European Ombudsman

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European Ombudsman

Decision

in joint cases 1570/2018/JF-JN and 1973/2018/JF-JN on how the European Commission approves substances used in plant protection products (pesticides)

This inquiry concerned how the European Commission approves 'active substances' used in pesticides. In particular, the Ombudsman looked into the Commission´s practice of approving active substances for which the European Food Safety Authority ('EFSA') - the EU body in charge of the scientific safety assessment - said that it identified critical areas of concern or that it identified no safe use. The Ombudsman also revisited the Commission´s practice of approving substances for which additional data confirming their safety is needed.

The Ombudsman set out in detail to the Commission why she considers that its current practices raise concerns. While the Commission maintained that its practices comply with the applicable legal provisions, it listed changes and improvements it has made to address the issues raised. Specifically, it informed the Ombudsman of several measures that should improve the approval process and increase its transparency.

The Ombudsman is now closing this inquiry with three suggestions to the Commission to ensure that it approves substances based only on uses that have been confirmed to be safe by EFSA, that the approval process is fully transparent and that its use of the confirmatory data procedure is further restricted. Bearing in mind the commitment by the Von der Leyen Commission to take action to reduce by 50% the overall use of – and risk from – chemical pesticides by 2030, the Ombudsman expects that the Commission will follow up satisfactorily on her suggestions.

Background to the complaint

1. 'Plant protection products' are pesticides that are used to protect crops or other 'useful plants'. Pesticides contain at least one 'active substance'[1], which acts against pests.

[1] An active substance is any chemical, plant extract, pheromone or micro-organism (including viruses), that has action against 'pests' or on plants, parts of plants or plant products: https://ec.europa.eu/food/plant/pesticides_en

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2. According to the applicable EU laws, notably the 'Pesticides Regulation'[2], before an active substance can be used in a pesticide, it must be approved at EU level. A producer of a new active substance (the applicant) must first submit an application to the appropriate authority in an EU Member State (the Rapporteur Member State).[3] The Rapporteur Member State verifies the application and, if it is admissible, submits a 'draft assessment report' to the European Food Safety Authority (EFSA). EFSA peer reviews the assessment in cooperation with all Member States and submits a report setting out its conclusions to the European Commission.[4] The Commission then — based on the opinion of Member State representatives[5] — decides whether, and under what conditions, to approve the substance.

3. The complainant is an umbrella organisation for non-governmental organisations, which works to minimise the negative effects of pesticides.[6]

4. In 2013, the complainant raised with the Ombudsman a set of concerns about the Commission's role in approving active substances used in pesticides. In particular, the complainant alleged that the practices of the Commission regarding the approval of active substances in the EU are, in some instances, unsafe and/or not in accordance with the relevant legislation. The complainant also raised concerns about the practice by which the Commission approves active substances but allows the applicant to submit certain data only at a later stage ('confirmatory data'). In order to be applicable, such data should represent new scientific or technical knowledge.

5. The Ombudsman investigated the matter and, having identified certain issues with the procedures, made a solution proposal, which the Commission accepted in 2015.[7] In February 2016, the Ombudsman asked the Commission to submit a report within two years, detailing how it had implemented the measures she had set out.

6. In February 2018, the Commission informed the Ombudsman about the steps it had taken.

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[2] Regulation 1107/2009 concerning the placing of plant protection products on the market, https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R1107.
[3] More detail on the application and approval procedure for active substances in pesticides can be found on the Commission's website: https://ec.europa.eu/food/plant/pesticides/approval_active_substances_en.
[4] More information on EFSA's role in evaluating applications for active substances can be found on its website: https://www.efsa.europa.eu/en/applications/pesticides.
[5] The Commission presents a draft regulation to the Standing Committee on Plants, Animals, Food and Feed, which includes representatives of Member State governments. The committee votes on the draft regulation. Where the committee supports approving the substance, the Commission adopts the regulation.
[6] https://www.pan-europe.info/about-us/profile
[7] See Case 12/2013/MDC, available here: https://www.ombudsman.europa.eu/en/decision/en/64069.

7. In September 2018, the complainant contacted the Ombudsman to raise concerns with how the Commission had implemented the Ombudsman's findings.[8]

8. Separately, the complainant contacted the Ombudsman to raise concern about the fact that the Commission had approved several substances even though EFSA had identified "*critical areas of concern*" with the substances.[9]

The inquiry

9. The Ombudsman opened a joint inquiry into the two complaints. The inquiry focused on: (i) the Commission´s approval of active substances for which EFSA had identified areas of concern or no safe uses; and (ii) how the Commission uses the procedure by which it approves an active substance but requests additional data to confirm its safety (the ´confirmatory data procedure´).

10. In the course of the inquiry, the Ombudsman's inquiry team met with the Commission and inspected the Commission's files in respect of five active substances[10] that were approved by the Commission, but where EFSA's report had stated either that no safe use could be identified[11] or that there was a critical area of concern[12].

11. Following the meeting and inspection, the Ombudsman asked EFSA for information, which she considered necessary for the inquiry. The complainant commented on the Ombudsman's report on the meeting and inspection, as well as on the additional information provided by EFSA. Following this, the Ombudsman issued her preliminary findings on the complaint and invited the Commission to reply. In her letter to the Commission President, the Ombudsman pointed to the Commission's announcement that it will take action to reduce by 50% the overall use of – and risk from – chemical pesticides by 2030.[13]

12. The complainant commented on the Ombudsman's preliminary findings and, after the Commission replied to those findings, also on the Commission's reply.

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[8] Complaint 1570/2018.
[9] Complaint 1973/2018.
[10] *Flazasulfuron*, *isofetamid*, *picolinafen*, *benzovindiflupyr* and *epoxiconazole*. The Ombudsman chose these five substances from a list provided by the complainant in an effort to examine, in greater detail, how the procedure works in practice. The Ombudsman understands that the approval for *epoxiconazole* expired on 30 April 2019.
[11] *Flazasulfuron*, *isofetamid* and *epoxiconazole*. For *picolinafen* and *benzovindiflupyr* EFSA did not say that "*no safe use can be identified*" but, nevertheless, entirely greyed the relevant columns in the summary tables.
[12] *Picolinafen*, *benzovindiflupyr* and *epoxiconazole*.
[13] Commission Communication - EU Biodiversity Strategy for 2030 (COM/2020/38) https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1590574123338&uri=CELEX:52020DC0380

Approval of active substances for which EFSA had identified critical areas of concern or no safe uses

Arguments presented to the Ombudsman

13. The complainant argued that the Commission was wrong to approve active substances for which EFSA identifies "*critical areas of concern*", as this essentially means that they have not been confirmed to be safe and should not be approved.

14. The Commission, for its part, said that EFSA's reports could create the impression that an active substance is generally unsafe, even though it may be possible to identify some specific uses that are safe.

15. The Commission explained that pesticides containing approved active substances are authorised by Member State authorities at national level, where specific agricultural and environmental conditions are taken into account. Pesticides containing a given active substance may be safe for specific uses in certain Member States. However, EFSA's conclusion on that active substance may not be sufficiently detailed to cover all potential uses and, therefore, may not indicate that a safe use was identified during the scientific examination. According to the Commission, EFSA changed how its reports present its conclusions in 2018 to address this problem.

16. If the Commission considers that at least one safe use in at least one Member State has been identified, it approves the active substance, in accordance with the Pesticides Regulation.[14] In its 'review reports', the Commission explains why it has approved a given active substance, taking into account EFSA´s findings and conclusions.[15]

17. EFSA stated that it identifies an issue as a ***"critical area of concern"*** when, having regard to the current scientific and technical knowledge at the time of the application, **the active substance is not expected to meet the approval criteria** provided for in the Pesticides Regulation[16]. EFSA identifies a *critical area of concern* when (i) there is enough information available to perform an assessment for the representative uses; (ii) it may be expected that a pesticide containing the active substance has harmful effects on human or animal health

[14] Article 4(5).
[15] The Commission stated that these explanations are found in section 3 of its review reports, which are published on its webpage containing the EU pesticides' database. See: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN.
[16] EFSA referred to Article 4 of the Pesticides Regulation, which states that, in order to be approved, an active substance or its residues must not have any harmful effects on human or animal health or the environment or groundwater, taking into account how it is used.

or on groundwater, or an unacceptable effect on the environment; and (iii) the concern applies to all representative uses indicated by the company that applied for approval (the applicant)[17].

18. EFSA stated that it does not evaluate all possible scenarios under which pesticides may be used. Specific pesticides containing a given active substance may be safe for specific uses in some Member States, even if EFSA has not evaluated that use. EFSA is trying to go further in identifying possible safe uses and scenarios under particular conditions of use.

19. EFSA said that its reports have evolved over time. Until October 2018, EFSA used in the summary table of its reports a separate colour (grey) for uses that could not be identified as safe throughout the representative uses indicated by the applicant in the EU. This was the case for the reports reviewed by the Ombudsman in the context of this inquiry. Specifically, EFSA said that the Commission had not asked for clarifications in respect of three of the active substances included in the inquiry[18].

20. Since October 2018, EFSA no longer marks the columns in its tables grey. It realised that the previous practice may have given the impression that it had concluded that the use of an active substance was unsafe. In fact, it is possible that uses indicated in this column could be safe with adequate restrictions or mitigation measures. However, at the time of EFSA's scientific evaluation, these restrictions or measures had not been indicated in the application.

21. In March 2019, EFSA published guidance on submitting files and assessment reports with instructions for both applicants and Member State authorities. The guidance seeks to encourage applicants to indicate clearly all intended uses and to include risk mitigation options in their applications at an early stage. Additionally, EFSA provides feedback to the Commission during the decision-making phase in case further clarifications are needed regarding the concerns identified in its conclusions.

22. Finally, EFSA said that it is planning to change how its reports present data gaps and clarify what such missing data implies for its conclusions regarding safe uses and critical areas of concern. This will make EFSA's reports more clear.

23. In its comments, the complainant argued that EFSA merely acts on the information it receives from applicants, in accordance with the Pesticides Regulation. If EFSA concludes that there is a *critical area of concern*, this means, in the complainant's view, that no safe use was identified on the basis of that information, and that the substance should not be approved.

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[17] EFSA referred to Article 29(6) of the Pesticides Regulation and of the Commission Regulation 546/2011 of 10 June 2011 implementing Regulation 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (the 'Regulation implementing the Pesticides Regulation'), available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011R0546

[18] Namely, *flazasulfuron*, *isofetamid* and *epoxiconazole*.

24. The complainant agreed that pesticides containing a given active substance may be safe for specific uses in some Member States. However, for the active substances covered by the Ombudsman's inquiry, there was no data available to demonstrate this. Had EFSA had this data, it would have used it in its conclusions. The complainant claimed that the Commission had ignored the *critical areas of concern* raised by EFSA, and failed to include mitigation measures in its approval decisions. This was in violation of the Pesticides Regulation.[19]

25. The complainant argued that the Commission regularly approves active substances for which EFSA has identified critical areas of concern.

The Ombudsman's preliminary assessment

26. In her preliminary findings[20], the Ombudsman pointed out that it is not her role to question the merits of scientific evaluations carried out by specialised agencies, such as EFSA or the relevant national bodies. This inquiry therefore did not cover the substantive scientific assessments at issue in this case. However, engaged members of the public should be in a position to review decisions on the approval of substances used in pesticides, and feel confident that they are in line with the applicable legislation. The Pesticides Regulation authorises the Commission to approve active substances only if they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment.

27. Having carefully reviewed the matter, the Ombudsman expressed two concerns.

28. First, the Ombudsman was concerned about the Commission´s approval of substances based on uses that had not been assessed by EFSA.

29. The Ombudsman considered that, where EFSA has identified critical areas of concern or failed to identify safe uses, it would seem reasonable for the Commission — in order to apply the precautionary principle properly — to seek to obtain clarifications from EFSA before approving the active substance in question. **EFSA's confirmation that the Commission did not ask it for clarifications in respect of the absence of certain data concerning three active substances[21] examined during this inquiry was particularly problematic, given that it is EFSA's role to perform the scientific assessment.**

30. The Ombudsman's understanding was that, because EFSA did not receive all relevant data, it did not assess the uses for which the active substances were ultimately approved by the Commission. EFSA should have been in a position

[19] The complainant referred to Articles 4(5) and 6(i) of the Pesticides Regulation.
[20] The full text of the Ombudsman´s preliminary findings is available at: https://www.ombudsman.europa.eu/en/correspondence/en/129444
[21] *Flazasulfuron*, *isofetamid* and *epoxiconazole*.

to take a view on all the uses put forward by the applicants and considered by the Commission, since it is EFSA's role to assess the risks linked to the uses of substances.

31. The Ombudsman expressed the view that the Commission should have asked EFSA to complete the 'dossiers' (which the Ombudsman understood was the practice in new cases). The Commission should then have based its decision to approve a substance, and the conditions linked to its use, on that assessment. **This inquiry suggested that the Commission, as risk manager, took it upon itself to fill the gaps, which EFSA had not been able to assess.**

32. Second, the Ombudsman expressed concerns about the lack of transparency of the Commission´s conduct.

33. The Ombudsman considered that, **for the substances reviewed in this inquiry, the relevant section in the Commission´s review reports does not clearly explain why the Commission approved the substances in question, in spite of EFSA´s conclusions.** The failure to do so risks creating the public perception that the Commission is approving substances with unacceptable effects on the environment.

34. The Ombudsman emphasised that, as the body responsible for approving the active substance, the Commission must ensure that its decisions are clear and convincing. In particular, if EFSA's view is that the active substance is not expected to meet the approval criteria provided for in the Pesticides Regulation, and the Commission subsequently approves it, the onus is on the Commission to allay all doubts. This implies explaining more clearly the basis on which it took its decision, where possible, avoiding overly complex, technical language. If it proves unavoidable to include complex and technical language in a formal decision, the Commission should ensure that it also publishes an explanation of its decision in clear language which is readily understandable to the public. Only by doing so, can the approval process be conducted in full transparency and be subject to effective public scrutiny.

The Commission's reply to the preliminary findings

35. In its reply to the Ombudsman's preliminary findings[22], the Commission said that where EFSA's conclusions do not allow for the identification of any safe use in at least one Member State, the Commission refuses to approve the active substance concerned. The Commission seeks clarifications from EFSA where its conclusions are ambiguous or lack the necessary detail. It also imposes certain conditions or restrictions on the approval of an active substance

[22] The full text of the Commission's reply is available at: https://www.ombudsman.europa.eu/en/correspondence/en/134381

to address concerns or gaps identified by EFSA[23]. The new format of EFSA's conclusions should reduce the need to seek further clarifications over time.

36. As regards the three active substances reviewed in this inquiry, the Commission said that it had not asked EFSA for further clarifications because the information available, namely from EFSA's conclusions and the accompanying documents, was sufficiently clear. The Commission and the Member States, that is, the risk managers, agreed that EFSA's concerns did not apply to all the uses of those active substances and that they could be examined further at national level during the evaluation of applications for the authorisation of pesticides. The explanations as to why the issues identified by EFSA did not prevent the active substances from being approved were included in the relevant Commission review reports and its subsequent regulations approving the active substances and setting out the conditions for the Member States to take into consideration when deciding on the authorisations of the pesticides.

37. As regards transparency, the Commission agreed that communication of the reasons underlying its decisions should be clear and understandable to citizens to the greatest extent possible. It acknowledged that review reports for two of the substances reviewed in this inquiry were drafted in a way that could be difficult for people other than experts to understand. It said that it has already undertaken efforts and is committed to further improving readability of the review reports and that it attempts to strike a balance between providing concise information to the public on all essential elements on which it bases its decisions, while avoiding too much technical detail. In particular, the Commission aims to justify, in a transparent way, the need for any conditions imposed or necessary risk mitigation measures to ensure safe use of a pesticide containing the active substance in question. Additionally, with the aim of being transparent towards citizens, the Commission provides dedicated information, drafted in clear and concise language, on specific substances that are of particular public interest (such as neonicotinoids or glyphosate) on its website.[24]

38. In its comments, the complainant took the view that the conclusion drawn by the Commission in its review reports (that issues identified by EFSA did not apply to all uses of the active substance) was pure speculation as there was no evidence available to sustain the conclusion that there was a use that was safe. The Commission failed to apply the Pesticides Regulations and it did so to "*please some Member States that insist on getting the pesticide available for their farmers*".

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[23] The expressions "*review report*" and "*approval*" are to be understood as including also "*renewal reports*" and "*renewal of approval*".

[24] https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en and https://ec.europa.eu/food/plant/pesticides/glyphosate_en

The Ombudsman's final assessment

39. The Ombudsman reiterates her preliminary findings that (i) according to the Pesticides Regulation, pesticides containing an active substance may be considered to have at least one safe use with no harmful effects only "*on the basis of the dossier submitted*"[25]; and (ii) EFSA's independent review of the draft assessment report submitted by the Rapporteur Member State is done on the basis of an application that the Rapporteur Member State regards as complete[26].

40. When EFSA identifies a critical area of concern and/or concludes that no safe use could be identified, this conclusion is made on the basis of the information that was made available to it in the application and in the Rapporteur Member State's draft assessment report. While the active substance included in certain pesticides may be safe if used under certain conditions in certain Member States, EFSA cannot conclude that the identified uses are safe if the application, and/or the Rapporteur Member State's draft assessment report, does not demonstrate this.

41. The Ombudsman thus understands that, because EFSA did not have the data, it did not assess the uses for which the active substances reviewed in this case were ultimately approved. However, EFSA should have been in a position to take a view on all the uses considered by the Commission, since it is EFSA's role to assess the risks linked to the uses of active substances in the context of the administrative procedure leading to the approval of those substances.

42. In such circumstances, and given that EFSA´s reports on the substances under review do not reveal a clear basis for the Commission´s finding that they are indeed safe, the Ombudsman understands the complainant's concerns in respect of those active substances.

43. While the new format of EFSA's conclusions is expected to improve EFSA's reports considerably and reduce the need for clarifications, the Ombudsman insists that where EFSA identifies critical areas of concern or does not identify a safe use, the Commission should seek clarifications from EFSA before approving the active substance in question, in accordance with the precautionary principle. She will make a corresponding suggestion for improvement below.

44. The Ombudsman reiterates that performing scientific assessments is EFSA's role. While approval regulations adopted by the Commission must take due

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[25] Article 2.1 of Annex II of the Pesticides Regulation.

[26] The Ombudsman notes that, in the REFIT evaluation report issued on 20 May 2020, the Commission recommends that Member States accept only complete dossiers of high quality as admissible. See *Report from the Commission to the European Parliament and the Council - Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides, available at:* https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0208; p.5.

account of the other factors legitimate to the matter under consideration,[27] including societal, economic, traditional, ethical and environmental factors, and the feasibility of controls, they must have a solid scientific basis in EFSA´s findings.[28] As a matter of good administration, the Commission should publish and present the basis for its conclusions in a way that allows EU citizens to scrutinize them, with a view to verifying how the other factors the Commission may consider as legitimate to the matter under consideration, relate to the scientific assessment of risk carried out by EFSA.

45. As regards, more generally, the transparency of the approval process, the Ombudsman notes the Commission's commitment to enhance cooperation with EFSA, avoid using overly complex technical language and improve the general readability of its review reports. The information which the Commission has already made available in respect of substances that have attracted significant public interest, such as glyphosate, is a good starting point to allow engaged members of the public to follow the approval process and the issues that are of concern.

46. Further efforts should be made in relation to review reports of cases, such as those reviewed in this inquiry, where the public may be under the impression that the Commission approves substances that EFSA considers to be unsafe. The Ombudsman will make a second suggestion for improvement in this respect below.

The use of the confirmatory data procedure

Arguments presented to the Ombudsman

47. The complainant argued that the Commission has not effectively implemented the Ombudsman's solution proposal of 2015, and continues to use the confirmatory data procedure excessively. It claimed that, since 2015, there has been no significant decrease in the number of active substances approved on the condition that the applicant provides additional data to confirm that they can be used safely. The complainant contended that the widespread use of the confirmatory data procedure is not in line with the Pesticides Regulation.

48. The Commission explained that, for some substances[29] approved using the confirmatory data procedure, the additional data represents "*new technical knowledge*", "*confirmatory in nature*", within the meaning of the Pesticides

[27] See Article 13.2 of the Pesticides Regulation.
[28] See Recital 19, Article 3.12 and Articles 6 and 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32002R0178
[29] The Commission referred during the Ombudsman's meeting and inspection to two of the substances covered by the Ombudsman's inquiry, *benzovindiflupyr* and *isofetamid*.

Regulation[30]. The Commission sets short time limits for this type of information to be provided and, as a result, the confirmatory data is received before the Member States authorise pesticides containing the active substance. Member States authorise such pesticides only after at least one year has passed since the approval of the active substance by the Commission.

49. For other substances approved using the confirmatory data procedure, the additional data resulted from "*new scientific knowledge*", within the meaning of the Pesticides Regulation. The Commission referred to three of the substances covered by the Ombudsman's inquiry[31] for which the applications did not include adequate data on the effect of water treatment processes on the nature of residues present in surface and groundwater. The Commission claimed that the applicants had not been able to provide the necessary data in their applications because EFSA had not issued guidance on what data is acceptable for evaluating the effect of water treatment processes. Some applicants had tried to include such data, but EFSA did not accept it.

50. According to the Commission, EFSA has still not produced the guidance in question. The Commission therefore approved the substances in question on the understanding that the confirmatory data will be submitted and assessed once EFSA issues the guidance (which could take EFSA two years to develop).

51. EFSA explained that, in order to be approved, a pesticide should not have immediate or delayed harmful effects on human or animal health.[32] Applicants are required to submit data that demonstrates this. EFSA assesses the data, and may identify data gaps or unresolved issues. Where applicable, EFSA draws attention to concerns on the possible effects of water treatment processes on the ground or surface water that is used for drinking water.

52. EFSA acknowledged that no guidance is yet available to applicants on how they should address this issue, but argued that applicants could submit data based on already available information, such as peer-reviewed research. Where EFSA requests additional information, it indicates how applicants can comply with the request. However, EFSA noted that some applicants have not been able to provide the necessary data before it completed its evaluation.

53. For such substances that have been approved in the absence of data confirming that they do not have harmful effects on water, the Commission and Member State authorities, as risk managers, should ensure sufficient measures are in place to ensure that the substances are not released into the environment under inadequate conditions.

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[30] The Commission referred to Article 6(f) of the Pesticides Regulation and Article 2.2 of Annex II to the Pesticides Regulation.

[31] *Benzovindiflupyr*, *isofetamid* and *flazasulfuron*.

[32] EFSA referred to Article 4(3)(b) of the Pesticides Regulation and stated that the active substances should not lead to harmful effects either directly or through drinking water that may have residues of the substances in question.

54. In its comments, the complainant argued that applicants must submit all relevant information in their applications.[33] If an applicant fails to do so, the Rapporteur Member State should declare the application inadmissible and stop the procedure. The Commission should not give applicants a "*second chance*" to provide important missing information after it has approved the active substance. However, the Commission uses this procedure regularly.

55. In the complainant's view, the additional data in the cases in question cannot be qualified as truly "*new technical knowledge*".

56. The complainant further claimed that the applicants should have been able to submit research including the necessary data on the effects on water even if EFSA has not published specific guidance on this. As such, it claimed that the Commission's decision to use the confirmatory data procedure for such cases breached the Pesticides Regulation.[34]

The Ombudsman's preliminary assessment

57. In her preliminary findings[35], the Ombudsman reiterated her view that the Commission should use the confirmatory data procedure with particular caution and restraint.[36] This is so because any possible errors in the Commission's assessment due to insufficient data may cause serious, possibly irreversible harm to human or animal health or to the environment. As such, the Commission should be guided by the 'precautionary principle' in using this procedure.

58. The Ombudsman pointed to the fact that the report drawn up by the Commission, following the Ombudsman's earlier inquiry, shows that, in two out of ten cases under review, the assessment of the confirmatory data led to amendments to the conditions of approval.

59. The Ombudsman considered that it is not her role to assess whether the information requested under the confirmatory data procedure was due to what can genuinely be considered *new* scientific and/or technical knowledge. At the same time, it is clear that the Commission still makes regular use of the confirmatory data procedure.

60. The Ombudsman further noted that the Commission acknowledged that, for active substances approved under this procedure since 2015, the confirmatory data on the effects of water treatment processes on the nature of residues

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[33] To this end, the complainant referred also to Articles 1(4), (9), (10) and (11) of Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances (the 'Regulation on Data Requirements for Pesticides'), available here: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32013R0283.

[34] The complainant referred to Article 6(f) of the Pesticides Regulation.

[35] See footnote 20.

[36] See paragraph 22 of the Ombudsman's Decision in case 12/2013/MDC on the practices of the European Commission regarding the authorisation and placing on the market of plant protection products (pesticides), available here: https://www.ombudsman.europa.eu/en/decision/en/64069

present in surface and groundwater has not yet been provided as the necessary guidance document does not yet exist. The Ombudsman found it concerning that the active substances in question have been approved since 2015; there is still no sign of the guidance being finalised; and, even when it is finalised, a significant amount of time will elapse before the applicant is in a position to produce the data required under this guidance. Further time will be required for the data to be assessed and for the Commission to take any follow-up measures.

61. Although EFSA argued, essentially, that applicants should be able to submit such data without guidance, the Commission disagreed. Thus, the Commission was likely to continue approving substances, through the confirmatory data procedure, where applicants do not provide information on the effects on water. Therefore, the Ombudsman took the view that the Commission should apply particular caution and restraint in using the confirmatory data procedure to approve substances missing this important information.

The Commission's reply to the preliminary findings

62. In its reply to the Ombudsman's preliminary findings[37], the Commission said that it applies the confirmatory data procedure in accordance with the applicable rules.[38]

63. The Commission emphasised that the applicable rules require that assessments for approval of active substances are carried out in light of the current scientific and technical knowledge using a guidance document available at the time of application.[39] The fact that EFSA was not satisfied by the applicants' data in 80 out of 112 cases shows that a guidance document is necessary.

64. In October 2019, the Commission formally mandated EFSA and the European Chemicals Agency (ECHA) to develop, within a period of two years, a guidance document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water. The two agencies were asked to develop joint guidance since the issue is also relevant for the assessment of biocidal active substances.

65. The Commission acknowledged that the possible formation of harmful residues in drinking water is an important point that must be addressed for active substances. In addition to setting a requirement to provide confirmatory

[37] See footnote 22.
[38] The Commission referred to Article 6(f) and Point 2.2(b) of Annex II of the Pesticides Regulation.
[39] The Commission referred to Article 12(2) of the Pesticides Regulation and Article 13(1) of the Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0844-20200213)

data on this aspect, other measures exist and are applied to minimise the pollution of water bodies by active substances and their metabolites.

66. In its comments, the complainant emphasised that, in addition to water treatment, there are hundreds of other examples of confirmatory data procedures being applied by the Commission with an impact on the environment.

The Ombudsman's final assessment

67. According to the Pesticides Regulation, the Commission may ask applicants to submit confirmatory data where new requirements are established during the evaluation process or as a result of the emergence of new scientific and technical knowledge.[40] Such information must be confirmatory in nature, such as to increase confidence in the decision to approve the substance.[41]

68. The Ombudsman reiterates that it is not her role to assess whether the information requested under the confirmatory data procedure was due to what can *genuinely* be considered *new* scientific and/or technical knowledge. She nonetheless finds it reasonable for the Commission to use the confirmatory data procedure when the necessary conditions are present and the legal requirements duly fulfilled.

69. In addition, the Ombudsman notes the Commission's references to measures to manage and/or mitigate potential risks linked with issues under the confirmatory data procedures. The Ombudsman finds it reasonable that the Commission, as risk manager, takes due account of these mitigating measures.

70. Regarding the guidance document, the Commission insists that such a document is necessary. The Ombudsman does not have the required scientific expertise to decide whether such a document is or is not needed. She notes nevertheless the reference to "*guidance documents*" in the Pesticides Regulation[42] and the fact that such a document will apply also to biocidal active substances, justifying also the involvement of ECHA.

71. The Ombudsman remains concerned by the time that will elapse before applicants are in a position to produce the data under the future guidance and that will be required to assess the data once it is available. The information provided by the Commission further to the Ombudsman´s earlier inquiry (12/2013/MDC) shows that authorised active substances may be used in the environment under inadequate conditions for years before the Commission takes further restrictive measures based on confirmatory data. The Ombudsman thus reiterates her call on the Commission that it apply particular caution and

[40] Article 6(f) of the Pesticides Regulation.
[41] Point 2.2(b) of Annex II to the Pesticides Regulation.
[42] Article 12(2) of the Pesticides Regulation: "*The Authority... shall adopt a conclusion in the light of current scientific and technical knowledge using **guidance documents** available at the time of application...*" (emphasis added)

restraint in using the confirmatory data procedure to approve substances missing this important information. The amount of time needed to produce and assess confirmatory data, and to implement follow-up measures, is a factor the Commission should bear in mind when approving an active substance. A third suggestion for improvement will be made in this respect below.

Conclusion

Based on the inquiry, the Ombudsman closes this case with the following conclusion:

No further inquiries are justified at this stage.

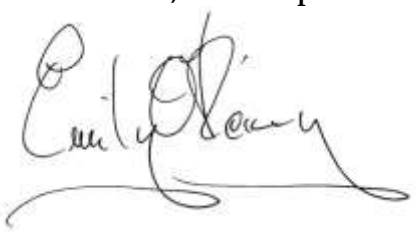
The complainant and the Commission will be informed of this decision.

Suggestions for improvement

1. The Commission should approve active substances based only on uses that have been reviewed and confirmed to be safe by EFSA. Where the Commission intends to approve a substance based on a use that EFSA has not been in a position to review, it should consult EFSA on the matter.

2. As a matter of transparency and accountability, the Commission should systematically publish an explanation of its approvals of active substances in clear language which is readily understandable to the public.

3. The Commission should use the confirmatory data procedure with particular caution and restraint, with due regard to the precautionary principle. It should be particularly mindful of cases in which applicants are unlikely to be in a position to submit confirmatory data for an extended period of time, for example due to the absence of guidance documents.



Emily O'Reilly
European Ombudsman

Strasbourg, 30/11/2020