

Development of Legislation and Other Instruments

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Stakeholder consultation on exemptions from the substance restrictions in the RoHS Directive – Comments from the Swedish Chemicals Agency on Exemption request 2013-6

FEI Company has applied for the following exemption from the provisions of The RoHS Directive (2011/65/EU) regarding *“Lead and hexavalent chromium in reused spare parts, recovered from industrial monitoring and control instruments placed on the global market before 22 July 2017 and used in category 9 equipment placed on the market before July 22 2024, provided that use and reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer.”*

We suggest that the wording of the exemption should be revised as proposed below. For clarity two versions are presented, one with track changes indicated and one clean version.

*“Lead and hexavalent chromium in reused spare parts, recovered from industrial monitoring and control instruments **electronic microscopes and equipment used for the operation of the electron microscopes** placed on the global market before 22 July 2017 and used in category 9 equipment **electronic microscopes and equipment used for the operation of the electron microscopes** placed on the market before July 22 2024**2021**, provided that use and reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the ~~consumer~~ **recipient.**”*

“Lead in reused spare parts, recovered from electronic microscopes and equipment used for the operation of the electron microscopes placed on the market before 22 July 2017 and used in electronic microscopes and equipment used for the operation of the electron microscopes placed on the market before 22 July 2021, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the recipient. “

Swedish Chemicals Agency

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Justification

Hexavalent chromium

The applicant states in their answers to the 1st Questionnaire from Öko-Institute e.V. that chromium VI has been substituted by the suppliers to the manufacturer of electron microscopes during the last ten years. There will take around three years before any new exemption will enter into force. This means that during 13 years there has been a considerable amount of equipment set on the market that is free of hexavalent chromium. For that reason, we see no reason to exempt the content of hexavalent chromium in the spare parts.

Scope of the exemption

The applicant has suggested an exemption for reused spare parts in all category 9 equipment. In our view the application does not fulfil the criteria set up in Annex V in the RoHS directive for any other equipment than electron microscopes. The impact assessment covers only electron microscopes and thus provides no grounds as a basis for a decision for a wide exemption for all category 9 equipment and as a consequence we propose to limit the exemption to electron microscopes.

Global access of reused spare parts

We suggest that the word global is deleted. Even if we understand from the application that it is not the most effective solution for the manufacturers of electron microscopes to divide the spare part into an EU and a non-EU part, we cannot see that it can be solved in any other way in the long run. Otherwise all countries around the world need to adopt the same (or lower) concentration limits on lead as required by the RoHS directive. If the manufacturers are unable to separate reused spare parts from different markets, it will be necessary to prolong the exemption after the first date of expire.

There is a risk that the circulation of lead and hexavalent chromium increases on the EU market if the exemption is granted for all items that belong to category 9 and import of reused parts from non-compliant equipment from non-EU countries is allowed.

As RoHS does not apply to equipment placed on the non-EU market, there are no guarantees that the requirements on other substances restricted in annex II are fulfilled for reused spare parts when imported from non-EU countries. This aspect was not mentioned in the assessment.

Date of expire

Electron microscopes are not related to category 9 only. Electron microscopes are also used for medical diagnosis and will then belong to category 8. We do not share FEI Company's view that the electron microscopes for medical diagnosis are mainly operated by students. On the contrary, we have experience that they are solely operated by a very limited number of highly qualified professionals.

We believe that the same date of expiry shall apply to exemptions regarding electron microscopes for medical diagnosis and industrial use respectively. Thus we suggest to use the same date of expire as for reused spare parts for medical devices in the new entry 31 in Annex IV, namely 21 July 2021.

Notification of consumers

Even if "*consumer*" is not defined in the RoHS directive or in the 'New legislative framework' for marketing of products', it is implicitly used as a description of private individuals; See RoHS Annex I, Category 4. Thus we suggest that the word consumer is replaced by recipient in the wording of the exemption as recipient is already used in REACH in the corresponding context.

Other comments

It must be totally clear that refurbished spare parts containing lead or hexavalent chromium can never be used in new equipment set on the market for the first time after 22 July 2017.