Questionnaire 1 (Clarification) Exemption 31a of RoHS Annex IV

Lead, cadmium, hexavalent chromium, and deca brominated diphenyl ethers (deca BDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed loop business to business return systems and that each reuse of parts is notified to the customer.

Requested validity: *Maximum validity period*

1. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[1] by the European Commission through for the evaluation of applications for the review of requests for new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

COCIR has submitted a request for the renewal of the above-mentioned exemption, which has been subject to a first review. As a result we have identified that there is some information missing. Against this background the questions below are intended to clarify some aspects concerning the request at hand.

We ask you to kindly answer the below questions until 1st September 2020 latest.

2. Questions

1. You request for an exemption for spare parts recovered from old medical equipment. As described in the request you refer to closed-loop business-to-business return systems: How can you guarantee, that no newly produced parts will enter this system, which contain critical substances under RoHS Directive 2011/65/EU? Are there precautions for monitoring the flows of spare parts and preventing misuse of this exemption?

   New spare parts for medical devices are all manufactured complying with RoHS since 2014. Spare parts are part of the certification of the equipment, so the RoHS compliance is ensured by the CE marking, the Notified Body, etc. No OEM would ever have a parallel production line for non-RoHS parts as well as RoHS compliant parts as this would be simply inefficient and extremely costly would (need to have a parallel supply chain). The only non-RoHS compliant parts available on the market are the ones that had been first integrated within old products, sold before 2014. Such parts are recovered and used for reuse/refurbishment/repair etc. Article 4.5 allows for such parts to be also used for manufacturing new devices (RoHS-compliant devices that can use non-RoHS parts. Nonetheless, this option is not used as there are other legal hurdles, but such a possibility is probably the only one that can realize the potential of a circular economy).

   Moreover, the collection of used parts and refurbishment of used equipment is carried out at separate production lines that are not connected to sites for manufacturing of new equipment. This segregation is important to avoid non-compliances that can have devastating effects on the production and delivery of new equipment to hospitals and clinics.

[1] It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017

Collected used parts are used wherever possible for refurbishment but if none are available, then a new part would need to be used and these parts will not contain RoHS-restricted substances, except where permitted by exemption (as said all spare parts produced today are RoHS compliant).

2. You state that manufacturers do not collect medical devices made by other manufacturers and typically ~95 % of assemblies are returned to the original manufacturer. Nevertheless, you indicate that it is usually not possible to reliably determine whether a spare part had been removed from a medical device originally sold in the EU before 21st July 2014 or it is from equipment that had previously been sold to a user outside of the EU.

   a. What are the hurdles to obtaining this information?

In practice, it is not possible to mark each and every spare part with the required information and keep it updated throughout the whole life cycle. Spare parts cannot be marked as there are up to 50,000-100,000 spare parts per manufacturer, used in different markets and repaired multiple times over their whole life-cycle. The only way would be to manually mark parts and there is no technology that would make it possible. It is impossible to place a bar code or any other identification on any existing single part, without considering the risk that such marking can impair the safety or performance of the part, not considering that there needs to be enough space available per design.

If exemption 31a was not approved, it would be impossible to reuse existing parts as all parts should be marked and kept divided according to where they come from and when the original product was placed on the market.

Spare parts, in the hundreds of thousands to millions, are recovered during maintenance by field engineers, during repair in repair centers and operations in refurbishment facilities. The flow of parts is redirected to refurbishment facilities or directly to storage for regional repair and service centers. The attached file developed by COCIR clarifies what are the elements that should be considered when reusing spare parts. The combinations are endless as exemptions are renewed and changed constantly. Spare parts are manufactured with a serial number and this number is the only recognizable mark that can be used by companies to store them and find them whenever useful. OEMs recover hundreds of thousands of parts. No manufacturer would ever reuse parts without the simplification of procedures permitted by exemption 31a. This is why we have been claiming, since the introduction of circular economy in the agenda of the EC, that RoHS conflicts with circular economy and that reuse should not be permitted only by an exemptions, but should be a principle at the base of the directive.

Even more important, when a spare part is needed, OEMs cannot have to choose between 10 different versions of the very same identical part. The attached file shows that it is already complex. But without exemption 31a OEMs may find themselves having hundreds of the same part but none that can be used to repair a medical device that needs to be repaired. Using new parts would then be the most efficient option, shutting down all the reuse/refurbishment business with resultant waste of materials. It is also important to consider that given the lifetime of medical devices, the “new spare part” option is not feasible for any equipment that is older than 7-10 years as these will often no longer be manufactured.

So even if considering that it might be possible to mark parts, it would lead to many parts not anymore being repaired, as the additional costs for separate storage, manufacturing lines and all other associated business operations would then not anymore justify the costs-savings gained by reusing those parts.

It is also important to consider that given the lifetime of medical devices, the "new spare part" option is economically often not feasible for any equipment that is older than 10 years. Manufacturers do mostly extend the guaranteed life-time of 10 years by taking back parts and devices from the field not only for cost savings, but also to harvest service-parts and with that not only to extend the life time of a single service-part, but of a whole medical device (e.g. an MRI scanner of 15 tons). This not only decreases the amount of additional RoHS substances (in exempt forms) to the market, but also decreases the amount of all known and unknown substances of concern.

b. Isn't there any data base used by the companies for monitoring their own flows of devices?

Companies monitor sales of refurbished medical devices, but no single database exists.

Please note that answers to these questions will be published 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.