Médiateur européen

Décision du Médiateur européen dans l'affaire 2000/2015/ANA sur le respect par la Commission européenne des règles relatives à l'approbation de produits phytopharmaceutiques

Décision
Affaire 2000/2015/ANA - **Ouvert le** 16/03/2016 - **Décision le** 22/03/2018 - **Institution concernée** Commission européenne (Pas d'acte de mauvaise administration constaté) |

Dans cette affaire, la question était de savoir si la Commission européenne respectait les dispositions réglementaires régissant les procédures d'approbation de pesticides.

Le plaignant (l'association de l'industrie européenne des fabricants de pesticides) a contesté la manière dont la Commission conduit les procédures (i) d'approbation de la substance active contenue dans un pesticide et (ii) d'établissement des limites maximales de résidus liées à cette substance active. La Commission a fait valoir que le droit et la logique imposent que la substance active soit approuvée avant que les limites maximales de résidus (LMR) puissent être établies. Le plaignant a notamment soutenu que l'établissement des LMR doit se dérouler parallèlement à l'approbation de la substance active.

La Médiatrice a enquêté sur la question et a considéré que la position de la Commission était acceptable. Elle a ajouté que la Commission doit agir de sorte à réduire autant que possible le délai entre l'approbation d'une substance active et l'établissement des LMR. Compte tenu de ces divers éléments, la Médiatrice a clôturé l'affaire.

The background to the complaint

1. The complainant, the European Crop Protection Association (ECPA), is an association of companies producing pesticides for use on plants. It complains about the manner in which the European Commission applies the procedure (a) to approve ' **active substances** ' in pesticides and (b) to set the ' **maximum residue levels** ' for such substances.

2. Pesticides are used to protect agricultural crops from pests (for example, insects) and plant diseases. Traces of the active substances in pesticides may remain on treated crops and in animals feeding on those crops and the EU has rules in place to ensure that the active substances contained in pesticides are approved only if they are safe, and that the maximum residue levels ("MRLs") for these active substances are set, before a pesticide is placed on the market in the EU. MRLs reflect the highest permitted amount of residue of the active substance in the crop when the pesticide is applied in accordance with approved conditions of use. For a

pesticide product to be on the market it must be allowed by a Member State. A precondition for allowing it is in general that the active substance has been approved and a MRL set at Union level.

3. The approval process for active substances and pesticides is governed by Regulation 1107/2009 concerning the placing of plant protection products on the market [1] (the " **Active Substance Regulation** "). The setting of MRLs in or on food and feed of plant and animal origin is governed by Regulation 396/2005 [2] (the " **Maximum Residue Levels Regulation** "). The most relevant provisions of these two Regulations are set out in Annex I.

a. The submission of an application

4. When the approval of an active substance is sought, the procedure begins by the applicant (normally the producer of the pesticide) submitting an application to a Member State (known as the " *rapporteur Member State* ") for the approval of an active substance in a pesticide. The application must include, where relevant, an application for the setting of MRLs, or information showing that no MRLs need to be set.

5. The rapporteur Member State then submits a draft assessment report to the Commission and to the European Food Safety Authority (EFSA) [3] within **12 months** . This draft assessment report contains, where relevant, a proposal to set MRLs.

6. EFSA then has **120 days** in which to adopt its position on whether the active substance can be expected to meet the approval criteria. That deadline can be extended if EFSA requires further information from the applicant (which will also require further input from the rapporteur Member State on that additional information), or if EFSA needs to consult with experts.

7. The Commission then has **six months** in which to submit a report and a draft Commission Regulation on the active substance to the Standing Committee on Plants, Animals, Food and Feed (hereinafter, the PAFF Committee), which is made up of Member State representatives. [4] In the normal course, if the PAFF Committee approves of the draft Commission Regulation, the Commission then adopts the Commission Regulation.

8. The Maximum Residue Levels Regulation provides for a similar procedure, albeit with shorter deadlines. The rapporteur Member State drafts an evaluation report " *without delay* " [5] . EFSA then assesses the application and the evaluation report and gives a reasoned opinion to the Commission within **three months (** that may be extended to six months in exceptional cases) [6] . The Commission then has **three months** to prepare a Commission Regulation on the setting of the MRLs, which is submitted to the PAFF Committee for its approval. [7] In the normal course, if the PAFF Committee approves of the draft Commission Regulation, the Commission then adopts the Commission Regulation.

9 . A MRL procedure may take place independently of a procedure for the approval of an active substance, for instance when a MRL for an active substance already approved is reviewed. On the other hand, the procedure for approval of an active substance will in general also involve setting a MRL.

b. The Commission's practice

10. Where an applicant has submitted a request for the approval of a substance under the Active Substance Regulation, **and** a request to set MRLs under the Maximum Residue Levels Regulation, the Commission, upon receipt of EFSA's conclusions, **prepares** a draft Commission Regulation under the Active Substance Regulation and another draft Commission Regulation under the Maximum Residue Levels Regulation. The Commission then sends the draft Commission Regulation based on the Active Substance Regulation to the PAFF Committee. However, it **does not immediately** send the PAFF Committee the draft Commission Regulation it has prepared under the Maximum Residue Levels Regulation. Rather, it awaits the approval of the active substance by the PAFF Committee before submitting the draft Commission Regulation for the setting of MRLs to the PAFF Committee (the Ombudsman refers to this as the " *sequencing* " approach). According to the information provided by the Commission, the Committee's vote on the draft Regulation for the setting of MRLs follows within three months from the vote on the draft Regulation on the active substance.

11. The complainant considers that the Commission's practice of " *sequencing* " wastes time and causes losses to both the industry and farmers (since a new product cannot be used until the MRLs are set). In the complainant's view, the Commission should submit the draft Commission Regulation setting the MRLs to the PAFF Committee as soon as EFSA has delivered its opinion. It should not, the complainant argues, **await the approval of the active substance** by the PAFF Committee before submitting the draft Commission Regulation setting the MRLs. In the complainant's view, the Commission's practice of sequencing is illegal as it has no basis in the applicable provisions.

12. The complainant raised its concerns about the Commission's practice many times. [8] The Commission insisted that it applied the relevant rules correctly. [9] As it was not satisfied with the Commission's position, the complainant lodged this complaint with the European Ombudsman.

The inquiry

13. The Ombudsman opened an inquiry into the following issue:

The Commission's practice, of not setting the maximum residue levels for pesticides until after the approval of the active substance, is contrary to the relevant legislation.

14. In the course of the inquiry the Ombudsman received a reply from the Commission to the complainant's concerns on 13 July 2016, the complainant's comments on the Commission's reply on 30 August 2016, and additional information submitted by the complainant on 20 and 24 February 2017. The Ombudsman has taken account of the arguments and views put forward by the parties in their submissions.

The timing for setting MRLs

Arguments presented to the Ombudsman

15. The complainant argues that the Commission's practice of waiting for the approval of the active substance **before** submitting a draft Commission Regulation on the setting of MRLs is contrary to the relevant legislation and leads to considerable delays.

16. The complainant argues that MRLs should be set in parallel with the ongoing procedure for the approval of an active substance, when there is such an ongoing procedure.

17. The complainant argues that the Commission should submit the draft Commission Regulation on the setting of MRLs to the PAFF committee **within three months** after receiving EFSA's conclusions. In the complainant's view, this deadline applies even if the active substance has not yet been approved by the PAFF Committee.

18. The Commission argues that its practice is legally correct. It argues that it is required to **prepare** the two proposals simultaneously, but not to have them submitted for approval simultaneously. The reason for not submitting the draft Commission Regulation setting MRLs until **after** the active substance is approved is, it states, because the decision approving the active substance has an important impact on the setting of MRLs. If the active substance is not approved, setting MRLs is devoid of purpose. Similarly, if the approval of the active substance is subject to specific conditions, such as a restriction or ban on using the pesticide on certain crops, these conditions will affect the setting of the MRLs. Moreover, if MRLs were set *before* the active substance approval, the MRLs might not reflect the subsequent approval conditions, such as the agreed toxicological reference values or the acceptable daily intake for chronic risk levels. These parameters are needed to determine whether a proposed MRL is safe for consumers. The level of the proposed MRLs also depends on the definition of a "residue", which could for instance comprise several different metabolites of the pesticide (a pesticide can be broken down, through metabolism inside an insect or plant, into one or more metabolites). The reference values are agreed by the Member States in the PAFF Committee and may differ from the values proposed in the conclusions of EFSA and the draft Commission Regulation. Thus, according to the Commission, if MRLs were set **before** the active substance was approved, either unsafe food or feed could be placed on the market, or the Commission would have to subsequently amend the MRLs, setting them at a level consistent with the approved uses of the substance. This would be disruptive.

19. On the other hand, the Commission readily concedes that once the active substance is approved, it must act with diligence as concerns the setting of MRLs.

The Ombudsman's assessment

20. The Ombudsman notes that the case revolves around an issue of statutory interpretation and involves the interplay of two different Regulations. The relevant provisions make difficult reading, the procedures that the two Regulations establish are elaborate and the interplay between the Regulations is complex. There is no case law that casts light on what is the better interpretation.

21. Both parties have made a convincing case for what they believe to be the right interpretation. It may be that when considering the provisions at issue literally, the complainant has a slightly better case than the Commission. On the other hand, the Commission has argued that the interpretation it advocates is the one that is best in line with the purpose of ensuring consumer protection and the overall scheme of the provisions; the conditions under which an active substance is approved may affect the MRLs which thus should be set subsequent to the approval of the active substance.

22. In those circumstances, the Ombudsman should err rather on the side of caution and therefore she accepts the position of the Commission.

23. The Ombudsman notes also that the Commission has readily conceded that once an active substance is approved, it must act with diligence so as to minimise the time span between that approval and the setting of MRLs. In doing so the Commission acts in accordance with the principles of good administration and the Ombudsman therefore encourages the Commission to maintain its practice. Should it happen that the Commission acts in breach of those principles, the complainant may wish to raise the matter by way of a new complaint to the Ombudsman.

Conclusion

On the basis of the inquiry into this complaint, the Ombudsman closes it with the following conclusion:

There is no maladministration on the part of the European Commission.

Emily O'Reilly

European Ombudsman

Strasbourg, 22/03/2018

Annex I

Relevant applicable rules

Active Substance Regulation

Article 11

Draft assessment report

" *1. Within 12 months of the date of the notification provided for in the first subparagraph of Article 9(3), the rapporteur Member State shall prepare and submit to the Commission, with a copy to the Authority, a report, referred to as the 'draft assessment report', assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4.*

2. The draft assessment report shall also include where relevant, a proposal to set maximum residue levels.

The rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge.

Where, pursuant to Article 4(1), the assessment establishes that the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are not satisfied, the draft assessment report shall be limited to those parts of the assessment. ..."

Article 12

Conclusion by the Authority

" *2. ... Within* 120 days *of the end of the period provided for the submission of written comments,* [EFSA] *shall adopt a conclusion in light of current scientific and technical knowledge...*

3. Where [EFSA] *needs additional information, it shall set a period of a maximum of* 90 days *for the applicant to supply it to the Member States, the Commission and* [EFSA] .

The rapporteur Member State shall assess the additional information and submit it to [EFSA] *without delay and at the latest within* 60 days *after receipt of the additional information. In that case the 120-day period provided for in paragraph 2 shall be* extended *by a period which shall cease at the moment when the additional assessment is received by* [EFSA].

6. The time limits for [EFSA] *'s opinion on applications concerning maximum residue levels set out in* Article 11 *and for decisions on applications concerning maximum residue levels set out in* Article 14 *of Regulation (EC) No 396/2005 shall be* without prejudice to the time limits laid down in this Regulation .

7. Where the conclusion of [EFSA] *is adopted within the time limit set out in paragraph 2 of this Article, extended by any additional period set in accordance with paragraph 3, the provisions of* Article 11 *of Regulation (EC) No 396/2005* shall not apply *and the provisions of* Article 14 *of that Regulation* shall apply without delay .

8. Where the conclusion of [EFSA] *is not adopted within the time limit set out in paragraph 2 of this Article, extended by any additional period set in accordance with paragraph 3, the provisions of* Articles 11 and 14 *of Regulation (EC) No 396/2005* shall apply without delay *."*

Article 13

Approval Regulation

" *1. Within six months of receiving the conclusion from the Authority, the Commission shall present a report, referred to as 'the review report', and a draft Regulation to the Committee referred to in Article 79(1), taking into account the draft assessment report by the rapporteur Member State and the conclusion of the Authority . ...*"

Article 30

Provisional authorisations

" *1. By way of derogation from Article 29(1)(a), Member States may authorise for a provisional period not exceeding 3 years, the placing on the market of plant protection products containing an active substance not yet approved, provided that:*

...

(d) maximum residue levels have been established in accordance with Regulation (EC) No 396/2005 . "

Maximum Residue Levels Regulation

Article 11:

" *1. [EFSA] shall give its reasoned opinion as provided for in Article 10 as soon as possible and at the latest* within three months *from the date of receipt of the application.*

In exceptional cases where more detailed evaluations need to be carried out, the time limit laid down in the first subparagraph may be extended to six months *from the date of receipt of the valid application. "*

Article 14:

" *1. Upon receipt of the opinion of* [EFSA] *and taking account of that opinion, one of the following* shall be prepared by the Commission without delay and at the latest within three

months *:*

(a) a regulation on the setting, modification or deletion of an MRL *. That regulation, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(4);*

(b) a decision rejecting the application *, which shall be adopted in accordance with the regulatory procedure referred to in Article 45(2). "*

[1] Regulation (EC) no 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ 2009, L 309, p. 1. The latest consolidated version is available at http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1511556073703&uri=CELEX:02009R1107-20170828

[2] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, OJ 2005 L 70, p. 1.

[3] Article 11(1) and (2) of the Active Substance Regulation.

[4] Article 13 of the Active Substance Regulation. This is a Committee bringing together representatives of Member States to control the Commission's exercise of implementing powers in accordance with Regulation (EU) no 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ 2011 L 55, p. 13, which replaced and repealed Decision 1999/468/EC (the earlier Comitology decision to which Article 45 of the Maximum Residue Levels Regulation refers).

[5] Article 8(1) of the Maximum Residue Levels Regulation.

[6] Article 11 of the Maximum Residue Levels Regulation.

[7] Article 14 of the Maximum Residue Levels Regulation.

[8] Correspondence of 27 April 2015, 13 May 2015, 21 May 2015, 8 July 2015, and 12 November 2015.

[9] Correspondence of 27 April 2015, 8 June 2015, and 30 June 2015 and the minutes of a meeting held on 16 November 2015.