

## **Note for the attention of Tim Bowmer, Chairman of the Committee for Risk Assessment, and of Tomas Öberg, Chairman of the Committee for Socio-economic Analysis**

**Ref: Request to the Committee for Risk Assessment and to the Committee for Socio-economic Analysis to review a derogation request for the restriction of perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (entry 68 of Annex XVII to REACH)**

The Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) are requested to prepare an opinion in view of a possible derogation from the existing Annex XVII restriction on perfluorooctanoic acid (PFOA), its salts and related substances. The RAC and SEAC opinions should be based on an analysis to be prepared by ECHA.

### **1. Background**

The Commission has received a request for re-examination of the existing restriction on PFOA and related substances (entry 68 of Annex XVII) in view of including a derogation for the use of PFOB for the manufacturing of certain pharmaceutical products using pressurised metered-dose inhalers for the treatment of pulmonary diseases.

The companies concerned have informed the Commission that the relevant products contain low-density phospholipid porous particles as a functional component indispensable for the efficient delivery of the medicine to the lungs. The manufacture of the porous particles uses PFOB as a processing aid and unavoidable traces of PFOI are present in the PFOB at around 200 ppm. Whereas PFOB is not restricted, PFOI is a PFOA-related substance covered by the REACH PFOA restriction under entry 68 of Annex XVII.

The companies concerned have provided the Commission services with documentation on risk assessment, analysis of alternatives and socio-economic assessment, in order to support their request. This information has been made available to ECHA.

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 17<sup>th</sup>-20<sup>th</sup> October 2017, proposed in its risk management evaluation a specific exemption for this same use.

## **2. Terms of Reference**

The Committees are requested to prepare an opinion in view of a possible derogation from the existing Annex XVII restriction on perfluorooctanoic acid (PFOA), its salts and related substances. The RAC and SEAC opinions should be based on an analysis to be prepared by ECHA, preferably in the form of a complement to the Annex XV dossier which supported the existing restriction.

## **3. Timescale for the RAC and SEAC opinions**

ECHA shall enter the relevant intention for the possible derogation of the PFOA restriction into the Registry of Intentions (RoI) no later than 1 month following the receipt of the letter from the Commission (dated 30 April 2018) with the aim of having a first discussion in the June 2018 RAC and SEAC meetings.

Given the limited scope of the derogation and taking into account that the information on risk assessment, analysis of alternatives and socio-economic assessment is already available, it is considered realistic that the analysis, can be prepared in a shorter time than usually required for the preparation of an Annex XV dossier. The Commission also requested ECHA to conduct a public consultation, for which the duration can be reduced compared to normal Annex XV-related consultations.

The Commission would like to receive the RAC and SEAC opinions with a view to the possible granting the requested derogation by 1 December 2018.

## **4. Remuneration**

The task for RAC and SEAC following from this request is not considered to fulfil any of the requirements of a transfer of funds to the competent authorities of the Member States pursuant to Article 14(1) of Regulation (EC) 340/2008 and therefore no remuneration will be paid by the Agency.

***[Signed]***

Bjorn Hansen  
Executive Director

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