KEMI
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Swedish Chemicals Agency

MEMO

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Development of Legislation and Other Instruments

To:
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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

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Comments submitted by the Swedish Chemicals Agency on 28 February 2014 on the original exemption request from FEI are still valid and and the new comments should be seen as complementary.

FEI Company has applied for 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.*"

In addition to the original application FEI provided some new information by e-mail on 27.02.2014. The new information requested changes in the exempt proposal in three different areas:

1. All 6 substances in Annex II to be exempted.
2. "Initially recovered" added: it should be possible to reuse parts which have been already reused.
3. "Spare parts" changed with "parts": there is no clear difference between parts and spare parts.

Contribution to the stakeholder consultation by Cocir[1], submitted 7 February 2014, is also available at the webpage for Exemption request consultations. They propose a

[1] European Coordination Committee of the Radiological, Electromedical and Healthcare IT

new wording for the exemption as follows: "*Lead and hexavalent chromium in reused parts, initially* 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, lead, cadmium, hexavalent chromium, mercury, PBB and PBDE in reused parts initially* recovered from medical devices placed on the global market before 22 July 2014 and used in category 8 equipment placed on the market before July 22 2021 and lead, cadmium, hexavalent chromium, mercury, PBB and PBDE in reused parts initially* recovered from in-vitro medical devices placed on the global market before 22 July 2016 and used in category 8 equipment placed on the market before July 22 2023 ; provided that use and reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts are notified to the consumer. "Placed on the global market" means making available for the first time globally*".

Scope of the exemption

The Swedish Chemicals Agency does not support the wording of the originally requested exemption. Furthermore, we do not consider that it is legally possible to extend the scope of the application under the RoHS directive during the consultation.

Our proposal for a new wording is:
"*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.* "

For clarity a version of our proposal with track changes indicated is also presented below:

"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**."

We agree that reuse of spare parts, in many cases, may be beneficial for the environment. However, this is not a valid reason for not following the legal provisions of the RoHS directive. Any new requests for amendments in annex III and Annex IV of the directive has to conform to the current legislation, in this case Article 5 and Annex V in the RoHS directive. An exemption can only be adopted if the criteria in article 5.1.a are fulfilled for the specific uses. The information required in Annex V thus needs to cover all specific uses that are to be assessed under article 5.1.a.

In this case, the additional requests have still not been justified for any other equipment than electron microscopes in category 9. The impact assessment provided by the applicant covers only electron microscopes and thus provides no grounds as a basis for a decision for a wide exemption for all category 9 (or category 8) equipment. In the answers from the applicant to the questionnaire it is also completely clear that all category 8 equipment is out of the scope (Q2c, Q2d). Therefore the applicant has not proved that the criteria in article 5.1.a are fulfilled for any other EEE than electron microscopes in category 9.

This is also the reason why we do not regard the new information as "*small changes*" as FEI refers to in their email from 27 February 2014.

Our opinion is in line with the guidelines for this consultation provided by Öko-Institute e.V. where it is stated that "*additional request for exemptions will not be taken into account*". We consider that this is valid for both the additional request from FEI as well as the new request from Cocir.

Annex III and IV are not intended for general unspecified exemptions

We question whether the purpose of the exemption system is to provide the kind of wide and general exemptions that the FEI and COCIR now are requesting. In the relevant parts of the directive itself the articles suitable for exemptions are described in more specific terms, showing that the exemptions in the annexes are meant for very specific uses. This is also expressed in the recital, in the articles of the directive and in the annex, se examples below.

Recital 19: "Exemptions from the restriction for *certain specific materials or components* should be *limited in their scope* and duration,"

Article 5.1.a inclusion of materials and components of EEE *for specific applications* in the lists in Annexes III and IV

Annex V. paragraph b "information on the material *or component and the specific uses* of the substance in the *material and component* for which an exemption, or its revocation, is requested and *its particular characteristics*"

Definition of placed on the global market

FEI applies for an exemption that covers EEE "*placed on the global market*" We do not agree with this wording. Our comments regarding uncontrolled inflow of EEE containing substances restricted in RoHS annex II submitted on 28 February 2014 are still valid. In addition, the RoHS directive is aimed to ensure that EEE *placed on the market* does not contain the substances listed in Annex II. There is no legal reference in the directive to any definition of EEE *placed on the global market.*

Definition of spare parts

FEI suggests that "*spare parts*" should be replaced by "*parts*". We do not agree. "*Spare parts*" have a definition in the RoHs directive Article 3.27. There is no definition of parts. "*Spare parts*" are thus regarded to be better defined when included in the annexes of the directive.