FRESENIUS KABI

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March 2, 2021

Oeko-Institut e.V.
Yifaat Baron
Via Email (rohs.exemptions@oeko.de)

Re: Stakeholder consultation on nine exemption requests from the substance restrictions in electrical and electronic equipment (RoHS Directive) for "Pack 22"

Dear Yifaat Baron,

The following is a response in favor of renewing"Pack 22" RoHS exemptions. These exemptions are necessary to facilitate the future production of several life-extending and life-saving medical devices and laboratory instruments, including apheresis instruments used for extracorporeal photopheresis, mononuclear cell collections, plasmapheresis, plateletpheresis, red blood cell exchange, therapeutic plasma exchange, and preparation of therapeutic biologics. These instruments are used to treat a variety of chronic medical conditions, and allow us to support clinical staff and care professionals as they provide the best therapies for patients.

The majority of Fresenius Kabi instruments are classified as category 8 medical devices. A few Fresenius Kabi instruments are classified as category 9 Monitoring and control instruments including industrial monitoring and control instruments. As such, we are advocating specifically for the extension of these requests for categories 8 and 9.

Following is our response. Original text mapping back to the Oeko-Institut Initial Consultation Questionnaire for all Exemptions is reproduced below *in italics*, while Fresenius Kabi responses are presented **in bold.**

The applicant has requested the renewal of an exemption currently listed in RoHS Annex III (see exemption specific page accessible through the links above):

a. Do you agree with the scope of the exemption as proposed by the applicant?

Regarding exemption 6(a)/6(a)-I , we agree with the more broadly-stated scope statement in the Röhm GmbH application. Given that we don't know the applicability of exemption 6(a)-I vs. 6(a) for those components we use that currently appeal to exemption 6(a), our preference would be the less restrictive 6(a) scope.

Regarding exemption 6(b)/6(b)-I, we agree with the more broadly-stated scope statement in the Umbrella Project application for the renewal of exemption 6(b). We are unable to speak to the feasibility or availability of the proposed alternatives. Given that we don't know the applicability of exemption 6(b)-I vs. 6(b) for those components we use that currently appeal to exemption 6(b), our preference would be the less restrictive 6(b) scope.

Regarding exemption 6(b)-II, we agree with the scope statement in the Umbrella Project application for the renewal of exemption 6(b)-II, specifically the extension of exemption 6(b)-II to categories 8 and 9.

Regarding exemption 6(c) for copper alloy containing up to 4 % lead by weight, we agree with the scope statement in the Umbrella Project application for the renewal of exemption 6(c).

Regarding exemption 7(a), we agree with the scope statements in the Bourns and first Umbrella Project applications for the renewal of exemption 7(a).

Regarding exemption 7(c)-I, we agree with the requests to renew the exemption with its current scope statement and for the maximum duration possible.

Regarding exemption 7(c)-II, we agree with the request to renew the exemption with its current scope statement and for the maximum duration possible.

b. Please suggest an alternative wording and explain your proposal, if you do not agree with the proposed exemption wording.

See above.

c. Please explain why you either support the applicant's request or object to it.

We support the applicants' requests in each case. Stated positively, all of the extensions requested, as articulated above, will facilitate our continued ability to provide life-saving and life-extending medical devices. Stated negatively, failure to extend any of these exemptions will negatively impact our continued ability to provide life-saving and life-extending medical devices.

To support your views, please provide detailed technical argumentation / evidence in line with the criteria in Art. 5(1)(a) to support your statement.

We are not in a position to speak to the technical feasibility or availability of the alternatives, but if the exemptions are expired without feasible alternatives readily available, or where reliability of substitutes is not assured, expirations are likely to have negative public health impacts.

2. Please provide information concerning possible substitutes or elimination possibilities at present or in the future so that exemption could be restricted or revoked:

a. Please detail substitution and elimination possibilities and for which part of the applications in the scope of the requested exemption they are relevant.

No substitution or elimination possibilities have been identified for any of the in-scope exemptions currently under consideration used by Fresenius Kabi.

b. Please provide information on research to find lead-free alternatives (substitution or elimination) that may cover part or all of the applications in the scope of the exemption request at present or in the future.

We defer to the relevant industry suppliers (as represented, e.g., by the Umbrella Project) for this information.

c. Please provide a roadmap of such on-going substitution/elimination efforts and research (phases that are to be carried out), detailing the current status as well as the estimated time needed for further stages.

We defer to the relevant industry suppliers (as represented, e.g., by the Umbrella Project) for this information.

3. Please provide any further information and/or data that you think is of importance to substantiate your views.

Renewal of the these exemptions is essential to ensure that Fresenius Kabi is able to continue to offer products for collection of blood components and extracorporeal therapies.

Please specify for which exemption your contribution is submitted.

All exemptions mentioned above.

Please do not hesitate to contact me if you have any questions, comments, or concerns.

Thanks,

Brian Case
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Transfusion Medicine and Cell Therapies Division

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