

MedTech Europe Views on the European Commission Delegated Regulation amending Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards Dechlorane Plus

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MedTech Europe welcomes the opportunity to comment on the European Commission draft delegated Regulation amending Regulation (EU) 2019/1021 to include Dechlorane Plus¹. This substance is used in several medical technologies, including both medical devices (MDs) and *in vitro* diagnostic medical devices (IVDs). MedTech Europe welcomes the SC-11/10 Stockholm Convention listing of Dechlorane Plus, which foresees derogations for replacement parts for **both medical devices and IVDs** under Part XI, 3(a) & 3(b) respectively². This decision entails that from a global perspective, medical devices and IVDs and spare parts that are manufactured with Dechlorane Plus, can continue to be used. However, the proposed implementation of this Stockholm Convention listing made by the European Commission in the draft delegated Regulation subject to public consultation until 24 July 2024, **omits** to include the derogation for replacement parts for medical devices and IVDs, which is already adopted at the Stockholm Convention level.

We would therefore like to call on the Commission to **amend its implementing draft Regulation on Dechlorane Plus to align with the derogations in the Stockholm Convention listing and therefore include both the medical device and IVD spare part derogations**.

The EU must remain consistent in its implementation of the inclusion of exemption decisions stemming from the international level. Decisions on exemptions taken at an international level are an important means to avoid the fragmentation of rules across regions. However the exact implementation should reflect EU specificities including the necessary timelines to implement, and for industry to transition. The derogation for spare parts for both medical devices and IVDs is relevant not only from a consistency standpoint, but also supports the 'repair as produced principle' which is applied in EU chemical legislation, such as RoHS, and is an important tool in achieving a circular economy, which is supported by the EU and MedTech Europe. The need for aligning chemical regulations and exemptions is also highly relevant in the context of the 'One Substance, One Assessment' approach that the EU is striving for. The industry, as well as authorities, enforcement organizations, users, all need predictability and consistency in chemical legislation.

¹ Available at the link here: [Persistent organic pollutant - dechlorane plus \(europa.eu\)](https://europea.europa.eu/persistent-organic-pollutant-dechlorane-plus)

² Available at the link here: <https://www.pops.int/Portals/0/download.aspx?d=UNEP-POPS-COP.11-SC-11-10.English.pdf>

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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