



EUROPEAN COMMISSION

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

REACH

Brussels, 27/5/2019

Meeting with AstraZeneca and Daikin
REACH PFOA Restriction and the Stockholm Convention
7 May 2019

Participants

[REDACTED], AstraZeneca

[REDACTED], Daikin

[REDACTED], Kreab

DG GROW: Carlo Pettinelli, [REDACTED], [REDACTED]

DG ENV: [REDACTED]

AstraZeneca requested a meeting with Timo Pesonen in view of the non-progress of their request for a derogation for the use of a perfluorooctanoic acid (PFOA)-related substance, i.e. perfluorooctyl bromide (PFOB) containing perfluorooctyl iodide (PFOI) for the production of pharmaceutical products for the treatment of respiratory diseases under entry 68 of Annex XVII to REACH.

Following several meetings at service level, Astrazeneca was now asking DG support to proceed quickly with the adoption of the derogation under REACH as this is a key factor to decide on additional investment in the Swedish manufacture plant.

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).

Carlo Pettinelli asked the reason why 15 years is not sufficient time to find an alternative.

Astrazeneca representatives explained that the 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 under pharmaceutical legislation, which includes carrying out clinical trials in particular to prove safety and efficacy.

Carlo Pettinelli was surprised to see the time and resources needed so far for finding an agreement with DG ENV on this derogation when the total emissions to the environment is estimated to be at maximum 4 g/year. 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 which are maximum 4 g per year (worst case).

DG ENV representative explained the recent listing of PFOA and related substances under Annex A of the Stockholm Convention, which contains a derogation with a time limit until 2036 for the use of PFOI for the production of PFOB for manufacturing a pharmaceutical product. DG ENV raised doubts whether the import into the EU of PFOB containing PFOI would still be permitted after 2036. DG GROW does not agree with this interpretation: after 2036, the company could still use PFOI under the Stockholm Convention to produce PFOB as a closed system site limited intermediate. PFOI could in this case considered being an "Unintentional Trace Contaminant" (UTC). The threshold defining UTCs is not specified under the Stockholm Convention, but it is the EU setting this threshold. Therefore, the REACH derogation is needed

to import the PFOB containing PFOI above 1 ppm.

Carlo Pettinelli informed that DG GROW and ENV will continue to discuss this issue at technical level to try to find a solution to the currently stalled decision on whether the derogation should be limited until 2036 or not, as recommended by RAC and SEAC.

END