Odluka u predmetu 12/2013/MDC - Odluka u predmetu 12/2013/MDC o praksi Europske komisije o odobravanju i stavljanju sredstava za zaštitu bilja (pesticida) na tržište

Odluka
Slučaj 12/2013/MDC - **Otvoren** 30/01/2013 - **Odluka donesena** 18/02/2016 - **Predmetna institucija** Europska komisija (Mirno rješenje) |

Podnositelj pritužbe, tvrtka Pesticide Action Network Europe, istaknuo je da su prakse Europske komisije o odobravanju aktivnih tvari za sredstva za zaštitu bilja (pesticida) u Europskoj uniji u nekim slučajevima nesigurne i/ili nisu u skladu s relevantnim zakonodavstvom. Ombudsmanica je proučila prakse Komisije.

Ombudsmaničina analiza bavila se (i) odobrenjima Komisije aktivnih tvari te u isto vrijeme i zahtijevanju podataka koji podupiru to odobrenje, (ii) odobrenjem deset pojedinih aktivnih tvari s obzirom na rezervacije koje je iskazala Europska agencija za sigurnost hrane (EFSA), (iii) načinom na koji Komisija upotrebljava mjere ublažavanja i (iv) inspekcijama Komisije u državama članicama.

U lipnju 2015. ombudsmanica je Komisiji predložila rješenje ovog slučaja. U prijedlogu rješenja ombudsmanica je procijenila da je Komisija, čija je dužnost osigurati da aktivne tvari koje odobri nisu štetne za zdravlje ljudi ili životinja ni za okoliš, možda pretjerano popustljiva u svojoj praksi te da možda ne uzima dovoljno u obzir načelo predostrožnosti. Ombudsmanica je stoga iznijela nekoliko prijedloga s ciljem poboljšanja praksi Komisije u cilju osiguranja da su zdravlje ljudi i životinja te okoliš učinkovito zaštićeni u Europskoj uniji.

Ombudsmanica je utvrdila da je Komisija sada široko prihvatila njegove prijedloge za rješenje. Budući da provedba prijedloga nužno traje, usklađenost Komisije s tim prijedlozima može se provjeriti samo ako Komisija izvijesti ombudsmanicu o radnji koju je poduzela u svrhu usklađivanja s prijedlozima. Ombudsmanica je stoga zatražila od Komisije da joj dostavi izvješće koje pokriva određen broj posebnih točaka unutar dvije godine od njezine odluke.

The background
1. The complaint, submitted by the Pesticide Action Network Europe (PAN-Europe), concerns the approval of active substances in plant protection products (pesticides, hereinafter 'PPPs') and their placing on the market in the EU. It also relates to a special resubmission procedure envisaged by Regulation (EC) No 33/2008 [1] , 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') [2] .

2. The complainant published a report entitled " *TWISTING AND BENDING THE RULES: In 'Resubmission' all efforts are aimed to get pesticides approved* " [3] . It took 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.

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 [4] 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 [5] .

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 [6] (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. On 16 June 2015, the Ombudsman made a proposal for a solution to the Commission [7] , to which the Commission replied on 20 October 2015. The complainant sent its observations on the Commission's reply on 9 November 2015.

5. In conducting the inquiry, the Ombudsman has taken into account the arguments and opinions put forward by the parties.
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

The Ombudsman's proposal for a solution

6. In her proposal for a solution, the Ombudsman pointed out that the complainant had challenged the Commission's use of the confirmatory data procedure ('CDP') under two distinct legal regimes: (i) Directive 91/414, which was in principle applicable until 14 June 2011; and (ii) Regulation 1107/2009, which repealed and replaced that Directive [8] .

7. The Ombudsman considered that Directive 91/414 does not contain an 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 relied, 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. The Ombudsman stated that she has serious doubts whether these provisions could be regarded as constituting a sufficiently specific legal basis for the CDP applied by the Commission and pointed out that public authorities can act only on the basis and within the limits of the powers that have been conferred on them. The reference to " *requirements* " and " *conditions* " contained in Articles 5 and 6 of Directive 91/414 could 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 did not think that the Commission's discretion in defining conditions and requirements could result in such an extensive interpretation.

8. The Ombudsman therefore reached the preliminary conclusion that the Commission's reliance on CDPs was not compatible with the provisions of Directive 91/414 and that its use of CDPs appeared to constitute maladministration.

9. As for the legal regime under Regulation 1107/2009, the Ombudsman accepted that when it acts under Regulation 1107/2009, and provided it respects the restrictive conditions set out in the relevant provisions, the Commission's decision to use a CDP must be regarded as having a legal basis under Regulation 1107/2009. However, she added 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 a course of action does not endanger human health, animal health or the environment.

10. The Ombudsman considered, first, that from a reading of the relevant provisions of Regulation 1107/2009, it is clear that the legislature intended to reserve the use of the CDP to exceptional cases where the risk that the assessment will be changed is minor. Moreover, since the CDP was conceived as an exception, the conditions for its application should be interpreted restrictively. Second, the Regulation lays emphasis on the protection of human and animal health and of the environment. It gives precedence to this objective over the objective of improving plant protection. Third, the EU constitutional order also protects health and the environment. Accordingly, where the Commission considers that additional data are needed to complete the assessment, it should take these factors into account when

deciding whether to approve an active substance. Fourth, the precautionary principle which, according to Regulation 1107/2009, must be applied, is also to be regarded as a principle of good administration. It requires the Commission to ensure that it does not approve active substances in cases where public health or the environment could be endangered.

11. 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 took the view that the CDP needs to be applied with particular caution and restraint. She therefore made the following proposal for a solution with regard to the CDP:

" *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. "

12. In its reply to the Ombudsman's proposal, the **Commission** stated that, since the entry into force of Regulation 1107/2009, the situations where requests for confirmatory information may be made are limited to those listed in Article 6(f) and Annex II of the Regulation. The Commission confirmed that it would request confirmatory information strictly in line with the provisions of Regulation 1107/2009. By way of example, it explained that confirmatory information may be requested when, due to new scientific knowledge in the area of risk assessment, a new guidance document becomes available in the course of the evaluation. In that case, the applicant is not in a position to submit the studies performed according to the guidance document at the time of the application. If relevant, the approval regulation may provide for the submission of such information as confirmatory information at a later stage. It stated that the submission of confirmatory information should not concern data requirements which existed at the time of the submission of the application in relation to the assessment of risks to health and for which adequate guidance documents were available.

13. The Commission added that approval may be granted only to substances which are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment. It stated that confirmatory information may also be required in order to increase confidence in the decision to approve the substance. The Commission stated that it would continue to take the utmost care so that the assessment of the substance and the decision on approvals or renewals take duly into account the consequences for human and animal health as well as the environment and that these decisions are underpinned by the

precautionary principle as provided for in Article 1(4) of Regulation 1107/2009.

14. The Commission stated that the extent to which confirmatory information would be requested would depend on whether new requirements are established as a result of new scientific and technical knowledge.

15. The Commission agreed with the Ombudsman that priority should be given to requesting and assessing any relevant missing information before taking a decision on approval. It stated that this is also envisaged by the legislation and is embodied in the procedure for the evaluation of applications for approvals.

16. The Commission explained that applicants wishing to apply for the approval of a substance must provide an application in accordance with Article 8 of Regulation 1107/2009 and the data requirements laid down in Regulation (EU) No 283/2013 [9] and Regulation (EU) No 284/2013 [10] . In accordance with Article 9 of Regulation 1107/2009, the Rapporteur Member State checks whether the application contains all the necessary elements. If, in the course of the evaluation, the Member States or EFSA need additional information, they may request such information from the applicant within a certain period of time. This additional information is to be evaluated with the rest of the application by the Rapporteur Member State and EFSA. The additional information cannot concern new requirements which did not exist at the time of the application. The Commission concluded that the procedures envisaged by Regulation 1107/2009 provide for a strict framework for the submission of data, for its assessment by Member States and EFSA and for the submission of confirmatory information. The Commission stated that it is committed to comply with this framework.

17. The **complainant** contended that the Commission's reply to the Ombudsman's first proposal is misleading. The complainant stated that, whereas the Ombudsman clearly proposes a "restrictive use" of the procedure, " *the Commission is not clear on agreeing to a 'restrictive use'* ". According to the complainant, the Commission claimed that it will request confirmatory data " *strictly in line* " with the provisions of Regulation 1107/2009. However, the complainant pointed out that the Commission has constantly claimed that it follows the rule, whereas in the complainant's view, the Commission breaches the rules " *as a standard procedure* ".

18. The complainant argued that it is clear from the Commission's reply that the institution does not agree with the proposal and that it will continue to carry out the illegal practices criticised by the complainant and some EU Member States. A sample of 25 recent approval decisions of synthetic pesticides (taken between 20 November 2013 and 27 July 2015) examined by the complainant shows that the Commission is still using the CDP as a standard procedure since, in 22 of these cases, the CDP procedure was used. According to the complainant, " *this is not restrictive at all* ".

19. The complainant also argued that the Commission's assertion that paragraph 2.2 [11] of Annex II of Regulation 1107/2009 is respected is not correct . It stated that in none of the 22 cases (i) did EFSA or the Commission argue that the data requirements had been amended or refined, and (ii) is it possible to argue that the information is " *confirmatory in nature* ",

since EFSA demonstrated (high) risks and, often, unacceptable risks or missing information that could include risks. The complainant stated that it is solely evidence of " *the absence of risks* [that] *could be 'confirmed', but such ... evidence is not presented by the applicant . There is simply no justification for the standard use of the 'confirmatory information' procedure.* "

20. Moreover, according to the complainant, the sample of decisions it examined also shows clearly that the Commission's decisions are not in line with Article 4(5) [12] of Regulation 1107/2009. The complainant stated that at least one " *safe representative use* " needs to be demonstrated by the applicant for the Commission to be able to approve a pesticide. However, in the sample of decisions it examined, the complainant " *could easily find examples of ... 'issues of critical areas of concern'* " identified by EFSA [13] . It gave seven such examples where " *the conclusion is that the 'one safe representative use' is not demonstrated at all and - as EFSA writes - will not allow* [the] *Commission to conclude that the substance will not have any harmful effect on humans or any unacceptable influence on the environment* ." Nevertheless, in all these cases, the Commission concluded that the requirements of Article 4(2) are met. The complainant added that " *the approvals are therefore unlawful and since it is done intentionally likely fraudulent* ". According to the complainant, since it 'interprets' the Ombudsman's proposal in this manner, it is clear that the Commission has no intention of changing its behaviour and will continue to carry out its illegal practices.

21. The complainant contended that the Commission's statement, that it agrees with the Ombudsman that priority should be given to requesting and assessing missing information before taking a decision, is contradicted by its current practices. It stated that " *the very crucial information on what 'batches'* **[14]** *are tested by the applicant (the applicant could use less toxic batches or less polluted batches of the pesticide for doing animal testing) is allowed to be delivered by the applicant in future after the approval as 'confirmatory information'* ." Since the regulatory procedure takes several years, the Commission could easily request this information before taking a decision, and it could wait for the information to be sent to it before taking a decision. If it turns out that the batches are not compliant, citizens and the environment are put at risk and may possibly be harmed. The complainant stated that in its reply, the Commission gives no indication that from now on, it will await this information before taking a decision.

The Ombudsman's assessment after the proposal for a solution

22. The Ombudsman points out that the Commission submitted its reply to the proposal for a solution on 20 October 2015 and that it used the future tense when declaring that it " *will request confirmatory information strictly in line with the provisions* " of Regulation 1107/2009. The examples given by the complainant of the approval decisions published by the Commission in which the CDP was used were based on decisions taken between 20 November 2013 and 27 July 2015. The Ombudsman understands that when the Commission replied to the three proposals which she made concerning the CDP to the effect that it agreed with them, the Commission made a serious commitment to implement them. She trusts that the Commission will therefore take the necessary steps to give full effect to her

proposals and not to repeat the shortcomings mentioned by the complainant in paragraphs 18 to 21. Moreover, the Ombudsman reminds the Commission of her finding in paragraph 37 of her proposal that " *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... 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.* "

23. The Ombudsman expects that, from now on, the Commission will use the CDP in a more restrictive manner. Thus, she trusts that if the complainant were to repeat the exercise it carried out when examining a sample of approved substances, in a few years' time, it will note a significant decrease in the use of the CDP. In her conclusions, the Ombudsman will ask the Commission to submit a report which, among other things, shows that the CDP is being used restrictively, and strictly in line with the applicable legislation.
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

The Ombudsman's proposal for a solution

24. The Ombudsman inquired into the complainant's argument that, when evaluating ten 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. The complainant contended that in these cases, although EFSA identified data gaps or even risks, the ten active substances were approved by the Commission. The latter disagreed with the complainant and provided detailed explanations for its position with regard to each of the ten substances identified as problematic by the complainant.

25. The Ombudsman considered that, since the complainant claimed that the Commission should reassess its evaluation of the ten active substances concerned, the main issue was not so much the allegedly " *misleading* " character of the review reports and decisions but, rather, whether they were substantively correct when considered in the light of EFSA's conclusions. She therefore focused her analysis on that issue.

26. The Ombudsman pointed out 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.

27. The Ombudsman noted 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 still

granted approval. It did so even though it appeared to lack 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. The Ombudsman considered that 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. She stated that, taking into account the possible consequences for human health, animal health and the environment, such inadequacies would be particularly worrying. The Ombudsman considered 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.

28. The Ombudsman observed that, in certain cases, EFSA identified, in addition to data gaps and simple concerns, 'critical areas of concern'. She considered that, taking into account the definition of that term (which basically refers to situations in which harmful effects cannot be ruled out completely [15]), it is difficult to 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. The Ombudsman considered that, at the very least, a satisfactory explanation in this regard had not been provided by the Commission.

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

30. The Ombudsman considered that her findings were of particular concern because all ten substances were approved many years ago and it appeared that in most of these cases, in spite of the passage of time, the Commission had 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 are not expected to have any harmful effects for human health, animal health, underground water or the environment, the Ombudsman stated that she could understand the complainant's impression that the Commission's review reports and approval decisions are " *misleading* " and inaccurate.

31. The Ombudsman therefore made the following proposal for a solution:

" *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. "

32. In its reply to the Ombudsman's proposal, the **Commission** included an updated table on the status of the assessment of the confirmatory information for the ten substances at issue. The table showed that all confirmatory data had been provided for all ten substances. Their assessment was either finalised or was in its final stages at Member State level, within EFSA or the Commission. The Commission stated that it is fully committed to conclude the assessments and, where appropriate, amend the conditions of approval.

33. As for the review of the approval of substances, the Commission stated that, since all confirmatory information was received and their evaluation was progressing, it believed that all assessments can be concluded. It added that [a] *ctually the review of confirmatory information leads to the re-assessment of the approval of the substance and may trigger a change in the approval conditions. With the involvement of Member States and EFSA, the assessment of confirmatory information involves the same level of scrutiny as would a review of the approval.* "

34. As for other substances for which confirmatory information was requested, the Commission stated that it " *can only confirm that a systematic tracking and follow-up of all confirmatory information requests are performed. Member States and EFSA are fully involved. The review of confirmatory information constitutes an important aspect of the work of the unit in the Commission in charge of the plant protection products legislation, the Member States and EFSA* ." It stated that this is confirmed by the agenda and minutes of meetings of the Standing Committee on Plants, Animals, Food and Feed – plant protection products section. The Commission pointed out that, as it had explained in its reply to the Ombudsman dated 6 October 2014, the evaluation of the confirmatory information follows a detailed procedure, laid down in an *ad hoc* Guidance document, agreed upon by all Member States. It added that "[t] *he confirmatory information is assessed under the same high standards as any other data in the original dossier* ."

35. The **complainant** referred to the term "without delay" used in the Ombudsman's proposal and stated that it is not convinced that the Commission is working without delay "[g] *iven the fact that for most of these pesticides* ([the complainant] *took a sample of 10 out of a total of 88 in Resubmission) it was known by the Commission already about 10 years ago (see for instance the Draft Assessment Report Bromuconazole 2006) that information was lacking* ." According to the complainant, a decision on the confirmatory information has not been taken in the majority of the cases (six out of ten). It stated that "[f] *or the 'virtual' non-approval decision - the decision for non-approval while the pesticide could remain on the market - (example Bromuconazole 2008) the very reason for non-approval was the lack of information. Finally in 2010 (Bromuconazole) confirmatory information was requested with a deadline in 2013 which is still not decided upon end 2015* ." According to the complainant, this means that " *people and the environment have not been protected for about 10 years for dozens of pesticides and possibly put at harm, for no other reason than serving the industry's interests* ".

36. The complainant considered untrue the Commission's contention that the assessment of

confirmatory information involves " *the same level of scrutiny* " as would a review of the approval. The complainant argued that for every pesticide involved in the resubmission procedure, the Commission mandated EFSA to provide an opinion on the scientific basis of the information. It stated that " *EFSA discovered at that time a lot of high risks and data gaps... For the confirmatory information there was no mandate for an EFSA opinion and no opinion published ... and therefore no evaluation of the scientific basis of the confirmatory information submitted by the applicant* ."

37. The complainant contended that an independent peer review by EFSA is the most important element of the risk assessment procedure. However, this element is lacking. Therefore, the Commission does not apply the same level of scrutiny. It added that the " *Commission is again redefining the Ombudsman's proposal in an unacceptable way* ".

The Ombudsman's assessment after the proposal for a solution

38. The Ombudsman appreciates the complainant's vigilance. However, she believes that there are sufficient reasons for her to be generally satisfied with the Commission's reply to her proposals regarding the assessment of the ten substances at issue.

39. First, the Ombudsman takes seriously the Commission's statement that " *it is fully committed to conclude these assessments and, where appropriate, amend the conditions of approval* ". The Ombudsman reminds the Commission, however, that she proposed that it should act 'without delay' and exhorts it to do so. The Ombudsman also reminds the Commission that it should be extremely cautious when making these assessments in view of the possible consequences which inadequate assessments may have on human health, animal health and the environment. The Ombudsman notes from the updated table (drawn up by the Commission in its reply to the Ombudsman's proposal) on the status of the assessment of the confirmatory information for the ten substances at issue that, by the time the Commission submitted its reply to the Ombudsman's proposal, the assessments of three active substances [16] were concluded and the relative review reports were amended. Revised Review Reports relating to two other active substances [17] were to be discussed at the Standing Committee on Plants, Animals, Food and Feed in December 2015. With regard to one active substance [18] , the Commission intended to present its views on the outcome of the assessment to the Standing Committee on Plants, Animals, Food and Feed in October 2015 and with regard to another substance [19] , the Commission was in the process of preparing an amendment to the approval regulation, restricting the uses of the substance. Finally, the assessment of the confirmatory data submitted in relation to three active substances [20] had not been finalised. In her conclusions, the Ombudsman will ask the Commission to submit a report which, among other things, shows, with regard to those active substances out of the ten examined in this case in relation to which the confirmatory data still needs to be assessed, that the Commission completed and updated that assessment without delay.

40. Second, the Ombudsman notes that the Commission's *ad hoc* Guidance document

concerning the evaluation of confirmatory information states (under the heading "Procedures for assessment of confirmatory information") that it " *would be useful if EFSA briefly indicates the main open points and its overall view whether an EFSA peer review might be necessary when sending the completed Reporting Table to* [the Commission] *and* [the Rapporteur Member State]... *If the* [Rapporteur Member State or the Designated Member State] *or EFSA raises concerns or differences of opinion, then* [the Commission] *will determine whether to instigate a formal EFSA peer review* " [21] . The updated table mentioned above shows that EFSA was mandated to proceed to a peer review of the confirmatory data with regard to three of the ten active substances. Since in her proposal, the Ombudsman did not state that EFSA should be asked to proceed to a peer review every time confirmatory data is requested, the Ombudsman cannot agree with the complainant's statement that the " *Commission is again redefining the Ombudsman's proposal in an unacceptable way* ". Nonetheless, the Ombudsman invites the Commission to consider whether, from now on, all confirmatory information should systematically be subject to an EFSA peer review and whether the Guidance document should be amended accordingly. This point will be mentioned in the Ombudsman's conclusions.
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

The Ombudsman's proposal for a solution

41. The Ombudsman noted that the third allegation referred to two main issues: (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.

42. As regards **the alleged transfer of responsibility** , the Ombudsman was generally satisfied with the Commission's explanations concerning the fact that 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 stated that she understood 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 correctly reflects the principles of subsidiarity and proportionality.

43. On the other hand, the Ombudsman also understood the complainant's argument 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. The Ombudsman added that, 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 would be implemented effectively at Member State level [22] .

44. On the basis of the arguments and evidence provided by the parties, the Ombudsman considered that the Commission may sometimes be too lenient when it approves active substances for which EFSA indicates data gaps or even risks, and at the same time leaves the exact definition of mitigation measures to Member States. The Ombudsman observed that 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* " [23] 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* " [24] . These formulations are very open-ended and the Ombudsman had doubts whether they can be legally described as *requiring* mitigation measures at all. She considered this 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 therefore invited the Commission to reconsider its current approach.

45. As regards **the audits** carried out by the Commission, the Ombudsman noted 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.* " The Ombudsman considered that 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.

46. The Ombudsman analysed a sample of ten audit reports published on the FVO (Food and Veterinary Office) website concerning audits carried out in the period 2012-2014 [25] . 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. The Ombudsman concluded that, contrary to the complainant's allegations, these audit reports confirmed that the FVO 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.

47. However, although the Ombudsman did not doubt the Commission's explanations and assurances, she was 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 Ombudsman observed that 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 suggested that the FVO audits also cover, to an extent which was however not very clear, the examination of certain active substances or PPPs which includes their authorisation and use within that Member State. However, it seemed 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 appeared, 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.

48. The Ombudsman fully agreed 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. She stated that 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.

49. The Ombudsman examined the FVO reports referred to by the Commission. The Ombudsman noted that in some cases in the sample, the FVO found that a Member State had failed to comply with certain restrictions imposed at EU level [26] . However, it seemed that the number of PPPs examined by the FVO audit team was rather limited and thus there might have been 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 [27] . The Ombudsman took the view that a more systematic approach to such issues is thus warranted.

50. The Ombudsman therefore made the following proposal for a solution, with the aim of ensuring that the Commission sufficiently and adequately verifies compliance with the terms of its approvals of use of active substances:

" *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. "

51. In so far as the **risk mitigation measures** are concerned, the **Commission** agreed with the Ombudsman that " *in the setting of risk management measures in the Regulation approving a substance, attention should be paid to the proposed risk mitigation measures where these are included in the conclusions of EFSA.* " It stated that one should distinguish the conclusions of EFSA from the Regulation on the approval or renewal of the substance. According to the Commission, "[t] *here is a clear distinction of the responsibility of the two bodies, EFSA being responsible for the risk assessment and the Commission and the Member States for risk management. This is in conformity with Regulation (EC) No 178/2002 on general principles and requirements of food law* **[28]** *, which has established EFSA.* "

52. The Commission explained that risk mitigation measures laid down in the approval regulation may therefore differ from those reflected in EFSA's conclusions. " *The reason is that risk mitigation measures in the approval regulation are only those which are relevant for any product containing the substances used in EU. They cannot include the risk mitigation measures which are only specific for some products authorised at national level. In addition, risk mitigation measures indicated in EFSA conclusions are standardised risk mitigation measures, which are not directly applicable, as such conclusions are scientific opinions without legal status. They need to be transposed into specific measures at national level to be suited to the national conditions.* "

53. The Commission contended that responsibility for setting risk mitigation measures for products and for checking them lies with Member States in line with the Regulations approving the active substances. These measures are decided at national or zonal level, because the appropriate measure to mitigate risk varies according to specific uses in Member States and also according to different climatic, geological and environmental conditions. The Commission stated that this is in accordance with the principle of subsidiarity.

54. As for the **FVO audits** , the Commission repeated that these audits verify whether the systems put in place by Member State authorities for granting authorisations comply with the requirements of Regulation 1107/2009. The FVO audits also verify that Member State authorities check whether plant protection products are used in accordance with the authorisations and the mitigation measures imposed by Member States.

55. The Commission stated that the FVO has recently published an overview report on the last audit series on pesticide controls, in which systematic problems in the national authorisation systems for plant protection products are identified and highlighted. The deficiencies include the delays incurred by Member States in implementing Commission regulations approving active substances and laying down appropriate mitigation measures. The Commission explained that the deficiencies identified by the FVO are followed up systematically through a number of measures, including general review audits in the

Member States concerned. The conclusions of the overview report were presented and discussed with all Member States. The Commission stated that where appropriate, the Commission may initiate infringement procedures against Member States. Furthermore, a new audit series is planned for 2016, which will specifically focus on authorisations of plant protection products in Member States. In preparing for this audit series, a questionnaire was sent to all Member States. The Commission stated that the " *FVO therefore follows a risk-based approach to assess national authorisation systems, and has stepped up its activity in this area.* "

56. The Commission stressed that " *it is technically impossible and not appropriate to assess all national authorisations for all approved active substances, taking into account that there are many thousands of authorisations granted (and permanently renewed and updated) in the Member States* ".

57. The Commission argued that the FVO audits on pesticide controls have a larger scope than the assessment of mitigation measures in the national authorisations, and have provided a comprehensive on-the-spot evaluation of checks on the marketing and use of pesticides carried out by Member States. The Commission added that " *the implementation of environmental requirements of EU legislation for the sustainable use of plant protection products, as specified in Directive 2009/128/EC7, was also checked* ".

58. The Commission agreed with the Ombudsman that it is of utmost importance to ensure that its audits are carried out with sufficient frequency and in a timely manner. It stated that this is why the FVO has adopted an adequate and systematic approach to assess the national authorisation systems for plant protection products.

59. In so far as the **risk mitigation measures** are concerned, the **complainant** contended that the Ombudsman's proposal is clear in stating that the Commission should review the approach to risk mitigation measures. On the other hand, the Commission's position is not clear. It simply states that " *attention should be paid* " to risk mitigation measures and that it is the national authorities' responsibility to put mitigation measures in place. According to the complainant, this means that the Commission is not going to review its approach.

60. The complainant contended that the arguments put forward by the Commission " *tell half the truth. The 'fine-tuning' of risk mitigation measures on national level is indeed needed but without any (minimum) rules provided by Commission, Member States lack guidance. Therefore a minimum-level of mitigation should be included on EU level by the Commission. If EFSA is saying a non-spraying zone of 20 metres is necessary, the Commission should include this 20 metre non-spraying zone and add 'or mitigation measures with a similar emission reduction'.* " According to the complainant, by not reviewing its approach and by not including minimum mitigation measures, the Commission does not guarantee that the use of the active substances is without harmful effects for humans or without unacceptable effects for the environment.

61. With regard to the **FVO audits** , the complainant observed that the Commission acknowledged that the FVO finds 'deficiencies' also in the implementation of mitigation measures. It stated that this is in line with the point it had made in earlier observations. It

added that there is no guarantee that people and the environment will be protected if the Commission does not include any (minimum) mitigation measures in its decisions.

62. The complainant also considered that the Commission failed to comment on or agree with parts of points 2 (where it was suggested that the Commission should consider checking whether there is similar non-compliance in other Member States) and 3 (concerning measures to ensure that withdrawals of approvals be reflected without delay at Member State level) of the Ombudsman's proposal.

The Ombudsman's assessment after the proposal for a solution

63. The Ombudsman considers that the Commission has not explained very clearly whether it accepts her first proposal concerning mitigation measures and audits in full. However, the Ombudsman is ready to accept that, by stating that " *in the setting of risk management measures in the Regulation approving a substance* **, attention should be paid** *to the proposed risk mitigation measures where these are included in the conclusions of EFSA* ", the Commission agrees that it will review its approach to the definition of mitigation measures and will include further requirements, which reflect EFSA's conclusions, in its approval decisions. As for the Commission's argument concerning the principle of subsidiarity, the Ombudsman has already stated (in her proposal for a solution) that she understands that the exact definition of mitigation measures should be left to national authorities. However, the Ombudsman considers that this does not rule out that, in its approval decisions, the Commission lay down minimum risk mitigation measures when such measures are proposed by EFSA.

64. As for her second proposal, the Ombudsman welcomes the Commission's statement that the FVO has stepped up its activity in the area of the assessment of national authorisation systems and that a new audit series planned for 2016 will specifically focus on authorisations of plant protection products in Member States. The Ombudsman also welcomes the fact that the deficiencies identified by the FVO in its overview reports are followed up systematically through a number of measures, including general review audits in the Member States concerned.

65. The Ombudsman understands the Commission's position that it is technically impossible to assess all national authorisations for all approved active substances because of the sheer number of authorisations granted. On the other hand, the Commission did not comment on the Ombudsman's suggestion, contained in her second proposal that "[i] *f 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* ." The fact that, as the Commission stated, the conclusions of the recent overview report were presented and discussed with all Member States is indeed a step in the right direction. However, the Ombudsman's proposal goes beyond that. In the event of a finding of non-compliance in one Member State, it should not be too difficult for the Commission to audit the other Member States on that matter and alert the other

Member States to the FVO's findings, asking them to reply to a number of questions aimed at finding out whether the approval decision in question is being complied with.

66. With regard to the Ombudsman's third proposal, although the Ombudsman is pleased to note that the Commission agrees that it is of utmost importance to ensure that its audits are carried out with sufficient frequency and in a timely manner, she notes that the Commission failed to comment on her proposal that " *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.* " Again, it should not be difficult to put in place an alert system whereby once an approval is withdrawn or amended, all Member States are informed thereof and are asked to report on the action they have taken in that regard.

67. In her conclusions, the Ombudsman will ask the Commission to submit a report which, among other things, shows how the Commission has implemented her proposals relating to mitigation measures and audits.
The Ombudsman's general proposal
68. The Ombudsman made the following 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.* "

69. The **Commission** confirmed that it would inform its employees orally and in writing of the Ombudsman's findings. It stated that specific instructions would be provided to the staff " *to remind them of the principles governing the approval of substances including the setting of risk management measures and the requirement of confirmatory information in the regulations approving and renewing approvals of substances.* "

The Ombudsman's assessment after the general proposal

70. The Ombudsman welcomes the Commission's undertaking to inform its employees orally and in writing of the Ombudsman's findings and to provide them with specific instructions. She therefore considers that the Commission has accepted her general proposal.
Concluding remarks

The complainant's concluding remarks

71. In its concluding remarks, the **complainant** considered that the Commission did not agree with the proposal on several crucial points, that it redefined the Ombudsman's text and that it misled the Ombudsman. Moreover, it stated that the Commission should be asked to give a simple " *yes or no* " answer to the question whether it agrees with the proposed solution. If the Commission fully agrees with the solution, it proposed that the

Ombudsman then ask the Commission to draft a report within two years of her decision showing that: " *(i) the number of decisions with confirmatory information has substantially gone down compared to the current approach, (ii) an official EFSA opinion on the confirmatory data is published, (iii) in case of "issues of critical concern" (EFSA opinion), an approval will not be given, (iv) (minimum) mitigation measures are included in the decisions,(v) special audits are run by FVO on the level of national implementation of the mitigation measures.* "

The Ombudsman's assessment

72. The Ombudsman considers that although the Commission has largely accepted her proposals, its compliance with them can be verified only if, as the complainant suggested, the Commission reports to the Ombudsman on the action it has taken in order to comply with the proposals within two years of this decision .

73. The Commission's report should, in particular, (i) show that the confirmatory data procedure is used restrictively, and strictly in line with the applicable legislation; (ii) show, with regard to those active substances out of the ten examined in this case in relation to which the confirmatory data still needs to be assessed, that the Commission completed and updated that assessment without delay; (iii) show that the Commission has considered whether all confirmatory data should systematically be subject to an EFSA peer review (and whether the *ad hoc* Guidance document concerning the evaluation of confirmatory data should be amended accordingly). In the event that the Commission decides that EFSA peer reviews concerning confirmatory data need not be systematic, the report should give reasons for that position; (iv) show that the Commission has reviewed its approach to the definition of mitigation measures and that its approval decisions include further requirements which reflect EFSA's conclusions; (v) show how the Commission has implemented the Ombudsman's proposal that, in the event that the FVO makes findings of non-compliance with the terms of an approval decision on an active substance in one Member State, it checks, without delay, whether there is similar non-compliance in other Member States; and (vi) show how the Commission has implemented the Ombudsman's proposal that, if the Commission decides to withdraw or amend an approval, it ensures that this is duly reflected at Member State level without delay .
Conclusion
On the basis of the inquiry into this complaint, the Ombudsman closes it with the following conclusion:

The Commission has largely accepted the Ombudsman's proposals for a solution concerning the confirmatory data procedure, the assessment of the ten substances and the mitigation measures and audits. However, the Commission's compliance with the Ombudsman's proposals can be fully verified only if the Commission reports to the Ombudsman on the action it has taken in order to comply with the proposals. Since the implementation of the agreed measures necessarily takes time, the Ombudsman requests the Commission to submit to her a report covering the points listed in paragraph 73 of this decision within two years of her decision.

The complainant and the Commission will be informed of this decision.

Emily O'Reilly

Strasbourg, 18/02/2016

[1] 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.

[2] 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.

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

[4] 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. "

[5] 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.

[6] See footnote 4 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 ... "

[7] For further information on the background to the complaint, the parties' arguments and the Ombudsman's inquiry, please refer to the full text of the Ombudsman's proposal available at: http://www.ombudsman.europa.eu/en/cases/correspondence.faces/en/63623/html.bookmark

[8] 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.

[9] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, OJ 2013 L 93, p. 1.

[10] Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, OJ 2013 L 93, p. 85.

[11] Paragraph 2.2 of Annex II of Regulation 1107/2009 provides as follows: " *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. "

[12] Article 4(5) of Regulation 1107/2009 stipulates that "[f] *or approval of an active substance, paragraphs 1, 2 and 3 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance* ."

[13] In its 2014 Conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor, EFSA stated 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 in line with the Uniform Principles in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011, 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.*

An issue is also listed as a critical area of concern 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 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.*

An issue is also listed as a critical area of concern where in the light of current scientific and technical knowledge using guidance documents available at the time of application the active substance **is not expected to meet the approval criteria provided for in Article 4** *of the Regulation* " (emphasis added by the complainant).

[14] The complainant explained that " *product streams -batches- from production plants differ always in quality, like on the percentage of the active substance of the pesticide, the level of impurities, the number and level of metabolites, etc.. It is therefore crucial for the evaluation of the toxicity of the pesticide that the pesticide quality sprayed on the fields is the same as the pesticide quality tested in animal testing* ."

[15] See footnote 13 above.

[16] Hymexazol, metosulam and oryzalin.

[17] Bromuconazole and myclobutanil.

[18] Quinmerac.

[19] Haloxyfop-p.

[20] Pyridaben, napropamide and malathion.

[21] http://ec.europa.eu/food/plant/pesticides/approval_active_substances/docs/gd_confirmatory-data_rev6- , pp 5 and 6.

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

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

[24] 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.

[25] 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

[26] 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). The audits also 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 in the Czech Republic and Romania (page 7 of the 2013 audit report on the Czech Republic and page 7 of the 2014 audit report on Romania).

[27] See footnote 21 above.

[28] 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 procedures in matters of food safety, OJ 2002 L 31, p.1.