



EUROPEAN COMMISSION

INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMEs DIRECTORATE-GENERAL
Consumer, Environmental and Health Technologies

REACH

Brussels, 7/7/2017

Meeting with W. L. Gore Associates

7 July 2017

Participation

- [REDACTED] (both W.L. Gore Associates), [REDACTED] (cambre Associates)
- For DG GROW: [REDACTED] (D4), [REDACTED], [REDACTED] (D1)

Background

W.L. Gore Associates requested the meeting to discuss the possible implications of listing perfluorooctanoic acid (PFOA) as a persistent organic pollutant (POP) under the Stockholm Convention. Gore is a producer of medical devices containing PFOA. On 4 July 2017 a restriction on PFOA under REACH entered into force. This restriction contains time-limited exemptions for non- implantable medical devices (until 4 July 2032) and an exemption without time limit for implantable medical devices. Gore asked for the meeting to discuss how to ensure that similar exemptions as those under REACH are introduced under the Stockholm Convention.

Summary of the meeting

The representatives of Gore explained that they produce almost exclusively implantable medical devices, for which the REACH restriction foresees an exemption without time limit. Those medical devices are manufactured of the polymer polytetrafluorethylene (PTFE) with PFOA as an additive. Gore has already found for many of their medical device products alternative substances to PFOA, however, there are still some medical devices (e.g. stents) for which a substituting substance is not available yet. Even if they are actively working in a replacement their best estimations to implement it are for 2025-2030. Gore highlighted that these medical devices are for treating serious life threatening conditions of patients.

Gore asked how to best provide information to the bodies under the Stockholm Convention to ensure that exemptions for medical devices containing PFOA are included once the substance will be listed in one of the Annexes of the Convention.

The COM representatives explained the procedures under the Stockholm Convention. The POP Review Committee (POPROC) has drafted a risk management evaluation document according to Annex F of the Stockholm Convention. For this purpose, the POPROC launched a call for information, which ended on 12 May 2017 (remark: W.L. Gore Associates was not aware of the call for information, which shows the difficulties of companies to be informed about such calls). The COM representatives gave the advice to nevertheless submit information to the Secretariat of the Stockholm Convention, if Gore would deem this to be necessary. Furthermore, the COM representatives said they expect the POPROC to finalise its work at its next meeting in October 2017 and to forward then a recommendation for listing PFOA under one of the Annexes and possibly for exemptions. The current draft risk management evaluation document is mentioning an exemption for "medical devices (time limited or not; Annex A/B)" as possible conclusion. The COM representative promised to Gore to send a link to the website of the Stockholm Convention, at which the draft document is listed. The Commission will probably have to decide on the mandate to be asked from the Council between early 2018 and early 2019, since the next meeting of the Conference of Parties under the Stockholm Convention will convene in April/May 2019.

[REDACTED]