1st Questionnaire Exemption Request No. 2013-3

Exemption for "Lead in solders used in boards of heart-lung machines", exemption to expire in 2017"

Abbreviations and Definitions

HLM heart-lung-machine

Background

The Öko-Institut together with Fraunhofer IZM has been appointed within a framework contract for the evaluation of applications for granting, renewing or revoking 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]

Maquet 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 in solders on the boards of the heart-lung-machine (HLM) until December 2015, and for the Rotaflow pump until December 2017. In your proposed exemption wording, only the HLM is in the scope, and the expiry date is proposed for 2017.
   a) Please clarify the scope of your exemption request. Shall it comprise the HLM only, or the pump as well?

   Maquet response: It shall comprise both, the Heart Lung Machine HL 20 and the Centrifugal pump Rotaflow. The Rotaflow Pump System can be used together with the HL 20 but also as a stand – alone device for specific applications.

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

b) Please explain the discrepancy of 2 years in the proposed expiry dates for the HLM in the text of your exemption request and the proposed wording.

Maquet response: The development of the new HLM was started in 2009 which is before the publication date of July 2011 of RoHS II, 2011/65/EU with the due date to be RoHS conform of 22nd July 2014.

The development of the new Rotaflow pump system was started in 2011. Both systems have about the same development time and this explains the 2 years difference in our replacement plan.

2. Please explain when you started your RoHS compliance efforts and indicate the works you've conducted so far including the timing of the various steps.

Maquet response: Enclosed please find the project plans for the new HLM and the new RF system. According to our procedures a project plan is detailed after the final Business Case Review. As for the RF system this is scheduled for Sept. 2013, we have submitted for the new RF system the high level Milestone project plan.

Main schedule for the new HLM and the new RF system

	New HLM	New RF system
Market analysis, Marketing Requirements and Business case	**2009 - 2011**	**2011 - 2013**
Business case Review	**Q3 2011**	**Q3 2013**
Development	**2011 - 2015**	**2013 - 2017**
CE / FDA Approval	**2015**	**2017**
Launch EU / US	**2015**	**2017**

3. Please provide a detailed roadmap towards RoHS compliance for the HLM and the pump including timelines for the various tasks and results to be accomplished.

Maquet response: This is covered by project plans (see answer 2).

4. You claim in your exemption request that "[…] the market is dependent on MAQUET Cardiopulmonary AG continuing to deliver life supporting machines until the new machines become available, Hence, we conclude that the benefit of continuing to sell the existing machines until the new machines become available, outweighs the risks of the restricted substances."
   Besides MAQUET, there are at least three other producers of HLM.[2] As none of them has asked for an exemption, it must be assumed that they achieve RoHS compliance in time. HLM and the accessory pumps will thus remain available on the market in case the exemption is not granted.

   a) How many models of HLM and centrifugal pumps does the MAQUET Group offer?

   Maquet response:

   HL20 Family
   - **HL20 Vario Flex 4Pumps or 5Pumps**
   - **HL20 Vario Single 4Pumps or 5Pumps**
   - **HL20 Vario Twin 4Pumps or 5Pumps**
   - **Accessoires**

   ROTAFLOW Family
   - **ROTAFLOW console**
   - **ROTAFLOW console with ICU Kit**
   - **ROTAFLOW Drive**
   - **ROTAFLOW Emergency Drive**

   b) Please explain why the market is dependent on MAQUET HLM and pumps while there are three other manufacturers that can supply such devices.

   Maquet response:

   1. **Hospitals very often buy an extension of their existing fleet to minimize training and to increase safety by having their processes standardized when using the same equipment in all OR's.**
   2. **Medtronic is within the EU almost not existent and does not offer a modular HLM which in Europe is one of the most important tender specifications, therefor Medtronic cannot be taken into the equation**

[2] See webpage "Herz-Lungen-Maschine", http://www.herz-lungen-maschine.de/herz-lungen-maschine/hersteller.html; last accessed 27 June 2013

3. **Terumo as a Japanese company also has a very low market share in Europe and does not offer state of the art data acquisition software as required in more and more hospitals within the EU.**
4. **Sorin who has 80% market share in the EU followed by 17% market share with Maquet. If Maquet would not be able to deliver a monopoly would be created and customers could not decide with regards to user preference or customer safety aspects. Both machines fulfill state of the art requirements but address certain features very differently.**
5. **The HL20 is also the only heart-lung machine which is compatible with the ROTAFLOW. ROTAFLOW has a very high market share especially when transporting patients. If HL20 would be ceased from the market a patient safety risk would be created since receiving hospitals could not use the lifesaving equipment the patients have been provided with when the system was implanted.**
6. **For this specific reason the new HLM being developed right now being RoHS conform will allow to incorporate a RoHS conform ROTAFLOW drive, that if in the case of hospitals transporting patients from one hospital to the other the patient treatment does not have to be interrupted.**
7. **The PLS-Set (prolonged life support) does only work in combination with ROTAFLOW and it is the only extracorporeal life support system for intensive care units which is approved for 14 days. 80% of all ECLS procedures are performed while running PLS-Sets using ROTAFLOW.**