1st Questionnaire Exemption Request No. 2013-6

Exemption for "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."

Abbreviations and Definitions

IMCI Industrial monitoring and control instruments

Background

The Öko-Institut has been appointed within a framework contract for the evaluation of an application for granting an exemption to be included in or deleted from Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS 2) by the European Commission.[1]

FEI has submitted the above mentioned request for 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 a few questions to clarify concerning your request.

Questions

1. In the text of your exemption request you ask for an exemption for lead and hexavalent chromium in reused spare parts recovered from IMCI. The scope of the proposed exemption formulation is left open and may apply to the reuse of recovered parts from all IMCI. In the information provided to clarify why such an exemption is needed, however, only the relevance of such an exemption for electron microscopes is explained.
   a) Does FEI presume that such an exemption would be needed for other devices as well? FEI produces mainly Electron Microscopes, but there are also other devices

[1] Contract is implemented through Framework Contract No. ENV.C.2/FRA/2011/0020 led by Eunomia

related to electron microscopy, which are produced as FEI products. We see these other devices also part of Category 9 products and if possible would not limit the proposed exemption only to Electron Microscopes. This exemption request is limited to those parts that are collected within closed-loop systems which will be predominantly B2B equipment. Another reason for requesting this exemption for all category 9 products is that reuse is encouraged by the EU as this is accepted to be preferable environmentally and this will be the case with all category 9 types of equipment, even though other manufacturers of these types of products have not yet realised that this exemption is needed in order for them to reuse parts.

b) Assuming that the practice of spare part reuse is only relevant for electron microscopes in scope of category 9 products and devices, please suggest an exemption wording that limits the scope to this practice in these devices. As said, we would apply for Exemption of all Category 9 products, one example could be Sample Preparation equipment connected to the workflow in cryogenic Biology and cell- and protein analysis, but we would envisage a long list of types of equipment if this approach were to be pursued.

2. You state in your application that the requested exemption is also relevant for medical products or other monitoring and control instruments besides IMCI.
   a) Does FEI market electron microscopes for non-industrial purposes? Our systems are classified as industrial according RoHS Directives. Our products are designed for professional use; Article 3 (24) IMCI=industrial OR professional use. Furthermore we can state that FEI's designs and products are too complex to be used by students and other non-professionals.
   b) As the RoHS substance restrictions shall apply to the general category 9 starting July 2014 it is assumed that if such an exemption were relevant, this need would have already been communicated in light of the standard time needed for processing a request for exemption. On what basis do you assume that the requested exemption would be relevant for electron microscopes, falling under the general category 9 and not under the industrial category 9 subgroup (IMCI)? FEI manufacture the most advanced and sophisticated electron microscopes available world-wide. Their complexity means that they can be used only after the user has received extensive training and so they are intended to be used only by professionals. University undergraduates, for example would not have the time to be trained to use these types of microscope and so they are typically used by permanent University employees. Simpler designs of electron microscope are sold in the EU by other manufacturers which are used by University students but these simpler designs are not produced by FEI.
   c) The RoHS Directive clarifies that devices to be covered by the scope of category 8 are defined under the relevant Directives specified in the definitions for the various

medical devices sub-groups specified in Articles 3(21), 3(22) and 3(23) of the Directive. According to this definition, do some of the devices for which this exemption is sought fall under category 8? no, none of FEI products fall under category 8 devices

d) If so, assuming that the exemption requested for medical devices, similar to the requested exemption[2], is to be granted, do you have any reason to assume that this exemption would not cover the relevant operations for electron microscopes falling under category 8? none of FEI products fall under category 8 devices

3. Besides FEI, you mention additional manufacturers of electron microscopes who may also benefit if this request is to be granted, please provide a list of such enterprises which operate in the EU market. Main suppliers of electron microscopes are: Zeiss, JEOL and Hitachi.

4. You provide estimates as to the quantities of lead and Cr VI that are expected to circulate on the market if this request is to be granted, however it remains unclear if these amounts regard new substance quantities placed on the market in the course of refurbishment of components, or if these quantities regard the substance quantities already in parts, to be refurbished and reused in the future.

   a) If these quantities regard both, please clarify how these amounts break down to substance brought on the market for the first time and to substance being recirculated. Please refer in your answer to the various types of components that may be repaired, including PCBs, column and stage components, parts with Cr VI passivation coatings etc.

   The quantities of lead and CrVI provided in the exemption request are the amounts that will already be in circulation. They will not be newly used substances as any new parts placed on the market after 22 July 2017 with not contain restricted lead or CrVI.

   The waste created and energy consumed for the two options; i) with exemption and ii) without exemption are quantified below for the years until 2027 in table below.

[2] Former Exemption request 2, reformulated and recomended to be granted as *„Lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before July 22 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 consumer" for a duration of 7 years. Request evaluation report available under:*
http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/20130412_RoHS2_Evaluation_Proj2_Pack1_Ex_Requests_1-11_Final.pdf

Future year quantities of waste					Compliance deadline									
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
With exemption														
PCBs available for reuse	5500	5500	5500	**5500**	5500	5500	5500	5500	5500	5500	5500	5500	5500	5500
Stages / columns, etc available for reuse	4238	4238	4238	**4238**	4238	4238	4238	4238	4238	4238	4238	4238	4238	4238
Mass of PCB waste [kg]	550	550	550	550	550	550	550	550	550	550	550	550	550	550
Mass of stage / column waste [tonnes]	580	580	580	580	580	580	580	580	580	580	580	580	580	580
Without exemption														
PCBs available for reuse	5500	5500	5500	**2644**	0	825	2090	2915	3520	3905	4235	4455	4620	4785
Stages / columns, etc available for reuse	4238	4238	4238	**2119**	0	636	1610	2246	2712	3009	3263	3433	3560	3687
Number of new replacement PCBs	0	0	0	**2856**	**5500**	**4675**	**3410**	**2585**	**1980**	**1595**	**1265**	**1045**	**880**	**715**
Number of replacement stages, columns, etc	0	0	0	**2119**	**4238**	**3602**	**2628**	**1992**	**1526**	**1229**	**975**	**805**	**678**	**551**
Mass of PCB waste	0	0	0	**285.6**	**550.0**	**467.5**	**341.0**	**258.5**	**198.0**	**159.5**	**126.5**	**104.5**	**88.0**	**71.5**
Mass of additional waste stage / column waste (tonnes)	0	0	0	**278**	550	467.5	341	258.5	198	159.5	126.5	104.5	88	71.5
Energy consumption for replacement parts (GJ)	0	0	0	30,766	61,070	51,998	35,257	22,905	15,246	21,282	12,741	8,047	15,776	14,506
Accumulated additional energy consumed (GJ)	0	0	0	30,766	91,836	143,834	179,091	201,995	217,241	238,523	251,263	259,310	275,086	289,591

This calculation shows that if the exempt is not granted we cannot use the parts coming from the field and we have to throw this away, thus creating waste (PCB=550kg, solder=110kg, components=580 tonnes) and the accumulated extra energy needed would be around 290GJ over 10 years.

b) Where refurbishing of components is to require soldering operations, can lead-free solders eliminate the use of further lead based solders? Only partly since not all components of the spare parts will be replaced during repair and re-use loops. Those that will be replaced will use lead-free solder so no additional lead solder will be used.

5. The requested exemption formulation suggests that parts may be reused in the repair of both “old products”, placed on the market before July 2017, and “new” products, placed on the market thereafter. Can components that are not RoHS conform be used to replace components that were RoHS conform in new products without affecting the integrity of the product? In many cases this will indeed be possible, our new designs typically ensure backwards compatibility and often this also means that the old parts perform well in our new products
6. You mention that Cr VI passivation coatings have already been phased out and are no longer produced by FEI. When did phase out occur? How long are remaining parts expected to stay in circulation, requiring that the requested exemption be in place to allow their use in the EU market? This has not been actively done by FEI, our parts suppliers changed their Cr VI coating processes to RoHS compliant coatings in the course over the last 10 years. This did not affect the performance of our parts and we approved this changeover as improvement in the manufacturing process of our suppliers. To our best knowledge, none of the current suppliers is using Cr VI coating processes anymore.