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REVIEW ARTICLE

Regulatory framework for the assessment of the impacts of plant protection products on biodiversity: review of strengths and limits

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Abstract

The placing of plant protection products (PPPs) on the market in the European Union is governed by numerous regulations. These regulations are among the most stringent in the world, however they have been the subject of criticisms especially because of the decline in biodiversity. The objectives of this work were to review (1) the functioning and actors involved in the PPP framework processes, (2) the construction of the environmental risk assessment focused on biodiversity, and (3) the suggested ways to respond to the identified limits. Both literature from social sciences and ecotoxicology were examined. Despite the protective nature of the European regulation on PPPs, the very imperfect consideration of biodiversity in the evaluation process was underlined. The main limits are the multiplicity of applicable rules, the routinization of the evaluation procedures, the lack of consideration of social data, and the lack of independence of the evaluation. Strengths of the regulation are the decision to integrate a systemic approach in the evaluation of PPPs, the development of modeling tools, and the phytopharmacovigilance systems. The avenues for improvement concern the realism of the risk assessment (species used, cocktail effects…), a greater transparency and independence in the conduct of evaluations, and the opening of the evaluation and decision-making processes to actors such as beekeepers or NGOs. Truly interdisciplinary reflections crossing the functioning of the living world, its alteration by PPPs, and how these elements question the users of PPPs would allow to specify social actions, public policies, and their regulation to better protect biodiversity.

Keywords Pesticides · Regulation · Law · Risk assessment · Ecotoxicology

Introduction

The placing of plant protection products (PPPs) on the market in the European Union is mainly governed by the Regulation (EC) No 1107/2009 (2009) which entered into force on 14 June 2011, and repealed Council Directive 91/414/EEC (1991). According to this regulation, PPPs are defined as products that consist of or contain active substances, safeners or synergists, and are intended for several uses such as to protect plants or plant products against all harmful organisms or to prevent the action of such organisms, to influence the life processes of plants, to preserve plant products, and to destroy undesired plants or parts of plants. The Regulation (EC) No 1107/2009 (2009) shall also apply to the substances or preparations which are used or intended to be used in a PPP but are neither active substances nor safeners or synergists, and are referred to as co-formulants and to adjuvants which enhance the

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product effectiveness or other pesticidal properties (Regulation (EC) No 1107/2009 2009). This regulation states that before PPPs are placed on the market, it should be demonstrated that they present a clear benefit for plant production and do not have any harmful effect on human or animal health, including that of vulnerable groups, or any unacceptable effects on the environment. Regulation (EC) No 1107/2009 (2009) is associated with five other main regulations (Commission Regulations (EU) No 283/2013 2013; No 284/2013 2013; No 546/2011 2011; No 547/2011 2011; Regulation (EU) 2019/1381 2019) and is part of the "Pesticides package" bringing together Directive 2009/127/EC (2009) and Directive 2009/128/EC (2009), and Regulation (EC) No 1185/2009 (2009) (Fig. 1). At the European level, EFSA (European Food Safety Authority) is responsible for the peer review of the risk assessment of active substances and corresponding representative PPPs. Then, the decision to approve (or not) an active substance is taken by the European Commission. The approved substances are included in the list of approved active substances annexed to Commission Implementing Regulation (EU) No 540/2011 (2011), implementing Regulation (EC) No 1107/2009 (2009) (Fig. 1).

In addition, the assessment and approval procedures specific to PPPs and their components are supplemented by rules aiming at protecting the environment and the biodiversity (e.g., water law, law on protected species and areas; Council Directive 92/42/EEC 1992; Directives 2000/60/EC 2000; 2008/56/EC 2008; 2009/147/EC 2009), which may set stricter conditions for the use of PPPs, or even prohibit them, as they do for other activities and products that are potentially harmful to the environment and biodiversity. Indeed, for several years, an unprecedented decline in biodiversity is observed (IPBES 2019). The main drivers of this decline are change in land and sea use, unsustainable direct exploitation of biological resources, climate change, chemical pollution generated by human activities, including PPPs, and invasive alien species (IPBES 2019). At the European level, PPPs were identified as one of the main important pressure for bird and invertebrate (terrestrial, aquatic) declines (Pesce et al. 2024; Rigal et al. 2023).

In this context, the objectives of this work were to review (1) the functioning and actors involved in the PPP regulatory processes; (2) the construction of the environmental risk assessment focused on biodiversity; and (3) the suggested ways to respond to the identified limits. Both literature from social sciences and ecotoxicology related to the regulations specific to PPPs, i.e., the rules setting out the conditions for approval and marketing authorization and in particular those governing the evaluation of these products, have been studied. The cross-analysis of tools for controlling the placing of PPPs on the market with those for managing their use is of real interest in that it sheds light on the organization of risk-taking, an eminently political issue, by public authorities and private actors (Leonelli 2018; Noiville 2003).

Bibliographic corpus

Social sciences

The literature search was conducted on Web of Science™ (WoS), Scopus, Springer, Sage Publications, Doctrinal+, Westlaw Next, Westlaw UK, and on a database specialized in French-speaking publications in social sciences (Cairn), from 2000 to 2020. The following keywords were used (they were also used in French): "Plant protection products," "Pesticides," "Biodiversity," "Sociology," "Anthropology,"

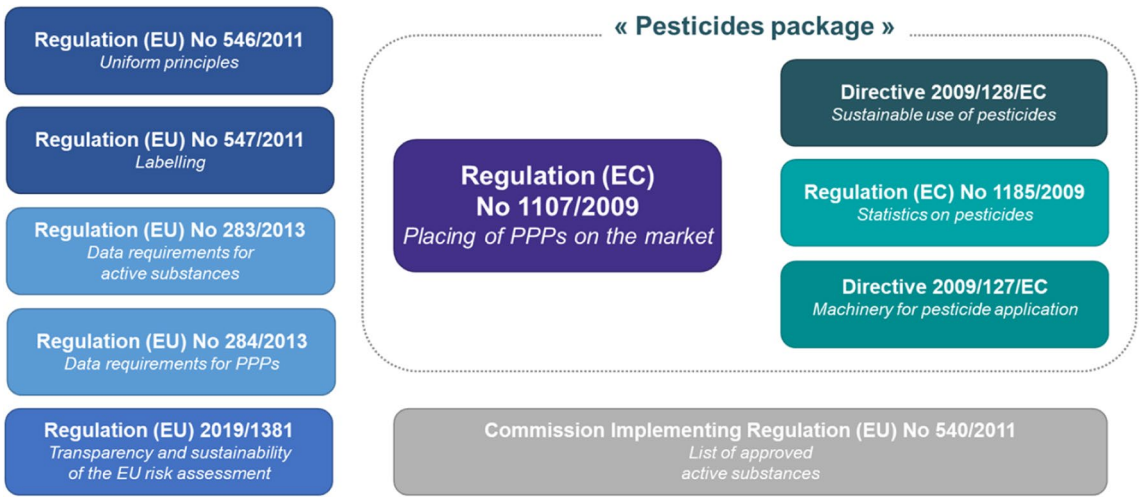

Fig. 1 Main regulatory texts concerning plant protection products (PPPs) in force in the European Union

"Political science," "Political ecology," "Law," "Conflicts," "Power," "Regulation," "Regulatory sciences," "Market." A total of 793 references was obtained, which were first sorted after reading the titles, abstracts, and keywords. This step led to the selection of 114 references which were read in detail: 41 for WoS, 26 for Scopus, 21 for Cairn, 10 from Doctrinal+; 10 from Westlaw Next and Westlaw UK, and 6 for Springer and Sage Publications.

More than half of these references dealt with the dynamics of regulation by social actors (other than scientific, institutional, and political actors): study of the social representations of individuals, knowledge and practices of farmers, and mobilization concerning worker health problems, which did not correspond to the objective of this work. In addition, as the literature search focused on the regulation of PPPs, understood as the rules relating to their placing on the market, and more particularly on Regulation (EC) No 1107/2009 (2009) and its implementing texts, legal works on the various rules for the protection of environments (e.g., water, protected species, and biodiversity) that may concern pollution by PPPs were not included.

Finally, 30 publications were retained. They were related to the relationship between science, regulation, and public policy regarding the effects of PPPs on health and, to a lesser extent, on biodiversity (consideration of scientific uncertainties in public decision making, right of public access to scientific data, regulation of PPPs including the normative production process, conditions of application of the rules relating to the marketing of PPPs). Some works focused on human health were relevant to the present study because the processes they describe were, in most cases and to a certain degree, transposable to what is happening with regard to ecosystem health, particularly in the context of PPP regulation.

Ecotoxicology

In the field of ecotoxicology, five main queries ("Regulation," "Evaluation," "Plant protection products," "Biodiversity," "Ecotoxicology") based on sets of keywords were defined in the WoS and then combined (Table SI1). The literature search covered the 2000-2020 period. A total of 894 references was obtained dealing with European and international regulations. A first large corpus of 183 papers was selected based on titles, abstracts, and keywords. Among this corpus, several papers were discarded because they were too old, as the regulations had evolved significantly from 2009 to 2020, and others were too focused on human health (thus outside this work). At the end, 30 articles were retained. Most of them dealt with the European regulatory context, but some focused on North American regulations, and a majority of articles were concerned with aquatic ecosystems.

Finally, in both social sciences and ecotoxicology, the bibliographic corpus was updated until 2022 with 14 relevant references.

European regulation of plant protection products: requirements and complexity

The complexity of the European regulation (Fig. 1) provides a high degree of legal protection due to the application of the precautionary principle, and strict conditions for approval and placing on the market (in particular, absence of harmful effects on human health and of unacceptable effects on the environment), under conditions of application that comply with good plant protection practices and under realistic conditions of use (Robinson et al. 2020). The European Union has thus withdrawn (and continues to withdraw) from the market a large number of active substances that are potentially problematic in terms of human, animal, or environmental health, unlike the USA, Brazil, or China, which continue to authorize them (acetochlor, atrazine, clothianidin, thiamethoxam, imidacloprid...) (Donley 2019; EPA 2023; EU Pesticides database 2023; Friedrich et al. 2021).

The European regulation concerning PPPs is one of the most stringent in the world, and demanding in terms of ecotoxicology (Gehen et al. 2019; Robinson et al. 2020). In particular, in Article 4-3, Regulation (EC) No 1107/2009 (2009) states the need to assess the effects of PPPs on biodiversity and the ecosystem. In parallel, over the last 20 years, a significant increase in the regulatory arsenal regarding the effects of PPPs on biodiversity has been observed, illustrated for example by the aforementioned "Pesticides package" (Fig. 1) or by the establishment of the list of plant protection substances of concern that must be given special attention with regard to their level of hazard and phytopharmacovigilance (PPV) data (Marty-Chastan et al. 2017). In addition, several EFSA guidance documents addressing specific protection goals related to biodiversity and ecosystem services provided by organisms have been published and adopted (EFSA PPR Panel 2015a; EFSA Scientific Committee 2016).

However, though it is ambitious, current regulation does not sufficiently protect biodiversity and avoid impacts to the extent of the intended goals. Indeed, regardless of this demanding legislation, numerous studies suggest that PPPs contribute to the decline in biodiversity (invertebrates, birds, etc.), and to the degradation of certain ecosystem functions and services (IPBES 2019; Pesce et al. 2024; Rigal et al. 2023). A discrepancy between the ambitions stated by European Union law and the environmental degradation attributable to PPPs is therefore observed.

Thus, the bibliography consulted at the interface of social sciences and ecotoxicology converges toward a criticism of

the current regulation concerning the a priori assessment of the effects of PPPs on biodiversity. Largely inspired by the effects of PPPs on human health, this criticism emphasizes in particular the routine nature of the assessment procedures, which does not allow for the complexity of the effects of PPPs on biodiversity, and the lack of independence of the assessment from the economic stakeholders and the actors who bear them (OECD-Organization for Economic Co-operation and Development, "mixed" groups of public and private scientists) (Arcuri and Hendlin 2019; Boivin and Poulsen 2017; Brock et al. 2016; Bruhl and Zaller 2019; European Commission Directorate-General for Research and Innovation 2018; Martin 2020; Schäfer et al. 2019; Storck et al. 2017; Topping et al. 2020). Moreover, the complexity of the rules for knowledge production on PPPs hinders their readability and effectiveness: there is a great profusion of texts that are delicately articulated, the content of these texts is excessively technical, and their legal nature is sometimes difficult to identify between binding standards (hard law) and voluntary standards (soft law) (Martin 2016).

Though crucial for risk assessment, the large amounts of data provided by the applicant in the application dossier (containing the required scientific information and studies) for approval and placing on the market makes it difficult to any researcher not involved in the registration processes to verify (Robinson et al. 2020). Furthermore, the data taken into account do not always correspond to the real conditions of use (treated surfaces, interactions between PPPs, ecosystem functioning, etc.), despite the expectations of Regulation (EC) No 1107/2009 (2009), which aim at "realistic conditions of use" and "good plant protection practice." These expectations are based on the principle of compliance with the regulation and conditions of use of PPPs (Good Agricultural Practices) as set out in the marketing authorization, but it has been proven that there are situations where these conditions are not respected: incorporating PPPs at a certain depth, respecting weather conditions, cleaning nozzles, etc. (Millot et al. 2017). It has to be underlined that the regulatory risk assessment considers assessment factors to compensate these uncertainties (Regulation (EC) No 1107/2009 2009; Topping et al. 2020).

Despite PPPs are evaluated by EFSA, the co-formulants they contain are evaluated by ECHA (European Chemicals Agency) according to procedures and models that are different from those of EFSA (Dobe et al. 2017; Commission Implementing Regulation (EU) 2023/574 2023). Therefore, different conclusions may be reached, since the regulatory requirements, uses, and quantities emitted are not the same (Regulation (EC) No 1907/2006 2006; Regulation (EC) No 1107/2009 2009). In addition, there is an overall lack of data regarding co-formulants because of the inadequacy of the current European Union testing requirements for assessing the PPP which is based on representative uses and PPPs (Nagy et al. 2020). Recently, to limit these divergences and to respond to a request from the European Commission's REFIT (European Commission's regulatory fitness and performance program) process of the European pesticide legislation, EFSA has provided a number of reflections about a global process for the scientific assessment of active substances, co-formulants, and PPPs (EFSA 2018a).

The administrative organization of regulation can also lead to ignoring warning signals from actors outside the regulatory sphere (Jouzel 2019). For example, some authors emphasized the need to better consider the effects of glyphosate on biodiversity in aquatic environments, due to its high occurrence in these ecosystems, but this did not translate into regulatory recommendations (Hendlin et al. 2020; Székács and Darvas 2018).

The marketing authorization decision is a political one, resulting from a compromise between conflicting interests (Hamlyn 2015; Hamlyn 2017): crop protection and economic interests (economic benefits PPPs produce in terms of food production, costs of damage by PPPs to human health and the environment, economic impact of a ban of PPPs on industry and jobs, etc.) versus protection of human health and protection of the environment. However, the combination of Regulation (EC) No 1107/2009 (2009) and Regulation (EC) No 1272/2008 (2008) allows the marketing of substances qualified as dangerous in return for hazard communication (Martin 2016). Moreover, the scientific uncertainty inherent in any risk assessment is not assumed by political decision-makers. This observation partly explains the distrust of evaluation agencies by citizens (Bauer et al. 2021; Pénet 2019).

Finally, the coherence of the regulations is affected by the multiplication of derogations that reduce the effect of the withdrawals. Among the examples that can be cited, a recent emblematic case in France concerns the derogation granted for the use of coated seeds treated with neonicotinoids (imidacloprid or thiamethoxam) in the context of the infestation of beet crops by aphids in Europe (JORF 2021; JORF 2022). Similarly, in the French overseas territories, chlordecone could continue to be used from 1990 to 1993 to control the banana weevil, whereas it was banned in mainland France in 1990 (Procaccia and Le Deaut 2009). More recently, asulam was the subject of a derogation from 2012 to 2018 for the weeding of sugarcane crops (MAAF 2016). It should be emphasized that derogations allow to respond to health emergencies which cannot be controlled by other means (Article 53 of Regulation (EC) No 1107/2009 2009), and to give the necessary time to research to provide the sectors with alternative. In a context of withdrawals or non-renewal of approval of substances of greatest concern at the European level, the problem of orphan uses is becoming more significant.

For some years, a disengagement of the state in the control of PPPs has been observed, illustrated for example by the case of PPP user training (Ansaloni 2017). By delegating to private actors the training of users giving access to the purchase of PPPs, the French state has initiated a new market, a central modality for the exercise of contemporary political power, which consists in taking on a public problem by initiating a market (Ansaloni 2017). As an illustration of this same movement, there are the certificates of savings of PPPs (Certificats d'Economie de Produits Phytopharmaceutiques - CEPP), implemented in France by the 2014 law on the future of agriculture (French Republic 2014), which also give rise to a market (Ansaloni 2017; Doussan 2020).

Intrinsic limits of the regulation

Incomplete consideration of scientific knowledge

Though Regulation (EC) No 1107/2009 (2009) indicates that scientific peer-reviewed literature published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier, the scientific basis mobilized in the regulatory framework partly ignores this knowledge (Robinson et al. 2020; Topping et al. 2020). Indeed, agencies tend to discard data when they have not been developed according to regulatory standards (Jouzel 2019; Robinson et al. 2020; Röttger-Wirtz 2020). However, the lessons learned from regulatory tests can be invalidated by field observations documented a posteriori in the bibliography, often based on methods and models (species, development stages tested, test conditions) different from those used in regulation and which can provide complementary results. The interactions between expertise, industry, the market, and the state result in what Demortain and Boullier (2019) call "expertise by the market." The expertise of products and their risks is carried out in a situation that is built at the confluence of scientific competence, administrative issues, and the market.

Most of the European standards governing the production of knowledge on PPPs were developed by the OECD, which took over the subject of PPPs (from that of chemicals in general) to harmonize rules and protect trade. However, the literature shows the lack of transparency in the processes for developing these standards (Lavarde et al. 2020; Martin 2020). In particular, the management of the links and conflicts of interest of the scientists involved remains unclear. Furthermore, these highly framed standards are not designed to estimate all possible risks for the environment (Lavarde et al. 2020; Martin 2020).

The regulatory framework also does not allow for the consideration of certain scientific approaches: the integration of scientific knowledge into regulation is a lengthy process that introduces a time lag between the knowledge available and that which is taken into account (Dedieu 2022; Topping et al. 2020). For example, in 2013, the EFSA Guidance Document on the risk assessment of PPPs on bees was published after many years of debate on the effects of neonicotinoids on insect pollinators (EFSA 2013). Several EFSA scientific opinions have subsequently been published on this topic (EFSA PPR Panel 2014; EFSA PPR Panel 2015b). The latest one (EFSA Scientific Committee et al. 2021) proposes a global risk assessment model (ApisRAM) which will be implemented progressively until 2025. Thus, it will have been almost 12 years between the first EFSA publication and the actual implementation of an integrated risk assessment model for bees while the scientific literature on bees, PPPs, and modeling increased at the same time (Larras et al. 2022a).

In addition, while the principle that it is up to the petitioners to provide proof of the safety of the substance or product they wish to place on the market, and thus to conduct the studies enabling them to provide this proof, is sound, its application leads to questionable effects: for example, studies sponsored by industry and/or those with authors affiliated with industry are much more likely to conclude that they are safe than studies conducted by scientists independent of industry (Robinson et al. 2020). Consequently, the purpose of regulation, i.e., to protect health and the environment, may be threatened (Spiroux de Vendômois et al. 2021). However, this issue remains complex and controversial.

At the regulatory level, risk assessment in the context of active substance approval is limited to one use and one product, based on an assumption of proper use (Regulation (EC) No 1107/2009 2009). The ecotoxicological regulatory report partly relies on tests carried out in the laboratory on species supposed to represent the diversity of species in the field and their place in the ecosystem (Fig. 2). However, these tests do not take into account, or do not take into account sufficiently (Brühl and Zaller 2019; EFSA et al. 2023; EFSA PPR Panel 2013; EFSA PPR Panel 2015a; EFSA PPR Panel et al. 2018; Ford et al. 2021; Köhler and Triebskorn 2013; Levine and Borgert 2018; Topping et al. 2020): (1) the cocktail effects of the use of several PPPs (herbicides, fungicides, insecticides…) in crop management during one crop season and during several successive crop seasons (though the huge number of combinations makes a comprehensive assessment difficult); (2) the effects on juveniles (adult organisms are less sensitive); (3) the effects on several groups of organisms considering their interactions; (4) the effects on vulnerable species, in particular amphibians and reptiles; (5) the sublethal effects such as the alteration of physiological processes, behavior or immune system; (6)

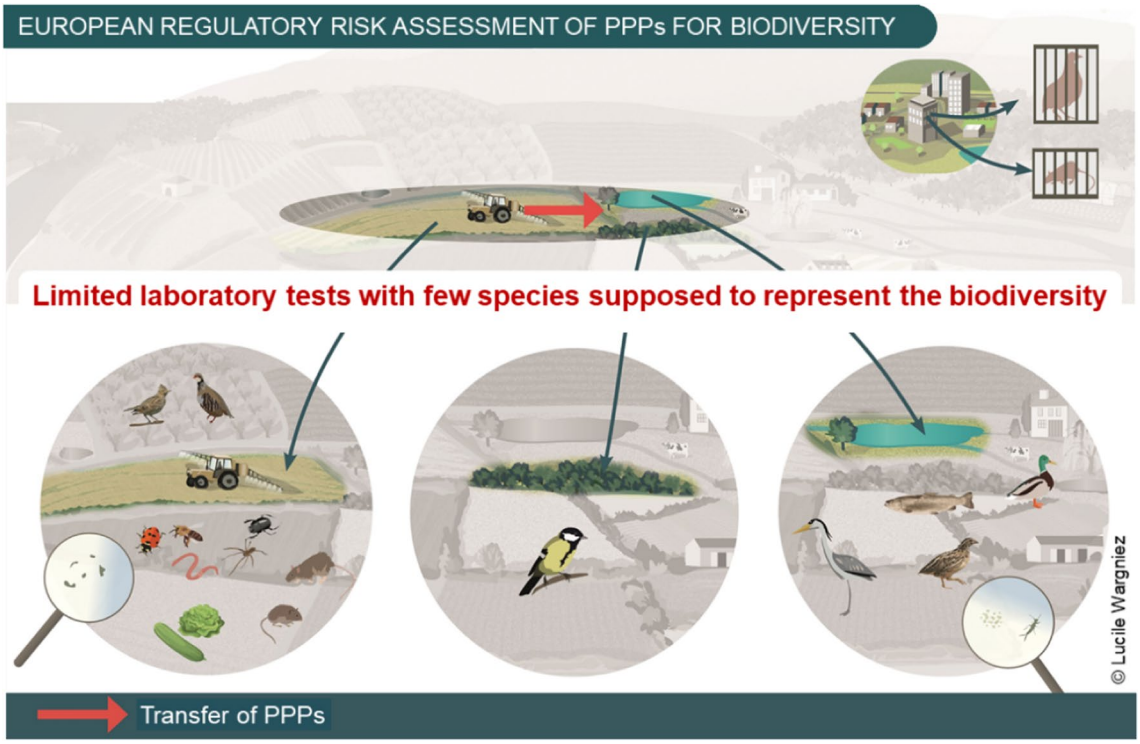

Fig. 2 Area concerned by the a priori European regulatory risk assessment of plant protection products (PPPs) for biodiversity

the micro-evolutionary effects that can lead to long-term adaptation or maladaptation of populations; (7) the effects over several generations; (8) the indirect effects (except for secondary poisoning); (9) the effects on populations, communities, and ecosystem functions and services.

The regulatory ecotoxicological risk assessment is based on a tiered approach which starts with a simple, conservative assessment (Tier 1), and carries out more complex and environmentally realistic assessments only when the lower tiers indicate there is a risk (EFSA PPR Panel 2013). However, if this tiered approach offers a sufficient level of protection for the acute direct lethal effects (Devos et al. 2016), it is criticized for being reductive and unrealistic, at least for the first decision levels of chronic risk assessment (Brock et al. 2016; Schäfer et al. 2019). Rico et al. (2019) questioned whether the assessment of the effects of fungicides as presented in the EFSA PPR Panel (2013) was sufficiently protective for freshwater ecosystems. After evaluating the three tiers, they concluded that the level of protection provided by this tiered analysis was in general correct, but that there were some exceptions. Thus, the authors pointed to a possible bias in estimating the risk of exposure to PPP only at Tier 1, and proposed to also take into account risk assessment at Tier 2. This will bring some environmental realism where a risk has been identified (Brain et al. 2015; Rico et al. 2019).

Risk assessment of PPPs is mostly based on experimental data, but it can also be based on modeling. However, the models used are mainly limited to QSAR (quantitative structure-activity relationship), DR (dose-response), and SSD (species sensitivity distribution) (Larras et al. 2022b). TKTD (ToxicoKinetic-ToxicoDynamic), population, community, food web, mixture, landscape scale models, and exposome models are rarely used (Larras et al. 2022b). Indeed, these complex models are difficult to use in a regulatory framework because they pose the problem of the acceptance and validation procedure by EFSA at the European level (and by ANSES-French Agency for Food, Environmental and Occupational Health Safety, at the French level), which is time-consuming as stated above. Moreover, the models used in the regulatory framework are sometimes based on assumptions that are not valid in natura, and on incomplete physiological, biological, and ecological data (Larras et al. 2022b).

Overall, the routine assessment procedures, as defined in the regulation, do not allow the consideration of the complexity of the effects of PPPs on biodiversity and cannot be translated to this high biological scale or to ecosystem functions and services (Topping et al. 2020). Furthermore, there are no clear criteria to assess and quantify the effects of PPPs on biodiversity, nor on ecosystem functions and services (Brown et al. 2017; European Commission Directorate-General for Research and Innovation 2018). Finally, it is difficult to adapt models and assessment methods to a systemic

view (exposome; multiple environmental exposures; chronic, ubiquitous, multidimensional effects...) due to a lack of data.

Lack of consideration of social science data

The inclusion of social science data in the marketing process, in addition to natural science (understood as life and environmental sciences) data, would allow for a more informed cost/benefit assessment of PPPs (Möhring et al. 2020; Topping et al. 2020). Many authors in sociology, law, political science, and geography point out the lack of consideration of the socio-ecological complexity inherent in the effects of PPPs on biodiversity and associated ecosystem functions and services. Systems thinking, as observed for example in the field of beekeeping, is mostly ignored in regulatory procedures: even if the epistemic form of knowledge of naturalist beekeepers is founded on knowledge based on field observation considering the real contexts of observation of natural dynamics, it is not taken into account (Adam et al. 2020; Aureille 2020). These so-called "integrated" knowledges can lead to research on the long-term (i.e., more than a few weeks) effects of certain PPPs, cumulative effects, and sublethal effects (Suryanarayanan 2013). Similarly, non-academic knowledge (farmers, citizen collectives, residents, NGOs, etc.), especially based on experience, is not taken into consideration.

Thus, some authors believe that the shortcomings of current PPP evaluation procedures are due to the fact that these procedures only consider data from natural science, without taking into account data from social sciences (Hamlyn 2017). For example, sustainable development, the subject of Directive 2009/128/EC (2009), is not only a matter of science or economics, it is political and based on social and moral values. Hamlyn (2017) thus recommends a holistic and inclusive approach, not only based on scientific data. This type of approach would allow for better consideration of the cost/benefit ratio in decision making.

Though the regulatory arsenal concerning the effects of PPPs has increased over the past 20 years at the European level, particularly with regard to biodiversity, there are still a number of deficiencies.

Limits of the monitoring post PPPs placing on the market

The literature highlights that monitoring post PPPs placing on the market does not sufficiently capture the impacts of PPPs on biodiversity (Topping et al. 2020). Although mentioned in Regulation (EC) No 1107/2009 (2009), this monitoring has not been the subject of any specific recommendation at the European level. At the French level, the ANSES set up the PPV in 2015 (ANSES 2021; Volatier et al. 2019). This system is unique in Europe and represents a significant development in the monitoring of the unintended effects of PPPs: it collects and analyzes monitoring data (environmental contamination; exposure, impregnation, and impacts on living organisms and ecosystems as a whole, including humans; resistance in target organisms) on PPPs that are made public. Ongoing review of these data may lead to prevention or risk mitigation measures to protect the health of living organisms and ecosystems. Within the framework of the PPV, biodiversity and soil are the subject of particular attention, but monitoring should be developed for the fate of PPPs, and for the ecological functions of soils and biodiversity (diversification of species monitored, see below).

Recently, as part of the Ecophyto II+ plan (2022) and a French monitoring program launched in 2012 (Biovigilance 500 ENI network) (Andrade et al. 2021), the unintended effects of PPPs on farmland biodiversity are being assessed, focusing on several taxonomic groups not targeted by agricultural practices (earthworms, plants, beetles, birds), on 500 agricultural plots. The objectives are to detect changes in the frequency or abundance of indicator species and simultaneous changes in agricultural practices. After 4 years of study, initial results show a higher species richness in organic agriculture than in conventional agriculture, mainly related to the higher number of species at the field edge. This open-air laboratory has identified the key elements for carrying out this type of in situ study. Problems were nevertheless raised concerning missing explanatory variables or the heterogeneity of the observer identification skills for certain taxa, with, however, a solid and consistent contribution of data in the agricultural context (Andrade et al. 2021).

In general, the available knowledge is still insufficient to assess the effects of PPPs after they are placed on the market (Topping et al. 2020). Data (contamination, effects) remain limited for the air, soil, and continental aquatic environments (to a lesser extent), and are particularly lacking for the marine environment. The range of species (and communities) monitored should be extended to phototrophic and heterotrophic microorganisms, including protozoa, wild pollinators, amphibians, reptiles, and bats, for terrestrial and aerial environments, and invertebrates and vertebrates for aquatic environments (Mougin et al. 2018; Pesce et al. 2024).

Moreover, when data exist, they are not sufficiently mobilized: for example, the OZCAR (Observatoires de la Zone Critique: Applications et Recherche - French network of Critical Zone Observatories: Research and Applications) network (2023), which groups together instrumented sites for long-term measurements of biological, chemical, and physical parameters of groundwater, rivers, glaciers, soils, and wetlands in France and in the overseas territories, is not enough used.

Finally, for many years, the scientific community has pointed out gaps in long-term, landscape-scale field monitoring of the fate of PPPs (dynamically, as their point presence is already being measured) in the land-to-sea continuum and biota, and their effects on organisms (Pesce et al. 2024).

Avenues for improvement

Several possible avenues for improvement in PPPs risk assessment for biodiversity have been identified at the scientific level (experimentation and modeling, monitoring post-placing on the market, systemic approach) and at the regulatory level (transparency and independence, consideration of published data, involvement of other actors).

Scientific avenues for improvement

Before substances are approved and placed on the market, risk assessment could be improved by taking into account juveniles; the effects at the population, community, and ecosystem levels; the effects on amphibians, reptiles, and of species of the marine environment; the effects of the combination of several PPPs as well as the multi-stress effects taking into account other types of chemical or non-chemical pressures; and the sublethal, micro-evolutionary, and indirect effects. The bulk of these avenues for improvement were identified by Brühl and Zaller (2019), EFSA et al. (2023), Ford et al. (2021), Köhler and Triebskorn (2013), Levine and Borgert (2018), Topping et al. (2020), and van Dijk et al. (2021). It has to be underlined that EFSA Scientific Committee et al. (2019) has proposed harmonized methodologies for risk assessment of combined exposure to multiple chemicals. The methodologies are based on an additive approach to toxic effects which assumes no interaction among PPPs (Belden and Brain 2018; Cedergreen 2014); however, this is not compatible with all types of dose-response data, and they only cover mixtures of PPPs (i.e., preparations with several active substances or extemporaneous mixtures of PPPs) (Larras et al. 2022a; Ritz et al. 2021).

At the modeling level, this would involve using ecological models that integrate individual-level effect models, toxicokinetic models, and population models; and developing models to assess risks for biodiversity (Accolla et al. 2021; Brain et al. 2015; Hommen et al. 2016; Larras et al. 2022b; Rohr et al. 2016). A major effort is needed to make the models more comprehensive, more ecologically relevant and less uncertain, and more consistent.

In addition, there is also a need to integrate a systemic approach into assessment methods, as proposed by EFSA (EFSA Scientific Committee 2016; Tissier-Raffin et al. 2020). This framework, considering biodiversity and ecosystem services in risk assessment, should make the assessment more spatially relevant for management decisions (e.g., which services and geographic areas to protect) by improving transparency in communicating risks and trade-offs, incorporating different stressors, scales, and habitats, as well as policy issues.

The management of risks related to PPPs can be achieved through the implementation of alternative agricultural practices (Tibi et al. 2022). However, Grimonprez and Bouchama (2021) emphasized that the notion of alternative should be thought as the set of methods and practices to be deployed at the plot or farm level that allow for comparable control of the PPP risk. In addition, in order to give legal status to more ecologically virtuous practices, the authors proposed that they should be subject to genuine standardization (like organic farming), recognized by an independent authority.

Finally, after PPPs placing on the market, the literature shows that it is necessary to strengthen monitoring in all environments and to extend it to other organisms (Mougin et al. 2018; Pesce et al. 2024). As biodiversity decline is multi-causal (IPBES 2019), the monitoring design should allow to identify the contribution of PPPs in the observed effects. The monitoring of bioagressors resistance is also of crucial importance (Barres et al. 2021).

Regulatory avenues for improvement

Many authors highlighted the need to increase the transparency and independence of the conduct of assessments (i.e., making available all data used for the regulatory reports) (Brock et al. 2021; Robinson et al. 2020). The Regulation (EU) 2019/1381 (2019), which entered into force on 27 March 2021, addresses these concerns by increasing the transparency and sustainability of the European Union risk assessment in the food chain, and the reliability, objectivity, and independence of studies used by EFSA. Robinson et al. (2020) also recommend to strengthen the independence of the EFSA panels of scientists from the economic interests of industrial producers to search for biases, invalid or outdated hypotheses, and possible violations of the precautionary principle in the methodologies used, to revise them independently of the administrative authorities. Another possible way to increase transparency is to make all data and value judgments used in regulatory decision making accessible for public interpretation following the concepts of Open Science (Brock et al. 2021).

It is sometimes suggested that studies for PPP risk assessment should be commissioned by bodies such as EFSA (Robinson et al. 2020; Storck et al. 2017). While the petitioners would still bear the financial cost of these studies, it would no longer be possible for them to choose the laboratory or scientists conducting the studies, nor would it be possible to choose the design and the conduct of the studies or

interpretation of the results and risk assessment (Robinson et al. 2020; Storck et al. 2017).

Another avenue for improvement concerns the consideration of peer-reviewed data, including epidemiological and field data, as well as data from the social sciences. Indeed, industry studies are predominant in risk assessment, and the criteria used to validate or invalidate a study make studies conducted according to OECD protocols and respecting good laboratory practice (GLP) procedures the majority, which is generally not the case for academic studies (Jouzel 2019; Robinson et al. 2020; Röttger-Wirst 2020). The academic literature is well taken into account in the evaluations (Regulation (EC) No 1107/2009 2009), but the obligation to provide data in a broad way with a systematic, transparent, and reproducible selection of relevant studies to objectively gather as many peer-reviewed papers as possible implies that the Rapporteur Member State can verify these data and request any information it deems missing. In any case, for new substances, no data can be available.

After PPP placing on the market, an action plan should be put in place that accelerates responses (restrictions) to newly identified risks according to the benefit/risk balance principle, limits the number of derogations for the use of withdrawn PPPs, puts in place a ban on sales of withdrawn PPPs to other continents, and makes available to the public any new results obtained post placing on the market, as in France with the PPV (Storck et al. 2017).

Finally, it is important to open up the PPP issue to other actors and other knowledge than that mobilized in the framework of regulatory processes (Möhring et al. 2020). Consultations on EFSA scientific outputs on PPPs are in line with this approach: they allow the collection of comments from either the public in its entirety or from specific groups of stakeholders (academics, NGOs, industry, Member States, and other potentially interested and affected parties) who therefore contribute to scientific debates (EFSA 2018b). Some case studies and comparisons show how taking on PPP issues outside the regulatory sphere, through farmers unions, environmental or consumer associations, contributes to modify decision-making. This is the case, for example, with neonicotinoids, for which decisions were made by managers that were not in line with the results of the a priori evaluation, to respond to the concerns expressed by stakeholders about pollinating insects (Demortain 2021). Alternative knowledge had emerged because actors producing and using knowledge from ecotoxicological research (public researchers, beekeepers, NGOs, politicians advocating environmental action) had joined forces to intervene in the regulatory space (Demortain 2021; Kleinman and Suryanarayanan 2013; Kleinman and Suryanarayanan 2020). Some neonicotinoids have thus been banned in France even though they were approved at the European level. An advancement in regulation would be to be able to guide public decision making by considering the social, economic, and environmental values of a society (Hamlyn 2017).

Conclusion

The review of the European PPP regulation from social sciences on the one hand, and ecotoxicology, on the other hand, showed the very imperfect consideration of biodiversity in the PPP evaluation process, even though Regulation (EC) No 1107/2009 (2009) expressly mentions biodiversity as one of the protected interests. Where a systemic, global assessment of the effects of PPPs on biodiversity would be necessary, the assessment appears to be fragmented and partial.

The questionable scientific foundations of the evaluation are pointed out, as well as the fact that the evaluation of PPPs does not allow for the reality of the use of these products to be considered. It is therefore not very surprising to observe, as did a report of the French Parliamentary Office for evaluation of scientific and technical options devoted to this subject in 2019 (Médevielle et al. 2019), that a climate of mistrust regarding the regulation of PPPs has been in place for several years, as in other fields affected by health and environmental risks.

Truly interdisciplinary reflections, i.e., which cross the functioning of the living world, its alteration by PPPs, and the way in which these elements question the users of PPPs, should be developed. They would allow to specify social actions, public policies, and their regulation in relation to living organisms and not only to human health. They would open relevant comparisons to determine whether the health of humans, animals, plants, and environment are treated differently or whether there are complementarities or interrelationships as recommended by the "Eco Health" concept.

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