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

REACH

Brussels, 26/1/2018

Meeting with AstraZeneca and Daizin
REACH PFOA Restriction and the Stockholm Convention
25 January 2018

Participants

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

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

Background

The meeting was organized at the request by [redacted] (Kreab[redacted]) for AstraZeneca a pharmaceutical company, and Daikin, leading producer of fluoroproducts and air-conditioning company.
The topic for discussion is the need for and exemption for the use of PFOB containing traces of PFOI for the production of certain pharmaceuticals. PFOI is a PFOA related substance covered by the REACH PFOA Restriction

The pharmaceutical product under concern

The pharma product under concern is a new generation of inhaled pharmaceutical products (pressurised metered-dose inhaler medicines =pMDI). The pMDI medicines are manufactured using the "Co-Suspension™ Technology that contains low-density phospholipid porous particles. These porous particles are a functional component which provides for uniform suspension and an optimal distribution of drug crystals in the lungs for alleviation of lung diseases such as Chronic Obstructive Pulmonary Disease (COPD).

The manufacture of the porous particles uses perfluorooctyl bromide (PFOB) as a processing aid, which is critical to delivering the unique aerodynamic properties of the porous particles, which ensures the efficient delivery of the medicine to the lungs.

AstraZeneca has manufacturing capability in Snäckviken, Sweden for the production of porous particles. The suspension manufacture and filling into cans is performed in France and the UK.

Legislation

PFOB is not restricted in the EU or harmful to humans. The company informed us that the PFOB is produced outside the EU and that the PFOB they use typically contains up to 200 ppm traces of PFOI. PFOI is a PFOA-related substance covered by the REACH restriction with a threshold of 1 ppm.

As there is no exemption for that use in the restriction, this would no longer make the import of PFOB to Europe possible after the entry into effect of the Restriction on 4 July 2020 and as a consequence the

porous particle manufacture described at the manufacturing facility in Sweden will need to be discontinued, with significant knock on effects for onward manufacturing activities in France and the UK.

PFOB is approved by the FDA for medicinal use.

Currently, PFOA and related substances are also assessed as potential persistent organic pollutant (POP) under the Stockholm Convention, with the aim to ban manufacturing and uses of those substances. Similar as in the REACH restriction, PFOI would be subject to the ban. The Persistent Organic Pollutants Review Committee (POP Review Committee of the Stockholm Convention), which met in Rome 17th – 20th October 2017, proposed in its risk management evaluation the exemption that the company is asking:

"(an exemption) For use of perfluorooctane iodide, production of perfluorooctane bromide for the purpose of producing pharmaceutical products with a review of continued need for exemptions. The specific exemption should expire in any case at the latest in 2036.

It is anticipated that the UNEP exemption described above will be adopted by the European Union eventually, but a time gap is expected between the entry into effect of the REACH PFOA Restriction and the amended POP Regulation, the length of which cannot be determined.

The request

AstraZeneca is asking for an exemption to the existing REACH restriction to ensure there is not a temporary gap, which would force AstraZeneca to move the manufacture outside the European Union, or withdraw the medicines from sale, with potential negative impacts for patients.

AstraZeneca explained they are now in the process to decide on further important investment in the Swedish site and that they would need some certainties to make the decision. If the derogation is not granted they would need to move the manufacture to the US, which is not their preferred option.

Our analysis

Daikin and AstraZeneca presented the risk assessment, analysis of alternatives and socio-economic assessment, in order to support their exemption request under the REACH PFOA Restriction (enclosed).

They explained that they were not aware about the presence of PFOIs at the time of the discussions on the restrictions, and as PFOB was OK they thought they were not affected.

Proposed way forward

We discussed with ENV colleagues after the meeting. We agreed that the request for a derogation is well founded and to go ahead with the requested derogation.

This would be (to our knowledge) the first time that a restriction is revised to include a derogation after adoption of the restriction. The next steps need to be explored with the lawyers and the LS.

What we preliminary discussed with ENV was as follows:

1. To include the point as AOB to explain the case to the February REACH committee. AstraZeneca has already contacted Sweden and France on this and said they were going to contact other MS affected.

2. The COMM either (a) drafts a legal text or (b) informs the REACH committee ((a) or (b) to be agreed and decided with legal colleagues) on the need to amend Annex XVII entry 68 - Ideally this should be done by June committee.

   Article 69.5: *…if it is proposed by either a Member States or the Agency that an existing restriction listed in Annex XVII should be re-examined a decision on whether to do so shall be taken in accordance to the procedure referred to in Article 133 (2) based on the evidence presented by the Member State or the Agency.*

3. COMM asks ECHA to prepare Annex XV dossier for the amendment of the restriction with the information provided by the company.

4. Following ECHA opinion, the Commission decides whether to propose and amendment of Annex XVII entry 68 to include the derogation for the requested use in the restriction.

Again, the correct procedure, especially the order of the different steps, needs first to be established by the units' lawyers/the LS.