[redacted] [redacted]

From: ECHA Restriction PFAS
Sent: 19 September 2023 14:05
To: [redacted]@astrazeneca.com'
Cc: ECHA Restriction PFAS; [redacted]@echa.europa.eu'
Subject: RE: Eurotox: PFAS discussion

Dear [redacted]

Thank you very much for your message and submission to the consultation on the broad PFAS restriction proposal.

Please note that the consultation webform on ECHA's website is the official input channel for submission of comments on the restriction proposal. We would like to assure you that ECHA's committees will assess all information submitted via the official input channel before the consultation deadline, and will consider any relevant and substantiated information received in their opinions.

If you consider that a derogation or a longer transition period for your use is justified, then you must submit relevant information and supporting evidence in the consultation. Requests for derogations and longer transition periods must be justified by risk or socio-economic arguments. Your submission should also include a sound justification for why the information is representative of the entire use or sector. More information can be found in the Information Note and the Consultation Guidance. The latter includes information on the implications of incomplete, unsubstantiated or no information submitted in the consultation.

For any further queries you may have, please kindly refer to the ECHA contact webform:
https://echa.europa.eu/contact

Best regards,
[redacted] on behalf of the universal PFAS restriction team

Universal PFAS Restriction Team
European Chemicals Agency
P.O. Box 400, FI-00121 Helsinki, Finland
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https://echa.europa.eu/

[#RESTOD-PFAS-1#]

From: [redacted]@astrazeneca.com>
Sent: Monday, September 18, 2023 2:25 PM
To: [redacted]@echa.europa.eu>
Subject: Eurotox: PFAS discussion

Dear [redacted]

Good to meet at EUROTOX this week. As discussed, you suggested that I share a brief summary of AstraZeneca's comments on the proposed PFAS restriction and signpost our ongoing submissions to the ECHA public consultation.

I should reiterate we support the goals of the restriction proposal and are committed to protecting the environment and public health as part of our broader sustainability efforts. This is evidenced by our development programme for a novel propellant for use in inhaled respiratory medicines, HFO-1234ze(E), which has near-zero Global Warming Potential (GWP).

HFO-1234ze(E) has been classified as a PFAS within the restriction proposal based on its chemical structure. However, comprehensive evidence demonstrates this substance is non-persistent, non-bio accumulative and non-toxic. This evidence is outlined in our first response to ECHA (Submission 4448), and we are providing further details via the portal in the next weeks.

Inhaled respiratory medicines are recognised by the World Health Organization and clinical guidelines around the world as essential life-saving medicines for millions with respiratory diseases, including vulnerable populations. Our work to transition our medicines to use of HFO-1234ze(E) represents important climate action, as this is the only propellant able to meet targets of the Kigali Amendment to the Montreal Protocol, with 100x less GWP than the alternative - HFC-152a - which is subject to phase-down within the EU's F-Gas regulation.

To avoid the unintended consequence of limiting patient access to essential medicines and risking the transition to environmentally-friendly respiratory inhalers, AstraZeneca has requested an exemption for HFO-1234ze(E) from the PFAS restriction.

Thank you for your consideration.

Kind regards,

[redacted]

[redacted]

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