EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
The Director

Brussels
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Request for an ECHA opinion - Mandate

"Eligibility of peanut butter active substance for inclusion into Annex I to the BPR"

1. Background

(1) Article 28(1) of Regulation (EU) No 528/2012 (the BPR) empowers the Commission to adopt delegated acts in order to include active substances into Annex I to the BPR after receiving the opinion of ECHA that there is evidence that they do not give rise to concern according to the conditions set out in Article 28(2) of the BPR.

(2) Article 15(b) of Regulation (EU) No 1062/2014 (the Review Regulation) provided companies with an opportunity to support those active substances that benefitted from the food and feed derogation provided for by Article 6 of Regulation (EC) No 1451/2007. A declaration of interest to notify had to be submitted to ECHA by 30 October 2015.

(3) In that context, an applicant submitted a declaration of interest to notify peanut butter. The applicant then submitted a notification for peanut butter that was rejected by the Agency because it found that the notification did not comply with the data requirements laid down in Annex I to the Review Regulation.

(4) In 2017, a case was brought by the notifier to the ECHA Board of Appeal which annulled[1] the decision of the Agency and instructed it to examine the eligibility of peanut butter for inclusion in the review programme as per its interpretation of Article 15 of the Review Regulation. According to the Board of Appeal, the Agency should have assessed whether the following conditions stemming from Article 15 of the new RPR were met:

(a) the substance for which the Declaration of Interest was submitted is an existing active substance that was neither approved, nor included, in the Review Programme or Annex I to the BPR,

(b) the existing active substance benefited from the derogation for food and feed under the previous RPR,

(c) the product which consists of, contains or generates the existing active substance is a biocidal product falling within the scope of the BPR, and

(d) the biocidal product is placed on the market.

[1] BoA case A-013-2017

(5) In December 2020, the Agency informed the applicant that peanut butter fulfils the requirements of Article 15 of the Review Regulation and that its new notification was found compliant. The Agency updated its list of compliant notifications accordingly[2].

(6) On 8 February 2017, the Commission requested ECHA to provide its opinion on the eligibility of several food and feed active substances for their inclusion into Annex I to the BPR. The request included peanut butter. However, due to the initial rejection of the notification by ECHA, the ECHA BPC opinion did not analyse whether peanut butter was eligible for Annex I inclusion[3].

(7) At the 91st meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 of 10-11 March 2021, it was agreed that the Commission should request a formal opinion of ECHA in order to check whether peanut butter is eligible for inclusion into Annex I to the BPR.

2. The questions referred to ECHA

(8) Taking into consideration this background information, pursuant to Article 75(1)(g) of the BPR, ECHA is requested to formulate an opinion on the following questions for the active substance peanut butter:

a) Does the active substance not give rise to concern in accordance with Article 28(2) of the BPR, and is it therefore eligible for inclusion into Annex I?

b) If the active substance is eligible for inclusion into Annex I, is the active substance a traditionally used substance of natural origin?

(9) Elements that will be provided by ECHA to answer question b will be useful to decide in which category the active substance may be included in Annex I.

3. Elements to be considered by ECHA when addressing those questions

(10) When addressing these questions, it will be important that ECHA provides appropriate identifiers (name of the active substance, EC number, CAS number, or other appropriate identifiers), as much as possible, so that it is clear which active substance could be listed into Annex I, and therefore which active substance companies can use in their biocidal products.

(11) To define if the active substance gives rise to concern, ECHA shall use any information available in the declarations of interest to notify, information submitted in the notification, the Classification and Labelling Inventory, other bibliographic information easily accessible to ECHA, and its expert judgement.

4. Deadline for the ECHA opinion

(12) ECHA shall adopt its opinion by 31 January 2022 at the latest.

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[2] https://echa.europa.eu/documents/10162/27434452/list_of_notifications_en.pdf/0ad3b68a-1e01-304e-722d-f4a8457842c3

[3] ECHA/BPC/186/2017 on the eligibility of certain food and feed active substances for inclusion into Annex I to the BPR.