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

Correspondence - 22/06/2020
Case 1570/2018/JF - **Opened on** 08/03/2019 - **Decision on** 30/11/2020 - **Institution concerned** European Commission (No further inquiries justified) |

Ms Ursula von der Leyen

President

European Commission

Strasbourg, 22/06/2020

Complaints 1570/2018/JF-JN and 1973/2018/JF-JN

Preliminary findings of the European Ombudsman in the above cases on how the European Commission approves substances used in plant protection products (pesticides)

Dear President,

I am writing to inform you of my preliminary findings, following my inquiry into the above complaints, received from Pesticide Action Network Europe. Before I proceed further, it would be useful to hear the Commission's views, particularly given the policies your Commission has brought forward, which have implications for future pesticide use. I note, in particular, that the Commission has announced that it will take action to reduce by 50% the overall use of – and risk from – chemical pesticides by 2030. [1]

This inquiry has focused on: (a) the Commission´s approval of active substances for which the European Food Safety Authority (EFSA) has identified areas of concern or no safe uses; and (b) 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´). While I appreciate that these decisions are taken by the Commission, after Member States have

provided their input in the relevant Standing Committee, my inquiry has identified the following issues that I bring to your attention.

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

The Commission can 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. While, as Ombudsman, I am not best placed to conclude whether or not the Commission has consistently respected this obligation, this inquiry has identified the following concerns:

(i) Risk assessment competence - 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** [2] [Link] **examined during this inquiry is particularly problematic, given that it is EFSA's role to perform the scientific assessment.**

Our understanding is that, because EFSA did not have the data, it did not assess the uses for which the active substances were ultimately approved. EFSA should have been in a position 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.

Arguably, what the Commission should have done, when faced with the problem of taking a decision on uses of substances that had not been assessed by EFSA, would have been to ask EFSA to complete the 'dossiers' (which I understand is the practice in new cases). The Commission should then have based its decision to approve the uses of a substance, and the conditions linked to that use, on that assessment. **This inquiry suggests that the Commission, as risk manager, took it upon itself to fill the gaps, which EFSA had not been able to assess.**

(ii) Transparency - The Commission said that its review reports on approved active substances aim to explain the reasons behind its approval decisions. However, **for the substances reviewed in this inquiry, the relevant section in the 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.

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.

(b) How the Commission uses the 'confirmatory data procedure'

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. [3] Such information **must be confirmatory in nature** , such as to increase confidence in the decision already taken to approve the substance. [4] [Link]

It is not my role to assess whether information requested under the confirmatory data procedure is due to what can genuinely be considered *new* scientific and/or technical knowledge. In my previous inquiry on this matter, however, I pointed out that the Commission should use the confirmatory data procedure with particular caution and restraint. [5] [Link] 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. In two of the ten substances examined in my previous inquiry, problems were identified after the confirmatory data was submitted.

The Commission acknowledges that, for active substances approved under this procedure since 2015, the confirmatory data on the **effect of water treatment processes** on the nature of residues present in surface and groundwater has not yet been provided as the necessary guidance document does not yet exist **. I find 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. I am also mindful that, although EFSA argues, essentially, that applicants should be able to submit such data without guidance, the Commission disagrees.** Since the Commission is therefore likely to continue approving substances, through the confirmatory data procedure, where applicants do not provide information on the effects on water, the Commission should apply particular caution and restraint in using the confirmatory data procedure to approve substances missing this important information.

As noted at the outset, this letter sets out my preliminary findings, with further explanations contained in annex. I would be grateful if you could inform me by **30 September 2020** of your views in relation to the concerns set out. I will also share these preliminary findings with the complainant for its views. Once I have obtained the views of the Commission and the complainant, I will proceed to a decision in this case or to a recommendation, if necessary.

Thank you in advance for your cooperation on this important matter.

Yours sincerely,

Emily O'Reilly European Ombudsman

Enclosures:

● Annex containing the Ombudsman's preliminary findings; [Link]

[1] [Link] Commission Communication - EU Biodiversity Strategy for 2030 (COM/2020/38)

https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1590574123338&uri=CELEX:52020DC0380 [Link]

[2] [Link]*Flazasulfuron* , *isofetamid* and *epoxiconazole.*

[3] [Link] Article 6(f) of the Pesticides Regulation.

[4] [Link] Point 2.2.(b) of Annex II to the Pesticides Regulation.

[5] [Link] 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 [Link]