Final

Commission Report in reply to a further remark from the European Ombudsman in her closing decision

Complaint by Mr Hans Muilerman on behalf of Pesticide Action Network (PAN Europe), ref. 12/2013/MDC

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1. INTRODUCTION

In her 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) of 18 February 2016[1], in paragraphs 72 and 73 the Ombudsman stated:

> "*72. The Ombudsman considers that although the Commission has largely accepted her proposals, its compliance with them can be verified only if, as the complainant suggested, the Commission reports to the Ombudsman on the action it has taken in order to comply with the proposals within two years of this decision.*
>
> *73. The Commission's report should, in particular, (i) show that the confirmatory data procedure is used restrictively, and strictly in line with the applicable legislation; (ii) show, with regard to those active substances out of the ten examined in this case in relation to which the confirmatory data still needs to be assessed, that the Commission completed and updated that assessment without delay; (iii) show that the Commission has considered whether all confirmatory data should systematically be subject to an EFSA peer review (and whether the ad hoc Guidance document concerning the evaluation of confirmatory data should be amended accordingly). In the event that the Commission decides that EFSA peer reviews concerning confirmatory data need not be systematic, the report should give reasons for that position; (iv) show that the Commission has reviewed its approach to the definition of mitigation measures and that its approval decisions include further requirements which reflect EFSA's conclusions; (v) show how the Commission has implemented the Ombudsman's proposal that, in the event that the FVO makes findings of non-compliance with the terms of an approval decision on an active substance in one Member State, it checks, without delay, whether there is similar non-compliance in other Member States; and (vi) show how the Commission has implemented the Ombudsman's proposal that, if the Commission decides to withdraw or amend an approval, it ensures that this is duly reflected at Member State level without delay."*

In view of the decision of the Ombudsman of 18 February 2016, the Commission has prepared this report covering the points (i) to (vi).

[1] https://www.ombudsman.europa.eu/cases/decision.faces/en/64069/html.bookmark

2. IMPLEMENTATION OF THE CONFIRMATORY DATA PROCEDURE UNDER REGULATION (EC) NO 1107/2009 ON PLANT PROTECTION PRODUCTS

The objective of the present section is to provide the Ombudsman with the relevant information to show that the confirmatory data procedure is used restrictively and strictly in line with the applicable legislation. Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market provides a framework for the submission of data in applications for approval or renewal of approval of active substances with prescribed data requirements and set deadlines. It also provides in Article 6(f) for the possibility to request submission of additional information after the approval or renewal of approval of a substance (hereafter called 'confirmatory information').The approval Regulation shall provide for the time limit to submit confirmatory information (Article 13(3) of Regulation (EC) No 1107/2009).

2.1. Data requirements and application

Companies wishing to apply for the approval of a substance or the renewal of approval must provide an application to the Rapporteur Member State (RMS) and in the case of renewals also to the co-rapporteur Member State (co-RMS) in accordance with Articles 7 or 14 of Regulation (EC) No 1107/2009 and Regulations (EU) No 283/2013 and No 284/2013 on data requirements.

The RMS has the obligation to check whether the application and in particular the information dossier contains all the necessary elements.

It is foreseen that, if in the course of the evaluation the Rapporteur Member States or the European Food Safety Authority (EFSA) need additional information or studies, they may request such information or studies from the applicant within a certain period of time. There are strict time lines for the submission of such information or studies in the course of the evaluation. In the approval procedure for new active substances the RMS can request additional information/studies from the applicant and this information has to be delivered within a maximum period of 6 months (Article 11(3) of Regulation (EC) No 1107/2009). For renewals, the RMS can also require additional information, and shall set a period for the applicant to supply this information. Such request does however not lead to an extension of the assessment period of 12 months for the RMS' assessment (Article 11(5) of Commission Implementing Regulation (EU) No 844/2012). EFSA may also request additional information: The maximum period of time for the applicant to submit this information is 90 days for new substances (Article 12(3) of Regulation (EC) No 1107/2009) and 1 month for renewals ((Article 13(3) of Commission Implementing Regulation (EU) No 844/2012). Additional information is to be evaluated with the rest of the application by the RMS and EFSA, again within a set period of time. The application and additional information requested during the assessment only address data requirements which existed at the time of the submission of the application in cases where further information was considered necessary.

2.2. Types of confirmatory information

Further confirmatory information can be requested as a condition in a Regulation approving an active substance, or renewing an approval, or amending the approval

of an active substance. The applicant is required to submit such additional scientific information or studies within a period specified in the respective Regulation.

The Commission wishes to confirm to the Ombudsman that confirmatory information requests which are included in the Regulations on approval of substances, or on renewal or amendment of approval are limited to the cases listed in Regulation 1107/2009: under Article 6(f) the approval may be subject to the condition of "*submission of further confirmatory information to Member States, the Commission and the European Food Safety Authority (the Authority), where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge*". In exceptional cases, submission of confirmatory information may be also required in accordance with Annex II, point 2.2.(b) in order to increase confidence in the decision to approve the substance.

In the course of the implementation of Regulation (EC) No 1107/2009, in a minority of cases, requests for confirmatory information were included in Regulations approving or renewing approvals of active substances[2]. Three types of confirmatory information have been requested in such approval and renewal Regulations:

a) In some cases the confirmatory information is needed to link the technical specification of an active substance (i.e. its precise composition) manufactured in the past, which was used for the generation of the toxicological and/or ecotoxicological studies in the application dossier, and the more recent specifications of the substance as manufactured for use in pesticides. The objective is to demonstrate that there is no significant difference in composition between the two specifications. One needs to take into consideration that there are at minimum three years between the preparation of the dossier including performance of the studies and the decision on the approval of the substance and in most cases far more time has lapsed. It is normal that companies improve or amend their production processes during that period of time. In particular for new active substances, the specification of the substance and the batches used for the testing may have come from a pilot production as new active substances are often not produced on industrial scale at the moment of application for approval. The reason is that the substance does not yet have an approval in the EU and therefore companies wait until approval has been obtained before committing to commercial production. By contrast the products that will then be marketed will contain a substance produced on industrial/commercial scale. It may, therefore, happen that the production method has changed since the tests were performed. Therefore it is important to control that the specification of the substance which will finally be included in plant protection products is equivalent to the specification of the substance used to prepare the application and to perform the studies. Such information could not have been provided earlier. This type of information request relates to the development of technical knowledge in the production process (Article 6(f)) and to the need to increase confidence in the decision, in accordance with Annex II, point 2.2. of Regulation (EC) No 1107/2009.

[2] As regards amendments of approvals, there have been requests for confirmatory information regarding 3 substances - clothianidin, thiamethoxam and imidacloprid; see Commission Implementing Regulation (EU) No 485/2013, OJ L139/12 of 25.5.2013) but they are more recent than the substances targeted by this request by the ombudsman.

b) In some cases the request for confirmatory information addresses issues identified by EFSA only at a late stage of the evaluation process. For example, in some cases a harmonised classification in accordance with Regulation (EC) No 1272/2008[3] is adopted during the assessment process or EFSA provides in its conclusion that the active substance should be classified in a certain way. These developments occur at a stage at which the applicant may no longer submit additional information. In case this new classification is not leading to a non-approval due to the implementation of the so-called cut-off criteria in Annex II, points 3.6.2 to 3.6.5 of Regulation (EC) No 1107/2009, this new harmonised classification or proposal for it may trigger the requirement for additional data, for example additional studies on one or several metabolites of the substance. Such additional data could not have been provided by the applicant at the time of the application as the classification of the substance was different. One should keep in mind that many studies are on vertebrate animals, which the applicant must not perform unless there is a specific requirement and it is fully justified. The objective of the requirement for confirmatory information in this case is to provide the complementary information needed within a clear timeframe for submission. It can be categorised as a request linked to a new requirement established during the evaluation process in the meaning of Article 6(f) of Regulation (EC) No 1107/2009.

c) The request for confirmatory information may also relate to new data to be generated in accordance with a new guidance document which did not yet exist when the application was submitted or even not yet when the evaluation procedure was concluded. This type of request is thus motivated by progress in science in accordance with Article 6(f) of Regulation (EC) No 1107/2009. It is information that cannot yet be delivered at the moment of decision on approval or renewal of approval. But if not requested under the confirmatory information procedure as a condition for the approval, the applicant would only need to provide such information in the context of the next renewal of the substance, which is not considered appropriate in the light of the already established scientific advancement. The absence of a confirmatory information requirement in the approval or renewal Regulation would thus significantly delay the submission of this information. In those cases, the procedure for confirmatory information should be seen as a powerful tool to obtain in a timely manner more data or studies that actually would not be required under the data requirements applicable at the time of submission of the application for approval or renewal of approval. One example is the request for information on the impact of water treatment processes on substances that may be formed in drinking water. Other examples are requests for studies to assess the potential for endocrine disrupting activity of the substance, in a situation where neither the concrete scientific criteria nor the related guidance were available so that the regulators could not inform the applicant of the nature of the study or tests to be performed.

[3] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353/1 of 31.12.2008: Under this Regulation, a substance may become subject to an EU wide harmonised classification and labelling, whereas, in the absence of harmonised classification and labelling provisions, economic operators are obliged to self-classify substances in accordance with the classification rules established by the regulation for all hazards not covered by harmonised classification and labelling rules.

It is very important to highlight that the requests for confirmatory information adopted so far have not concerned data requirements which existed at the time of the submission of the application and for which adequate guidance documents were available. In case data required for the assessment of an active substance were missing in the application this led to the non-approval of the substance or a restricted approval, depending on the area concerned. The Commission firmly intends to pursue such course of action also in the future.

2.3. Statistics on confirmatory information requests made under Regulation 1107/2009

A total of 65 active substances were approved or their approval was renewed based on applications submitted under Regulation (EC) No 1107/2009 applying the approval criteria under that Regulation.

Out of that total of 65 Regulations on approval or renewal of approval, 24 Regulations contained requests for confirmatory information (see Annex I - List of Regulations including requests for confirmatory information).

In 5 cases the request for confirmatory information concerned only the technical specification of the active substance as manufactured (based on commercial scale production) and the equivalence of the active substances used for toxicity/ecotoxicity testing with the confirmed technical specification[4]. In a further 3 cases such information was requested in addition to other confirmatory information.

In 4 cases the request for confirmatory information concerned only the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater when such water is abstracted for drinking water[5]. In these cases, although the uniform principles enshrined in Regulation (EU) No 546/2011 address this issue, there is no available guidance document on how to perform the relevant studies and tests. In a further 6 cases such information has been requested in addition to other confirmatory information.

In 6 cases, the request for confirmatory information concerned data in order to confirm that a certain metabolite is not genotoxic[6]. In 4 of these cases the request was related to the same metabolite, which is common to the substances and it was considered prudent to apply a consistent approach to comparable situations. Therefore, a common confirmatory information requirement was set.

In 5 cases the request for confirmatory information concerned data to further confirm that the substance has no endocrine disrupting properties. The corresponding active substances were not identified as endocrine disruptors according to the interim criteria currently provided in Regulation (EC) No 1107/2009 and thus could be approved. Nevertheless in its assessment EFSA had underlined the need for further information in order to exclude potential endocrine disrupting properties. The submission of further information will allow addressing

[4] See for example Commission Implementing Regulation (EU) 2015/1165 concerning halauxifen-methyl.

[5] See for example Commission Implementing Regulation EU) 2016/1414 concerning cyantraniliprole.

[6] See for example Commission Implementing Regulation (EU) 2016/147 of 4 February 2016 renewing the approval of the active substance iprovalicarb.

this issue which was not foreseen under the data requirements applicable at the time of submission of the application for approval or renewal of approval[7].

In one case, there was a possibility that the substance would be subject to harmonised classification under Regulation (EC) No 1272/2008. If such a classification was to be adopted, this would trigger the requirement for additional studies on the metabolites of the substance[8].

2.4. Submission and assessment of confirmatory information under Regulation 1107/2009 and listed in Annex I

The deadline for submission of confirmatory information varies depending on the time needed to generate the data.

Concerning substances for which a request for confirmatory information was set with a deadline before 31 July 2017, the Commission can confirm that the confirmatory information was submitted by the applicants. The Commission can confirm that the assessments of confirmatory information for which the deadline was in 2016[9] were performed by the Rapporteur Member States (RMS) and EFSA, except in the case of confirmatory information pertaining to the substance flumetralin where the RMS' assessment is delayed. Depending on the results of the assessment, the last steps of the procedure will consist in the endorsement of the assessment by the Standing Committee on Plant, Animals, Food and Feed or in the adoption by the Commission of a Regulation to withdraw or amend the approval in accordance with Article 21(3) of Regulation (EC) No 1107/2009.

In some approval Regulations, requests for confirmatory information do not have a specific date set as a deadline for its submission, for example when there is no agreed methodology available to perform the studies or the assessment, but the information will have to be submitted within a specific time period once guidance documents and test guidelines will have become available. This is the case of the confirmatory information pertaining to the effect of water treatment processes on the nature of residues present in surface and groundwater. Nevertheless when guidance documents and test guidelines will be available, the applicant for the substance will have to perform these tests and submit this new information within a deadline included in the legislation and linked to the publication of the guidance document (e.g. within 2 years from the adoption of specific guidance).

3. UPDATE OF THE INFORMATION ON THE 10 SUBSTANCES LISTED IN PAN'S REPORT OF 2013

An update of the status of the assessment of the confirmatory information for the ten substances listed in the report published by PAN in 2013 is provided in Annex 2.

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7 See for example Commission Implementing Regulation (EU) 2017/725 of 24 April 2017 renewing the approval of the active substance mesotrione.

8 See for example Commission Implementing Regulation (EU) 2016/1424 of 25 August 2016 renewing the approval of the active substance thifensulfuron-methyl.

9 These are the confirmatory information requests pertaining to terpenoid blend QRD-460, halauxifen-methyl, sulfoxaflor, flupyradifurone, mandestrobin, 2,4 D, iprovalicarb, flumetralin, metsulfuron-methyl, benzovindiflupyr.

For those substances all requested confirmatory information was provided and the assessment is finalised. Although the Commission accomplished its task for all 10 cases, in some cases the completion of the assessment took more time than foreseen due to delays by the Rapporteur Member State in providing its assessment or due to delays incurred in the finalisation of the procedure at EU level, such as discussions within the Commission or with Member States in the Standing Committee for Plants, Animals, Food and Feed.

- In 8 cases the assessment did not lead to the modification of the conditions of approval – the confirmatory information thus indeed confirmed the Commission decisions on approval. The assessment was completed for all the substances and led to no change in approval conditions.

- In 2 cases the assessment of the confirmatory information led to amendments of the conditions of approval:

  For the substance haloxyfop-P, in order to avoid risks to groundwater, it was decided to set limits for the application rates (maximum of 0,052 kg of active substance per hectare per application) and frequency of application (one application every 3 years). [10]

  For the substance malathion, the Commission considered that the confirmatory information provided was not sufficient to conclude that risks to birds were acceptable. Because other possibilities of mitigating such risk could not realistically be implemented, the Commission has proposed the adoption of an act restricting the approval of the substance to uses in greenhouses. The procedure is still ongoing.[11]

- The assessment of the confirmatory information did not lead to the withdrawal of the approval for any of the substances.

4. ASSESSMENT OF THE CONFIRMATORY INFORMATION BY EFSA

The Ombudsman asked if the Commission had considered whether all confirmatory data should systematically be subject to an EFSA peer review and whether the ad-hoc guidance document concerning the evaluation of confirmatory data should be amended accordingly.

The procedure for the assessment of confirmatory information is described in a guidance document[12] (reference SANCO/5634/2009 rev. 6.1) which the Ombudsman refers to as ad-hoc guidance document. This document was amended in December 2013 in order to include a systematic involvement of EFSA in the assessment.

In accordance with this guidance document the confirmatory information is submitted by the applicant to the Rapporteur Member State (RMS) responsible for

[10] Commission Implementing Regulation (EU) 2015/2233, L 317/26 of 3.12.2015.

[11] The procedure to notify to the World Trade Organization under the Technical Barriers to Trade (TBT) Agreement was launched on 18 January 2018 (reference G/TBT/N/EU/535).

[12] http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_aas_guidance_confirmatory-data_rev6-1_201312_en.pdf

the substance. When the assessment is concluded by the RMS, a commenting period of six weeks is initiated for other Member States, EFSA and the applicant.

The guidance states: *"At the same time as placing the assessment on CIRCABC, the RMS/DMS will inform via an e-mail the applicant, other MS using the confirmatory information contact points, COM and EFSA of the conclusion as to the acceptability of the confirmatory information (highlighting any concerns raised). The RMS/DMS will at the same time also ask for comments within 6 weeks, using the standard header 'Outcome of RMS/DMS assessment of confirmatory information for [active substance]'. The EFSA standard commenting table template should be included. The assessment should also be sent to the applicant. The comments from the applicant, other MS and EFSA should be compiled in the same format as comments on the original DAR (using the EFSA standard commenting table template) and sent to COM and RMS/DMS by the 6 week commenting deadline."* (Emphasis added)

The outcome of the consultation is in the form of a technical report including a reporting table where EFSA provides its assessment. This process can be considered a fast-track peer review. On the basis of the reporting table, the Commission may decide to further mandate EFSA to conduct a full or focused peer review[13] and to provide its conclusions on specific points. In many cases EFSA actually suggests itself whether a full or focused peer review is needed. In these cases the Commission mandates EFSA to provide a risk assessment and prepare conclusions. The process is fully transparent and all technical reports and conclusions are published on the EFSA website[14].

In conclusion, the Commission confirms that EFSA is always involved in the assessment of the confirmatory information submitted by the applicant and conducts a peer review when necessary. A decision, whether a full peer review is warranted or whether a focused peer review is sufficient to address the issue at stake, is taken by the Commission on a case by case basis following consultation of EFSA and Member States.

5. RISK MITIGATION MEASURES

The Ombudsman requested that the Commission reviews its approach on the definition of mitigation measures and that its approval decisions include further requirements which reflect EFSA′s conclusions.

In its reply of 20 October 2015 to the Ombudsman, the Commission had indicated that the responsibility to set risk mitigation measures for plant protection products and to control compliance with them lies with Member States taking into account the approval conditions for the active substances and the EFSA conclusions. The Commission had explained that these risk mitigation measures are decided at national or zonal level, because the appropriate measure to mitigate risk will vary according to specific uses authorised in Member States but also depending on

[13] The difference between a mandated and a "fast track" peer review is that in the first case, EFSA may organise physical expert meetings dedicated to discussing specific points, whereas the "fast track" takes place in written procedure.

[14] See for example the Technical report "*Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for dicamba in light of confirmatory data*", published on the EFSA website on 1st April 2016: http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2016.EN-1008/pdf.

different climatic, geological and environmental conditions. The Commission had emphasised that this was in accordance with the principle of subsidiarity.

The Commission has carefully examined the request of the Ombudsman to review its approach. The Commission wishes to clarify what it understands by risk mitigation measures in the EFSA assessment and what it understands by risk mitigation measures in the authorisation process.

5.1. EFSA's assessment

The risk assessment performed by Member States and EFSA is carried out using agreed protocols and guidelines. This methodology includes the use of standard conditions of use of substances (e.g. spraying with standard spray boom) as well as standard risk mitigation measures (e.g. a no-spray buffer zone). Such a standardised approach allows to compare substances and to establish their risk profiles. This is necessary in order to assess whether in a typical situation a substance can meet the approval criteria set by the legislation. But this methodology for the assessment of an active substance in view of its approval does not imply that other risk mitigation measures would not be appropriate. On the contrary, there could be more efficient risk mitigations measures in some Member States or in some agricultural conditions which reduce the risks from the use of a product containing the active substance even more. A salient example is the use of no-spray buffer zones in EFSA risk assessments. The parameters used by EFSA are derived from widely accepted spray drift tables which were established in the 1990ies, by using spray nozzles commonly used at that time. Modern application technology considerably reduces the amount of spray drift compared to then, i.e. the standard buffer zone would nowadays be larger than strictly necessary. On the other side the same buffer zones may be too small in e.g. windy weather, as the values used in modelling only represent calm conditions. The mitigation measures as to the width of a buffer zone suggested by EFSA therefore must not be seen as recommendation on how to best mitigate a risk, but as reference values which allow regulatory authorities in the Member States (and users) to scale the effectiveness of measures applied in real life and to frame the extent to which risk mitigation is necessary.

Science and technology are both quickly developing in the area of risk mitigation measures and it is important that the most up-to-date and most efficient measures can be put in place by the authorising authorities and users.

In addition, EFSA assesses only one or few representative uses and product(s) containing the active substance. This should be seen in contrast with the numerous products and uses which are assessed by Member States for which a number of other possible risk mitigation measures could be more adequate.

5.2. Risk assessment performed at national level for products and the risk mitigations measures available at national level

In line with the principle of subsidiarity, the EU pesticide legislation has created a two-step evaluation system where active substances are approved at EU level and formulated plant protection products containing them are authorised at national level. Member States have to perform a full risk assessment of the products for each of the uses they envisage authorising. The authorisations granted at national level can cover more uses or different uses than the representative use(s) which has/have

been evaluated at EU level as part of the assessment in the approval procedure of the active substance. For example, the representative use assessed at EU level may be on maize but the authorisation in a Member State could be for potatoes. And even for the same crop, use conditions can be very different as the agricultural practices may differ considerably between Member States: e.g. grapes can be produced from vertically growing (Germany, France), horizontally growing (Portugal, Austria) or creeping (Greece, Canary Islands) vines. The risk mitigation measures which will be imposed by the Member State as a result of its assessment are specific to the uses envisaged at national level.

In addition agricultural methods, as well as soil and climate conditions differ widely in the 28 Member States. A single risk mitigation measure set at EU level, such as a fixed buffer zone of 10 meters would not constitute an adequate measure for the protection of the health and environment in all Member States neither would it respond to the specific agricultural situation. For example, in Member States where the field sizes are small, if such a measure was imposed at EU level, the authorities could not revert to alternative, innovative and effective risk mitigation measures suitable to such a situation. In addition, the technical risk mitigation measures available in different regions of Europe differ widely depending on the level of technology available to farmers and their levels of investment. For example, in Germany the authorities can impose the use of specific nozzles which will reduce spray drift. In this case, instead of buffer zones, these specific nozzles prevent the drifting of the plant protection product. However, this kind of specific nozzles may not be available in other Member States, where buffer zones would be adequate risk mitigation measures.

In order to highlight the potential risks identified in the conclusions of EFSA which have to be taken into consideration by the Member States when evaluating plant protection products and setting risk mitigation measures, the Commission, where appropriate[15], always includes in the approval or renewal Regulations specific provisions destined to Member States[16]:

> "*Member States shall pay particularly attention to …/... Conditions of use shall include risk mitigation measures, where appropriate*".

In summary, it is the responsibility of the Member States to establish adequate risk mitigation measures as a result of the assessment of an application for a product authorisation for a particular use taking into account the prevailing specific conditions in their territory. In Regulations on approval and on the renewal of an approval the Commission specifies the particular risk areas, such as risk to operators or risk to groundwater where there is a need for risk mitigation measures at national level under the authorisation procedure, taking into account the results of the risk

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15 Some active substances do by their nature not require specific risk management measures (e.g. low risk substances).

16 For example, Regulation (EU) 2017/375 on the approval of prosulfuron states in Part A of the Annex :

"*For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prosulfuron, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to:*

- *the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;*
- *the risk to non-target terrestrial and aquatic plants.*

Conditions of use shall include risk mitigation measures, where appropriate."

assessment conducted for the active substance and in particular the conclusions of EFSA.

As requested by the Ombudsman the Commission has carefully reviewed its approach but, for the reasons which are set out above, it considers that it is suitable to the current legal framework.

6. FVO FINDINGS OF NON-COMPLIANCE OF AN AUTHORISATION WITH THE TERMS OF AN APPROVAL (AUDITS BY THE COMMISSION OF MEMBER STATES' AUTHORISATION SYSTEM)

The Ombudsman suggested that, in the event that the Commission's then Food and Veterinary Office (FVO)[17] makes findings of non-compliance with the terms of an approval Regulation on an active substance in one Member State, it checks, without delay, whether there is similar non-compliance in other Member States.

The Commission takes the view that inspecting the compliance of individual national authorisations with the terms of the EU approval Regulations would be resource intensive and not be the most effective approach as only a limited number of authorisations could be verified. Instead, the Commission followed a more strategic approach by performing a survey and audits in order to verify the functioning of the national system of authorisations of plant protection products (PPPs) in Member States.

In 2015, the Commission undertook a survey of all Member States on the authorisation of PPPs. The responses to the survey showed that the majority of the Member States did not comply with the legal requirements laid down in the Regulation (EC) No 1107/2009 regarding deadlines for the authorisations of PPPs.

In 2016 and 2017, audits on the authorisation of PPPs were conducted in 7 Member States: Germany, the United Kingdom, Luxembourg, Portugal, France, Lithuania, and Spain. Audit reports can be found on the Commission website[18].The audits confirmed that the national re-evaluations of PPPs on the market, which must take account of the EU approval Regulations and their related conditions, are significantly delayed. In three Member States there were significant numbers of PPPs still authorised which had not been evaluated in accordance with EU agreed uniform principles[19],[20]. In these Member States the percentage of authorised PPPs that had not been evaluated in accordance with the uniform principles ranged from 9% to 33%.

This means that for the PPPs involved, Member States had not yet applied the conditions set in approval Directives under EU plant protection legislation for the respective active substances.

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17 The Food and Veterinary Office (FVO) is now called DG SANTE Directorate F.

18 http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

19 The uniform principles for evaluation of PPPs were established under Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1)

20 These PPPs had been authorised prior to the adoption of Directive 91/414/EEC.

The overview report of this series has been published on the Commission website in July 2017[21].

The individual audit reports contained recommendations to the authorities of the audited Member States. Following each audit, the audit report was sent to the national authorities, with a request to specify the actions which will be undertaken by the Member State, and the deadlines for their completion, to address each recommendation. The actions taken to address recommendations are followed up through correspondence, dialogue and in subsequent audits to verify their implementation. In cases where the actions are insufficient to rectify the weakness, the Commission services actively pursue the matter with the authorities concerned. While recommendations have been addressed to the audited Member States, the 2015 survey showed that most Member States are facing similar problems, and therefore the Overview Report invited all Member States to review and improve their authorisation systems. In addition, the Commission supports the implementation of Regulation (EC) No 1107/2009 through several actions, such as workshops, training programmes and technical guidance documents.

However, the Commission believes that a systematic approach may be needed to address such a widespread problem. To this end, the Commission expects that the ongoing REFIT exercise concerning Regulation (EC) No 1107/2009 will identify the reasons behind this problem and feed into the Commission's reflection on how the current system could be improved.

7. CONTROL BY THE COMMISSION OF THE IMPLEMENTATION AT MEMBER STATES LEVEL OF NON-APPROVAL REGULATIONS OR REGULATIONS AMENDING THE APPROVAL OF A SUBSTANCE

The Ombudsman requested that the Commission shows how it has implemented the Ombudsman's proposal that, if the Commission decides to withdraw or amend an approval of an active substance, it ensures that this is duly reflected at Member State level without delay.

7.1. Re-assessment of product authorisations

7.1.1. Renewal/non-renewal of approval of active substances

Active substances are approved for a limited period of time: 7 years for substances identified as candidates for substitution, 15 years for low-risk active substances, 10 years for other substances and 15 years for renewal of approvals except for candidates for substitution.

In contrast with the previous EU pesticide legislation, under Regulation (EC) No 1107/2009, if the approval of an active substance is not renewed, the authorisations for products containing it will at the latest expire within one year. In accordance with Article 32, authorisations may not be granted by Member States for a period longer than one year after the expiry of the approval of the active substance.

Regulation (EC) No 1107/2009 also requires that all authorisations for products containing an active substance are re-assessed when the approval of that substance

[21] http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=108

is renewed. Article 43 (2) requires that, within 3 months of the renewal of the approval of an active substance, authorisation holders apply for the renewal of the authorisations for all the products containing that active substance. Therefore, in the case that the approval of an active substance is renewed with some changes in the conditions of approvals, all product authorisations shall be systematically re-assessed taking into account the newly set conditions of approval as well as new data requirements, new scientific developments and new guidance documents.

In accordance with Article 44(4) the Member State needs to inform the authorisation holder, the other Member States, the Commission and EFSA immediately of a withdrawal or amendment of an authorisation.

7.1.2. Other amendments of approval conditions or withdrawal of approval

Regulation (EC) No 1107/2009 does not provide for a specific time-line for Member States to re-assess or withdraw authorisations in cases where approval conditions are modified or approval is withdrawn before the regular expiry date (e.g. following a review triggered in accordance with Article 21 of the Regulation, or as a result of the assessment of confirmatory data). Therefore, the Commission Regulations on amendment of conditions or withdrawal of an approval always contain a transitional regime, which specifies the date, by which Member States must have amended or withdrawn existing product authorisations. Article 44 (4) also applies to these situations.

For the active substance glyphosate, the Commission did not wait for Member States to notify actions taken under the provisions of article 44(4), but proactively enquired directly with Member States about the implementation of restrictions to the conditions of approval of active substances: Commission Implementing Regulation (EU) 2016/1313[22], which entered into force on 22 August 2016, required that Member States ensure that plant protection products containing glyphosate do not contain the co-formulant POE-tallowamine (CAS No 61791-26-2). The Commission enquired with the Member States and Norway about the implementation of this restriction. The vast majority of Member States confirmed that they withdrew the authorisations for products containing glyphosate and the co-formulant POE-tallowamine between 30 June and 31 December 2016.

Also, following adoption of Regulation (EU) 485/2013 restricting the approval of three neonicotinoid substances, the Commission's Joint Research Centre (JRC) carried out a survey[23] on the impacts of the restrictions on pest management practices in selected crops (maize, oilseed rape and sunflower) in eight regions of the European Union. The JRC surveyed more than 800 farmers as to changes in pest management practices and found that in the Member States where the survey was performed, the restrictions on neonicotinoids had been implemented by farmers, and that they had been able to find alternative means of crop protection.

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22 Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate (OJ L 208, 2.8.2016, p. 1)

23 http://onlinelibrary.wiley.com/doi/10.1002/ps.4715/full

7.2. Databases on authorisations of plant protection products

A database[24] established by the Health and Food Safety Directorate General (DG SANTE) for the active substances assessed is publicly available. At least once a year the database is updated indicating in which Member States plant protection products containing the respective approved active substance are authorised. As the database is focused on active substances, the information concerning the actual plant protection product authorisations granted is limited.

In order to provide transparency on the authorisations granted by the Member States at national level, the Commission is developing the *Plant Protection Products Application Management System* (PPPAMS) as foreseen under Article 57(3) of Regulation (EC) No 1107/2009[25]. This comprehensive on-line system will allow controlling, in the future, whether authorisations granted by Member States are withdrawn or amended by them without delay, when the approval of an active substance is withdrawn or amended.

Since mid-2015 the PPPAMS has been available for the submission of new applications for plant protection products, enabling applicants to create applications and submit these to Member States for evaluation. Member States then manage these applications within the system, concluding with authorisation of the product or refusal of the application. The PPPAMS is also designed to include all existing authorisations granted by Member States before its deployment.

When fully operational the PPPAMS will deliver complete and up-to-date information on all authorised or withdrawn plant protection products in all Member States, and also in Norway, to the Commission and all interested parties, including farmers and other stakeholders.

PPPAMS is already operational – on a voluntary basis - for applications for authorisation for new products.

In conclusion the Commission is developing a system which will allow the Commission to monitor and follow-up promptly how and to which extent withdrawn or amended approvals are reflected in the authorisations granted at Member State level.

8. UPDATE ON THE MID-TERM REVIEW PUBLISHED BY PAN IN APRIL 2017

The Ombudsman specifically requested with a letter dated 8 June 2017 that the Commission takes into account a new report published by PAN Europe in April 2017[26].

Information related to 14 actives substances is collected and considered by PAN Europe in the newly published report of April 2017. PAN Europe assessed the 14

[24] http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN

[25] http://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/pppams_en

[26] Mid-term review of EU Ombudsman's verdict regarding DG SANTE's pesticide decision taking methods. http://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/ombudsman-confirmatory-data-mid-term-review-april-2017.pdf

actives substance on the basis of two major elements: risk mitigation measures and request of confirmatory information.

As regards the risk mitigation measures, a detailed explanation is already included in section 5 of this report.

As regards the confirmatory information: in 9 cases (for acibenzolar-S-methyl, benzovindiflupyr, cyantraniliprole, isofetamid, lambda-cyhalothrin, metsulfuron-methyl, thifensulfuron-methyl, thianbendazole and oxathiapiprolin) the Commission's assessment is already included in Annex I to this report; in 3 cases (for ethofumesate, picolinafen, oxyfluorfen) no request of confirmatory information is included in the approval Regulations; in 2 cases (for pinoxaden and sulfuryl fluoride), the assessment is summarised in Annex III to this report.

9. CONCLUSION

The present report shows that the Commission uses the confirmatory information procedure under Regulation (EC) No 1107/2009 restrictively and strictly in line with the applicable legislation.

It also provides an update with regard to the ten active substances listed in the PAN report of 2013 and shows that the Commission completed and updated the assessment of all confirmatory data for these substances, which led the Commission to propose modifications of the approval conditions in only 2 cases[27] and in no case to the withdrawal of the approval.

The Commission confirms that EFSA is systematically involved in the evaluation of confirmatory information as EFSA provides comments on the assessment performed by the Rapporteur Member State. When necessary, confirmatory information is the subject of an additional peer review. This procedure is fully documented in a Guidance document concerning the evaluation of confirmatory data which was amended in 2013 in line with the recommendation of the Ombudsman.

The Commission also ensures that risk mitigation measures are established at national level, taking into account the approval conditions of the active substances and the conclusions of EFSA.

The Commission has considered the proposal of the Ombudsman that, in the event that the Commission makes findings of non-compliance with the terms of an approval decision on an active substance in one Member State, it checks, without delay, whether there is similar non-compliance in other Member States. The Commission did not follow the related recommendation but opted, instead, for carrying out audits in 2016 and 2017 of the system for authorisations of plant protection products in seven Member States and performed a survey of all Member States, through which significant systemic deficiencies have been found. The Commission will follow-up the specific non-compliances in each of the seven audited Member States.

[27] In one case, for the active substance malathion, the decision making process in not yet finalised. The proposal to restrict the uses to glasshouses was discussed during the relevant meeting with Member States and EFSA (Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals - Plant Protection Products – Legislation) and the TBT notification to WTO is ongoing (see above).

Finally the present report also shows how the Commission has implemented the Ombudsman's proposal to ensure that withdrawal or amendments of substance approvals are duly reflected at Member State level without delay. One very relevant procedure is the systematic review of all authorisations of products in all Member States after the renewal of each active substance. A new tool will, in the future, allow controlling the withdrawal and the amendments of the authorisations granted in the Member States (the plant protection product authorisation system (PPPAMS)). The Commission would like to emphasise that the compliance of the authorisations with the provisions of Regulation (EC) No 1107/2009 and with the individual approval regulations, require the full commitment of every Member State to evaluate the applications for authorisations in a timely manner.