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

REACH

Brussels, 4/2/2019

Meeting with AstraZeneca and Daizin
REACH PFOA Restriction and the Stockholm Convention
1 February 2019

Participants

- [redacted], [redacted], AstraZeneca
- [redacted], Daikin
- [redacted], Kreab
- [redacted], Kreab

DG GROW: [redacted], [redacted]
DG ENV: [redacted], [redacted].

Background

- The meeting was organized at the request of AstraZeneca a pharmaceutical company, and Daikin, leading producer of fluoroproducts (Manufacturers of PFOI/PFOB).
- ECHA opinion submitted on 6 November 2018 supported the derogation under REACH based on the minimized emissions, the lack of suitable alternatives and the significant economic and social costs in case the use is restricted. SEAC recommended derogation no limited in time.
- In a meeting in mid-January 2019, ENV informed them that "the EU" (in fact DG ENV) would like to align the time granted for the derogation with the proposal from the POPRC i.e. a derogation until 2036, and not to follow ECHA opinion that recommends a no time limit derogation for the use as described in the application.
- ENV wants to push for the inclusion of PFOAs into Annex A to the Stockholm convention (SC) and not Annex B. Derogations (= specific exemption in the jargon of the SC) of substances listed in Annex A are in general time-limited. ENV demands now that all suggested derogations under REACH are time-limited. as According to ENV, supporting a derogation under REACH without a time-limit will undermine their position in the Council discussions (in February) and in the Council of Parties (meeting in April-May). For ENV this is a political decision.

Discussions

- AstraZeneca representatives confirmed that the REACH PFOA restriction derogation is not in contradiction with the Stockholm convention and that without a no-time limit derogation under REACH **they will not invest in the new plant in Sweden and they will take the production to the US.**

- ENV argued that under the Stockholm convention discussions the companies accepted this time limit until 2036. AstraZeneca explained that they tried to get as much as they could to understand EU position and that their plans is to be able to manufacture PFOB as an on-site close system intermediate that would benefit from a general exemption under the convention. Then they will still need the derogation for the impurity threshold on PFOI.

  AstraZeneca confirmed that they are in contact with the Japanese authorities and that Sweden and France support the no time limit derogation as well.

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- GROW highlighted that this is the discussion under REACH where ECHA has given an opinion on the support of the no time limit derogation. All the conditions to grant it are met under REACH.
- GROW said it needs to be checked whether the proposed derogation under the Stockholm Convention with time limit is compatible with the derogation without time-limit under REACH (same of different scope of derogation?). There is in particular a need to check whether the Stockholm convention prohibit the use or export of a non-POP substance containing a POP as an unintentional trace contaminant and whether the Stockholm Convention sets thresholds such trace contaminants.

Conclusions of the meeting

1. Confirmation from industry that without the no time limit derogation they will take the production to US.
2. Confirmation from ENV that they will support derogation under REACH only until 2036
3. Need to explore possibilities under the Stockholm convention to permit some threshold presence of PFOI in PFOB

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