

## How the European Commission adopted a guidance document on comparative assessment in the context of the substitution of hazardous substances in pesticides

Case opened

**Case 177/2023/VB - Opened on 24/02/2023 - Institution concerned** European Commission |

Ms Ursula von der Leyen

President

European Commission

Dear President,

I have received a complaint against the European Commission concerning its adoption of a guidance document on comparative assessment in the context of the substitution of hazardous substances in pesticides [1] .

The complainant, Pesticide Action Network Europe (PAN Europe), is concerned that the Commission included in its guidance document a standard developed by the European and Mediterranean Plant Protection Organization.

The complainant considers that the standard developed by this organisation is not in line with the provisions of the Plant Protection Products Regulation [2] (“the PPP Regulation”) and hinders the substitution of dangerous substances. It also takes the view that the organisation does not meet EU standards of transparency and independence in its work and that the pesticides industry heavily influenced the preparation of the standard.

I have decided to open an inquiry into this complaint. I have concluded that it would be useful to receive a written reply from the Commission to the complainant’s concerns and



taking into account the questions set out in annex.

Please note that I have sent a copy of this letter and related annex to the complainant. I am also likely to send your reply and related enclosures to the complainant for comments [3]. We may also decide to publish your reply. The responsible inquiries officer is Mr Vieri Biondi.

I would be grateful to receive the Commission's reply by 24 May 2023. If, in the course of this inquiry, the Commission becomes involved in court proceedings concerning the same subject matter as this complaint, I would ask you to let us know.

Yours sincerely,

Emily O'Reilly European Ombudsman

Strasbourg, 24/02/2023

**ANNEX - 177/2023/VB**

**1.** Could the Commission please address the complainant's claim that the standard developed by the European and Mediterranean Plant Protection Organization does not comply with the PPP Regulation and hinders the substitution of substances that are identified as candidates for substitution? In particular, I would appreciate it if the Commission could address the complainant's arguments that the organisation's standard

(a) uses the concept of "available chemical diversity of mode of actions" instead of that of "chemical diversity of the active substances", as required by Article 50 of the PPP Regulation; and

(b) treats "minor uses" in a way that is not compliant with the Regulation.

**2.** Could the Commission please comment on whether the reference in its guidance document to a standard developed by an international organisation, of which non-EU countries are members, for the purpose of interpreting EU legislation implies or, at least, may create an impression that the international standard has to be treated as an official EU standard and applied accordingly?

**3.** When the Commission refers in a guidance document (which authorities of EU Member States are likely to rely on) to a standard developed by non-EU bodies or international organisations, how does it ensure that such standards are in line with EU law and that they are developed based on independent expertise?

**4.** In this case, what concrete actions did the Commission take before issuing the guidance document to ensure that the standard developed by the organisation complied with EU law? Did the Commission review the procedure that led to the adoption of the standard before including it in the guidance document to ensure that it had been developed independently? If so, did the Commission carry out similar assessments for the updated



versions of the standards, which were adopted after the guidance document had been issued?

[1] Draft Guidance document on Comparative Assessment and Substitution of Plant Protection Products, SANCO/11507/2013 rev. 12,  
[https://food.ec.europa.eu/system/files/2016-10/pesticides\\_aas\\_guidance\\_comparative\\_assessment\\_substitutio](https://food.ec.europa.eu/system/files/2016-10/pesticides_aas_guidance_comparative_assessment_substitutio)

[2] Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107> .

[3] If you wish to submit documents or information that you consider to be confidential, and which should not be disclosed to the complainant, please mark them 'Confidential'. Encrypted emails can be sent to our dedicated mailbox. Information and documents of this kind will be deleted from the European Ombudsman's files shortly after the inquiry has ended.