Pesticide Action Network Europe

Brussels, 26 September 2023

Bernhard Url
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Parma
Italy

Concerns: Your letter on glyphosate Ref. BU/ct-OC-2023 - 29763357

Dear Bernhard Url,

Thank you for your reply to our letter from 13 July on EFSA's main findings on glyphosate. Unfortunately, we regret to observe that EFSA has not responded to the main points from our letter. Our legal, scientific and regulatory arguments remain to be addressed. We feel that the lack of will of EFSA to dialogue with us on the content of its work is unacceptable, and will unfortunately inevitably increase the distrust in the institution. The lack of will to engage on scientific, legal and regulatory arguments has also been evident during the conference on glyphosate from 18 September, hosted by MEPs Paulus and Clergeau in the European Parliament. Considering the important shortcomings that were identified, both by PAN Europe and by independent scientists, it is of major importance that EFSA accepts to enter in dialogue, in order to enable thorough scrutiny of its work. We therefore, in a second attempt, ask for your answers on the major deficiencies of EFSA's work on the risk assessment of glyphosate, regarding the following points:

I. The necessity for EFSA to finally implement EU law and case-law

1. Critical area of concern

As mentioned in our letter, we consider that EFSA does not apply its own definition of the Critical Area of Concern (CAoC). EFSA should also make sure that both the law (regulation (EC) 1107/2009) and the case law (e.g. the Blaise ruling[1]) are taken into account in its work. In

[1] See C-616/17: "need to take into consideration the effects of the constituents of a plant protection product as a whole is, moreover, confirmed by the rules laid down in Articles 25 and 27 of Regulation (...) it is clear that the placing on the market of safeners, synergists and co-formulants contained in such a product must also be subject to assessments to determine whether they have any harmful effect"
"It is therefore the task of the competent authorities, when examining an application for the authorisation of a plant protection product, to verify that the material submitted by the applicant, and primarily the tests, analyses and studies of the product, is sufficient to exclude, in the light of current scientific and technical knowledge, the risk that that product exhibits such carcinogenicity or toxicity."

particular, the Blaise ruling clarified that, in order to carry out the risk assessment of the representative formulation, EFSA must carry out a risk assessment of the individual ingredients of the formulation, as well as a risk assessment of the entire representative formulation, and in particular the long term carcinogenicity and toxicity. According to the available information, no higher tier study has been carried out on the long term toxicity of the representative formulation, nor on its individual ingredients. No higher tier ecotoxicity study is available regarding individual ingredients. As for glyphosine impurity, the only available scientific data you have indicates genotoxicity, while no higher tier study has been performed, which corresponds precisely to the second indent of the definition of what a CAoC. All these gaps in the file should have, according to your own definition, been reported as a CAoC.

The last indent of your definition of a CAoC is in complete contradiction with EU law and case law. Nowhere is it written in EU law or case law that only science carried out according to guidance documents has to be taken into account, in the frame of the identification of CAoCs. Indeed, article 4 from the pesticide regulation, setting the approval criteria, mentions 'in light of the current technical and scientific knowledge', with a specific reference to carcinogens, mutagens, reprotoxics and endocrine disruptors. Nowhere is it written that the establishment of a CAoC should be limited to data produced following guidance documents. By applying such a restrictive approach, the EFSA gives a near exclusivity to industry-sponsored data, in the frame of the definition of a CAoC. This increases the bias towards an industry-favorable assessment. Furthermore, as PAN Europe identified[2], the pesticide industry has heavily influenced the writing of guidance documents. Taking non-industry science allows to compensate for the vested negative influence of the current guidance documents on the one hand, and for the inherent imperfection of risk assessment.

Non-industry studies[3] have established the genotoxicity of both glyphosate and its representative formulation. In the absence of long-term toxicity studies regarding the representative formulation, EFSA should have taken into account the evidence from the independent scientific literature, which repeatedly have pointed at the genotoxicity of both glyphosate and its formulation.

1. Absence of information on short term and long term toxicity of ingredients

When concluding this point by "*In these conditions, in line with the definition set in the Conclusions' template, EFSA considered it appropriate to report the data gap as an outstanding issue without qualifying it as a critical area of concern. As such, EFSA's Conclusion is compliant with the applicable legal framework, relevant case-law and the definitions set in the Conclusions' template*." it seems obvious that you have not included in your answer a reflection

[2] https://www.pan-europe.info/press-releases/2018/02/industry-writing-its-own-rules
[3] See presentations of the glyphosate conference organised by PAN Europe on 18 September 2023

on the relevant case law mentioned in our letter. You have indicated in your letter that "*a critical area of concern is indicated in cases where the identified concern is relevant for all representative uses proposed by the applicants*." In our letter, we have provided you with the legal information that should de facto lead to CAoCs. We respectfully would like to know:

a. The Blaise ruling clarifies that a formulation is deemed safe if its individual components have been individually risk assessed and if the formulation has also been risk assessed, in particular for its long-term carcinogenicity and toxicity. Can you guarantee that EFSA is in possession of regulatory studies on the long-term toxicity and carcinogenicity of all individual components of MON 52276 as well as on the formulation itself, in particular according to regulation (EC) 214/2013? Is EFSA in possession of all toxicity studies needed to guarantee the absence of toxicity of all individual components to bees, earthworms, birds, aquatic organisms, etc.? In the absence of a clear regulatory framework, in our view such data should be produced according to regulation 213/2013.
b. If the answer to one of the questions raised above is "negative", how can EFSA justify to not have set it as a CAoC as, which de facto means that the Blaise ruling and regulation (EC) 1107/2009 are not respected and that in reality EFSA is not able to finalise its risk assessment on glyphosate and therefore no safe use can be ensured? As you stated in your reply (*"a critical area of concern is indicated in cases where the identified concern is relevant for all representative uses proposed by the applicants*."), it is evident that, if EFSA were to respect the ruling of the Court of Justice of the EU, these major gaps in the file would have led to CAoCs.

You also mention "the Member State experts considered that the available toxicological information was sufficient to conclude on the safety of the formulation 'MON 52276' ". While we understand that EFSA involves the risk assessors from Member States in its work, EFSA is responsible for its outputs. The General Food Law sets EFSA as an autonomous risk assessor and not just as a secretariat of the will of Member State 'experts' who often depend directly on ministries of agriculture and may have a strong interest in biasing the outcome of the peer review. EFSA must thus take responsibility for its peer reviews.

2. About impurity glyphosine

The second indent of your definition of a CAoC indicates that a CAoC is established when "the assessment at a higher tier level could not be finalised due to lack of information, and the assessment performed at the lower tier level does not permit the conclusion 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;".

Glyphosine has been established to be potentially carcinogenic, as an individual substance, following an *in vitro* chromosome aberration test. No higher tier has been provided. As far as we understand, this corresponds to the second indent of your definition of a CAoC.

Why has the absence of a higher tier study not been classified as a CAoC for glyphosine, while the lower tier study identified genotoxicity?

3. Dietary risk assessment to consumers

Thank you for your explanations, we will further analyse them.

4. Public literature on neurotoxicity

Your response shows the absence of uptake of ruling C477/14[4] which clarifies that when an indication of a risk is identified, authorities must take action. The Weight of Evidence approach from EFSA opposes this ruling, as it dilutes scientific information providing evidence on the neurotoxicity potential of glyphosate and gives the impression it is irrelevant as other studies provide different results. EFSA gives precedence to the industry-sponsored studies that show negative results and other such studies, where all other studies indicating neurotoxicity are considered either supplementary or not acceptable for the assessment because of deviations from the relevant OECD protocol, rather than because of scientific shortcomings. .
The Blaise ruling has clarified that "*it is the duty of the competent authorities, in particular, to take account of the most reliable scientific data available and the most recent results of international research and not to give in all cases preponderant weight to the studies provided by the applicant*" (point 94). Giving little weight and discarding the conclusions of the most recent scientific findings from international research, on the basis that industry studies, often decades old, prevail over such publications is simply unlawful.

Furthermore, ruling C477/14 underscores the obligations of Member States to take action, even in case of doubt. By applying its weight of evidence approach, EFSA prevents Member States from applying the law by taking action, even in case of doubt.

[4] Amongst many of case law, cf. e.g. C-477/14, Pillbox 38, 4 May 2016, EU:C:2016:324, pt. 55; T- 817/14 Zoofachhandel Züpke and Others v. Commission, 17 March 2016, EU:T:2016:157, pt. 51; T-333/10, ATC and Others v. Commission, 16 September 2013, EU:T:2013:451, pt. 81. "is a general principle of Union law requiring the authorities concerned to take, in the specific context of the exercise of the powers conferred on them by the relevant legislation, appropriate measures to prevent certain potential risks to public health, safety and the environment, giving precedence to the requirements the protection of these interests over economic interests, without having to wait for the reality and seriousness of these risks to be fully demonstrated. In particular, where it proves impossible to determine with certainty the existence or extent of the alleged risk because of the insufficient, inconclusive or imprecise nature of the results of the studies carried out, but the likelihood of real damage to public health persists

While the available data point at the neurotoxicity potential of a glyphosate salt (trimesium phosphate), and of some glyphosate-based herbicides, the absence of long-term toxicity study does not allow EFSA to discard the neurotoxicity potential of the representative formulation, or its co-formulants. The EFSA here does not implement the Blaise ruling or the precautionary principle as defined by the case law. The available evidence should have led to another CAoC as it concerns all uses.

Does EFSA give more weight to more recent scientific studies from the international scientific literature than to decade old regulatory industry studies, in line with the case law?
How does EFSA justify that the Weight of evidence approach aligns with the case law on the precautionary principle, that in case of doubt, risk managers are obliged to take protective actions?

5-6. Microbiota and biodiversity

In your answer, you claim that the absence of harmonised guidelines or the absence of definitive link between disruption of gut microbiota and diseases prevent EFSA from drawing conclusions out of studies from the independent literature reporting disruption of the microbiome following exposure to glyphosate and glyphosate-based herbicides, including the representative formulation. Similarly, regarding biodiversity, you indicate a lack of harmonised approach to assess the toxicity of a pesticide on biodiversity, and a lack of specific protection goal.

As a scientific agency that recently received a substantial increase in budget, we consider that you should be capable of concluding on the toxicity of a pesticide on human health or on the environment, based on available science, independently from the availability of harmonised guidelines. If a peer reviewed scientific study shows, at field-relevant concentrations, an effect of a pesticide on a test species, this needs to be taken into account. If a few studies point in the same direction, this should be enough to claim that a negative impact on biodiversity exists. Furthermore, instead of remaining inactive because no arbitrary and theoretical specific protection goals have been politically set by risk managers, EFSA should apply the precautionary principle: if an effect is observed at field-realistic dose, a negative impact on biodiversity should be concluded.

This would be aligned with the case law previously mentioned: no matter how well defined the risk is, if the risk is characterised, it should lead to actions on behalf of risk managers, and this needs to be reflected in your conclusions. Regarding disruption of microbiota, the same should apply.

Does EFSA confirm that in the absence of harmonised guidelines, it refuses to conduct a risk assessment based on available scientific knowledge from the open literature? In case the answer is "yes": Regulation 1107/2009 foresees that all scientific evidence must be taken into account,

not limiting the work to the data produced under harmonised guidelines; how does EFSA justify its deviation from the provisions of the EU law? In the same line, how does EFSA justify that some organisations like INSERM (France) or IARC (WHO) manage to draw conclusions, based on independent science, that does not necessarily follow harmonised guidelines? What is the difference in staff skills/expertise or approach between these institutions and EFSA?

Finally, regarding the data gap identified for 12 out of the 23 proposed uses of glyphosate, as for the impurity glyphosine, it seems that you, again, do not respect your own definition of a CAoC. If tiers 1 identify an unacceptable risk and that no higher tiers are performed, and studies from independent literature indicate adverse effects then a CAoC should be defined for 12 out of 23 scenarios, rather than an unimportant data gap. Why have you not applied your own definition of a CAoC and why was this not set as a CAoC?

II EFSA's lack of transparency

We took good note of your explanations, thank you.

III EFSA influencing risk managers

Thank you for your answer. You explain that out of the 16,000 studies 780 resulted to be considered relevant for the assessment by the applicants and an additional 300 were brought to the attention of risk assessors during the public consultation and 200 after this period. Nevertheless, you miss to provide important information: how many of these studies were considered supplementary or non relevant and therefore were given very little weight in the assessment? Considering the evidence of deception by the pesticide industry, can you please indicate to us if Rapporteur Member States and EFSA have made sure that these more than 15 000 studies truly deserved to be discarded? Considering the importance of the weight of evidence approach in this dossier, the rejected studies represent an important aspect to be clarified. Among the 300 additional studies provided during the public consultation, how many of them should have been part of the applicant's dossier? Among the 200 additional studies assessed until the end of the risk assessment, how many should have been part of the initial dossier from the industry?

As said in our initial letter, by not implementing the Blaise ruling nor the case law around the definition of the precautionary principle, EFSA influences risk managers in a way that major issues identified in the frame of the risk assessment, are mentioned as simple data gaps, while they fall under your own definition of a Critical Area of Concern.

Furthermore, by refusing to carry out a scientific work, when it comes to assessing the risk for biodiversity or human health (microbiota, neurotoxicity), EFSA refuses to implement the General Food Law: nowhere is it written that the EFSA scientific opinions should be conditioned to the availability of harmonised guidelines. On the contrary, EFSA's mission is to provide

independent advice based on all available data. By arbitrarily deciding to avoid concluding on thousands of scientific studies, EFSA unilaterally decides to leave the environment and citizens' health unprotected, which is in total contradiction with EFSA's founding regulation. What is the legal ground for EFSA to refuse to draw conclusions on the risk assessment based on studies from the independent literature ini absence of harmonised guidelines?

When carrying out the risk assessment of neonicotinoids on bees, the EFSA had a much more precautionary approach. For instance, at the time, when assessing available information from the literature, EFSA would conclude "*The available evidence does not give a clear picture and provides only weak evidence that effects on honeybees which breach the SPG for honeybees may occur. Consequently, a low risk to honeybees from exposure to pollen and nectar residues in winter oilseed rape has not been demonstrated*" (e.g. Treated crop scenario for winter oilseed rape, appendix F, clothianidin peer review). Likewise, in the maize low dose scenario, you concluded "*As detailed above, there are numerous uncertainties with the risk assessment. The identified uncertainties point both in a positive and negative direction and therefore do not suggest that the overall assessment is over or under conservative. There was only very weak evidence to suggest a potential effect on the Class 1 endpoint overwintering assessment. All other lines of evidence are considered to offer weak to moderate evidence for negligible effects. Consequently, a low risk to honeybees from exposure to residues in pollen in maize has not been demonstrated*".
While, at the time, you were using the 'non-endorsed' Bee Guidance Document (2018), how can you justify that weak evidence would result in a "low risk has not been demonstrated", while for biodiversity, strong evidence on harm caused by glyphosate is rejected? How does EFSA justify that, when there is clear evidence from the scientific literature that a significant impact on biodiversity exists, it refuses to identify it as a risk, while for bees, the absence of a "clear picture" leads to a "low risk has not been demonstrated" conclusion?

IV Final remarks

The fact that your answer falls short in addressing the questions we raised in our first letter raises even more concerns on EFSA's work. We have provided you with legal, scientific and regulatory arguments and questions and did not receive specific information regarding the first part of the letter (non-alignment with EU law and case law). For the sake of clarity, we have, therefore, underlined a series of questions we would like you to address. The lack of constructive and effective engagement from EFSA, both in your reply to our letter and in the conference we have organised on 18 September is not acceptable. As a civil society organisation, we expect EFSA to be transparent and accountable. We therefore are looking forward to your detailed answers to our questions.

Thank you in advance for your reply.

Best regards,

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Head of Science and Policy

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Executive Director