



EUROPEAN COMMISSION

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

REACH

Brussels, 12/3/2019

Meeting with AstraZeneca and Daikin **REACH PFOA Restriction and the Stockholm Convention** **22 February 2019**

Participants

[REDACTED], AstraZeneca

[REDACTED], Daikin

[REDACTED], Kreab

[REDACTED], Kreab

DG GROW: [REDACTED], [REDACTED], [REDACTED]

- AstraZeneca representatives confirmed that the decision on whether further investing in the existing Swedish plan is postponed waiting for the decision on whether the REACH derogation will be limited in time (until 2036).
- It was confirmed that substitution of PFOB by another processing aid would require a change in the specification of the pharmaceutical product leading to a need to undergo an approval process again, which includes carrying out clinical trials in particular to prove safety and efficacy (required by pharmaceutical legislation).
- Astrazeneca confirmed that there is no risk to workers in the manufacture and that with regards to emissions into the environment, there is an alarm system in case of higher emissions and that the estimation of the emissions is maximum 4 g per year (worst case). Swedish authorities are happy about the controls in place.
- The number of workers currently working in France is 450. In Sweden, numbers will increase from 20 now to potentially 120 when the production capacity increases.
- GROW explained that DG ENV will not agree for the moment to a no time-limit derogation under REACH due to their position of pushing for the inclusion of PFOA and its related substances into Annex A of the Stockholm Convention with having only time-limited derogations

Conclusions of the meeting

1. It was proposed to wait until the Conferences of Party (COP) under the Stockholm Convention which takes place from 29 April to 10 May. If the EU mandate is finally agreed by the Council and if the COP of the Stockholm convention has adopted a decision to list PFOA and its related substances under the Stockholm Convention, the argument of DG ENV of undermining the negotiation position of DG ENV or the EU is not valid any more, and all other arguments can be used to agree for a no time limit derogation under REACH:
 - 1- No time limit derogation under REACH is supported by RAC and SEAC
 - 2- This derogation with emission of 4 g/year (worst case scenario) can be duly justified in

terms of risk and proportionality.

- 3- For the future transposition of the COP decision of listing PFOA and its related substances into the EU POPs Regulation, it is the EU setting the threshold for an unintentional trace contaminant (UTC) such as PFOI. The Commission could propose a threshold for PFOI that allows the import and use of PFOB containing PFOI.
2. Astrazeneca confirmed that the proposal to wait until after the COP, i.e. around May/June, to consider further how to bring forward the exemption request under REACH without a time limit was acceptable to them.

END