Preliminary findings of the European Ombudsman 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)

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) |

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.

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] 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.

7. In September 2018, the complainant contacted the Ombudsman to raise concerns with how the Commission had implemented the Ombudsman's solution proposal. [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 additional 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.

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

Arguments presented to the Ombudsman

12. 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.

13. 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.

14. 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 reports 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 it structures its reports in 2018 to address this problem.

15. If the Commission identifies at least one safe use in at least one Member State, it approves the active substance, in accordance with the Pesticides Regulation. [13] In its 'review reports', the Commission explains why it has approved a given active substance, taking into account EFSA´s findings and conclusions. [14]

16. EFSA stated that it identifies an issue as a **"** *critical area of concern* **"** when, having regard to the current scientific and technical knowledge available at the time of the application, **the active substance is not expected to meet the approval criteria** provided for in the Pesticides Regulation [15] . 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 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) [16] .

17. EFSA stated that it does not evaluate all possible uses. 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, for example, because of insufficient data in the application. EFSA is trying to go further in identifying possible safe uses and scenarios under particular conditions of use.

18. EFSA confirmed 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 *flazasulfuron* , *isofetamid* and *epoxiconazole* .

19. Since October 2018, EFSA no longer marks the columns in its tables grey. It accepted 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.

20. 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.

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

22. 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.

23. 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. [17]

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

The Ombudsman's preliminary assessment

25. Since the new Commission took office at the end of 2019, it has adopted the European Green Deal, the EU Biodiversity Strategy for 2030 and the Farm to Fork Strategy, all with far-reaching implications for the use of pesticides. Specifically, the Commission has announced that it will take action to reduce by 50% the overall use of – and risk from – chemical pesticides by 2030. [18] As part of this, the environmental risk assessment of pesticides will be strengthened.

26. While these goals are laudable, the Commission must ensure that, with each decision it takes, it is working to give effect to this approach and to meet the public's expectations. The Commission itself has pointed out that, when it comes to food safety, pesticides are among the most frequently reported concerns that Europeans express. [19]

27. It is not the role of the Ombudsman to question the merits of scientific evaluations carried out by specialised agencies, such as EFSA or the relevant national bodies. As such, the Ombudsman is not in a position to ask the Commission to review the substantive decisions it takes, together with the Member States, in approving substances, based on such evaluations. This inquiry therefore does 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.

28. 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 the Ombudsman is not best placed to conclude whether or not the Commission has

consistently respected this obligation, the complainant - a civil society organisation with considerable expertise in the matter - has serious substantive concerns.

29. Having carefully reviewed the matter, the Ombudsman's concerns are twofold, as follows.

Risk assessment competence

30. 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* " [20] .

31. The Rapporteur Member State decides on the admissibility of an application for the approval of an active substance and the accompanying files. In the draft assessment report that it submits to EFSA, the Rapporteur Member State should include risk mitigation options for any uses of an active substance for which concerns may exist. These risk mitigation options should then be addressed in EFSA's conclusions report.

32. EFSA conducts an independent review of the draft assessment report submitted by the Rapporteur Member State. This is done on the basis of an application that the Rapporteur Member State regards as complete [21] . All necessary information should have already been provided to the Rapporteur Member State by the applicant. The Commission, the 'risk manager', is informed throughout.

33. 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.

34. EFSA has acknowledged that, in the past, it may not have received all necessary available information on possible uses and mitigation measures. To address this EFSA has recently issued guidelines aimed at ensuring applicants and Member States provide complete information on the uses of active substances and potential mitigation measures at an earlier stage. This is welcome.

35. 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** [22] **examined during this inquiry is particularly problematic, given that it is EFSA's role to perform the scientific assessment.**

36. The Ombudsman's 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.

37. 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 the Ombudsman understands 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.**

Transparency

38. 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.** [23] The failure to do so risks creating the public perception that the Commission is approving substances with unacceptable effects on the environment.

39. 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 use of the confirmatory data procedure

Arguments presented to the Ombudsman

40. 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.

41. During the meeting and inspection, the Commission explained that, for some substances [24] approved using the confirmatory data procedure, the additional data represents " *new technical knowledge* ", " *confirmatory in nature* ", within the meaning of the Pesticides

Regulation [25] . 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.

42. 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 [26] for which the applications did not include 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.

43. 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).

44. EFSA explained that, in order to be approved, a pesticide should not have immediate or delayed harmful effects on human or animal health. [27] 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.

45. 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.

46. 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.

47. In its comments, the complainant argued that applicants must submit all relevant information in their applications. [28] 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.

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

49. 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. [29]

The Ombudsman's preliminary assessment

50. 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 [30] . Such information must be confirmatory in nature, such as to increase confidence in the decision to approve the substance. [31]

51. In her previous inquiry, the Ombudsman pointed out that the Commission should use the confirmatory data procedure with particular caution and restraint. [32] 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.

52. The report drawn up by the Commission, following the Ombudsman's earlier inquiry, shows that, in two cases, the assessment of the confirmatory data led to amendments to the conditions of approval. In one case (haloxyfop-P), it was decided to set limits for the application rate and frequency of application to avoid risks to groundwater, while in the other (malathion), the Commission considered that the confirmatory data provided was not sufficient to conclude that the risks to birds were acceptable. The Commission had therefore proposed the adoption of an act restricting the approval of malathion to uses in greenhouses.

53. Again, it is not the role of the Ombudsman 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 and that in two of the ten substances examined by the Ombudsman in her earlier inquiry, problems were identified after the confirmatory data was submitted.

54. The Commission acknowledges 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 present in surface and groundwater has not yet been provided as the necessary guidance document does not yet exist. The Ombudsman is not in a position to review whether the Commission and Member State authorities, as 'risk managers', have put

in place sufficient measures so that the substances are not released into the environment under inadequate conditions.

55. The Commission, for its part, insists that the confirmatory data procedure allows it to obtain, in a timely manner, data or studies that are not required when the application is submitted. Specifically, regarding risks to groundwater, the confirmatory data requests relate to new data to be generated in accordance with a new guidance document that does not yet exist. If not requested under the confirmatory data procedure as a condition for the approval, the applicant would need to provide such information only in the context of the next renewal of the substance. [33]

56. The Ombudsman finds this to offer little reassurance in this case. It is 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.

57. Although EFSA argues, essentially, that applicants should be able to submit such data without guidance, the Commission disagrees. Since it 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.

Annex

Excerpt from section 3 of the Commission's review report on *flazasulfuron*

"The following points could not be finalised or were considered as a critical area of concern by EFSA (2016) for *flazasulfuron* :

....

- The groundwater metabolite relevance assessment for metabolite TPSA could not be finalised while the available information was insufficient to determine reference values that might be used to complete a consumer risk assessment consequent to the consumption of drinking water derived from groundwater where 80th percentile annual average concentrations of TPSA moving below 1m have been estimated to be > 0.75 lg/L for all the representative uses assessed.

The PEC GW calculations included in the EFSA conclusion indicated that the parametric drinking water level of 0.1 µg/L may be exceeded in all FOCUS groundwater scenarios by the metabolite TPSA (SSRE-001), which triggered further assessment of the relevance of this metabolite. The TPSA metabolite was not found to be toxic by oral route and its genotoxic potential was ruled out. Since TPSA was identified in mammalian metabolism studies, it has also been considered as part of the toxicity studies along with the parent flazasulfuron that is not classified as toxic, carcinogenic or toxic for reproduction. Therefore, it is considered appropriate to apply the threshold of toxicological concern approach which sets the upper

limit for the concentration of a metabolite of 0.75 µg/L that would assure an acceptable consumer exposure levels. The EFSA conclusion indicates that the TPSA metabolite may occur below 0.75 µg/L in 70% to 100% of the scenarios, depending on the representative uses, thus demonstrating a number of safe scenarios.

As regards the remaining FOCUS groundwater scenarios where the levels of estimated concentrations of metabolite TPSA lie between 0.75 µg/L and 10 µg/L (2/7 of the scenarios for the representative use in grapes and 1/4 of the scenarios for olives with a March application date), the demonstration of acceptable consumer exposure would require refined toxicity data and risk assessment. However, the information available is not sufficient (repeated dose study is missing) to determine reference values and complete a consumer risk assessment for these particular cases.

Member States should carry out appropriate groundwater assessments for intended uses. Member States should in particular consider the outcome of the PEC GW calculations for metabolite TPSA when making decisions on authorisation of plant protection products.

- For the representative use on olives, the groundwater metabolite relevance assessment for metabolite HMTU could not be finalised, while the available information was insufficient to conclude on its genotoxic potential.

For the representative uses on grapes, citrus ad olives (with a March application), all the groundwater scenarios result in levels of metabolite HMTU (SSRE-006) below the drinking water limit of 0.1 µg/L, thus demonstrating acceptable uses.

However, for the October and December application in olives, the level of 0.1 µg/L is exceeded in most of the FOCUS groundwater scenarios. As regards the relevance of the metabolite HMTU, its genotoxic potential was tested in a battery of in vitro studies including a negative Ames test, negative HPRT gene mutation assay and positive chromosome aberration (CA) test. An appropriate in vivo test that could override or confirm the positive in vitro CA test was not available, therefore the genotoxic potential of metabolite HMTU cannot be currently ruled out. It is therefore considered appropriate to remove the representative uses on olives with October and December application dates from Appendix II to this Renewal Report.

Member States should carry out appropriate groundwater assessments for intended uses, and in the event of exceedance of the 0.1 µg/L trigger value by metabolite HMTU, consider the request for additional information as regards its relevance when making decisions on authorisation.

Taking into account these points and the specific conditions under section 6, the Committee considered that an overall acceptable use of products containing flazasulfuron is expected".

[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

[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 .

[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] Article 4(5).

[14] 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=
.

[15] 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.

[16] 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

[17] The complainant referred to Articles 4(5) and 6(i) of the Pesticides Regulation.

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

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

[19] Commission Communication COM/2020/381 A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system. See: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0381

Source: Special Eurobarometer (April 2019), *Food safety in the EU* .

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

[21] 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.

[22] *Flazasulfuron* , *isofetamid* and *epoxiconazole.*

[23] See, by way of example, the Commission's explanation in the case of *flazasulfuron* , set out in annex.

[24] The Commission referred to two of the substances covered by the Ombudsman's inquiry, *benzovindiflupyr* and *isofetamid* .

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

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

[27] 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.

[28] 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 .

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

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

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

[32] 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

[33] See Commission Report in reply to a further remark from the European Ombudsman in her closing decision in case 12/2013/MDC; p.5.