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Study of the different evaluation areas in the pesticide risk assessment process

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Abstract

Approval of active substances and authorisation of plant protection products in the EU is made based on a strict risk assessment of the agronomic use of the plant protection products. Regulation 1107/2009 regulates the procedure in the EU with complex procedures involving many actors. 'The Farm to Fork strategy' and 'The Biodiversity for 2030 strategy', that are the heart of the 'European Green Deal', aiming to make food systems fair, healthy, environmentally friendly and put Europe's biodiversity on the path to recovery by 2030, for the benefit of people, climate and the planet. Therefore, 'The Farm to Fork strategy' and 'The Biodiversity for 2030 strategy' represents a challenge for the evaluation and authorisation of plant protection products in which the risk management will constitute a key element on the approval of active substances and authorisation of plant protection products. The aim of the work was to get knowledge of the large body of EU legislation and guidelines in the plant production products, identifying the most critical points of the pesticide evaluation in each of its areas, analysing the complexity and the interaction between these different areas. This study allowed to have a global and clearer vision of these procedures, with the focus on highlighting inconsistency and to propose speed up alternatives. Finally, this work will also facilitate not only the risk assessment but also the decision-making on the approval of active substances and the authorisation of plant protection products.

Keywords: authorisation, active substance, approval, plant protection products, maximum residue level, risk assessment, pesticide

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1. Introduction

The focus of the European Food Risk Assessment Fellowship Programme (EU-FORA) is to provide hands-on skills in chemical and microbiological risk analysis for food safety, especially focus on risk assessment, with an overview of risk management and risk communication.

This specific project *Study of the different evaluation areas in the pesticide risk assessment process* was performed at the National Institute for Agricultural and Food Research and Technology (INIA), the unique Independent Evaluation Institution authorised in Spain to carry out the assessment in the areas of identity and physical-chemical properties, methods of analysis, residues, fate and behaviour in the environment, ecotoxicology and efficacy in the field of the active substances, plant protection products (PPP), safeners and synergists (Resolución 2015, complying with Real Decreto 971/2014). While the Ministry of Health, Consumer Affairs and Social Welfare carries out the assessment in the area of human toxicology.

In Spain, the Ministry of Agriculture Fisheries and Food is the National Competent Authority, in charge of the implementation of Regulation (EC) No 1107/2009 concerning the placing of PPPs on the market; while the competent authorities at Autonomous Community level are responsible for implementing all other controls (e.g. on marketing, maximum residue level (MRL)).

Details of the Spanish organisation for authorisation and control of PPPs and residues are provided in the Appendix A.

PPPs 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: 1) protect plants or plant products against weeds, pests and diseases, before or after harvest; 2) influence the life processes of plants (such as substances influencing their growth, excluding nutrients); 3) preserve plant products; and 4) destroy or prevent growth of undesired plants or parts of plants.

Pesticides contain and at least one active substance, such as any chemical, plant extract, pheromone or microorganism (including viruses), that has action against *pests* or on plants, parts of plants or plant products. They may also contain other components including safeners, synergists and co-formulants.

It is also important define the term *pesticide*, that is often used interchangeably with *plant protection product*. However, pesticide is a broader term which also covers non plant/crop uses, for example biocides. Nevertheless, the most common use of pesticides is in the form of PPPs.

For active substances and PPPs (chemical and microbiological), respectively, a risk assessment must be carried out to ensure that these substances/products do not have harmful effects on human or animal health or unacceptable effects on the environment.

2. Description of work programme

The work follows the uniform principles for evaluation and authorisation of PPPs as in the wide EU legislation and guidelines which regulate the authorisation, use of PPPs and their residues in food. Those areas of evaluation are under responsibility of INIA.

The first step of the work was the participation in the extensive training *corpus iuris* delivered by the coordination team of the *Unidad de Productos Fitosanitarios* (UPF) in INIA allowed to get a global view of the different areas of evaluation.

This global view is a key point for interpreting the results of evaluations, with their uncertainty, in order to ensure that the chances of failing to detect adverse effects or of under-estimating their importance are reduced to a minimum. All this picture shall be taken into consideration in the decision-making process, identifying critical decision points or items of data for which uncertainties could lead to a false classification of risk.

The training was complemented with the analysis of some specific cases for which Spain is the rapporteur Member State (RMS) in order to identify critical aspects of the risk assessment process when applied.

2.1. Aims

The aim of the work was to get knowledge of the large body of European Union (EU) legislation and guidelines in the plant production products, identifying the most critical points of the evaluation in each of the its areas, analysing the interaction between the different areas and defining the most appropriate risk mitigation measures, based on the good agricultural practice. This study will allow to

have a global and clearer vision of the risk assessment results and of the risk mitigation measures that should be established, with the focus on highlighting inconsistency and to propose speed up alternatives. Finally, this work will also facilitate not only the risk assessment but also the decision-making on the approval of active substances and the authorisation of PPPs.

2.2. Regulation of plant protection products

Plant protection products and their residues are regulated at the EU level by Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005, respectively. They are complemented by the so-called Sustainable Use Directive 2009/128/EC that requires Member States (MSs) to establish National Action Plans for the sustainable use of pesticides by promoting the adoption of Integrated Pest Management (IPM) and alternative approaches or techniques.

Regulation (EC) No 1107/2009 is in force since June 2011 and lays down harmonised rules for the approval of active substances and the placing on the EU market of PPPs. While Regulation (EC) No 396/2005 is in force since April 2005 and lays down the rules and procedures for setting maximum levels of pesticide residues (MRL) in or on food and feed of plant and animal origin, taking into account also international Codex Alimentarius levels.

The main objectives of these regulations are the following: 1) to ensure safety for operators, workers, bystanders, residents, consumers (including vulnerable groups of consumers) non-target species and the environment; 2) to allow an efficient use of resources for risk assessment and risk management in the policy area of pesticides; and 3) to shorten the time for new products to come on the market. Their purpose is also to facilitate the free movement of PPPs and plant products treated with PPPs and their availability in MSs, and to safeguard the competitiveness of EU agriculture.

These regulations clearly define the European Food Safety Agency (EFSA), MSs and Commission' responsibilities for risk assessment, risk management and control for active substance approvals, product authorisations and MRL setting. The regulations set a centralised procedure for active substance approvals and MRL setting, which avoids fragmentation of the internal market for food products and difficulties for importers having to deal with differing national rules on MRLs. While all PPPs undergo a double authorisation procedure before they can be placed on the market.

The first step is in the applicant' hands – the company that has commercial interest in placing the new substance on the market – submits an *application* (dossier) with the required data, described in the Regulation (EU) No 283/2013 for active substances and Regulation (EU) No 284/2013 for PPPs, to a MS of its choice (RMS) and to the European Commission, then a comprehensive assessment of the active substance is carried out by experts of MSs; while for renewals, the Commission, not the applicant, assigns the dossiers on pesticide active substances to the MSs on the basis of a country quota rule. EFSA then performs a final peer review and adopts a conclusion on whether the substance meets the approval criteria.

The following step is taken under the examination procedure: The Commission makes a proposal for approval to the MSs representatives in the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), who votes on the proposal; a positive vote by a qualified majority results in the approval of the pesticide active substance at the EU level.

Once an active substance has been approved, an authorisation of individual formulations based on the active substance at the level of the individual MSs can be requested and one MS of the zone carries out an assessment on behalf of the other MSs of the same zone (zonal evaluation). Authorisations are granted on a national basis because local environmental conditions and the occurrence of pests (therefore, use of pesticides) may differ. Each MS can do it at its national level, indifferently of how huge country is and how those differences can be also inside itself are, e.g. in Spain, *Ministerio de Agricultura, Pesca y Alimentación* authorises the PPPs that can be used in region with different environmental conditions, where the occurrence of pests may differ such as *Comunidad Autónoma de Galicia* or *Comunidad Autónoma de Andalucía*.

Authorisation of PPPs by MSs follows the provisions of the zonal evaluation of the Regulation (EC) No 1107/2009 (Articles 33–39). The zones for the evaluation of PPPs are defined in the Annex 1 of this regulation: Zone A –North (Denmark, Estonia, Latvia, Lithuania, Finland, Sweden); Zone B – Centre (Belgium, the Czech Republic, Germany, Ireland, Luxembourg, Hungary, the Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, the United Kingdom); Zone C – South (Bulgaria, Greece, Spain, France, Croatia, Italy, Cyprus, Malta, Portugal). EU countries assess applications on behalf of other countries in their zone and sometimes on behalf of all zones. Mutual recognition is an important part of this: an authorisation in one MS can be used for mutual recognition in another MS, either in the

zone or even in another zone if the product is used in greenhouses, as post-harvest treatments, for treatment of empty storage rooms, or for seed treatments. Mutual recognition is built on the assumption that any assessment which was already done by one MS shall not be repeated by another MS when recognising an authorisation. The procedure could be improved with a well structure and easily public available database, to ensure best exchange of information for zonal application and particularly important for interzonal applications. Sharing zonal and interzonal elements of assessment is highly recommended, providing these and others information to EFSA, with a clear reorganisation of the arrangements for risk assessment (SAPEA, 2018).

Another issue which was examined was the emergency authorisation for an active substance that is under evaluation at the EU level or for a substance not approved at the EU level, as long as the provisions in art. 53 of Regulation (EC) No 1107/2009 are guaranteed: e.g. 1,3-dichloropropene in *Región de Murcia* (Spain), granted for the same crops, functions and methods for the periods from 24 January 2018 to 15 April 2018; from 1 January 2019 to 15 April 2019 and from 1 January 2020 to 30 March 2020 (Database of Emergency Authorisations).

Several provisions of the two regulations have not been implemented yet, and several others cannot be fully enforced. Moreover, timelines for procedures is challenging, particularly for MSs and legal timelines are widely exceeded, especially those set for the mutual recognition of authorisations. This hinders innovation and affects the capacity of the sector to replace hazardous substances with either other substances or alternative methods. The lack of innovative solutions may have a negative effect on the objectives of improving agricultural production and safeguarding the competitiveness of the European agriculture.

Therefore, there is a need to reduce the complexity through a better coordination of work. This could reduce duplications, improve effectiveness and foster efficiency. Simplification is necessary to tackle the future work overload in the risk assessment, but the risks of pesticide use vary considerably from one pesticide to another, depending on the intrinsic characteristics of the active substances (toxicity, persistence, etc.) and on the use patterns (applied volumes, application period and method, crop and soil type, etc.). Most of the intrinsic characteristics of active substances are known, although they are not always easily available.

Simplification can also be achieved through the implementation of tools, useful for a quick screening of the hazard, as the hazard approach is foreseen by Regulation (EC) No 1107/2009, and can be useful for focusing on the critical areas of the assessment. One of such tools, it has been proposed at the 13th European Pesticide Residues Workshop (EPRW, 2020).

2.3. Regulation on residues

Regulation (EC) No 396/2005 covers compliance with legal limits for pesticide residues in food and feed, including provisions on official controls of pesticide residues in food (plant or animal origin).

The regulation defines the roles of the MSs, EFSA and the Commission in setting of MRLs, and sets a common EU assessment scheme for all agricultural products.

The procedure foresees that applicant proposes MRL, providing experimental data on the expected residues when the pesticide is applied according to Good Agricultural Practice (GAP) and on toxicological reference values. One MS evaluates this application and produces an evaluation report that it is verified by EFSA. The evaluation performed by the MS verifies that residues are safe for all European consumer groups, including vulnerable groups such as babies, children and vegetarians. When a risk is established for any consumer group, the MRL application is rejected and the pesticide may not be used on that crop and MRL is set at the lowest limit of analytical quantification (LOQ): default lowest limit in EU law is 0.01 mg/kg. That is the MRL also for crops on which the pesticide has not been used or when its use has not left detectable residues.

The data requirements for the analytical methods are set in Regulation (EU) No 283/2013, Regulation (EU) No 284/2013 and in the guidance SANCO/825/00 rev. 8.1.

However, a current trend in monitoring food for chemical residues and contaminants is to combine as many analytes as possible into a single method with an emphasis on developing laboratory methods which simultaneously analyse compounds from multiple categories including pesticides, veterinary drugs, mycotoxins, and other organic chemicals in a variety of food commodities (Turnipseed and Jayasuriya, 2020). A review describes several methods developed for simultaneous analysis of veterinary drugs and pesticide residues (Garrido Frenich et al., 2014.

Improvements in instrumentation and in data processing software, for both liquid chromatography–mass spectrometry (LC–MS) and gas chromatography–mass spectrometry (GC–MS), have facilitated

the ability to quickly query the mass data for hundreds of analytes in an automated manner and to find out unexpected analytes. This will allow regulatory agencies to better ensure the safety of the global food supply. For example, the United States Food Drug Administration (US FDA) recommends developing these analytical methods for imported products (FDA, 2019). In the light of the management adage that 'if you can't measure it, you can't change it'.

Regulation (EC) No 396/2005 establishes harmonised Community provisions relating to maximum levels of pesticide residues in or on food and feed of plant and animal origin. However, the note in Annex I specify that MRLs do not apply to products or part of products that by their characteristics and nature are used exclusively as ingredients of animal feed, until separate MRLs are set in the specific category 1,200,000. It should be also noted that article 1 (Subject matter) of the regulation mentioned only 'maximum levels of pesticide residues in or on food and feed of plant and animal origin', therefore, it excludes feed of mineral origin. These drawbacks could be overcome with a risk analysis (Circulaire, 2019), but nowadays a European harmonised approach is missing, although working for harmonisation is on-going.

Regarding the risk assessment for surface and ground water, some details are provided in the Appendix B.

PPPs can also contain safeners, synergists, adjuvants and co-formulants for which there are not MRL at the EU level. Nowadays, they can be only regulated at national level, although working for harmonisation is ongoing.

2.4. Regulations, guidance and procedures

Risk assessment methodologies are methods of – and criteria for – evaluating data, which form the basis of regulatory decision-making. They are written into hard law (legislation and implementing acts) and in soft law (non-legally binding guidance documents, administrative and peer-reviewed scientific literature), with a significant role left to the latter (Robinson et al., 2020). Deviations from non-legally binding guidelines are allowed provided a full description and scientific justification in the risk assessment.

Regulation (EC) No 1107/2009 art. 12(2) stipulates that EFSA ('the Authority') shall adopt a conclusion in its opinion on the substance 'in the light of current scientific and technical knowledge using guidance documents available at the time of application'. In this regulation, an article dedicated to guidance is the art. 77 (Guidance documents), which concerns micro-organisms, pheromones and biological products. Annex II of the same regulation mentions also 'any further guidance developed in the framework of the SCoPAFF for the purposes of refining, where relevant, the risk assessments'. In addition, the art. 78 states: 'Any further measures necessary for the implementation of this Regulation may be adopted'. Therefore, Commission can initiate the work to produce new guidance documents at any time, although guidance documents for risk assessment are made normally by EFSA, under a mandate from EU Commission or by its own initiative. Pesticide Steering Network Group, integrated by EFSA, all MS and EU Commission has identified the list of guidance documents that are necessary and has prioritised them.

Regulation (EU) No 284/2013 also refers to specific guidelines adopted by international organisation, i.e. European and Mediterranean Plant Protection Organization (EPPO) and Organisation for Economic Co-operation and Development (OECD).

There are national guidance, too, e.g. Guidance for the Comparative Assessment and Substitution of Plant Protection Products, implementing Regulation (EC) No 1107/2009. In Spain, it is nowadays used the *Guía complementaria de evaluación comparativa y sustitución de productos fitosanitarios en España*, which is based on the guidance document SANCO/11507/2013 (rev. 12) and on the EPPO standard – PP1/271 (1) as well as on the guidance elaborated by the UK (Comparative Assessment and substitution: guide for UK applicants for PPPs authorization) and Portugal (Comparative assessment and substitution – Guide for Plant Protection Product authorization).

The International guidelines can help the harmonisation of specific pesticide topics and even improving the procedure with the joint review of pesticide (OECD, 2011).

Science moves fast and the guideline update is fundamental, taking into consideration also the relevant scientific literature (Court of Justice of the European Union, 2018).

A European audit within the legal framework defined by the Regulation (EC) No 1107/2009 and Regulation (EU) No 546/2011 identified weaknesses for prioritisation of official controls, co-ordination and co-operation between and, in some cases, within Competent Authorities due to the complex highlighted system. In particular, with regard to PPP authorisation, the significant delays of MSs in the

evaluation or re-evaluation of PPPs highlight the difficulty to implement authorisation systems based on EU legislation (SANTE, 2017).

3. Conclusions

Pesticide risk assessment is governed by hard and soft laws, with complex procedures involving many actors, and these procedures have been analysed to get the global view of the process.

Specific areas of evaluation, within the remit of the UPF, such as method of analysis, efficacy, residues, ecotoxicology, environmental fate and behaviour, have been analysed. As result of this analysis, several points that should be improved have been highlighted, such as the coordination with other legislative areas, the effective strategies for replacement of substances of concern or how to use monitoring data, to reduce the risk assessment burden.

In conclusion, this report has analysed regulations, guidance and procedures of the pesticide risk assessment in the areas of which the UPF in INIA is in charge. Finally, the report has highlighted some shortcoming of the process and has also proposed some ways to overcoming them, such as tools (EPRW, 2020), simplification procedures (SAPEA, 2018) and suggestion for the next European audits to be comprehensive of the whole process.

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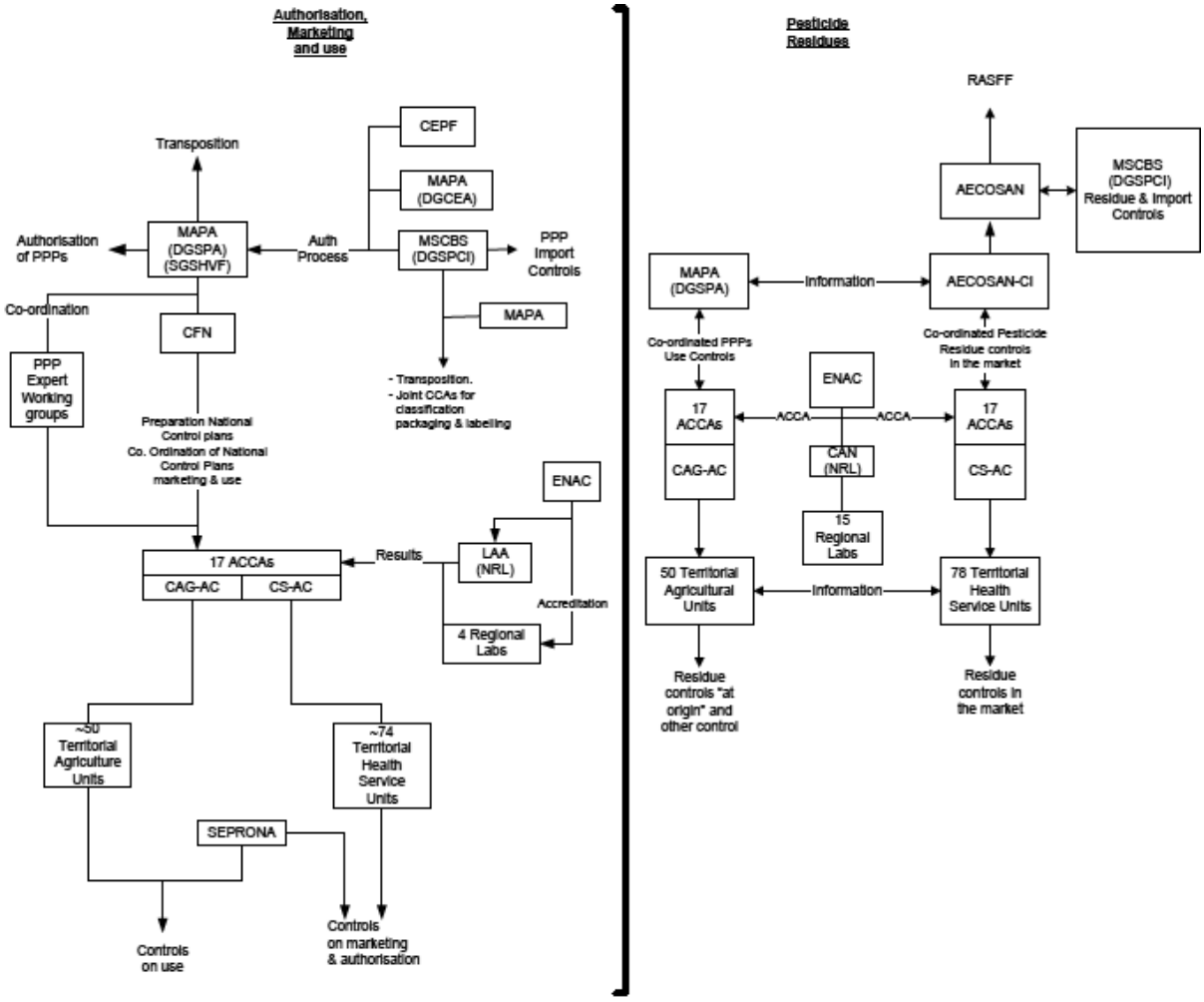
Abbreviations

EPPO	European and Mediterranean Plant Protection Organization
EPRW	European Pesticide Residues Workshop
EQS	environmental quality standard
ERO	ecological recovery option
ETO	ecological threshold option
EU-FORA	European Union Food Risk Assessment
GAP	Good Agricultural Practice
GC–MS	gas chromatography–mass spectrometry
IPM	Integrated Pest Management
LC–MS	liquid chromatography–mass spectrometry
LOQ	limit of quantification
MRL	maximum residue level
OECD	Organisation for Economic Co-operation and Development
OJ	Official Journal of the European Union
RAC	regulatory acceptable concentration
RMS	rapporteur Member State
SCoPAFF	Standing Committee on Plants, Animals, Food and Feed
SPG	specific protection goals
US FDA	United States Food Drug Administration
WFD	EU Water Framework Directive

Appendix A – Control system for PPPs and residues



AC	Autonomous Community
ACCA	Autonomous Community Competent Authority
AECOSAN	Spanish Agency for Consumers, Food Safety and Nutrition
AECOSAN (-CI)	Spanish Agency for Consumers, Food Safety and Nutrition (- Institutional Committee).
CAG-AC	Ministry of Agriculture and Livestock of the AC
CEPF	Commission for Evaluation of Phytosanitary Products
CFN	National Phytosanitary Committee
CS-AC	Ministry of Health of the AC
CNA	National Food Centre
DGCEA	Directorate-General for Quality and Environmental Assessment of MAPA
DGSPA	Directorate-General for Agricultural Production Health
DGSPCI	Directorate General for Public Health, Quality and Innovation
SGSE	Sub-directorate-General for External Health
ENAC	National Body for Accreditation
LAA	Agri-Food Laboratory in Madrid
MAPA	Ministry of Agriculture, Fisheries and Food
MSCBS	Ministry of Health, Consumer Affairs and Social Welfare
NRL	National Reference Laboratory
PPP	Plant protection products
SEPRONA	Civil Guard Environmental Protection Service
SGSHVF	Sub-directorate-General for Plant and Forestry Health and Hygiene
RASFF	Rapid Alert System for Food and Feedingstuffs

(Source: DG(SANTE)/2018-6516 Final Version date: August 2018).

Appendix B – Risk assessment for water

In Europe, different legislations have been developed with different methodologies to assess the aquatic risks of PPPs. In particular, these differences are apparent when comparing the authorisation criteria for the compartment water according to the Regulation (EC) No 1107/2009 and the water quality standards according to the Directive 2000/60/EC or, for short, the EU Water Framework Directive (WFD). These criteria and standards are a reflection not only of differences in the use of data on environmental fate and ecotoxicology of PPPs, but also of different policy decisions about the acceptance of risks in relation to formulated protection goals. Although the generic protection goals of the WFD and PPP Regulation do not differ substantially, the specific protection goals (SPGs) of the Plant Protection Product Regulation do not exclude that under certain conditions short-term effects followed by recovery are acceptable ecological recovery option (ERO), while environmental quality standard (EQS) setting within the context of the WFD in principle is based on the ecological threshold option (ETO) (EFSA, 2013).

The PPP Regulation has its focus on edge-of-field surface waters in agricultural landscapes assessment schemes and the EFSA guidance allow for the derivation of regulatory acceptable concentrations (RACs) (EFSA, 2013).

The EU WFD Water Framework Directive (2000/60/EC) aims to ensure good chemical status of both surface water and groundwater bodies across Europe. For surface waters, this goal is defined by limits on the concentration of certain pollutants relevant across the EU, known as priority substances. Good chemical status means that the concentrations of all of the priority substances and certain other pollutants do not exceed the environmental quality standards (EQSs). Priority substances are set out in the Directive 2008/105/EC and are defined as those substances presenting a significant risk to or via the aquatic environment. The Groundwater Directive 2006/118/EC, as a daughter of the WFD, established specific measures to prevent and control groundwater pollution. The Drinking Water Directive 98/83/EC sets special quality requirements for water for human consumption. These directives set enforcement limits for the drinking water and the groundwater at 0.1 μg/L. The Drinking Water Directive sets also concentration limit for total pesticides at 0.5 μg/L (EEA, 2018).

The limits are default legal limit, although the detection systems based on mass spectrometric techniques such as tandem mass spectrometry and quadruple-time-of-flight mass spectrometry can have lower LOQ with high sensitivity and selectivity (Alcântara et al., 2019).

Other polices and regulations that are not specifically aimed at protecting the environmental *medium water*, but are significant concerning chemicals in water, e.g. Directive on the Sustainable Use of Pesticides 2009/128/EC, are listed in the European Environment Agency Report (EEA, 2018).