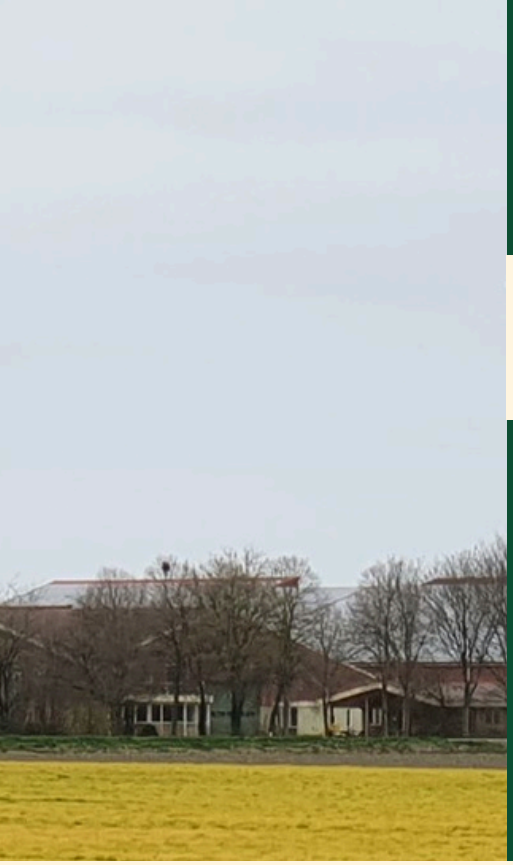

GUIDANCE DOCUMENT

BANNING GLYPHOSATE-BASED HERBICIDES AT NATIONAL LEVEL

June 2024

Pesticide Action Network Europe

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Summary

In November 2023, the EU renewed the approval of the active substance glyphosate for 10 years, despite ten EU Member States not voting in favor. This decision was made in disregard of major objections from scientists, policymakers, and the general public. It overlooked numerous reported adverse effects linked to glyphosate exposure, documented in scientific literature. It also downplayed several data gaps and pending issues, identified by the European Food Safety Authority (EFSA). Thus, the renewal of glyphosate contradicts the fundamental objective of the EU Pesticide Law, which is to provide a high level of protection for human and animal health, as well as the environment from pesticides.

Following the re-approval Regulation, EU Member States now shoulder a crucial responsibility. They have to assess the toxicity of all glyphosate-based herbicides and decide whether or not to authorise or re-authorise products containing this active substance within their borders. In this process, Member States must take into account the effects of the complete product formulations and all the toxicity issues highlighted by EFSA in its risk assessment peer review of glyphosate and by the Commission and Member States in the glyphosate's renewal Regulation.

In the past, Austria and Luxembourg attempted to ban glyphosate-based products. They did not succeed, not because it contradicts the law, but because they used the wrong legal basis. This guidance document aims to serve as a non-exhaustive handbook for Member States. It details the legal provisions under the EU Pesticide Regulation to either ban or severely restrict the use of glyphosate-based herbicides at the national level. It first provides a summary of the scientific evidence indicating that glyphosate-based herbicides (GBH) fail to meet the EU law's requirements for the authorisation of pesticide products. Next, it explains how Member States interested in banning GBHs in their country can:

- refuse the authorisation of GBHs or re-authorisation of GBHs
- review, at any time, and withdraw a national authorisation of a GBH
- ban specific uses or restrict the conditions of use of glyphosate-based herbicides by performing a comparative assessment.

The guidance document offers a comprehensive list of legal arguments accessible to Member States. It also includes concrete case examples, where pesticide products were banned or their use restricted at the national level, providing practical insights into justifying the use of these provisions to apply them effectively.

PAN Europe would be pleased to provide detailed information to interested parties. For further inquiries, please contact Dr Angeliki Lysimachou, our Head of Science and Policy (angeliki@pan-europe.info) or Lysiane Copin, our Glyphosate Campaign & Policy Assistant (lysiane@pan-europe.info).

1. Introduction

1.1 The EU law prioritises the protection of human health and the environment from pesticides

The European Union adopted in 2009 the Regulation 1107/2009, commonly known as the EU Pesticide Regulation. It recognises the potential risks that pesticides can pose and provides a high level of protection of both human and animal health as well as the environment (Article 1(3)). Central to its provisions, Article 4(1-3) stipulates strict rules to ensure that pesticide active substances and products are only approved if they, or their residues, have no harmful effects on human health, including vulnerable groups, or animal health or cause unacceptable effects on the environment. Ecosystems and biodiversity must be taken into account. Importantly, the provisions of the regulation are underpinned by the precautionary principle (Article 1(4)). This principle mandates that in cases of scientific uncertainty concerning risks, or when there are indications of harm, both EU and national authorities are obligated to intervene to safeguard health and the environment. The precautionary principle has been further defined by the case law of the Court of Justice of the EU (hereafter CJEU), which specifies that competent authorities must act when a risk exists, rather than waiting for harm to materialise, even when there is a lack of information that prevents drawing firm conclusions in a risk assessment[1].

With all these provisions, the EU Pesticide Regulation is meant to stand as a safeguard for the protection of human health and the environment. Unfortunately, however, the Regulation is not properly implemented and substances and products that may cause harm to human and animal health or the environment continue to be approved. This has been the case for glyphosate and glyphosate-based products.

1.2 An 'unlawful' renewal of the glyphosate active substance

There are several reported adverse effects linked to glyphosate exposure in the scientific literature. They range from environmental harm (soil degradation, water pollution, and biodiversity loss) to potential genotoxicity, carcinogenicity and neurotoxicity in laboratory animals and even humans[2]. Many of these adverse effects have been observed following exposure to pure glyphosate (the active substance) but also to glyphosate-based herbicides (GBH), particularly in studies from the academic, independent scientific literature. Even the European Food Safety Authority (hereafter EFSA), which has been criticised for failing to acknowledge all the health and environmental risks linked to the use of glyphosate, clearly states

[1] 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; T-257/07, France v. Commission, 9 September 2011, EU:T:2011:444, pt. 68; T-74/00 e.a., Artedogan e.a. c. Commission, 26 November 2002, EU:T:2002:283, pt. 184. T.

[2] https://stopglyphosate.eu/why-ban-glyphosate/

in its glyphosate peer review conclusions that impacts of GBHs on developmental neurotoxicity (DNT), microbiome and biodiversity have been found[3]. Despite this evidence, the EU Commission and Member States renewed the approval of the active substance for 10 years. This decision came into force on 29 November 2023[4], with the publication of the approval Implementing Regulation in the Official Journal of the European Union (EU). In response, PAN Europe and 5 of its members initiated a legal challenge against the renewal by submitting a request to the European Commission to review its decision[5].

1.3 The role of EU Member States

In the approval Regulation of glyphosate, the Commission has offloaded the responsibility for the risk management of a series of issues related to the toxicity of the active substance glyphosate to Member States. It is now their turn to carefully assess the toxicity of GBHs by reviewing the applications for the renewal of the national authorisations they receive and set specific conditions and restrictions on use. This has to be done within 12 months of receiving the applications. They have to follow the renewal Regulation's list of recommendations to Member States, which outlines specific issues they should "pay particular attention to" during the assessment of GBHs and the establishment of conditions or restrictions on use.

While the approval of glyphosate was renewed at the EU level, it is crucial to clarify that Member States retain the authority to decide whether to authorise or re-authorise products containing this active substance within their territories, and under which conditions. Within the framework of the EU Pesticide Regulation, there are several legal and scientific grounds for banning GBHs (or significantly restricting their use). Individual parties from EU Member States may also challenge the national decisions on the authorisation of GBH and ask for their cancellation, based on pesticide regulation (EU) 1107/2009, and on the case law of the CJEU. This guide offers a detailed examination of the legal avenues accessible to Member States (and other interested parties) for banning glyphosate-based herbicides.

Please refer to the Annex for an overview of the pesticide product authorisation procedure in the European Union under Regulation (EC) 1107/2009.

[3] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8164
[4] https://eur-lex.europa.eu/eli/reg_impl/2023/2660/oj
[5] https://www.pan-europe.info/press-releases/2024/01/ngos-initiate-legal-challenge-against-eu-glyphosate-re-approval

2. Legal grounds for Member States to ban glyphosate-based herbicides

2.1 Failure to meet the authorisation requirements

Whether a GBH is authorised for the first time or not; in order to receive a national authorisation for use, its application must comply with the requirements provided under Article 29 of the EU Pesticide Regulation (see Annex for details). These include demonstrating, among others, that based on current scientific and technical knowledge, the requirements provided for in Article 4(3) are met: the use of the GBH causes no harm to human and animal health and no unacceptable effects on the environment (Article 29(1e)). In case of scientific uncertainty, Member States are entitled to invoke the precautionary principle, which is at the core of the EU Pesticide Regulation and aims to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment (Article 1(4))[6].

Today, there is broad evidence that GBHs do not meet these requirements, as their use has been linked to adverse effects on humans and the environment. Therefore, as explained in Article 36(1)(3) and 43(1) (see Annex for details), a Member State may refuse an authorisation in its territory, following the examination of the application and concluding that the requirements provided in Article 29 are not fulfilled. They may do that by invoking the precautionary principle to ensure a high level of protection from the risk identified concerning the use of GBH (Article 1(4)). Below we provide some examples of the adverse effects linked to GHB exposure indicating that the authorisation requirements of Article 4(3) are not met.

2.1.1 Impacts of glyphosate-based herbicides relevant to human health

First of all, it is important to highlight that for glyphosate, as an active substance, the independent scientific literature shows evidence of the risks for mammals and human health with regards to genotoxicity, carcinogenicity, developmental neurotoxicity, damage to the gut microbiome, endocrine disruption and biodiversity, among other harmful effects[7]. These risks have been overlooked or not appropriately assessed by EFSA and the European Chemicals Agency (ECHA)[8] during the renewal process.

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[6] Article 1(4) Reg 1107/2009: *"…In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory."*

[7] Examples of evidence: https://stopglyphosate.eu/why-ban-glyphosate/

[8] Examples evidence: NGOs letter to Health Commissioner on glyphosate carcinogenicity; PAN letter to EFSA following its peer review conclusions on glyphosate risk assessment; undisclosed study on developmental neurotoxicity of glyphosate and other pesticides & insufficient assessment of glyphosate exposure and Parkinson's disease.

Evidence of harm is even stronger for GBHs than for the active substance alone. Researchers across the world have extensively studied the impacts of these widely used pesticide products revealing a broad spectrum of adverse effects to users and non-target species. Several such studies indicate that GBHs are often more toxic than glyphosate itself. Indeed, apart from increasing the herbicide's efficacy, co-formulants increase the product's overall toxicity[9] (See the next section). Unfortunately, all these research studies were disregarded or undervalued during the EU glyphosate assessment procedure, one reason being that they were carried on the product instead of the active substance. By considering this evidence, Member States should deny authorisation of glyphosate-based herbicides within their territories.

Impacts on human health

- **Evidence of carcinogenicity:** In 2015, the International Agency for Research on Cancer (IARC) of the World Health Organisation classified glyphosate as probably carcinogenic (equivalent to category 1B in the EU), based on data on the active substance, as well as data on GBHs. According to the EU Pesticide Regulation products containing active substances falling under this classification should not be authorised. In 2020, the Belgian Health Council concluded that the carcinogenicity of glyphosate cannot be excluded[10] whereas in 2021, the French National Institute of Health and Medical Research (Inserm), concluded that there is a moderate presumed link between glyphosate exposure and non-Hodgkin lymphoma[11]. Independent scientific studies examining animal experimental data and epidemiology evidence on the use of GBHs have also concluded that glyphosate is carcinogenic[12]. The EU cancer assessment of glyphosate's failure to recognise the cancer potential of glyphosate has received strong criticism from the scientific community, politicians and civil society organisations. This criticism includes the failure of the pesticide companies to provide all the genotoxicity data requirements, misuse of statistical methods in experimental animal studies and undervaluing scientific literature on epidemiology and oxidative stress (potential of glyphosate to cause DNA damage), among others.

[9] Makame et al. Oxidative Stress and Cytotoxicity Induced by Co-Formulants of Glyphosate-Based Herbicides in Human Mononuclear White Blood Cells. Toxics. 2023 Dec 1;11(12):976. https://doi.org/10.3390/toxics11120976

[10] Belgian Health Council, 2020 https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/20200303_shc-9561_glyphosate_vweb.pdf.

[11] Inserm, 2021. Collective Expert Review; see Inserm Communication: https://presse.inserm.fr/en/inserm-publishes-its-latest-collective-expert-review-on-the-health-effects-of-pesticides/60325/.

[12] Weisenburger DD. A Review and Update with Perspective of Evidence that the Herbicide Glyphosate (Roundup) is a Cause of Non-Hodgkin Lymphoma. Clin Lymphoma Myeloma Leuk. 2021 Sep;21(9):621-630. https://doi.org/10.1016/j.clml.2021.04.009

Recently, a multi-institutional international study (the Global Glyphosate Study[13]) on glyphosate and two glyphosate-based products, released its first long-term carcinogenicity data following exposure at the "acceptable daily intake" (ADI) level. The results show that low doses of GBHs, assumed to be safe by the EU, caused cases of leukaemia in young rats, following early life exposure. One of the products tested was the representative formulation BioFlow (MON 52276), for which EFSA has concluded that it fulfilled the criteria to be approved.

- **Neurotoxicity:** Regarding the neurotoxicity potential of glyphosate, EFSA acknowledged that there are indications that GBHs cause developmental neurotoxicity (DNT). Independent scientific studies show that exposure to GBHs, and to some extent glyphosate, has been linked to various neurological disorders and diseases: autism spectrum disorders in children exposed from prenatal age[14], as well as amyotrophic lateral sclerosis (ALS)[15] and Parkinson's disease in adults[16]. It is important to note that it was recently highlighted that the studies submitted by the companies in the course of the EU glyphosate assessment were insufficient to conclude on such long-term neurodegenerative effects[17]. Moreover, there was no DNT study on glyphosate in the application dossier. When EFSA and ECHA became aware, during the public consultation on glyphosate, of a DNT study carried out on glyphosate trimesium salt in which prenatally exposed animals developed signs of neurotoxicity[18], the authorities did not consider the study as relevant and disregarded the adverse effects. They claimed that glyphosate trimesium salt is a different compound, without having any proof from the applicant or scientific literature that neurotoxicity in this DNT study was caused by the trimesium ion or the salt rather than glyphosate acid (all glyphosate salts are metabolised to glyphosate acid, which exerts the herbicidal action). In the meantime, a systematic review study in 2022, examined 163 publications on the neurotoxicity of glyphosate and GBHs and concluded that it is unequivocal that exposure to glyphosate produces important alterations in the structure and function of the nervous system of humans, rodents, fish,

[13] Panzacchi, S., Tibaldi, E., De Angelis, L., Falcioni, L., Gnudi, F., Iuliani, M., Manservigi, M., Manservisi, F., Manzoli, I., Menghetti, I., Montella, R., Noferini, R., Sgargi, D., Strollo, V., Antoniou, M., Chen, J., Dinelli, G., Lorenzetti, S., Mesnage, R., … Mandrioli, D. (2023). Leukemia in Sprague-Dawley Rats Exposed Long-Term from Prenatal Life to Glyphosate and Glyphosate-Based Herbicides. https://doi.org/10.1101/2023.11.14.566013.

[14] von Ehrenstein et al. Prenatal and infant exposure to ambient pesticides and autism spectrum disorder in children: population based case-control study. BMJ. 2019 Mar 20;364:l962. https://doi.org/10.1136/bmj.l962.

[15] Andrew et al. Pesticides applied to crops and amyotrophic lateral sclerosis risk in the U.S. Neurotoxicology. 2021 Dec;87:128-135. https://doi.org/10.1016/j.neuro.2021.09.004.

[16] Caballero et al. Estimated Residential Exposure to Agricultural Chemicals and Premature Mortality by Parkinson's Disease in Washington State. Int J Environ Res Public Health. 2018 Dec 16;15(12):2885. doi: 10.3390/ijerph15122885.

[17] Bloem and Boonstra. The inadequacy of current pesticide regulations for protecting brain health: the case of glyphosate and Parkinson's disease. Lancet Planet Health. 2023 Dec;7(12):e948-e949. doi: 10.1016/S2542-5196(23)00255-3.

[18] Mie A, Rudén C. What you don't know can still hurt you - underreporting in EU pesticide regulation. Environ Health. 2022 Sep 5;21(1):79. doi: 10.1186/s12940-022-00891-7.

and invertebrates[19]. Acknowledging the evidence from scientific literature and the DNT study, EFSA concluded that there was a data gap in the assessment, to identify whether the DNT findings reported in the studies with glyphosate trimesium and with GBHs are due to glyphosate[20].

- **Impact on the microbiome:** EFSA acknowledged that there is evidence indicating adverse effects of glyphosate and GBHs exposure on the microbiome but stated that no conclusions could be drawn as no internationally agreed guidelines are available. The absence of such conclusions is deeply concerning as glyphosate is patented as an antibiotic agent[21] and the link between alterations in microbiome and several diseases in humans and other species is well established in the scientific literature. Moreover, alterations in the microbiome-gut-brain axis are considered to be a significant contributor to several neurological disorders, including Parkinson's disease[22]. More specifically, in 2019, a review examining the impact of glyphosate on gut microbiome and potential neurological effects, found that glyphosate, even following realistic environmental exposures, can cause intestinal dysbiosis affecting the populations of beneficial bacteria. This in turn can have an impact on the central nervous system due to the gut-brain axis and it has been associated with a range of neuro-biological disorders[23].

- **Endocrine disruption:** Although this point has received less attention, studies from the scientific literature indicate that glyphosate can interfere with the normal function of hormones in different animal species, including humans, and therefore may cause endocrine disruption. Some reported effects are alterations in the hormone levels, but also effects related to reproduction such as lower sperm quality and altered testis morphology in males, as well as shorter gestational length in pregnant women and infants born with higher anogenital distance (a clear indication of endocrine disruption)[24]. In a 13-week pilot study, where rats were exposed from prenatal age to low levels (ADI) of glyphosate Bioflow (the representative glyphosate formulation), female and male pups had increased anogenital distance, whereas hormonal imbalances were found at 6 and 13 weeks of age[25].

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[19] Costas-Ferreira et al. Toxic Effects of Glyphosate on the Nervous System: A Systematic Review. Int J Mol Sci. 2022 Apr 21;23(9):4605. doi: 10.3390/ijms23094605.

[20] EFSA, 2023. Peer review of the pesticide risk assessment of the active substance glyphosate. https://doi.org/10.2903/j.efsa.2023.8164 Section 10; outstanding issues.

[21] Glyphosate was originally patented as a broad-spectrum antibiotic under U.S. patent number 7771736.

[22] Kulcsarova et al. Pesticides and the Microbiome-Gut-Brain Axis: Convergent Pathways in the Pathogenesis of Parkinson's Disease. J Parkinsons Dis. 2023;13(7):1079-1106. https://doi.org/10.3233%2FJPD-230206.

[23] Rueda-Ruzafa L, Cruz F, Roman P, Cardona D. Gut microbiota and neurological effects of glyphosate. Neurotoxicology. 2019 Dec;75:1-8. https://doi.org/10.1016/j.neuro.2019.08.006.

[24] See collection of studies: https://stopglyphosate.eu/why-ban-glyphosate/endocrine-disruption-and-reproduction/.

[25] Manservisi et al. The Ramazzini Institute 13-week pilot study of glyphosate-based herbicides administered at human-equivalent dose to Sprague Dawley rats: effects on development and endocrine system. Environ Health 18, 15 (2019). https://doi.org/10.1186/s12940-019-0453-y.

2.1.2 Impacts of glyphosate-based herbicides exposure on biodiversity

From bee colonies, fish, amphibians, birds, plants and algae, exposure to GBHs has been linked to adverse effects that may affect species' populations and therefore biodiversity[26,27]. In its glyphosate peer review, EFSA states that certain studies from the scientific literature reported adverse effects on fish, amphibians and insects but these were not found sufficiently reliable and relevant, compared to the ones provided by the applicant[28]. To our knowledge, the applicant did not submit any chronic ecotoxicity studies on the representative formulation (only acute/subchronic toxicity). EFSA, however, identified high long-term risks to mammals in at least 12 out of the 23 proposed uses of the representative formulation under assessment and could not finalise the risk assessment for aquatic macrophytes exposed via drift. Regulatory tests as submitted by the applicant also showed 100% mortality of insects in first-tier tests in beneficial insects. Moreover, EFSA stated that it was necessary to assess the risk to biodiversity via indirect effects and trophic interactions, which could not be finalised based on the data submitted by the applicant. By referring to the absence of a harmonised approach to assess biodiversity within the prospective risk assessment, EFSA stated that firm conclusions could not be drawn and that risk managers (i.e. Commission and Member States) should consider mitigation measures.

2.2 The EU law and case law on the toxicity of the whole product & data gaps on products, co-formulants, and other ingredients

2.2.1 Legal requirements and shortcomings in product ingredients' assessment

The EU Pesticide Regulation requires the same level of protection from pesticide active substances and products, as well as their residues: they should cause no harm to human health and animal health, and no unacceptable effects on the environment (Article 4(1-3)). This includes all the ingredients that products consist of (i.e. safeners, synergists, co-formulants, and even impurities)[29]. More specifically, according to the 'uniform principles' of the evaluation of pesticide

[26] PAN Europe, 2023. Glyphosate's impact on bee health. https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/briefings/Glyphosate%20based%20herbicides%20and%20their%20impact%20on%20bees%27%20health.pdf.

[27] Klatyik et al. (2023) Terrestrial ecotoxicity of glyphosate, its formulations, and co-formulants: evidence from 2010–2023. Environmental Sciences Europe 35, 51 (2023) https://doi.org/10.1186/s12302-023-00758-9.

[28] EFSA, 2023. Peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 21(7): e08164 https://doi.org/10.2903/j.efsa.2023.8164.

[29] Co-formulants are part of the mixtures contained in pesticide products, serving to enhance product efficiency and usability. These are for instance surfactants, anti-foaming agents, solvents or wetting agents. According to Reg (EC) 1107/2009 Article 2(3c) they are used or intended to be used in a plant protection product or adjuvant but are neither active substances nor safeners or synergists. Impurity means any component other than the pure active

products "the interaction between the active substance, safeners, synergists and co-formulants must be taken into account when evaluating plant protection products" (Article 29(6)). However, in reality, the level of assessment carried out is not the same between pesticide active substances and products (or their ingredients), with active substances being the ones for which the pesticide companies deliver most studies.

While the data requirements for active substances, safeners and synergists (Data Requirements Regulation (EC) 283/2013) provide a list of several long-term toxicity studies required under mammalian toxicity and ecotoxicity assessment, the data requirements for products include mainly acute and subchronic studies (Regulation (EC) 284/2013), having some ecotoxicity long-term toxicity studies as optional. These two regulations fulfil only partly the requirements of the pesticide regulation. Indeed, regulation (EU) 1107/2009, clearly states that tests should not be restricted to the ones listed in the data requirements regulations. The data should be sufficient to evaluate immediate or delayed risks that pesticide products might entail for humans, including vulnerable groups and the environment, and include any known data and all available data from peer-reviewed scientific literature (Annex 1.1-1.4 Regulation 284/2013).

The Regulation 284/2013 on products, and the 'uniform principles' of Regulation 546/2011 also highlight that the contribution of the components to the toxic potential of the total mixture, and their metabolites and residues, should be taken into account.

In terms of co-formulants[30] (e.g. surfactants, anti-foaming agents, solvents, etc.) a study from 2016 revealed that glyphosate without its co-formulants only showed a low herbicidal activity at the recommended dilutions in agriculture, while co-formulants alone presented a similar herbicidal activity, compared to the Roundup formulation[31]. Moreover, the co-formulants alone

substance and/or variant which is present in the technical material (including components originating from the manufacturing process or from degradation during storage) (Article 3(33)).

[30] Products contain a significant proportion of other ingredients, such as co-formulants, synergists and safeners, which are added to enhance the effectiveness of the product as a pesticide, or in the case of safeners to protect the non-target plants. Safeners and synergists are defined in Article 2(3) of Reg. 1107/2009 as : *(a) substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants, referred to as 'safeners'; (b) substances or preparations which, while showing no or only weak activity as referred to in paragraph 1, can give enhanced activity to the active substance(s) in a plant protection product, referred to as 'synergists; (c) substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists, referred to as 'co-formulants';*

[31] Defarge, N., Spiroux de Vendômois, J., & Séralini, G. E. (2018). Toxicity of formulants and heavy metals in glyphosate-based herbicides and other pesticides. *Toxicology Reports*, *5*, 156–163. https://doi.org/10.1016/j.toxrep.2017.12.025.
At the time, POE-tallowamine Genamin was used as a co-formulant. It was banned for use in 2017 but since then, to our knowledge, no such test was carried out with the other used co-formulants.

were more toxic than glyphosate[32,33]. Worryingly, for many co-formulants used in pesticide products, their toxicity is completely unknown or the toxicity data available is insufficient, creating a 'black box'. This is particularly concerning as added co-formulants can make up more than 50% of a product formulation[34]. According to the EU Pesticide Regulation, a co-formulant shall only be accepted for use if it causes no harm to human, animal health and the environment (Article 27) and a list of unacceptable co-formulants is provided (Annex III). Although these provisions were meant to be implemented in 2016, unfortunately, it was only in 2021 that a first list of unacceptable co-formulants was adopted, which is based on 'weak' criteria that will inevitably leave several dangerous substances outside of the list[35].

Safeners and synergists, on the other hand, should theoretically be assessed at the same level as active substances, with the same data requirements. However, only recently has a regulation been endorsed by Member States to establish a harmonised methodology. Therefore, it is unclear to what extent safeners and synergists are currently assessed. Member States have the responsibility to ensure that these substances undergo the same level of assessment as active substances.

Without the assessment of long-term toxicity on all individual components of the products as well as the products as a whole, it is impossible to estimate the safety of the entire product. In such cases, the product in question should not be authorised for market use. Thanks to civil society, these inconsistencies in the assessment of pesticide products have been brought to the CJEU, who provided clarifications of the Case law on implementation of the EU law. Member States should now align their evaluation of the authorisations of pesticide products with the decisions of the Court.

2.2.2 The case law - a clarification of the legal requirements

It was initially Case C-616/17 (commonly referred to as the 'Blaise ruling'), where the CJEU recalled that proving the safety of a pesticide product is an obligation: "*in accordance with Article 4(3)(b) and Article 29(1)(e) of the Pesticide regulation, a product can be authorised only if it is established that* ***it has no immediate or delayed harmful effect on human health****, the burden of*

[32] On the toxicity of co-formulants contained in glyphosate based herbicides, see also : Defarge, N., Takács, E., Lozano, V. L., Mesnage, R., Spiroux de Vendômois, J., Séralini, G. E., & Székács, A. (2016). Co-Formulants in Glyphosate-Based Herbicides Disrupt Aromatase Activity in Human Cells below Toxic Levels. International journal of environmental research and public health, 13(3), 264. https://doi.org/10.3390/ijerph13030264.

[33] In the renewal of glyphosate's approval in 2017 the EU banned a specific co-formulant called POE-tallowamine from glyphosate products in Europe, because of its toxicity. However, several glyphosate products that do not contain POE-tellowamine have also shown to be toxic, including the representative formulation. This indicates that other co-formulants may be toxic too, or result in increased toxicity of the whole product formulation.

[34] Schaller U.; Balmer M. Co-Formulants in Plant Protection Products: Initial Study on the Risk Assessment of Co-Formulants in Plant Protection Products. Fed. Food Saf. Vet. Off. Switz. 2018, 1–30. https://zenodo.org/records/3600029.

[35] PAN Europe position paper on co-formulants and on the Implementing Regulation https://www.pan-europe.info/resources/briefings/2022/11/position-paper-implementing-regulation-identification-unacceptable-co.

adducing proof of that lying, in accordance with Article 29(2) of that regulation, on the applicant". And therefore "*A plant protection product cannot be considered to satisfy that condition where it exhibits any long-term carcinogenicity and toxicity*."

The Court concluded that it is the task of the competent authorities (Member States), 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. In a few words, **if the material submitted is insufficient to exclude any long-term risk, a Member State may refuse an authorisation in its territory**.

Finally, the Court highlighted that the assessment carried out by the Member States must be independent, objective and transparent, and hence the authorities are bound to take into account relevant evidence "*other than the tests, analyses and studies submitted by the applicant that might contradict the latter*" and such an approach is compatible with the precautionary principle. More specifically it is the duty of Member States "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**". Hence, Member states may request additional studies than those listed in the Communication of the data requirements Regulation for pesticide products and/or their ingredients.

In another case C-162/21[36] brought to the CJEU by PAN Europe, the Court reiterated the provisions of the EU Pesticide Regulation (EC) 1107/2009 (recital 24 of the Regulation) when granting authorisations of plant protection products, that the objective of protecting human and animal health as well as the environment "should take precedence" over the objective of improving plant production. Therefore, a Member State may refuse an authorisation based on environmental or agricultural circumstances specific to the territory of one or more Member States or if the high level of protection of human and animal health, and the environment cannot be assured (recital 29 of the Regulation).

In the recent CJEU ruling of merged cases C-309/22 and C- 310/22[37] initiated by PAN Europe, the Court went into more detail to clarify the legal requirements under Article 29(1e) that the most recent scientific and technical evidence should be taken into account when a Member State is carrying out the assessment of a product. In this regard, a Member State is not obliged to authorise the marketing of the product containing substances that have been approved if there is scientific and technical knowledge available, which identifies an unacceptable risk to human or animal health or the environment of the pesticide product or its components (Article 4(3)) (point 83 of the ruling). More specifically, a product may be authorised only if it is established that it has no immediate or delayed harmful effect on human health [Article 29(1)(e) and Article 4(3)] (point 81 of the ruling). The Court stated that Member States should always take into account such

[36] Judgment of January 19, 2023, Pesticide Action Network Europe and others, C-162/21, EU:C:2023:30
[37] Judgment of 25 April 2024, Pesticide Action Network, Joined Cases C-309/22 and C-310/22, EU:C:2024:356

scientific information, even if this was not yet accessible at the time of the submission of the application (point 100 of the ruling). And this scientific information should "no doubt" include endocrine disruption (criteria set in 3.6.5 of Annex II to Regulation No 1107/2009), even though the data requirements are listed under Regulation 283/2013 for active substances and not Regulation 284/2013 for products (point 85 of the ruling). In a parallel CJEU ruling of the related case C-308/22[38] also initiated by PAN Europe, the Court clarified that a Member State should not limit basing its risk assessment solely on the available guidance documents if these do not sufficiently reflect the current state of scientific and technical knowledge. Moreover, in the absence of a guidance document, a Member State must be able to carry out its risk assessment based on the most reliable scientific information available and the most recent results of international research (point 94 of the ruling). In short, recent scientific knowledge should be taken into account, in the presence or the absence of specific guidelines.

Following the clarification of the Court in the merged cases C-309/22 and C- 310/22, it is evident that products shall not be authorised if they are not properly risk assessed for delayed harmful effects. This means that the assessment must include -as a minimum- evidence to address all the endpoints listed under the human health impacts section of point 3.6 of Annex II in Regulation 1107/2009. Therefore, developmental neurotoxicity and immunotoxicity should be considered critical effects when establishing appropriate safety margins of exposure (3.6.1), and it should be ensured that pesticide formulations are not known/presumed mutagen (3.6.2), carcinogen (3.6.3), toxic to reproduction (3.6.4) or endocrine disruptor (3.6.5).

2.2.3 Implementing the EU case law in the assessment of glyphosate-based products

For the glyphosate EU assessment, there were no long-term toxicity tests in mammals for the representative formulation MON 52276, neither in fish, frogs or birds. Several issues were found for its individual components, specifically for one co-formulant and an impurity (N,N-bisphosphonomethylglycine, also known as glyphosine). EFSA highlighted that for one co-formulant, which was present in a significant amount in the final formulation, certain long-term and short-term studies were completely missing[39]. In its glyphosate peer-review, it states that this data must be assessed by Member States to reach final conclusions. Additionally, for the impurity glyphosine, there was evidence of genotoxicity in one in-vitro test[40], which was not followed up with further testing. Furthermore, and EFSA did not highlight it, co-formulants were not tested for their toxicity on soil organisms, non-target arthropods or other organisms.

[38] Judgment of 25 April 2024, Pesticide Action Network, Case C-308/22, ECLI:EU:C:2024:350

[39] Repeated dose toxicity studies, their primary goal is to characterise the toxicological profile of the test compound following repeated administration. This includes identification of potential target organs of toxicity and exposure/response relationships.

[40] An in vitro chromosome aberration test showed positive results indicating its clastogenic potential [i.e. potential to cause DNA breakages] (EFSA, Conclusions on glyphosate, EFSA Journal 2023;21(7):8164)

As recalled in the Blaise ruling (point 74 of the ruling), the EU Member States, however, need to ensure that all components of the pesticide product do not pose a risk to health and the environment in order to authorise a pesticide product in its territory. Hence, in the absence of scientific data on the long-term toxicity of the GBH under examination, or of any of its components, Member States are to withdraw or refuse its market authorisation. For the representative formulation MON 52276 particularly, Member States are to directly refuse its authorisation, since no long-term toxicity or carcinogenicity studies have been performed on the product, one of its components is potentially genotoxic and more importantly, independent literature indicates it can cause leukaemia to young rats (see page 7).

Member States should examine all the GBHs dossiers for any data gaps, especially regarding carcinogenicity, neurotoxicity and impacts on the microbiome, as these effects are extensively documented in scientific literature and were also addressed by EFSA. Furthermore, in the absence of studies to assess delayed effects (long-term toxicity and carcinogenicity, developmental neurotoxicity and endocrine disruption), Member States must refuse authorisations of the products since there is evidence from independent scientific literature indicating long-term adverse effects as clarified recently in the case law (CJEU ruling of cases C-309/22 and C- 310/22). Lastly, considering EFSA's recognition of the impact on biodiversity, any dossiers lacking long-term ecotoxicity tests, listed in Regulation 284/2013 (Annex Section 10), should be promptly rejected, and the associated products removed from the market. Here, it is important to note that the Court clarified that all most recent relevant and reliable scientific or technical knowledge must be taken into account, indicating immediate or delayed adverse effects, including that of endocrine disruption, even in the absence of established guidelines and criteria. This contradicts EFSA’s conclusions, which stated that in the absence of agreed protocols, no conclusions could be drawn for the impact of glyphosate on biodiversity and microbiome, despite the wide range of evidence in the scientific literature and the fact that glyphosate has antimicrobial action.

2.3 Implementation of the recommendations in the EU glyphosate re-approval Regulation

The EU re-approval Regulation of glyphosate provides a list of several aspects that Member States should ‘pay particular attention to’ when performing the risk assessment of GBHs. These include, for example, the protection of small herbivorous mammals, the protection of groundwater in vulnerable areas and of surface waters, or the protection of non-target terrestrial and aquatic plants from exposure by spray drift. Most pre-harvest uses of GBHs should be prohibited and uses by non-professional users should be carefully assessed. Member States are asked to apply their own methods to assess the indirect impacts of glyphosate on biodiversity via trophic interactions and set conditions and restrictions, especially where alternative control and prevention methods with lower impact on biodiversity exist. In this context, the renewal Regulation highlights the obligation of Member States to implement integrated pest management and alternative approaches or techniques in order to reduce their dependence on the use of pesticides. Furthermore, the re-approval regulation calls for Member States to prohibit or restrict the use of

glyphosate in areas used by the general public or by vulnerable groups; these include public parks and gardens, sports and recreation grounds, school grounds, children's playgrounds and the close vicinity of healthcare facilities. Through these provisions, the responsibility of the management of the risks of glyphosate use has been transferred to the Member States, who are tasked with carrying out a complete evaluation of GBHs and defining adequate mitigation measures and use restrictions (i.e. banning the use of pesticides in public areas), particularly with regards to the pending issues in EFSA's peer-review. Based on these recommendations, Member States can reject the authorisations of GBHs in their territories, particularly in the absence of proof that mitigation measures will be sufficient in protecting aquatic species and biodiversity, and of methods and guidance agreed upon at the EU level to assess the indirect effects on biodiversity via trophic interactions.

Such an example is the case of GBHs in France, where on May 12, 2023, the Montpellier Administrative Court cancelled the authorisation of two GBHs. This was partially because a full assessment of the effects on biodiversity and ecosystems had not been carried out, despite the specific requirements in the 2017 renewal of glyphosate approval at the European level (Regulation 2017/2324) that particular attention should be paid to the "risk for the diversity and abundance of diversity and abundance of non-target terrestrial vertebrates and arthropods via trophic interactions" (more details in case example n°2).

3. Refusing to grant or renew national authorisations of glyphosate-based herbicides.

As demonstrated in the section above, GBHs fail to meet the requirements for authorisation outlined in Articles 29 and 4(3). By referring to these unmet requirements, Member States should deny the initial authorisation of GBHs (Article 36(3)) and refuse to renew those which have been previously authorised (Article 43(1)) (see Annex for details). Member States should also refer to the precautionary principle (Article 1(4)) when using article Article 36(3) and Article 43(1), in light of the evidence pointing to the potential harm resulting from exposure to GBHs.

According to the EU Pesticide Regulation, once an application for renewal of a GBH is received, the Member State examining the application shall decide within 12 months of receiving it, whether the requirements for authorisation are met and may refuse the authorisation (Article 37). If the authorisation of this specific GBH is approved, then applicants can apply for authorisations in different Member States of the same (or different) zones under Mutual recognition as explained in Article 40 (see Annex for details). In this case, the Member States have 120 days to decide on the application (Article 42(2)).

In addition to meeting the safety criteria to be approved, application dossiers must be complete and satisfy all of the requirements listed in Articles 33 and 34. If information is missing from the application dossier, the authorisation for a product should be deemed inadmissible (Article 37). When data is missing from the conclusions of the risk assessment carried out by a zRMS, or if information is missing from the application dossier, the authorisation of a product should not be accepted.

Case example N°1 - Refusing the renewal of a market authorisation based on Article 43 / Article 29

In 2019, the French Agency for Food, Environmental and Occupational Health and Safety (Anses) delivered a decision not to renew the national authorisation of the glyphosate-based herbicide AZURAL EXPRESS following an application from the company Monsanto. This refusal was based on the grounds that the data provided by the applicant did not allow the Anses to assess the genotoxic potential of the product. The studies provided by the pesticide firm were considered invalid, hence a genotoxic effect could not be excluded. The Anses concluded that the requirements of Article 29 were not met for the GBH. Later, the Anses announced[41] that it had given a negative opinion to 4 out of 11 new authorisation applications, on the same grounds. The data provided by manufacturers did not enable the agency to reach a decision on their possible genotoxicity.

Case example N°2 - Incomplete application/data gaps

In 2023, the Montpellier Administrative court overturned the decision[42] by which the Anses renewed the marketing authorisation of the two GBHs Touchdown Système 4 and Touchdown Forêt, following appeals by the NGO Générations Futures. The court found that the precautionary principle had not been respected, as the full risk assessment procedure had not been implemented. It was considered that several aspects had not been assessed by the Anses, in the absence of data submitted by the applicant Syngenta for certain risks concerning the impact on bees and other pollinators and concerning risks to non-target terrestrial vertebrates and arthropods. Yet the Commission's Implementing Regulation of December 12, 2017, on the renewal of glyphosate approval at the European level, required particular attention to "the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions". It was therefore concluded that the marketing authorisations disregarded the 2017 requirements renewing the approval of glyphosate. In its decision, the court refers to the requirements of Articles 29(1 to 3 and 6), 36(1) and 43(1 to 3), and provisions of the French national law.

[41] https://www.anses.fr/en/content/anses-announces-withdrawal-36-products-containing-glyphosate.
[42] Tribunal administratif de Montpellier, 12 mai 2023, n° 2026224.

4. Reviewing and withdrawing national authorisations of glyphosate-based herbicides.

Upon Article 44, a Member State may review the authorisation of a pesticide product it has already granted at any time, and not solely upon the application of a pesticide company for the renewal of a national authorization (see Annex for details). For GBHs under authorisation, a Member State may resort to Article 44 (1) on the ground that it no longer satisfies the requirements referred to in Article 29 of the EU Pesticide Regulation.

Application of Article 44

Case example N°3 - The Luxembourg "glyphosate decisions"

On 30 March 2023, a Luxembourg administrative appeal Court cancelled the Luxembourg government's decision to ban GBHs. Interestingly in its judgement, the Administrative Court clarified that Luxembourg is entitled to ban GBHs but failed because:

(1) Although it notified the holder of the application (Bayer) in line with its national law (Article 9 of the Grand-Ducal Regulation of 8 June 1979) and EU law (Article 44(2) of the EU Pesticide Regulation) it did not indicate the factual and legal reasons justifying its decision to withdraw their national authorisation. The justification provided by the Minister to the authorisation holder was a political argument instead of providing new scientific information demonstrating that GBHs do not meet the safety criteria from the EU Pesticide Regulation. As a result *"The Administrative Tribunal considered that Bayer was not properly informed and therefore could not exercise its rights of defence."* (Donati, 2013[43]) as foreseen in the EU Pesticide law.

(2) The Luxembourg State breached EU law by using Article 44(3) of the EU Pesticide Regulation as the unique legal basis for its glyphosate decisions. Indeed, the Luxembourg State should have also referred to Article 36(3) concerning the zonal approach in the evaluation of the authorisation of GBHs. For the Administrative Tribunal, the Luxembourg State could have refused Belgium's conclusions, being the zonal Rapporteur Member State, that the GBHs assessed were safe on the grounds that due its specific environmental or agricultural circumstances, there were substantiated reasons to consider that glyphosate-based products posed an unacceptable risk to human or animal

[43] Donati A. The Glyphosate Saga in Luxembourg: The Annulment by the Judiciary of the Legislative Ban of Glyphosate-Based Products – A Breach of European Union Law? European Journal of Risk Regulation. 2023;14(4):816-822. https://doi.org/10.1017/err.2023.63.

health or the environment. The Court identified that such a justification was missing from the ministry's decision.

However, according to a legal analysis of the Luxembourg case, Article 36(3) applies when Member states need to decide whether to grant the authorisation of a plant protection product following the conclusion of a zRMS, not when a Member State wishes to withdraw a marketing authorisation of a plant protection product, which has already been authorised in its territory (Donati, 2023). Therefore the statement of the Administrative Tribunal and the Court of Appeal were incorrect, in the sense that the Luxembourg State could withdraw the glyphosate decisions on the grounds of Article 44(3) of Regulation no 1107/2009 not only of Article 36(2) and (3) (Donati, 2023).

The Luxembourg case provides clear indications to Member States on the legal procedures required to ban, withdraw or restrict GBHs.

Case example N°4 - France withdraws 36 glyphosate-based herbicides from the market

In 2019, the Anses reviewed the marketing authorisations of 69 products containing glyphosate and marketed in France[44]. It first started carrying out a comparative assessment of the available alternatives (see next section) but quickly proceeded to withdraw the authorisation of 32 products (and refuse the authorisation of 4), due to a lack or absence of scientific data ruling out any genotoxic risk. In its communications, the Anses explains that its approach followed the more stringent requirements included in the re-assessment of glyphosate in 2017, "involving the provision of additional data on the health and environmental risks, and in particular on the genotoxicity of all the components of products containing glyphosate". These new provisions require specific studies to be conducted according to robust, standardised methods, and found that for 36 GBHs these requirements were not fulfilled and therefore withdrew their market licence.

Applying the precautionary principle

Case example N°5 - Neonicotinoids, fipronil & the precautionary principle

Following the observation of massive bee deaths in France, the French government decided to ban specific uses of neonicotinoids and fipronil, based on the precautionary principle. In order to protect bees, imidacloprid and fipronil were banned on sunflower and maize as early as 1999, while the EU banned these substances only in 2018.

[44] https://www.anses.fr/en/content/anses-announces-withdrawal-36-products-containing-glyphosate

Since 2018, all neonicotinoids (including the ones that were still approved at EU-level at the time, namely acetamiprid and thiacloprid) were banned in France, including substances with a similar mode of action (flupyradifurone and sulfoxaflor).

5. The voluntary substitution scheme - banning or restricting specific uses of glyphosate-based herbicides by performing a comparative assessment

Embedded within EU law is a commitment to promote the transition from chemical pesticides to safer, non-chemical alternatives. The Sustainable Use of Pesticides Directive mandates Member States to promote the development and implementation of integrated pest management and alternative approaches or techniques, to reduce their dependence on the use of pesticides. Article 50(2) of the EU Pesticide Regulation reflects this objective.

When a pesticide company applies for national authorisation for a GBH, they typically request approval for multiple uses of the product, for example on various types of crops. If a Member State, when evaluating an application for a GBH, identifies an already used non-chemical control or prevention method as an alternative to the product for the uses requested for authorisation, it has the option to reject the authorisation of the product for the proposed uses. This is done by performing a **voluntary comparative assessment**[45] (Article 50(2)).

A **voluntary comparative assessment** studies how well a pesticide product performs for a specific use(s) compared to an alternative(s). Factors such as agronomic efficiency, economic impact and effects on human health and the environment are considered. If the assessment concludes that the alternative(s) complies with the requirements set out in Article 50(1), Member States can refuse to grant or renew the authorisation for a specific product in favour of the studied alternative (see **case example n°6**) or restrict the conditions of use for a specific product (see **case example n°7).**

[45] Article 50(2) specifies that performing a voluntary comparative assessment should only happen in "exceptional cases". The EU Pesticide Regulation does not provide a definition of "exceptional cases", but the Commission Guidance Document SANCO/11507/2013 clarified that it can be interpreted as "pest/crop-situations where a non-chemical control or prevention methods are of equivalent agronomic effect, significantly safer, and in common use as an alternative. In these cases, the existence of these methods can be regarded as exceptional".

Application of Article 50(2)

Case example N°6 - Swedish Chemicals Agency - voluntary substitution of an acetamiprid product[46]

With the expiry date of its authorisation in sight, a company had applied for the renewal of its authorisation for the insecticide formulation 'Imprid Skog'. This product contains the active substance acetamiprid, a neonicotinoid, for use in forest nurseries and on small forest plants against pine weevil (*Hylobius abietis*). Having in mind the adverse effects of this substance on bees and other species, and the availability of alternative practices that can be applied in the field, the competent authority, the Swedish Chemicals Agency (KEMI) decided to conduct a voluntary comparative assessment to examine the possibilities of substitution for this specific use, i.e. if it is possible to manage these pests without it.

In May 2019, the Swedish Chemicals Agency (KEMI) rendered the decision to reject the application for the renewal of 'Imprid Skog'. The conclusions of its voluntary comparative assessment showed that since 2010, non-chemical alternative methods had been developed and increasingly used by the Swedish forest industry. While in 2014 these non-chemical methods were used for 17% of the forest plants, in 2020 it had reached 50%. During the same period, the proportion of plants treated with insecticides containing acetamiprid dropped from 28% to 3%. On this basis, KEMI concluded that: 1) most of the forest plants are treated with non-chemical methods or untreated (are in general use: 60%), 2) these alternative methods are safer 3) have no significant economical and practical disadvantages, and 4) have no consequences on minor uses. These conclusions led to the rejection of the renewal application.

KEMI's substitution decision was challenged by the company, but the Swedish Supreme Court sided with KEMI's decision, validating the substitution of the acetamiprid product. The Court of Appeal upheld the decision to reject the application on the grounds, inter alia, that the use of non-chemical control methods was more common than chemical control methods against pine and spruce weevils at the time of the decision, therefore a ban on the use of 'Imprid Skog' would not entail any significant economic or practical disadvantages for forestry owners.

This decision is very important as it is one of the first judgments in the EU demonstrating that chemical authorities can decide to replace pesticide formulations even in cases where they do not contain a substance that is classified as a Candidate for Substitution. This means that if there is a non-chemical control method or a preventive method in

[46] Retrieved and adapted from PAN Europe (2022). PESTICIDE PARADISE - How industry and officials protected the most toxic pesticides from a policy push for sustainable farming. URL : https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/PestPar_report%2020092022.pdf.

general use, the chemical method can always be replaced by this non-chemical method and the application for use of the chemical can be rejected.

Case example N°7 - ANSES - modification of the conditions of use of some glyphosate-based products

In France, the conditions of use of some GBH products were modified[47], following an assessment of non-chemical alternatives, based on Article 50(2) of the EU Pesticide Regulation. The Anses performed voluntary comparative assessments on four main areas of use of GBHs: viticulture, fruit growing, field crops and forestry. Based on the reports of the comparative assessments, the Anses has banned some uses and restricted the conditions of use in the four areas, when renewing or issuing national authorisations for glyphosate-based products. For example, the maximum authorised annual use rate of glyphosate has been lowered in viticulture and arboriculture and banned between rows of vines and fruit trees. (Anses, 2020)

[47] See for instance the decision from the Anses to modify the authorisation for the GBH Glister Ultra 360, adding restrictions on conditions of use [document in French], URL : GLISTERULT_PMAUT_2020-4318_D.pdf (anses.fr)

Annex - Authorisation of pesticide products in the EU (Regulation (EC) 1107/2009)

The Zonal System for the assessment of pesticide products and the principle of mutual recognition - in a nutshell

After an active substance receives an EU-approval, the pesticide company seeking to market a pesticide product that contains this substance can apply for authorisation in each Member State, where it intends to sell it. According to Article 29(1) of Regulation (EC) 1107/2009, the application must fulfil certain requirements, among them those under Article 4(3) demonstrating that "in the light of the current scientific and technical knowledge" the pesticide product (with all its ingredients, metabolites and degradation products) will cause no harm to human and animal health and no unacceptable effects to the environment. This Article underscores that the use of a pesticide product shall have, among others, no harmful effects on human health, including vulnerable groups, directly or through food or drinking water or air, taking into account known cumulative and synergistic effects (point b) and no unacceptable effects on the environment, taking into account its impact on biodiversity and ecosystems (point e(iii)). Moreover, according to Article 29 (6) interaction between the active substance, safeners, synergists and co-formulants shall also be taken into account during the evaluation procedure in line with the 'uniform principles' (Commission Regulation (EU) No 546/2011). All the specific requirements and contents of the application are listed in Articles 29 and 33, which include information and data on toxicity for products (data requirements, Commission Regulation (EU) No 284/2013) in line with Article 8(2); if any of these elements are missing the application should not be accepted. In a few words, if safety is not demonstrated a pesticide product shall not be authorised.

The EU Zonal system: To divide the workload of the assessment of pesticide products, the EU Pesticide Regulation foresees a 'zonal system', where EU Member States are grouped into 3 geographic zones: North, Central and South. The zones are defined on comparable agricultural, plant health and environmental conditions. EU countries assess the applications they receive on behalf of other countries in their zone and for certain uses, on behalf of all zones. The Member State, which receives the application for authorisation of a product for use in its geographic zone and carries out the assessment, is called the zonal Rapporteur Member State (zRMS). The applicant has the privilege to select a zRMS of their choice, who must then confirm whether it accepts the role. The zRMS has to evaluate whether the approval requirements for pesticide products laid down in Article 29 of Regulation (EC) No 1107/2009 are fulfilled by carrying out "an independent, objective and transparent assessment in the light of current scientific and technical knowledge" (Article 36). During the assessment, other Member States of the same zone are consulted for their views. Based on the conclusions of the assessment by the zRMS, the Member States of a zone may grant or refuse an authorisation (Article

36(2)). Refusal may be further justified if, due to specific environmental or agricultural circumstances, a Member State has substantiated reasons to consider that the product in question poses an unacceptable risk to human, or animal health or the environment (Article 36(3)), as well as if a non-chemical control or prevention method exists for the same use (Article 50(2)). When refusing authorisation for a pesticide product, Member States are required to notify the applicant and the Commission of their decision and provide a technical or scientific justification (Article 36(3)). The zRMS has 12 months from receiving the application to decide whether the requirements for authorisation are met.

Mutual recognition: Once an authorisation is granted, the pesticide company may apply for an authorisation "for the same plant protection product, the same use and under the comparable agricultural practices in another Member State under the mutual recognition procedure" (Article 40). This can be a Member State of the same zone or a different zone, depending on the agricultural conditions and intended uses of the pesticide product. The Member State has 120 days to respond (Article 42(2)) and may refuse the authorisation because of an unacceptable risk to human or animal health or the environment, due to specific environmental and agricultural circumstances (Article 41 (1) and 36 (3)). In this case, it shall inform the applicant and the Commission.

Renewals: The pesticide companies may apply for the renewal of the authorisation of a specific pesticide product, following the renewal of the approval of the active substance (Article 43). Considering that the requirements under Article 29 are still met, Member states may renew the authorisation of the product within 12 months.

Withdrawal or amendment, in cases of concern: According to Article 44 a Member State may review the authorisation of a pesticide product at any time if there are indications that the conditions of Article 29 are not met and the provisions of the EU law for a high level of protection are violated. It may decide to withdraw or amend the authorisation (e.g. restrict its use). The Member State should inform the applicant, the other Member States and the Commission. The Member States of the same zone may also withdraw or amend the authorisation.

Emergency measures: A Member State may request the Commission to take "emergency measures" (Article 69) if it is clear that an approved active substance, a pesticide product, or some of its ingredients (safeners, synergists, co-formulants) are likely to constitute a serious risk to human or animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned. These measures may consist of restricting or prohibiting the use and/or sale of that substance or product and shall be taken immediately. The Commission may request an opinion from EFSA.

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