GAPS IN THE EU PESTICIDE AUTHORISATION

A review of implementation four years after European Parliament recommendations

Pesticide Action Network Europe

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Summary

In 2019 the PEST Committee in the European Parliament concluded after 9 months of investigations, hearings, missions and commissioning of studies that the current system of pesticides authorisation is failing to achieve its purpose, highlighting the need for urgent change. The Committee report listed 116 recommendations calling for independence, objectivity, transparency and better use of science in the whole procedure, in order to achieve the high level of protection required by the EU pesticides Regulation. The report was endorsed by the European Parliament (European Parliament resolution, 2019).

According to PAN Europe's analysis, to date:

- 15% of the PEST recommendations have been sufficiently implemented,
- 28% of the PEST recommendations have either been partly or insufficiently implemented, or the work is ongoing (and its outcome remains uncertain),
- 57% of the PEST recommendations have not been implemented or the implementation has not led to the requested improvement. In a few cases, the situation got worse.

We conclude that both health and environment are seriously at risk by the current pesticide use. Our roadmap describes 10 priorities that urgently need to be addressed to meet the level of safety required by EU regulation.

INTRODUCTION

Background:

The EU pesticide regulation (EC) 1107/2009 is, in theory, one of the strictest regulations in the world. Its purpose is to ensure a high level of protection for humans, animals and the environment. Nevertheless, many potentially harmful pesticides remain on the EU market. This received publicity in 2017 with the re-approval of glyphosate in the EU, the active ingredient of the most used herbicide products in the world, exposure to which has been linked to cancer in humans and to environmental degradation.

During that time a series of events took place that raised concerns across EU citizens about the reliability of the whole risk assessment procedure. Scientists, civil society groups and legal experts published a 'White Paper' coordinated by PAN Europe, exposing a series of scientific and procedural misconducts in the assessment of glyphosate and other pesticides in Europe. On the other side of the Atlantic, internal documents and emails of Monsanto, - known as "Monsanto Papers"- that were released in the course of US litigation cases against the company, revealed that Monsanto had ghostwritten scientific papers, hidden evidence that glyphosate causes cancer and launched a campaign to discredit independent scientists. In the meantime, a successful European Citizens' Initiative brought to the EU decision-makers the demand of over 1 million people calling to ban glyphosate, reform the risk assessment procedure and set pesticide reduction targets towards a pesticide-free future. To respond to all the concerns raised by Europeans, the European Parliament set up in 2018 a Special Committee to investigate the authorisation procedure for pesticides (thereafter the PEST committee).

"in the light of the concerns raised by several stakeholders about the assessment of glyphosate, the Special Committee on the Union's authorisation procedure for pesticides (PEST) aims to identify areas that can be further improved with regard to the Union authorisation procedure for plant protection products, by providing recommendations that it considers to be necessary in order to ensure the achievement of a high level of protection of both human and animal health and the environment" (recital B, PEST resolution)

After 9 months of investigations, hearings, missions and commissioning of studies, the Committee concluded in 2019 that the current system is failing to achieve its purpose, highlighting the need for urgent change (recital F). The PEST Committee report listed 116 recommendations calling for independence, objectivity, transparency and better use of science in the whole procedure, in order to achieve the high level of protection required by the EU pesticides Regulation. The report was endorsed by the European Parliament (European Parliament resolution, 2019).

Among the recommendations, the PEST resolution calls to:

- Apply the precautionary principle throughout the pesticide authorisation procedure to ensure that pesticide products that enter the EU market do not cause harm to humans, animals and the environment.

- Establish a strong conflict of interest policy in the whole process and ensure independence and expertise of all European experts involved in the risk assessment procedure and development of guidelines
- Set up a post-market vigilant system of pesticide exposure, taking into account real-life exposures as well as a full implementation of the sustainable use of pesticides directive, giving priority to sustainable and ecological alternatives
- Ban the use of pesticides in areas used by the general public or vulnerable groups (schools, hospitals) as well as for crop desiccation that speeds up cereals' maturation

Four years have passed and with this work PAN Europe is assessing whether the PEST Committee recommendations were followed up by the Commission, the EFSA and Member States. Indeed with the European Green Deal and its flagship strategy Farm to Fork, the Commission has made pesticide reduction a priority. Nevertheless, questions remain on whether this has resulted in the improvement of the current pesticide authorisation procedure and the relevant legislations for the benefit of people's and environmental health.

This analysis is very timely as the EU institutions are negotiating the Commission's Sustainable use of Plant Protection Products Regulation proposal, which aims to reduce the use of chemical pesticides (hereafter referred to as Sustainable use of Pesticides Regulation or SUR). Such a proposal addresses several of the issues raised in 2019 in the PEST recommendations and shows how crucial this file is in building citizen's trust on the institutions.

SCOPE & METHODOLOGY

PAN Europe made a "state of play" of the recommendations of the PEST Committee resolution, to the extent that is possible for a civil society organisation in terms of transparency of the procedures. Due to the large volume of information to process, the current briefing is limited to what PAN Europe considered the most important areas for improvement, in the light of what was highlighted by the PEST Committee as well as by the Commission's European Green Deal. The scope is to increase the level of protection from pesticides, in line with the aim of the EU Pesticides Regulation (EC) 1107/2009 and general considerations of the European Parliament resolution (PEST):

"*the evaluation of the implementation of the Regulation has revealed that the objectives of protecting human and animal health and the environment are not being fully achieved and that improvements could be made in order to achieve all the objectives of the Regulation*;" (recital F, PEST)

"*concerns have been raised by several stakeholders about the assessment of glyphosate, in particular as to whether an independent, objective and transparent assessment has taken place, whether the classification criteria of Regulation (EC) No 1272/2008 have been properly applied, whether relevant guidance documents have been properly used and whether the approval criteria and the precautionary principle have been properly applied;*" (recital D, PEST)

Based on these highlights the presentation of the results is divided in 5 sections:

1. Setting a regulatory framework that drives pesticide-reduction and monitoring in the context of the EU Green Deal;
2. Addressing shortcomings in risk assessment to better assess the toxicity of pesticides;
3. Ensuring independent, objective and high-quality risk assessment;
4. Respecting the precautionary principle and the high level of protection of human health, animal health and the environment, as defined in EU law;
5. Addressing transparency shortcomings obstructing public scrutiny in pesticide authorisation procedures.

RESULTS & DISCUSSION

There were 116 recommendations in the PEST resolution. Out of these, six were not actual recommendations and one was unclear and was excluded, resulting in a total of 109 actual recommendations analysed by PAN Europe. Most of these recommendations target both Member States and the Commission, some involve EFSA and sometimes the European Chemical Agency (ECHA). The recommendations primarily address the shortcomings in the implementation of the pesticide authorisation system outlined in the EU pesticides regulation, but a few of them refer to other pieces of legislations and policies relevant to pesticides.

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- 57% of the PEST recommendations have not been implemented or the implementation has not led to the requested improvement. In a few cases, the situation got worse.

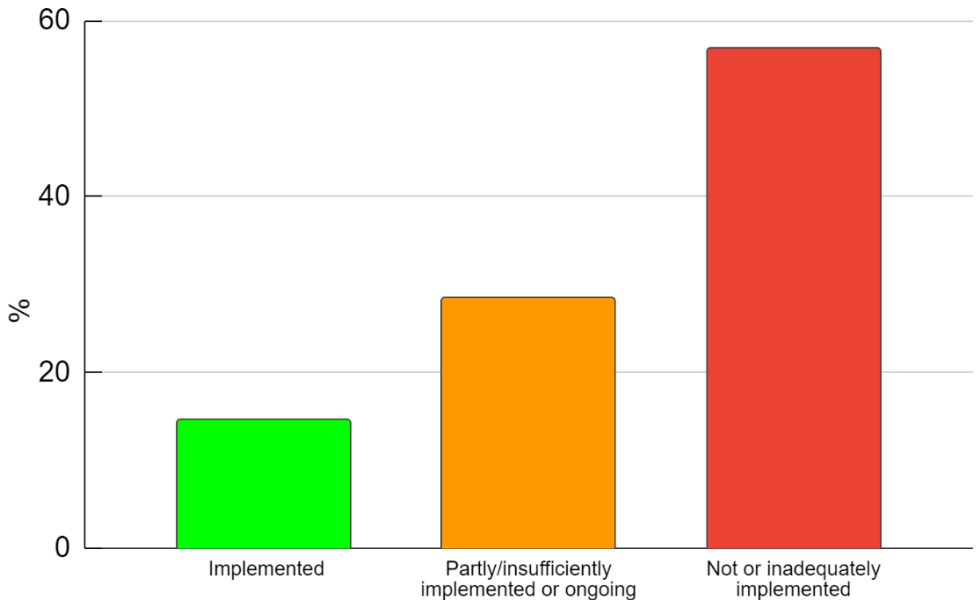

Figure 1 Percentage (%) of Pest Committee recommendations implemented, partly/ insufficiently implemented and not or inadequately imple mented between 2019 -2023 by the European Commission, Member States and European Food Safety Authority (PAN Europe analysis)

With the proposed Commission proposal for a regulation on the sustainable use of pesticides (SUR), an additional proportion of 7% of the recommendations would be implemented, including the one calling for a ban of pesticide use in areas used by the general public.

1. Setting a regulatory framework that drives pesticide reduction and monitoring in the context of the EU Green Deal

The demand to have "pesticide use statistics further improved" (15) has been implemented by updating the rules on compiling statistics for EU farming in the context of the statistics on agricultural inputs and outputs (SAIO) Regulation (EU) 2022/2379. From 2025, data on the active substances marketed and used in agricultural activities, in particular crops and treated areas , will be collected. However, this data will only be published as from 2028.

The Commission has also followed up on the demand to facilitate the approval of low-risk substances of biological origin (88) by updating the approval rules for active substances to incorporate micro-organisms that are naturally occurring. These new rules are applicable from November 2022. In complement, Horizon 2020 and Horizon Europe support resear ch and innovation projects on this sustainability transition (23).

The demands to "no longer allow the use of pesticide products in areas used by the general public or by vulnerable groups" and to "end the application of all pesticides over long distances in the vicinity of schools, childcare facilities, playing field, hospitals and care homes" (13,14) are now incorporated by the Commission in its proposal for a Regulation on the Sustainable Use of Pesticides (SUR). The latter proposal however answers poorly the call for "specific measures for the effective protection of vulnerable groups" (14) by proposing to set buffer zones no broader than three metres[1], which is insufficient to avoid exposure of such groups.

PAN Europe noted that the demand to "no longer approve active substances and plant protection products for desiccation" (12) and the calls in favour of a post-market vigilant system to monitor real-life impacts of pesticides to humans and the environment (16, 17, 19, 85) have not been acted upon. They could still be integrated in the Regulation on the Sustainable Use of Pesticides (SUR) in the context of the ongoing negotiations.

Moreover, the recommendation of the EU Parliament dealing with the adoption of maximum residue limits for the environment (55), has been inadequately addressed for surface waters, as only a

[1] PAN Europe recommends setting the distance of buffer zones to at least 100 metres around sensitive areas and at least 50 metres around houses, gardens and roads.

limited number of authorised pesticides have been included in Commission's proposal for a Directive, whereas for soils it must still be addressed in the context of the EU Soil Strategy. This Strategy calls indeed for a reduction "*by 2050 of soil pollution to levels no longer considered harmful to human health and natural ecosystems and respect the boundaries our planet can cope with*". To that end, the setting of common thresholds is raised in the context of the forthcoming Soil Health Law. The recommendation could therefore be implemented by integrating to that Law mandatory thresholds for pesticide residues and their metabolites in soil (individual and total concentration) as well as monitoring programmes.

2. Addressing shortcomings in risk assessment to better assess the toxicity of pesticides

The EU pesticide Regulation (EC) 1107/2009 requires pesticide companies to assess the safety of their products and their components for a range of adverse effects on specific exposed groups (operators, consumers, etc.) or living organisms, through mammalian risk assessment and environmental/ecotoxicity risk assessment. Some important aspects of this assessment are insufficiently covered since the Regulation has entered into force, and hence a series of recommendations address this issue. Among them, to complete or update the required methodologies and data requirements for risk assessment foreseen by the regulation. More specifically, the European Parliament asked for: a full assessment of environmental risks (54, 59, 61, 62), the developmental neurotoxicity potential (21), cocktail effects (62, 63, 64) and long-term effects (59, 81, 96).

- *Environmental effects (ecotoxicology and fate/behaviour into the environment)*

The progress made to improve the environmental risk assessment is either extremely limited or problematic. Before the publication of the PEST report, the Commission and EFSA had already started working on an overarching environmental risk assessment system called the "Specific Protection Goals" (SPGs) for ecosystem services. The aim is to address the requirement of the Regulation that pesticides should have no 'unacceptable effect' to the environment, taking into consideration their impact on biodiversity and ecosystems that so far is not adequately assessed. Therefore, the underlying idea of this approach is to set "protection goals" and acceptable thresholds of exposure for different species in the risk assessment. However, this approach only focuses on the protection of the parts of the ecosystem that deliver human services, which enable it to overlook harm to biodiversity against the scope of the EU pesticide regulation. Even more problematic, in the design of this system the Commission failed to ensure impartiality, independence, and objectivity in the recruitment of "SPG" experts, as confirmed by the Ombudsman in an enquiry by PAN Europe. Although this maladministration has now been rectified

by requiring conflict of interest declarations, the industry has already left its mark on the initial design of this overarching SPG system. The Commission was not capable of ensuring that the SPG system would protect biodiversity as a whole, as required by EU law. In practice, this SPG system has so far only been applied to bees. The guidance document on honey bees has now lowered the mortality threshold to 10%, instead of the original 7% which was set in 2013 but was never adopted by Member States, leaving the situation unchanged (62). The 10% acceptable mortality rate has been agreed by Member States after lengthy political discussions: it is a political decision not a science-based one. This can hardly be considered a successful implementation . According to NGO experts such a threshold should be set to 3% to ensure protection of bee colonies. EFSA is now working on SPGs for wild bees, but with significant delays, which still leaves wild bee species unprotected. Apart from bees, the only other guidance document that has been finalised was the one on birds and mammals, which hadn't been updated since 2009. Other than that there has been no progress on other species such as amphibians (no guidance document yet), terrestrial invertebrates other than bees (guidance document from 2002), or aquatic species (guidance document from 2015). If the Commission continues with its intention to roll out this system to all species, the work on guidelines will take decades and, considering what was highlighted above, will anyway fail to ensure the level of environmental protection required by the Regulation. Regarding fate and behaviour in the environment of pesticides, there has been sectorial progress on the revision of the guidance document on the relevance of metabolites in groundwater and a guidance document on aged sorption. However, there is still no guidance document on air pollution by pesticides, except for long-range transport, and no consideration for indirect effects.

- *Cocktail effects (cumulative and synergistic effects)*

As reminded by the Parliament in its resolution (AB, PEST), both the EU pesticide Regulation and the Maximum Residue Levels (MRL) Regulation (EC) No 396/2005 require cumulative and synergistic effects of pesticides to be risk assessed and prevented, "where the scientific methods accepted by the Authority (EFSA) to assess such effects are available". In 2005, EFSA thus started working on a pilot assessment which has been strongly criticised by PAN Europe for its great limitations. Namely, we pointed out the lack of sensitivity of the studies used in this 'assumption -based' methodology, designed with the involvement of the food industry, and which is expected to cover (only) dietary exposure. In its resolution, the Parliament called for the "completion (...) and rapid implementation of cumulative risk assessments" (63) and on regulators "to apply an extra safety factor when calculating the 'safe' dose of exposure, with a view to addressing potential mixture toxicity in cases of high remaining uncertainty" (64). These two recommendations have been insufficiently implemented. EFSA has not delivered any further assessment and is not expecting to deliver its methodology before 2030. Further, while the EU Chemical Strategy for Sustainability is proposing to apply a mixture factor on other chemicals, the Commission has so far refused to apply it to pesticides. As a result, almost 20 years after the MRL regulation, cocktail effects remain to be addressed in pesticide risk assessment.

- *Brain development effects*

The potential of pesticides to affect brain development is not systematically examined in the risk assessment, as neurotoxicity is not a 'cut-off' criterion for pesticide active substances in the EU and therefore, is not considered a priority in the assessment. This has not changed since 2019 as requested by the PEST Committee (21). In the meantime information continues to emerge on the potential of pesticides, particularly insecticides, to pass the blood brain barrier and affect early life development in humans leading to disorders and disease at a later age. Moreover EFSA, as well as European Commission's Joint Research Centre are focusing on the development of non-animal methods to be used in future risk assessment, nevertheless without validating those against the *in vivo* tests or real life situation to ensure they effectively detect neurotoxicity, which raises concerns that these tests may lower the level of protection.

- *Long-term effects of pesticides- formulations and data gaps*

Pesticide products that are placed on the EU market are not as thoroughly assessed as active substances. For example, long term toxicity, carcinogenicity and reproduction toxicity studies are only carried out on pesticide active substances. However, pesticide products contain co-formulants that are added to enhance the efficacy of the active substance by increasing its bioavailability and toxicity. Moreover, certain co-formulants are not necessarily inactive and might also have toxic properties. According to the EU Court of Justice, Member States should ensure that products that receive market approval do not exhibit any long-term carcinogenicity and toxicity. Nevertheless, in contrast to this and against the recommendations from the PEST committee, the product formulations are still not tested for their long term impacts on human health (59) and the independent scientific studies on pesticide products that could provide information on long-term effects continue to be disregarded from the risk assessment of active substances (48). In terms of co-formulants, the Commission has followed up on the demand (87) to better regulate them by providing a Regulation listing 144 unacceptable co-formulants that can no longer be used in pesticide products and by setting harmonised criteria to identify further unacceptable co-formulants. However, the information on the toxicity of co-formulants remains very limited and in certain cases completely absent as no data requirements were adopted by the Commission to make this identification system practically workable. Indeed, it leaves these substances only regulated under the regulation (EC) 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), under which long-term toxicity studies are not required for the ones sold in low volumes. Similarly, with the current system, no toxicity tests are required on key species such as earthworms, honey bees or birds. As a result, the long term impact on human health and the environment of co-formulants remain largely unknown, which violates the requirements of the EU pesticides Regulation.

3. Ensuring independent, objective and a high-quality risk assessment

The demand emphasised the most by the Parliament is to increase the quality, objectivity and independence of the risk assessment carried out by Rapporteur Member States and EFSA.

- *Independence*

To ensure independence, the resolution specifically calls for the adoption of strict policies for the prevention and management of conflicts of interests by rapporteur Member States (36), by EFSA and national experts seating in EFSA's bodies (71, 72, 73) and by the national experts and Commission in comitology (80). Most of these recommendations have been left without action. Indeed, the decision to adopt an independence policy for their national authorities remains at the discretion of each Member States. No minimum harmonised requirements have been proposed since the publication of the PEST report. Likewise, experts of these competent authorities participating in EFSA's work are still exempted from EFSA's independence rules. Furthermore, we observe that applicants can still choose their rapporteur Member States when applying for the first time for approval of a substance, contrary to the Parliament's demand for this designation to be made by the Commission (34).

At EFSA's level, the rules within its "independence policy" have remained unchanged compared to 2019. Members of EFSA scientific committees, panels, working groups, candidates to call for tenders, participants to peer review processes appointed or representing Member States must communicate to the Authority a Declaration of interest of the 5 recent years and must respect a "cooling off" period of only 2 years. Nevertheless they can be involved in research where 25% of the funding could come from the private sector. However, hearing experts, observers and experts representing the views of Member State authorities or international organisations are not subject to these rules.

Finally, while the Commission's independence policy applies to its staff working in comitology, national representatives in the Committees chaired by the Commission are not subject to any conflict-of-interest restrictions.

- *Endorsement of independence literature*

According to the PEST committee, equivalent weight should be given to the findings from scientific peer reviewed literature and those from industry-sponsored studies carried under Good Laboratory Practice (GLP) conditions (44), which has not been the case. This is evident in the ongoing assessment of glyphosate, where results from industry-sponsored studies overrule the results from the scientific literature; this was very clear in the case of the genotoxicity assessment. Furthermore, during the ECHA's hazard assessment of glyphosate, the authorities dismissed all arguments brought forward from independent scientists on: (a) key OECD genotoxicity studies that were missing that could provide important information (b) tumour incidents in animal cancer studies and (c) oxidative stress and its importance in the development of cancer. All this took place despite epidemiology studies from independent literature indicating a potential link between glyphosate and certain types of blood cancer for glyphosate users. In the case of glyphosate, the Commission did not follow up on the PEST recommendation to carry out a systematic review on the carcinogenicity of glyphosate and glyphosate-based products (77), even though these are the most popular pesticides in Europe. The Parliament also identified that the guidance document on the use of independent scientific literature should be updated to ensure that the scientific findings are incorporated adequately in the assessment according to Article 8(5) of the EU Pesticide Regulation. This recommendation has also not been followed up (46).

- *Objective and high-quality assessment*

Since the aim of the EU Pesticides Regulation is to ensure that pesticides that enter the market do not adversely affect human health and the environment, the European Parliament called for a high quality and objective assessment to be carried out by Member States (36,48), with the appropriate expertise (4). Specifically, only Member States that can guarantee a high quality and objective assessment should become Rapporteurs, which is not the case since there are no harmonised rules to ensure high expertise nor an independence policy for the risk assessors. Adding to the examples of glyphosate presented above, an independent review on the reliability of the genotoxicity studies submitted by the glyphosate companies and assessed by four Rapporteur Member states showed that many of the glyphosate studies were in fact unreliable.

In relation to EFSA's work, the Parliament called for high expertise (75), which has been addressed partly in the Transparency Regulation for EFSA's scientific Panels; the scientists involved are requested to have published relevant work in peer-reviewed scientific journals. Nevertheless, it is unclear whether this has been implemented, as currently this information is missing from EFSA's website. The parliament also called for high quality assessment in the guidance documents (60), however, the examples we have from the bees guidance document or ongoing work on Specific Protection Goals, among others, raise concerns that the level of protection is lower than what the EU law foresees. In terms of resources, the Parliament requested more resources to be allocated to

EFSA (70) and to Member States (4) to increase capacity and quality. Although this has been followed to an extent, it appears that EFSA has allocated significant resources on communication, which does not necessarily relate to an increased quality and objectivity of its work. For Member States, the continuous delays and prolongations of the authorisation periods of pesticide substances reveal a similar situation.

4. Respecting the precautionary principle and the high level of protection of human health, animal health and the environment as defined in EU law.

In its resolution, the Parliament asked for a strict implementation of the approval criteria, laid down in Article 4 of the EU pesticide regulation, including the cut-off criteria, and of the precautionary principle (5, 6, 81). The implementation of these recommendations remains highly problematic in several ways explained below.

- *Delay in the ban of cut-off substances*

The cut-off approval criteria in the EU pesticide regulation means that if a substance is identified on one hand as a known or presumed carcinogen, mutagen, or toxic for reproduction (CMR) or an endocrine disruptor (ED) for human health, or on the other hand as persistent organic pollutants (POP), persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB) or endocrine disruptor (ED) for the environment, it must be prohibited from use in pesticides. The exceptions are minor. Indeed, there is no safe threshold for exposure to these substances as their potential to cause harm to human health and the environment is too great to allow for them to be in contact with humans and the environment. In practice, however, once identified as cut-off, substances remain on the market for several years. For instance, the substance Ipconazole was banned in March 2023 while it was classified as toxic for reproduction in March 2018. Likewise, Thiacloprid was banned in September 2021 although it was classified as tox ic for reproduction in March 2015. Other examples show that little progress has been made to speed up their ban since 2019. As a result, some substances identified as cut-off are still currently approved in the EU. PAN Europe has listed the following: 8-Hydroxyquinoline (Toxic to reproduction Cat 1B), Asulam-sodium (ED to humans), Benthiavalicarb (ED to humans), Clofentezine (ED to humans), Dimethomorph (Toxic to reproduction Cat 1B and ED to humans & non-target organisms), Flurochloridone (Toxic to reproduction Cat 1B), Halosulfuron-methyl (Toxic to reproduction Cat 1B), Thiabendazole (ED to humans), Triflusulfuron-methyl (ED to humans and non target organisms). The main reason for these delays is that, instead of banning these substances immediately, the Commission gives first the possibility to the applicants (the pesticide companies) to ask for derogations (e.g. for negligible exposure or serious danger to plant health) that trigger a new lengthy evaluation procedure. This

inevitably results in further delays, the hazardous substance in question remains in the market putting people's health and that of the environment at risk. In the case of negligible exposure, the assessment is still based on a controversial draft guidance document, which remains to be adopted by Member States. This unacceptable reading of the Regulation gives priority to the industry's interest over the protection of human health, animal health and the environment.

- *Approval of active substances with critical areas of concern and (or) confirmatory information*

PAN Europe points out that active substances continue to be approved in cases where EFSA cannot conclude that the approval criteria are met, or even more worrisome, when EFSA concludes that the criteria are not met. A striking example in this regard is the renewal of the substance Cypermethrin in 2021, when EFSA had established that the substance was not safe for aquatic species, for bees and for other non-target arthropods. However, the renewal was adopted on the grounds that these unacceptable effects could be addressed by Member States by setting risk mitigation measures in their national authorisations[2]. This tampering with the approval criteria of the Regulation is currently challenged by PAN Europe in front of the EU Court of Justice. In addition, Cypermethrin was renewed even though EFSA could not finalise its assessment on its endocrine disruption potential. The same happened to the substance Flumioxazin, which was renewed in 2021. In both cases, these significant data gaps on the endocrine disruption potential, which is one of the cut-off criteria as it can be harmful for health, were addressed through confirmatory information, which is a post-approval procedure, while its approval should have been denied. These two examples demonstrate that the Commission has not changed its practice of approving substances with confirmatory data, contrary to the Parliament's request (82). Likewise, the way confirmatory information is handled at post approval level remains as unacceptable as in 2019, as demonstrated by the recent case of Flutianil. The substance was approved in 2019 provided that confirmatory information on its endocrine disruption potential for non-target organisms would be submitted within 2 years. Due to the poor and flawed design of the "confirmatory" studies submitted in this context by the applicant, EFSA's experts agreed that this poorly reliable data failed to address the issue of potential endocrine disruption. While the EU pesticide regulation and the guidance document on confirmatory information required the Commission to review the approval, the Commission has kept fluatinil's existing approval until 2029.

[2] We note that in the context of the renewal discussions, the Commission has attempted to set specific and binding risk reduction measures as demanded by the Parliament (84), but that this has been refused by the Member States who want to maintain complete discretion over the choice of these measures. However, the level of mitigation to be achieved was explicitly set in the approval regulation.

- *Prolongation of the approval of more hazardous active substances*

The issue of extending the approval periods for active substances is related to delays in risk assessment by Member States as highlighted in the PEST report (78). Compared to 2019, these delays continue to occur and are now longer. They lead to the increasingly frequent and lengthy authorisation periods for substances that are often hazardous. To date, 72% of the substances that are candidates for substitution have received at least one extension in their approval period due to delays in their risk assessment, and in most cases this prolongation is repeated for several consecutive years. The high number of substances concerned and the fact that many of them end up getting banned once their assessment is completed show that this prolongation pattern hampers the achievement of the high level of protection required by the Regulation. The most recent example is the proposed non-renewal of the approval of the substance dimoxystrobin, which remained in the market for 7 additional years because of the repetitive prolongation of its approval. Without these delays and prolongations, its non renewal would have occurred as early as 2016. This led PAN Europe to lodge a legal complaint to the EU Court of Justice. A second complaint was lodged by Pollinis against the prolongation of Boscalid. To remedy this bottleneck situation, the European Commission has proposed a grant system to Member States for 2023. According to this proposal, Member States would have to commit to hiring more experts based on European and national co-financing. This system has not yet been put in place to PAN Europe's knowledge and it remains unsure whether Member States will apply it. EU law already defines the duration of the risk assessment in the Rapporteur Member State as well as at EFSA-level. Furthermore, Member States have the possibility to raise fees to pesticide applicants, to cope with the costs of risk assessment. PAN Europe thus considers that with the proposed grant system, the Commission is using public money to pay national regulatory authorities, instead of having the applicant/industry bearing such cost, according to the polluter pay principle. This is not acceptable.

Moreover, PAN Europe wants to point out the case of S-metolachlor, a substance where the negative conclusions by EFSA had already been published but did not stop Member States and the Commission from prolonging its approval period. Indeed, while the conclusions of EFSA on S-metolachlor were published in February 2023 and clearly indicated that the substance does not meet the approval criteria anymore, its current approval's period was anyways extended for another year, until the end of 2024. This case reflects the fact that procedural delays systematically take precedence over the fastest possible protection of our health and the environment.

- *Emergency authorisation granted to EU-banned pesticides*

A provision in the EU pesticide regulation (Article 53) allows Member States as an exception to put on the market, in circumstances that are considered "emergency situations" and for a limited period of time, pesticides that have not been authorised in their country. Member States have to demonstrate that the product will control "a danger which cannot be contained by other reasonable means". Although Article 53 does not allow Member States to disregard the safety requirements of

the Regulation, many Member States have misused this provision to grant authorisations to substances that have been banned in the EU because of their toxicity to human health, an imal and/or the environment. This situation has not improved despite the Parliament's call for a strict implementation of Article 53 (102), increased transparency (104, 105) and the Commission to use its repealing power in case of infringement (103). According to a report by PAN Europe, between 2019 and 2022, 236 national derogations were granted by Member States for 14 banned active substances (out of the 24 that were examined in total). Neonicotinoid insecticides represented 47.5% of such derogations. In early 2023, a judgement of the EU Court of Justice clarified that Article 53 cannot be applied to pesticides containing substances that have been explicitly banned or restricted in the EU following their risk assessment by EFSA and a Commission's decision (of non approval). However, the European Commission and Member States have to date not formally acknowledged the judgement, with several national countries intending to reduce the scope of this ruling only to neonicotinoids applied on seeds. Some Member States have even granted new derogations to banned pesticides and the European Commission has so far not acted to repeal these illegal decisions.

5. Addressing transparency shortcomings obstructing public scrutiny in pesticide authorisation procedure

On numerous occasions of the PEST resolution, the European Parliament emphasised the lack of transparency in the evaluation and decision-making procedures for pesticides.

- *Toxicity studies in the assessment*

The EU parliament called for raw data and complete studies to be provided by the industry for risk assessment and made public (40, 41, 42). This request was in line, partly, with the second demand of the European Citizens Initiative "stop glyphosate" requesting a reform of the risk assessment procedure of pesticides and that the "scientific evaluation of pesticides is based on published studies". The relevant recommendations have been successfully followed up in the (already proposed at that time) Transparency Regulation by amending Articles 7 and 8 of the EU pesticide regulation. This change, which is implemented to pesticide applications submitted as from 27 March 2021 aims to positively increase public scrutiny over the assessment of substances.

- *Decision procedures*

The EU Parliament has also been demanding more transparency at the level of approval decision-making "to ensure political accountability for the adoption of implementing acts using the

comitology procedure" (79). Here, however, PAN Europe cannot see any progress, or even deplores a voluntary obstruction by the Commission. The only action on transparency is the publication by the Commission of its meeting agenda, on average two weeks before the meetings are held, as well as drafts of some of the documents discussed. The minutes of the meetings, however, are published more than two or three months later and contain very little detail. The individual position of the Member States béfore or during the meeting or the file timetables are never specified. Besides the discussions on the approvals of substances, where stakeholders are invited to provide comments only once ahead of the EFSA's peer review, it is very difficult for civil society organisations to watchdog the rest of the ongoing work of Member States or the Commission (particularly on technical issues such as guidance documents) as we are rarely consulted. For instance, PAN Europe is aware that the Commission has been reviving the work on its guidance document on negligible exposure for just over a year but has not been consulted since 2015. Furthermore, NGOs are rarely invited to the Commission's working groups with member states. In that respect, when organisations make active use of their right of access to information to obtain non-published working documents and positions during and between these meetings, the Commission systematically denies access to these requests claiming it's an "ongoing policy discussion". In 2016, PAN Europe brought such a case to the European Court of Justice, who rejected the Commission's claim that disclosure of documents undermines the decision-making process and highlighted that the access of citizens to information relevant for the public prevails. In relation to the position of Member States, the Commission has repeatedly rejected our requests in relation to the discussions on the bee guidance document, the renewal of sulfoxaflor and of cypermethrin. Therefore, the NGO Pollinis, took the case to the EU Court of Justice, which confirmed that the Commission is not entitled to systematically dismiss requests for information on the positions of Member States expressed in the frame of (re)approval procedures. The Commission decided to appeal this decision. In the meantime, the Commission should implement the judgement of the Tribunal of the EU but contrary to their legal obligation, they refuse to do so. Furthermore, in a recent request of access to information to the Commission made by PAN Europe, the request was rejected based on the possibility that PAN Europe could use this information in a further legal case. Such a reasoning could be used at any time for any request for information by the Commission, and PAN Europe thus launched a new legal action against this Commission's secrecy. Another case by ClientEarth is challenging the secrecy of Member States' vote. These three actions against the Commission demonstrate the real difficulties that civil society faces in having their right to access environmental information implemented.

At national level, significant transparency gaps in decision making also persist in the area of pesticide authorisation. For example, with regard to Article 53 of emergency authorisations (105), Member States are abusing their use to authorise EU-banned pesticides claiming they are necessary and there are no other means. Similarly, with regard to Article 50 for the authorisations of "more hazardous" pesticide products i.e., those that contain candidates for substitution (108), Member States claim there are no alternatives. In both cases, the information submitted by the applicant and processed by the Member States on the mandatory comparative assessment of the alternatives

are not made public. This is very problematic in view of the number of emergency authorisations granted to EU-banned pesticides each year and the very few cases where more hazardous (approved) pesticides have been substituted, accounting for less than 1% of the total of authorisations since 2015. In the meantime, candidates for substitution are more and more detected in EU-grown fruits and vegetables. In theory, substitution is mandatory as soon as a safer alternative is available.

CONCLUSION

It is concerning to note that more than a decade after the EU pesticide regulation was put into effect, its objective of protecting human and animal health and the environment is still not fully achieved. Since the adoption of the PEST resolution there have been some efforts for improvement, for example to set a new policy regulatory framework driving the transition towards a pesticide-free Europe, to protect the vulnerable population, to improve public access to industry studies, and to reform procedural guidance documents. Nevertheless, very little improvement has been observed in practice to fully address the adverse effects of pesticides, to ensure independent and of high expertise risk assessment, as well as endorse the precautionary principle in decision -making. In some areas, such as the delays in risk assessment, emergency authorisation requests of EU-banned pesticides and transparency in decision-making, things appear to have worsened since the adoption of the PEST resolution.

PAN Europe considers that there is still much work to be done to achieve the intended goals of the EU pesticide regulation, and greater seriousness and action must be taken by risk regulators and managers in Commission and Member States to ensure that human and animal health and the environment are properly protected. We therefore urge the Commission, Member States and the Parliament to acknowledge where progress has stalled or even regressed and take necessary action to address them.

ROADMAP FOR PRIORITIES FOR COMMISSION & MEMBER STATES

As required by Regulation (EC) 1107/2009:

1. Apply **the precautionary principle** and ensure a **high level of protection of human health, animal health and the environment** in line with the provisions of the EU law. Member States and the European Commission shall also take preventative measures, when the first evidence of potential harm appears. More specifically:

2. Strictly apply the **hazard-based approach** and the approval criteria, *including by:*
→ Immediately banning active substances that do not meet the approval criteria in relation to human health and/or the environment and applying the precautionary principle in cases of contradictory results
→ Putting an end to the repeated prolongations of the approval periods of active substances particularly of those for which concerns have been raised by the European Food Safety Authority (EFSA), Member States or the European Parliament.
→ Stopping the abuse of the 'confirmatory information' procedure to approve substances whose safe use has not been established by EFSA;
→ Stopping the abuse of the derogation to provide an "emergency authorisation" to products with substances that have been banned in the EU because of human health and environmental concerns, as directed by the Judgement of the European Court.

3. **Strengthen the assessment of the toxicity** of pesticides, *including by*:
→ Addressing existing gaps in human and environmental risk assessment by updating or adopting new relevant guidelines and regulations (e.g. data requirements for neurotoxicity & immunotoxicity for humans; toxicity to amphibians, terrestrial invertebrates, aquatic species and wild bees for the environment);
→ Regulating 'cocktail' effects by establishing a risk assessment for mixtures that takes into account additive and synergistic effects of all pesticide residues that people are exposed to daily, as well as of other chemicals. While this method is developed an additional mixture assessment factor of at least 10 should be applied.

4. Ensure the **objectivity and reliability** of data and studies used in pesticide risk assessment, *including by*:
→ Giving important weight to independent and peer-reviewed studies in risk assessment and amending the relevant guidance document on Article 8(5);
→ Increasing expertise among scientists involved in risk assessment by requesting to provide scientific peer-reviewed publications and ensuring that all areas of human and environmental health are adequately covered. EU scientific agencies should further remunerate non-staff experts taking part in scientific panels or working groups, and should be allowed to reach out to high-level experts.

5. Ensure the **independence** of pesticide risk assessment, *including by:*
→ Setting an EU harmonised, strict 'conflict of interest' policy for those involved in risk assessment procedure, applicable to EU and national competent authorities and experts representing Member States in EFSA's bodies;
→ Strengthening EFSA's existing independence policy, including by extending the cooling off period applied to experts to 5 years and applying a zero tolerance policy to any funding by the chemical industry.

6. Increase the **transparency** on the European Commission's work and Member States's position, *including by:*
→ Complying with the judgement of the European Court of Justice, highlighting that the Commission cannot systematically refuse access to its working documents and positions from Member States;
→ Making systematically public the individual position of Member States in the minutes and publishing them no later than two weeks after the day of the meeting;

7. Ensure the **strict assessment of pesticide products** foreseen by Regulation (EC) 1107/2009, *in particular by:*
→ Adopting a whole-mixture approach assessment of the long term effects on human health and the environment of the representative formulations during the procedure of active substance approval;
→ Addressing chronic toxicity of all components of pesticide products individually (co-formulants, safeners and synergists);
→ Ensuring a risk assessment of all pesticide products sold at national-level, with relevant data in line with the data requirements from Regulation (EC) 284/2013

As pledged under the EU Green Deal & Farm to Fork Strategy

8. **Reduce significantly the use of synthetic pesticides** and replace them with safer non-chemical and ecological alternatives in line with the Sustainable Use of Pesticides Regulation proposal (SUR) by:
→ Endorsing strict & legally binding pesticide reduction targets and the demands of the European Citizens Initiative 'Save Bees and Farmers' to reduce by 80% the use of synthetic pesticides by 2030, starting with more hazardous pesticides
→ Promoting the implementation of the principles of Integrated Pest Management Principles (IPM) and prioritising agro-ecological and organic practices across all Member States;

9. **Protect the general public and vulnerable groups** from pesticide exposure, in relation with the SUR proposal including by:
→ Prohibiting the use of pesticides in all spaces used by the general public and their surroundings;
→ Setting buffer zones to at least 100 metres around sensitive areas and at least 50 metres around houses, gardens and roads;
→ Implementing health and environmental post-market monitoring;

As pledged under the EU Green Deal & Chemical Strategy for Sustainability

10. **Prohibit the export of all EU banned pesticides** in line with the EU Chemical Strategy for Sustainability without further delay and adopt a zero-tolerance policy for such residues in imported food. Pesticide active ingredients and products which are prohibited for use in the EU because of health and environmental concerns are still produced within the Union and exported to third countries. Often, they find their way back to Europe as residues in imported food.
→ Europe should lead by example and stop exporting pesticides whose human health and environmental toxicity is proven and set a zero tolerance for residues of such pesticides in imported food.

Contact:

Salomé Roynel salome@pan-europe.info

Angeliki Lyssimachou, angeliki@pan-europe.info

Pesticide Action Network Europe - Rue de la Pacification 67- 1000 Brussels - www.pan-europe.info