

**DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY**

4 April 2019

(Scope of the Biocidal Products Regulation – Review Programme Regulation – Notification procedure – Food and feed)

Case number	A-013-2017
Language of the case	English
Appellant	SwissInno Solutions AG, Switzerland
Representative	Bobby Arash Ramberg Advokater KB, Sweden
Contested Decision	NOT-D-1260170-08-00/F of 1 September 2017 adopted by the European Chemicals Agency (the 'Agency') under Article 17(5) of Commission Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1)

THE BOARD OF APPEAL

composed of Mercedes Ortuño (Chairman), Andrew Fasey (Technically Qualified Member) and Sari Haukka (Legally Qualified Member and Rapporteur)

Registrar: Alen Močilnikar

gives the following

Decision

Legal framework

1. According to Article 3(1)(a) of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1; the 'Biocidal Products Regulation' or 'BPR') a biocidal product is a substance, mixture or treated article which is used to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism. A biocidal product consists of, contains or generates one or more active substances. Article 3(1)(c) of the BPR defines an active substance as a substance or a micro-organism that has an action on or against harmful organisms.
2. Article 2(5)(a) of the BPR exempts food and feed used as repellents or attractants from the scope of the BPR. In December 2013, the Member State Competent Authorities for Biocidal Products endorsed a Note for Guidance on the interpretation of Article 2(5)(a) of the BPR (CA-Dec13-Doc.11.3 – Final; the 'Note for Guidance'). The Note for Guidance states that Article 2(5)(a) of the BPR only exempts food or feed from the scope of the BPR when it is supplied to the end user as food or feed and is not accompanied by an attractant or repellent claim.
3. Prior to the date of application of the BPR, the placing on the market and use of biocidal products was governed by Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1; the 'Biocidal Products Directive' or 'BPD'). Following the adoption of the BPD, the European Commission started a 10-year work programme for the systematic examination of certain active substances already on the market on 14 May 2000 ('existing active substances').
4. Article 89(1) of the BPR states that the European Commission shall carry on with the work programme for the systematic examination of all existing active substances commenced under the BPD.
5. The systematic examination of existing active substances (the 'Review Programme') was implemented by different Regulations. Commission Regulation (EC) No 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3, the 'previous Review Programme Regulation' or 'previous RPR') was in force when the BPR was adopted.
6. The previous RPR was repealed and replaced by Commission Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1; the 'new Review Programme Regulation' or 'new RPR').
7. The previous RPR included a derogation for food and feed. Under Article 6 of the previous RPR, Member States were allowed to accept *'until 14 May 2010 at the latest the placing on the market of active substances consisting solely of food or feed that are intended for use as repellents or attractants of product type 19'*.
8. Recital 3 of the new RPR states that food and feed that has benefited from the derogation under the previous RPR, but is not covered by the exemption for food and feed in Article 2(5)(a) of the BPR, should be evaluated under the Review Programme.

9. Articles 15 to 18 of the new RPR lay down rules for the notification of food and feed that was exempt under the BPD from the Review Programme but is not exempt under the BPR.
10. Article 16(1)(b) of the new RPR requires any person with an interest in notifying food or feed for inclusion in the Review Programme to submit a declaration of interest to the Agency by 30 October 2015.
11. Article 16(4) of the new RPR requires the Agency to publish a list of food and feed for which declarations of interest have been submitted. On 24 August 2016, the Agency published that list (the '24 August 2016 list'). Pursuant to Article 16(5) of the new RPR the deadline for submitting the actual notifications of food and feed for inclusion in the Review Programme is six months from the publication of the 24 August 2016 list. The notifications for inclusion of food and feed in the Review Programme, as required under Article 17 of the new RPR, therefore had to be submitted by 24 February 2017.
12. Annex I of the new RPR sets out the information requirements for notifications for inclusion of food and feed in the Review Programme. Under Article 17(5) of the new RPR, the Agency was required to verify whether a notification complied with these information requirements. After providing the notifier the possibility to complete or correct its notification, if necessary, the Agency had to declare the notification compliant or reject the notification.

Background to the dispute

13. The Appellant manufactures and places on the market mechanical mousetraps that use baits consisting of peanut butter (the 'peanut butter bait'). The Appellant also places on the market replacement baits.
14. On 30 October 2015, the Appellant submitted, under Article 16 of the new RPR, a declaration of interest to notify peanut butter for inclusion in the Review Programme for the product-type 19 (repellents and attractants) (the 'Declaration of Interest').
15. On 3 March 2016, the Agency acknowledged receipt of the Declaration of Interest and informed the Appellant that it was necessary '*to define if [peanut butter] is a substance or a mixture*' according to the definition in Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; the 'REACH Regulation'). The Agency asked the Appellant for the name of, and detailed information on, '*the relevant active substance*'.
16. On 4 March 2016, the Appellant informed the Agency that the peanut butter bait consists of '*the same peanut butter used for food*'. The Appellant also supplied a '*formula specification*' including information on the production process, ingredients and '*physical and chemical specifications*', such as salt content, colour and grind.
17. On 5 July 2016, the Agency sent a letter to the Appellant acknowledging that peanut butter '*appear[s] eligible for inclusion in the [R]eview [P]rogramme*' as a substance that previously benefited from the food and feed derogation in Article 6 of the previous RPR (the 'Decision on the Declaration of Interest').
18. On 20 February 2017, the Appellant submitted, under Article 17 of the new RPR, a notification for inclusion of peanut butter in the Review Programme (the 'Notification').
19. On 12 May 2017, the Agency sent a letter to the Appellant stating that the Notification did not comply with the information requirements in Annex I to the new RPR. The Agency requested the Appellant to update the Notification within 30 days with, amongst other things, information on the method of manufacture, identity of any impurities and

additives, and the analytical profile of at least five representative batches of peanut butter.

20. On 14 June 2017, the Appellant submitted an update to the Notification as well as an explanatory statement. In the explanatory statement the Appellant explained, amongst other things, that it is not possible to provide the requested additional information on peanut butter as *'peanut butter [does not] fit well into the system made for chemical active substances'*. The updated Notification did not contain the additional information requested by the Agency.
21. On 1 September 2017, the Agency adopted the Contested Decision that rejected the Appellant's Notification. According to the Contested Decision, the information provided in the Notification *'does not comply with the data requirements laid down in Annex I to the [new] Review Programme Regulation'*.

Procedure before the Board of Appeal

22. On 30 November 2017, the Appellant filed this appeal.
23. On 5 February 2018, the Agency submitted its Defence.
24. On 8 June 2018, the Appellant filed its observations on the Defence and responded to questions from the Board of Appeal.
25. On 14 August 2018, the Agency filed its observations on the Appellant's observations on the Defence and responded to questions from the Board of Appeal.
26. On 14 and 19 September 2018 respectively, the Agency and the Appellant informed the Board of Appeal that they do not request a hearing to be held in the present case.

Form of order sought

27. The Appellant requests the Board of Appeal to:
 1. annul the Contested Decision,
 2. remit the case to the competent body of the Agency for re-evaluation against the criteria set out in Article 15(b) of the new RPR in order to determine whether peanut butter, as a mixture, should be excluded from the scope of the new RPR and the BPR,
 3. refund the fee paid for the Notification or apply the SME reduction to the fee, and
 4. refund the appeal fee.
28. The Agency requests the Board of Appeal to dismiss the appeal as unfounded *'and/or partly inadmissible'*.

Reasons

29. The Appellant raises four pleas in support of its appeal:
 1. the Agency breached Article 15 of the new RPR because it did not examine in its Decision on the Declaration of Interest (see paragraph 17 above) whether peanut butter is covered by the exemption in Article 2(5)(a) of the BPR, whether peanut butter is an active substance under the BPR, and whether the peanut butter bait is a biocidal product,

2. the Agency did not take into account all the facts and circumstances of the case when it found in the Contested Decision that the Notification did not comply with the information requirements of Annex I to the new RPR,
3. the Agency did not take into account in the Contested Decision the Appellant's request to waive the information requirements of Annex I to the new RPR, and
4. the Agency breached Article 80(3)(c) of the BPR as it did not apply the SME reduction to the Notification fee.

First plea, alleging that the Agency breached Article 15 of the new RPR

Arguments of the Appellant

30. The Appellant argues that peanut butter falls within the definition of food in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law (OJ L 31, 1.2.2002, p. 1, the 'General Food Law Regulation'). Peanut butter does not fall within the scope of the BPR because Article 2(5)(a) of the BPR states that it '*shall not apply to [...] food or feed used as repellents or attractants*'. In the present case, peanut butter is food and is used as an attractant. The Appellant further argues that the exemption in Article 2(5)(a) of the BPR applies regardless of whether food or feed is a substance or mixture and regardless of whether it has been placed on the market with or without a claim that it acts as a repellent or attractant.
31. The Appellant argues that peanut butter does not fulfil the eligibility criteria for inclusion in the Review Programme set out in Article 15 of the new RPR because:
 - (a) it is '*most likely*' not a biocidal product as it only exerts a controlling effect on mice by being food,
 - (b) it is not an existing active substance under Article 3(1)(c) and (d) of the BPR as it is food consisting of products of plant origin and other food ingredients, and
 - (c) it benefits from the exemption in Article 2(5)(a) of the BPR which takes precedence over the new RPR.
32. The Appellant argues that there was a lack of clarity regarding how Article 2(5)(a) of the BPR will be applied. As a result, the Appellant had to adopt a cautious approach and submit the Declaration of Interest under Article 15(b) of the new RPR in order to avoid the risk that its mousetraps and replacement baits would need to be removed from the EU market.
33. According to the Appellant, it is clear from the Decision on the Declaration of Interest that the Agency did not examine whether the food and feed exemption in Article 2(5)(a) of the BPR applies to peanut butter. The Appellant argues that the peanut butter bait does not even fulfil the definition of biocidal product within the meaning of Article 3(1)(a) of the BPR. In the Appellant's opinion, it is also clear that the Agency did not assess whether peanut butter is an active substance within the definition of the Article 3(1)(c) of the BPR.
34. As the Agency did not determine whether peanut butter fulfils the conditions in Article 15 of the new RPR, it incorrectly accepted the Declaration of Interest. The Appellant argues that the Agency should have concluded that peanut butter does not fall within the scope of the BPR and rejected the Declaration of Interest.

Arguments of the Agency

35. The Agency argues that, in accordance with the Note for Guidance, only food placed on the market as food, without a claim that it acts as a repellent or attractant, is covered by the exemption in Article 2(5)(a) of the BPR. The Agency states, however, that the Member States are not bound by the interpretation in the Note for Guidance as regards the application of the food and feed exemption in the BPR. Therefore, the Appellant has the option of asking the authorities in each Member State in which the mousetraps are marketed whether the peanut butter used in them is covered by the exemption or not.
36. The Agency argues that, when checking the Declaration of Interest submitted under Article 16 of the new RPR, it had no role in assessing whether the exemption in Article 2(5)(a) of the BPR applies to peanut butter.
37. The Agency argues that Article 16(2) of the new RPR only requires a declaration of interest to contain the name of the substance and the product-type. Given these limited information requirements, the Agency could not '*undertake an in-depth assessment*' of the substances for which a declaration of interest had been submitted. However, the Agency states that, '*in the interests of good administration*', it checked that the food and feed for which declarations of interest had been submitted were '*related to food or feed*' and '*could foreseeably concern a substance*'. In this case, the Agency concluded that peanut butter is food within the meaning of Article 2 of the General Food Law Regulation and may be a substance within the meaning of Article 3(39) of the REACH Regulation. As a result, peanut butter may fall within the scope of the BPR. The Agency states that it did not examine whether peanut butter is an active substance as defined by the BPR.
38. The Agency argues that the peanut butter bait is '*most likely*' a biocidal product, and falls within the scope of the BPR. According to the Appellant's own description, the bait attracts mice and '*is used to control harmful organisms (in this case mice) by any means other than mere physical or mechanical action*'.
39. The Agency argues that a declaration of interest is voluntary. In this case, on the basis of a preliminary check, it appeared plausible that peanut butter is a substance that falls within the scope of the BPR. The Agency therefore concluded that peanut butter appears to be eligible for inclusion in the Review Programme. As a result, the Agency was correct to accept the Declaration of Interest.

Findings of the Board of Appeal

40. As explained in paragraphs 3 to 6 above, the Review Programme was introduced under the BPD and was continued under the BPR. The Review Programme is a mechanism to systematically examine existing active substances as defined by the BPR. However, a substance can be included in the Review Programme only if it is an existing active substance within the meaning of the BPR and if a product which consists of, contains or generates that existing active substance is a biocidal product falling within the scope of the BPR.
41. The present case concerns peanut butter used as bait in mousetraps. The Appellant argues that peanut butter is neither a biocidal product nor an active substance and is therefore outside the scope of the Review Programme. The Agency's assessment of the Appellant's Declaration of Interest was limited to examining whether it was plausible that peanut butter is a substance that falls within the scope of the BPR. The main issue in this case, however, is whether the Agency should have accepted the Appellant's Declaration of Interest to notify peanut butter for inclusion in the Review Programme without assessing whether whether peanut butter is an existing active substance within

the meaning of the BPR and whether the peanut butter bait is a biocidal product falling within the scope of the BPR.

Scope of the first plea

42. By its first plea, the Appellant argues that the Agency breached Article 15 of the new RPR by accepting the Declaration of Interest.
43. The Appellant's first plea therefore concerns a different act than the Contested Decision, namely the Agency's Decision on the Declaration of Interest.
44. The inclusion of food and feed in the Review Programme included a step-wise decision-making procedure. A declaration of interest was a pre-requisite for a notification under Article 16 of the new RPR (see paragraphs 9 to 12 above).
45. Although a preparatory act cannot be the subject of an appeal, legal defects in a preparatory act may be relied upon in an appeal directed against the definitive decision. In light of the Appellant's first plea, the Board of Appeal must examine the administrative procedure leading to the adoption of the Contested Decision. If there is a legal defect in that administrative procedure, the Board of Appeal must examine whether that defect affects the legality of the decision taken by the Agency at the conclusion of the administrative procedure (see, to this effect and by analogy, judgment of 18 June 2013, *Fluorsid and Minmet v Commission*, T-404/08, EU:T:2013:321, paragraph 133, and order of the General Court of 14 September 2016, *Pagkyprios organismos ageladotrofon Dimosia v Commission*, T-584/15, EU:T:2016:510, paragraph 36).
46. If the Agency had not accepted the Declaration of Interest, the Appellant could not have submitted a notification and the Contested Decision would not have been adopted. Consequently, the Decision on the Declaration of Interest was a preparatory act to the Contested Decision. It follows that a legal defect in the Decision on the Declaration of Interest could affect the legality of the Contested Decision.
47. The Board of Appeal will therefore examine whether the Agency in adopting the Decision on the Declaration of Interest made a mistake which could affect the legality of the Contested Decision.

Legality of the Decision on the Declaration of Interest

48. Recital 3 of the new RPR states that:
'[w]here a product has benefitted from the derogation for food and feed provided for by Article 6 of [the previous RPR], but is not covered by the exemption for food and feed laid down in Article 2(5)(a) of [the BPR], the active substances it contains should be evaluated in the [R]eview [P]rogramme for the relevant product-type. Subject to national rules, it should be allowed to be made available on the market and used until the end of that evaluation. A system of prior declaration should define which products benefit from this provision. [...]'
49. Article 15 of the new RPR states that:
'[w]here a biocidal product covered by the scope of [the BPR] and being placed on the market consists of, contains or generates an existing active substance which is neither approved, nor included in the [R]eview [P]rogramme, for the product-type, and is not included in Annex I to that Regulation, that substance shall be eligible for inclusion in the [R]eview [P]rogramme for the relevant product-type on any of the following grounds:

- (a) [...];
 - (b) *the substance has benefitted from the derogation for food and feed provided for by Article 6 of [the previous RPR];*
 - (c) [...].'
50. Before reaching a decision on the Declaration of Interest, the Agency should have assessed whether the substance/product-type combination concerned fulfils the eligibility criteria laid down in Article 15 of the new RPR (see paragraph 49 above). Therefore, 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.
51. In applying the eligibility criteria laid down in Article 15 of the new RPR in the present case, the Agency should have first assessed whether the peanut butter bait is a biocidal product within the meaning of Article 3(1)(a) of the BPR. In the affirmative, the Agency should have next assessed whether it falls within the scope of the BPR. In particular, this would have required the Agency to examine whether the peanut butter bait is covered by the exemption for food and feed used as repellents or attractants laid down in Article 2(5)(a) of the BPR. If the peanut butter bait was found to fall within the scope of the BPR, the Agency should have next assessed whether it consists of, contains or generates an existing active substance. In the affirmative, the Agency should have assessed whether the active substance is already approved, or included in the Review Programme.
52. In the Decision on the Declaration of Interest, the Agency states that peanut butter '*formerly benefitted from the food and feed derogation under Article 6 of [the previous RPR] and accordingly appear[s] eligible for inclusion in the [R]eview [P]rogramme*' (see paragraph 17 above). The Agency does not provide any further reasoning in support of the Decision on the Declaration of Interest.
53. In these appeal proceedings, the Agency explained that '*in the interests of good administration*', it checked that the food and feed for which declarations of interest were received are '*related to food or feed*' and '*could foreseeably concern a substance*' (see paragraph 37 above).
54. It is therefore apparent that the Agency did not, as required by Article 15 of the new RPR (see paragraph 49 above), assess whether the peanut butter bait is a biocidal product that falls within the scope of the BPR before issuing the Decision on the Declaration of Interest (see paragraph 50(c) above).
55. Moreover, the Agency should also have assessed whether the peanut butter bait consists of, contains or generates an existing active substance that was neither approved, nor included, in the Review Programme or Annex I to the BPR (see paragraph 50(a) above). The Decision on the Declaration of Interest contains no assessment in this regard either.

56. Therefore, the Agency breached Article 15 of the new RPR by not assessing whether the Declaration of Interest fulfilled all of the eligibility criteria set out in that Article.

Consequences of the mistake made in the adoption of the Decision on the Declaration of Interest

57. There was therefore a legal mistake in the Agency's acceptance of the Declaration of Interest. It is clear that the acceptance of the Declaration of Interest was a preparatory act in the process leading to the Contested Decision.
58. If the Agency had assessed whether all the eligibility criteria in Article 15 of the new RPR had been met, one of the possible outcomes is that the Agency could have decided that peanut butter is not eligible for inclusion in the Review Programme. Consequently, the Agency could have rejected the Declaration of Interest. If this were the case, the Contested Decision would not have been adopted. It is therefore possible that the Agency's failure to assess whether the Declaration of Interest fulfilled the eligibility criteria set out in Article 15 of the new RPR led to an erroneous acceptance of the Declaration of Interest and to a subsequent notification that was not required.
59. As the Declaration of Interest was accepted without a proper assessment of whether peanut butter needed to be notified, it follows that the Contested Decision has to be annulled (see paragraphs 42 to 46 above).
60. The Appellant's first plea is therefore upheld. As the Contested Decision has been annulled, it is not necessary to examine the Appellant's other pleas.
61. The Declaration of Interest should consequently be re-assessed by the Agency following the criteria set out in Article 15 of the new RPR. The case is therefore remitted to the competent body of the Agency for re-examination.

Refund of the notification fee

62. The Appellant submitted the Notification following the Agency's acceptance of the Declaration of Interest. Had the Declaration of Interest not been accepted the Appellant would not have been able to submit the Notification and the fee to make the Notification would not have been charged. Following the re-examination of the Declaration of Interest the Agency should take the appropriate actions regarding the Notification fee.

Refund of the appeal fee

63. In accordance with Article 4(4) of Commission Implementing Regulation (EU) No 564/2013 on the fees and charges payable to the European Chemicals Agency pursuant to the BPR (OJ L 167, 19.6.2013, p. 17), the appeal fee shall be refunded if the appeal is decided in favour of the appellant.
64. As the Board of Appeal has decided the appeal in favour of the Appellant, the appeal fee must be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Annuls decision NOT-D-1260170-08-00/F adopted by the Agency on 1 September 2017.**
- 2. Remits the case to the competent body of the Agency for re-examination.**
- 3. Decides that the appeal fee must be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal