



EUROPEAN COMMISSION

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

REACH

Brussels, 3/7/2019

Meeting AstraZeneca /Cabinet Bienkowska

REACH PFOA derogation to ensure continuation of medicines production in Europe

2 July 2019

Participants

[REDACTED] AstraZeneca

[REDACTED], AstraZeneca

[REDACTED] Kreab

Cabinet: [REDACTED]

DG GROW: [REDACTED], [REDACTED]

AstraZeneca (AZ) requested a meeting in view 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.

[REDACTED] stressed that the derogation is required before entry into effect of REACH restriction on PFOA on 4 July 2020, otherwise EU production in Sweden will have to be discontinued.

AZ has invested EUR 160 million in the plant in Sweden where the production takes places under high environmental and safety standards. The company has an alternative facility in the USA. AZ is postponing the final decision on additional investments in this plant with a potential creation of 100 additional jobs pending on the decision on whether the REACH derogation will be limited in time (until 2036 as now agreed under the Stockholm Convention for the manufacture of PFOB). AZ needs longterm perspective and assurances to be able to continue to use the substance beyond 2036 for approval of further investments in the plants in Sweden and France.

AZ highlighted that the emissions of POP (Persistent Organic Pollutants) to the environment is quasi absent in Sweden with an estimation already for the possible increased production in 2025 of maximum 4 g/year which is the limit at which the alarms will prevent higher emissions.

The Stockholm Convention has a 2036 expiry date for the manufacture of PFOB (with no reference to impurity thresholds), after which AZ would have to use alternative methods of sourcing PFOB but still the derogation to import into the EU would be needed. AZ has another site in the USA that could host the production without a deadline (as US is not contracting party to the Stockholm Convention), however with not such high environmental protection standards as in Sweden. 2036 limit derogation would risk moving jobs and expertise from the EU to the USA for no environmental benefit as the 2036 deadline on the impurity threshold would be imposed only in the EU

AZ clarified that the impurity presence of PFOI in the PFOB is a result of the production process, which does not allow to remain below this requested threshold limit; furthermore it is according to AZ not possible that the process can be optimized to meet the current threshold of 1 ppm (as laid down in the REACH entry 68). The typical concentration range does not exceed 200 ppm, 250 ppm includes a safety margin. Despite extensive efforts, suitable alternatives to PFOB have not been identified.

ECHA's time unlimited recommendation takes into account (1) demonstration of quasi absence of emissions and (2) socio-economic benefits of maintaining the production of the medicinal product.

██████████ welcomed the explanations. He referred to the 16 years-derogation (in case a time limit of 2036 is set) which is in the REACH context a very long period, even if it is clear that the risks are low in this case. The argument to have a long-term legal certainty for future investments is not sufficient to defend the case in discussion with other services. AZ is invited to come forward with a stronger argument. Alternatively, he asked whether the inclusion of a review clause together with the 2036 deadline could be satisfactory to AZ.

██████████ suggested AZ to ask for a meeting with Commissioner Vella cabinet, with whom Commissioner Bienkowska co-shares the responsibility of the REACH Regulation in order to clarify the issues with them as well.

AZ informed that they have requested for meetings at high level in DG ENV, which were so far not accepted.

END