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HEALTH, FOOD CHAIN SAFETY
AND ENVIRONMENT

Directorate-General for Environment
Risk Management Service

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Interpretation of the exemptions from authorization obligations

(for use in medical devices in comparison with the other exemptions: biocides, plant protection products, cosmetics, food contact materials...)

Belgian Position

Different articles of REACH deal with exemptions of uses from authorization: Art.2, Art.56, Art.60, Art.62. We consider that these exemptions may be sort in 3 groups:

1st group: No application required when the product falls into the exempted category

Following paragraphs of **Art.2** deal with an exemption of the provisions of title VII (AUTHORISATION):
-**On-site isolated intermediates and transported isolated intermediates** {Art.2(8b)}
-Use in **medicinal products for human and veterinary use** within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC {Art.2(5a)}
-Use in **food or feedingstuffs** according to Regulation (EC) No 178/2002 including use as a **food additive in foodstuffs** within the scope of Council Directive 89/107/EEC, as a **flavouring in foodstuffs** within the scope of Council Directive 88/388/EEC and Commission Decision 1999/217/EC or on foodstuffs drawn up in application of Regulation (EC) No 2232/96, as an **additive in feedingstuffs** within the scope of Regulation (EC) No 1831/2003 and in **animal nutrition** within the scope of Council Directive 82/471/EEC {Art. 2(5b)}

Art.56 deal with general provisions under Chapter 1 (Authorisation requirement) of Title VII (AUTHORISATION),
-with **paragraph 3** dealing with use in **scientific research and development** {Art.56(3)}. Annex XIV shall specify if the authorisation requirement applies to product and process research and development.
-with **paragraph 4** dealing with exemption of paragraphs 1 (placing of the substance on the market) and 2 (use of the substance) of Art.56:
Use in **plant protection products** within the scope of Council Directive 91/414/EEC {Art. 56(4a)}.
Use in **biocidal products** within the scope of Directive 98/8/EC {Art. 56(4b)}.
Use as **motor fuels** covered by Directive 98/70/EC {Art. 56(4c)}.
Use as **fuel in mobile or fixed combustion plants of mineral oil products** and use of **fuels in closed systems** {Art. 56(4d)}.

For all the exemptions listed above, we understand therefore that there is no need to introduce an application for authorization.

2nd group: No application required when the product falls into the category exempted AND it fulfills the additional condition

Paragraph 5 of Art.56 is more restricted as these exemptions apply to substances listed on Annex XIV on the basis of their hazard to human health only:
Use in **cosmetic products** within the scope of Council Directive 76/768/EEC {Art. 56(5a)}.
Use in **food contact materials** within the scope of Regulation (EC) No 1935/2004 {Art. 56(5b)}.

Therefore, for use in cosmetic products and food contact materials, application for authorization has to be introduced for substances listed on Annex XIV on the basis of their hazard to the environment, as paragraphs 1 (placing of the substance on the market) and 2 (use of the substance) of Art.56 apply.

Paragraph 6 of Art. 56 relates to exemption of the authorization when the substance in annex XIV is present in mixture below a limit of concentration:
- for substances referred to in Article 57(d), (e) and (f), below a concentration limit of 0,1 % weight by weight (w/w) {Art. 56(6a)}.;
- for all other substances, below the lowest of the concentration limits specified in Directive 1999/45/EC or in Annex I to Directive 67/548/EEC which result in the classification of the preparation as dangerous {Art. 56(6b)}.

3rd group: Application still required, but a specific part of the dossier may be omitted

Exemption for use in medical devices are covered by paragraphs 2 and 3 of **Art.60** and paragraph 6 of **Art.62**. Art.60 and Art.62 are under Chapter 2 (Granting of authorisations requirement) of Title VII (AUTHORISATION).

Article 60(2) states:
"Without prejudice to paragraph 3, an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with Section 6.4 of Annex I and as documented in the applicant's chemical safety report, taking into account the opinion of the Committee for Risk Assessment referred to in Article 64(4)(a). When granting the authorisation, and in any conditions imposed therein, the Commission shall take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision.

The Commission shall not consider the risks to human health arising from the use of a substance in a medical device *regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices."*

Preliminary observations:

- This exemption applies only for substances for which a threshold can be determined (**Art.60** (2) and (3)).
- This exemption is limited to risks to human health: a full dossier is required for substances identified on an environmental basis.

On the basis of the following arguments, we consider that, in the framework of this exemption, a dossier has to be filed:

1. An application contains information concerning the whole life-cycle, and only one stage of the life-cycle is exempted:

a. REACH:

Recital 70 of REACH states that "Risk management measures should be applied to ensure, when substances are manufactured, placed on the market and used, that exposure to these substances including discharges, emissions and losses, **throughout the whole life-cycle** is below the threshold level beyond which adverse effects may occur."
This is clearly reflected in the "guidance on a preparation for authorization" by these 2 examples:
"For example, if a manufacturer or importer applies for a use of his downstream user, but there is a formulator in between him and the DU, his application has also to cover the use of the substance in formulation" (p.13 of the guidance)
"For example, if the end use applied for is part of a mixture, the step formulating the mixture will need to be included." (p.32 of the guidance)

Applications need to include a CSR or refer to one submitted as a part of a registration dossier.
Article 62(4)(d) states that the application include notably a "chemical safety report in accordance with Annex 1". Annex I, 0.3, states that: "The assessment shall consider **all stages of the life-cycle of the substance resulting from the manufacture and identified uses**."

Conclusion: The manufacture of the substance is not subject to authorization, however authorization has to be made for placing on the market and this authorization should take into account all identified uses
The use of the medical devices articles themselves is not subject to authorization, however the service life of articles containing the substance may need to be considered for the authorization.

b. Protection afforded by medical devices' legislation:

In Art.60(2), the medical devices are those *regulated by Council directive 90/385/EEC (…), Council directive 93/42/EEC (…) and directive 98/79/EC (…)*".
Directives 90/385/EEC, 93/42/EEC and 98/79/EC states in their respective annex I, as general requirements that:
"The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise (…) the clinical condition or the safety of the patients, the safety or health of users or, where applicable, other persons (…)

The characteristics and performances (…) must not be adversely affected to such a degree that the health or the safety of the patient or the user and, where applicable, of other persons, are compromised during the lifetime of the device"

Furthermore, the risk must be compatible with a high level of protection of health:
-Any risks which may be associated with their (..) use must/are (…) be compatible with a high level of protection of health and safety(Directives 98/79/EC and 93/42/EEC)

-The devices (…) must not present any risk to the persons implanting them or, where applicable, to other persons. (directive 90/385/EEC)

Conclusion: The protection afforded by medical devices' legislation only applies to the use of the medical device itself. The risk to human health arising from the use of the substance in the medical device is thus only managed during this stage of the substance's life-cycle. The risk arising at other stages – and, particularly, the integration of the substance in the medical device (especially the risk for workers at that stage) – and the environmental risk are not managed.

2. The phrasing and location of the exemption in the REACH regulation indicates clearly that an application must be filed:

In **Art.62** (Applications for authorisations):
-paragraph 6 states that "the application **shall not include** the risks to human health arising from the use of a substance in medical devices (…)"
Conclusion: The mere fact of specifying what the application shall not include presupposes that the application in question does exist.

Moreover, the exemption is written in chapter II "granting of authorization", instead of in chapter I "authorization requirement" or in article 2 "application" of REACH, which suggests that the obligation to request an authorization does exist.

Final conclusion on the exemption concerning the risks to human health arising from the use of a substance in a medical device (articles 60(2) and 62(6)):

Therefore, for use in medical devices, a dossier for authorization has to be submitted, but the dossier doesn't need to consider the aspects linked to the impact on human health of the use of the device, intended for the final user.
However, all risks arising before and during the incorporation of the substance into the device (for workers, for human health via the environment) need to be assessed, in order to authorize the use(s).

We regret the use of preamble 18 of Regulation 143/2011 for what we consider as a misinterpretation of art.60(2) and 62(6) of the REACH Regulation (EC) No 1907/2006.