Proposal of the European Ombudsman for a solution to complaint 12/2013/JN against the European Commission

Solution - 30/01/2013
Case 12/2013/MDC - **Opened on** 30/01/2013 - **Decision on** 18/02/2016 - **Institution concerned** European Commission (Friendly solution) |

Made in accordance with Article 3(5) of the Statute of the European Ombudsman [1]

Summary

The complainant alleges that the practices of the European Commission regarding the approval of active substances for plant protection products (pesticides) in the EU are, in some instances, unsafe and/or not in accordance with the relevant legislation. The Ombudsman inquired into the Commission's practices and found a number of issues which need to be addressed by the Commission.

The Ombudsman's analysis deals with (i) the Commission's approvals of active substances while at the same time also requesting data which supports that approval, (ii) the approval of ten specific active substances in light of reservations expressed by the European Food Safety Authority (EFSA), (iii) the way in which the Commission uses mitigation measures and (iv) the Commission's inspections in Member States.

On the basis of her **preliminary** *conclusions, it appears to the Ombudsman that the Commission, which has the duty to ensure that the active substances it approves are not harmful for human health, animal health, or the environment, may be too lenient in its practices and may not take sufficient account of the precautionary principle.*

In order to avoid any possible misinterpretation, it is however important to stress that **this proposal does not mean or imply that any of the ten active substances analysed here are unsafe** *. It merely reflects the Ombudsman's* **preliminary** *view that the Commission's conclusions as regards the safety of these substances do not appear to be sufficiently supported by the findings made by EFSA at the relevant point in time.*

The Ombudsman makes several proposals which aim at improving the Commission's practices

in order to ensure that human health, animal health and the environment are effectively protected in the EU.

The background to the complaint

1. The complaint concerns the approval of active substances in plant protection products (pesticides, hereinafter 'PPPs') and their placing on the market in the EU. It relates also to a special resubmission procedure envisaged by Regulation (EC) No 33/2008 [2] , in the context of which the Commission approves active substances used in PPPs after considering the conclusions of a scientific assessment carried out by the European Food Safety Authority ('EFSA'). It also concerns the Commission's practice of approving an active substance while simultaneously requesting data confirming its safety (the "confirmatory data procedure"). [3]

2. The complainant - Pesticide Action Network Europe (PAN-Europe) - published a report entitled " *TWISTING AND BENDING THE RULES: In 'Resubmission' all efforts are aimed to get pesticides approved* " [4] . It takes the view that in certain cases, the Commission approves active substances for PPPs where the legal requirements are not met, in particular because of insufficient data allowing it to exclude risks for human health, animal health, groundwater and the environment. In 2012, the complainant had several exchanges with the Commission on the matter.

The inquiry

3. The Ombudsman opened an inquiry into the complaint and identified the following allegations and claims:

1. By using the confirmatory data procedure for the approval of active substances for pesticides, the Commission breached the provisions of Article 5 [5] of Directive 91/414 and infringed the precautionary principle. The Commission should stop using the confirmatory data procedure with respect to both approvals of active substances for PPPs granted under Directive 91/414 and future approvals granted under Regulation 1107/2009 [6] .

2. The Commission adopted misleading review reports and decisions concerning the active substances for certain pesticides approved through the process of resubmission. The Commission should reassess all the review reports and decisions on active substances for pesticides which it adopted over the past few years and include in them all facts and information assessed by EFSA in relation to these substances, including those relating to missing data, unfinished risk assessments, and high risks assessed.

3. When evaluating the active substances for certain pesticides through the process of resubmission, the Commission did not apply correctly the provisions of Article 5(1)(b) of Directive 91/414 [7] (which is similar to Article 4(3) of Regulation 1107/2009). The Commission should properly assess whether the provisions of Article 5(1)(b) of Directive 91/414 (which is

similar to Article 4(3) of Regulation 1107/2009) are complied with and it should set up a verification system to check whether Member States adequately impose and enforce mitigation measures in order to guarantee that the risks to the environment are acceptable.

4. In the course of the inquiry, the Ombudsman received the opinion of the Commission on the complaint and, subsequently, the comments of the complainant in response to the Commission's opinion. The Ombudsman made further inquiries and received an additional reply from the Commission and the complainant's comments on it. Regrettably, the Commission's opinion on the complaint was delayed by more than three months and its reply to the Ombudsman's further inquiry by more than two months. In conducting the inquiry, the Ombudsman has taken into account the arguments and opinions put forward by the parties. These arguments and opinions are, due to their extensive character, summarised below only to the extent which is necessary in order to understand the Ombudsman's analysis and conclusions.

Allegation that, by using the confirmatory data procedure, the Commission infringed Article 5 of Directive 91/414 and the precautionary principle and the corresponding claim

Arguments presented to the Ombudsman

5. The complainant submitted that under the confirmatory data procedure ('CDP'), the Commission approves active substances although it does not have all the information required by the applicable rules, in particular to rule out and avoid any undue risks for human health, animal health and the environment. It is not until some time later that applicants are requested to submit the required scientific studies that are missing, when the substance is already on the market and has been released into the environment. The CDP is unlawful because Directive 91/414 contains no reference to it. It is " *an invention* " of the Commission, which appears for the first time in Regulation 1107/2009. This Regulation however makes provision for special conditions. The Commission applies the CDP on a routine basis.

6. The complainant further submitted that the CDP is used incorrectly because the Commission applies it even where EFSA concludes that there is a high risk to the environment. The CDP infringes Article 5 of Directive 91/414 which requires that there be sufficient data demonstrating that there is no high/unacceptable risk. Thus, the CDP disregards the high standard of protection enshrined in Directive 91/414 and the precautionary principle. By approving substances for which the Commission does not have sufficient documentation evidencing their safety, the Commission exposes human beings and the environment to potential harmful risks.

7. The Commission disagreed with the complainant's submissions. In its view, using the CDP is compatible with Article 5(4) of Directive 91/414 which expressly provides that the approval may be subject to requirements. The request for confirmatory information constitutes a requirement

within the meaning of Article 5(4). In addition, the provisions of Article 5 of Directive 91/414 have been implemented since 1997 and the CDP has been in use since 2003. Had such requirements really been contrary to Directive 91/414, this would already have been pointed out by the Court of Justice. Furthermore, Regulation 1107/2009, which replaced Directive 91/414 as from 14 June 2011, provides in Article 6 [8] for the possibility to subject the approval to conditions. One such condition, which is included in Article 6(f), is the provision of confirmatory information. This is confirmed in Section 2.2 [9] of Annex II to the Regulation. These provisions clearly reflect the legislature's intention regarding the use of the CDP.

8. The Commission pointed out that the CDP allows it to increase the robustness of the scientific basis for some of its decisions by requiring new scientific and technical information from the applicant. The confirmatory information is then assessed by the rapporteur Member State. If the assessment is unfavourable, the EU authorities can rapidly take the necessary restrictive measures on a scientific basis. If the confirmatory information is not provided as required, the Commission may withdraw or amend the approval of the substance.

9. The Commission further submitted that the precautionary principle must be applied in a proportionate manner. A total ban is not necessarily a proportionate response in all cases. In fact, a total ban should be applied only if the risk cannot be maintained to a level acceptable for society and if it is the sole possible response to a given risk. As the Commission bears the final political responsibility, it is fully entitled to investigate whether a risk can be dealt with in some other fashion. Acting on the basis of the precautionary principle requires that the scientific evaluation of the data pertaining to a given risk be done as thoroughly as possible. Thus, the complainant should not oppose the scientific assessment of such data.

10. In its observations, the complainant challenged the Commission's account and maintained its views. A decision to request confirmatory data cannot be regarded as a " *requirement* " within the meaning of Article 5(4) of Directive 91/414. Accepting the Commission's approach would result in turning the decision process on its head because normally a decision is to be taken on the basis of an assessment of the information provided by the applicants. The Commission approves substances for which it lacks sufficient data and accepts that the data will be provided only after approval has been granted. If it does not have sufficient information to take a decision, it should request and assess the missing information before taking that decision. The complainant expressed its concern that Article 6(f) of Regulation 1107/2009 (providing for the CDP approach) might be used too extensively.

11. In reply to this, the Commission re-stated its position on the lawfulness of the CDP. In its view, the legal basis is to be found in Article 5(4) of Directive 91/414, which expressly mentions the possibility of subjecting the inclusion of an active substance to " *requirements* ". Article 6 of that Directive mentions specifically that " *any conditions for inclusion* " shall be decided upon. Thus, according to the Commission, it is clear that it may set requirements and conditions and also that it enjoys wide discretion as regards their nature and extent. This approach is confirmed by Article 6(f) of Regulation 1107/2009 and Section 2(2) of Annex II to that Regulation (applicable since 14 June 2011), which explicitly refer to requests for confirmatory information.

12. As regards the reasons for the introduction of the CDP, the Commission said that the assessment process had been slow due to the complexity of the matter and to the acceptance by the evaluating authorities of new studies and continuous improvements to the file by the applicants. A new approach laid down strict time lines for the submission of materials but, while this accelerated the procedure, it prevented the applicants from improving the content of the file by submitting new relevant data.

13. The Commission said that the confirmatory information submitted by the applicants is examined with the same level of rigour as the information submitted with the initial application. Requests for confirmatory information are made only where necessary, in duly justified cases and for EU-level relevant matters. Such information is requested for the purpose of confirming assessments on certain points only. It is never requested with regard to issues essential and critical to the assessment of the safety of active substances or in circumstances where critical endpoints as regards exposure of consumers, operators, workers and bystanders are exceeded.

14. The Commission also said that requests for confirmatory information are included in the approval decisions in cases where it may be expected that, in general, PPPs containing the active substance at issue satisfy the approval criteria but where, at the same time, the Commission as a risk manager considers that it is appropriate to further increase the robustness of the scientific evaluation and the confidence in the scientific findings or to address new elements that emerge in the course of the evaluation process. This is beneficial not only in the context of the EU approval, but also at the national level, when applicants seek product authorisations.

15. According to the Commission, requests for confirmatory information may also be necessary where it is following new evaluation guidelines introduced after the submission of the file by an applicant. For instance, a request for confirmatory information can take the form of a request for refined assessments, closer to realistic conditions of use. Importantly, in addition to the nature of the requested information, its provision within certain time frames is also a part of the requirement. Usually, such information must be provided between 6 months and 2 years after the entry into force of the relevant approval decision, depending on the type of information sought. Finally, the Commission contended that the CDP is not an "easy surrogate" in the case of an incomplete file or of flawed data and that it meets the same rigorous criteria that apply to the original data submission procedure.

16. In the Commission's view, the EU legislature considers that the CDP is compliant with the precautionary principle, since it is expressly included in Regulation 1107/2009. The Commission stated that the assessment of pesticides is risk-based, which means that a dangerous substance can be authorised if exposure remains within acceptable limits. The CDP also respects the principle of proportionality since it allows the Commission to protect human and animal health and the environment in a less restrictive way than if it were not to approve a substance.

17. In its further observations, the complainant reiterated its views. It contended that if the

Commission lacks data, it is simply not possible for it to carry out a proper risk assessment. As regards the legality of the CDP, the complainant referred to a letter from the Danish Environmental Protection Agency which warned the Commission in 2005 that there was no legal basis for the CDP. The complainant also disagreed that the Commission uses the CDP only exceptionally but took the view that it is used on a regular basis and even for high-risk PPPs. According to the complainant, the Commission thus gives priority to the industry over the protection of human and animal health and the environment.

The Ombudsman's preliminary assessment leading to the first proposed solution

18. The complainant challenged the Commission's use of the CDP under two distinct legal regimes. The first is that under Directive 91/414, which was in principle applicable until 14 June 2011. As of that date, the Directive was repealed and replaced by Regulation 1107/2009 [10] .

Legal regime under Directive 91/414

19. As regards Directive 91/414, the Ombudsman does not find the explanations provided by the Commission either convincing or sufficient.

20. The Commission seems to agree that Directive 91/414 does not contain any express legal basis for the CDP comparable to the one contained in Regulation 1107/2009. Instead, Articles 5 and 6 of Directive 91/414, on which the Commission relies, refer in a general manner to " *requirements* " and " *conditions for inclusion* " and Article 5 provides a list of examples of such requirements. The CDP is however not included among these examples [11] . The Ombudsman has serious doubts whether these provisions could be regarded as constituting a sufficiently specific legal basis for the CDP applied by the Commission. In this respect, the Ombudsman points out that public authorities can act only on the basis and within the limits of the powers that have been conferred on them [12] .

21. The Ombudsman understands that the CDP, as applied by the Commission, implied that the Commission approved an active substance even though it considered that it was necessary to obtain additional data in order to confirm that its approval was in fact justified. In particular, the need for additional data was something established on the basis of EFSA's scientific analysis which the Commission would have had available to it before taking any decision. Should no confirmatory data be provided, or should such data be unsatisfactory, the Commission reserved the right to withdraw its initial approval or to impose further restrictions [13] .

22. The parties disagree on whether or not the Commission takes the CDP approach in cases where the level of risk is unacceptable for society; they disagree also on what limits should apply in the Commission's management of risk. In the Ombudsman's understanding, the CDP necessarily means that, in certain cases, the Commission approves the placing on the market of active substances although it is well aware that it might turn out, on the basis of the confirmatory

information, either that its approval may not be justified or that additional restrictive measures may be warranted. In fact, the very purpose of requesting confirmatory data is to verify that the approval is justified. This in turn implies the possibility of the existence of an undue risk for the environment or human or animal health.

23. The Commission's line of argument seems contradictory because, on the one hand, it contends that the CDP does not imply any undue risk for society (see point 13 above) and, at the same time, it explains that the procedure is used where it is " *appropriate to further increase the robustness of the scientific evaluation and the confidence in the scientific findings or to address new elements that emerged in the course of the evaluation process* " [14] . In addition, the Ombudsman has carefully examined the documents and submissions relating to the ten active substances discussed in detail by the parties and is concerned that the Commission requested confirmatory data for all ten substances, both in situations where EFSA stated that a large part of its analysis could not be completed during its assessment due to data gaps and where risks or 'critical areas of concern' were identified [15] . This seems to confirm the complainant's argument that the CDP is used on a " *standard basis* " even in situations where serious risks are identified. It also calls into question the Commission's submission that the CDP is never used with regard to " *issues essential and critical to the assessment of the safety of active substances* ".

24. The Ombudsman considers that it is not easy to see how the CDP, as described in paragraphs 21 and 22 above, may be regarded as compatible with the provisions of Articles 5 and 6 of Directive 91/414. The reference to " *requirements* " and " *conditions* " contained therein can hardly be read as implying that the Commission may grant an approval while admitting that it is not yet in a position to confirm that it may be expected that the active substance does not have any harmful effects for human and animal health or for the environment. The Ombudsman does not think that the Commission's discretion in defining conditions and requirements could result in such an extensive interpretation.

25. In fact, Article 5(4) of Directive 91/414 lists five examples [16] which seem to be based on the idea that an active substance may be approved on condition that certain safeguards are observed in its practical application/use. These examples aim at providing measures for containing risks already identified during the examination of the active substance; they do not provide a basis for taking new risks by virtue of its approval and release in situations where a sufficient examination has not been carried out because of insufficient evidence.

26. The Ombudsman is also of the view that the provisions of Article 5(4) of Directive 91/414 need to be read in conjunction with the rest of Article 5 and the Directive, including the recitals. The recitals and Article 5(1) make it clear that no active substance may be approved by the Commission if it is not sufficiently established that there are no harmful effects for human and animal health and no unacceptable influence on the environment.

27. The legislature's intention, clearly, was to ensure the protection of public health and the environment. The fact that the legislature introduced the possibility to request confirmatory data in Regulation 1107/2009 does not retrospectively validate the Commission's previous practice.

In addition, the Ombudsman notes that (as shown in the paragraphs which follow) even Regulation 1107/2009 lays down restrictive conditions for use of the CDP, which may not necessarily correspond to the Commission's practice.

28. The rights and principles protected by Directive 91/414 are also protected by the EU constitutional order and need to be taken into account in the interpretation of the relevant provisions. The EU Charter of Fundamental Rights enshrines every person's right to life (Article 2) and provides that a " *high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities* " (Article 35). Article 31 of the Charter further provides for specific health and safety protection for workers. In accordance with Article 37 of the Charter, a " *high level of environmental protection and the improvement of the quality of the environment must be integrated into the policies of the Union and ensured in accordance with the principle of sustainable development.* " Under Article 191 of the Treaty on the Functioning of the European Union ('TFEU'), the Union's environmental policy is based on preserving, protecting and improving the quality of the environment as well as protecting human health and on the precautionary principle.

29. For all these reasons, the Ombudsman does not find convincing the Commission's explanation regarding the conformity with Directive 91/414 of its reliance on CDPs. Having carefully examined the parties' submissions and the relevant legal framework, the Ombudsman takes the preliminary view that the Commission's reliance on CDPs (as described above) is not compatible with the provisions of Directive 91/414 [17] . Such use of CDPs therefore appears to constitute maladministration. In light of this conclusion , it is not necessary to examine whether and the extent to which such use of CDPs, under Directive 91/414, may be incompatible with the precautionary principle.

Legal regime under Regulation 1107/2009

30. The parties agree that the Commission has been explicitly authorised to make requests for confirmatory data under Regulation 1107/2009. Article 6(f) of that Regulation provides that "[a] *pproval may be subject to conditions and restrictions including: ... submission of further confirmatory information to Member States, the Commission and the European Food Safety Authority ... where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge* ". Section 2(2) of Annex II to the Regulation provides that "[i] *n principle an active substance ... shall only be approved where a complete dossier is submitted. In exceptional cases an active substance ... may be approved even though certain information is still to be submitted where: (a) the data requirements have been amended or refined after the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.* " The Ombudsman accepts that when it acts under Regulation 1107/2009, and provided it respects the restrictive conditions set out in the above provisions, the Commission's decision to use a CDP must be regarded as having a legal basis under Regulation 1107/2009.

31. However, although there is now an express legal basis for the CDP, the Ombudsman is of

the view that this cannot be interpreted as implying that *any* application of the CDP is compatible with (i) the requirements of safeguarding human and animal health and the environment expressed in Article 4 of Regulation 1107/2009 and other provisions, and (ii) the precautionary principle. On the contrary, the Ombudsman considers that when the Commission decides to approve an active substance and to request confirmatory data under Article 6 of Regulation 1107/2009, it needs to make sure that such course of action does not endanger human health, animal health or the environment.

32. The Ombudsman notes, *first* , that the legislature authorised the Commission to request confirmatory data in specific cases only. Annex II to Regulation 1107/2009 makes it clear that " **[i]** *n principle an active substance ...* **shall only** *be approved where a complete dossier is submitted* " (emphasis added). It follows that it is possible to approve an active substance without sufficient data only where the specific conditions set out by the legislation are met. Section 2 of Annex II makes this possible only where either the data requirements have been amended or refined or where the information is considered **confirmatory in nature** and is required merely to increase confidence in the decision. From the wording of both Article 6 of Regulation 1107/2009 and Section 2 of Annex II, it is clear that the legislature intended to reserve use of the CDP to exceptional cases where the risk that the assessment will be changed is minor. Since the CDP was conceived as an exception, the conditions for its application should be interpreted restrictively.

33. *Second* , Regulation 1107/2009, like Directive 91/414, lays emphasis on the protection of human and animal health and of the environment. Recital 8 of the Regulation mentions that "[t] *he purpose of this Regulation is to* **ensure a high level of protection of both human and animal health and the environment** *and at the same time to safeguard the competitiveness of Community agriculture.* **Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children.** *The* **precautionary principle should be applied** *and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market* **do not have any harmful effect on human or animal health or any unacceptable effects on the environment** " (emphasis added). Recital 24 adds that " *... the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production. Therefore, it should be demonstrated,* **before** [PPPs] *are placed on the market, that they present a clear benefit for plant production and do not have any harmful effect on human or animal health, including that of vulnerable groups, or any unacceptable effects on the environment* " (emphasis added). Similarly, Article 4(2) of the Regulation provides that "[t] *he residues of* [PPPs] *... shall not have any harmful effects on human health ... or animal health ...* " or " *any unacceptable effect on the environment* ". Finally, the second indent of Article 4(1) establishes a certain hierarchy within the provisions of Annex II giving priority to its provisions concerning the protection of human health and the environment over the provisions concerning the CDP [18] .

34. *Third* , human health and the environment are protected not only by Regulation 1107/2009 but also by the EU constitutional order. Accordingly, the Commission is required to take these latter factors into account when deciding whether to approve an active substance where it

considers that additional data is needed to complete the assessment.

35. *Fourth* , Regulation 1107/2009 makes it clear that the precautionary principle is to be applied [19] . This principle is enshrined in Article 191 TFEU which provides that the Union's environmental policy is based, amongst other things, on the precautionary principle. In accordance with the case-law of the Court of Justice, the precautionary principle is a general principle of EU law which requires the authorities to take appropriate measures to prevent specific potential risks to public health, safety or the environment by giving precedence to the protection of those interests over economic interests. In particular, it permits the adoption of protective measures where the information available suggests that there might be harmful health effects even though there is scientific uncertainty on the matter [20] . **The Ombudsman believes that the precautionary principle is also to be regarded as a principle of good administration requiring the Commission to ensure that it does not approve active substances in cases where public health or the environment could be endangered** .

36. In light of the above, the Ombudsman is of the view that, as a matter of good administrative practice, the CDP provided for in Regulation 1107/2009 should be used only in duly justified cases strictly corresponding to the conditions specified by the legislature and **where there is no risk that the conclusion on the safety of the active substance might be flawed** .

37. Since use of the CDP constitutes an exception, it needs to be applied restrictively and the conditions for its application also need to be interpreted restrictively. It cannot be applied automatically simply 'because the legislature authorised it', rather the Commission has to take full account of the possible consequences for human and animal health as well as for the environment in each specific case before applying the CDP. These interests are protected by the EU constitutional order and must be taken into account. The Commission must also take into account the precautionary principle. In every case, it should give priority to the possibility of requiring and assessing the information that is needed before taking a decision on approval. **Bearing in mind that any possible error in the Commission's assessment based on insufficient data may cause serious, possibly irreversible harm to human health, the health of animals or to the environment in general, the Ombudsman takes the view that the CDP needs to be applied with particular caution and restraint.** The Ombudsman proposes a solution below, in accordance with Article 3(5) of the Statute of the European Ombudsman.

Allegation that the Commission adopted misleading review reports and decisions for active substances and the claim that the Commission should reassess all the review reports and decisions concerned and include in them all relevant EFSA conclusions

Arguments presented to the Ombudsman

38. The complainant argued that, when evaluating active substances for certain pesticides through the resubmission procedure, the Commission failed to take into account the scientific conclusions of the peer reviews carried out by EFSA. It referred to ten particular active substances. In these cases, although EFSA identified data gaps or even risks, the active substances were approved by the Commission.

39. In its opinion, the Commission disagreed with the complainant and claimed that it had adopted proper and accurate review reports and decisions for the active substances concerned, which take EFSA's conclusions fully into account.

40. The Commission said that it may sometimes be legitimate to depart from EFSA's conclusions and that the Commission enjoys broad discretion [21] . In particular, according to the Commission, scientific risk assessment cannot always provide all the information on which a risk management decision should be based. Other factors need to be taken into account. The Commission's decision may approve a substance but provide for appropriate prevention and control options [22] . It is for the risk manager to decide on the acceptance of any residual risk and the measures to minimise and reduce it to acceptable levels. The Commission may consider that, despite identified data gaps or potential remaining risks, certain acceptable uses of PPPs can be identified taking into account restrictions on use or risk mitigation measures.

41. The Commission contended that when EFSA's conclusions make mention of remaining uncertainties or data gaps, this does not necessarily mean the 'absence of data'. Such a conclusion may simply indicate a certain disagreement among experts; it does not necessarily constitute evidence of a serious risk which cannot be contained. Such a data gap can arise where, during the peer review, some evaluators consider that further information would be welcome so as to increase the robustness of the assessment. In many cases, such data gaps refer to local situations and can be addressed at Member State level or through confirmatory data that can be submitted at EU level after approval. In other cases, EFSA identifies a risk " *on the basis of very conservative and theoretical models* ", which need to be confirmed or dismissed by more realistic in-field data. The Commission may request such data by means of confirmatory data requests. It is the role of the Commission and of the Member States to evaluate the impact of such uncertainties and identified data gaps, and to assess the need for refinement on the potential acceptability of the substance. It is their task to see to what extent remaining uncertainties could be counterbalanced by adequate risk mitigation measures.

42. In its observations, the complainant disputed the Commission's submissions. It stated that if the Commission departs from EFSA's conclusions, it (i) has to do so in light of current scientific and technical knowledge (Article 5(1) of Directive 91/414), (ii) has to provide proper reasons, and (iii) should follow a specific procedure for incomplete files. Where EFSA identifies a data gap, the Commission should first request additional information. The Commission should not approve active substances where there are data gaps because its decisions would not be based on scientific information but on assumptions as to the potential risks. The precautionary principle should apply and commercial interests should not prevail over safety as (it claims) has been the case thus far.

43. In reply, the Commission contended that the existence of data gaps in an otherwise very comprehensive and complex file must not always be seen as a reason for not approving a substance. Some data gaps do not raise immediate concerns or are not relevant for all European conditions of use. In such cases, they are further examined at the national level.

44. The Commission provided detailed explanations in the case of each of the ten substances identified as problematic by the complainant:

A. Bromuconazole

[23]

- EFSA identified two 'issues that could not be finalised' [24] (due to data gaps): (i) the assessment of the potential for endocrine disruption in fish and birds and (ii) the assessment of consumer risk. As regards the first issue, there was no agreed methodology or guidance document for assessment. Therefore, the Commission requested confirmatory data within two years of the adoption of the OECD test guidelines on endocrine disruption or, alternatively, EU test guidelines. As regards the second issue, the Commission also requested confirmatory information. In addition, the Commission requested mitigation measures as proposed by EFSA (use of personal protective equipment and adequate buffer zones).
- EFSA identified two critical areas of concern: (i) a " *potential risk* " for the consumer with regard to bromuconazole metabolites and (ii) a " *high long-term risk* " for herbivorous mammals. The Commission addressed these risks by way of confirmatory information requests.
- The confirmatory data were submitted within the time limits and were still being assessed. Additional data gaps identified by EFSA were to be covered in the context of the national PPPs authorisation procedures.

B. Myclobutanil

[25]

- EFSA's conclusions listed no critical areas of concern but merely issues that could not be finalised due to data gaps: (i) uncertainties in the estimation of the nature and level of residues in grapes, and (ii) the consumer risk assessment could not be finalised for a number of reasons. EFSA however considered that the substance seemed sufficiently safe to exclude a risk for the consumer and recommended completing the information. The Commission accordingly requested confirmatory data.
- As regards additional data gaps, they were to be covered at Member State level. Although not recommended by EFSA, the Commission included an obligation for Member States to pay particular attention to operator safety and ensure that conditions of use stipulate that adequate protective equipment must be used, where appropriate.
- The confirmatory data were provided within the prescribed deadline and the assessment is currently ongoing.

C. Hymexazol

[26]

- The Commission stated that hymexazol was approved under highly restrictive conditions since only " *uses as fungicide for seed pelleting of sugar beets in professional seed treatment facilities may be authorised* ". Its use on tomatoes was considered unacceptable after full assessment. Thus, it was not legally possible for national authorities to authorise its use on tomatoes or any other use not respecting the EU restrictions in Member States. Many of the issues raised by EFSA concerned its use on tomatoes which, in the event, was not approved.
- As regards other uses, EFSA identified several issues that could not be finalised. They also corresponded to the areas of critical concern identified by EFSA. These are: (i) the consumer risk assessment could not be finalised and (ii) the long-term risk assessment for granivorous birds and mammals could not be finalised. The Commission contended that it was "highly unlikely" that consumers of sugar, which is obtained after significant processing and refinement from sugar beet, the seed of which has been treated with the substance, would be at risk. Nonetheless, to be on the safe side, it included a provision requesting confirmatory information. That information has been submitted and its assessment is close to finalisation. As regards the second issue, the Commission requested confirmatory information and requested Member States to pay particular attention to the protected species. The information has been submitted and the assessment is close to finalisation.

D. Pyridaben

[27]

- EFSA did not find any critical areas of concern but merely referred to a number of issues which could not be finalised due to data gaps. These were: (i) the aquatic risk assessment, (ii) the assessment of long-term risk for mammals when pyridaben is used in citrus, (iii) the assessment of fat-soluble residues, and (iv) the consumer risk assessment when it is used in citrus.
- The Commission requested confirmatory data for all four categories. As regards the long-term risk for mammals and the consumer risk, the data gaps concerned only one use (citrus). Another safe use was identified (tomato) and therefore the approval was valid since one safe use is sufficient. In any event, the Commission identified particular conditions that have to be taken into account at Member State level for its use in citrus. Member States are responsible for laying down specific risk mitigation measures in order to reduce the risk to bees. All the confirmatory data were submitted and their assessment is ongoing.

E. Haloxyfop-P

[28]

- EFSA pointed to several issues that could not be finalised: (i) the groundwater exposure assessment and (ii) the assessment of long-term risk to herbivorous mammals and to insectivorous mammals. The first issue was also regarded as a critical area of concern.
- As regards the first issue, the Commission explained why, in its view, the risk was limited. In fact, no " *exceedance* " was expected and some of the metabolites were considered toxicologically not relevant. Thus a consumer assessment would be required only should the legal limits on presence be exceeded. In order to be on the safe side, the Commission invited

Member States to pay particular attention to consumer safety in cases where two metabolites would occur above the legal limit. In addition, confirmatory information was requested. It was submitted and was still being assessed. Finally, the Commission followed EFSA's recommendation and prescribed adequate buffer zones, where appropriate.
- As regards the second issue, the Commission considered that the data gap concerns only long-term risk for certain mammals from the substance's use on oilseed rape in Southern Europe. This is to be addressed by the competent authorities before granting national authorisations. Therefore, it did not need to be addressed at EU level in the Directive.

F. Quinmerac

[29]

- EFSA listed one critical area of concern, namely, that the existing data gave indications of a high long-term risk to earthworms. EFSA considered that this issue needed to be addressed further. Accordingly, the Directive requested confirmatory data and provided that Member States should pay particular attention to the long-term risk for earthworms.
- Three additional issues could not be finalised: (i) the determination of the likely occurrence of significant residues in rotational crops and the fact that maximum residue levels could not be proposed, (ii) the consumer risk assessment, and (iii) the assessment of the potential risk for birds and mammals. In order to address the first two issues, the Commission requested confirmatory data. In addition, Member States were required to pay particular attention to the dietary exposure of consumers to residues of quinmerac in rotational crops. The third point was not addressed in the Directive because the toxicity studies indicated a low risk to birds and mammals.
- As regards EFSA's further recommendations (groundwater, aquatic organisms, data gap on rotational crop residue trials), the Commission made corresponding recommendations to Member States in the Directive.
- All confirmatory data were submitted within the prescribed time limits and the assessment is still ongoing.

G. Metosulam

[30]

- EFSA listed one critical area of concern, namely, the absence of an agreed technical specification covered by the toxicological assessment. In addition, the assessment of the genotoxic potential of one impurity could not be finalised. Accordingly, the Commission requested confirmatory data. After the requested data (as regards the technical specification only) were received and evaluated, the review report was updated [31] .
- In addition to the issues mentioned under the critical area of concern, one further issue could not be finalised, namely, the groundwater, surface water and sediment exposure assessments for two metabolites. Thus, the assessment of the aquatic risk for these metabolites could not be finalised. In addition, as the proposal for classification of the active substance includes a carcinogenic categorisation, the existing toxicity information on these metabolites was considered insufficient to conclude that they are not relevant, should any subsequent exposure assessment indicate that the parametric drinking water limit might be exceeded in groundwater.

The Commission addressed this matter by requesting confirmatory data. The data in question have been submitted and the assessment is ongoing.

H. Napropamide

[32]

- EFSA listed no critical areas of concern but merely identified some issues that could not be finalised: (i) the impact on the environmental fate [33] and behaviour and/or environmental effects in relation to the enantiomers of napropamide, (ii) the groundwater exposure assessment for one metabolite and the consumer risk assessment from exposure to that metabolite via drinking water obtained from groundwater, (iii) the aquatic risk assessment for several metabolites, (iv) the risk assessment for aquatic plants, (v) the aquatic risk assessment for the use on tomatoes in Southern Europe, and (vi) the soil exposure assessment, risk to earthworms and soil non-target macro- and micro-organisms for Southern European uses.
- As regards the first issue, the Commission requested confirmatory data. However, since no agreed methodology that would allow the assessment of such data exists, the data would be required only once guidelines in this field are finalised.
- As regards the second issue, EFSA noted the possibility of an underestimation of leaching due to some uncertainties. Once this is correctly established, there will be a need for updated simulations. The Commission however stated that EFSA did not consider this metabolite toxicologically relevant. Therefore, a consumer assessment would be carried out only in geoclimatical cases where a presence above a certain limit would be expected. This could be addressed by a further localised refined assessment. The Directive nonetheless requests Member States to pay particular attention to consumer safety.
- As regards the third issue, the Commission requested confirmatory data to address the data gap. In addition, Member States were requested to apply specific risk mitigation measures to protect aquatic organisms such as defining no-spray zones in the vicinity of aquatic bodies.
- As regards the fourth issue, confirmatory data were requested.
- As regards the fifth and sixth issues, they concern Southern Europe only. They will therefore be evaluated by the competent local authorities before granting national authorisations. Consequently, these issues do not need to be reflected in the approval decision, which is applicable in all Member States.

I. Oryzalin

[34]

- EFSA listed three critical areas of concern, namely that (i) the equivalence between the proposed technical specification and the batches used in the toxicological studies was not demonstrated, (ii) the potential for groundwater contamination above a limit could not be excluded for two potentially relevant soil metabolites, and (iii) a high risk to aquatic organisms was identified. All issues were addressed by confirmatory data requests [35] . In addition, as regards the second issue, the Commission requested Member States to establish monitoring programmes to verify potential groundwater contamination and to lay down specific provisions for the protection of groundwater. As regards the third issue, the Commission also requested Member States to pay particular attention to the protection of aquatic organisms.

- EFSA also identified two issues that could not be finalised due to data gaps: the above-mentioned potential groundwater contamination and the toxicological relevance of a number of impurities. The Commission requested confirmatory information.
- EFSA identified one additional data gap which was addressed by inviting Member States to pay particular attention to the protection of groundwater, where the active substance is used in regions with vulnerable soil and/or climatic conditions.
- EFSA made a number of recommendations that needed to be taken into account (use of personal protective equipment, no-spray buffer zones or comparable measures to protect non-target plants, mitigation of a potential risk to herbivorous birds and mammals and bees). These recommendations were addressed in the Directive by asking the Member States to pay particular attention to these matters.
- In this case, the confirmatory data were submitted within the deadlines and the assessment has been finalised and considered satisfactory. Since the active substance has not yet been classified, the confirmatory data request as regards groundwater is not yet applicable.

J. Malathion

[36]

- The Commission submitted that Malathion was approved subject to restrictions, namely that authorisations at Member State level be limited to professional users only.
- EFSA recommended particular risk mitigation measures such as establishing 30-40m buffer zones for use in strawberries to protect the aquatic environment, since only then would the risk for aquatic invertebrates be low. However, it added that the buffer zones may differ for other uses (10-20m in the case of alfalfa), which is why the Commission decided not to specify them in the Directive. The Directive however requests Member States to pay particular attention to the protection of aquatic organisms and to include mitigation measures such as buffer zones where appropriate.
- EFSA also recommended measures to address the risk to bees. Since insecticides such as malathion may by their nature cause harm to honey bees, warnings and instructions for proper use are necessary. The Directive accordingly invites Member States to take appropriate measures to protect insectivorous birds and bees. The Directive specifically provides that " *As regards bees, the necessary indications shall be provided on the labelling and the accompanying instructions so as to avoid exposure.* "
- EFSA identified a number of issues which could not be finalised: (i) quantification of the different potency of malaoxon and malathion, and (ii) the consumer risk assessment (data gap on isomers and metabolites, data gap on residues in rotational crops). The Commission requested confirmatory data.
- EFSA identified one critical area of concern, namely, that based on the available data, it was not possible to address the acute and long-term risks to insectivorous birds from the intended field use in strawberries. The Commission addressed this issue by requesting confirmatory data and by requesting Member States to pay attention to this issue and to include mitigation measures where appropriate.

45. The complainant disputed the Commission's submissions (summarised above). It maintained that due to data gaps and risks identified by EFSA, the Commission was not correct

in reaching the conclusion that there were no risks for human and animal health or for the environment. Therefore, it should not have approved the substances concerned, even taking into account the conditions, restrictions and mitigation measures imposed.

The Ombudsman's preliminary assessment leading to the second proposed solution

46. The complainant claims that the Commission should reassess its evaluation of the ten active substances concerned. Accordingly, the Ombudsman understands that the main issue is not so much the allegedly " *misleading* " character of the review reports and the decisions but, rather, whether they are substantively correct when considered in the light of EFSA's conclusions. Therefore, the Ombudsman's analysis focuses on this issue.

47. The Ombudsman points out that it is not the purpose of her inquiry to carry out a second scientific assessment of the active substances concerned or to substitute her views for those of the Commission. The Ombudsman's review of this case is limited to procedural issues; these include an examination of the reasons provided by the Commission for its decisions, and checks as to whether the Commission committed any manifest error of assessment, in particular in the light of EFSA's conclusions.

48. The Ombudsman understands that all of the active substances concerned were approved under Directive 91/414. Article 5(1) of Directive 91/414 provides that an active substance shall be approved only " *if it may be expected* " that the PPPs containing it (their residues or their use) will have no harmful effect on human health, on animal health or on groundwater or any unacceptable influence on the environment.

49. The Ombudsman notes that the Commission admitted in its replies that each of the ten active substances was approved at a time when relevant parts of the assessment could not be completed because the applicants had provided insufficient information (data gaps). EFSA also pointed out several concerns as regards each of these substances. Even though it suggested mitigation measures at the level of the Member States, the Commission proceeded with the granting of approval. It did so even though it may have been the case that it lacked sufficient documentation in order to be able to take properly informed decisions that the substances approved had none of the harmful effects identified in Article 5(1) of Directive 91/414. If this in fact proved to be the case, then this procedural course of action would be unlawful and contrary to the principles of good administration. Taking into account the possible consequences for human health, animal health and the environment, such inadequacies would be particularly worrying. The Ombudsman considers that the Commission should be extremely cautious in this regard. In such situations, the Commission would clearly be better advised to investigate the issues concerned before taking a decision on approval.

50. As regards napropamide, the Ombudsman does in any event not understand how the Commission addressed the data gap concerning the "impact on the environmental fate and behaviour and/or environmental effects in relation to the enantiomers of napropamide" since it

appears that the confirmatory data requests included in Directive 2010/83/EU do not cover this issue. In addition, it appears that the missing data, the assessment of which needed to be completed, concerned important matters. For example, EFSA observed as regards myclobutanil that, while the safety margin seemed sufficient to exclude a risk to the consumer from the use of the substance in grapes, "[d] *ata gaps need* [ed] *... to be addressed in order to finalise the risk assessment and to confirm that the toxicological reference values* [were] *effectively not exceeded* " [37] . And as regards hymexazol, pyridaben, metosulam and napropamide, EFSA stated in its conclusions that "[o] *verall, the risk assessment could not be finalised for any of the representative uses* " [38] . In the case of metosulam, the Commission granted the approval even though the missing data concerned the genotoxic potential of one impurity.

51. In certain cases, EFSA identified, in addition to data gaps and simple concerns, 'critical areas of concern'. [39] . In its 2013 Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance oryzalin, EFSA states that "[a] *n issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses ... and where this assessment* **does not** *permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment ...* " (emphasis added). The term 'critical area of concern' is further used " *where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a* [PPP] *containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.* " [40] Taking into account this definition, the Ombudsman does not understand how the Commission could legitimately decide, having regard to Article 5(1) of Directive 91/414, that the residues of these substances, or the use of PPPs containing these active substances, would have no harmful effect on human or animal health and no unacceptable influence on the environment. At the very least, a satisfactory explanation in this regard has not been provided by the Commission so far.

52. In light of the evidence submitted to her, the Ombudsman is not convinced by the Commission's argument that confirmatory data requests are never made in respect of important matters.

53. The above findings are of particular concern because all ten substances were approved many years ago and it appears that in most of these cases, in spite of the passage of time, the Commission has not completed the assessment of the confirmatory data requested. Taking into account the apparent discrepancy between EFSA's findings and the Commission's conclusion that the substances in question may be expected not to have any harmful effects for human health, animal health, underground water or the environment, the Ombudsman understands the complainant's impression that the Commission's review reports and approval decisions are " *misleading* " and inaccurate. All these findings will be reflected in the Ombudsman's second proposal (below) for a solution.

Allegation that the Commission did not apply the provisions of Article 5(1)(b) of Directive 91/414 correctly and the corresponding claim that the Commission should properly assess whether those provisions are complied with and should set up a verification system to check whether Member States adequately impose and enforce mitigation measures

Arguments presented to the Ombudsman

54. The complainant argued that the Commission (i) disregarded the available data pertaining to the risk assessment for public health and the environment, (ii) transferred responsibility for Article 5(1)(b) of Directive 91/414 to the Member States by imposing mitigation measures, and (iii) failed to ensure that proper risk mitigation measures are imposed and enforced.

55. In its opinion, the Commission disagreed with the complainant. It said that the argument that it had disregarded the available data was "redundant" and referred to its submissions relating to the second allegation. The Commission then pointed to the division of responsibilities provided for by the applicable legislation. While the EU is responsible for approving the substance contained in a PPP, responsibility for the authorisation of PPPs lies with the Member States.

56. The Commission said that, where needed, the approval decisions include a general statement that: " *Conditions of use (or of authorisation) shall include risk mitigation measures, where appropriate* ". It is then up to the Member States to choose and apply the most appropriate mitigation measures, as they often differ from one Member State to another, given the different geographic and climatic conditions, the agricultural practices and the specific vulnerable situations. However, in the majority of cases, the Commission lays down in its approval decisions specific risk mitigation measures, which contribute to the achievement of the objectives of the protection of health and the environment in the Union.

57. The Commission denied that there would be any transfer of responsibility to the Member States concerning risk mitigation measures. Under the principle of subsidiarity, decisions should be taken at the level best adapted for their implementation. The Commission provides the framework and the considerations necessary for the Member States to adopt and enforce the most appropriate risk mitigation measures. Thus, the approval specifies the conditions or requirements concerning the active substance. Then, when authorising the specific PPPs, the Member States have to implement the conditions set in the approval decision. The Commission argued that the Member States are in a better position than the Commission to take account of specific local conditions.

58. Finally, the Commission stated that national authorities have primary responsibility for providing the necessary control mechanisms and for the enforcement of mitigation measures. Under Article 17 [41] of Directive 91/414 (currently Article 68 [42] of Regulation 1107/2009),

Member States have the obligation to perform official checks and to send to the Commission a yearly report on enforcement. The Commission's Food and Veterinary Office ('FVO'), performs general and specific audits in the Member States for the purpose of verifying the implementation and enforcement of EU legislation by the competent authorities and the carrying out of official checks. Each year, the FVO develops an inspection programme, identifying priority areas and countries for inspection. FVO audits are very regularly performed and cover the activities of national authorities concerning PPPs, including the monitoring of products on the market, as well as the monitoring of maximum residue levels. The findings of each audit are set out in an inspection report, together with conclusions and recommendations. The FVO makes recommendations to the country's competent authority to deal with any shortcomings revealed during the inspections. The Commission may take action against a Member State if there is evidence of serious and systematic shortcomings at Member State level.

59. In its observations, the complainant maintained its views. It pointed out that there is a two-step procedure. The EU level stage calls for a full evaluation of the risks inherent in each active substance; the second (national) stage cannot be taken into account in the assessment carried out during this first stage. The Commission approves substances regardless of EFSA's scientific opinion, data gaps or high risks. The Commission thus disregards Article 5 of Directive 91/414 which obliges it to verify that the substance has no unacceptable influence on the environment in light of current scientific and technological knowledge. It transfers this duty to the Member States by way of mitigation measures.

60. As regards the FVO reports, they do not evaluate the enforcement of mitigation measures and the quality of inspections, such as checking if mitigation measures are imposed. In fact, they are merely administrative reports listing the number of staff members in national bodies, the number of pesticides authorised or delays in procedures. Therefore, these reports cannot be regarded as sufficient for ensuring that Members States adequately impose and enforce mitigation measures.

61. In a further reply, the Commission explained that risk mitigation measures are taken by Member States when authorising PPPs. They are decided upon individually because the risks can differ considerably between different formulations of the same active substance or different uses of the same product. The mitigation measures suggested by EFSA or in the approval decisions are therefore given by way of example in order to address typical risks when a specific active substance is used. The EU list of measures is neither comprehensive nor appropriate for all possible uses of a product. Since the EU authorisation system is based on a two-level structure, only the Member State can decide on appropriate risk mitigation measures because it is the Member State which decides on the authorisation of a specific PPP. Thus, it can assess the possible risk caused by a specific product used in a specific manner based on very detailed information on all formulations and uses.

62. According to the Commission, there are different ways of ensuring that risk mitigation measures are implemented by Member States. First, the Member States check each other through the 'zonal procedure'. Regulation 1107/2009 provides for three zones; the applications are submitted to the zonal rapporteur Member States and other Member States involve

themselves in the procedure.

63. Second, the FVO carries out audits on pesticide controls in Member States during which a comprehensive assessment of the effectiveness of the checking system in the Member States is carried out. The FVO can verify that Member State authorities check whether products are placed on the market in accordance with the authorisations and whether they are used according to the authorisations and the mitigation measures imposed by the Member States. Since 1998, four series of audits have been carried out. From January 2012 to June 2014, 19 Member States were audited. In 2015-2016, another 13 audits verifying the use and marketing of PPPs and 10-12 audits checking the evaluation of national authorisations of these products will be carried out. All reports are published online [43] .

64. The 2012-2014 series included on-the-spot observations of the official user checks. The audits consisted of a full week's visit by two to three FVO inspectors and experts from Member States. The auditors accompanied members of national Member State authorities during inspections at retailers and wholesalers and at farm level. The audits included checks on whether products were properly labelled and whether users complied with the instructions on the label of PPPs. The label instructions reflect the mitigation measures imposed by the Member States on the authorisation holder.

65. However, the audits have a broader scope and allow the Commission to verify that the Member States comply with their obligations and that they have adequate resources to do so. The 2012-2014 series covered both the granting of authorisations and the evaluation of official checks. The audits provide the Commission with the assurance that a high standard of protection of health and environment is enforced in Member States.

66. In its further observations, the complainant expressed doubts as to whether the Member States check each other and pointed out that Directive 91/414 did not provide for the zonal system of authorisation. As regards the FVO audits, the complainant stated that they rarely concern pesticides but focus on other issues such as plant health or meat inspection. When they concern pesticides, they focus on residues but not on the authorisation system. There has been no report concerning the Netherlands in the last five years and there has been only one report (in 2009) concerning Belgium. As regards France and Germany, only one report was drawn up (in 2012). It concerned merely the verification of residues in food. The reports do not deal with mitigation measures and even admit that there is a lack of sufficient data for assessment. [44]

The Ombudsman's preliminary assessment leading to the third proposed solution

67. The main issues for the Ombudsman here are (a) the alleged unwarranted transfer of responsibility to the Member States by way of mitigation measures and (b) the Commission's supervision of implementation at the national level.

68. As regards **the alleged transfer of responsibility** , the Ombudsman is satisfied, in general, by the Commission's explanations (see in particular paragraphs 55-57 and 61 above). The current system is based on a division of responsibilities between EU and Member State levels. Under the relevant rules, the Commission is responsible for approving active substances and Member States are responsible for authorising PPPs containing these active substances. The Ombudsman understands that, for a number of reasons, the Commission may consider, in a wide range of cases, that it is best to leave the exact definition of mitigation measures to national authorities (notably due to the specific characteristics of specific PPPs, and specific local conditions). This approach reflects the principles of subsidiarity and proportionality.

69. On the other hand, the Ombudsman is also sensitive to the complainant's arguments that the Commission should not give up its competences by systematically leaving the definition of mitigation measures to Member States only. As the Commission pointed out, it is competent to approve active substances and to define conditions and requirements that are needed to ensure that there are no harmful effects for human and animal health or to the environment. In addition, in some cases, it may be useful to define certain minimum mitigation measures at EU level in a legally binding document, in order to ensure that they will be implemented effectively at Member State level [45] .

70. On the basis of the arguments and evidence provided by the parties, the Ombudsman considers that the Commission may sometimes be too lenient when it not only approves active substances, for which EFSA indicates data gaps or even risks, but also leaves the exact definition of mitigation measures to Member States. The ten cases discussed by the parties show that the Commission often simply provides in its Directives that " *Member States shall pay particular attention to* " [46] certain issues such as operator safety, groundwater or protection of certain organisms. Another frequent formulation used in the Directives is that " *conditions ... shall include risk mitigation measures, where appropriate* " [47] . These formulations are very open-ended and the Ombudsman has doubts whether they can be legally described as *requiring* mitigation measures at all. This is problematic since the Commission's responsibility is to ensure that no unsafe active substance is approved and therefore also that the conditions or requirements that are necessary to ensure their safe use are fully observed and implemented. The Ombudsman will make a corresponding proposal below, inviting the Commission to reconsider its current approach.

71. As regards **the audits** carried out by the Commission, the Ombudsman notes that the current legislative framework is based on the principle of subsidiarity. Under Article 68 of Regulation 1107/2009 " *Member States shall carry out official controls in order to enforce compliance with this Regulation* ". Furthermore, they must report on the scope and the results of such checks to the Commission. As regards the Commission, its " *experts shall carry out general and specific audits in the Member States for purposes of verifying the official controls carried out by the Member States.* " It is clear from these provisions that, while the Commission is empowered to carry out audits, its role is limited in that its duty is to verify the checks carried out by the Member States. Therefore, the primary responsibility for carrying out checks and for ensuring that the rules set out in the Regulation are complied with, lies with Member States.

72. The Ombudsman has analysed a sample of ten audit reports published on the FVO website concerning audits carried out in the period 2012-2014 [48] . The ten reports were selected to cover the entire timespan, to be geographically representative and to cover both the Member States which acceded to the Union in 2004 and 2007 and the other Member States. Contrary to the complainant's allegations, these audit reports confirm that the FVO indeed also carries out audits which focus entirely on pesticides. It is true that the purpose of these audits is to verify the adequacy of the system of checks in each Member State. Nevertheless, as submitted by the Commission, they also involve specific on-the-spot checks which, in the Ombudsman's view, also allow for the verification of compliance with the requirements set out by the Commission in its approval decisions.

73. However, although the Ombudsman does not doubt the Commission's explanations and assurances, she is not entirely convinced that the FVO audits allow the Commission to verify effectively whether Member States comply with the conditions, restrictions and mitigation measures provided for in the EU legal acts approving active substances. The main purpose of the audits seems to be to verify the very system of checks carried out by Member States (Article 68 of Regulation 1107/2009). The FVO audit reports examined by the Ombudsman suggest that the FVO audits also cover, to an extent which is however not very clear, examinations of certain active substances or PPPs which includes their authorisation and use within that Member State. However, it would seem that supervision of compliance with the terms of the Commission's approvals is very limited. In particular, the Ombudsman found no evidence that the FVO **systematically** verifies whether the conditions, restrictions and mitigation measures imposed at EU level are complied with at Member State level. It appears rather that the Commission relies on the results of the checks put in place by the Member States in order to supervise, compliance with the conditions, restrictions and mitigation measures imposed at EU level.

74. The Ombudsman fully agrees with the complainant that the Commission cannot discharge its responsibility for ensuring effective protection of human health, animal health and the environment when approving active substances if it allows Member States almost absolute discretion as regards the definition of mitigation measures for potentially unsafe substances. This situation is even more problematic in circumstances where the Commission does not verify that the necessary precautions are in fact taken and that the restrictions or instructions, envisaged by the Commission's approvals of use of active substances, are complied with.

75. The Ombudsman has examined the FVO reports referred to by the Commission. The Ombudsman notes that in some cases in the sample, the FVO did find that a Member State failed to comply with certain restrictions imposed at EU level [49] . However, it would seem that the number of PPPs examined by the FVO audit team was rather limited and thus there might be other instances of non-compliance which escaped the audit team's attention. In a similar vein, the Ombudsman found that PPPs containing an active substance, for which the approval was withdrawn in April 2013, were still authorised in the Czech Republic as late as September 2013 and in Romania as late as March 2014 [50] . The Ombudsman takes the view that a more systematic approach to such issues is thus warranted.

76. For all the above reasons, the Ombudsman will make several proposals aimed at ensuring

that the Commission sufficiently and adequately verifies compliance with the terms of its approvals of use of active substances. This includes compliance at Member State level with any conditions, restrictions, mitigation measures and even possible withdrawals of an approval. The Commission should also ensure that audits or checks are carried out with sufficient frequency and in a timely manner. For instance, if the Commission decides to withdraw or amend an approval, measures should be taken to ensure that this is acted upon at Member State level without delay.

The proposed solutions

Taking into account the above findings, the Ombudsman proposes the following:

As regards the confirmatory data procedure

When acting under Regulation 1107/2009, the Commission should agree to:

(i) use the procedure restrictively, only in duly justified cases strictly corresponding to the conditions specified by the legislature and where there is no risk that the conclusion on the safety of the active substance could be flawed;

(ii) take duly into account all possible consequences for human and animal health as well as the environment, following the precautionary principle, before applying the procedure in a specific case; and

(iii) give priority to requesting and assessing any relevant missing information before taking a decision on approval.

As regards the assessment of the ten substances

1. The Commission should complete the assessment of the confirmatory data without delay, and update its assessment.

2. Where this is not possible, the Commission should review its approvals and consider whether they were justified in view of the terms under which they were granted taking into account (i) the fact that the scientific assessment of the substances could not be completed due to data gaps at the time the approvals were issued and (ii) the identified risks.

3. The Commission should adopt the same approach with respect to other active substances which do not form part of this inquiry and in respect of which a comparable shortcoming is identified.

As regards the mitigation measures and audits

1. The Commission should review its approach to the definition of mitigation measures (conditions, restrictions) and include further requirements, which reflect EFSA's conclusions, in its approval decisions.

2. The Commission should reflect on how best to improve the FVO audits carried out under Article 68 of Regulation 1107/2009. For instance, a more systematic approach to verifications, ideally covering all active substances approved by the Commission, could be envisaged. If the FVO makes findings of non-compliance with the terms of an approval decision on an active substance in one Member State, it should consider checking, without delay, whether there is similar non-compliance in other Member States.

3. The Commission should take appropriate measures to ensure that its audits are carried out with sufficient frequency and in a timely manner. In particular, if the Commission decides to withdraw or amend an approval, it should consider what measures ought to be taken in order to ensure that this will be duly reflected at Member State level without delay.

General proposal

The Commission should take appropriate measures to inform its employees active in the field concerned of the Ombudsman's findings in order to make sure that they are reflected in the Commission's practice. The Commission should update its internal guidelines accordingly.

Emily O'Reilly

European Ombudsman

16/06/2015

[1] Decision of the European Parliament of 9 March 1994 on the regulations and general conditions governing the performance of the Ombudsman's duties (94/262/ECSC, EC, Euratom), OJ 1994 L 113, p. 15.

[2] Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I, OJ 2008 L15 p. 5.

Re-submission refers to the submission of an application for approval of an active substance for which the approval was previously not granted.

[3] The current system is based on a division of responsibilities between EU and Member State levels. Under the relevant rules, the Commission is responsible for approving active substances and Member States are responsible for authorising PPPs containing these active substances.

[4] http://www.pan-europe.info/Resources/Reports/PAN Europe - 2012 - Twisting and bending the rules.pdf

[5] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJ 1991 L 230 p. 40.

The relevant parts of Article 5 read as follows:

" *1. In the light of current scientific and technical knowledge, an active substance shall be included in Annex I for an initial period not exceeding 10 years, if it may be expected that* [PPPs] *containing the active substance will fulfil the following conditions:*

(a) their residues, consequent on application consistent with good plant protection practice, do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, and the said residues, in so far as they are of toxicological or environmental significance, can be measured by methods in general use;

(b) their use, consequent on application consistent with good plant protection practice, does not have any harmful effects on human or animal health or any unacceptable influence on the environment as provided for in Article 4 (1) (b) (iv) and (v).

(...)

4. Inclusion of an active substance in Annex I may be subject to requirements such as:

— the minimum degree of purity of the active substance,

— the nature and maximum content of certain impurities,

— restrictions arising from evaluation of the information referred to in Article 6, taking account of the agricultural, plant health and environmental (including climatic) conditions in question,

— type of preparation,

— manner of use. "

[6] 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 2009 L 309 p. 1.

[7] See footnote 5 above. The relevant part of Article 4 of Directive 91/414 reads as follows:

" *1. Member States shall ensure that a* [PPP] *is not authorized unless:*

(a) its active substances are listed in Annex I and any conditions laid down therein are fulfilled, and, with regard to the following points (b), (c), (d) and (e), pursuant to the uniform principles provided for in Annex VI, unless:

(b) it is established, in the light of current scientific and technical knowledge and shown from appraisal of the dossier provided for in Annex III, that when used in accordance with Article 3 (3), and having regard to all normal conditions under which it may be used, and to the consequences of its use:

(i) it is sufficiently effective;

(ii) it has no unacceptable effect on plants or plant products;

(iii) it does not cause unnecessary suffering and pain to vertebrates to be controlled;

(iv) it has no harmful effect on human or animal health, directly or indirectly (e.g. through drinking water, food or feed) or on groundwater;

(v) it has no unacceptable influence on the environment, having particular regard to the following considerations:

— its fate and distribution in the environment, particularly contamination of water including drinking water and groundwater,

— its impact on non-target species ... "

[8] The relevant part of Article 6 reads as follows:

" *Approval may be subject to conditions and restrictions including:*

... (f) 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; ... "

[9] Section 2.2 reads as follows:

" *2.2. Submission of further information*

In principle an active substance, safener or synergist shall only be approved where a complete dossier is submitted.

In exceptional cases an active substance, safener or synergist may be approved even though

certain information is still to be submitted where:

(a) the data requirements have been amended or refined after the submission of the dossier; or

(b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision. "

[10] See Articles 83 and 84 of Regulation 1107/2009. Article 80 however provides for a number of transitional measures which mean that the Directive continued to apply even after that date to certain cases.

[11] The Ombudsman notes that the Commission stated in its reply to the complainant dated 13 July 2011 that the CDP was " *judged to be* **comparable to** *a "condition" for inclusion under Article 6(1) of Directive 91/414/EEC* " (emphasis added).

[12] See the Ombudsman's friendly solution proposal in case 406/2013/JN, paragraph 30.

[13] In the Commission's "Guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009" (SANCO/5634/2009 rev. 6.1, December 2013), it is clearly stated that "[i] *n the event that the applicant does not submit the confirmatory information then the COM will need to determine the appropriate action, which could be a withdrawal or a restriction of the approval of the active substance* " (point 4, page 3). The document further states that "[i] *f the confirmatory information is acceptable, the approval will continue either un-amended or amended to reflect any changes in conditions or restrictions resulting from the assessment of the confirmatory information. If the confirmatory information fails to address the points raised in the approval Regulation or where it appears that the criteria for approval are no longer met, then the approval of the active substance may be withdrawn or restricted* " (point 6, page 6).

[14] When making this statement in its reply to the Ombudsman's further inquiry, the Commission refers to Article 6(f) of Regulation 1107/2009. However, the Ombudsman notes that the wording of that provision is substantially different.

[15] For more detail, see paragraphs below 47-52.

[16] (i) the minimum degree of purity of the active substance, (ii) the nature and maximum content of certain impurities, (iii) restrictions arising from the evaluation of the information referred to in Article 6, taking into account the agricultural, plant health and environmental (including climatic) conditions in question, (iv) type of preparation, (v) manner of use.

[17] The Ombudsman understands that only the Court of Justice can give an authoritative interpretation of EU law. It appears that no case-law exists on this issue.

[18] The second indent of Article 4(1) reads as follows: " *The assessment of the active substance*

shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied. " Point 2 corresponds to "section 2" referred to by the Commission while point 3.6 concerns the impact on human health and point 3.7 the environment.

[19] Recital 8 provides inter alia that "[t] *he precautionary principle should be applied …* ". Article 1(4) provides that: "[t] *he provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the* [PPPs] *to be authorised in their territory* ".

[20] See Case T-257/07 *French Republic v European Commission* [2011] ECR II-5827, paragraphs 66-69 and the case-law cited therein.

[21] Case T-311/06, *FMC&Arysta v EFSA* , order of 17 June 2008, not published in the ECR, paragraphs 52-56, Case C-174/05, *Stichting Zuid-Hollandse Milieufederatie* [2006] ECR I-2443, paragraph 29; Case T-13/99 *Pfizer Animal Health SA v Council* [2002] ECR II-3305, paragraphs 166-169; Case T-158/03, *Industrias Químicas del Vallés SA v Commission* [2005] ECR II-2425, paragraph 95 (confirmed on appeal Case C-326/05P, *Industrias Químicas del Vallés SA v Commission* , 18 July 2007, paragraphs 75-76).

[22] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down the procedures in matters of food safety OJ 2002 L 31, p. 1, recitals 18, 35, 53 and Article 3(12).

[23] Bromuconazole was authorised by Commission Directive 2010/92/EU of 21 December 2010 amending Council Directive 91/414/EEC to include bromuconazole as active substance, OJ 2010 L 338, p. 44. The substance was authorised as of 1 February 2011.

[24] EFSA explains that the phrase "issue that could not be finalised" is used " *where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses … and where the issue is of such importance that it could, when finalised, become a concern …* " (see EFSA 2013 Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance oryzalin. See http://www.efsa.europa.eu/en/efsajournal/pub/3351.htm [Link], page 8).

[25] Myclobutanil was authorised by Commission Directive 2011/2/EU of 7 January 2011 amending Council Directive 91/414/EEC to include myclobutanil as active substance and amending Decision 2008/934/EC, OJ 2011 L 5. p. 7. The substance was authorised as of 1 June 2011.

[26] Hymexazol was approved by Commission Directive 2011/5/EU of 20 January 2011 amending Council Directive 91/414/EEC to include hymexazol as active substance and amending Decision 2008/934/EC, OJ 2011 L 18 p. 34. The substance was authorised as of 1 June 2011.

[27] Pyridaben was approved by Commission Directive 2010/90/EU of 7 December 2010 amending Council Directive 91/414/EEC to include pyridaben as active substance and amending Decision 2008/934/EC, OJ 2010 L 322 p. 38. The substance was approved as of 1 May 2011.

[28] Haloxyfop-P was approved by Commission Directive 2010/86/EU of 2December 2010 amending Council Directive 91/414/EEC to include haloxyfop-P as an active substance, OJ 2010 L 317 p. 36. The substance was approved as of 1 January 2011.

[29] Quinmerac was approved by Commission Directive 2010/89/EU of 6 December 2010 amending Council Directive 91/414/EEC to include quinmerac as active substance and amending Decision 2008/934/EC, OJ 2010 L 320 p. 3. The substance was approved as of 1 May 2011.

[30] Metosulam was approved by Commission Directive 2010/91/EU of 10 December 2010 amending Council Directive 91/414/EEC to include metosulam as active substance and amending Decision 2008/934/EC, OJ 2010 L 327 p. 40. The substance was approved as of 1 May 2011.

[31] It appears from the Commission's reply that the confirmatory data regarding the potential genotoxicity of one impurity have been received but are still being examined.

[32] Napropamide was approved by Commission Directive 2010/83/EU of 30 November 2010 amending Council Directive 91/414/EEC to include napropamide as active substance, OJ 2010 L 315 p. 29. The substance was approved as of 1 January 2011.

[33] One definition of this term is as follows: "Life of a chemical (such as a pesticide [Link]) or biological (such as an enzyme) pollutant [Link] after its release [Link] in the environment [Link]."

[34] Oryzalin was approved by Commission Directive 2011/27/EU of 4 March 2011 amending Council Directive 91/414/EEC to include oryzalin as active substance and amending Decision 2008/934/EC, OJ 2011 L 60 p. 12. The substance was approved as of 1 June 2011.

[35] As regards the second issue, the confirmatory information was requested only on condition that the active substance becomes classified.

[36] Malathion was approved by Commission Directive 2010/17/EU of 9 March 2010 amending Council Directive 91/414/EEC to include malathion as active substance, OJ 2010 L 60 p. 17. The substance was approved as of 1 May 2010.

[37] EFSA conclusions on myclobutanil, pages 20 and 36 (http://www.efsa.europa.eu/en/efsajournal/doc/1682.pdf [Link])

[38] EFSA conclusions on hymexazol, pages 13-14; EFSA conclusions on pyridaben, page16; EFSA conclusions on metosulam, page14, EFSA conclusions on napropamide, page 35.

[39] EFSA identified critical areas of concern in seven out of the ten cases discussed by the parties.

[40] EFSA 2013 Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance oryzalin. See http://www.efsa.europa.eu/en/efsajournal/pub/3351.htm [Link], page 8.

[41] Article 17 reads as follows:

" *Member States shall make the necessary arrangements for* [PPPs] *which have been placed on the market and for their use to be officially checked to see whether they comply with the requirements of this Directive and in particular with the requirements of the authorization and information appearing on the label.*

The Member States shall report annually before 1 August to the other Member States and the Commission on the results of the inspection measures taken in the previous year. "

[42] Article 68 reads as follows:

"Member States shall carry out official controls in order to enforce compliance with this Regulation. They shall finalise and transmit to the Commission a report on the scope and the results of these controls within six months of the end of the year to which the reports relate.

Commission experts shall carry out general and specific audits in the Member States for purposes of verifying the official controls carried out by the Member States... "

[43] http://ec.europa.eu/food/fvo/index_en.cfm [Link]

[44] There is a lack of clarity, in the complainant's comments, regarding the frequency of the FVO audit reports.

[45] The Commission acknowledged that EFSA's conclusions are not of a binding nature.

[46] This phrase appears in all ten authorisation Directives discussed by the parties.

[47] See, for instance, Commission Directive 2010/92/EU on bromuconazole, Commission Directive 2011/2/EU on myclobutanil or Commission Directive 2011/5/EU on hymexazol.

[48] France 2012, Germany 2012, Italy 2012, Latvia 2012, Czech Republic 2013, Spain 2013,

the United Kingdom 2013, Romania 2014, Slovakia 2014, Sweden 2014.

http://ec.europa.eu/food/fvo/audit_reports/index.cfm [Link]

[49] The audit team discovered that one PPP was authorised in Romania for four uses which did not comply with the Directive authorising the relevant active substance (page 6 of the 2014 audit report). In the case of the Czech Republic and Romania, the audits revealed that PPPs containing the same active substance for which the Commission authorisations had to be withdrawn in April 2013 continued to be authorised on the market (page 7 of the 2013 audit report on the Czech Republic and page 7 of the 2014 audit report on Romania).

[50] See footnote 49 above.