EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR

"Evaluation of the availability and suitability of alternatives to hexaflumuron for PT18"

1. Background

(1) On 23 September 2020, Dow AgroSciences Switzerland S.A submitted to ECHA an application for the renewal of approval of hexaflumuron for PT18 "insecticides" in accordance with Article 13 of Regulation (EU) No 528/2012 on Biocidal Products (the BPR). This application is currently under examination by the competent authority of Greece.

(2) Hexaflumuron meets the criteria for being very persistent (vP), very bioaccumulative (vB) and toxic (T) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006, and therefore meets the exclusion criteria set out in Article 5(1)(e) of the BPR.

(3) The approval of an active substance meeting the exclusion criteria should not be renewed unless it is shown that at least one of the criteria set out in Article 5(2) is met. When deciding on whether the approval of an active substance may be renewed, the availability of suitable and sufficient alternative substances or technologies is a key consideration.

(4) During the last meetings of the Standing Committee on Biocidal Products and the Member States' Competent Authorities, discussions took place in order to find possible ways to streamline the renewal process of active substances meeting the exclusion criteria. Proposals were made to find ways to give early indications to the evaluating competent authority (eCA) whether the conditions for derogations from exclusion would be met or not. If there are indications that suitable and sufficient alternatives are available, the eCA could decide to speed up its work (for instance by renouncing to request additional data) with the objective to limit to the minimum the time necessary to be able to conclude the examination of the application. This would help to conclude the renewal process as soon as possible and, assuming that the active substance would not be renewed, the relevant procedures could be initiated to remove biocidal products containing the substance from the market.

(5) Among others, it was agreed during the 68th Standing Committee on Biocidal Products of 15 May 2020 that an opinion should be specifically requested from ECHA's Biocidal Product Committee at the beginning of the renewal examination of the concerned active substances on whether there are suitable and sufficient alternative substances and technologies for the use(s) referred to by the applicant.

(6) It is therefore necessary to obtain such opinions for hexaflumuron for PT 18 (insecticides) for the use(s) presented in the application for renewal.

(7) This work also contributes to the implementation of ECHA's strategy to promote substitution of hazardous substances to safer chemicals.

2. The questions referred to ECHA

(8) ECHA is requested to provide an opinion on whether suitable and sufficient alternative substances and technologies exist to substitute hexaflumuron in biocidal products in PT 18 (insecticides) for the use(s) presented in the application for renewal.

3. Elements to be considered by ECHA when addressing this question

(9) ECHA should collect relevant information and reach a conclusion on the availability of suitable and sufficient alternative substances and/or technologies.

(10) Relevant information to be considered by ECHA should include at least:

(a) The list of active substances included in Annex I, approved, or under examination (under the review programme set up in Article 89 of the BPR, or outside the review programme) for the same product-type, and similar uses (pattern of use, target organism, etc.).

(b) The list of biocidal products authorised in R4BP for the same product-type, and similar uses (pattern of use, target organism, etc.).

(c) Any information available to Member State's Competent Authorities, including on biocidal products still placed on the market under the transitional period set up under Article 89 of the BPR.

(d) Information collected during the public consultation to be organised by ECHA in accordance with Article 10(3) of the BPR.

(e) Consultations with stakeholders.

(f) Information on non-chemical alternatives.

(g) Literature search.

(11) If no alternative active substance(s) or biocidal product(s) is directly identified as already placed on the market for the same use(s), ECHA should also consider if another active substance that is not currently on the market for the same use(s) referred to by the applicant could be a suitable candidate to develop alternative products for the use(s) referred to by the applicant (ex: active substances allowed for the same PT, but without known products on the market for the same use(s) yet).

(12) If ECHA does not identify suitable alternative active substances and technologies, ECHA is invited to indicate the reasons, including the possible obstacles to the development of chemical and non-chemical alternatives by economic operators in the short/medium/long term, as far as discernible from the available information.

4. Deadline for the ECHA opinion

(13) ECHA shall adopt its opinion by 30 June 2022 at the latest.