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FATE AND IMPACT OF PESTICIDES: NEW DIRECTIONS TO EXPLORE

Environmental risk assessment of pesticides: state of the art and prospective improvement from science

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Abstract Pesticide risk assessment in the European regulatory framework is mandatory performed for active substances (pesticides) and the plant protection products they are constituents of. The aim is to guarantee that safe use can be achieved for the intended use of the product. This paper provides a feedback on the regulatory environmental risk assessment performed for pesticide registration at the EU and member state levels. The different steps of pesticide registration are addressed considering both exposure and hazard. In this paper, we focus on the environmental fate and behaviour in surface water together with the aquatic ecotoxicity of the substances to illustrate pesticide regulatory risk assessment performed for aquatic organisms. Current methodologies are presented along with highlights on potential improvements. For instance, as regards exposure aspects, moving from field based to landscape risk assessments is promising. Regarding ecotoxicology, ecological models may be valuable tools when applied to chemical risk assessment. In addition, interest and further developments to better take into account mitigation measures in risk assessment and management are also presented.

Keywords Pesticides · Regulation · Risk assessment · E-fate · Ecotoxicity · Improvements

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Introduction: risk assessment for the environment

The most common use of pesticides is in the form of plant protection products. Plant protection products are 'pesticides' that protect crops or desirable or useful plants. They are primarily used in the agricultural sector but also in forestry, horticulture, amenity areas and in home gardens. They contain at least one active substance and have one of the following functions: protecting plants or plant products against pests/diseases, before or after harvest; influencing the life processes of undesired plants (destroying or preventing their growth or parts of them) or preserving cultivated plant products. Plant protection products may also contain other components including safeners and synergists. European countries authorize plant protection products on their territory and ensure compliance with European rules as defined in European Regulation EC 1107/2009 (Official Journal of each European Union 2009).

Regulatory framework of pesticide risk assessment

For the placing on the market and the use of pesticides in agricultural and non-agricultural areas, risk assessment and authorization are required for each active substance and plant protection product (PPP). These products must meet a large number of criteria to ensure the protection of workers, consumers and the environment, for the intended use. These criteria are defined European Regulation EC 1107/2009, adopted by all countries of the European Union. It lists all the studies to be provided by the applicants in order to characterize their products. These tests are applicable to both the plant protection products and the active substances they contain. Active substances are evaluated individually by one of the European countries. This assessment, after discussions and agreement among European experts, is used by all 28 countries of the European Union. In France, it is the regulated products directorate (DEPR) from the French Agency for food, environmental and occupational health and safety (ANSES) that performs this assessment when France is in charge of an active substance. Substances have to meet the criteria defined by risk managers in the regulation. The criteria are related to the efficacy of the substance, its composition and properties, the available analytical methods, its effects on human health, the presence of pesticide residues in food, its fate in the environment to determine the exposure in soil, ground and surface water and air, and its effects on the organisms living in the environment. Only active substances listed in the 1107/2009 regulation can then be marketed in the form of plant protection products in the Member States of the European Community (Fig. 1). Granting authorisations to place plant protection products on the market remains within the competence of the Member States. One of the main changes in the 1107/2009 regulation compared to the previous one (91/414 EC) was the implementation of a zonal approach. European countries were divided within three zones: the Northern, the Central and the Southern zones, the latter including France.

According to the new regulation 1107/2009, one member state of each zone, the zonal Rapporteur Member State (zRMS) takes the lead on PPP risk assessment. When France is zRMS, Anses-DEPR is in charge of the assessment of the plant protection product dossiers prior to its authorisation. The zRMS has to ensure that the conducted risk assessment fits for all member states of the zone. Ideally, every member state of the zone is able to use the risk assessment as proposed by the zRMS to deliver an authorisation of the PPP in its own country via mutual recognition. As a consequence, the zonal approach has transformed the risk assessment working. The challenge is to share a common dossier that includes an agreed risk assessment and potentially additional risk assessments, in order to meet the specific requirements or enforcements of the member states of the considered zone. This paper aims at providing a feedback on the regulatory risk assessment performed for pesticide registration. Pesticide risk assessment is a scientific process that can be described by three main steps. First, the hazard assessment (ecotoxicity) of the compound must be defined. Second, the exposure assessment (expressed as Predicted Environmental Concentrations, PEC) must be determined to predict the occurrence of the compound. Finally, the risk assessment is performed with the combination of both ecotoxicity and exposure to the compound by deriving a risk characterization ratio which is "exposure/effect", i.e. predicted environmental concentrations (PEC)/predicted no effect concentration (PNEC). Current methodologies used for the different steps are presented below, together with highlights on potential improvements to consolidate risk assessment practises. To illustrate this purpose, a focus on the risk assessment performed for aquatic organisms is made in this paper. It concentrates on the exposure and the hazard assessment together with new main challenges identified in this field. This paper also provides information related to mitigation measures that may be used for pesticide regulatory purpose.

Exposure assessment

Predicted environmental concentrations

The environment exposure to pesticides and their metabolites has to be scrutinized in the different compartments (soil, water, air). In soil, the degradation pathways in different incubation conditions (aerobic, anaerobic and photolysis) have to be described. The fate and behaviour of an active substance and its metabolites are mainly characterized by the experimental estimation of their degradation and adsorption properties. Potential mobility in soil is described using adsorption/desorption studies. In water, the fate and behaviour is described using hydrolysis, photolysis and water/sediment studies. In air, information regarding volatilisation from soil and/or plant surface together with degradation has to be provided.

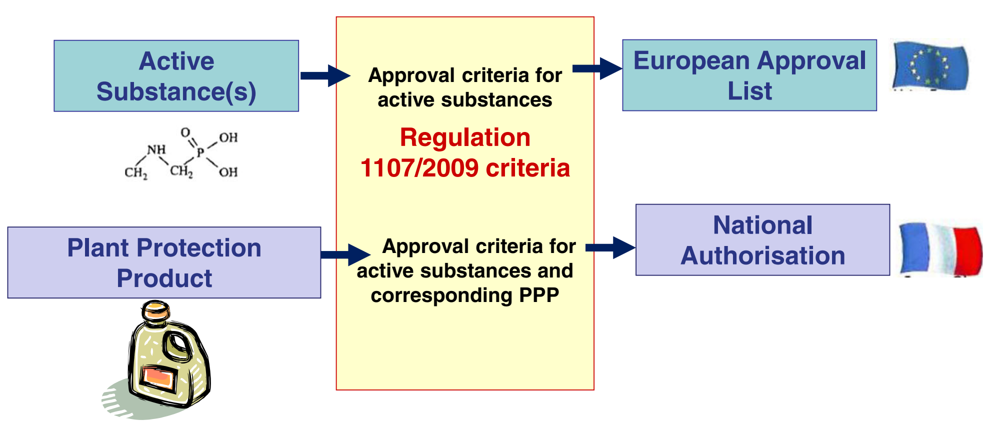

Fig. 1 Regulatory context for pesticide active substances and plant protection product (PPP) granting

This step is intended to determine the predicted concentrations of active substance and possible degradation products, which may affect humans and the environment during the use of a plant protection product. When considering the water compartment, the objective is to estimate the amount of pesticides that may be present in surface waters and groundwater. The fate and behaviour of an active substance and its metabolites is mainly characterized by their degradation and adsorption capacities. Studies used to define these parameters are mandatory for regulatory risk assessment. Data sets derived from degradation and adsorption studies are used to implement models. These concentrations are estimated using models that represent the main routes of contamination. For example, for surface water risk assessment, numerical models are used. For surface water, the predicted environmental concentrations are first estimated using simplified tools (focus step 1–2) then using MACRO (Jarvis et al. 1994) and PRZM (Carsel et al. 1984). They account for potential transport by spray drift during the application, by drainage into the artificial pipe systems (agricultural field equipped with buried drains to remove water excess) and runoff at soil surface. The numerical models are built to account for specific properties of each substance and its potential degradation products that may be formed in soil, water or sediment (solubility, retention and rate of degradation in soil and sediment) together with properties of the natural environment (soil type, climate, culture). Finally, the models are used to derive predicted environmental concentrations (PEC) for the different intended uses required. Each intended use is defined by an application rate per hectare on each crop; the PPP is intended to be used on a number of applications per year and a period of application in the year. For surface water, the derived PEC (PECsw) is then compared to ecotoxicological endpoints. The PECsw is compared to a predicted no effect concentration (PNEC) derived from the toxicity endpoint of the most sensitive species tested. PEC can also be directly compared to trigger values. This would be the case with PEC derived for groundwater (PECgw), which is compared to the regulatory trigger of 0.1 μg/L for active substances.

Exposure assessment: challenges from laboratory to field scale

For regulatory purpose, many laboratory studies, but also field and semi-field experiments, are carried out to derive endpoints for the forthcoming evaluation and provide robust datasets to perform reliable risk assessments. In the future, accurate quantitative tools based on relevant input data and scenarios being more representative of field conditions would need to be developed and validated for risk assessment purpose. Some other quantitative tools would be of great interest for some compounds (i.e. metabolites) when specific parameters are missing. This could be the case for transformation compounds identified in specific conditions (hydrolysis, photolysis) and for which no experimentations have already been performed or when study are rejected if not consistent with current guidelines. In these particular cases, using quantitative structure-activity relationships (QSAR) may be more than appropriate. Yet, these tools are very rarely used in pesticide risk assessment since none of them has been identified as being able to produce robust enough data. A comprehensive review of QSAR allowing the prediction of the fate of organic compounds in the environment from their molecular properties was performed by Mamy et al. 2015.

Based on this review, it is foreseen that the relevant QSAR equations may already exist to predict the fate of a wide diversity of compounds in the environment such as regional approach should be thoroughly explored. Field experiments are also used in the context of pesticide registration for a higher tier risk assessment. While the current risk assessment (exposure and toxicity) focuses on the impact at single field scale, moving from the field based to larger areas of interest for pesticide risk assessment may also be a major improvement and challenge. Regarding the groundwater exposure, spatial approaches are already used to predict the fate and behaviour of pesticides (Moeys et al. 2012). Still, estimating pesticide leaching risks at regional scale requires data, such as soil and land-use maps, to parameterise pesticide fate models. When field data are missing, parameterisation is usually achieved through pedotransfer functions, predicting soil properties from soil characteristics as texture or field morphology, etc. Such an approach may help to identify vulnerable situation (soils, crops, practices) where specific mitigation measures would be needed. Existing tools, like MACRO—DB (a decision-support tool for assessing pesticide fate and mobility in soils), based on detailed and/or high resolution maps (geo-referenced data), are already available as decision-support tools for assessing pesticide fate and mobility in soils (Jarvis et al. 1997; Boesten et al. 1995). While these tools are promising, an effort should be made to validate such approaches at both field and regional scales. Harmonizing the modelling practises at the European level would also facilitate their validation and implementation at the national level. As concerns surface waters, new developments are still necessary especially to better take into account the landscape level. Some recent approaches allowing to identify the specific routes contributing to surface water contamination at the water body catchment scale still need to be consolidated and validated. For instance, Gauroy et al. (2014) developed the ARPEGES method to assess the risk of contamination of each surface water body by pesticides in France. This tool aims at representing the complex relationships between agro-pedo-climatic parameters, pesticide uses and the main route of contamination. The interest to use this method for the post-homologation assessment of active substances should be estimated. In addition to exposure, further high resolution maps (geo-referenced data) which include all important landscape elements (as fields, non-cropped areas, ditches, buffer zones, etc.) and maps of the distribution of species of interest would need to be developed for risk assessment and management purposes. Recent examples show how landscape-based pesticide risk assessments could be developed in the future (Efsa 2013).

For example, in the case of non-target arthropods, Topping et al. (2015) explain that an approach considering the landscape and population levels for environmental risk assessment also demonstrates that there is a potential to change from regulation of a pesticide taken in isolation, towards the consideration of pesticide management at landscape scales and the provision of biodiversity benefits via the inclusion and testing of mitigation measures effects in authorisation procedures. As identified, important points for a spatially explicit risk assessment and risk mapping for the different regions in Europe are, for example, the definition of specific protection goals for the landscape level as well as associated trigger values and risk assessment schemes.

Hazard assessment

Current risk assessment

This step aims at establishing ecotoxicological properties of an active substance, its metabolites and the plant protection products it is contained in. For ecotoxicity, the effect on birds, bees, earthworms, aquatic organisms and other non-targeted organisms have to be characterized in short- and long-term studies to determine the PNEC and many other endpoints. Reference values for each species must be derived. For surface water risk assessment, the performed ecotoxicological tests must be the representative of the biological diversity of natural freshwaters. For each of the major groups of organisms (fish, crustaceans, insects, plants), the toxicity of substances and formulations is estimated by conducting laboratory tests on standard species whose sensitivity has been well established (Fig. 2). These tests are performed to determine the acute and chronic ecotoxicity for the active substance, its metabolites and each associated plant protection product. Based on these tests, harmonized classification for the active substances and formulations, according to regulation (EU) No 286/2011, can be established and reported on the packaging (cans, bottles, bags, ...) of the corresponding formulation.

As a matter of fact, all living species cannot be tested in the laboratory. One or more model organisms are chosen to represent the others. For example, to estimate the toxicity of substances or formulations for fish living in cold water habitat, the laboratory representative organism is the trout. However, even using this representative species as a requirement for water quality standard, it is unlikely to claim protection of all fish species in cold water. Therefore, safety factors are then applied to the results obtained from the ecotoxicological tests in order to minimize the uncertainty and increase the chance of protecting a vast majority of the wildlife. In addition to ecotoxicological tests performed in the laboratory, tests mimicking natural conditions can also be conducted to assess the effects of a substance on aquatic ecosystems. For aquatic life, installations in which these tests are conducted are called microcosms (micro-ecosystems) or mesocosms (meso-ecosystems) depending on the size (scale) of the experiment. These systems are generally ponds containing aquatic species from several levels of organization. The tested substance or formulation is introduced into the pond, and its impact on the miniature ecosystem functions and structure (number of individuals and species, weight, height, etc.) is monitored for several weeks or months and compared to control systems (uncontaminated). The results obtained from these experiments are used to estimates PNEC and compared to PEC.

Hazard assessment: new challenges

Most of the risk assessments of pesticides focus on risk at the level of the population, by comparing exposure (predicted environmental concentrations) to ecotoxicological endpoints for single species. Moving to community level would mean addressing the effects of pesticides not only on exposure and toxicity ratios but also on factors such as population structure and interactions in the ecosystem, timing of application and landscape structure. The scientific literature gives some examples of existing ecological models that could be used for chemical risk assessment (Topping et al. 2003). Still, their specificity, complexity and parameterisation (ever-increasing amounts of data) are major constraints for rapid implementation in regulatory risk assessment of pesticides. Fortunately, those limits are already identified and some proposals have been made to enable their use in the future (Schmolke et al. 2010). Given the recent initiatives to articulate environmental protection goals in terms of ecosystem services, a next major challenge for ecological modelling is to link service-providing units (e.g. populations, communities) with ecosystem service provision (e.g. water purification, pollination, pest regulation), both mechanistically and dynamically (Forbes and Calow 2013).

Current mitigation measure in risk assessment

Mitigation measure and risk assessment: current practice

The risk assessment for aquatic organisms takes into account both the hazard (ecotoxicity) and the exposure (predicted concentrations in the environment). Thus, the more toxic a substance or a plant protection product is, and/or the higher the

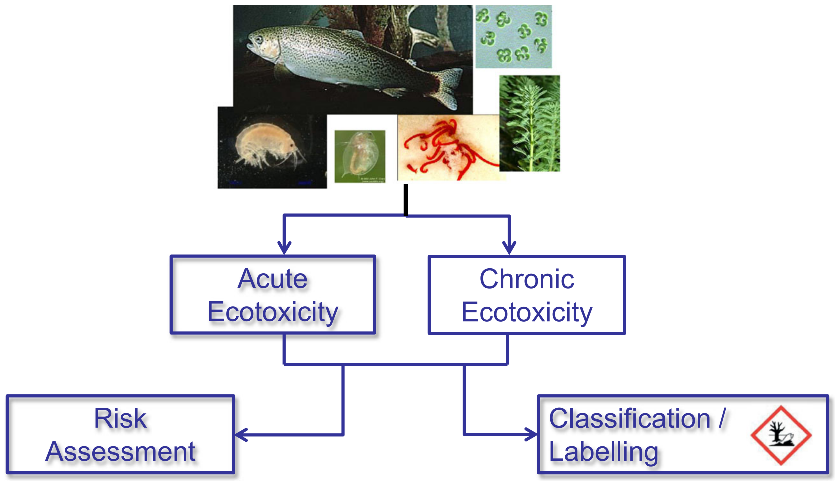

Fig. 2 Example of the aquatic ecotoxicity with the use of the test results performed in laboratory or in mesocosms

predicted concentrations in the environment are, the higher the potential risk is. It is possible, in some cases, to reduce the exposure of organisms by establishing mitigation measures to be applied during product application in the field. Following the risk assessment made prior to the placing on the market of plant protection products, it may be recommended to implement different mitigation measures for their use. Regarding the protection of surface water, recommendations are for instance to avoid spraying the product within a certain distance from a water point and/or to respect an untreated zone. This untreated area aims at reducing the direct exposure of the aquatic environment via spray drift during the application of the product. It may also be advisable to set up a vegetative buffer strip alongside streams to reduce the exposure of aquatic organisms by mitigating the transport of pesticides by spray drift and runoff (Fig. 3). Finally, to reduce the transport by artificial drainage networks, it may be recommended not to apply a formulation on field plots equipped with tile drain systems.

Mitigation measure and risk assessment: needed improvements

Besides current practises, other complementary mitigation measures could be implemented for risk assessment and management in European countries together with indication of their benefits and possible constraints, where relevant. In addition to the vegetated filter strips as implemented in the regulatory risk assessment, other measures in the field like no-till or reduced tillage, edge-of field bunds, artificial wetland/retention pond, vegetated ditch and inter-row vegetated strips (mainly for permanent crops) could be proposed. In a management purpose, the measures should enable a flexible approach for the mitigation of runoff in the field, and different measures or combinations of measures should be made available together with the efficiency of such measures. Ideally, an approach based on an appropriate field-specific runoff diagnosis at the catchment scale would be a powerful tool to better manage this route of exposure. Finally, the panel of measures should come with practical details on their requirements for implementation and management as well as the need to adapt them within the member states according to agro-pedo-climatic or socio-economic considerations. The integration of mitigation measures in a risk assessment or decision making process is also of major importance. As for that, a mitigation measure needs to come with numerous relevant publications in order to support its implementation at EU level. This aspect has been so far a limit for the integration of many mitigation measures for which few literature was available. Risk assessors and managers may however implement practice and management measures already available at the national level, and take the opportunity to highlight local expertise in order to implement and/or develop additional suitable mitigation measures (Alix et al. 2015; Le Hénaff et al. 2016). Finally, as regards the evaluation of the efficacy of the risk mitigation measures and possible needs for additional

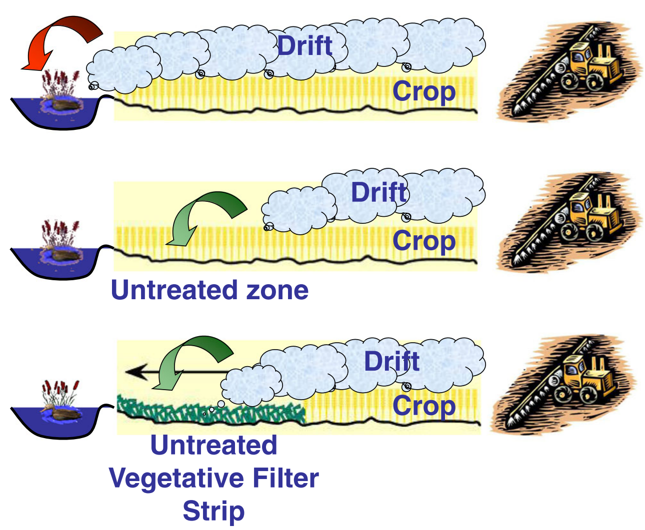

Fig. 3 Untreated zones and vegetative filter strips to mitigate aquatic organisms exposure

monitoring data, one has to acknowledge that further studies would be useful, especially at the catchment scale. The enforcement of local operational services also seems necessary to encourage mitigation measures implementation and provide relevant advises on the best mitigation options so as to help to achieve the defined protection goals.

Conclusion

Regulatory risk assessment performed in Europe for pesticide active substances and plant protection products guarantees a high level of protection of Human and the Environment. This is mainly due to the fact that current practises are based on experimentations and/or modelling tools originating from the academic board. Pesticide risk assessment is then in perpetual improvement and it does constantly benefit from academic inputs. Even if academic and regulatory constraints, objectives and schedules are known not to be the same, it has been obvious in recent years that collaboration between them has been fruitful for both sides and would benefit to human and environment protection. Modelling will probably continue to play a major role in pesticide exposure with the implementation of new models able to handle always more relevant processes. These models could also be used to design the most effective mitigation measures or combination of measures to be implemented. Ecotoxicological modelling will also need to be developed and implemented for risk assessment. The analysis of the current risk assessment and management practises highlights that eco-modelling is now needed for future steps. Both eco-modelling and modelling of exposure to pesticides will need to be done at the landscape level and are major forthcoming challenges.

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