Comments of the Commission on a request for information from the European Ombudsman - Complaint by Mrs [redacted] on behalf of Pesticide Action Network Europe, ref. 177/2023/VB

I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY

Candidates for substitution are active substances complying with the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009[1] (the "PPP Regulation") but meeting one or more of the additional criteria laid down in point 4 of Annex II to the PPP Regulation. As follows from Article 24 of the PPP Regulation, and by way of derogation from the regular approval periods, active substances that are candidates for substitution can only be approved and renewed for periods not exceeding seven years.

Article 80(7) of the PPP Regulation requires the Commission to establish a list of active substances included in Annex I to Directive 91/414/EEC which satisfy the criteria set out in point 4 of Annex II to the PPP Regulation (i.e. a list of candidates for substitution). Based on an analysis[2] of the properties of the active substances approved until 31 January 2013, the Commission adopted the list of candidates for substitution in January 2015 by means of Commission Implementing Regulation (EU) 2015/408[3]. 77 active substances were included in this initial list.

The Annex to Implementing Regulation (EU) 2015/408 is progressively superseded by Part E of Commission Implementing Regulation (EU) No 540/2011[4] which lists the candidates for substitution after approval or renewal under the provisions of the PPP Regulation on the basis of Article 13(4) of the PPP Regulation. Currently, there are 48 active substances approved as candidates for substitution: 35 active substances are still listed in the Annex to Implementing Regulation (EU) 2015/408 while Part E of Implementing Regulation (EU) No 540/2011 lists 13 active substances identified as candidates for substitution. The downward trend in the number of active substances approved as candidates for substitution is expected to continue as the periodic review of approvals continues and as active substances that are currently still approved as candidates for substitution might not be renewed.

Plant protection products (PPPs) containing active substances that are candidates for substitution are subject to specific authorisation conditions under the PPP

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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 Ad-hoc study to support the initial establishment of the list of candidates for substitution as required in Article 80(7) of Regulation (EC) No 1107/2009 https://food.ec.europa.eu/system/files/2016-10/pesticides_ppp_app-proc_cfs_report-201307.pdf

3 Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution (*OJ L 67, 12.3.2015, p. 18*).

4 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (*OJ L 153, 11.6.2011, p. 1*).

Regulation. In accordance with Article 50 of the PPP Regulation and Annex IV thereto, Member States must carry out a so-called comparative assessment for each evaluation of a PPP containing active substances that are candidates for substitution. The aim of the comparative assessment is to replace the PPPs containing candidates for substitution by PPP containing active substances which are less hazardous, or by non-chemical control or prevention methods where available. The assessment of the alternatives must be performed in order to demonstrate whether alternatives can be used with similar efficacy and without significant economic and practical disadvantages to the user, taking into account authorisations for minor uses. Based on the results of that comparative assessment, Member States must maintain, withdraw or amend the authorisations of PPPs containing candidates for substitution.

In October 2014, a guidance document on comparative assessment and substitution (the "EU Guidance Document")[5] was endorsed in the Standing Committee on Plants, Animals, Food and Feed[6] (SCoPAFF). This document gives Member States guidance on how to conduct comparative assessments when evaluating applications for authorisation of PPPs containing candidates for substitution. This document was meant to supplement the European and Mediterranean Protection Organization ("EPPO"), standard PP 1/271[7] and to provide an overall framework for comparative assessment involving the assessment of potential risks to health or the environment. As any guidance document, it is not legally binding and the Member States may deviate from it.

In 2018 as part of its regulatory fitness and performance programme (REFIT), the Commission carried out an evaluation of the PPP and Maximum Residue Level[8] Regulations covering the period of their respective entry into application until end 2018 in order to assess whether these regulations were fit for purpose and achieve their objectives while keeping EU law simple and remove unnecessary burdens. The final report[9] was adopted on 20 May 2020 at the same time as the Farm to Fork Strategy and the second report on the implementation of the Sustainable Use Directive. One of the main findings of the evaluation showed that "*the rules for active substances that are candidates for substitution are both ineffective and inefficient. Available evidence shows that the comparative assessments for products containing active substances that are candidates for substitution carried out by Member States is complex and requires resources but did not lead to any*

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5 The guidance document on comparative assessment and substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009 (SANCO/11507/2013 rev. 12), available at: https://food.ec.europa.eu/system/files/2016-10/pesticides_aas_guidance_comparative_assessment_substitution_rev_1107-2009.pdf

6 https://food.ec.europa.eu/system/files/2020-11/sc_phyto_20141009_pppl_sum.pdf

7 Bulletin OEPP/EPPO Bulletin (2011) 41, 256–259

8 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (*OJ L 70, 16.3.2005, p. 1*).

9 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 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0208&from=EN

substitution, mainly due to the lack of alternatives with proven better risk profiles. Thus, the expected benefits for human health or the environment from substituting these more hazardous active substances have not materialised. In addition, comparative assessments have made the authorisation process costlier than for standard authorisations."

Therefore, the Commission committed in the report to make use of its delegation of power to amend Annex IV to the PPP Regulation to improve the effectiveness of comparative assessments of products containing candidates for substitution.

To implement this commitment, the Commission organised in 2021 two meetings with experts from the Member States to better understand the reasons that hinder substitution and to analyse possibilities for improvement. The Commission also carried out a survey in the 4th quarter of 2021 that showed a tendency towards increased substitution i.e. a refusal or non-renewal of authorisations, especially for products containing broad spectrum active substances that are effective against a wide variety of pests for a few major uses. Based on this work, the Commission is now analysing the most suitable way forward to simplify and increase efficiency while fully respecting the legal obligations in Article 50 of the PPP Regulation, such as an amendment of Annex IV to the PPP Regulation and/or an amendment of the EU Guidance Document.

II. THE COMPLAINT

The subject of the complaint is the endorsement by DG SANTE of the European Commission of a pesticides' "standard" written by EPPO, an organisation external to the EU Institutions, without allegedly having checked its independence or the compliance of the standard with the EU legislation beforehand. In particular, the complainant alleges that EPPO Standard PP 1/271 Guidance on efficacy aspects of comparative assessment (the "EPPO Standard") is not compliant with the EU legislation, in particular with Article 50 of the PPP Regulation and Annex IV thereto. Another allegation is related to the treatment of the minor uses mentioned in Article 50(1)(d) of the PPP Regulation in the EPPO Standard.

III. EUROPEAN OMBUDSMAN'S INQUIRY

The European Ombudsman has decided to open an inquiry into the complaint and requested the Commission to provide a reply to several questions, listed in Part IV below. The questions concern the EPPO Standard, its compliance with the PPP Regulation, its status, as well as how the Commission ensures that such standards developed by international organisations are in line with EU law, that they are developed based on independent expertise and what concrete actions have been taken in this respect.

IV. THE COMMISSION'S COMMENTS TO THE COMPLAINANT'S ARGUMENTS

The complaint concerns a guidance document that was endorsed by the Member States in 2014 upon proposal by the Commission, and following preparatory work and discussions that took place in 2013. The Commission would like to note that no

such concerns were raised by the complainant during the drafting process of the EU Guidance Document.

The complainant notes that the EU Guidance Document was endorsed 'by DG SANTE of the European Commission'. This is not correct. The EU Guidance Document was, on proposal of DG SANTE, endorsed by all but one Member State represented in the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) at its meeting on 19 October 2014[10]. It must be noted that the reservations from that one Member State related to the reference to Article 29 of the PPP Regulation contained in the EU Guidance Document – while all Member States supported the use of the EPPO Standard contested by the complainant.

Furthermore, the EU Guidance Document states in its introduction that it is complementary to the EPPO Standard: *'This document is meant to supplement the EPPO standard, i.e. to give Member States guidance on how to perform the comparative assessment of risks to health and the environment, and to provide an overall framework for comparative assessment.'* In addition, many Member States have developed their own national guidance to carry out comparative assessments, such as Croatia, France, Greece, Portugal, Slovakia, Slovenia, Spain, and The Netherlands.

It also needs to be clarified that the report on the REFIT evaluation of the EU pesticides legislation to which the complainant refers actually states that *"comparative assessment did not lead to any substitution, mainly due the lack of alternatives with proven better risk profiles"*. In the study[11] underlying the REFIT report, Member States provided several reasons for this situation: in particular smaller countries reported the absence of viable authorised alternatives in their jurisdiction to which a PPP containing candidates for substitution could be compared. Consequently, a substitution cannot take place. Another reason raised was that substitution was not possible due to the need to avoid potential resistance of the target pests to active substances – having more available PPP for a given pest reduces the likelihood of them developing resistance. Several Member States stressed that the lack of specific knowledge on, and the availability and efficacy of non-chemical alternatives, severely limits the potential for substitution. Moreover, alternatives are considered to be either not available or do not appear to be efficient enough to allow for substitution. This range of reasons indicated by the Member States demonstrate that the EPPO Standard about which the complainant is concerned – and in particular its analysis related to diversity of mode of action – was not the main reason hampering the substitution.

Finally, the claim from the complainant that the Commission shows no willingness to engage or to stop using the EPPO Standard is unfounded. The Commission has committed to and is already working on a better implementation of the provisions in the PPP Regulation related to the substitution of candidates for substitution, on its

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10 sc_phyto_20141009_pppl_sum.pdf (europa.eu)

11 COMMISSION STAFF WORKING DOCUMENT Accompanying the document 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 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020SC0087

own initiative and in light of the findings of the REFIT evaluation. Moreover, at a meeting with the complainant in October 2022, DG SANTE explicitly acknowledged the possibility to consider other relevant tools, e.g. protocols used by the European Food Safety Authority (EFSA) which became available as from 2016 (see below for more details), after the issuance of the contested EU Guidance Document (Minutes of the meeting and a subsequent letter are attached to this response).

Responses to the specific questions from the Ombudsman in her inquiry:

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;

The allegation of the complainant that the EPPO Standard is not compliant with the PPP Regulation is unfounded. The reference to "available chemical diversity of mode of actions" instead of "chemical diversity of the active substances" is compliant with Article 50 of the PPP Regulation, as explained below.

The purpose of the reference to "chemical diversity of active substances" in Article 50(1)(c) of the PPP Regulation is to avoid the development of resistance in the target pests.

Active substances combat pests via a particular mode of action (i.e. a specific interference in a pest's life-sustaining functions). There is general agreement that if substances having the same mode of action are used against the same target pest repeatedly, the potential to induce resistance of the pest to those substances increases, which renders the active substances useless and the pest difficult or impossible to control. To maintain the efficacy of pest control, it is therefore crucial to have active substances with a variety of modes of action available, which can be used in alternation so that induction of resistance in the target pest is avoided.

Chemicals of the same or closely related structures operate via the same mode of action for combatting a pest. For instance, all organophosphates (insecticides) act via acetylcholinesterase inhibition, all triazoles (fungicides) act by blocking the synthesis of ergosterol. Hence, it is fully justified from a scientific perspective to translate the concept of "chemical diversity" referred to in the PPP Regulation into difference of "modes of action" – as done in the EPPO Standard to determine the risk of resistance induction in a target pest.

Furthermore, EFSA also uses the concept of "mode of action" in its protocols[12] for the evaluation of whether an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means within the context of Article 4(7) of the PPP Regulation.

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

The PPP Regulation recognises explicitly that the so-called minor uses[13] deserve special attention. Article 51 of the PPP Regulation foresees specific procedures to facilitate the granting of authorisations for minor uses by widening the range of actors who can apply for authorisation (in addition to authorisation holders for major uses, these are official or scientific bodies involved in agricultural activities, professional agricultural authorisations or professional users of PPPs) and by facilitating the extension of authorisations granted for major uses. Cancelling or refusing an authorisation for a PPP containing an active substance that is a candidate for substitution may thus have consequences for the availability of products to protect minor crops. It must also be noted that Article 51 makes no distinction between PPPs containing active substances that are candidates for substitution or other active substances.

Article 50(1)(d) of the PPP Regulation states that the consequences on minor use authorisations are to be taken into account in the context of comparative assessments. The EU Guidance Document explicitly states on top of page 3: '*Hence, it is not considered relevant to apply substitution …. in cases that would have adverse consequences on minor use authorisations*' and on top of page 5: *'In addition, the consequences on minor use authorisations should be taken into account. This is interpreted to mean that the major uses of the product are the ones for which the alternatives are considered and, if the conclusion is reached that a substitution may be appropriate for some or all of them, a consideration of the consequences on the minor use authorisations is then the key aspect of comparative assessment involving minor uses'.*

The complainant criticises that in the EPPO Standard the consideration of the impacts on minor uses is done in the beginning of the process of comparative assessment. However, whether this consideration is done at the beginning of the process or rather at the end is irrelevant and Article 50(1) does not prescribe a

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[12] For insecticides: Protocol for the evaluation of data concerning the necessity of the application of insecticide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, https://doi.org/10.2903/sp.efsa.2017.EN-1201

For fungicides: Protocol for the evaluation of data concerning the necessity of the application of fungicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, https://doi.org/10.2903/sp.efsa.2017.EN-1345

For herbicides: Protocol for the evaluation of data concerning the necessity of the application of herbicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, https://doi.org/10.2903/sp.efsa.2016.EN-1060

[13] Minor use is defined in Article 3, point 26, of the PPP Regulation as a use on plants or plant products which are not widely grown in a Member State or if widely grown to meet an exceptional plant protection need.

temporal order of the four elements to be considered in the context of comparative assessments.

In conclusion, the EPPO Standard does not contradict and is not non-compliant with the requirements in the PPP Regulation.

However, as noted in the introduction to the EU Guidance Document, the EPPO Standard covers assessment of efficacy (effectiveness, crop safety, risk for resistance, practicability, economical disadvantages, alternative measures and effects on minor uses), but does not address comparative safety from the human and the environmental perspective, as required in Article 50(1)(a) of the PPP Regulation. The EU Guidance Document therefore supplements the EPPO Standard by specifically addressing this aspect.

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?***

   As noted in the above, the EU Guidance Document, which contains the reference to the EPPO Standard, is, as any guidance document, not legally binding and the Member States may deviate from it. Nevertheless, the aim of guidance documents is to foster uniform implementation of the PPP Regulation, including via references to international standards.

   In terms of organisational set-up, EPPO is a regional organisation under the umbrella of the International Plant Protection Convention (IPPC)[14], which is a Treaty set up under the auspices of the Food and Agriculture Organisation of the United Nations (FAO). The countries which signed the IPPC convention are represented in IPPC by their governments and/or their national plant protection organisations (NPPOs), the competent authorities for plant health. The NPPOs are organised into regional organisations, the so-called RPPOs (Regional Plant Protection Organisations), such as EPPO[15]. All EU Member States are members of EPPO.

   All EPPO Standards must be approved by the EPPO Council, which meets once a year and consists of representatives of the governments of the EPPO member countries, plus, as observers, the EU (represented by the European Commission) and the Eurasian Economic Union. Only the member countries are allowed to vote.

   The fact that the EU has entered into international mutual commitments in the context of its external relations, and that one of the EU's objectives is to keep the world's trading system fair, predictable and based on common rules, justifies the fact that internationally agreed standards – such as EPPO standards – are referred to in EU guidance documents. EPPO standards are also used by Member States in

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14 https://www.ippc.int/en/about/overview/

15 https://www.eppo.int/index

national decision-making and by the EFSA Plant Health Panel when drafting scientific opinions.

As regards the implementation of the PPP Regulation, many EPPO standards are referenced in guidance documents[16] or in the Commission Communications[17] to support the data requirement Regulations (which also refer frequently to test guidelines developed by another international body – the Organisation for Economic Cooperation and Development (OECD)). Such references and the manner in which they are framed make clear that the relevant EPPO Standards are recommended to be used in the context of the application of the EU guidance document in which they are referenced. However, they are clearly not labelled or treated as EU Standards from one of the EU Standardisation Bodies (CEN, CENELEC or ETSI)[18].

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?***

EPPO process

The work of EPPO is split into two Working Parties: the Working Party on Plant Protection Products and the Working Party on Phytosanitary Regulations. Each Working Party oversees the work of several Panels and Expert Working Groups, which carry out the technical work.

Experts participating in Panels or Expert Working Groups are nominated by their national plant protection organisations (NPPOs). According to information received from the EPPO Secretariat, experts from industry may participate in

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16 Guidance document on data requirements on efficacy for the dossier to be submitted for the approval of new active substances contained in plant protection products (SANCO/10054/2013 - rev. 3) https://food.ec.europa.eu/system/files/2016-10/pesticides_ppp_app-proc_guide_efficacy_nas.pdf

Guidance document on the efficacy composition of core dossier and national addenda submitted to support the authorisation of plant protection products (SANCO/10055/2013 Rev. 4) https://food.ec.europa.eu/system/files/2016-10/pesticides_ppp_app-proc_guide_efficacy_ppp.pdf

Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (SANTE/2019/12752) https://food.ec.europa.eu/system/files/2020-11/pesticides_mrl_guidelines_app-d.pdf

17 Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ C 95, 3.4.2013, p. 1).

Commission communication in the framework of the implementation of Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ C 95, 3.4.2013, p. 21).

18 https://single-market-economy.ec.europa.eu/single-market/european-standards/key-players-european-standardisation_en

EPPO Panels and Expert Working Groups in order to take their knowledge into account to develop good EPPO Standards and other guidance. The membership of experts from industry in EPPO's work on pesticides is approved by the EPPO Executive Committee consisting of 7 government representatives from EPPO member countries. They regularly discuss the participation of experts from industry in EPPO's work and, if needed, the balance of experts.

In all reports of meetings of Panels and Expert Working Groups, experts from industry are clearly indicated as such in the participants list and opinions expressed are clearly linked to the experts. This makes the input from different experts transparent.

Expert Working Groups take decisions by consensus. In case there is no consensus because the experts from industry are against a decision, then the decision is taken only by the experts nominated by member countries, by consensus amongst them. In this way it is avoided that industry experts can block a decision for whatever reason including for vested interests. Moreover, in all EPPO Panels on Plant Protection Products the Chair of the meeting (the Director-General of EPPO) guards the overall process to achieve balanced EPPO Standards and guidance and avoid conflicts of interest.

While the EPPO Panels and Expert Working Groups develop draft Standards and databases, they do not approve them. It is the respective Working Party that decides whether draft Standards are ready for approval. Only representatives of EPPO's member countries are taking part in the decision making in the Working Party. Industry representatives are observers at the meetings of the Working Party but do not take part in the decision-making.

Before draft Standards are discussed by the Working Party, all member countries are explicitly consulted. During this consultation all EPPO member countries have the opportunity to propose modifications to the draft Standards and they can also make an objection to approval of a draft Standard. The EPPO Secretariat and the Working Party consider all comments made by EPPO member countries. Any objection needs to be addressed before the approval procedure can continue. Industry is not involved in this consultation process.

Lastly, as mentioned already in the answer to the preceding question, the final approval of Standards is done by the member countries in the annual meeting of the EPPO Council. Industry is not invited to meetings of the EPPO Council, only representatives of EPPO's member countries are present at this meeting and taking the decisions to approve Standards and the work programme of EPPO. The European Commission and the Eurasian Economic Commission are the only observers allowed in the meeting of the EPPO Council.

All the above are elements of EPPO's policy to avoid conflicts of interest and to ensure that Standards are based on independent expertise.

It should also be noted that while EPPO Standards are mainly based on the expertise of the experts drafting them, occasionally they are also based on publications as was the case for EPPO Standard PP 1/271. The publication on which the Standard was based (Rotteveel T, Jorgensen LN & Heimbach U (2011) *Resistance management in Europe: a preliminary proposal for the determination*

of a minimum number of active substances necessary to manage resistance. Bulletin OEPP/EPPO Bulletin 41, 432–438), was written by three authors who are all experts from authorities or universities of EPPO member countries - none of them was an expert from industry.

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As appears from the above, Member States are involved in EPPO's work and participate in the decisions of the EPPO Council on the adoption of all Standards – in so doing, they are bound by the applicable EU Regulations (in this case, the PPP Regulation). EU Member States have sufficient weight in the EPPO Council (27 out of 52 Member countries) to prevent the adoption of a Standard that would not be in line with EU law.

The Commission itself is also involved in the EPPO work although it does not have decision-making powers. The Commission can raise any concern during Panel discussions (where the Commission may participate as observer), during the meetings of the EPPO Working Parties, during coordination meetings of Member States at the Council of the European Union where Member States agree on the positions to be taken in the EPPO Council and/or during the final adoption of the standard in the EPPO Council (where the Commission participates as observer).

As regard reference to EPPO Standards in guidance documents prepared by the Commission, the Commission always checks whether a Standard to which it will make a reference is in line with the legal framework. Where appropriate, the Commission also consults draft guidance documents with stakeholders, mainly through the Advisory Group on Sustainability of Food Systems[19], of which the complainant is a member and can thus raise any concerns in relation to a draft guidance document, including the reference to an EPPO Standard.

Finally, all guidance documents relevant for the PPP Regulation, including those referring to standards from EPPO or from other relevant international organisations such as OECD, are developed in close cooperation between the Commission and experts from Member States, and are scrutinised in SCoPAFF for compliance with the legal requirements before endorsement by the Member States.

There are, therefore, in addition to the process within EPPO as explained above, ample opportunities for Member States or stakeholders to signal concerns about the compliance of an EPPO Standard with the relevant EU legislation.

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?***

19 https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3832

As explained above, the Commission considers that the contested EPPO Standard has always been compliant with EU law. The EPPO Standard and subsequently the EU Guidance Document were prepared in line with the processes described in the responses to questions 2 and 3. In the concrete case, the draft guidance document was discussed in SCoPAFF during meetings in 2013 and 2014 prior to its endorsement in October 2014.

The updates of the EPPO Standard referred to in the EU Guidance Document followed the same procedure as the initial adoption of the Standard. Therefore, both Member States and the Commission had the possibility to comment on each update and to influence the respective decision-making to ensure that the updates remained compliant with EU law.

V. CONCLUSIONS

The Commission considers that there is no reason to consider that EPPO Standard PP 1/271 is not compliant with the applicable EU legal framework.

Sufficient safeguards are in place within EPPO to ensure that its Standards are free of conflicts of interest as only representatives of the governments of EPPO member countries are involved in decisions on the adoption of draft Standards. Furthermore, the Commission and the EU Member States scrutinise EPPO Standards in the Standing Committee on Plants, Animals, Food and Feed before referring to them in EU guidance documents related to the PPP Regulation. Where appropriate, stakeholders are consulted on draft EU guidance documents via the Advisory Group on Sustainability of Food Systems.

Finally, the Commission has committed to and is already working on a better implementation of the provisions in the PPP Regulation related to comparative assessment and the substitution of candidates for substitution on its own initiative and in light of the findings of the REFIT evaluation of the pesticides legislation. This may involve an amendment of Annex IV to the PPP Regulation and/or of the Guidance Document on comparative assessment and has been clearly mentioned to the complainant in a meeting in October 2022 and in a written communication in November 2022.

For the Commission

Stella KYRIAKIDES

Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION

List of enclosures

1) Minutes of meeting with PAN Europe on 11 October 2022 to discuss Candidates for Substitution and other pesticide-related topics (ARES(2022)7093254)

2) Letter to PAN Europe on 16 November 2022 on comparative assessment (ARES(2022)8618466)

From: [redacted] (SANTE)
Sent: jeudi 13 octobre 2022 16:30
To: [redacted] (SANTE); [redacted] (SANTE-EXT); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE)
Subject: BTO: Meeting with PAN Europe to discuss Candidates for Substitution and other pesticide-related topics - 11 Oct 2022

BTO: Meeting with PAN Europe to discuss Candidates for Substitution and other pesticide-related topics

11 October 2022, 14h30-16h, DG SANTE premises

Participants:
PAN Europe: [redacted]
SANTE: [redacted] (E4)

The meeting took place at the request of PAN Europe in light of their recent publication on the use of Candidates for Substitution (CfS) in the EU. The following points were discussed.

1. <u>Candidates for Substitution:</u>

PAN Europe:

- Stated that, according to their report, the use of Candidates for Substitution in the EU was not decreasing but increasing, contrary to the objectives of the Farm-to-Fork strategy.
- Expressed that Annex IV to Regulation (EC) No 1107/2009 is ok but that their concerns are on the use by MS of a guidance developed by EPPO (European and Mediterranean Plant Protection Organization) to perform the comparative assessments (CA) according to Article 50 of Regulation (EC) No. 1107/2009. PAN Europe called instead for urgent action on the development of a guidance at EU level and mentions that the protocols for Art 4.7 could be used as a basis for CAs. PAN Europe believes EPPO has conflicts of interest and that the Commission should not rely on EPPO.
- Called for more transparency on the comparative assessments performed by MS.

SANTE:

- Explained that, as noted in the REFIT exercise, it was committed to work on improving the process. The Commission has already discussed this topic with MS at several meetings and collected feedback from MS on hurdles they encounter and on possible improvements.
- Clarified that EPPO is a body that is independent from the EU and to which, for the time being, the Commission does not participate.
- Highlighted that the Commission's resources remain limited while workload has increased in recent years, including on Access to Documents requests and court cases, so that work on the topic is not progressing as fast as desirable given the resource constraints.
- Invited PAN Europe to send information they have collected during their investigation, namely a list of concrete obstacles encountered by MS and concrete proposals for the guidance document on comparative assessments.

2. Sustainable Use Regulation:

PAN Europe:

- Informed that they plan to ask MEPs to submit an amendment to the SUR proposal to include explicit references to Comparative Assessments and an obligation for reporting and more transparency by MS.

3. Extension of approval periods under Article 17 of Regulation (EC) No. 1107/2009:

PAN Europe:

- Expressed concerns that the extensions are automatically granted to large numbers of substances at the same time.

SANTE:

- Explained that under Article 17, extensions of approval periods have to be granted if delays in the process are due to reasons beyond the control of the applicant.
- Explained that it is for the purpose of administrative efficiency that the Commission is preparing proposals covering several substances at the same time.
- Noted that delays arise mainly during the assessment by the Rapporteur MS and that the Commission was taking action to urge MS to improve the situation. Among others, the Commission has launched a process to provide grants to MS to receive additional resources subject to structural improvements.

4. Specific CfS and other topics:

SANTE provided the following information:

- Pendimethalin: The Commission is preparing two mandates, one for EFSA and one for EFSA and ECHA. Several studies on bioaccumulation on various species have been submitted by the applicant and their interpretation is not straightforward.
- 8-hydroxyquinoline: EFSA is currently conducting the peer-review assessment; all MRLs are already set at the Limit of Quantification (LOQ). The applicant has provided information to demonstrate negligible exposure, which must be assessed.
- Ipconazole: The Commission has initiated a review of approval under Article 21 of Regulation (EC) No. 1107/2009 and will submit a proposal to MS probably early 2023.
- Quizalofop-p-tefuryl: The Commission only follows the harmonised classification; the substance is currently not falling under cut-off criteria (classified as Reprotoxic, Cat. 2).
- Tebuconazole: The Rapporteur MS is still conducting the assessment of the dossier.

- Glyphosate: The extension of the approval of glyphosate under Article 17 of Regulation (EC) No. 1107/2009 is proposed for discussion and vote at the SCoPAFF meeting on 13-14 October 2022.
- benthiovalicarb, asulam sodium, clofentezine are currently under discussion at ScoPAFF, in particular as regards possibly fulfilling the criteria for essential use in Article 4(7) of Regulation (EC) No. 1107/2009.
- Recent judgment in the Pollinis court case with regards to the confidentiality of MS positions: This is a horizontal question related to comitology and the Legal Service and the Secretariat General are currently reviewing the judgment.
- Lowering of MRLs for environmental reasons of global nature: The draft Regulation lowering MRLs for clothianidin and thiamethoxam had been voted at the SCoPAFF meeting end of September 2022 A very large number of comments had been received during the WTO consultation. The next substances for which the MRLs will be reviewed with this perspective are quinoxyfen and lufenuron.
- Co-formulants: The CIS on a draft Regulation setting out a procedure and criteria for identifying unacceptable co-formulants is ongoing and the public consultation is expected to be launched in the coming weeks.
- The draft implementing Regulation on electronic records of PPP uses by professional users is currently under public consultation.
- SANTE wondered if PAN Europe would not have interest to initiate activities with other NGOs as regards retailers and consumers: farmers do not have a market for resistant fruit varieties (they are not bought by retailers) and even less for "imperfect" fruits/vegetables. This situation puts farmers under pressure to produce perfect products and to use more pesticides for this purpose. SANTE suggested that PAN Europe could work on this issue with retailers/consumers and include this aspect in their reports on residues findings.

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Dears and

Subject: Your letter dated 16 November 2022 on Comparative Assessment and Substitution of the most hazardous pesticides

Thank you for your letter of 16 November 2022 sent as follow-up to our meeting on 10 October 2022 on Candidates for Substitution (CfS) and comparative assessment.

In your letter you submit a position paper with a number of recommendations on how to improve the efficiency of the comparative assessment procedure. We would like to thank your organisation for your work and have shared your position paper with all Member States. As explained at our meeting, after the publication of the report[1] on the REFIT evaluation of the pesticides legislation, in 2021 we organised meetings with experts from the Member States to analyse possibilities for improvement. We also carried out a survey that showed a tendency towards increased substitution, especially for broad spectrum active substances[2], authorised for a few major uses. Based on this work, we are now reflecting with the Member States on the most appropriate way to strengthen the implementation of Article 50 including an update of the Guidance Document[3] to which you refer in your position paper. Your recommendations will be carefully considered in the ongoing work.

Let me also mention that the number of active substances approved as candidates for substitution today is significantly lower than when the first such list was established in 2015 in Commission Implementing Regulation (EC) 2015/408[4]. At that time, 77 approved active substances were identified as candidates for substitution, while today, only 53 active substances are approved as candidates for substitution, while the approval

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0208&from=EN

[2] In 5 cases the comparative assessments led to substitution and in 6 cases to an amendment of the authorisation.

[3] Guidance Document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009- 10 October 2014 (SANCO/11507/2013 rev.12)

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R0408&from=EN

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of the others was not renewed. We expect this downward trend to continue in the coming years, which, in addition to a more efficient comparative assessment will lead to reduced exposure and risks from substances that are candidates for substitution, in line with the objective of the Farm to Fork Strategy[5] to reduce the use of more hazardous pesticides by 50% in 2030.

As to your question about the status of the EU in EPPO, please note that upon further verification I was mistaken in mentioning that the EU is seeking observer status in EPPO. In fact, the EU is already an observer and is now seeking to obtain full membership with the objective to ensure better coordination among Member States and coherence of EPPO's output with EU legislation, which has not always been the case in the past.

Yours sincerely,

[redacted]

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0381