European Ombudsman

Letter to the European Commission in cases 1570/2018/JN and 1973/2018/JN on the Commission's approval of active substances for plant protection products

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

Mr Jean-Claude Juncker

President

European Commission

Strasbourg, 08/03/2019

Complaints 1570/2018/JN and 1973/2018/JN

Subject: The European Commission's approval of active substances for plant protection products (pesticides)

Dear Mr President,

I have received two complaints (1570/2018/JN and 1973/2018/JN) from Pesticide Action Network Europe about how the Commission approves active substances for plant protection products. These complaints are related to my earlier inquiry into complaint 12/2013/MDC from the same complainant.

On 5 October 2018, I informed you of complaint 1570/2018/JN which focuses on how the Commission implemented the findings and proposals I made in the context of inquiry 12/2013/MDC.

I have now received a second complaint (1973/2018/JN) in which the complainant contends that the Commission "distorts science" in that it does not draw the appropriate conclusions from EFSA's identification of "critical areas of concern". The complainant mentions **several substances** which the Commission approved in spite of the fact that EFSA had identified

critical areas of concern. The complainant refers to the definition contained in EFSA's reports and claims that the Commission could not legitimately consider the substances as safe. In the complainant's view, the Commission thus altered EFSA's scientific findings without providing adequate explanations.

The issues raised by the complainant are of public interest as you will of course appreciate in that any possible shortcomings in the Commission's work in this area may have serious implications for human health, the health of animals or the environment.

Complaints 1570/2018/JN and 1973/2018/JN are closely related and I have decided to look into both complaints simultaneously and to open an inquiry.

As a first step in this inquiry, I would like to request a meeting and inspection of documents, in relation to the following active substances: *flazasulfuron* , *isofetamid* , *picolinafen* , *benzovindiflupyr* and *epoxiconazole.*

During the meeting and inspection, I would appreciate it if the Commission could:

1) Provide yearly figures showing that the Commission uses the confirmatory data procedure in a limited number of cases only and that the use of this procedure has decreased over time.

2) Provide the inquiry team with the Commission's files concerning the approval process (as provided for in Regulation 1107/2009 [1]) for the above five substances [2] .

3) (Regarding those substances out of the five for which the Commission requested confirmatory data), provide evidence showing that it approved these substances and requested confirmatory data in line with the legal requirements (Article 6f of Regulation 1107/2009 and Article 2.2 of Annex II of Regulation 1107/2009).

4) Explain how it interprets "critical area of concern" and "no safe use identified" taking into account the definitions in EFSA's reports.

I note, in relation to *flazasulfuron* , *isofetamid* and *epoxiconazole* , that EFSA explains in a table summarising its concerns: " *Columns are grey if no safe use can be identified.* " For the three substances the whole table is grey, which appears to imply that no safe use could be identified. On this basis, and bearing in mind that EFSA is the risk assessor and the Commission the risk manager:

5) Could the Commission clarify what action it takes when it approves substances for which EFSA has identified "critical areas of concern" or considers that "no safe use could be identified"?

6) Would the Commission be ready to include in future review reports a section explaining its approach to such EFSA findings?

7) If the Commission considers the information and definitions in EFSA's reports to be misleading, could the Commission set out what action might be taken to address this issue?

If the Commission prefers to reply to these questions in writing rather than during the meeting [3] , that is of course possible.

I would be grateful if your office could contact Mr Josef Nejedly (+33 3 88 16 41 48, josef.nejedly@ombudsman.europa.eu), who is in charge of this inquiry, to agree the arrangements for the meeting and inspection to take place before 30 April 2019.

Information or documents that your institution considers to be confidential will not be disclosed to the complainant or any other person without the prior agreement of the Commission. Information and documents of this kind will be deleted from the European Ombudsman's files shortly after the inquiry has ended [4] .

Finally, please note that my inquiry deals with the above issues only. The purpose of my inquiry is not to re-examine the scientific assessment of the substances in question.

Emily O'Reilly

European Ombudsman

Enclosure: -Complaint 1570/2018/JN -Complaint 1973/2018/JN

[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 L 309 24.11.2009, p. 1.

[2] If the files are particularly voluminous, the Commission can contact the inquiry team to discuss how to proceed.

[3] The Commission's replies would be documented in the report from the meeting combined with the inspection of documents.

[4] In accordance with Articles 4.8 and 9.4 of the European Ombudsman's Implementing Provisions: https://www.ombudsman.europa.eu/en/resources/provisions.faces [Link]