REACH and MDR hazardous substances

REACH is the abbreviation for 'Registration, Evaluation and Authorization of Chemicals'. REACH requires manufacturers and importers to register all chemicals produced or imported in significant quantities in the European community. REACH demonstrates the European desire to participate very actively in the global concern about the effect of human activities on society and the environment.

Registration

Under REACH medical devices distributed in the EU are articles. This determination is based on the "Guidance Document on Substances Contained in Articles" published by the European Chemical Agency (ECHA, 2017). According to this guidance document, substances contained in articles do not need to be registered except where a substance exceeds 1 metric ton per year per manufacturer or importer and the substance is intended to be released from the article (see Figure 1).

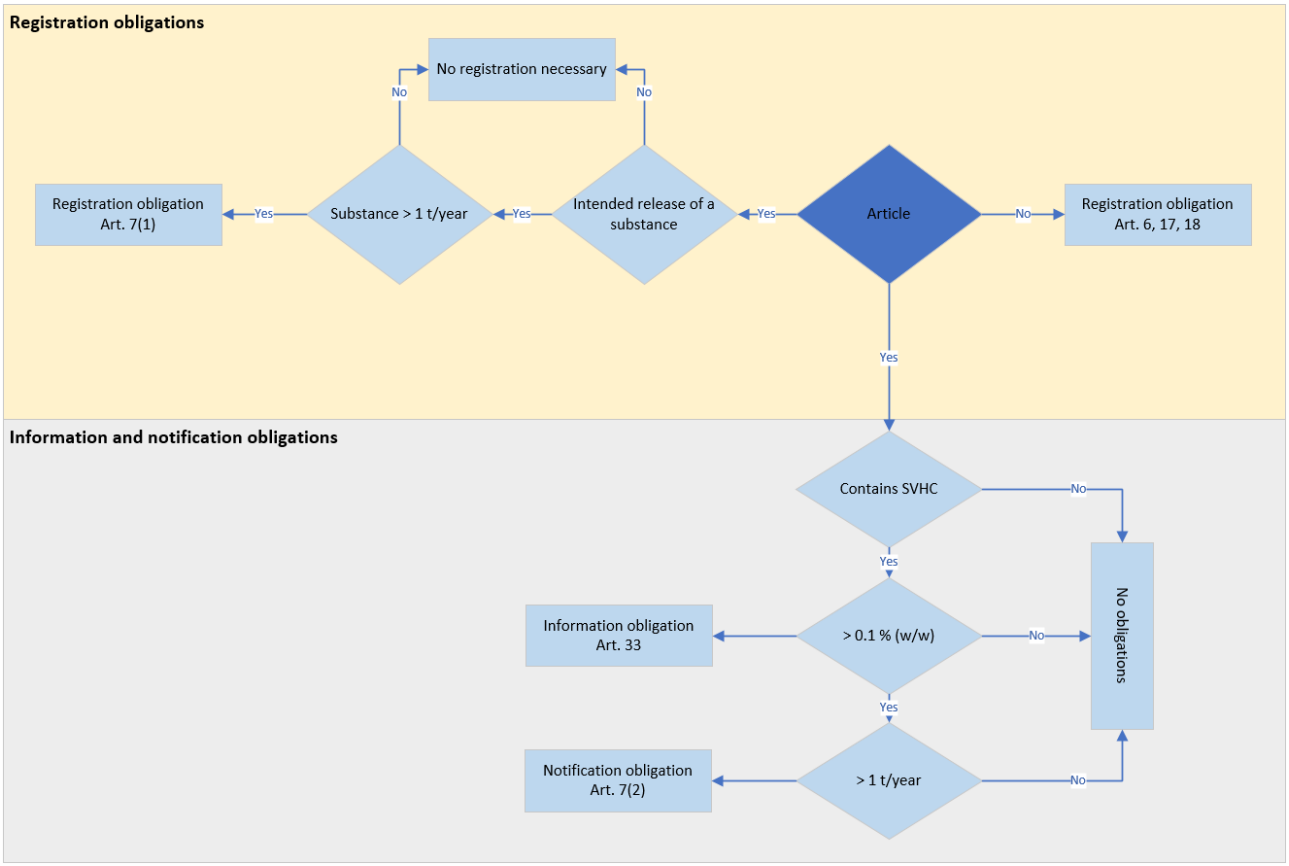

Figure 1 Registration, information and notification obligations for articles under the REACH regulation

Substances presenting a significant risk - Substance of Very High Concern - (SVHC)

For articles containing a substance classified by the ECHA Agency as a substance presenting a significant risk - Substance of Very High Concern - (SVHC) with concentrations greater than 0.1% by weight, the manufacturer or the importer is in the obligation to inform the recipients of the article of the presence of the substance and the conditions of safe use of the article (see Figure 1).

The information is to be provided to the recipient of the article when the article is supplied for the first time after the inclusion of the substance into the candidate list and to the consumer upon request by that consumer, within 45 calendar days of that request and free of charge. If no particular information is necessary to allow

safe use of the article containing a candidate list substance, e.g. when exposure can be excluded at all life cycle stages of the article including disposal, as a minimum the name of the substance in question has to be communicated to the recipients of the article or to the consumers. The information provided should make it clear that the substance is on the most recent update of the candidate list and that this is the reason for giving the information. It has to be noted that there is no tonnage trigger for the information obligation. According to Article 33(1) and Article 33(2) the following two conditions are sufficient:

- The substance is included in the candidate list for authorization (ECHA, n.d.-b), and
- The substance is present in articles produced and/or imported above a concentration of 0.1% (w/w)

The identification of a substance as an SVHC and its inclusion in the candidate list for authorization (ECHA, n.d.-b) under certain conditions additionally triggers notification obligations for EU producers and importers into the EU of articles that contain the substance.

The notification obligation of importers and producers of articles is described in Article 7(2) of the REACH regulation and aims at providing European Chemical Agency (ECHA) and the Member State competent authorities with information on the presence of Candidate List substances in articles. This information may be used to identify a need for initiating regulatory risk management procedures under REACH (authorization and restriction) or under other EU legislation. For the notification obligation to take effect, the conditions of for the information obligation have to be met, as well as the following:

- The total amount of the substance present in all articles produced and/or imported, which contain more than 0.1% (w/w) of the substance, exceeds 1 tonne per actor per year

According to the ECHAs guidance on requirements for substances in articles (ECHA, 2017) a notification is not required for a substance in articles which have been produced or imported before the substance has been included in the candidate list for authorization.

Restriction and authorization

The next step in the REACH process, which is subject to public debate, is to assess whether a substance from the candidate list will be added to the authorization list (Annex XIV). The substances listed in Annex XIV (ECHA, n.d.-a) will need an authorization for each of their uses. Substances will be regularly added to the candidate list and the priority for addition of substances to Annex XIV is reviewed every two years.

The purpose of the authorization is to ensure that the risks posed by the substances presenting a risk are properly controlled or that a substitution is made if this is economically and technically possible. The regular update of the candidate list is a first step in the identification of substances that may require authorization for their use.

It is expected that the authorization work by ECHA will identify approximately some 25 substances that are added to the authorization list. Since the European Commission has decreed that the substances contained in articles are not subject to authorization, medical devices are unlikely to require authorization unless a substance on the authorization list is incorporated in a newly developed product.

MDR hazardous substances and REACH

According to the MDR regulation (MDR 2017/745, 2017) invasive components shall only contain “hazardous substances” in a concentration that is above 0.1% (w/w) where justified. The definition of hazardous substances according to MDR is shown in Figure 2. Hence, substances from the REACH candidate list are a subset of MDR hazardous substances. However, MDR hazardous substances do not coincide with the REACH candidate list, since MDR hazardous substances additionally contain CMR substances of Annex VI of the CLP

regulation. The REACH candidate list also contains CMR substances. However, CMR substances from the REACH candidate list and the CLP Annex VI do not match completely since regulatory process for the classification and inclusion of substances differ between the two lists (ECHA, 2012, 2020). For example, Cobalt (CAS 7440-48-4), one of the substances that currently requires labelling under MDR, has recently been added to CLP Annex VI as a CMR substance and is not included in the REACH candidate list.

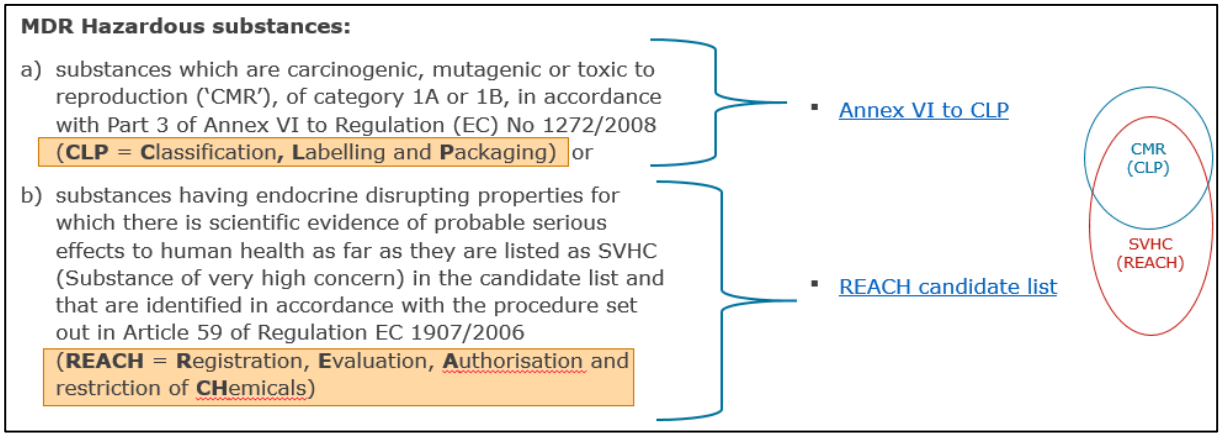

Figure 2: MDR hazardous substances

Conclusion

If the portfolio of a medical devices manufacturer includes an article with an identified hazardous substance above the 0.1% (w/w) limit that originates from the REACH candidate list, the information and notification obligations of the REACH regulation are relevant for these articles. Updates to the REACH candidate list should be followed to ensure compliance with the REACH regulation.

Author note

Please note that the above information has been put together on the basis of the authors current knowledge of the REACH regulation and guidance's. Please note that new interpretations and guidance may affect the conclusions made in this document.

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