PAN Europe's feedback on Commission's public consultation:

European Food Safety Authority – evaluation of performance 2017-2024

BACKGROUND

The European Food Safety Authority (EFSA) was established in 2002 in compliance with Regulation (EC) No 178/2002 on the General Food Law, known as Founding Regulation, to provide **scientific advice and scientific and technical support** for the Community's legislation and policies related directly or indirectly with food and feed safety (Article 22(2)). **All advice and information must be independent** and **shall contribute to the high level of protection of humans, animals and the environment**. Article 61 of the Founding Regulation requires that EFSA goes through regular independent evaluation. Following the recent update with the adoption of the Transparency Regulation in 2019, the Commission shall evaluate by 2026 EFSA's performance in relation to "*its objectives, mandate, tasks, procedures and location, in accordance with Commission guidelines*", and every 5 years. In this respect, the Commission has launched a public consultation to collect evidence.

Considering the key role that EFSA has in the assessment of pesticides, as well as in the production of opinions, guidance documents and risk assessment methodologies, in this document PAN Europe provides its feedback on EFSA's performance during 2017-2024.

EFSA MUST STAY TRUE TO BEING SCIENTIFIC, INDEPENDENT AND TRANSPARENT

PAN Europe supports the mission of EFSA. The EU needs an independent & transparent scientific agency to support the decisions about the protection of human and animal health, the environment, its resources and ecosystems from chemical pollution including that of pesticides.

Pesticides, particularly the synthetic ones, may cause cancer, toxicity to reproduction, neurodegenerative diseases and other serious disorders, even in small amounts. Environmental species are at high risk, as pesticides are sprayed on open fields. Taking this into account, in 2009, Europe adopted a landmark regulation (Reg (EC) 1107/2009) to prevent all human contact with

pesticides that may cause harm and protect the environment from potential adverse effects. In case of scientific uncertainty, the precautionary principle should be implemented.

EFSA plays an important role in delivering scientific methodologies and guidances to correctly implement the EU law, assess objectively the risks based on all available science and provide the required high level of protection from pesticides. EFSA should examine all scientific evidence from scientific literature, and objectively highlight the identified risks, as well as the uncertainties enabling risk managers to take the most protective decisions, including to apply the precautionary principle.

EFSA's support should be purely scientific, without taking into consideration economic or political factors. It should remain independent from the influence of the food industry or any party supported by the business sector.

Therefore, it is crucial to ensure that EFSA is an independent, scientific body that European citizens can trust, which prioritises the protection of their health and environment, before any other interest. EFSA must thus comply with its founding regulation, and its work must be in line with the pesticide regulation (EC) 1107/2009.

Below we provide evidence indicating the areas that EFSA should improve to become fully aligned with its mission, and with EU law.

EFSA needs to improve its independence

One of the crucial roles in the mission of EFSA is to be independent; its work should not be influenced by companies that have a commercial interest to place their pesticide products in the market and therefore would like to influence the decisions in relation to the approval of pesticides to protect their profit. We regret to see **that EFSA is still not fully independent from industry interests**, which significantly lowers the scientific excellence and objectivity of its work, and in many cases, results in providing 'misguidance' to risk managers. In 2012, the exposure of the collaboration of EFSA with industry sector, and particularly with scientists from the industry lobby International Life Sciences Institute (ILSI) resulted in the European Parliament voting against the approval of EFSA's budget. Some such scientists were in the management board of EFSA. EFSA adopted an independence policy to set some basic rules in relation to its collaboration with scientists with conflict of interest, such as setting cooling off periods for experts involved in certain activities and submission of conflict of interest declarations. An analysis in 2018 showed that nearly half (46%) of all experts sitting on the scientific panels of EFSA were still in a direct and/or indirect financial conflict of interest situation with the agribusiness and food industries[1]. In 2017, this policy was strengthened further, nevertheless collaboration with experts involved in ILSI or

[1] Corporate Europe Observatory, 2017. "Recruitment Errors" https://corporateeurope.org/en/efsa/2017/06/recruitment-errors

in other activities in the industry sector is still permitted to an extent and is influencing EFSA's work.

In 2018, research carried out by PAN Europe on the different methods and approaches used in pesticide risk assessment at EU level, showed that **11 out of 12 were originally designed or promoted by the pesticide industry (92%)**[2]. Such methods are used to dismiss tumours observed in animal toxicity testing of pesticides, to approve the presence of carcinogenic pesticides in our food, to classify polluting pesticide metabolites in groundwater as 'irrelevant', to allow the dying of 50% of the insects in every spraying application, to construct 'safe' levels for harmful pesticides without any experimental evidence. In most of these cases it was EFSA who drafted the guidelines on these risk assessment methodologies, which ultimately lower the protection of public health or the environment, permitting the approval of pesticides that can cause harm. In 75% of the cases, the ILSI industry lobby group, not only designed the methods but their experts managed to infiltrate regulatory panels of EFSA and global WHO to get these methods adopted. In 50% of the cases studied, EU regulators and EFSA had exclusive meetings with industry on the methods, excluding other stakeholders such as NGOs.

In 2021, PAN Europe did a background check and found that **several of the members of the management board of EFSA still had links to the industry sector**, either worked for chemical or food industry, and very few had carried out experimental or research work (based on scientific publications)[3]. The selection of these members, despite their declarations of interests that prejudice their independence, leads to decisions that are not in line with Article 37 of EFSA's Founding Regulation, which mandates that the members of the management board and the executive director **act independently in the public interest**.

In a recent paper, PAN Europe together with other scientists and legal experts highlight these EFSA independent issues and provide recommendations for improvement[4].

EFSA must carry out objective scientific & technical assessment

The key mission of EFSA is to provide scientific advice and scientific and technical support for the community's legislation and policies, be independent in all matters and communicate the risks. Its task is to provide "the best possible scientific opinions", "interpretation and consideration of

[2] Pesticide Action Network Europe, 2018. "Industry writing its own rules" https://www.pan-europe.info/press-releases/2018/02/industry-writing-its-own-rules

[3] Pesticide Action Network Europe, 2018. "EFSA Science or ideology?" https://www.pan-europe.info/press-releases/2021/06/new-report-dangerous-pesticides-given-flawed-eu-safety-clearance-fresh

[4] Robinson et al. Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions. European Journal of Risk Regulation. 2020;11(3):450-480. doi:10.1017/err.2020.18

risk assessment opinions", and "express independently" its own conclusions (Article 23; Reg. 178/2002).

Evidently, close collaboration with the food or chemical industry has compromised the objectivity and independence of EFSA's work to a degree, significantly diminishing the integrity of its scientific evaluations and assessments. While the work of EFSA finally contributed to the non-renewal of dangerous pesticides that had been in the market for many years (e.g. chlorpyrifos and chlorpyrifos-methyl, mancozeb & thiacloprid), others still remain in the market partly because EFSA failed to highlight objectively the adverse effects reported in the independent scientific literature (2,4-D, glyphosate, lambda-cyhalothrin) or overestimated the impact of the mitigation measures (e.g. captan, cypermethrin, abamectin). Moreover, as mentioned previously, the designing of risk-assessment methodologies and approaches in collaboration with the industry sector has "standardised" the approval of pesticides that should otherwise be banned, if the EU law was to be implemented correctly.

Below we provide evidence showing that EFSA's work has not been scientifically "objective" but has been influenced by political opinions.

Margin of Exposure particularly for genotoxic carcinogens substances.

The industry promoted method of Margin of Exposure (MoE) was incorporated in EFSA's work in 2005, when experts did not have to provide a conflict-of-interest declaration, and many had ties with the industry (e.g. ILSI)[5]. This approach ultimately permits low levels of substances that are both genotoxic (damage DNA) and carcinogens to be present in food because at this exposure level they are considered 'safe'. The MoE level for non-genotoxic carcinogens was set arbitrarily at 10,000 based on an animal study. The problem with this approach is twofold. First, MoE derives from toxicity or carcinogenicity tests that use adult animals and high levels of exposure, therefore neglects exposure during the vulnerable early life stages to lower doses. Second, this approach indirectly permits the use of these substances in the field, neglecting the impact to other non-target species. Today, EFSA (2023) still proposes the use of MoE for genotoxic carcinogens, below which the public concern is considered low and therefore of a low priority for risk management actions. This permits indirectly the presence of dangerous pesticide metabolites in food or the environment, that should otherwise be banned according to the UE law. In 2021, PAN Europe highlighted the approval of at least 12 pesticide active substances that give rise to carcinogenic metabolites[6].

The MoE also applies for substances that are neither genotoxic nor carcinogenic, but in this case the exposure ratio is 100, which is also arbitrary.

[5] Pesticide Action Network Europe, 2018. "EFSA Science or ideology?" https://www.pan-europe.info/press-releases/2021/06/new-report-dangerous-pesticides-given-flawed-eu-safety-clearance-fresh

[6] Ibid p.22 table 4

Other scientific integrity issues in relation to MoE, Threshold of Toxicological concern (TTC), and the evaluation of carcinogenic and/or genotoxic substances are presented in our 2021 report.

Assessment of Mixtures of Pesticides: Industry involvement & misleading conclusions.

Addressing cumulative (additive) and synergistic effects of pesticides and their residues is a legal requirement in Europe since 2005 [Reg. (EC) 396/2005 and later Reg. (EC) 1107/2009] that has not yet been implemented. Instead, the safety of a pesticide is still based on the assessment of a single substance, which is highly unrealistic. More than 30% of EU food contains at least one pesticide, and up to 15 different pesticides can be detected in a single fruit.

Since the beginning of EFSA's work on cumulative risk assessment (CRA) in 2006, industry has been very interested in the topic. Already in 2011 (A toxic mixture[7]) and later in 2014 (A poisonous injection[8]), PAN Europe criticised the involvement of industry-linked scientists in EFSA's expert panels and groups working on CRA, as well as in the EU-funded research programme ACROPOLIS, where probabilistic models to assess cumulative pesticide exposure were developed. The involvement of industry-linked scientists (e.g. ILSI) in the management board and scientific panels is what resulted in EFSA's budget being suspended for 6 months.

Although experts that were working in parallel in the industry sector were removed from EFSA because of the conflict of interest, former industry-employees remained and are still involved in CRA methodology. In the meantime, the research programme ACROPOLIS, was refunded and continued under the name EuroMix with partners some of the same experts that were removed from EFSA panels due to conflicts of interest. Many of the methods developed in this period (e.g. margin of exposure, considering potency of chemicals in cumulative risk assessment groups, probabilistic modelling) were the basis of EFSA's CRA pilot studies published in 2020.

Despite the extensive work carried out by EFSA staff on the cumulative assessment of pesticide residues in food, the results of the two pilot studies published in 2020, were far from reassuring. The studies examine the risk of dietary exposure to pesticides mixtures for acute effects on the nervous system and chronic effects on the thyroid, and they're hypothetical: no experimental studies using pesticide mixtures have taken place. They only look at cumulative (additive) effects based on common toxicity pathways, but do not look at synergistic effects (magnifying). For the first study, it's puzzling why EFSA selected to investigate the acute toxicity of pesticides, found as residues in food, on the nervous system of consumers, since this is not a probable exposure/risk scenario (acute toxicity is normally investigated in farm workers who might be exposed to high levels of pesticides in the field or through handling of pesticide products). For both studies, we

[7] https://www.pan-europe.info/old/Resources/Reports/PANE%20-%202011%20-%20A%20Toxic%20Mixture%20-%20Industry%20bias%20found%20in%20EFSA%20working%20group%20on%20risk%20assessment%20for%20toxic%20chemicals.pdf

[8] https://www.pan-europe.info/old/Resources/Reports/PANE%20-%202014%20-%20A%20Poisonous%20injection.pdf

were surprised to find out that (1) only the studies provided by the industry were taken into consideration (all independent literature was excluded) and (2) the most recent and sensitive tests were excluded from the assessment as these were not available for all the pesticide substances included in the study (e.g. neurodevelopmental toxicity and extended one generation reproductive toxicity tests are excluded). Excluding independent peer reviewed scientific literature, that often examines impact at lower doses of exposure, is concerning, particularly for the thyroid study, as it assesses the risk of chronic exposure to pesticides. Therefore, by omitting the most sensitive studies performed at lower doses the conclusion is bound to be biassed. Interestingly, EFSA's study found a risk, even using as a reference old industry studies and MoE of 100. Nevertheless, EFSA 'corrected' these risks by applying an "uncertainty" analysis, communicating to risk managers that the pilot studies showed no cumulative chronic risk for thyroid toxicity.

These inadequate cumulative risk assessment studies not only have major limitations but also offer misleading guidance to risk managers, suggesting that there is no risk from exposure to mixtures of pesticides. As a result, no action is taken. Meanwhile, vulnerable groups within our population are exposed to mixtures of pesticides along with other chemicals daily, potentially contributing to the rise of certain diseases, such as endocrine cancers and neurodegenerative diseases.

Neurotoxicity still not properly assessed

With Parkinson's disease on the rise, along with other neurodegenerative disorders, it is important to update the current assessment of pesticides to ensure that farm workers, residents of agricultural zones and particularly children, are not exposed to pesticides that can cause neurotoxicity. France and recently Germany, recognise Parkinson's as an occupational disease for professional users of pesticides. It is unacceptable that the current data requirements for pesticides are inadequate to assess safety for Parkinson's, or neurological disorders in children.

In an EFSA conference organised in September 2022 with experts on neurobiology, there was broad consensus that "*the currently existing procedures, that are part of existing regulatory actions, are likely to give us an inadequate insight into the actual neurotoxic actions of specific pesticides for the substantia nigra, and consequently, offer an inadequate assessment of the risk of developing Parkinson's disease in case of human exposure*." Further it was highlighted that "*Additionally, there are clear ideas on how to perform experiments that will inform an improved screening procedure; this involves both improved in vivo experiments and the search for reliable in vitro alternatives*."

EFSA launched a call for tender that, surprisingly, does not include any of these research suggestions or developments, and therefore will not contribute to improving the assessment to better capture the onset of neurodegenerative diseases[9]. On the contrary the call focuses on non-animal testing methods that will need several years to be developed, and validated against *in vivo* testing. In the meantime, neurotoxic pesticides remain in the market and the number of scientific

[9] PAN Europe, 2023. Blog article https://www.pan-europe.info/blog/efsa-scandal-management-sabotages-effective-pesticide-neurotoxicity-assessment

studies linking exposure to pesticide with neurological disorders and diseases in children or adults is increasing.

Glyphosate- risks not properly assessed nor communicated

PAN Europe has expressed its disagreement with the EU assessment of glyphosate on several occasions, including in relation to the EFSA's conclusions on the peer review of glyphosate risk assessment[10]. Our criticism of EFSA's work is both on the scientific quality as well as on the communication to risk managers, which failed to highlight the real risks in relation to the assessment of glyphosate. In its conclusion EFSA states that the approval criteria of Article 4 (1-3) of Pesticide Regulation (EC) 1107/2009 are met, which means that it has been proven that the active substance (glyphosate), as well as its residues and product (at this stage, the representative formulation) cause no harm to human (including vulnerable groups) and animal health and no unacceptable effects to the environment, considering biodiversity and ecosystems. PAN Europe demonstrated that the EFSA does not respect the Pesticide Regulation (EC) 1107/2009.

This statement is misleading for the following reasons:

The risk assessment failed to demonstrate that exposure to the representative formulation is safe

First, the Blaise ruling states explicitly[11] 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.

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[10] See for example (1) PAN Europe letter to EFSA July 13th 2023 https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/Letters/Letter%20to%20B.%20Url%20on%20EFSA%27s%20main%20findings%20on%20glyphosate.pdf

(2) PAN Europe letter to EFSA September 2023 https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/Letters/20230926%20Answer%20to%20EFSA%27s%20reply%20to%20PAN%20E%20glyphosate%20observations.pdf

(3) 15 NGO letter to Commissioner of Health and Food Safety Kyriakides September 7th 2023 https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/Letters/CSO%20letter%20to%20Kyriakides%20-%20oxidative%20stress%20critique%2007092023.pdf

(4) 106 NGO letter to Commission President Von der Leyen November 14th 2023 https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/Letters/14%20Nov%202023%20Open%20letter%20from%20106%20organisations%20-%20Stop%20the%20re-approval%20of%20glyphosate%20in%20light%20of%20new%20scientific%20evidence%20on%20cancer%20risk.pdf

(5) Request for Internal Review https://www.pan-europe.info/press-releases/2024/01/ngos-initiate-legal-challenge-against-eu-glyphosate-re-approval

[11] 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

According to EFSA, there is an absence of information on short- and long-term toxicity of one of the components of the formulation, a co-formulant. As an argument, EFSA states that there were no indications of acute toxicity or carcinogenicity, which is misleading as no long-term carcinogenicity test has been carried out on the representative formulation. Only 2 in vitro tests have been performed by the applicant. In fact, the only available study in vivo with the representative formulation is the one from the Global Glyphosate Study that shows that life-cycle exposure of rats to this glyphosate formulation causes leukaemia deaths starting from young age[12].

Furthermore, there were indications that an impurity of the active substance may have genotoxic potential, but this was not investigated further by EFSA.

Neglecting to thoroughly assess the cancer potential of glyphosate formulations is unacceptable particularly since studies from the scientific literature have linked exposure to glyphosate to cancer. Communicating that there is no cancer risk to risk managers, despite the large number of studies indicating the opposite is misleading.

Neurotoxicity of glyphosate not sufficiently investigated by the applicant

EFSA acknowledges that the public literature indicates neurotoxicity from some Glyphosate Based Herbicides (GBHs), these link exposure to GBH with Parkinson's disease and autism spectrum disorders in humans, and related adverse effects in animal experiments. Moreover, there was a developmental neurotoxicity (DNT) study on a non EU-approved glyphosate salt, which clearly shows risk to the unborn. Worryingly this study was not originally disclosed by the applicants. Considering the absence of a DNT study for glyphosate acid and any long-term health toxicity studies for the formulation in the applicant's dossier, EFSA should have clearly communicated the risks identified to the risk managers and that the approval criteria for glyphosate are not met.

Glyphosate impacts microbiome

EFSA reports that effects of glyphosate 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 following glyphosate exposure. The absence of internationally agreed guidelines is in our view not a valid argument to not conclude on the wide range of available

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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."

[12] Global Glyphosate Study https://glyphosatestudy.org/press-release/global-glyphosate-study-makes-leukemia-data-publicly-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 risks for human and non-target species and conclude that the approval criteria of the Pesticide Regulation are not met.

Glyphosate impacts biodiversity

From bee colonies, fish, amphibians, birds, plants and algae, exposure to glyphosate and/or GBH has been linked to adverse effects that may affect population and therefore biodiversity[13]. EFSA acknowledges 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 high volume of scientific studies highlighting the negative impact of glyphosate and GBHs on biodiversity at field-realistic concentrations, it is incomprehensible how EFSA concluded that approval criteria of the Pesticide Regulation are met. 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 non-renewal of the approval of glyphosate. 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.

These two examples (risk assessment of the impact of glyphosate on biodiversity and microbiota) illustrate a systematic lack of compliance with EFSA's founding regulation, as well as the pesticide regulation. Indeed, even if thousands of scientific publications point at the toxicity of a pesticide, EFSA hides behind the absence of internationally-agreed guidelines to disregard independent science. Considering the proportion of PhD staff in EFSA, it is highly worrying to observe that the EFSA refuses to assess the available scientific knowledge in order to provide risk managers and citizens an up to date information. Instead: the EFSA prefers basing its work on decades old industry studies.

[13] See summary https://stopglyphosate.eu/why-ban-glyphosate/biodiversity/

Transparency

Transparency is at the core of EU legislation. According to the Aarhus Regulation 1367/2006, it is the Citizen's right to have access to information that relates to emissions to the environment and public health. European citizens should know what they and their environment are exposed to.

Experience up to date, has shown that by keeping the industry studies secret, may result in the potential toxicity of substances being kept concealed, leading to otherwise dangerous substances receiving market approval.

This has been the case with neurotoxic pesticide chlorpyrifos. Chlorpyrifos was banned in Europe thanks to the review of the industry 1998 DNT study by independent experts, with expertise in the field of neurotoxicity[14]. The experts however managed to get access to the study through freedom of information in the US and not Europe, as during that time the EU kept the industry studies undisclosed. The experts scrutinised the study and found an error in the reporting of the adverse effects observed in young pups; by correcting the errors the study was showing clear dose-response adverse effects in newborn rats. It was concluded that the substance fulfilled the criteria to be classified as reprotoxic category 1B (causing harm to the unborn). Therefore, in 2020, chlorpyrifos and its structural analogue chlorpyrifos methyl, were finally banned from the EU market. This means that for 22 years these substances remained in the market despite having an animal study where neurotoxicity had been found. To our knowledge, Dow Chemicals has not faced criminal charges for this 'error,' despite the fact that pregnant women and children continued to be exposed to this dangerous substance for two additional decades.

This is a clear indication why industry studies that form part of the risk assessment of pesticides should be disclosed to allow scrutiny from independent experts.

A recent investigation showed that it is common for companies to submit studies to the US EPA during the course of pesticide risk assessment but not to the EU[15]. More specifically, the authors found that out of the 35 DNT studies on pesticide active substances submitted to the U.S. EPA with the corresponding EU dossiers available, nine DNT studies (26%) were not disclosed by the pesticide company to EU authorities. For seven of these studies, the authors identified an actual or potential regulatory impact. This investigation was possible because of the transparency in toxicity studies in the U.S.

The transparency regulation, which took effect in March 2021, applies only to pesticide approvals submitted after that date. Considering that application dossiers must be submitted at least three years before the expiration of their market licence—and often receive extensions due to procedural

[14] Mie et al 2018. Safety of Safety Evaluation of Pesticides: developmental neurotoxicity of chlorpyrifos and chlorpyrifos-methyl. Environ Health 17, 77 (2018). https://doi.org/10.1186/s12940-018-0421-y

[15] Mie, A., Rudén, C. Non-disclosure of developmental neurotoxicity studies obstructs the safety assessment of pesticides in the European Union. Environ Health 22, 44 (2023). https://doi.org/10.1186/s12940-023-00994-9

delays—the current peer review conclusions of EFSA are based on substances submitted before 2021. As a result, their toxicity studies remain undisclosed. Therefore, it is too early to assess the impact of the transparency regulation on the disclosure of toxicity studies, though its effect is expected to be undoubtedly positive.

Regular disrespect of EU law and case law

As already mentioned previously, the EFSA in many instances, does not respect EU pesticide regulation (EC) 1107/2009 and the case law.

Example 1: Article 4 from the pesticide regulation foresees that EFSA publishes a peer review (i.e. scientific conclusions) on all aspects of toxicity of pesticides. In particular, some 'cut-off' criteria such as Carcinogenicity, Mutagenicity, Toxicity to Reproduction, Genotoxicity or Endocrine Disruption must be assessed in order to avoid citizens from being in contact with such substances.

PAN Europe has regularly identified that the EFSA accepts to provide a Peer review that presents major gaps with regards to what is planned in the pesticide regulation. Instead of concluding that the lack of data in the file does not allow the EFSA to conclude on any safe use of the pesticide, the EFSA presents as a simple 'data gap' the lack of information on major toxicity endpoints such as genotoxicity or toxicity to the environment (e.g. latest EFSA peer review on cypermethrin or on glyphosate).

Example 2: the case law foresees that any information showing that a pesticide might not fulfil the safety criteria foreseen in the pesticide regulation must lead to a reaction by risk managers and an implementation of the precautionary principle (Blaise *et al.* ruling, 2019). With its "Weight of Evidence" approach, the EFSA hides valuable and recent scientific information produced by academia, as they are outnumbered by industry studies. By doing so, the EFSA fails to communicate to risk managers this recent information and prevents risk managers from implementing the pesticide regulation, as specified in the Blais ruling.

Example 3: By establishing different categories in the way they provide the results of their Peer review (Critical Areas of Concern - CAoCs, Data gaps, Outstanding issues), the EFSA presents to risk managers its findings with different levels of importance. CAoCs are presented as "red lights" while a series of data gaps or outstanding issues are presented as acceptable to risk managers. This is in complete contradiction with EU law. Indeed, the EU pesticide regulation foresees that a (re-)approval dossier submitted by the industry must be complete. So the data gaps, as identified by EFSA, in most cases, should be presented as CAoCs (red lights), as it shows the dossier was incomplete and a complete risk assessment is not possible, according to the pesticide regulation. By doing so, EFSA promotes a low-level protection of citizens and the environment, and maintains the habit of industry to provide incomplete dossiers to risk assessors.

Lack of respect of legal deadlines to provide documents based on the Aarhus Regulation

In most instances, EFSA does not respect deadlines for the provision of information when PAN Europe runs an Access To Documents, under the Aarhus regulation. PAN Europe then needs to write and write to obtain documents with many months delay. Proofs can be provided upon request.

Lack of engagement with stakeholders to discuss scientific issues

In a series of instances (examples can be shared upon request), PAN Europe has tried to engage with EFSA on scientific issues related to a series of issues. Instead of replying to our scientific arguments, EFSA sent us a very general reply, not addressing our arguments, disregarding the science we had put forward. Only after sending a second letter, would EFSA start to engage, but always superficially.

Considering that EFSA is the only risk assessor with regards to a series of chemicals, it is highly problematic that the Authority refuses to engage in true scientific debates. This maintains a situation of confrontation and distrust.

Lack of acknowledgement of its lack of scientific expertise in a series of domains

In a series of areas, EFSA does not have in-house scientific expertise. The neurotoxicity example has been presented previously. Another example is the fact that EFSA lacks agronomic skills. EFSA was requested twice to provide to the Commission a scientific opinion on "derogations" given to neonicotinoid insecticides[16]. In both instances, it was evident that the EFSA carried out a "tick-the-box" administrative exercise, without any agronomic knowledge, validating a series of derogations for which there were alternatives and neonicotinoids were not necessary. Once again, the EFSA refused to engage in a discussion on how to obtain agronomic expertise from other national or European agencies. While it is acceptable that the EFSA cannot have in-house high-level experts on all matters related to the risks posed by food, pesticides, etc., it is unacceptable that the agency does not acknowledge the limitations of its knowledge and accepts to carry out scientific work for which it is not competent.

Lack of efforts to obtain the best scientific experts in EFSA panels

A series of points discussed previously highlight a recurrent lack of efforts by the EFSA to involve the best scientists in its panels. Those should be properly remunerated for the time it takes to prepare and attend the meetings. A minimum (and recent) record of publications should be demanded in order to ensure that the best available experts are involved.

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16 https://www.pan-europe.info/press-releases/2018/06/efsa-shows-its-scientific-limits-providing-low-quality-assessment-national

https://www.pan-europe.info/press-releases/2021/11/neonicotinoids-efsa-gives-blank-cheque-member-states-keep-abusing-toxic

Lack of use of self-mandates, lack of commissioning of scientific studies

The EFSA has the opportunity to produce self-mandates. PAN Europe observes an absence of use of this possibility to improve its risk assessment.

In the same vein, in case of doubt, the EFSA is allowed to commission its own studies on the toxicity of a substance. Even for highly toxic pesticides, PAN Europe observes that the EFSA never made use of this possibility to better investigate a risk or the hazard of a substance. In most cases EFSA appears to have a passive approach, waiting for the Commission to send them a mandate.