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Who can mandate the responsible person?

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Current legislation

Who can mandate a Responsible Person (article 4.4 and 4.5 regulation 1223/2009/EC)?

- When the manufacturer is located in the EU, he can appoint another EU entity as the responsible person.
- When the manufacturer is located outside the EU, he can appoint an EU entity as the responsible person if the products are manufactured in the EU (and not imported and exported back).
- When a manufacturer is located outside the EU, and the products are manufactured outside the EU, it is the importer who is the responsible person "by default". The importer can appoint another EU entity as responsible person.

Issues arising from the article 4.4 and 4.5 regulation 1223/2009/EC

This particular situation may pose several **practical** problems, e.g.:

- Some non EU manufacturers will sell their products directly to the end user, with no importer involved (e.g., internet sales);
- To secure product compliance, most of non-EU manufacturers would like to mandate a Responsible Person before they will have an importer. Indeed, in practice, importers will usually refuse to buy products which are not already in compliance (e.g. notified by an RP) or simply refuse to become responsible person as they neither have the expertise, skills or the resources to fulfill such tasks.
- It is not likely for importers to accept holding a product information file (PIF) 10 years after the last batch has been manufactured. A period during which most of it, they might no longer distribute the product nor have any relations with the specified manufacturer; in the same way, it is not likely for manufacturers to accept handing over their product specifications and unique formulations to entities which have a commercial interests (such as importers) with the product, under relations which can be terminated at any turning commercial events (sales, disagreement on prices and more);

Non-EU manufacturers producing outside the EU should therefore be entitled to mandate themselves the Responsible Person, which does not seem to be foreseen in the current regulation. Also they should be entitled to mandate an EU entity other than the importer to become the responsible person. It should be their legal right to decide whether they would like to mandate the importer or another entity to that effect. Indeed this should not be dependent on the exclusive importer's decision. In the last instance, products belong to their manufacturer. They should be entitled to decide to which EU entity they would like to entrust their own product's conformity[i].

Proposal for amendment of the article 4.5 regulation 1223/2009/EC

To tackle the legal uncertainty as to whether the non-EU manufacturer producing outside the EU may designate an EU Responsible Person, ERPA proposes to amend the current regulation as follows :

"Article 4.
4 .Where, for a cosmetic product manufactured within the Community, and not subsequently exported and imported back into the Community, the manufacturer is established outside the Community, he shall designate, by written mandate, a person established within the Community as the responsible person who shall accept in writing.

5. For an imported cosmetic product, each importer shall be the responsible person for the specific cosmetic product he places on the market, except if the non-EU manufacturer has already designated, by written mandate, a person established within the Community as the responsible person who shall have accepted in writing."

About ERPA
ERPA is the European Cosmetics Responsible Persons Association. More information: http://www.erpacosmetics.org/

[i] See for example the so-called REACH regulation for the Only representative appointment, or the Medical devices directive , as well as the decision of a common framework for the marketing of products. Although we can agree that the RP and OR concepts might slightly vary, new approach directives and other EU regulation allow non-EU manufacturers to appoint the OR or Authorised Representative :

a) REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
"Article 8
Only representative of a non-Community manufacturer
1. A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.
2. The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.
3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation. »;

b) COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices "Article 14.2.
Where a manufacturer who places a device on the market under his own name does not have a registered place of business in a Member
State, he shall designate a single authorised representative in the
European Union (…)".

c) DECISIONS ADOPTED JOINTLY BY THE EUROPEAN PARLIAMENT AND THE COUNCIL DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC
"Article *R3* **Authorised representatives** 1. A manufacturer may, by a written mandate, appoint an authorised representative. (…) 2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
   a. keep (…) the technical documentation at the disposal of national surveillance authorities
   b. for … [period to be specified in proportion to the lifecycle of the product and the level of risk];
   c. further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product;
   d. cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by products covered by their mandate. »