCIEX states that a RoHS compliant version was designed and built, but it did not pass failure analysis. A three stage conversion plan has been developed to study the reliability of substitutes and conduct conversion to RoHS where feasible with an estimated duration of 24 months. Alternative compliant materials will be used where such parts meet the required performance specifications of the equipment.

For details, please check the applicant's exemption request at:
http://rohs.exemptions.oeko.info/index.php?id=282

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. The applicant has requested an exemption for "*Lead in solder and hexavalent chromium in parts used to make RF detectors in Mass Spectrometers"* for category 8 and 9 products and for a duration of 2 years.
    a. Do you agree with the scope 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.
2. Please provide information concerning possible substitutes or developments that may enable reduction, substitution or elimination, at present or in the future, of lead in solders used in the RF detector and of CrVI present in the detector casing of mass spectrometers;
    a. In this regard, please provide information as to alternatives that may cover part or all of the applicability range of lead and CrVI in the RF detectors;
    b. In your answer please refer not only to substance substitutes, but also to possible technological alternatives that would eliminate the need for lead and CrVI in this application.
    c. Please provide quantitative data as to application specifications to support your view.
3. The exemption is requested for lead solders and CrVI coatings of RF detectors in use in mass spectrometers of category 8 and category 9. Devices covered by these categories

came into the scope of the Directive between July 2014 (medical devices and non-industrial monitoring and control instruments) and July 2017 (industrial monitoring and control instruments) and must be RoHS compliant in order to be placed on the EU market after the respective dates. At present the RoHS Directive annexes do not contain exemptions understood to be relevant for these applications. It is thus assumed that other RF detectors in use in mass spectrometers have achieved RoHS compliance.

   a. Do you support this view? If not, please specify why the requested exemption would be justified and how the SCIEX equipment differs from compliant Ms on the EU market.

   b. If relevant, please specify additional equipment for which the exemption would be needed aside from the SCIEX MS and how such equipment differs from compliant Ms on the EU market.

   c. Please provide a roadmap of on-going research into substitutes for lead and CrVI for such applications (phases that are to be carried out), detailing the current status as well as the estimated time needed for further stages.

4. Other manufacturers of mass spectrometers so far have not supported the applicant's exemption request. Please provide information as to other manufacturers' mass spectrometers with similar performance that achieve RoHS-compliance without the requested exemption.

5. As part of the evaluation, socio-economic impacts shall also be compiled and evaluated. For this purpose, please provide details in respect of the following:

   a. Please estimate the volume of equipment to be placed on the market annually through this exemption, should it be granted. Please provide relevant data and calculations to support your views.

   b. Sciex estimates that between 15 to 20 g of lead and 194 mg of CrVI will be placed on the EU market annually through this exemption. Please specify if you support this estimation or provide an alternative estimation backed with relevant data and calculations;

   c. Please estimate possible additional waste to be generated through a forced phase-out should the exemption not be granted;

   d. Please provide estimation of impacts on employment in total, in the EU and outside the EU, should the exemption not be granted. Please detail the main sectors in which possible impacts are expected –MS manufacturers, RF detector manufacturers, supply chain, retail, etc.

   e. For the case that the exemption is not granted, SCIEX details various impacts that could be expected in relation to suppliers of relevant equipment and consumers of such equipment (see response to clarification questions for further details).

      i. Please specify whether you support this view and estimate additional costs/benefits associated with a forced substitution should the exemption not be granted, and how they are to be divided between various sectors (e.g. private, public, industry: manufacturers, suppliers, retailers).

ii. Please provide data, where available, to allow a quantification of such costs and benefits.

In case parts of your contribution are confidential, please provide your contribution in two versions (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.