Pesticide Action Network Europe

Brussels, 13 July 2023

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Concerns: EFSA main findings on glyphosate

Dear Bernhard Url,

The recent communication from EFSA on its main findings from the peer review on the risk assessment of glyphosate[1] raises a series of concerns regarding the integrity of the work. We regret to note that the "excellence in science" that your institute should adhere to and promote is compromised and a series of basic legal considerations have not been respected. We are reaching out to you to raise these issues and ask EFSA to reconsider its work.

I. EFSA must respect EU law and EU case law

The published conclusions underline significant failures regarding EFSA's compliance with EU law and case law. EFSA, here, is taking an approach that favours the interests of the pesticide industry. This approach contradicts EFSA's mandate as an independent scientific risk assessor, obliged to act in the best interest of the general public, while operating within the boundaries of EU law and case law.

1. Critical areas of concerns

The terminology "Critical area of concern" is not foreseen by EU legislation. Nevertheless, EFSA's definition of a Critical Area of Concerns (CAoC)[2] is clear: if it is established that no safe use can

[1] https://www.efsa.europa.eu/en/news/glyphosate-no-critical-areas-concern-data-gaps-identified

[2] See for instance the definition of a Critical Area of Concern on the EFSA Peer Review on S-Metolachlor: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2023.7852
An issue is listed as a critical area of concern if 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 Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment 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.
An issue is also listed as a critical area of concern if the assessment at the higher tier level could not be finalised due to lack of information, and if 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

be guaranteed, if the risk assessment cannot be finalised, and if the criteria laid down in article 4 from the pesticide Regulation (EC) 1107/2009 (hereafter the Regulation) are not met, the EFSA must establish a critical area of concern for one or several endpoints. Such a definition links to several provisions in the EU legislation.

Regulation (EC) 1107/2009: Article 4 lays down the approval criteria for an active substance. Among others, article 4 highlights that: 1. The residues of the plant protection products containing the active substance shall not have a harmful effect on human health and animal health, taking into account cumulative and synergistic effects and shall not have any unacceptable effect on the environment. 2) The approval of an active substance is conditioned on the verification that at least one representative use of at least one plant protection product has been evaluated and considered to meet the criteria laid down in §1-3 from the same article. 3) Products shall have, among others, no immediate or delayed harmful effect on humans, including that of vulnerable groups (i.e. children and pregnant women) and in terms of the environment, no unacceptable effects with particular regard to the impact on biodiversity and the ecosystem.

Furthermore, article 1(4) stresses that the provisions of the regulation are underpinned by the precautionary principle. Article 191(2) TFEU states that "*Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken*".

The relevant EU case law: The precautionary principle has been further defined by the case-law from the Court of Justice of the EU. In particular, the Court considers that the precautionary principle entails competent authorities to not wait until a harm materialises but to act when a risk

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 if, 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 Regulation (EC) No 1107/2009.

exists, even when there is a lack of information that does not allow to draw firm conclusions in a risk assessment[3.4.5].

Furthermore, the Court of Justice of the EU also clarified that the risk assessment of a pesticide formulation needs to include the risk assessment of its components. Furthermore, the Court also clarified that in order to conclude on the risk assessment of a formulation, data must be provided by the applicant in order to conclude on the carcinogenicity or other toxicity from the formulation[6].

EFSA does not respect its own definition of a CAoC and the legal requirements:
Taking into consideration these legal requirements and EFSA's definition on CAoC it becomes evident that EFSA's conclusion has failed to align with these provisions, for the reasons we present below.

First of all, the Blaise ruling states explicitly[6] that in order to carry out a risk assessment for a formulation, the risk assessor needs to have all the toxicity data on its individual components. According to EFSA, there is an absence of information on short- and long-term toxicity of one of

[3] 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 should the risk materialise, this principle justifies the adoption of restrictive and objective measures*"

[4] See e.g. T-257/07, France v. Commission, 9 September 2011, EU:T:2011:444, pt. 68. The precautionary principle This principle thus allows "*institutions, when scientific uncertainties remain as to the existence or extent of risks to human health, to take protective measures without having to wait for the reality and seriousness of these risks to be fully demonstrated or for the adverse health effects to materialise*"

[5] Cf. T-74/00 e.a., Artedogan e.a. c. Commission, 26 November 2002, EU:T:2002:283, pt. 184. The precautionary principle also requires "*the competent authorities to take appropriate measures to prevent certain potential risks to public health, safety and the environment, giving precedence to the requirements of the protection of these interests over economic interests*"

[6] 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.*"

the components of the formulation, a co-formulant[7]. As an argument, EFSA states that there were no indications of acute toxicity or carcinogenicity. However, in this respect, the Blaise ruling clarifies the need for an assessment on one hand of all components of the formulation to determine whether they have harmful effects, and on the other hand of the whole formulation, to exclude the risk that the product exhibits carcinogenicity or long-term toxicity. As far as we know, a study on carcinogenicity or long-term toxicity of the formulation has not been provided by the applicant, and therefore such a toxicity cannot be excluded based on the available information provided by the applicant. On the contrary, studies from the scientific public literature indicate that exposure to glyphosate-based products has been linked to serious diseases such as carcinogenicity and neurotoxicity. Therefore, according to EFSA's definition of a CAoC, and in line with the law and the case law, the toxicity data gaps on the component(s) of the formulation, as well as of the representative formulation itself, should have been set as a CAoC.

Second, the risk assessment of an active substance includes the risk assessment of the impurities linked to the production of the active substance, as indicated in the Regulation. EFSA acknowledges that it was not possible to conclude on the genotoxicity of such impurity and the risk assessment could not be finalised for this crucial endpoint. Therefore, this should have been set as a CAoC according to EFSA's own definition.

Third, the dietary risk assessment to consumers has not been finalised. This prevents EFSA from disregarding harmful effects on human health, which is a mandatory requirement of article 4 of the Regulation. An Acceptable Daily Intake (ADI) needs to be established. Not being able to determine what is considered as a safe level of dietary exposure is not in line with the Regulation. This should have been set as a CAoC according to your own definition.

Fourth, you acknowledge that the public literature indicates neurotoxicity from some Glyphosate-Based Herbicides (GBHs). You also highlight that studies from the public literature on glyphosate based formulations and a developmental neurotoxicity (DNT) study on a non EU-approved glyphosate salt identify a risk to the unborn. Considering the absence of a DNT study for glyphosate and long-term health toxicity studies for the formulation in the applicant's dossier, and considering the case law defining the precautionary principle and that products should cause no toxicity, the EFSA should have set the identified risk of neurotoxicity and DNT as a CAoC, according to its definition.

Fifth, EFSA reports that effects on microbiome were taken into account but states that no action was taken as no internationally agreed guidelines are available and further research is needed to develop methodologies. Nevertheless, the link between alterations in human microbiome and disease is well established, and therefore these publications indicate a potential harm to human health and non-target species. The absence of internationally agreed guidelines is in our view not

[7] Our analysis is that information is missing on more than one co-formulant but since only the summary of the risk assessment is available for the moment, this prevents a complete assessment of the EFSA conclusions.

a valid argument to not conclude on the wide range of available information. The Regulation states that the assessment of the approval criteria is carried in the light of current scientific knowledge and must incorporate published scientific literature. The EU Court of Justice judgement C-616/17 also indicates that greater weight should not systematically be given to regulatory studies and that the most recent studies should be taken into account (§94: “With that in mind, 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”). Therefore, considering the rapidly developing scientific knowledge on the importance of a diverse and stable microbiota for human and animal health, EFSA should have set the identified risks on microbiome as a CAoC, according to its definition.

Sixth, EFSA seems to acknowledge the wide range of scientific evidence on the impact of glyphosate on biodiversity and even identifies that 12 out of the 23 uses of glyphosate lead to high long-term risks to mammals. Considering the colossal number of scientific studies highlighting the negative impact of glyphosate and GBHs at field-realistic concentrations, it is incomprehensible how EFSA did not consider it as a CAoC. As mentioned above the most recent studies of international research should be taken into account. Furthermore, the absence of information provided by the applicants on the representative formulation for key environmental toxicity endpoints should also have led to a CAoC. The EFSA opinion should thus respect the case law and align its conclusions: a plethora of scientific evidence indicates a high risk to biodiversity. Considering the disastrous state of biodiversity, in particular in agricultural areas, the EFSA should provide conclusions that allow risk managers to implement the precautionary principle, and not conclusions that work against it.

2. Respecting the General Food Law

PAN Europe considers that the summarised conclusions evidently demonstrate that the Authority is not aligned with the provisions of the General Food Law (GFL). Indeed, the GFL foresees that the Authority shall:

- provide independent information on all matters within these fields and communicate on risks
- contribute to a high level of protection of human life and health
- carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.

The elements developed in point I.1. establish that the work that EFSA carried out on glyphosate is not in line with the GFL. While glyphosate is one of the most used pesticides in the EU, to which farm workers but also citizens are exposed to, your ‘political’ classifications of the data gaps and shortcomings as CAoCs or not, is unacceptable. Not only this is against the law provisions and

the relevant case law but also against your “Missions” to ensure a high level of protection of human health and the environment (art. 22 of the GFL).

II. EFSA insufficiently transparent

EFSA published a summary of the risk assessment of glyphosate a few weeks ahead of the publication of the complete peer review conclusions, and three to four months ahead of publication of the background supporting documents. This prevents any public scrutiny on EFSA’s assessment and considering the major political sensitivity of the file, this lack of transparency is unacceptable.

It means that only nearly 4 months after the publication of EFSA’s summarised conclusions will the scientific community and NGOs have access to the details of its work. Taking into account the past controversies on the quality of EFSA’s work on this file, and considering the substantial increase in EFSA’s budget with the revision of the GFL, the procedure should be more transparent and inclusive.

III EFSA trying to influence risk management

From the elements detailed in section I.1, it is evident that the Peer review main findings you have published are not in line with the law, as well as with your role as a risk assessor. By failing to identify major data gaps in the assessment as CAoCs, you act against EU law and case law. By ignoring the wide range of independent scientific evidence and pretending that the absence of internationally agreed guidelines allows you to automatically dismiss thousands of peer reviewed scientific papers goes against the law and the case law. These are evident attempts to influence risk management to renew glyphosate’s approval, while reducing the level of protection of citizens and the environment. By doing so, the EFSA is discrediting its work and is losing citizens' trust in being considered an independent risk assessor.

IV Recommendations and requests

In order to address the issue of insufficient quality in EFSA’s work on glyphosate’s assessment, we kindly request to urgently take the following actions :

1. Review the summarised conclusions published on 6 July, in view of the highlighted shortcomings presented in this letter and ensure their alignment with your own definition of a CAoC, the provisions of the EU law and the relevant case law. Every situation where a risk assessment is incomplete according to the EU law, should be set as a CAoC. Where the scientific literature points at a potential risk, it should be set as a CAoC.

2. Request your legal unit to ensure that the output from EFSA is fully aligned with the EU law and the case law that has been developing since EFSA was created. From the elements detailed in this letter, it is evident that EFSA's publication is considerably below the level that EU citizens expect from a so-called independent EU agency, which is financed with taxpayers' money and whose aim is to produce opinions that prioritise the protection of citizens' health and the environment. This work is not aligned with your missions according to the GFL. EFSA's work on pesticides should be urgently updated and aligned with the provisions of the pesticide Regulation (EC) 1107/2009, the GFL, as well as with the case law published since the establishment of EFSA.

3. Act as an independent risk assessor. The framing of the EFSA conclusions must be aligned to the law and the case law, as well as be impartial. In particular, the framing of the conclusions must be aligned with the Regulation, as well as the case law on the precautionary principle, that obliges risk managers to take protective measures when a risk exists, even if its occurrence is uncertain. By presenting major data gaps (representative formulation, impurity, dietary exposure) and important independent scientific findings as acceptable, the EFSA suggests risk managers to take unlawful decisions.

It is not the first time that EFSA has lacked transparency, excellence in its work, as well as independence in its opinions, and we regret seeing this repeated in EFSA's communication on glyphosate. The EFSA has recently doubled its budget and still, we observe a lack of independence and respect of the law and the case law. We thus ask for your intervention to correct this regrettable and unacceptable situation. Not only it harms the trust of citizens in EFSA, but also undermines the overall confidence in EU institutions and decision-making process regarding pesticides.

Thank you in advance for your consideration.

Best regards,

Angeliki Lyssimachou
Head of Science and Policy

Martin Dermine
Executive Director