Comments of the Commission on the preliminary findings of the European Ombudsman - Complaints by Mr [redacted] on behalf of Pesticide Action Network, ref. 1570/2018/JF-JN and 1973/2018/JF-JN

I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY

On 22 June 2020 the European Ombudsman ('the Ombudsman') transmitted her preliminary findings following the inquiry into two complaints 1570/2018/JF-JN and 1973/2018/JF-JN, submitted by Pesticide Action Network, on how the European Commission approves active substances used in plant protection products to the President of the European Commission.

In her letter, the Ombudsman has identified issues related to the two matters of the inquiry: (a) approval of active substances for which the European Food Safety Authority (EFSA) had identified critical areas of concern or the absence of safe uses (complaint 1973/2018/JF-JN and (b), as a follow up to an earlier complaint (case 12/2013/MDC), the practice of the Commission to approve active substances subject to the subsequent submission of confirmatory information (complaint 1570/2018/JF-JN).

As set out in her earlier letter of 8 March 2019, the Ombudsman had decided to look into both complaints simultaneously and to open an inquiry. As a first step in this inquiry, the Ombudsman requested a meeting with the Commission services to obtain clarifications and inspecting documents, in particular in relation to the following active substances: flazasulfuron, isofetamid, picolinafen, benzovindiflupyr and epoxiconazole (object of complaint 1973/2018/JF-JN).

The meeting was held at the Commission premises on 17 May 2019. During the meeting, the Commission services provided the Ombudsman's inquiry team with tables and statistical data concerning all Regulations approving active substances adopted since 2015 under Regulation 1107/2009[1] (the 'PPP Regulation') and setting requirements for confirmatory data. As agreed during the meeting, on 22 May 2019 and on 28 June 2019 the Commission services submitted further documents to the Ombudsman.

On 28 August 2019, the Ombudsman services produced a report of the meeting and inspection, after having given the Commission services the possibility to comment on a draft version before finalisation.

In addition, by letter of 5 September 2019, the Ombudsman sought input from EFSA on two aspects of the above complaints: (1) the drafting of EFSA conclusions regarding the identification of 'critical areas of concern' and the identification of safe uses, and (2) the approval of active substances with a requirement for confirmatory data on effects of water treatment processes on the nature of residues in the absence of scientific guidance established by EFSA and the time that EFSA may need to develop such guidance. EFSA replied to the above request by letter dated 29 October 2019.

The Ombudsman also invited the complainant to comment on the report on the meeting on 17 May 2019 and the documents provided. The complainant sent his comments on 2 January 2020.

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[1] Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market (OJ L 309, 24.11.2009, p. 1).

II. THE COMMISSION'S COMMENTS TO THE OMBUDSMAN'S PRELIMINARY FINDINGS

In her preliminary findings, the Ombudsman comments on three issues: the Commission's approval of active substances for which EFSA has identified critical areas of concern or no safe uses, the transparency in explaining the Commission's reasoning in approving such active substances, and the setting of confirmatory data in approvals.

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

The Ombudsman finds that where EFSA has identified critical areas of concern or failed to identify safe uses, it would seem reasonable for the Commission to seek to obtain clarifications from EFSA before approving the active substance in question given that it is EFSA's role to perform the scientific assessment. In the Ombudsman's understanding, because EFSA did not have all the necessary data, it did not assess the uses for which the active substances were ultimately approved. The Ombudsman notes that the Commission did not ask for such clarification in respect of the absence of data concerning three active substances (flazasulfuron, isofetamid, epoxiconazole) examined during the inquiry, and that instead the Commission, as risk manager, took it upon itself to fill in the gaps, which EFSA had not been able to assess.

The Commission would like to recall that the structure of the EU regulatory framework, as laid down in the PPP Regulation, is comprised of two distinct steps: First, the EU wide approval of active substances for use in plant protection products, based on the determination that there is at least one safe representative use in one Member State of a plant protection product containing that substance (as stipulated in Article 4(5) of the PPP Regulation in conjunction with Annex II, point 2.1 thereto). This step comprises an assessment by a rapporteur Member State, which is subject to public consultation, followed by a peer review by all Member States and EFSA, leading to an EFSA conclusion.

The second step consists in the subsequent authorisation, at Member State level, of the actual use of a plant protection product containing the approved substance. The structure relies on the rationale expressed in recital 23 of the Regulation "*Plant protection products containing active substances can be formulated in many ways and used on a variety of plants and plant products, under different agricultural, plant health and environmental (including climatic) conditions. Authorisations for plant protection products should therefore be granted by Member States*."

As discussed during the meeting on 17 May 2019, the way the conclusions of EFSA on active substances were presented in the past, which is at the basis of the complaints, may have raised misunderstandings as to the findings about the possibilities for a safe use of the substances at issue. EFSA did sometimes not present its conclusions in sufficient nuances and details. Despite a statement in the conclusions that 'no safe use can be identified', there may well be some safe uses in individual Member States.

In fact, as set out above, plant protection products containing approved active substances are subject to authorisation at Member State level, taking into account the specific agricultural, plant health and environmental (including climatic) conditions. However, the assessment of the safety of the active substance for use in plant protection products is an

EU wide process, based on one or more representative uses and using a number of different models or scenarios for conducting the risk assessment that reflect the varied conditions in the Member States. EFSA may have stated in its conclusions that 'no safe use can be identified' where the outcome of the assessment for the majority of the models/scenarios for a particular use were considered to be unsafe although a minority may have been considered safe[2]. In such cases, authorisation of plant protection products in some Member States the conditions of which are reflected in these models/scenarios remains possible and therefore the active substance can be approved.

In the meantime, EFSA itself realised that the practice of greying columns in the table in section 9 of its conclusions and using the note 'Columns are grey if no safe use can be identified' could create confusion and stopped doing so in the course of 2018. In addition EFSA has started to provide more detail in its Conclusions where a safe use or safe scenarios may be identified under particular conditions of use, as confirmed in EFSA's reply of 29 October 2019 to the Ombudsman[3].

The Commission would however strongly underline that where the conclusions of EFSA do not allow the identification of any safe use in at least one Member State, it refuses (renewal of) approval of the active substance concerned. For the particular cases mentioned, the Commission does not share the Ombudsman's view that the Commission filled data gaps, which EFSA had not been able to assess, or acted itself as risk assessor.

EFSA identifies a data gap where it considers that the information provided by the applicant is too limited to allow concluding on certain aspects, i.e. where the assessment in some areas cannot be finalised. EFSA conclusions include a section listing the data gaps established during the peer review.

In each of the cases at issue, the Commission acted on the basis of all the information available, namely (i) the assessments carried out by the rapporteur Member States, (ii) the EFSA conclusions, (iii) comments received from applicants on the EFSA conclusion and the Commission's draft review/renewal reports, and (iv) comments from Member States during the decision-making process in the Standing Committee on Plants, Animals, Food and Feed.

The Commission did not seek further clarification on the issues that could not be finalised as the related concerns were detailed in the EFSA Conclusions or the accompanying documents in a manner that was sufficiently clear to be understood by the Commission and Member States. In their roles as risk managers they agreed that these issues did not

[2] For example, EFSA identified a critical area of concern in relation to the contamination of groundwater, if in more than half of the eight FOCUS scenarios (which are used to represent the different conditions across Member States), the active substance or relevant metabolites thereof were predicted to occur above the legal limit of 0.1 µg/L, even if this was not the case in up to three of these scenarios. Therefore, despite the overall negative conclusion, a safe use for groundwater was actually identified for Member States in which those 3 scenarios are applicable.

[3] See in particular the explanations provided by EFSA on page 2 and in footnote 3 : '*For this purpose, where relevant, footnotes are now added in the summary table to explain specific concerns or potential safe scenarios and give additional details e.g. in case safe use could be identified when the substance is used in permanent greenhouse structures, thus allowing risk managers to consider restricting the use in to applications only in greenhouses with permanent structures, consideration of the difference in risk to bees for a crop when harvested before flowering or when harvested after flowering in case of seed production, restriction of use to every X number of years, etc.*

apply to all uses and could be examined further during the evaluation of applications for the authorisation of plant protection products at national level. Section 3 of the Review/Renewal Reports provided explanations (see also next section as regards transparency) why the issues identified by EFSA did not preclude approval/renewal of approval and specific approval conditions were set in the Commission Regulations approving (or renewing the approval) of the substances as areas for Member States to pay attention to during product authorisation[4] or *via* a request for confirmatory information[5]. Epoxiconazole was approved in 2008 in accordance with conditions set out in Directive 91/414/EEC, at a time when both the regulatory framework and the working practices of explaining issues in the review reports were different. The Commission considers that the decision reflected the practice at the time, however, recognises that the level of transparency then was different to what is practiced now.

As noted by the Ombudsman in her preliminary findings, over recent years the Commission has established a practice of seeking clarification from EFSA where its conclusions are ambiguous or lacking the necessary detail, in order to document more transparently how it has come to a decision on approval or non-approval of an active substance. The Commission also fulfils its role as risk manager and, where considered relevant imposes certain conditions or restrictions on the approval of an active substance to address concerns or gaps identified by EFSA. Furthermore, in recent years the Commission has worked towards increasing the transparency as regards the rationale underlying the regulatory decision making at risk manager level which is reflected in the review/renewal reports (see also next section).

Furthermore, as explained during the meeting on 17 May 2019, the Commission, EFSA and the Member States are in dialogue since 2018 to improve the clarity of EFSA's conclusions on active substances[6]. As a consequence, the format of the EFSA Conclusions has been amended, as presented by EFSA at the meeting of the Standing Committee on Plants, Animals, Food and Feed in December 2019[7], and the format will be further adapted before the end of 2020 as explained by EFSA at the meeting of the Standing Committee in May 2020[8]. This process for seeking further improvements will continue.

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[4] For example, in the case of flazasulfuron: *'Member States must pay particular attention to …. the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate*'. In the case of isofetamid: '*Member States shall pay particular attention to the risk to …. aquatic organisms, in particular fish. Conditions of use shall include risk mitigation measures, where appropriate'.* This reflects the two-step process foreseen in the regulatory framework explained on the previous page.

[5] In both cases confirmatory information on the impact of water treatment process was requested, pending the development of guidance in this area. In the case of isofetamid, confirmatory information was also requested on the specification since this was a new active substance and the specification of the substance (i.e. main compound and impurities) in the dossier was based on pilot scale production, which might change if production is scaled up to higher volumes. The information was submitted by the applicant and considered sufficient to address the requirement, as detailed in the Technical Report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for isofetamid in light of confirmatory data (EFSA supporting publication 2018:EN-1403. 23 pp. doi:10.2903/sp.efsa.2018.EN-1403, available at: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1403. The Commission intends to amend in the near future the reference specification as agreed during the evaluation.

[6] See for example the minutes of meetings between the Commission and EFSA, and between EFSA, Member States and the Commission transmitted to the Ombudsman on 28 June 2019 and 22 May 2019, respectively.

[7] https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20191205_ppl_sum.pdf, agenda item A.15

[8] https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20200518_ppl_sum.pdf, agenda item A.12

Even though due to the inherent length of the evaluation process set out by the legislator (about 3 years between the submission of the application and the regulatory decision-making at the Standing Committee), it will take some time to implement these improvements and see the concrete results in the published EFSA Conclusions, they should reduce the need for seeking further explanations or clarification during the decision-making process.

2) Transparency

In her preliminary findings, the Ombudsman observes that, 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 Commission agrees that communication of the reasons underlying its decisions should be as clear as possible and understandable to citizens to the greatest extent possible, while taking into account the inherent highly complex scientific and technical nature of the assessment of pesticides. As mentioned above, efforts have been undertaken over the past several years to ensure more clarity of EFSA's conclusions, which underpin the decisions on active substance.

The Commission notes that the review/renewal reports for two of the substances referred to in the complaint did provide some explanations as regards the rationale of the Commission's decision[9], but recognises that these were drafted in a way that might be

[9] In her preliminary findings, the Ombudsman specifically refers to (and provides an excerpt of) the renewal report for flazasulfuron. The Commission would like to note that in relation to the points related to the leaching into groundwater of metabolites TPSA or HMTU, the Renewal Report explains that according to the outcome of the peer review, these metabolites are not predicted to occur above the relevant limit values in all scenarios for all uses, meaning that they are expected to remain below the limits (i.e. demonstrating safety) in a number of scenarios, which enables the renewal of approval.
In fact, according to the relevant guidance document, since TPSA is not a so-called 'relevant metabolite', it can occur in groundwater up to 0.75 µg/L without the need for a consumer risk assessment. For some scenarios (3 out of 7) this metabolite was indeed predicted to occur below 0.75 µg/L.
For the metabolite HTMU the assessment of 'relevance' could not be completed and therefore its occurrence in groundwater should remain below 0.1 µg/L unless data can be provided to exclude its relevance. The peer review concluded that this metabolite is expected to be below 0.1 µg/L for the use on citrus and grapes and also in olives when the substance is applied in March, while this was not the case, when used on olives in October to December. Therefore, use of the substance on olives in October or December (as also intended by the applicant) was not included in the list of supported uses in Appendix II to the Renewal Report (which is entitled: 'List of uses supported by available data'). As a consequence, Member States must be particularly vigilant when assessing applications for other uses not listed in Appendix II and carefully check that additional data are provided as they cannot assume that the same data as already provided for the renewal would be sufficient for granting an authorisation. This results in particular from the 2nd paragraph of Section 3 in the Renewal Report, which reads: '*Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this renewal report)'*.

As an example for isofetamid, the review report addresses in Section 3 on page 4 the point related to the assessment of the relevance of some individual impurities present in the technical specification in comparison with the (eco)toxicological profile of the parent compound. It explains that as the specification is based on pilot plant production and needs to be confirmed following commercial scale production, the equivalence of the final specification with the batches used in the toxicological assessment should be confirmed, including the relevance of impurities and that this will be resolved via the request for confirmatory information.

'High risk to aquatic organisms', explaining that the risk identified can be addressed by the application of risk mitigation measures, and that, given that there are higher tier options available to refine the risk assessment, Member States should consider the risk to aquatic organisms when considering applications for authorisation

difficult to understand for non-experts. Therefore, the Commission has already undertaken efforts and is committed to further improving readability of the review or renewal reports, which accompany the Implementing Regulations for the approval or renewal of approval of active substance, as recommended by the Ombudsman in her preliminary findings. The Commission attempts to strike a balance to provide concise information to the public on all essential elements on which the Commission bases its decision, while avoiding too much technical detail as this would make the review/renewal report less accessible to non-experts. In particular, the Commission in its role of risk manager aims to transparently justify the need for any conditions imposed or necessary risk mitigation measures to ensure safe use of a plant protection product 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[10,11].

3) Requests for confirmatory information

On the use of the confirmatory data procedure, the Ombudsman first recalls her earlier decision that the Commission should use the confirmatory data procedure with particular caution and restraint. While clarifying that it is not the Ombudsman's 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, the Ombudsman notes that the Commission still makes regular use of the procedure.

In particular, the Ombudsman finds it concerning that since 2015 active substances have been approved with confirmatory data requirements for the impact of water treatment processes on residues present in surface and groundwater abstracted for drinking water production without the respective 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 the guidance. Further time will be required for the data to be assessed for the Commission to take any follow-up measures. The Ombudsman also notes a difference of views between the Commission and EFSA as to whether applicants are able to submit relevant data in the absence of a guidance document.

The Commission agrees, as outlined in its report transmitted to the Ombudsman in 2018[12], to take a rigorous approach to the confirmatory data procedure within the strict limitations set out in the now-applicable EU Regulation on plant protection products which is different from what was provided in the earlier Directive 91/414/EEC.

The Commission considers that in all cases in which confirmatory information was required as part of the approval conditions, this was in accordance with the conditions for requesting such information in Article 6(f) and Annex II, Point 2.2 (b) of the PPP

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of plant protection products (to be noted: a high risk to aquatic organisms was actually identified only for some uses, not for all as indicated in Table 5 of the EFSA Conclusion).

[10] https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en

[11] https://ec.europa.eu/food/plant/pesticides/glyphosate_en

[12] Commission Report in reply to a further remark from the European Ombudsman in her closing decision on a complaint by Mr [redacted] on behalf of Pesticide Action Network (PAN Europe), ref. 12/2013/MDC https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_authorisation_ombudsman_case12-2013_en.pdf .

Regulation. This includes, as explained in the Commission's report of February 2018 in the context of case 12/2013, the requests related to the impacts of water treatment processes on residues in surface or groundwater abstracted for drinking water production (due to the absence of relevant EU wide guidance that is considered necessary to ensure that these impacts are comprehensively addressed).

The Commission would like to recall that both Article 12(2) of the PPP Regulation and Article 13(1) of Implementing Regulation (EU) No 844/2012 specifically acknowledge the important role of guidance documents. In fact, they require that assessments for approval and renewal of approval of active substances are carried out in light of the current scientific and technical knowledge using guidance document applicable at the time of application or submission of the renewal dossier.

The Commission acknowledges that the possible formation of harmful residues in drinking water is an important point that must be addressed for active substances. However, the Commission would like to emphasise that in addition to setting a requirement to provide confirmatory information on this aspect, other measures exist and are applied to minimise the pollution of water bodies by active substances and their metabolites. These measures, all together, reduce the potential for the formation of residues when water is treated for the production of drinking water. For example:

- if there is evidence that active substances and/or their metabolites may leach into groundwater under certain environmental conditions, a requirement for Member States to pay particular attention to the protection of groundwater is included in the Implementing Regulations approving active substances[13].

- appropriate risk mitigation measures must be determined by Member States for each plant protection product and its intended use when authorising plant protection products (2nd regulatory step under the PPP Regulation), also taking into account the specific agronomic and environmental conditions in the Member State to ensure that the levels of active substances and their metabolites are minimised in aquatic compartments.

- furthermore, Article 11 of Directive 2009/128/EC[14] obliges Member States to take measures to protect the aquatic environment and drinking water supplies from the impact of pesticides. Those measures shall support and be compatible with relevant provisions of the Water Framework Directive[15] and the PPP Regulation. The measures shall include, among others, the establishment of appropriately-sized safeguard zones for surface and groundwater used for the abstraction of drinking water, where pesticides must not be used or stored.

- if information comes to light that harmful residues may be present in drinking water, the Commission may take action under the emergency measures provided for in the PPP Regulation. For instance, the Commission acted to introduce

[13] If, however, active substances or their *relevant* metabolites are predicted to occur above the legal limit of 0.1 µg/L in all scenarios for all uses assessed, an active substance cannot be approved. Examples of substances that have not been renewed due to such concern are isoproturon and chlorothalonil.

[14] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides. *OJ L 309, 24.11.2009, p. 71*

[15] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, *OJ L 327, 22.12.2000, p. 1*

protective measures in the case of tolylfluanid when evidence emerged that water treatment processes could lead to the formation in drinking water of a compound that is harmful to health (NDMA)[16]. After further review the approval of the substance was withdrawn[17].

As to the question whether applicants can address successfully the effect of water treatment processes on the nature of residues present in surface or groundwater in the absence of guidance, the Commission would like to note that while some applicants provided data (either in the dossier or as part of a request for additional information) that was considered sufficient by EFSA to reach a conclusion on this aspect, this was not the case for the majority of active substances[18].

The fact that in the clear majority of cases (80 of 112), EFSA was not satisfied by the data provided by applicants further corroborates the need for guidance. 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 are asked to develop a joint guidance since the issue is also relevant for the assessment of biocidal active substances.

III. CONCLUSIONS

The Commission takes note of the Ombudsman preliminary findings following the inquiry into two cases 1570/2018/JF-JN and 1973/2018/JF-JN.

The Commission observes that the way EFSA's conclusions for active substances were drafted in the past did not always provide sufficient detail to contextualise concerns identified. In addition, sometimes the conclusions did not provide the necessary level of detail that would fully reflect the two-step regulatory system of approvals of active substances (EU level) and authorisations of individual plant protection products for specific uses (Member State level). The Commission is working with EFSA to improve the clarity of EFSA's conclusion on active substances; progress has already been made and further progress is expected before the end of the year. The Commission confirms that it is now systematically seeking further explanations from EFSA in cases where it considers that EFSA's conclusions may lack clarity before deciding on whether approval is possible, or not.

[16] Commission Decision of 4 May 2007 laying down protective measures concerning uses of plant protection products containing tolylfluanid leading to the contamination of drinking water. OJ L 119, 9.5.2007, p. 49.

[17] Commission Directive 2010/20/EU of 9 March 2010 amending Council Directive 91/414/EEC to remove tolylfluanid as active substance and on the withdrawal of authorisations for plant protection products containing that substance. OJ L 60, 10.3.2010, p. 20.

[18] Of the 112 substances assessed by EFSA for which the requirement to consider impacts of water treatment processes applied, i.e. all assessments for approval or renewal of approval under the PPP Regulation (excluding microorganisms for which the requirement is not relevant), only in 32 cases EFSA did not identify a data gap and an issue that could not be finalised for this point. In 20 of these cases, the applicant and/or the rapporteur Member States had already satisfactorily addressed the water treatment issue in the dossier or renewal assessment report. For a further 12 substances, EFSA requested additional information (which is in line with Article 12(3) of the PPP Regulation for new active substances or Article 13(3) of Regulation (EU) No 844/2012 for renewals) and the information supplied was considered sufficient to address the issue, while EFSA was not satisfied with the information provided for the remaining 80 cases.

The Commission agrees with the Ombudsman's suggestion to use more user-friendly and accessible wording in the documents explaining the reasons underpinning the decisions taken. The Commission has already initiated some improvements over the last year and endeavours to further improve clarity and transparency.

The Commission recalls that it has described the use of the confirmatory data procedure when approving or renewing active substances in the report transmitted to the Ombudsman in 2018 and confirmed the approach during the meeting on 17 May 2019 with regard to specific substances that are referred to in the inquiry. In particular, the Commission considers that the confirmatory information required as part of the approval conditions was in accordance with the conditions for requesting such information in Article 6(f) and Annex II, Point 2.2 (b) of the PPP Regulation. The Commission reaffirms the importance of the availability of guidance to allow applicants to be able to submit satisfactory data on the impact of water treatment processes on residues in surface or drinking water. In October 2019, the Commission sent a formal mandate to EFSA and ECHA to develop a joint guidance document on this topic.

For the Commission
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