

Brussels, 2-01-2020

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To: The Ombudsman

Concerning: Your letter of 15-11-2019, Complaints 1570/2018/JF and 1973/2018/JF, and your request for comments.

Dear Ms. Ombudsman, with this letter we respectfully comment to the “additional material obtained in the course of this inquiry”, the annexes to your November 15 letter (Complaints 1570/2018/JF and 1973/2018/JF).

We will follow the questions (in red below) you posed to Commission and react to the answers given by Commission as well as by EFSA.

1) Provide yearly figures showing that the Commission uses the confirmatory data procedure in a limited number of cases only and that the use of this procedure has decreased over time.

PAN Europe reaction:

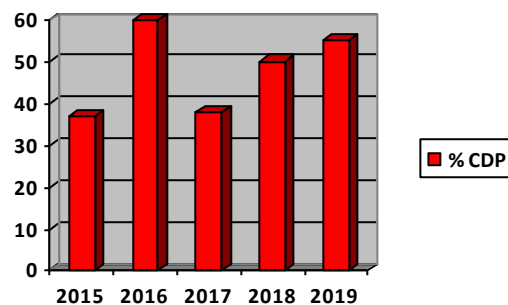
The Table provided by Commission clearly shows that confirmatory data (CDP) were not requested in a limited number of cases. The number of cases of CDP in approval decisions taken ranges from 37% - 60% which cannot be qualified limited at all.

In some years CDP is requested in the majority of the decisions even (see Figure below).

The use didn't decrease over time either, the percentage of approval decisions with confirmatory data (CDP), went from,

- 37% in 2015, to
- 60% in 2016, to
- 38% in 2017, to
- 50% in 2018, and up to
- 55% in 2019.

Average in the 5 years: 48%



This demonstrates that we were right over and over again in claiming that Commission did not reduce (or change) its confirmatory data derogation regime and bring it in line with Reg. 1107/2009 as it promised to do to the Ombudsman in 2016. In 2019 the percentage of 55% even exceeded the average percentage of CDP of the last 5 years of 48%, with a three-year increase from 37 -> 50 -> 55%. The Ombudsman unfortunately was wrong to trust Commission in her 2016-decision saying that “in a few years' time, it will note a significant decrease in the use of the CDP”.

2) Provide the inquiry team with the Commission's files concerning the approval process (as provided for in Regulation 1107/2009) for the above five substances (flazasulfuron, isofetamid, picolinafen, benzovindiflupyr and epoxiconazole).

PAN reaction: since these are documents already in the public domain, providing us with a USD with password would not have been necessary.

3) (Regarding those substances out of the five for which the Commission requested confirmatory data), provide evidence showing that it approved these substances and requested confirmatory data in line with the legal requirements (Article 6f of Regulation 1107/2009 and Article 2.2 of Annex II of Regulation 1107/2009).

PAN comment: Commission tries to construct a legal way out for its CDP regime in the two most-used categories of CDP, but there is no way out, almost all CDP's are illegal.

We will comment the three main categories for CDP, as indicated in Commission's reply (“Reply to Question 1 and 3”).

1. Composition of the active substance, including metabolites, impurities, etc.
Commission now claims that this is “*new technical knowledge*” according to Art. 6.f. But it isn't obviously.
Art. 1.4 of the data requirements, Reg. 283/2013 provides that industry has to submit all information on production and composition, please have a look at the following chapters,
1.9. Specification of purity of the active substance in g/kg
1.10. Identity and content of additives (such as stabilisers) and impurities
1.10.1. Additives
1.10.2. Significant impurities
1.10.3. Relevant impurities
1.11. Analytical profile of batches,
and have to report on the toxicity of all components as well (Annex II, 1.11): “*The information on the active substance, taken together with the information concerning one or more plant protection products containing the active substance and together, if appropriate, with the information concerning safeners and synergists and other components of the plant protection product, shall be sufficient to:*
(a) permit an assessment of the risks for humans, associated with handling and use of plant protection products containing the active substance;
(b) permit an assessment of the risks for human and animal health, arising from residues of the active substance and its metabolites, impurities, breakdown and reaction products remaining in water, air, food and feed”.

All this information needs to be presented at the time of application, three years before an approval decision can be taken. And for applicants failing to do so, the Rapporteur Member State (RMS) dealing with the dossier, should decide to non-admissibility and stop the procedure. Additionally, Commission should not create a second chance of handing over this information after the approval decision, as she does repeatedly, but decide to a non-approval.

Qualifying this information as “*new technical knowledge*” is a clear misinterpretation of the rules. It is technical knowledge but not new since the information should have been provided years ago in the application dossier.

Moreover, the phrase “*submission of further confirmatory information..... as a result of new scientific and technical knowledge*” is about new scientific and technical knowledge published that trigger CDP. Like a new scientific article that shows for instance that the substance is very harmful for wild bees while the dossier is empty on wild bees. In that case Commission can request CDP (testing outcome) from the applicant on wild bees. Here, in the case of the composition of the material, no “*new technical knowledge*” is published that is triggering a CDP that requires Commission **as a result** to ask for more information.

2. Confirmatory data requirements related to the **effect of water treatment processes**. Commission argues here that this CDP is requested due to “*new scientific knowledge*” according to Art. 6.f. Again, this is a gross misinterpretation of the rules. The line in Art. 6.f is “*submission of further confirmatory information..... as a result of new scientific and technical knowledge*”. And thus can information only be requested as a result of new scientific and technical knowledge that is published at the moment of the evaluation of the dossier. But there is no new technical knowledge published. We know for many years that the evaluation of water treatment is needed as part of the data requirements Reg. 283/2013 (Section 8.8). And CDP cannot be triggered.

The second argument used by Commission is that de Guidance is not drafted yet by EFSA, “*the Commission’s services clarified that the applicants could not provide the missing data until EFSA issues a guidance document*”. This is misleading since the data requirements are available since 2013, and there is an obligation to submit the studies on this topic (Reg. 283/2013, Section 8.8). Rightly, the SANTE-EFSA bilateral 2018 contradicts the opinion of Commission to the Ombudsman. It states: “*On this matter it was noted that applicants often use the unavailability of GD as an excuse to disregard certain data requirements. It was agreed that waiving of data requirements should always be substantiated with valid scientific justification and the **unavailability of test guidelines alone cannot be considered acceptable***”. Commission is contradicting itself, there is no excuse for the failure to deliver studies based on the data requirements in case the Guidance is still missing. And the CDP illegal.

On top of this, EFSA stated in the ‘bilateral’ that “*applicants can adress it (the data requirement for water treatment) using available information*”. There is simply no justification for the failure of applicants to deliver data.

In conclusion, Commission violates Art. 6.f as a standard procedure on this topic for two false reasons.

3. Issues identified by EFSA only at a late stage of the evaluation process. Commission mentions as an example when new information is published on classification (by ECHA) during EFSA's evaluation.

Indeed, in case of classification, the outcome of a peer-review process at ECHA, at the time of the evaluation, one can say that this is "*new scientific knowledge*" that can trigger CDP. This is a case where CDP is applicable. We note however, that we are aware of little, if any, examples of this third category. So it is a minor category.

We further note that the three categories of CDP suggested by Commission do not represent the hundreds of CDP's requested by Commission very well. Commission mentions 'transparency' as something they like to achieve, but the entire CDP regime of Commission remains in the dark. Some years ago Commission asked CDP's in case of high risks of birds, bees, aquatic organisms, etc; later they stopped doing so and included lines like "*shall pay particular attention*" in its decisions. So there is also an inconsistency over the years.

Additionally, there are CDP's on groundwater and metabolites (health effects via drinking water), on endocrine disruption, on air pollution, etc., etc., a few hundreds of CDP's in total in the last 10 years. We simply do not have the resources to give a clear overview.

Commission should have been more transparent on this major operation to bypass the law. A move that was silently introduced behind closed doors with MS and a legal change that directly concerns the health of its citizens and the environment. It is this type of "flexibility" and lack of scrutiny that Commission desires to have that undermines the very trust of the public that Commission likes to get.

The Ombudsman might consider demanding DG SANTE to publish and maintain a full list of CDP's on its website over all (past) years, and explain for every CDP how high risks, data gaps, critical areas of concern are translated in conditions and mitigation measures that prove and ensure safe use by actual calculations. And show how the same high risks, data gaps, critical areas of concern are implemented in the 28 MS in actual authorisations. And also insist that PAN Europe scrutinises the text to avoid misleading of the public.

Below we will give a few examples from the list of the 5 pesticides, to demonstrate the (il)legality of Commission's CDP practices:

- Benzovindiflupyr:
 - a. The toxicity of the impurity was requested in the CDP. This is misuse of the CDP since the toxicity should have been provided based on Regulation 283/2013, Art. 1.10 and thus is no "*new requirement established during the evaluation*" according to Art. 6.f from Regulation 1107/2009. Commission decided in clear violation of the rules, to approve while it is not established that the pesticide "*shall not have any harmful effects on human health*" (Art. 4.2.a of Reg. 1107/2009).
 - b. The compliance of the toxicity and ecotoxicity batches with the confirmed technical specification was requested in the CDP. This is misuse of the CDP since the toxicity should have been provided based on Regulation 283/2013,

Art. 1.11 and thus is no “*new requirement established during the evaluation*” according to Art. 6.f from Regulation 1107/2009. Commission decided in clear violation of the rules, to approve while it is not established that the pesticide “*shall not have any harmful effects on human health*” (Art. 4.2.a of Reg. 1107/2009).

- c. The effect of water treatment processes on the nature of residues was requested in the CDP. This is misuse of the CDP since the toxicity should have been provided based on Regulation 283/2013, Section 8.8 and thus is no “*new requirement established during the evaluation*” according to Art. 6.f from regulation 1107/2009. Commission decided in clear violation of the rules, to approve while it is not established that the pesticide “*shall not have any harmful effects on human health*” (Art. 4.2.a of Reg. 1107/2009). Commission and EFSA agreed in their 2018-meeting that “*On this matter it was noted that applicants often use the unavailability of GD as an excuse to disregard certain data requirements*”. Industry should have submitted the data from Reg. 283/2013, Section 8.8 and the RMS should have stopped the evaluation of the dossier until the missing information was submitted.

- Isofetamide:

The story on Isofetamide is very similar to Benzovindiflupyr. Three data gaps. And with data gaps, it is impossible to establish if the requirements Art. 4.2.a/b are fulfilled and thus an approval illegal. For the three a reference to Art. 6.f is not possible because industry should have delivered the data together with the dossier. They didn't while the data have to be submitted based on Reg. 283/2013. It's industry's own fault and Commission violated Reg. 1107/2009 by approving the substance.

4) Explain how it interprets “critical area of concern” and “no safe use identified” taking into account the definitions in EFSA's reports. I note, in relation to flazasulfuron, isofetamid and epoxiconazole, that EFSA explains in a table summarising its concerns: “**Columns are grey if no safe use can be identified.**” For the three substances the whole table is grey, which appears to imply that no safe use could be identified. On this basis, and bearing in mind that EFSA is the risk assessor and the Commission the risk manager:

PAN reaction: The SANTE/EFSA bilateral is very instructive for this question. Commission is suddenly putting all blame on EFSA, “*EFSA does not qualify its concluding statements enough and the conclusions are sometimes not sufficiently nuanced and detailed*” and “*need to be more clearer for the general public*”. This is unjustified and unfair,

EFSA is simply doing its job, to find out if according to Article 4.5 “*For 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*”. If data are available EFSA can decide if the pesticide meets the criteria for **a one representative use**.

EFSA uses the data provided by industry and concludes. That's their job and that's what they should do. This leads in several cases to a "*critical area of concern*", the conclusion by EFSA that safe use according to Art. 4.5 is not established and an approval impossible. And this is exactly what Commission asked them to do. Use all available data and conclude on safe use for one representative use. You cannot blame EFSA if there are data gaps and for this reason EFSA cannot conclude to a safe use. You also cannot blame EFSA for not applying mitigation measures if industry didn't put forward these mitigation measures (EFSA in the bilateral of 2018 feels that industry should be obliged by the Rapporteur MS of the RAR/DAR to propose mitigation measures if they want them to be taken into account).

Rightly EFSA states in its October-2019 letter (page 2) that since 2010 EFSA followed a consistent approach for the identification of a "*critical areas of concern*" that were duly discussed and agreed with Commission and Member States. And Commission never asked for a clarification, according to EFSA. Then suddenly, in 2018, Commission wants to change the agreement. We can infer that the intervention by the Ombudsman played a role in the requested change and the "pressure" Commission feels to reduce "flexibility" (read reduce approvals without demonstrated safe use). Commission's initiative will likely only create confusion in this expert-area and might be an attempt to silence critique with questionable language like making the conclusions "more user friendly" and "increase transparency".

We understand very well why Commission is unhappy with EFSA's conclusions. Commission has to deal with reluctant Member States (MS), its ministries of agriculture to be precise, that do not care much about the negative health effects of pesticides, let alone the disastrous environmental effects. A constant pressure is exerted by the MS to approve more pesticides for their farmers. All efforts in this political arena (the pesticide Standing Committee¹) go in the direction of constructing certain views or theoretical assumptions to qualify one representative use of a plant protection products as safe. To enable approval. The report also states: "*SANTE mentioned increased pressure from stakeholder groups and very intense scrutiny of EC decisions, thus reducing the flexibility that SANTE had previously when proposing decisions*" (EFSA/SANTE bilateral 2018, page 2). SANTE apparently doesn't like scrutiny, likely to be flexible with rules. And "*the challenge for SANTE is that less issues can be left to be addressed at MS level*". They admit, indirectly, that they violated the rules for many years.

Commission further argues "*As a consequence, specific formulations containing a given active substance may well be safe for specific uses in specific Member States*". Commission tries to say, yes, EFSA might be right for this "*one representative use*" but look at other uses. This is OK as far as data are available. But this is exactly what is missing. If EFSA would have had additional data, they would have been applied in the EFSA opinion. Commission therefore in their approval decisions is not using additional data but is speculating and assuming, and on this "*whisfull thinking*" based approach approves pesticides.

This concerns the vast majority of the decisions on the protection of the environment and biodiversity (Reg. 1107/ 2009, Art. 4.2.e.iii). The protection of the environment and biodiversity is deliberately stopped in 2005 (see attached document "*DK protest against stopping env protection 2005*". For more than 14 years now the European protection of the environment and biodiversity has been lifted by Commission. And one can clearly

¹ [ScoPAFF](#)

see what the result is of this illegal practices, a total collapse of biodiversity. And, not coincidentally, the main reason for this is pesticides used in agriculture². Commission (and the ministries of agriculture) are therefore guilty in helping destroying our heritage and ecosystems.

Please note that Commission in hundreds of cases failed to protect the environment and ignored the 'critical area of concern'. For high risks for birds we note at least 80 cases of illegal approvals, for mammals another 70, aquatic 60, arthropods 20, bees 20, earthworms 10, etc. This is a massive illegal operation that is never discussed openly. We hope for the Ombudsman's help to create maximum transparency.

The more 'political' document "*Questions 4-7 answers*" provides for more Commission text on this topic of 'critical areas of concern'.

Commission, in its answers, is mixing up "critical areas of concern" and "data gap" and tries to avoid the question posed. Especially by taking as an example "*in case a risk to aquatic organisms was identified for use on one crop but not others the approval conditions would include an obligation for Member States to pay particular attention to the risk to aquatic organisms*". This is misleading since this is not a very relevant example, more an exemption. In almost all cases (60) there is high risk for all crops. So the solution, decide based on the other crop, doesn't give an answer to "critical areas of concerns". Commission's reply is evading the question.

Commission also fails to demonstrate the "safe use" with mitigation measures (they even don't try to) and fail to mention that they didn't include the mitigation measures in the decisions, and thus violated Art. 4.5 of Reg. 1107/2009. EFSA is very clear about mitigation measures, and states in its October 2019 letter (footnote 3) that "*in case mitigation measures are indispensable to achieve a safe use, the required mitigation measures should also be described in the approval conditions for the active substance, see Art. 6.i of Reg. 1107/2009*". Voila. Also EFSA feels that there is a legal obligation to include mitigation measures such as buffer zones for the protection of aquatic organisms.

The line "*With regards to data gaps, in many cases data gaps identified are only relevant for a specific use, formulation or under certain conditions. These gaps can be filled by applicants before submitting applications for product authorisation (i.e. post approval)*" again shows the misinterpretation of the rules by Commission. Commission approves while data gaps are present (violation of Art. 4.5) because this can be repaired at national level, they suggest. Commission turns the approval in some kind of draft decision with a lot of white areas that can be repaired later.

For the rest of the arguments on conditions, restrictions and responsibilities of the MS, we countered these already in the beginning of Question 4 when we discussed the EFSA/SANTE bilateral that is very instructive to learn about the intentions of Commission.

To reiterate. EFSA did their job. They identified critical areas of concern based on available data, which are a blockade to an approval. Commission assumes and speculates about national conditions and mitigations measures but doesn't have

² <https://www.insect-respect.org › images › Rueckgang der Insekten › 2019...>

additional data either. Only in case of high risk for aquatic organisms mitigation measures are likely sufficient to arrive at safe use. But even in this case Commission didn't "establish" safe use by concrete mitigation measures (what concrete width of buffer zones?) and didn't include proper buffer zones in the approval decision. Not established, not legal. For all other approval decisions it is simply unclear if a safe use exists at all. Conditions and mitigation measures are left to the MS and the European approval decision is a blatant violation of Regulation 1107/2009 in the many dozens of cases.

The line *"In cases where the comprehensive scientific evaluation conducted by the RMS and EFSA indicates risks ... that cannot be resolved or mitigated through further refinement of the assessment or appropriate mitigation measures, the Commission proposes not to renew the approval"* is not true. We are not aware of any of the around 200 cases of high risks for the environment that Commission decided not to renew the approval.

Commission's example are also not convincing. The issue on Isoproturon is about drinking water, a matter of **health**, not the environment, while Beta-cypermethrin has several problems, including a metabolite that blocks consumer safety calculations. This makes it questionable if the environment was a reason for banning. Commission cannot put forward proper examples. On the contrary, we can name many dozens of cases where high risks were demonstrated by EFSA, and still the substance was approved while no safe use was established and no mitigation measures were included. Already for high risks for birds we can name the approvals of Triticonazole, Dazomet, Aclonifen, Imidacloprid, Zeta-cypermethrin, Fluopyram, Tebuconazole, Chlorpyrifos, Chlorpyrifos-methyl, Formetanate, Metiram, Tetraconazole, Triflumuron, Acequinocyl, Fenpropidin, Bromadiolone, Carboxin, Dimoxystrobin, Flutriafol, Metamitron, Prothioconazole, Malathion, that were approved with high risks.

For demonstration reasons, we just present a few more examples below, to illustrate how Commission manipulated EFSA's conclusions and designed a non-science based outcome that is used for the approval, see also (EFSA opinions, SANTE Review reports, <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>):

Pesticide substance	EFSA "critical area of concern": no safe use for the "one representative use"	SANTE interpretation: YES, "one representative use" is established (RR)	PAN comment.
Picolinafen	"A low dietary reproductive risk to mammals was concluded at the Tier I for all relevant generic focal species, with the exception of the scenario 'large herbivorous mammal' feeding on early shoots".	EFSA highlighted that some refinements/risk mitigations may be available at zonal or national levels, such as application rate or dietary refinements. It was noted by the Committee that based on the available data, an acceptable representative use for large herbivorous mammals was identified for an application rate of 60 g	SANTE admits that only for large herbivorous a safe use is present, not for small herbivores. Concluding to safe use is manipulation of the rules and of science; it is a clearly illegal approval decision. The line on application rate and dietary refinements, use under certain conditions, is pure speculation; without

		active substance per ha (TER = 5.98 > 5)".	data a safe use cannot be "established".
Benzo-vindiflupyr	High risk for aquatic organism, even with 2x 10 meter buffer zone	A high risk was identified for aquatic organisms. Since higher tier options are available with mitigations measures there is safe use	Very likely there is a safe use. One can put in place buffer zones of 20, 30, 40 of more meters and likely find safe use at some point. However SANTE still did not "establish" a safe use. And, at the minimum, they should have included conditions, the (minimum) 20 meter buffer zone as calculated by EFSA.
Flumetralin	High long-term risk to herbivorous mammals	A first-tier risk assessment highlighted the risks for herbivorous mammals. However, given that higher tier options are available, MS should consider the risks to herbivorous mammals.	Just speculation. What higher tier? How to calculate if there are no data? Concluding to safe use is manipulation of the rules and of science; clearly illegal approval. SANTE did not prove that a safe use is available, still they conclude to "safe use".
Pinoxaden	"...relevant metabolites M3, M11, M52, M54, M55 and M56 have the potential to exceed the legal parametric limit of 0.1 µg / L in ground water for all or the majority of scenarios simulated"	No explanation about the safety, the "one representative use", Only CDP on the 6 metabolites if Pinoxaden is classified as "suspected of damaging of the unborn child" (as proposed by EFSA)	Clearly illegal approval. Approving a substance with 6 potential dangerous pesticide metabolites. While the 'mother' substance is concluded by EFSA to be harmful for the unborn child, the same can be expected for the metabolites. And the exceedance of the groundwater standard stands in the way of an approval. No safe use demonstrated by SANTE. Clearly an illegal approval and a violation of the precautionary principle (putting commercial interests over health.
Disodium-phosphonate	The chronic risk to earthworms was indicated as high at the first tier risk assessment.	Nothing done to claim safety. Only CDP requested, "information to further address the long-term risks to earthworms"	Commission concludes to safe use (based on nothing) and completely ignores the high risks for earthworms. Only CDP is requested. This is a very obvious illegal act

Proa- quizafofop	There were effects above the trigger value of 50% (66%) on reproduction of non-target arthropods at the field rate. It was not possible to finalise the in-field risk assessment for non-target arthropods.	Nothing done by Commission to claim safety. Only “list of studies to be generated”	Commission concludes to safe use (based on nothing) and completely ignores the high risks for non-target arthropods. Only “studies” requested This is a very obvious illegal act to approve such a substance.
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5) Could the Commission clarify what action it takes when it approves substances for which EFSA has identified “critical areas of concern” or considers that “no safe use could be identified”?

PAN comment.

The only answer Commission gives is that it uses its Review Report “to explain how the issues or concerns are or can be managed (for example by taking into account mitigation measures or based on agronomic practices)”.

For the pesticide Picolinafen, this approach leads to the line “EFSA highlighted that some refinements/risk mitigations may be available at zonal or national levels, such as application rate or dietary refinements”. May be. And what would application rates change? What would dietary refinements help? This is very unscientific, and has nothing to do with the requirements in the rules to “establish”.

And on Epoxiconazole, “The long-term risk assessment for birds and mammals needs further refinement. Confirmatory information was requested”. No explanation about the high risks that suddenly are turned into safe use in the approval decision without new data or measures. What refinement? How will this lead to safe use? This is pure speculation.

No action is taken, as requested by the Ombudsman, but to approve the substance. Everything is referred to MS-level. There is no EU-wide protection put in place. And if this would be allowed (which it isn’t), why is Commission not monitoring if the MS do protect the environment and take action if this doesn’t happen?

And what to think of the line in the EFSA/SANTE bilateral: “SANTE reiterated that risk mitigation is an important aspect to consider during decision making. In all cases, the mitigation should be proposed by the applicant and put forward by the RMS in the DAR/RAR and on this basis EFSA”. Here Commission itself is saying that risk mitigation is an important point in decision making and industry should propose them. So why is the dossier accepted without risk mitigation measures and why is risk mitigation completely ignored in Commission’s own approval decisions?

And no protection of the environment is not a fantasy. Some MS have some protection, other do little. Slovenia and Belgium for instance don’t allow buffer zones.

Here is a illustrative example on the highly aquatic toxic pesticide Benzovindiflupyr:

- Benzovindiflupyr:

EFSA concluded to a “high risk for aquatic organisms in the majority of the relevant FOCUS SW scenarios when mitigation equivalent to a 10 m no-spray buffer zone + 10 m vegetated field strip has been implemented”. Nevertheless, in Commission Implementing

Regulation 2016/177 no mitigation measures are included at all and only “*shall pay particular attention to the risk to aquatic organisms*” is included. This is a violation of Art. 4.2.b, the requirement that “*they shall not have any unacceptable effect on the environment*”. Without the buffer and vegetated strips, no safe use is possible. Commission fails to put in place an European protection for aquatic organisms as they should and leaves it up to the MS to protect aquatic organisms. But can they trust the MS? We attach a December 2017-decision on Benzovindiflupyr from NL (“*CTGB Benzovindiflupyr – no buffer zone at all – page 29*”, attached), to show that in practice no buffer zone nor vegetated field strip is required in this national authorisation. We have no resources to do a full evaluation of the MS, but Commission should. This example makes it clear that failing to include mitigation measures at European level, allows member states to ignore the mitigation measures in national authorisations.

6) Would the Commission be ready to include in future review reports a section explaining its approach to such EFSA findings?

PAN comment: we do not agree with the answer of Commission that this is already being done. It is not. As illustrated above some speculations on refinements and mitigation are included but this doesn't explain how Commission arrives at a safe use. Commission should include actual calculations with concrete mitigation measures and concrete refinements that prove safe use. And include these refinements and mitigations measures as the European condition for approval.

7) If the Commission considers the information and definitions in EFSA's reports to be misleading, could the Commission set out what action might be taken to address this issue?

PAN comment; Commission's reply is quite irrelevant information about how MS push for approval and Commission asks EFSA to deliver more information to make this possible. Commission doesn't state now that EFSA is misleading. Please note that the examples used by Commission are about the health part of the assessment. In this health part Commission at least discusses mitigation measures and refinement to get a substance approved. For the environment part this is totally different since Commission already in 2005 decided to stop respecting Art. 4.5 for the environment and automatically refer the matter to the MS. First they asks for CDP, later just “*shall pay particular attention*”.

Finally.

Dear Ms. Ombudsman, we need your help to get things right. It is amazing how Commission manages to start such a massive derogation regime in 2005 to bypass the rules and keep it more or less under the carpet. And it has no intention to follow the law. You now know Commission doesn't keep its promises and we hope you will publicly condemn Commission and ask them to stop their CDP regime immediately. We also hope you will demand Commission,

- to stop producing approval decisions while EFSA concludes to a “critical area of concern”, unless safe use is proven with data, restrictions and measures that are included in the decision,
- to make all CDP’s transparent, especially those on the environment, including the rationale how their approval leads to safe use with concrete measures and calculations,
- to make transparent (actual website) how the 28 MS translate the approvals with “high risks for bees, birds, mammals, etc.” in their national authorisations and include calculations how these authorisations translate to safe use,
- instruct its audit unit to evaluate all national authorisations to find out if the mitigation measures and restrictions put in place actually do protect the environment and lead to safe use for birds, bees, mammals, etc.,
- start an infringement procedure in case of unsafe use demonstrated nationally.

Sincerely yours,

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke extending to the right.

Hans Muilerman,
Pesticide Action Network, Brussels.