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

REACH

Brussels, 5/9/2018

Meeting with W. L. Gore Associates
4 September 2018

Participation

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

Background

W.L. Gore Associates requested the meeting to discuss the developments on the ongoing work under the Stockholm Convention as regards a listing of perfluorooctanoic acid (PFOA) in one of the annexes of the Convention and their arguments to advocate for time-limited exemptions for medical devices.

In the EU the existing restriction on PFOA under REACH that entered into force on 4 July2017 contains time-limited exemptions for non- implantable medical devices (until 4 July 2032) and an exemption without time limit for implantable medical devices.

This meeting was a follow-up to the one that took place on 17 July 2017.

Summary of the meeting

The representatives of Gore briefly explained their product portfolio: The draft Risk Management Evaluation document according to Annex F of the Stockholm Convention distinguishes between implantable (e.g. stents, membranes for hernia repair) and non-implantable medical devices and medical textiles (such as surgical drapes). Ca. 95% of devices put by Gore on the market belong to the first group, 5% to non-implantable medical devices. The company does not manufacture medical textiles.

Gore informed that only some of their devices currently still contain polytetrafluorethylene (PTFE) manufactured with PFOA as an additive. Gore has already substituted PFOA for many of their products and they envisage being able to fully replace the substance by 31 March 2019. However, since some medical devices have a shelf life of 3-5 years, a time-limited exemption under the Stockholm Convention is required. Another reason appears to be that the regulatory approval process in some geographical areas (including Europe) is not yet finalised for all products. Gore mentioned that they currently use an amount of PFOA in the range of several grams per year.

Gore is providing actively input to the POP Review Committee via the Medical Technology Industry Association (MedTech). The Associations asked to grant time-limited exemptions for the use of PFOA in medical devices until 2030. According to Gore, all member companies of MedTech are confident to be able to replace PFOA by then.

The COM representatives briefly explained the procedures under the Stockholm Convention as well as the procedures leading to an EU position on proposals of listing a substance under the Convention.

COM asked which alternative substances are used by Gore, pointing to that several of the substances listed by the POP Review Committee in the draft Risk Management Evaluation document are substances for which regulatory measures are anticipated (e.g. siloxanes for the production of polydimethylsiloxane (PDMS); short chained per- or polyfluorinated substances). The company representative replied that the alternative substance was mentioned in the REACH Annex XV restriction dossier.

[redacted]