From: [redacted]@wlgore.com>
Sent: mercredi 12 septembre 2018 22:46
To: [redacted] (GROW); [redacted] (GROW); [redacted]@ec.europa.eu
Cc: [redacted]
Subject: Thank you!

Categories: consider later

Dear [redacted], [redacted] and [redacted],

I just wanted to send a follow-up email and thank you for your time last week. I sincerely appreciated the opportunity to talk with you about Gore's medical devices and our progress in completely phasing out fluoropolymers made with PFOA. Gore fully supports the European Commission's objective to curb all future uses of PFOA as well as the broader effort of the Stockholm Convention.

I also hope the information provided was helpful in understanding the need for a time-limited exemption for PFOA in implantable medical devices. Recognizing the clear challenges of transitioning to non-PFOA material for implantable medical devices, the broader socioeconomic concerns over production/supply of medical devices, and the extremely small amount of PFOA presented to the market by implantable medical devices, Gore considers it appropriate for the POPRC to recommend a modest exemption for implantable medical devices.

To recap our discussion, the main points of our position are as follows:

- Fluoropolymers are a critical component in the manufacture of implantable medical devices. Gore has chosen fluoropolymers as a key material in our implantable medical devices for over 4 decades due to it's biocompatibility, durability, strength, and resistance to degradation.
- Historically in the creation of some fluoropolymers, PFOA was used as a manufacturing aid during the emulsion polymerization process. Gore no longer purchases fluoropolymers manufactured with PFOA.
- For Gore's manufactured implantable medical devices, the PFOA is an unintended residual from the fluoropolymers used. The PFOA residual level in these fluoropolymer materials is less than 1 ppm.
- The remaining fluoropolymers that contain PFOA will be full transitioned out of Gore's manufacturing process by March 31, 2019. The remaining implantable medical devices containing fluoropolymers made with PFOA will be fully transitioned out of the market place by 2025.
- Taking into account all of Gore's medical devices sold globally, the aggregate amount of PFOA is less than 2 g, annually. With our phase out plan in place, the total amount of PFOA in our medical devices will drop to zero after 2025.
- Gore is encouraging the POPRC to recommend a time-limited exemption (through to 2030) to the COP as it relates to the listing of PFOA in implantable medical devices.

If you or your colleagues from the medical device unit have any additional questions about Gore or our implantable medical devices, please do not hesitate to contact me directly.

Best regards,

[redacted]

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