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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides

{COM(2020) 208 final}

Table of Contents

1. INTRODUCTION 1
1.1. Purpose of the evaluation 2
1.2. Scope of the evaluation 2
2. BACKGROUND 3
2.1. Intervention logic 4
2.2. Baseline — the situation before the PPP and MRL Regulation 8
2.2.1. Plant protection products under Council Directive 91/414/EEC 8
2.2.2. A patchwork regulatory system for MRLs of pesticides 12
2.3. Baseline — other points of comparison 14
3. IMPLEMENTATION / STATE OF PLAY 16
3.1. Societal and political developments 16
3.2. The PPP market 17
3.3. Approval of active substances 18
3.4. Authorisation of plant protection products 19
3.5. Setting and reviewing MRLs 19
3.6. Public information, risk communication and transparency 20
3.7. Enforcement and monitoring 20
3.8. Court cases and complaints 21
4. METHODOLOGY 22
4.1. Data collection 22
4.2. Limitations and robustness of findings 23
5. ANALYSIS AND ANSWERS TO THE EVALUATION QUESTIONS 24
5.1. Effectiveness 24
5.1.1. Protecting human health 26
5.1.2. Protecting the environment, including wildlife and water 37
5.1.3. Minimising animal testing 41
5.1.4. Improving the functioning of the single market 43
5.1.5. Improving agricultural production and competitiveness of EU agriculture 47
5.1.6. Facilitating international trade 52
5.1.7. Enforcement 55
5.1.8. Transparency and risk communication 57
5.2. Efficiency 61
5.2.1. Costs for industry, farmers and SMEs 62

5.2.2. Costs for the Member States, the Commission and EFSA 64
5.2.3. Benefits to human health and to the environment 76
5.2.4. Societal and agricultural benefits and costs related to PPPs in the EU 77
5.2.5. Benefits from the single market and international trade 78
5.3. Coherence 79
5.3.1. Pesticides policy area 80
5.3.2. Other EU policy areas 82
5.3.3. International agreements 85
5.4. Relevance 86
5.4.1. Sustainability 87
5.4.2. Innovation and scientific progress 90
5.5. EU added value 92
6. CONCLUSIONS 96
7. REFERENCE LIST 102

Annex 1. Procedural information
Annex 2. Synopsis report on the stakeholder consultation
Annex 3. Methods and analytical models
Annex 4. Costs and benefits
Annex 5. Court cases and complaints to the Ombudsman

GLOSSARY AND LIST OF ABBREVIATIONS

Acceptable daily intake (ADI)

ADI is a measure of the amount of a specific substance in food or drinking water that can be ingested (orally) on a daily basis over a lifetime without an appreciable health risk.

Active substances

An active substance is the active component against pests or plant diseases contained in a plant protection product.

Acute reference dose (ARfD)

The acute reference dose is an estimate of a daily oral exposure for an acute duration (24 hours or less) to humans that is likely not to have deleterious effects during a lifetime.

Adjuvant

An adjuvant is a chemical or mixture of chemicals that enhances the efficacy of a plant protection product.

Annex I renewal programme (AIR)

The Annex I renewal programmes are working programmes for the renewal of approval of active substances. They were drawn up to cover all approved active substances and to balance the workload for the evaluating authorities.

ALARA principle

As low as reasonably achievable (ALARA) is a safety principle designed to minimise radiation doses and releases of radioactive materials. This principle is also applied to other areas involving safety management in particular for issues where no quantified safety level can be established.

Basic substances

Basic substances are substances that are not predominantly used for plant protection purposes but that may be useful in plant protection. They can be approved for plant protection use provided they are of no concern to human health or the environment. Some of these substances have traditionally been used by farmers, and they may include foodstuffs.

Biopesticides

Biopesticides include naturally occurring substances derived from animals, plants or bacteria that control pests, as well as microorganisms that control pests (microbial pesticides)

Candidates for substitution (CfS)

Candidates for substitution are active substances approved in the EU that meet any of the seven criteria listed in Annex II to the Plant Protection Products (PPP) Regulation. The criteria are based on the active substance's intrinsic hazardous properties in combination with its use. The approval period of a CfS is limited to 7 years.

Codex Committee on Pesticide Residues (CCPR)

The CCPR is responsible for establishing Codex MRLs)for pesticide residues in specific food items or in groups of food or feed that move in international trade.

Codex Limits (CXLs)

These are international standards of maximum residue levels of pesticides set by the Codex Alimentarius Commission. CXLs that are considered safe for consumers by the European Food Safety Authority (EFSA) are taken over as MRLs in EU legislation to facilitate trade.

Commodity
Food or feed product of plant or animal origin.

Co-formulant
Plant protection products may contain one or more active substances as well as other materials such as solvents, carriers, inert material, wetting agents, etc. These other materials are referred to as co-formulants.

Cut-off criteria
Active substances that meet the cut-off criteria cannot be approved in the EU or can only be approved under restricted conditions. These are active substances that are mutagenic; carcinogenic; toxic for reproduction; have endocrine disrupting properties; are persistent organic pollutants (POPs); are persistent, bioaccumulative and toxic (PBT); or are considered to be very persistent and very bioaccumulative (vPvB).

Dossier
Dossiers are submitted to the rapporteur Member State to support the approval or renewal of approval of an active substance. The dossier contains the required data compiled through experimental studies in line with internationally validated test guidelines or through peer-reviewed scientific publications.

Draft (review/renewal) Assessment Report (dRAR)
The dRAR contains the scientific assessment by the rapporteur Member State. It is based on the dossier submitted by the applicant in support of the approval or renewal of approval of an active substance.

Emergency authorisation
The Plant Protection Product (PPP) Regulation allows Member States to grant emergency authorisations for plant protection products that are not authorised. These emergency authorisations are limited to 120 days to combat a danger to plants that cannot be controlled by other reasonable means.

Endocrine disruptor
Endocrine disruptors are chemicals that alter functions of the endocrine system and consequently causes adverse health effects in both humans and wildlife.

European Food Safety Authority (EFSA)
EFSA is the European agency responsible for risk assessment in the area of food safety.

Generic manufacturer
Generic manufacturers are companies (mostly smaller companies) that produce generic plant protection products, i.e. non-patent protected products.

Genotoxicity
Genotoxicity describes the property of chemical agents that damages the genetic information within a cell. This damage causes mutations, which may lead to cancer. Genotoxicity is often confused with mutagenicity - all mutagens are genotoxic, whereas not all genotoxic substances are mutagenic.

Good agricultural practices (GAPs)
Good agricultural practice means the nationally recommended, authorised or registered safe use of plant protection products under actual conditions at any stage of production, storage, transport, distribution and processing of food and feed. It also implies the application of the principles of integrated pest control in a given climate zone, as well as using the minimum quantity of pesticides and setting MRLs at the lowest level which allows the desired effect to be obtained.

Hazard
The terms ‘hazard’ and ‘risk’ are often used interchangeably. However, in terms of risk assessment, they are two very distinct terms. A hazard is the intrinsic property of an agent to cause harm to humans, property or the environment. Risk is defined as the probability

that exposure to a hazard will lead to a negative consequence. More simply: a hazard poses no risk if there is no exposure to that hazard.

Import tolerance

Imported commodities must comply with the MRLs established in EU legislation. Import tolerances can be set for specific products (e.g. exotic fruit) for which EU uses either do not exist (as no applicant applied for such a use in the EU) or do not take into account the specific conditions in the country of origin (e.g. different climatic conditions). An import tolerance appears as any other MRL in EU legislation and must be safe for consumers.

Integrated pest management (IPM)

Integrated pest management is the careful consideration of all available pest-control techniques and subsequent integration of appropriate pest-control measures. These appropriate pest-control measures should discourage the development of pest populations and keep pesticides to levels that are economically justified. They should also reduce or minimise risks to human health and the environment.

Limit of quantification (LOQ)

The limit of quantification is the smallest amount of an agent that can be measured with stated and acceptable imprecision and inaccuracy (e.g. the smallest concentration of a chemical that can be measured with sufficient precision in a millilitre of water).

Low-risk active substance

An active substance can be approved as a low-risk active substance if it meets the regular approval criteria and also meets the low-risk criteria as specified in Annex II, point 5 of Regulation (EC) 1107/2009. There are specific criteria for low-risk chemical substances and for micro-organisms.

Maximum residue level (MRL)

The traces pesticides leave in treated commodities are called ‘residues’. A maximum residue level (MRL) is the highest level of a pesticide residue that is legally tolerated in or on food or feed when pesticides are applied correctly according to good agricultural practice during the production of the food or feed.

Minor use

A minor use of a PPP is a use on crops that are either not widely grown in a Member State, or widely grown but meet an exceptional plant-protection need.

Mutual recognition

In principle, mutual recognition allows market access for products that are not subject to EU harmonisation. Products lawfully sold in one EU Member State can be sold in another. In the specific context of the PPP Regulation, the authorisation of a PPP in one Member State is to be recognised by other Member States unless there are specific environmental or agricultural circumstances not to do so.

Neonicotinoids

Neonicotinoids are a class of neuro-active insecticides chemically similar to nicotine. The neonicotinoid family includes acetamiprid, clothianidin, imidacloprid, nitenpyram, nithiazine, thiacloprid and thiamethoxam.

Non-governmental organisation (NGO)

NGOs are usually non-profit and independent of governments (though often funded by governments) that are active in humanitarian, educational, health care, social, human rights, or environmental causes.

Organisation for Economic Cooperation and Development (OECD)

The OECD is an intergovernmental economic organisation with 36 member countries, founded to stimulate economic progress and world trade.

Persistent, bioaccumulative and toxic (PBT) substances

A PBT substance is 'persistent' (i.e., the half-life in marine water is higher than 60 days; the half-life in fresh or estuarine water is higher than 40 days; the half-life in marine sediment is higher than 180 days; the half-life in fresh or estuarine water sediment is higher than 120 days; or the half-life in soil is higher than 120 days), AND 'bioaccumulative' (i.e. where the bioconcentration factor is higher than 2 000), AND 'toxic' (i.e., the long-term no-observed effect concentration for marine or freshwater organisms is less than 0,01 mg/l; the substance is classified as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2); or there is other evidence of chronic toxicity, as identified by the classifications STOT RE 1 or STOT RE 2).

Persistent organic pollutants (POPs)

Persistent organic pollutants are chemicals of global concern due to their: potential for long-range transport; persistence in the environment; ability to bio-magnify; and ability to bio-accumulate in ecosystems.

Plant protection product (PPP)

Plant protection products are formulations containing one or more active substances and intended to protect plants and plant products.

Plant Protection Products Application Management System (PPPAMS)

The PPPAMS is being developed by the European Commission to enable industry users to create applications for PPPs and submit these to EU Member States for evaluation, concluding with authorisation of the PPP or refusal of the application.

Precautionary principle

The precautionary principle is detailed in Article 191 of the Treaty on the Functioning of the European Union. It may be invoked when a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty [1].

Rapporteur Member State

The rapporteur Member State carries out the risk assessment for the approval of an active substance, which is then peer-reviewed by the other Member States and EFSA. A zonal rapporteur Member State is carrying out the risk assessment for the authorisation of a PPP on behalf of the other Member States in the same zone, e.g. in the northern, central or southern zone.

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Registration report (for authorisations)

The registration report is part of the procedure to authorise a PPP. The zonal rapporteur Member State makes the draft registration report available to the concerned Member States for commenting, and subsequently finalises the registration report after considering the comments received.

European Commission's regulatory fitness and performance programme (REFIT)

REFIT is part of the Commission's better regulation agenda. It makes sure that EU laws deliver their intended benefits for citizens, businesses and society while removing red tape and lowering costs. It also aims to make EU laws simpler and easier to understand.

Risk

1 European Commission (2000) Communication from the Commission on the precautionary principle, COM/2000/0001 final.

Risk is the probability that exposure to a hazard will lead to a negative consequence.

Safener

A safener is a chemical contained in a PPP that protects crop plants from damage from the PPP.

Small, medium and micro-sized enterprise (SME)

The main factors determining whether an enterprise is an SME are (1) staff headcount, (2) either turnover or balance sheet total:

Company category	Staff headcount	Turnover	Balance sheet total
Medium-sized	< 250	< 250	≤ € 43 m
Small	< 50	< 50	≤ € 10 m
Micro	< 10	< 10	≤ € 2 m

Stop-the-clock procedure

During the risk assessment stage, the rapporteur Member State or EFSA may request more data directly from the applicant, in which case the clock is stopped for the regulatory timetable until this is supplied. This period is a maximum of 6 months (where the rapporteur Member State triggers it) or 3 months (where EFSA triggers it).

Synergist

Synergists are chemicals that make the active substance in a PPP more effective.

Very persistent and very bioaccumulative (vPvB)

A vPvB substance is both 'very persistent' (i.e. the half-life in marine, fresh- or estuarine water is higher than 60 days; the half-life in marine, fresh- or estuarine water sediment is higher than 180 days; OR its half-life in soil is higher than 180 days), AND 'very bioaccumulative' (i.e. its bioconcentration factor is greater than 5 000).

World Trade Organisation (WTO)

The World Trade Organisation (WTO) is a global international organisation dealing with the rules of trade between countries.

World Trade Organisation — Sanitary and Phytosanitary Measures Agreement (WTO-SPS)

The WTO-SPS is an agreement on how governments can apply food-safety and animal-and-plant-health measures.

World Trade Organisation — Technical Barriers to Trade Agreement (WTO-TBT)

The TBT Agreement aims to ensure that technical regulations, standards, and conformity-assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade.

1. INTRODUCTION

Plant protection products (PPPs), also called *pesticides*, are used to protect crops against pests, diseases, or competing plants with the aim of optimising food production in conventional or organic farming[2]. Pesticides are also used to maintain food quality (e.g. during storage) or to maintain certain areas in the condition needed for their proper functioning (e.g. railways, golf courses). Pesticides can be of chemical or non-chemical origin (e.g. micro-organisms) and their residues in food and feed can be harmful to consumers.

Because of their potentially harmful effects, PPPs are strictly regulated in the EU to provide a high level of protection to the environment and to the health of everyone in the EU. Harmonised regulation of PPPs also improves the functioning of the internal EU market as it enables manufacturers of PPPs to apply for authorisation according to the same rules and producers of food and feed can sell their products without barriers. It also gives people in the EU increased access to safe food produced outside their national territory.

Pesticides and their residues are regulated under Regulation (EC) No 1107/2009[3], hereinafter referred to as 'the PPP Regulation', and Regulation (EC) No 396/2005[4], hereinafter referred to as 'the MRL Regulation' – in essence a risk management framework. The European Commission, the European Food Safety Authority (EFSA) and the Member States all play a role in the implementation of these Regulations. Based on scientific advice received from Member States and EFSA, the Commission approves active substances for use in PPPs and sets MRLs at safe levels for food and feed (including for imported products). Once an active substance is approved and its MRLs are set, Member States can authorise the use of PPPs containing the active substance in question. The Sustainable Use Directive[5] and Regulation 1185/2009 on statistics of pesticides are additional parts of the 'pesticide package', which was adopted in 2009. Both these instruments help ensure a high level of protection of human health and the environment from pesticides.

The European Parliament and the Council are involved in setting MRLs under the regulatory procedure with scrutiny. Both the Council and the European Parliament have addressed the issue of pesticides on several occasions in recent years. In 2016 and 2017, the European Parliament adopted resolutions on endocrine disruptors and on the active substances glyphosate and bentazone[6]. The AGRIFISH Council of June 2016[7] endorsed recommendations on the acceleration of sustainable plant protection.

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2 Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).

3 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

4 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

5 Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).

6 European Parliament resolution of 23 November 2016 on the draft Commission implementing regulation renewing the approval of the active substance bentazone in accordance with Regulation (EC) No 1107/2009 (D047341/00 – 2016/2978(RSP)).
European Parliament resolution of 13 April 2016 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 (D044281/01 — 2016/2624(RSP)).

1.1. Purpose of the evaluation

The objective of the evaluation is to perform an evidence-based assessment of the implementation and application of the PPP and MRL Regulations, taking stock of the experience gained. This staff working document accompanies a report to the European Parliament and to the Council on the functioning of both Regulations[8].

The evaluation assesses the accomplishment of the Regulations' objectives in line with the better regulation guidelines[9]. It covers the following five criteria: effectiveness, efficiency, relevance, coherence, and EU added value (including the potential for burden reduction, simplification and improving the delivery of the objectives).

1.2. Scope of the evaluation

The evaluation assesses the implementation and functioning of both the PPP and MRL Regulations in all 28 Member States[10] between their dates of application (in June 2011 and September 2008, respectively) and October 2018.

The evaluation covers the essential elements of: (i) the PPP and MRL regulatory systems, (ii) the links between the two Regulations, and their implementing regulations. The evaluation also discusses the following topics for which the Commission has legal reporting obligations:

- mutual recognition of PPP authorisations and the functioning of the zonal system;
- the functioning of comparative assessment when authorising PPPs containing candidates for substitution (CfS);
- the application of the approval criteria, including the cut-off criteria;
- the effects of the provisions on data protection for studies involving vertebrate animals.

The evaluation includes evidence-based conclusions and an assessment of whether, and to what extent, the Regulations have achieved their objectives. The results will be available to inform decisions on future policy actions, including potential amendments of the Regulations to improve their performance.

As stated above, there are several other pieces of legislation that are relevant to this subject, but are not covered by this evaluation, namely the Sustainable Use Directive and Regulation 1185/2009 on statistics of pesticides. The implementation period for the Sustainable Use Directive for Member States ended in November 2016 and in October 2017 the Commission presented a first implementation report[11], which concluded that the Sustainable Use Directive offers the potential to greatly reduce the risks derived from pesticide use. However, until it is more rigorously implemented by the Member States, the improvements are limited, and certainly insufficient to achieve the

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European Parliament resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 (D053565-01 — 2017/2904(RSP).
European Parliament resolution of 4 October 2017 on the draft Commission regulation amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (D048947/06 – 2017/2801(RPS)).

7 Outcome of the Council meeting available online: https://www.consilium.europa.eu/en/meetings/agrifish/2016/06/27-28/.

8 As required in Article 82 and 62(5) of Regulation 1107/2009 and Article 47 of Regulation 396/2005. The report was intended to be presented in December 2014. However, to allow for a meaningful assessment, a sufficient level of implementation had to be achieved before carrying out the evaluation.

9 European Commission Better Regulation Guidelines.

10 The assessment of the implementation in Croatia will start as of the date of its accession to the European Union on 1 July 2013.

11 European Commission (2017), Report from the Commission to the European Parliament and the Council on Member State National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides, COM/2017/0587.

environmental and health improvements it was designed to achieve. New assessments will soon begin of both the Sustainable Use Directive and Regulation (EC) No 1185/2009 on statistics of pesticides.

In addition, the link of the PPP Regulation with Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures is assessed in a separate 'fitness check' by the Commission[12]. Finally, the criteria for endocrine disrupting properties[13] are not addressed in this evaluation, as the application of the criteria started on 10 November 2018 and will be subject to a dedicated assessment[14] in the future.

2. BACKGROUND

Pesticides and their residues are regulated at EU level to respond to certain needs and to achieve several objectives. The PPP Regulation establishes a two-step system that reflects the principle of subsidiarity. In the first step, the active substance of a PPP is approved at EU level provided it is demonstrated that at least one use with a formulated product is safe. In the second step, Member States authorise PPPs containing the active substance for specific uses, according to harmonised EU standards (the so-called uniform principles[15]) and good agricultural practices (GAPs). The Member States consider local agricultural and geographical/climatic differences when authorising PPPs.

The Sustainable Use Directive provides the general rule on the use of PPPs. It aims to reduce the risks and impacts of pesticide use on human health and the environment. It also aims to promote the use of integrated pest management (IPM) and alternative approaches or techniques, such as non-chemical alternatives to pesticides. Finally, the MRL Regulation regulates the residues that are left on crops. It does this by setting MRLs at EU level to protect all consumers, including vulnerable groups (see Figure 1 below).

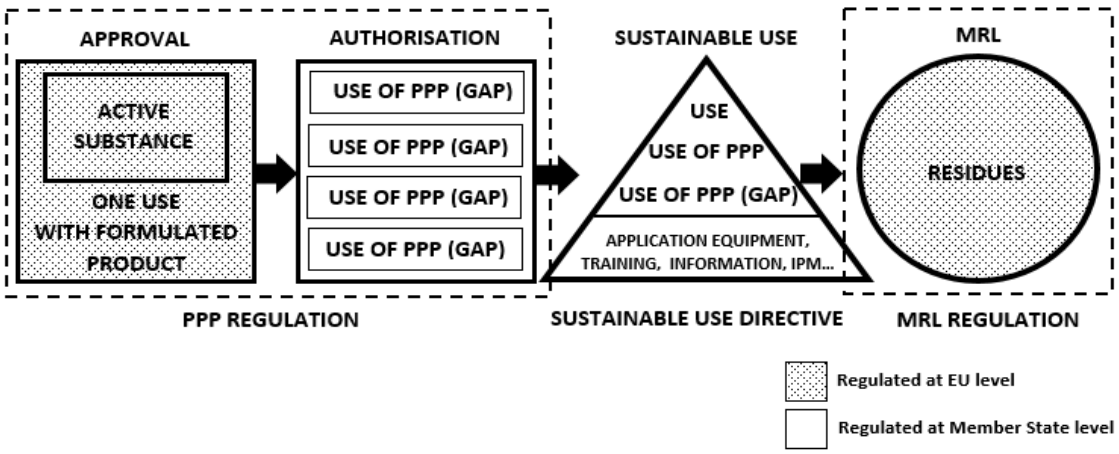


Figure 1. How pesticides and their residues are regulated in the EU

12 European Commission (2019) Commission Staff Working Document Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries. SWD/2019/199 final

13 Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

14 See Article 3 of Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

15 Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles of evaluation.

2.1. Intervention logic

The PPP Regulation was proposed after 13 years of experience gained from the application of Directive 91/414/EEC[16]. The proposal for the MRL Regulation built on both national requirements and EU Directives that co-existed for many years. The sections below outline the needs identified and objectives of the PPP and MRL Regulations and the actions that were expected to lead to positive long-term impacts.

PPPs can affect human health via direct exposure, i.e. through residues in food and occupational exposure, as well as indirect exposure through environmental contamination. Therefore, to address the need of **protecting the health of operators, bystanders, workers and residents** from the adverse effects of pesticides, the hazards and risks of active substances are rigorously assessed against strict approval criteria set in the PPP Regulation. Following the submission of a comprehensive data package by an applicant according to the provided requirements, a Member State assumes the role of rapporteur for the active substance. The rapporteur Member State conducts a scientific evaluation that is peer reviewed by EFSA and the other Member States. Based on the scientific evaluation by the Member States and EFSA, the Commission prepares a legal act to approve (or not) the active substance, which is discussed with and voted on by the Member States. Active substances that do not meet the approval criteria cannot be used in the EU.

To promote the **sustainable use of pesticides** and reduce risks from the use of PPPs to human health and the environment, active substances with less problematic hazard profiles are promoted in the PPP Regulation. These substances include basic substances, which benefit from unlimited approval periods, and low-risk active substances, which enjoy longer approval and data protection periods. At the opposite end of the spectrum, particularly hazardous active substances are approved as 'candidates for substitution' (CfS) with shorter approval periods. When they authorise PPPs containing these more hazardous active substances, Member States must conduct comparative assessments aimed at replacing them with less hazardous active substances. In addition, the PPP Regulation introduced cut-off criteria for active substances that are: mutagenic; carcinogenic; toxic for reproduction; have endocrine disrupting properties; are persistent organic pollutants (POPs); are persistent, bioaccumulative and toxic (PBT); or are considered to be very persistent and very bioaccumulative (vPvB). Active substances that meet the cut-off criteria cannot be approved in the EU, or can only be approved under severely restricted conditions. This regulatory system should result in less hazardous PPPs being placed on the market, thereby **ensuring a high level of protection of human and animal health and the environment**.

To **keep abreast of scientific developments** and the expectations of society, the Commission may review the approval of an active substance at any time. Active substances also have time-limited approvals and are periodically re-evaluated. The goal of this periodic review process is to create an up-to-date comprehensive set of data, ensure a clear division of tasks between the Member States, EFSA and the Commission, and reduce the hazardousness of PPPs on the market. In meeting these goals, the Regulation aims to create a transparent and predictable system with less administrative burden than the previous regulatory situation. The expected impacts on society of this

16 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1)

review process are continued high levels of safety for operators, bystanders and consumers, as well as a high level of protection of the environment.

Once an active substance is approved at EU level, applicants can submit applications for the authorisation of one or several PPPs containing that active substance to a Member State. To **improve access to PPPs** for farmers in different Member States and **the functioning of the internal market**, the EU is divided into three geographical zones: north, central and south. Applicants can choose one Member State in each zone to act as the zonal rapporteur. This zonal rapporteur Member State assesses the application on behalf of all Member States in the same geographical zone for which the application is intended, i.e. the concerned Member States. The zonal rapporteur Member State makes the draft registration report available to the concerned Member States for commenting, and subsequently finalises the registration report after considering the comments received. The finalised registration report then forms the basis for national product authorisations within the particular zone. Within each zone, Member States must, in principle, mutually recognise each other's authorisations. This should enable Member States to benefit from the evaluations made by other Member States, while manufacturers of PPPs benefit by not having to submit product authorisations in each individual Member State of a zone. This is expected to reduce administrative burden, thus **improving the functioning of the single market.** Nevertheless, national product authorisations allow to address specific climatic, geographical or agricultural concerns. This two-step authorisation system is meant to harmonise the availability of PPPs within zones, resulting in a **better functioning of the single market**. The consideration of national environmental and climatic conditions should ensure a **high level of protection of the environment**.

To address the problem of lengthy procedures under Directive 91/414/EEC, the PPP Regulation introduced strict deadlines for approval and authorisation procedures and encouraged cooperation between Member States with the aim of making PPPs timely available on the market. This would in turn help **improve EU agricultural production and safeguard its competitiveness**. Promoting low-risk active substances with faster market access is a way to improve the availability of such PPPs for EU farmers. The PPP Regulation includes further measures to ensure that farmers have access to PPPs in cases where they need to control a serious danger to plant health. At EU level, limited derogations are possible for the approval of active substances that meet the cut-off criteria, if the applicant has demonstrated that the active substance concerned is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods. At Member State level, emergency authorisations for non-authorised PPP can be issued for 120 days for limited use to address a danger to plant health which cannot be contained by any other reasonable means. The need to have **safe food for consumers** in the EU implies that PPPs should be used safely and assessed according to a predictable, trustworthy and transparent regulatory system, as described above. In addition, MRLs are set to ensure that pesticide residues on foods are safe in order to protect consumer health. When an application to authorise a PPP for a new use is submitted, the consumer risk assessment to establish MRLs is carried out in a two-step procedure: first by evaluating Member State and second by EFSA. Based on the scientific evaluation, the Commission prepares a legal act to set or amend MRLs. This legal act is then discussed with and voted on by the Member States. The result is meant to be an efficient procedure that ensures a high level of safety for consumers, including vulnerable groups.

Implementation and **enforcement** must be efficient and consistent in all Member States. To meet these needs, and to improve the functioning of the single market, MRLs are harmonised at EU level. Food-business operators that sell their products in several Member States must comply with a single MRL, which is valid across the EU and publicly available. This reduces administrative burden, and makes relevant information readily available to users and consumers. Ultimately, these rules are expected to **improve the functioning of the single market** and ensure the consistent protection of consumers.

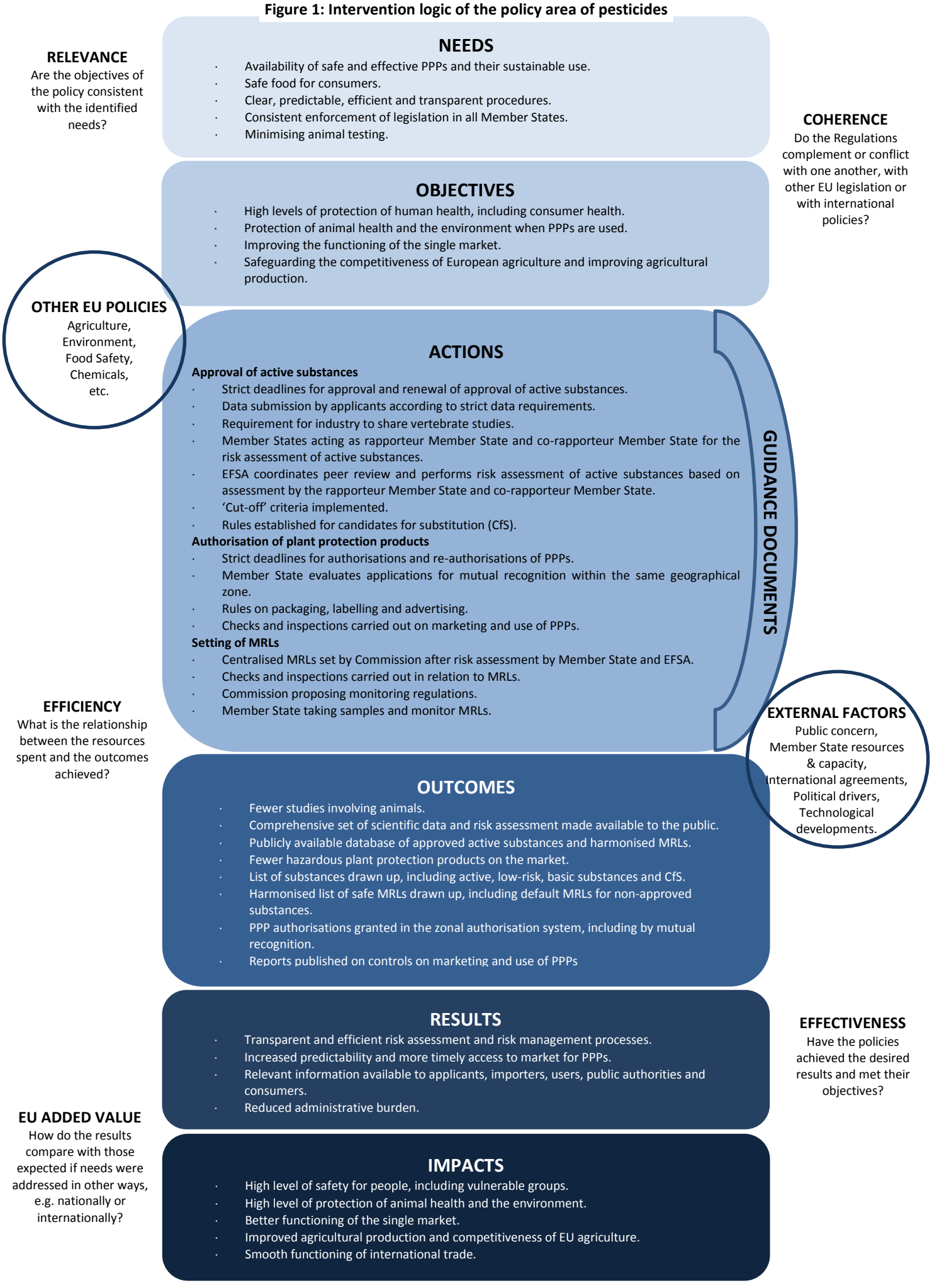
Another aim of the MRL Regulation is to promote the **smooth functioning of international trade** and ensure that non-EU countries can export their produce to the EU. This aim is met by setting MRLs for all relevant pesticide residue-commodity combinations, including import tolerances resulting from the use of PPPs in non-EU countries. The EU benefits from facilitating trade: consumers can buy imported crops that are not grown in the EU, and there is a greater range of food products available throughout the year at a competitive price.

The implementation of many actions, both procedurally and technically, is detailed in **guidance documents**. Guidance documents are produced by EFSA or the Commission together with the Member States. Because guidance is feeding into all areas the results and impacts are dependent on the availability of clear, commonly agreed and up-to-date guidance documents.

Finally, the identified need to **minimise animal testing** was addressed in the PPP Regulation by obliging industry to share data on studies involving vertebrate animals. This is expected to reduce the need to duplicate existing studies, and therefore reduce the number of animals involved.

Figure 2 summarises the paragraphs above with boxes visualising: the needs identified, the objectives to be pursued, the actions taken; the outcomes produced; the general results achieved, and the impacts seen.

Figure 1: Intervention logic of the policy area of pesticides



2.2. Baseline — the situation before the PPP and MRL Regulation

The baseline for the evaluation is the situation before the Regulations became applicable. This baseline is different for PPPs and MRLs. However, other different points of comparison are used as described below and in section 2.3.

2.2.1. Plant protection products under Council Directive 91/414/EEC

The situation in June 2011, when the PPP Regulation became applicable, is considered as the baseline for the evaluation of the PPP Regulation. The predecessor to the PPP Regulation was Directive 91/414/EEC[17], which laid down uniform rules on the approval of active substances and authorisations of PPPs in the EU. The system under Directive 91/414/EEC was similar to that created by the PPP Regulation: only PPPs containing approved active substances that did not pose a risk to human or animal health or the environment could be authorised. Authorisation was granted by Member States on their territory under uniform principles, and optional mutual recognition applied for the use of the same product under identical conditions. The PPP Regulation subsequently took on board these main principles and existing rules while reinforcing the approval criteria.

Approval of active substances

With Directive 91/414/EEC, there was a shift in the EU's PPP regulatory system from maintaining a negative list of 17 banned active substances[18] to maintaining a positive list of approved active substances deemed to be safe[19]. The implementation of Directive 91/414/EEC began with an inventory of all active substances on the market in the Member States. This was followed by the establishment of four work programmes[20] to evaluate these substances and which included calls for application. For most of the active substances in the inventory, no application or data were submitted by the industry and they thus disappeared from the market. As seen in Figure 3, this resulted in a reduction from around 1 000 active substances available in 1993 to less than 400 in 2010[21].

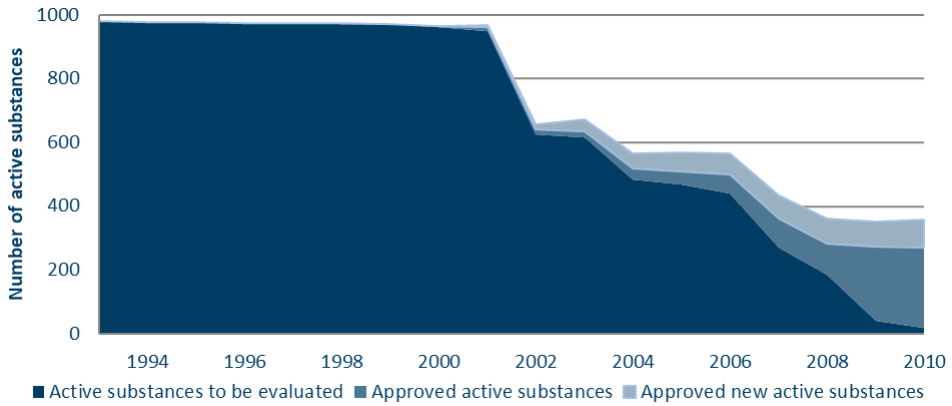


Figure 3. Number of available active substances in the EU between 1993 and 2010.

17 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

18 See Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances.

19 See the initial list of approved active substances in Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

20 See, for instance, Commission Regulation (EC) No 2266/2000 of 12 October 2000 amending Regulation (EEC) No 3600/92 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market.

21 EU Pesticides Database.

Decisions on the approval of active substances under Directive 91/414/EEC were based on the outcome of risk assessments. Hazards were determined for classification and labelling purposes, but were not decisive by themselves for the approval assessment. Even very hazardous active substances could be approved. Approvals were valid for 10 years if acceptable risks were demonstrated for at least one use.

To have an active substance approved under Directive 91/414/EEC, an applicant had to submit a dossier to a rapporteur Member State, which is similar to the current requirement in the PPP Regulation. The dossier had to contain the required data[22] compiled through internationally validated test guidelines (e.g. OECD) or peer-reviewed scientific publications. The rapporteur Member State carried out the first risk assessment, compiling a draft assessment report (dRAR), which was sent to EFSA (or before 2002 to the Commission[23]) which performed a peer review of the assessment. Within 1 year of receiving the dRAR, EFSA had to prepare a conclusion summarising the discussions that took place in the peer review. Based on the EFSA conclusion, the Commission prepared a draft review report and draft Directive that were discussed with the Member States in the Standing Committee on the Food Chain and Animal Health. Following a vote in the Committee, the Commission adopted the Directive. The first approval of an active substance under Directive 91/414/EEC was adopted in 1997[24].

The approval procedure was inefficient as in 2001 (10 years after adoption of Directive 91/414/EEC), only 30 of the 979 existing active substances had completed the full evaluation procedure[25]. In 2008, the number of evaluated and approved active substances had increased to 96, with another 186 active substances still under review. The average time from dossier submission until approval was 6 years. The preparation of the dRAR by the Member State took 27 months, and the peer-review process took between 5 and 87 months[26]. The identified reasons for these delays were lack of resources, complexity of procedures but also the lack of incentives for industry to provide quickly additional data after submission of the dossier as PPPs could in the meantime be placed on the market through provisional national authorisations[27].

Authorisation of PPPs

Under Directive 91/414/EEC, several types of authorisations could be granted by the Member States. These are outlined below.

- **National authorisations** were granted for a maximum of 10 years after the assessment of a product dossier. The assessment was made by the concerned Member State only, without the involvement of the Commission or other Member States.
- **Provisional national authorisations** (granted for 3 years) could be used to fast-track the introduction of PPPs containing new active substances before a decision was made on the approval of the active substance at EU level. These could be granted 2 years after submission of the application for approval of the active substance.
- **Emergency authorisations** could be issued temporarily by the Member States in special circumstances for a maximum period of 120 days. The use of emergency

22 Listed in Annex II and III of Directive 91/414/EEC.

23 Before the establishment of EFSA in 2002, a peer-review of the dRAR was organised by the Commission, with administrative support provided by the competent authorities of the UK and Germany.

24 Concerning the active substance Imazalil.

25 EU pesticide database, see: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database.

26 European Commission (2006). Report on the impact assessment for a Regulation replacing Directive 91/414/EEC on plant protection products, SANCO/10273/2006 Rev. 5.

27 European Commission (2006). Report on the impact assessment for a Regulation replacing Directive 91/414/EEC on plant protection products, SANCO/10273/2006 Rev. 5, pp. 67-68.

authorisations was limited to situations of an unforeseeable danger to plant health which could not be contained by other means. In 2007, there were 59 such emergency authorisations in the EU; in 2008 there were 63; in 2009 there were 107; and in 2010 there were 321[28].

- **Mutual recognition** of authorisations was optional for products already authorised in another Member State if applied for under identical conditions, but this provision did not work. Only three Member States applied mutual recognition to a significant extent. Member States often requested additional data or required the repetition of efficacy trials. This resulted in many Member States investing almost as much time in mutual recognition evaluations as in national authorisation evaluations[29].

Under Directive 91/414/EEC, the market for PPPs in the EU remained fragmented. The number of authorised PPPs in the Member States varied from a few hundred to more than 4 000. Unauthorised cross-border sourcing of PPPs was also a major problem: 17 of 22 Member States that answered to a survey reported problems with unauthorised imports or use; 3 Member States had minor problems; and only 1 Member State had no problems before 2006[30].

As Directive 91/414/EEC was transposed into national legislation, the processes, timelines and authorisation fees varied between Member States. According to the timelines in the Directive, getting a product authorised should have taken between 1 and 2 years. But in practice, depending on the Member State, the actual time for evaluating applications for authorisations was between 1 and 4 years[31]. Fees for the evaluation of applications for new active substances ranged between EUR 23 100 and EUR 450 000, with most Member States charging more than EUR 100 000. Fees for the authorisation of new PPPs ranged between EUR 10 000 and EUR 240 000, with most Member States charging more than EUR 50 000[32].

An impact assessment calculated the annual administrative burden of Directive 91/414/EEC for the EU-25 in 2005 at EUR 23 million[33].

Data protection, data sharing and animal testing

Provisions in Directive 91/414/EEC on data protection and data sharing for active substances caused several problems, both for Member States and applicants. The level of data protection granted depended on the status of the active substance and on when decisions were taken in the Member States.

The data protection rules presented a particularly serious obstacle for generic competition (i.e. products no longer protected by patents). The market share of generic companies was low in most EU Member States, and in several Member States the approval of an

28 European Commission. No data on emergency authorisations pre-2007.

29 Ecorys (2018), Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticide residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

30 Mattaar, H. (2010). Competent Authority Survey, A comparison of Member State Authorisation Processes, Pappas & Associates, Brussels, Belgium.

31 An overview table with the timelines, fees and staff for authorisations and applications under Directive 91/414/EEC is available in the support study carried out in the framework of this evaluation.

32 Phillips McDougall (2016), The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010 to 2014. R&D expenditure in 2014 and expectations for 2019.

33 European Commission (2006), Report on the impact assessment for a Regulation replacing Directive 91/414/EEC on plant protection products, SANCO/10273/2006 Rev. 5.

active substance led to a reduction in generic competition because of data protection rules[34].

Directive 91/414/EEC established rules on data sharing to avoid duplication of testing on vertebrate animals. Applicants were required to inquire with the Member States whether relevant experiments involving vertebrate animals had been already submitted and evaluated in earlier product authorisation applications. The applicant then had to reach an agreement with the existing authorisation holder so that the Member State concerned could use the data. If no such agreement could be reached, the Member State could, at its own discretion, introduce national measures to oblige sharing of the data within their territory. However, Directive 91/414/EEC did not oblige Member States to introduce these measures.

Court cases

Under the period of application of Directive 91/414/EEC, from 1991 to 2011, 21 court cases were initiated, mostly by industry. Almost all the cases related to the process of approval of active substances, and in particular contested the Commission's decision based on the outcome of the risk assessment. Except for 2 cases[35], the outcomes were favourable for the Commission. See Annex 5 for an overview of all court cases.

The PPP market

In 2004, the global PPP market was valued at EUR 24.7 billion of which the European market share amounted to EUR 6.8 billion (27.4 % of the total)[36]. At this time, the producers of agrochemicals could be separated into three main groups, as detailed below.

- **Multinational companies**: Following a consolidation wave between 1984 and 2003, the 'big six' multinational companies[37] held 75 % of the global agrochemical market and 81% of the EU market.
- **Smaller research-based companies**: A number of medium-sized companies[38] held 7% of the EU market in 2004[39].
- **Generic manufacturers**[40]: Generics are non-patent-protected products, and represented two thirds of sales globally. However, a large share of non-patent-covered products were sold by multinational companies.

Innovation was an important driver of growth in the global agrochemical market. However, only the multinational companies had a significant capacity to develop new active substances. Between 2005 and 2008, the average cost of discovery and development of a new plant protection product was estimated at EUR 189 million, including EUR 15.5 million fees for the approval and authorisation processes. In 2004, industry observers noted a decline in research and development activity in PPPs. This was illustrated by the declining rate of submissions of applications for the approval of

34 European Commission (2006), Report on the impact assessment for a Regulation replacing Directive 91/414/EEC on plant protection products, SANCO/10273/2006 Rev. 5.

35 Case T-158/03: Industria Químicas del Vallés, SA v Commission of the European Communities on the active substances — Metalaxil; and case T-229/04: Kingdom of Sweden v Commission of the European Communities on the active substance paraquat.

36 ECPA, Annual Report 2004-2005, p. 10. Estimates of different sources may differ considerably due to definitions applied etc.

37 Monsanto, Du Pont, Bayer, BASF, Dow, Syngenta.

38 Isagro, Crompton, Gowan, ISK, Taminco, Luxan, IQV, Janssen, Stahler, Japan Agro S.

39 Phillips McDougall (2005) Market Position in EU 25 for Small and Medium sized Agrochemical companies involved with Research and Development.

40 e.g. Maktheshim-Agan Industries, Nufarm, Cheminova, United Phosphorus, Sipcam Oxon, Cerexagri. This group included many smaller companies, most of them not operating in the EU market.

new active substances in the EU, which between 1994 and 2004 decreased to 5-10 per year from an earlier average of 15-20 per year[41].

By 2004, biotechnology was the fastest growing segment of the global crop-protection market. In response, some of the multinational companies began to dedicate an increasing share of their research and development effort into this area, and decreased their investment in traditional PPP portfolio development[42].

Pesticide sales fluctuated between 1994 and 2006, with an average of around 350 000 tonnes of active substances sold per year (the data covers 20 countries that are EU Member States in 2018)[43]. For example, in 1995, 330 000 tonnes of active substances were sold, and in 1999, 377 000 tonnes were sold demonstrating that the volumes could fluctuate between the years.

From Directive 91/414/EEC to the PPP Regulation

The PPP Regulation was proposed after 13 years of experience gained from the application of Directive 91/414/EEC. Considering the scientific and technical developments, it appeared that the basic approach of Directive 91/414/EEC was still acceptable but that the system was overloaded and inefficient[44]. To increase efficiency, corrective measures and new policy actions were proposed in the PPP Regulation. These are listed in the bullet points below.

- National provisional authorisations of not yet approved new active substances duplicated efforts in Member States, increased differences in the availability of PPPs between Member States and decreased incentives for industry to provide timely additional data requested to finalise the approval procedure. They were therefore removed in the PPP Regulation.
- The optional mutual recognition of authorisation of PPPs was only applied in rare cases. This led to a duplication of work and fragmentation of the single market for PPPs. The PPP Regulation introduced a zonal system and, in principle, mandatory mutual recognition within zones, thus encouraging cooperation and work sharing between Member States. The Regulation sets out three zones on the basis of similar climatic and agricultural conditions. For climate-independent uses (e.g. indoor uses, seed treatment) the zonal partition does not apply.
- To further protect human health and the environment the cut-off criteria in the PPP Regulation were introduced to increase the stringency of the approval criteria for active substances.
- To further minimise the risks to health and environment, the PPP Regulation sets out a list of active substances that are 'candidates for substitution' with shorter approval periods. When evaluating a PPP containing an active substance that is a candidate for substitution, Member States must conduct a comparative assessment to see if the PPP can be replaced with a safer alternative.
- The PPP Regulation harmonised the rules on data protection to facilitate competition by companies selling generic PPPs.

41 Uttley, N., The EU Market for Generic Agrochemicals, Enigma Marketing Research, 2004, p. 28.

42 European Commission (2006), Report on the impact assessment for a Regulation replacing Directive 91/414/EEC on plant protection products, SANCO/10273/2006 Rev. 5.

43 For Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Netherlands, Poland, Portugal, Slovakia, Spain, Sweden and United Kingdom. Data from OECD statistics database.

44 European Commission (2006), Report on the impact assessment for a Regulation replacing Directive 91/414/EEC on plant protection products, SANCO/10273/2006 Rev. 5.

2.2.2. A patchwork regulatory system for MRLs of pesticides

The situation in September 2008 when the Regulation came into force is the baseline for the evaluation of the MRL Regulation. Before 2008, there was a dual system in place for MRLs in the EU: Member States could set national MRLs, but some MRLs were set at EU level through a number of Directives[45]. These Directives established EU MRLs for fruit and vegetables, cereals, foodstuffs of animal origin, and other plant products. Between 1976 and 2008, more than 45 000 EU MRLs were set for 245 pesticide residues in 190 commodities. However, these EU-level MRLs represented only a small subset of the MRLs that were set at national level (around 500 000) - there were more than 1 000 active substances on the market and national MRLs covered a larger range of commodities.

The Directives setting EU-level MRLs were substantially amended several times. These amendments were transposed differently into national legislation by Member States. Moreover, minor crops were not always listed in the Directives, which led to legal uncertainty about the applicable MRLs for those crops. In view of the number of active substances which had been withdrawn under Directive 91/414/EEC in the early 2000s, a practical solution to this uncertainty had to be found to permit realistic enforcement action on MRLs.

Reports from annual monitoring carried out in the EU showed that the number of analysed samples increased from around 41 000 samples in 1996 to 65 000 samples in 2006. The compliance rate was high, with 54 % of samples free of quantifiable residues, an additional 42 % of samples within legal limits, and 4 % of samples with residues exceeding the legal limits in 2006. The reports covered the national situations for pesticide-residue monitoring in EU Member States and three European Free Trade Association (EFTA) states[46].

From a patchy regulatory system to the MRL Regulation

The Commission carried out a series of audits in the Member States between 1998 and 2003[47] and between 2003 and 2006[48] to evaluate the control systems in place for pesticide residues. The main findings are set out in the bullet points below.

- In general, the control system for pesticide residues was better developed than the control system for placing on the market and use of PPPs.
- The fact that MRLs were not harmonised for all the pesticide residue-commodity combinations caused some problems with compliance in Member States.
- There was great variance in the planning, priorities and scope of monitoring programmes. Sampling deficiencies were also found. One of the weakest points in the residue area was in follow-up and enforcement where non-compliance with MRLs had been found. In some Member States, no or only limited enforcement action was

45 Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables (OJ L 340, 9.12.1976, p. 26). Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals (OJ L 221, 7.8.1986, p. 37). Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin (OJ L 221, 7.8.1986, p. 43). Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables (OJ L 350, 14.12.1990, p. 71).

46 Norway, Iceland and Liechtenstein are members of the European Economic Area.

47 European Commission (2003), General report on the outcome of a series of missions carried out in all Member States from 1998 to 2003 in the field of control systems on placing on the market of plant protection products and residues in foodstuffs of plant origin, DG (SANCO)/9507/2003.

48 European Commission (2007), General report of a series of missions carried out between 2003 and 2006 in 25 Member States concerning controls of pesticides in food of plant origin. DG(SANCO)/7599/2007.

taken, and there was a long delay between sampling for analysis and reporting of the analytical results.

In the proposal for the MRL Regulation presented in 2003[49], the Commission identified several reasons that justified the introduction of the Regulation. These reasons are set out in the bullet points below.

- For simplification and clarity, and to improve consistency with Directive 91/414/EEC, a single Regulation would replace the earlier Directives.
- The Regulation was needed to define the role of EFSA and separate responsibilities in the areas of risk assessment and risk management.
- A practical solution was needed for the enforcement of MRLs for the active substances that were withdrawn under Directive 91/414/EEC.
- All existing MRLs needed to be harmonised at EU level and set on the basis of: (i) data on national diets, (ii) the authorisations granted by the Member States, and (iii) their agricultural practices. In exceptional cases, MRLs could be set on the basis of monitoring data.
- There was a need to recognise that different agricultural practices outside the EU led to different residue levels on imported products. This meant there was a need to set import tolerances for imported products provided they were safe for consumers.
- The workload for pesticide residues was expected to increase, and the existing legislation did not provide a basis to recover costs. A framework within which Member States could set fees for the evaluation of dossiers was desirable.

2.3. Baseline — other points of comparison

To complement the historical comparison, this evaluation will in a few places compare the MRL Regulation and PPP Regulation with other regulatory systems.

The regulatory system for review of pesticide registration in the United States

The United States has unlimited registration periods for active substances but has a re-registration process to review active substances to ensure that they meet current scientific and regulatory standards[50]. The United States Environmental Protection Agency (EPA) assesses both the active substances and the products containing it in one step[51]. The EPA is both the risk assessor and risk manager, which is different from the EU where there is a clear division between the risk assessors and risk managers[52].

To initiate a review of an active substance, the EPA establishes a 'public docket', which is open for public comment for at least 60 days. The docket contains a preliminary work plan with: (i) facts about the pesticide and its use, (ii) the anticipated risk assessment, (iii) the anticipated data needs, and (iv) an estimated timeline for the review.[53] Anyone may submit data or information to the public docket, and based on the information received, a final work plan is developed. The EPA then holds focus meetings, which typically involve registrants and other players such as NGOs. Focus meetings are intended to address any areas of uncertainty, such as unclear labels or missing studies. By obtaining

49 European Commission (2003), Proposal for a Regulation of the European Parliament and of the Council on maximum residue levels of pesticides in products of plant and animal origin, COM(2003), 117 final.

50 EPA website on reregistration of pesticides.

51 European Commission (June 2018), EU Authorisation processes of plant protection products — from a scientific point of view, Group of Scientific Advisors, ISBN 978-92-79-67735-9.

52 The EU is world-leading in its separation of the roles of risk assessor and risk manager, which is internationally-recognised best practice.

53 EPA website on the registration review process

better information early in the process, the EPA claims that it can narrow the scope of pesticide re-evaluations to areas that pose real concerns. The EPA then assesses any changes that have occurred since the last registration decision to determine whether the pesticide still satisfies the standard for registration or if a new risk assessment must be conducted. If a new assessment of the pesticide is needed, the EPA determines if they need new data or information. If additional data or information are needed, the EPA will issue a 'data-call in' notice to the registrants. The EPA then makes the draft risk assessment available for public review. If risks are identified, the public is invited to submit suggestions for mitigating the risks. Finally, the EPA decides whether a pesticide meets the standard for registration. In 2007, the median time for the re-registration process was 30 months and the average 54, i.e. some assessments were relatively straightforward while others required considerable resources[54]. In 2019, the review of an active substance was reported to take on average 6 years[55].

The regulatory system for review of pesticide registration in Canada

In Canada, re-evaluations of PPPs must be initiated no later than 16 years from the last major regulatory decision. This is to ensure that all pesticides continue to meet the health and environmental safety standards[56]. Each re-evaluation process takes about 2-4 years depending on the complexity and the implementation of the decision (e.g. amendments to product label) may take another 2-3 years. The number of re-evaluations that the Canadian authorities is required to initiate is increasing: there are currently 125 re-evaluations ongoing and 145 re-evaluations are anticipated in the next 5 years. This is double the number of initiations compared to the previous 5-year period.

The Canadian authorities have noted that the scale and complexity of re-evaluation reviews continue to increase. The main issues identified are (1) a continuous stream of new data being generated which needs to be considered; (2) multiple data providers with varying quality of information; (3) increased expectation for stakeholder engagement; and (4) users, registrants, public, health/environmental groups have opposing positions.

The EU Biocidal Products Regulation

The Biocidal Products Regulation[57] regulates pesticides used for non-agricultural purposes in the EU[58]. The Biocidal Products Regulation and the PPP Regulation are both built on a two-step approach, where active substances are first approved at EU level. However, the second step differs in the two Regulations. For the PPP Regulation, products containing the approved active substances are authorised by Member States. For the Biocidal Products Regulation, biocidal products containing the active substances are in most cases also authorised by Member States but can also be authorised at EU level by the Commission for certain products which have similar uses across the EU, e.g. hand disinfectants, and can then be placed on the market in all Member States.

The Biocidal Products Regulation provides for the risk assessment to result in a single opinion by the Biocidal Products Committee in the European Chemicals Agency (ECHA). In general, the opinion is adopted 'by consensus', which means unanimous

54 Environmental Protection Agency (2007) Evaluation of the U.S. EPA Pesticide product Reregistration Process: Opportunities for Efficiency and Innovation.
55 Estimate provided by the US EPA at a meeting with the Commission services on 2-3 April 2019.
56 Government of Canada (Health Canada's Pest Management Regulatory Agency) website on the Re-evaluation Program.
57 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1.
58 Biocidal products have diverse uses with 22 different product-types, including disinfectants, pest control, preservatives, antifouling, or embalming fluids.

support by the Member States experts in the Biocidal Products Committee. Consequently, most of the decisions on the approval of active substance proposed by the Commission were unanimously supported by the Member States in the Standing Committee on Biocidal Products. For new biocidal active substances, the procedure for approval takes on average 44 months.

The Biocidal Products Regulation provides for a coordination group to facilitate authorisations through mutual recognition by resolving disagreements between Member States. In the Biocidal Products Regulation, it is also possible to request the authorisation of a group of similar products via one application.

3. IMPLEMENTATION / STATE OF PLAY

This section describes the current situation in the EU. The MRL Regulation and PPP Regulation have been applicable since September 2008 and June 2011, respectively. The vast majority of the measures and activities provided for in the Regulations are in place, such as: the data requirements for active substances[59] and products[60]; the uniform principles for authorisations[61]; the labelling requirements[62]; the renewal Regulation[63]; criteria to define endocrine disruptors[64]; a list of potential low-risk active substances[65]; and five work programmes for renewals[66]. In addition, to detail and clarify the implementation, there are 39 procedural guidance documents and 49 technical guidance documents[67]. Additional guidance documents are also under development.

Some provisions in the PPP Regulation have not been fully implemented. Work is ongoing to identify unacceptable co-formulants. A work programme should be created to review safeners, synergists and adjuvants. However, this work has not yet started.

Parts of the MRL Regulation are not yet implemented. Work has not yet started on drawing up a list of harmonised concentration or dilution factors for certain processing and/or mixing operations. Nor has work begun on drawing up specific MRLs for processed products, feed and fish. The development and application of a methodology to take into account cumulative and synergistic effects of pesticides is still ongoing.

The evaluation focusses on the effectiveness of the implemented aspects of the PPP and MRL Regulations. Discussed is also the progress made to date and, to the extent possible, how the missing elements impact the overall effectiveness of the system.

59 Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

60 Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

61 Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles of evaluation.

62 Commission Regulation (EU) No 547/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products.

63 See Commission Implementing Regulation (EU) No 844/2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

64 Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

65 Commission notice concerning a list of potentially low-risk active substances approved for use in plant protection, C/2018/4828 (OJ C 265, 27.7.2018, p. 8).

66 Europa webpage on renewals.

67 Europa webpages on guidance documents for PPPs and for MRLs.

3.1. Societal and political developments

In recent years, there has been growing public and media attention on the way food is produced. Europeans are paying greater attention to the topic of pesticides for both health and environmental reasons. The European Citizens' Initiative on glyphosate, which collected over 1 million signatures across Europe in less than 9 months in 2017, is an example of this increasing societal interest. The European Citizens' Initiative called for a ban on glyphosate, and for more transparency in the process for assessing pesticides. It also called for a reduction in the use of PPPs, with the ultimate goal of a pesticide-free future.

In the run-up to the renewal of the approval of glyphosate, the European Parliament adopted two Resolutions in April 2016[68] and October 2017[69]. After the renewal, the European Parliament created a special committee on the EU pesticides authorisation procedure (PEST). This special committee had a mandate to analyse and assess the procedure for placing PPPs on the EU market and identify potential failures in the process. The Parliament adopted the final report of the Committee in January 2019[70]. In addition, the European Parliament adopted in September 2018 a report from the Environment Committee on the implementation of the PPP Regulation[71].

Citizens and their political representatives have repeatedly called for more transparency in the procedures leading to the placing on the market of PPPs — be it at the risk assessment stage or at the risk management stage. This led the Commission to adopt in April 2018 a proposal on the transparency and sustainability of EU risk assessment in the food chain[72]. The content of the proposal is described in a text box in section 5.1.8. This amendment of the General Food Law has been adopted by the Council and the European Parliament on 13 June 2019[73] and will become applicable in March 2021.

At international level, the EU strict approach to pesticides is often criticised by a number third countries who argue that certain aspects of the EU legal framework and practice are not in line with the WTO SPS Agreement and are too restrictive. There is a growing tension between the expectations of European consumers that imported food should not contain pesticides that are not approved in the EU and the international commitments of the EU, in particular in the context of the WTO. At the same time, there is criticism from within the EU that MRLs are set for non-approved active substances, which allow imports of products treated with active substances that are not available to EU farmers, thus negatively affecting the competitiveness of EU agriculture, as well as the environment in third countries.

68 European Parliament resolution of 13 April 2016 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (D044281/01 — 2016/2624(RSP)).

69 European Parliament resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (D053565-01 — 2017/2904(RSP).

70 European Parliament (January 2018) Report on the Union's authorisation procedure for pesticides (2018/2153(INI)) Special Committee on the Union's authorisation procedure for pesticides.

71 European Parliament (September 2018), Report on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009, (2017/2128(INI)).

72 Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain, COM/2018/0179 final — 2018/088 (COD).

73 Regulation (EU) 2019/1381 of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain, *OJ L 231, 6.9.2019, p. 1.*

3.2. The PPP market

In 2016, the six largest agrochemical firms[74] reported global agrochemical sales of EUR 32 billion[75]. In Europe, the crop-protection market generated revenues of EUR 12 billion in 2016[76]. Since 2016, the 'big six' firms have consolidated further, following three global mergers of Syngenta and ChemChina; Dow and Dupont; and Bayer and Monsanto. Together with BASF, these multinational companies are now the 'big four'[77]. There are also a number of smaller research-based PPP companies (see page 11), and generic manufacturers, i.e. for non-patent-protected products.

In 2014, the discovery and development of a new plant protection product was estimated to cost EUR 250 million and to take about 10 years[78]. Globally, biotechnology continues to play an important role, as demonstrated by the Bayer/Monsanto merger in which Monsanto's biotechnology portfolio was combined with Bayer's more traditional PPP portfolio.

Sales of pesticides were reported to be relatively unchanged between 2011 and 2016, with around 350 000 tonnes of active substances sold per year[79].

Based on the limited data provided by Member States, most active substances contained within PPPs marketed in the EU are manufactured abroad. Increasingly, formulation which is the mixing of PPPs, is also moving to non-EU countries. There is also a lot of trade within the EU, so most PPPs are not used in the Member State in which they are actually imported or manufactured[80].

3.3. Approval of active substances

As of December 2018, 484 active substances were approved in the EU[81]. This is a 15 % increase compared to 2011. In some cases, one approval decision covers several individual substances, so the number of approval decisions for these substances was around 430[82].

Active substances currently approved under the PPP Regulation have been subject to different approval criteria depending on when they were approved or when the application for approval was submitted. These differences are discussed in the bullet points below.

- Active substances approved under Directive 91/414/EEC were deemed to have been approved under the PPP Regulation. These active substances have then been reviewed under one of the renewal programmes. Some active substances in this category fall under the cut-off criteria. However, the cut-off criteria will only impact the approval status of the active substances at the time of renewal of approval.

74 Syngenta, Bayer, BASF, Dow, Monsanto and Dupont.
75 According to Agribusiness intelligence, Top 20 2017.
76 According to InkWood Research, https://www.inkwoodresearch.com/reports/europe-crop-protection-market/.
77 Syngenta/ChemChina, Corteva, Bayer and BASF.
78 According to CropLife and McDougal P. (2016), The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-2008 and 2010-2014.
79 Eurostat, Pesticide sales dataset [aei_fm_salpest09].
80 European Commission (2016) Overview report on a series of audits carried out in EU Member States in 2015 and 2016 to evaluate the control systems in place for the marketing and use of plant protection products, DG(SANTE) 2016-6004 – MR.
81 EU Pesticides Database
82 For instance 'copper compounds' covers 7 individual copper salts. 'Straight Chain Lepidoptera Pheromones' covers 27 individual strains of Straight Chain Lepidoptera Pheromones. See Regulation (EU) No 540/2011 as regards the list of approved active substances.

- New active substances for which applications had been submitted under Directive 91/414/EEC (i.e. before June 2011), but approved under the PPP Regulation were subject to the approval criteria in Directive 91/414/EEC.
- Active substances are reviewed and assessed according to the updated data requirements that came into force in 2013. If approval is renewed, the active substances are in most cases approved for another 15 years. As of December 2018, 68 renewal procedures have been completed. For 53 active substances the approval has been renewed, and for 15 active substances the approval has not been renewed. In addition, 72 active substances approved earlier are no longer supported by any company at EU level under the AIR 3 and AIR 4 work programmes.
- New active substances for which approval has been sought under the PPP Regulation must meet the strict approval criteria set out in the Regulation. Dossiers for these substances must be submitted according to the updated data requirements. Since June 2011, applications for 69 new active substances have been submitted. The rapporteur Member States for these applications have mostly been France, the Netherlands and the UK (France was rapporteur Member State for 16 applications, the Netherlands for 14 and the UK for 12). Table 1 provides an overview of the number of new active substance applications received per year: of the 69 applications between 2011 and 2018, 26 have been approved. New active substances can be new innovative active substances never before placed on the market in the EU. New active substances can also be active substances that were previously not approved in the EU or that were withdrawn from the market under Directive 91/414/EEC and for which the applicant is making a new application under the PPP Regulation.

Table 1. Applications for new active substances received from June 2011 to December 2018[83]

Year	2011	2012	2013	2014	2015	2016	2017	2018
New active substance applications	4	8	12	6	15	10	4	10

3.4. Authorisation of plant protection products

The number of PPPs authorised varies between Member States. For instance, in 2016 there were 134 in Malta, 322 in Sweden, 753 in Germany, 1 825 in France, 3 300 in the UK, and 4 200 in Italy[84]. The number of products available in a particular Member State somewhat correlates with the size of the Member States, the size of their agricultural sector, and their climatic conditions.

3.5. Setting and reviewing MRLs

When the MRL Regulation came into force in 2008, temporary MRLs[85] were set for all pesticide residue-commodity combinations previously covered by national MRLs. EFSA carried out a preliminary risk assessment of those temporary MRLs on the basis of the information provided by Member States[86]. The MRL Regulation requires a review of all existing MRLs for active substances 1 year after their initial approval or non-approval. MRLs for substances that were already approved at the time of the implementation of the Regulation must also be reviewed. This includes a review of existing import tolerances and Codex Limits (CXLs). The timeframe for this review (i.e. 1 year) was overly

83 Information from the summary reports from the Standing Committee on Plants, Animals, Food and Feed.
84 Member State survey.
85 100 000 MRLs were set in the MRL Regulation on a temporary basis to cover the most critical good agricultural practices that were authorised in single Member States.
86 Reasoned opinion on the potential chronic and acute risk to consumers health arising from proposed temporary EU MRLs. EFSA Journal, 2007; doi: 10.2903/j.efsa.2007.32r.

ambitious, in particular because the Regulation did not set out a procedure on how the review should work in practice (resources, responsibilities, etc.). Therefore, Member States, the Commission and EFSA agreed on an ad-hoc procedure under which Member States provide support to EFSA to share the workload. In spite of this effort, the MRLs of only about half of the substances have now been reviewed. Part of the initial delay can be attributed to the need for the development of a new procedure.

After a Member State revokes an authorisation for a PPP, the Commission may prepare a draft measure to delete the relevant existing MRLs. In practice, the Commission only makes use of this procedure when all existing authorisations for PPPs containing a specific active substance have been revoked (e.g. following non-approval or non-renewal). Provided they are judged safe for EU consumers, MRLs corresponding to CXLs based on uses in non-EU countries are not deleted, nor are MRLs that had been specifically set as import tolerances.

As a result, MRLs are either set to a default value of 0.01 mg/kg, or, where specific data on analytical feasibility are available, they are set to the relevant limit of quantification (LOQ) of the active substance. The EU reference laboratories for pesticide residues are consulted on the appropriate LOQ and residue definitions to be used for enforcement purposes. In exceptional circumstances, a lower level than the default can be set for substances with high toxicity. As the lowering of MRLs affects trade, WTO members must be consulted under the SPS agreement[87].

Since 2008, more than 1 000 applications were submitted to Member States to set or review MRLs, either for uses in the EU or to set import tolerances[88] (see Table 2). Currently, 486 approved and 247 non-approved substances are covered by the MRL Regulation, which sets 190 000 MRLs[89]. Note that for 130 active substances, no MRLs are required, because of their low-risk profile or because they naturally occur in the environment and are considered safe.

Table 2. Number of applications received to set and review MRLs since 2008

Procedure	Applications
Setting of MRLs	518
Setting of import tolerances	94
Review of MRLs	487

3.6. Public information, risk communication and transparency

Access to information has been built into the risk assessment and risk management processes. Efforts have been made to ensure that relevant information can be accessed easily and in a timely manner. The EU Pesticides Database[90] provides data on the status of all active substances and on all MRLs. The plant protection products application management system (PPPAMS)[91] currently being developed by the Commission aims at increasing transparency on authorisations granted in the Member States. It also aims at facilitating the implementation of mutual recognition and parallel trade permits. Since July 2016, Member States have accepted to notify emergency authorisations only within the PPPAMS. To populate the PPPAMS and create a public website, the Commission is currently working with Member States to collect data on all existing authorisations held in national databases.

87 The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).
88 EFSA Register of Questions.
89 For further explanation and calculation, see Annex 3.
90 EU Pesticides Database.
91 https://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/pppams_en.

3.7. Enforcement and monitoring

Member States are required to perform official checks to verify compliance with the PPP and the MRL Regulations. In addition to the general obligation laid down to this effect in Regulation (EC) No 882/2004, which requires Member States to plan and perform official controls at all stages of the agri-food chain, special rules are also laid down in the PPP and MRL Regulations[92].

For the MRL Regulation, checks consist mostly of: (i) an EU-coordinated programme[93] of sampling and analysis, the results of which are reported to EFSA on an annual basis, and (ii) risk-based official controls planned at national level, the results of which are also reported to EFSA along with the enforcement actions taken.

Under the EU-coordinated programme, the Commission and the Member States agree every year on the number of samples (approximately 80 000) to be taken that are representative of 'the residue situation of food products available to consumers'. They also agree on the active substances to be analysed. These two measures ensure the adaptability of the programme to cover those pesticides of high interest. Together with other relevant information, the results of the EU-coordinated programme are also used to determine whether increased levels of import controls are required on certain products[94].

For the PPP Regulation, Member States monitor and control the manufacturing, import, distribution and use of PPPs. They also send annual reports to the Commission to inform about the activities they have carried out.

Since 2011, the Commission has conducted several series of audits in Member States[95]. These audits have focused on how Member States organise their official controls and other official activities in this area (e.g. the controls of PPPs, official laboratories and sampling methods, the authorisation of PPPs). Further enforcement action to detect counterfeit and illicit PPPs is taking place through coordinated measures supported by Europol and the European Anti-Fraud Office through the Silver Axe joint operation.

Some significant changes have recently been introduced[96] to strengthen enforcement of the PPP Regulation by the Member States. These changes include:

- a new obligation for national enforcers to perform dedicated official checks aimed at identifying possible fraudulent and deceptive practices, including in imported products;
- explicit powers for national enforcers to inspect the production chain 'upstream' (including manufacturing, transport distribution of substances and products) and take remedial action in the event of established violations;
- strengthened rules for cross-border cooperation if fraudulent products move from one Member State to the other;
- strengthened penalties for fraud; and

92 These special rules will be replaced (by December 2022 at the latest) by the provisions of the recently adopted Regulation (EU) No 2017/625 (see Article 115 and Article 161 of Regulation (EU) n. 2017/625).

93 Commission Implementing Regulation (EU) 2018/555 of 9 April 2018 concerning a coordinated multiannual control programme of the Union for 2019, 2020 and 2021 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

94 As described in Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC.

95 Europa webpage with all overview reports.

96 By Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.

- the possibility for the Commission to adopt specific rules to govern official controls and other enforcement activities in this area.

3.8. Court cases and complaints

Since 2011, 25 court cases related to PPPs and MRLs have been initiated by industry and NGOs against the Commission. The cases are not only about approval or non-approval decisions of active substances. They also deal with: restrictions of approvals, internal reviews under the Regulation implementing the Aarhus Convention, the inclusion of active substances in the list of candidates for substitution, and requests for interim measures to suspend the action that is subject to the court case. Industry most often challenges the Commission's decisions on active substances based on arguments related to the risk assessment and procedural rights[97]. A comprehensive analysis of the outcomes cannot be performed at present as more than 50 % of the cases are still pending[98].

In addition, 4 complaints to the Ombudsman have been made both by industry and NGO's. These complaints relate to: (i) the Commission's practice of approving an active substance while simultaneously requesting data confirming its safety[99]; (ii) the Commission's practice of extending the approval periods of active substances; (iii) the Commission's compliance with rules on the approval of active substances, including whether MRLs for new active substances should be set after approval of a substance or before[100]; and (iv) the Commission's response to 18 applications for access to documents[101].

A complete list of court cases and complaints to the Ombudsman is provided in Annex 5.

4. METHODOLOGY

The roadmap[102] for the REFIT evaluation was published in November 2016 and this Staff Working Document answers the questions posed in the roadmap. Feedback on the roadmap was received from 21 stakeholders[103] and taken into consideration when drafting the terms of reference for the external support study. The final report of a study commissioned to an external contractor was published on 18 October 2018[104] (and is referred to elsewhere in this report as 'the support study'). The REFIT evaluation was supported by an inter-service steering group with representatives from relevant Commission DGs (see Annex 1 on procedural information). More information on the support study and methodology can be found in Annex 3.

In addition to the support study, several other reports and studies have been published recently on the implementation of the PPP Regulation and the functioning of the regulatory system for pesticides in the EU. These publications are listed in Annex 1 and have been carefully considered in the analysis.

97 This includes the right to be heard, the right of defence and the right regarding the protection of legitimate expectations.
98 In the cases where the Court has ruled, the Court upheld the Commission's restrictions for three neonicotinoids, as well as the inclusion of copper compounds and metalaxyl in the list of candidates for substitution. However, the Commission lost the case concerning the restriction of the active substance fipronil.
99 Complaint 12/2013/JN, see https://www.ombudsman.europa.eu/cases/correspondence.faces/en/93729/html.bookmark.
100 Complaint 2000/2015/ANA).
101 Complaint 1869/2013/AN.
102 Roadmap
103 Feedback can be accessed online.
104 External support study published in the EU bookshop.

4.1. Data collection

The Commission drew up a consultation strategy together with the terms of reference for the support study in order to collect stakeholder perceptions and quantifiable data. This quantifiable data included the costs for preparing a dossier for approval and renewal, and the number of full-time staff equivalents working with the PPP and MRL Regulations. A literature review was carried out to gather key information from: impact assessments; position papers; academic and scientific research; papers and reports prepared by relevant scientific bodies; and regulatory submissions. Stakeholders contributed to one or several consultations, as planned in the consultation strategy (see Table 3). These stakeholders included: public authorities in the Member States; EFSA; the Commission; the pesticides industry; the food industry; NGOs for environment, health, protection of animals and transparency; consumers, citizens and farmers; and authorities and other stakeholders from non-EU countries. Despite efforts to get their contribution, only three respondents from the research community participated in the stakeholder survey.

A summary of the views collected in the consultations is provided in the synopsis report on the stakeholder consultation in Annex 2. The Commission set-up a webpage to inform the public about the REFIT evaluation in general and the consultation activities in particular[105].

Table 3. Consultation activities carried out

Consultation	Target/participants	When?	Contributions
Open public consultation	Consumers, citizens and farmers.	13 Nov 2017 - 12 Feb 2018	9 847
SME consultation panel	Distributed via the Europe Enterprise Network to target small, medium and micro-sized companies.	14 Nov 2017 - 15 Jan 2018	294
Stakeholder survey	Trade and industry associations covering the chemical industry; retailers and wholesalers; the food and feed industry; environmental, health and consumer NGOs; farmers' associations.	14 Nov 2017 - 12 Jan 2018	240
Member State survey	Member States and European Economic Area (EEA) countries.	16 Nov 2017 - 19 Feb 2018	30
Focus groups	Member State authorities, EFSA, the Commission, stakeholders working with risk assessment.	24 Jan 2018 28 Feb 2018 5 Mar 2018 9 Mar 2018	8 9 7 8
First Workshop	Member State authorities; the Commission; trade and industry associations; NGOs at EU level.	12 Sep 2017	40
Second Workshop	Member State authorities; the Commission, trade and industry associations; NGOs at EU level.	16 May 2018	50
In-depth interviews	Trade and industry associations, NGOs at EU level, Member States, non-EU countries, EFSA, the Commission.	10 Jan 2018 - 25 Apr 2018	60

4.2. Limitations and robustness of findings

The following shortcomings and challenges limit the analysis.

105 REFIT pesticide webpage

- The Regulations are still at a relatively early stage of implementation, with some provisions still to be implemented. This is especially the case for the PPP Regulation as it takes a long time to evaluate each active substance. All active substances or MRLs have not yet been reviewed, so the evaluation will not capture all the impacts or expected benefits from the Regulations.
- It is difficult to quantify the benefits of the Regulations. This is due to attribution problems and a lack of studies establishing a causal link between the use of single pesticides or specific MRLs and health or environmental outcomes. Data on the use of pesticides also do not exist in a harmonised way in the EU, and quantities alone do not necessarily reflect risk, given that each substance has a particular hazard profile and some more recently introduced active substances have a more 'specific activity' affecting less non-target organisms. This limits the assessment of how effective the MRL and PPP Regulations are in protecting human health and the environment. An additional limitation is that most scientific publications rely on old data and consider effects from already non-approved active substances. They are therefore of little use in this evaluation, which focuses on impacts after 2008 and 2011, respectively. Better health and environmental information could be obtained through more and better targeted monitoring and controls. Health and environmental impacts could be investigated through research projects and epidemiological studies. Further inclusion of pesticides in human biomonitoring (such as HBM4EU[106]) could be considered. Possible solutions to collect use data are: new technologies such as intelligent application equipment that directly transmits the data or remote sensing by satellite (e.g. via Copernicus).
- Despite efforts to collect data on costs through surveys and specific queries (in addition to Eurostat data and other publicly available data), it was not always possible to fill data gaps. Therefore, cost estimates should be considered only as an approximation of the costs incurred by the different stakeholders. Better cost data could be collected by systematically requiring applicants to submit cost figures as part of their application dossiers. Member States could keep better records of the time and resource costs.
- Farmers were consulted as part of the public consultation, and efforts have been made to analyse the answers given by farmers in the part of the survey that contained an open question in which they were free to write at length.
- Data from Regulation 1185/2009 on statistics of pesticides[107] could only be used on an aggregated level due to confidentiality restrictions set in the Regulation by the European Parliament and the Council. This restricted the possibility of assessing the impacts of approval decisions on use patterns in the EU, and such analysis is therefore omitted.
- It has not been possible to distinguish the effect on human health and the environment of the approval of an active substance from the authorisation of the PPP containing that active substance. This is because of the difficulty in disentangling the impact from the two processes, as an active substance is only released into the environment in the form of a PPP.

Despite these limitations, the evaluation relied on, as described above, an extensive literature review and data collection through desk research. The wide stakeholder

106 Human biomonitoring for EU HBM4EU is a joint effort by 28 countries, the European Environment Agency and the European Commission, co-funded under Horizon 2020.

107 Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides (OJ L 324, 10.12.2009, p. 1).

consultation made it possible to collect the opinions of many stakeholders. To ensure the reliability of the data collected, different sources of data were compared, and opinions from stakeholders were examined against other evidence (i.e. triangulation) as much as possible.

5. ANALYSIS AND ANSWERS TO THE EVALUATION QUESTIONS

5.1. Effectiveness

- To what extent have the objectives been achieved as a result of the implementation of the PPP and MRL Regulations at both EU and at Member State level?
- Where expectations have not been met, what factors have hindered their achievement?
- Which unintended effects were observed?
- Did other factors influence the results observed?

MAIN FINDINGS

The Regulations are to a large extent effective in protecting human health. The number of highly hazardous active substances is low in the EU and will decrease in the future, while the proportion of low hazard active substances is increasing albeit slowly. The level of compliance with MRLs is high showing that the food available to consumers is safe. Although the Commission has not yet made use of the possibilities given by the MRL Regulation to establish specific MRLs for certain product groups (fish, feed, processed foods) as well as a harmonised processing factors, this has not decreased consumer protection. Developing a method for cumulative risk assessment for residues is still on-going as it turned out to be much more complex and require more resources than initially envisaged. The protection of human health is expected to improve in the coming years when the review programmes for active substances and MRLs will be finalised. Less progress has been made in the development of methodology for the cumulative risk assessment of active substances under the PPP Regulation.

The approval criteria in the PPP Regulation are effective in protecting the environment. Monitoring shows a reduction in the contamination of surface water by certain individual pesticides, although the monitoring data available do not cover all pesticides used. The restrictions on active substances with negative impacts on pollinators should contribute to their protection. However, increased monitoring would make it possible to assess the effectiveness of the PPP authorisation in more detail, and to identify illegal uses that may pose a threat to the environment.

Enforcement of the Regulations varies between Member States and this negatively affects overall effectiveness. It is estimated that illegal and counterfeit PPPs represent around 10 % of the EU market, which is a concern as this may decrease the level of protection of human health and the environment otherwise achieved by the PPP Regulation. The MRL Regulation ensures that effective and timely enforcement action can be taken, however some problems have been experienced in practice, in particular with substances coming from multiple sources.

The Regulations have overall improved the functioning of the single market, in particular the harmonisation of MRLs. The zonal system created with the PPP Regulation is not working as well as expected. The lack of cooperation between Member States and lack of harmonisation between national requirements decreases effectiveness. In some cases the

MRL Regulation was found to lack flexibility to provide quick responses to newly emerging issues, such as unexpected findings of pesticides residues in food and residues as a result of emergency uses to address plant health risks.

More information on the relationship between the use of different PPPs and agricultural productivity is needed in order to fully assess the PPP Regulation's impact on the competitiveness of EU agriculture. Farmers and food-business operators expressed concern about more active substances being taken off the market in the future and not being replaced by sufficient low-risk active substances. This would limit farmers' choices related to resistance management and the handling of pest outbreaks.

The setting of MRLs has contributed to the smooth functioning of international trade. However, when MRLs are decreased, the length of the procedure for setting import tolerances may create barriers to trade.

5.1.1. Protecting human health

Approval criteria for active substances

The approval criteria in the PPP Regulation, which are underpinned by the precautionary principle, are frequently referred to as the most stringent in the world. As seen in Figure 3 in section 2.1, the number of active substances placed on the market in PPPs decreased by more than 50 % under Directive 91/414/EEC. This means that the level of protection of human health was already increasing before the PPP Regulation came into force. With the PPP Regulation, active substances have been reviewed against the strengthened approval criteria to further increase the protection of human health in the EU.

When the PPP Regulation became applicable in 2011, there were 427 active substances available (see Table 4). On 31 December 2018, there were 484 approved active substances in the EU, a slight reduction compared to 2017 because of a number of recent non-renewals of approvals. The increase in available active substances between 2011 and 2018 is due to new active substances, for which applications for approval were submitted mostly still under Directive 91/414/EEC.

Table 4. Approved active substances per year[108]

Year	2011	2012	2013	2014	2015	2016	2017	2018
Total approved active substances	**427**	**432**	**443**	**467**	**483**	**490**	**494**	**484**
of which basic substances				3	9	12	18	20
of which low-risk active substances					3	7	11	13
of which candidates for substitution*					1	5	8	10

*This refers only to the active substances approved as candidates for substitution and listed in Annex E to Regulation 540/2011

Since 2011, the renewal process has been initiated for all approved active substances and finalised in 68 cases. A first full cycle should be finalised by 2025[109]. Only when all approved active substances have been re-assessed against the current criteria will it be possible to fully assess the impact of the PPP Regulation on the number of active substances and their toxicological profile — and by extension the positive effect on human health. The decisions to not approve, not renew the approval, or withdraw 22 active substances[110] because of health-related concerns has contributed to avoiding serious health risks in the EU. Potential hazards such as genotoxicity, long-term toxicity, carcinogenicity and reproductive toxicity have been reduced for consumers, operators, workers, bystanders and residents[111].

Even if some benefits are evident, it remains challenging to assess the impact of the PPP Regulation on human health because of the difficulties of linking exposure to a single active substance with a certain health effect. Only one relevant scientific study was found: it used data from 2003 to assess the health impact and damage cost of pesticides in the EU[112]. This study found that 13 active substances[113] contributed to 90 % of overall health impacts. Only 3 of these 13 active substances[114] are still on the market in the EU and they are currently being re-evaluated. The study concluded that, although it was

108 EU Pesticides Database.

109 This statement will hold true if all active substances are assessed on time. However, with the delays in the system it is possible that the full cycle of renewals will only be finalised after 2025.

110 2-naphthyloxyacetic acid, 3- decen-2-one, amitrole, chloropicrin, diphenylamine, diquat, etoxazole, fenamidone, flufenoxuron, flupyrsulfuron-methyl, flurtamone, iprodione, linuron, orthosulfamuron, oxasulfuron, picoxystrobin, propanil, propargite, propiconazole, propineb, Pseudozyma flocculosa ATTC 64874, thiram and tricyclazole.

111 Support study p. 57.

112 Fantke, P., Friedrich, R., and Jolliet, O., (2012) Health impact and damage cost assessment of pesticides in Europe. Environment International Vol 49, p 9-17. https://doi.org/10.1016/j.envint.2012.08.001.

113 1.3-D, amitrole, dazomet, diazinon, glufosinate, linuron, mancozeb, methomyl, parathion, propineb, simazine, terbuthylazine and trifluralin.

114 Dazomet, mancozeb and terbuthylazine.

possible to partially assess health impacts, more detailed statistics on PPP use are required to make a full assessment and to evaluate pesticide policy measures.

The study discussed above demonstrates that it is possible to link health impacts with individual active substances, even if results are uncertain as they rely on a series of assumptions. Regardless, the study's findings imply that the PPP Regulation has contributed to reducing adverse health effects in the EU. No other study was found that used more recent data and linked active substances used in the EU with health effects.

To further assess the effectiveness of the PPP Regulation as regards protecting human health, the following discussion in this section provides an overall picture of the hazard profile of active substances on the market in the EU.

To visualise the trend towards using less hazardous active substances, all active substances approved in the EU since 2011 have been mapped according to their hazard classification[115] and divided into three groups: low hazard, intermediate hazard and high hazard. Figure 4 compares the toxicological profiles of approved active substances for 2011, 2018 and a projection for 2022 (made by removing all active substances that are no longer supported at EU level[116]). The proportion of less hazardous substances used is increasing, and there is a small decrease in the proportion of more hazardous substances. Note that this comparison of the hazard profiles of active substances only considers the number of active substances and does not take into consideration the actual volume of PPPs used, nor their specific activity, as such data are not readily available and would be difficult to collect in the EU. As a second best option, data on pesticide sales could have informed the analysis. However, due to confidentiality restrictions, data on sales of individual active substances collected under Regulation 1185/2009 were not available[117].

By the end of 2022, the number of active substances will have decreased as the approval of 60 active substances that are no longer supported at EU level will have expired. Several of those are active substances with hazard classifications meeting the cut-off criteria or ones that are listed as candidates for substitution, which means that they will not adversely affect health much longer. Moreover, 40 % of all applications for the approval of new active substances are for micro-organisms or for presumed low-risk active substances. There was an increase in these in 2018 and a further increase is predicted in 2022.

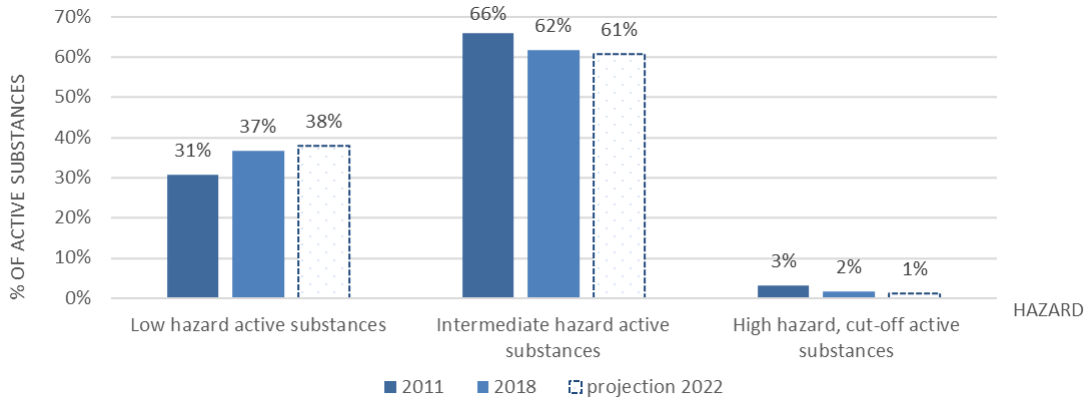


Figure 4. Distribution of toxicological profile of approved active substances in 2011, 2018 and 2022

115 See Annex 3 for a description on the methodology.

116 Where no application has been made 3 years before expiry of approval or where the applicant has communicated that they have withdrawn their support for the active substance in the EU.

117 The Commission has recently established harmonised risk indicators to estimate trends in the risk from pesticide use under Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides.

Furthermore, the proportion of high hazard active substances is very small (14 active substances) and it is expected that this will be reduced further by at least two thirds (five active substances) in 2022.

Although a full assessment of the impacts of the PPP Regulation's approval criteria cannot be carried out at this time, there is a clear positive trend towards less hazardous substances. The decisions on the non-renewal of approvals taken in recent years show the stringency of the PPP Regulation and confirm that active substances posing a risk to human health can no longer be placed on the EU market.

Cut-off criteria

The cut-off criteria introduced under the PPP Regulation are mainly based on the intrinsic properties of active substances, i.e. the properties that are considered so severe that any exposure to the substance poses an unacceptable level of risk. The criteria were introduced to improve the protection of human health and the environment. Their introduction also intended to reduce the workload for the evaluating authorities because if an active substance meets any of the cut-off criteria, the risk assessment can be discontinued and the active substance not approved. Very limited derogation possibilities exist for substances for which the applicant demonstrates that exposure is negligible[118], or which are needed in order to control a serious danger to plant health and this cannot be contained by other available means. Application of these derogations has caused delays in the re-assessment of several active substances (see the discussion of the inefficiency of cut-off criteria in section 5.2.2).

The cut-off criteria are both criticised (by industry and non-EU countries) and welcomed (by NGOs). Member States are divided in their opinions of the usefulness of these criteria. The main critique is that a substance's intrinsic properties do not accurately signal potential risk because exposure is not taken into consideration. Active substances might therefore not be approved even though they could pass the risk assessment if exposure to them is low. The main argument in favour of the cut-off criteria is that high hazard substances should never be used and that exposure assessments are hampered by uncertainty; in line with the precautionary principle, it is therefore appropriate to ensure that the risks related to exposure to these substances are completely avoided.

The main effect of the cut-off criteria observed so far is the low application rate for the renewal of approval of active substances that are expected to meet them. In the AIR 3 programme, six of nine active substances expected to meet the cut-off criteria were no longer supported[119]. In the AIR 4 programme, 12 active substances that may meet the cut-off criteria were identified. Of these, seven are no longer supported and their approval will expire by the end of 2021[120].

So far, the approvals of three active substances have not been renewed because of the cut-off criteria[121]. However, there were several other problematic issues with these active substances and they also failed the overall risk assessment[122].

118 One example of negligible exposure could be where the PPP is applied inside a trap and so there is no exposure outside of the trap.

119 These substances have a harmonised, proposed or notified classification in the Classification and Labelling inventory as toxic for reproduction 1B, mutagenic 1B, or a combination of toxic for reproduction and carcinogenic 2. The active substances that are no longer supported are carbendazim, glufosinate molinate, oxardiargyl, quinoclamine, tepraloxydim and warfarin.

120 The active substances that are no longer supported are difenacoum, triflumizol, spirodiclofen, bromadiolone, carbetamide, myclobutanil and profoxydim.

121 Linuron, iprodione and propiconazole.

122 The operator exposure was too high, there was a high risk to birds and wild mammals, the consumer risk assessment was not finalised and the risk assessment for groundwater could not be finalised.

In conclusion, the cut-off criteria have been effective in contributing to the protection of human health as they discourage applicants from re-applying for approval. However, it appears that for the cases in which the criteria were applied during decision-making, the outcome of the risk assessment would also have led to non-approval of the active substance. In addition, delays in assessing some active substances due to the application of derogations have possibly failed to protect human health as the substances remained on the EU market under the previous approval conditions for a longer time.

Authorisation of PPPs

Member States must authorise PPPs according to uniform principles, taking into consideration all product ingredients, i.e. active substance(s) and all co-formulants listed by the applicant. The risk assessment conducted for approved active substances feeds into the PPP assessments as Member States take into consideration all relevant information (endpoints). Member States must ensure that every use of an authorised PPP does not pose any unacceptable risk to human or animal health or to the environment. If an authorisation does no longer fulfil the criteria, the Member States concerned must withdraw or amend the authorisations. In 2017, Member States reported 378 authorisation amendments or withdrawals[123]. Withdrawals or amendments show Member States' continuous work to ensure that PPPs placed on the market are safe to use. However, the available evidence does not make it possible to measure the extent to which the authorisation procedure contributes to protecting human health. This is because of the difficulty in distinguishing between the impact of approving active substances and the impact of authorising PPPs.

NGOs and the European Parliament[124] have expressed concerns about the two-step approval and authorisation system and consider that the process is not rigorous enough to protect human health. They claim that the data requirements for PPPs are not sufficient and that the performance of Member States leaves room for improvement. This is despite the fact that: (i) the PPP Regulation requires the application dossiers for authorisations to be much more 'data rich' than registration dossiers under REACH; and (ii) Member States are required to assess the safety of the PPP with all its ingredients during the authorisation.

NGOs and the European Parliament[125] have further criticised the Commission for the delay in compiling a list of unacceptable co-formulants[126]. Many co-formulants are considered of no or low concern (e.g. water and dyes), but some of them have the potential to cause harm to human health or the environment. This was the case for the co-formulant POE-tallowamine, which was used in some PPPs containing glyphosate and according to EFSA had a significant toxicity level. To ensure a high level of protection of human health, the Commission proposed in 2016 to ban the use of this co-formulant in PPPs containing glyphosate[127]. This has led to Member States withdrawing hundreds of authorisations for PPPs containing glyphosate and POE-tallowamine, which is expected to have contributed to the protection of human health. For co-formulants in general, Member States agree that a harmonised list of unacceptable co-formulants at EU level

123 As reported under Article 44(4) in the Standing Committee of Plants, Animals, Food and Feed.

124 European Parliament (December 2018) Report on the Union's authorisation procedure for pesticides (2018/2153(INI)) Special Committee on the Union's authorisation procedure for pesticides.

125 European Parliament (September 2018) Report on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009.

126 This is required under Article 27 of Regulation 1107/2009, albeit without a precise deadline.

127 Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate. (OJ L 208, 2.8.2016, p. 1).

would be beneficial and could improve protection[128]. However, as co-formulants are already part of the scientific assessment of PPPs prior to authorisation, the additional protection of an EU list is likely to be relatively low. Nevertheless, the Commission has given priority to compiling such a list[129]: a first draft was discussed with Member States in the Standing Committee for Plants, Animals, Food and Feed in December 2018 and a draft Regulation was published for commenting under the Better Regulation Feedback Mechanism from 16 January until 13 February 2020. Adoption is foreseen in the course of 2020.

The review of safeners, synergists and adjuvants is delayed due to a lack of resources (see also section 5.2.2). However, it is expected that the added value from the EU-level assessment of safeners and synergists is lower than that arising from the identification of unacceptable co-formulants[130]. This is due to the relatively low number of safeners and synergists and their perceived low health risk. As regards adjuvants, a majority of Member States agree that a harmonised approach is required as adjuvants are effectively co-formulants[131].

After PPPs are authorised, users are obliged to use them correctly and according to their labels, in accordance with good agricultural practices[132] and the Sustainable Use Directive. A guidance document covering both human health and environmental monitoring is available for Member States enforcement activities[133]. In addition, human biomonitoring programmes have recently been agreed in the context of the HBM4EU project[134]. The project aims to support policy making by providing better evidence of citizens' actual exposure to chemicals and the possible health effects of such exposure. Several active substances used in PPPs have been included in the priority lists for monitoring. To further improve the protection of human health and the environment, there are calls to introduce similar chemical and biological monitoring in the post-authorisation phase in order to compare modelling results and estimations with empirical findings under realistic practical conditions[135,136,137]. There are also calls to give greater consideration to the effects of combined exposure to multiple substances (including other chemicals).

Emergency authorisations of PPPs

The PPP Regulation allows Member States to grant emergency authorisations for PPPs that are not authorised for use on a specific crop. These emergency authorisations are limited to 120 days and should only be used to combat a danger to plants that cannot be controlled by other reasonable means. Member States are required to inform immediately the Commission and other Member States about all emergency authorisations.

128 The support study p. 216.

129 Information has been collected and lists from five Member States have been used in the preparatory work to compile a first list of unacceptable co-formulants. The draft list has been shared with Member States and EFSA and was discussed in the Standing Committee for Plants, Animals, Food and Feed in December 2018.

130 The support study, p. 215.

131 The support study, p. 215.

132 Good agricultural practices are specific methods which, when applied to agriculture, create food for consumers or lead to further processing that is safe and wholesome.

133 https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_sup_monitoring-guidance_en.pdf.

134 Human biomonitoring for EU HBM4EU is a joint effort by 28 countries, the European Environment Agency and the European Commission, co-funded under Horizon 2020.

135 Milner, A. M. & Boyd, I. L. (2017) Toward pesticidovigilance. Science 357, 1232–1234

136 European Commission (June 2018) EU Authorisation processes of plant protection products — from a scientific point of view. Group of Scientific Advisors. ISBN 978-92-79-67735-9.

137 Schäffer A, Filser J, Frische T, Gessner M, Köck W, Kratz W, Liess M, Nuppenau, E-A, Roß-Nickoll M, Schäfer R, Scheringer M. The Silent Spring - On the need for sustainable plant protection. Leopoldina Discussions No. 16; 61.

The number of emergency authorisations in the EU has increased since the PPP Regulation entered into force and is considerably higher than during the 2007-2009 period (see Figure 5). This may indicate that not enough PPPs are available or that there are new emerging pests, problems with resistance, etc. There is growing criticism of Member States from the Commission, European Parliament and NGOs for misusing this possibility as a derogation from regular authorisations, in particular as it is being used for PPPs containing active substances that might not be approved, might be restricted or which might have never been approved in the EU. The main concern is that the use of emergency authorisations decreases the level of protection of human health and the environment.

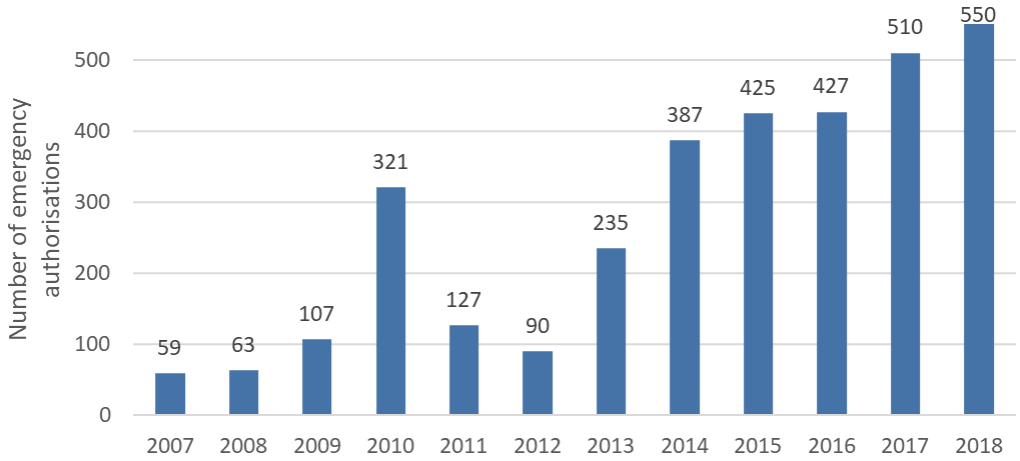


Figure 5. Emergency authorisations in the EU between 2007 and 2018. Source: European Commission

The rise in emergency authorisations has been attributed by some stakeholders to the decreasing availability of effective active substances and the lack of PPPs for specific uses[138]. However, given that 91 %[139] of emergency authorisations concern PPPs containing approved active substances, these are often misused to overcome procedural delays in the regular national authorisation process and to ensure increased availability of PPPs in Member States[140]. The main issues that contributed to the increase have been identified as follows[141]:

- emerging new pests for which the submission and evaluation of applications for regular authorisations takes some time;
- the loss of a number of pesticides with widespread use which have to be replaced by several PPPs containing different active substances;
- lack of applications for authorisations of PPPs for minor uses or small markets, such as the northern zone;
- procedural delays in granting zonal or national authorisations or in the mutual recognition of authorisations.

The need to use emergency authorisations as an answer to insufficient availability of PPPs is strongly criticised by NGOs, who claim that non-chemical methods are not

138 The support study, p. 74.
139 European Parliament Research Service (April 2018) European Implementation Assessment. Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market. ISBN: 978-92-846-2734-9.
140 European Commission (2017). Overview report on a series of audits carried out in EU Member States in 2016 and 2017 in order to evaluate the systems in place for the authorisation of plant protection products. DG(SANTE) 2017-6250.
141 PPP authorisation focus group.

sufficiently taken into consideration[142]. NGOs have also criticised the fact that emergency authorisations are granted for restricted or non-approved active substances. In fact, seven Member States have repeatedly granted emergency authorisations for use of neonicotinoids the approvals of which were restricted in 2013[143]. Such repeated emergency measures seem difficult to reconcile with the strict conditions envisaged under the PPP Regulation. In response, the Commission mandated EFSA to examine the emergency authorisations for neonicotinoids granted repeatedly by Member States for 2017 in light of these Member States' specific situations concerning pests and available alternatives. Based on this examination, EFSA concluded that around 25 % of the evaluated authorisations were not scientifically justified[144].

The frequent use of emergency authorisations is thus a signal of a dysfunctional PPP authorisation procedure. There are, however, examples of best practices. Some Member States are working with, for instance, farmers' organisations, to identify upcoming issues for specific crops. This aims to speed up the evaluation of suitable products and to grant regular authorisation before there is a need for emergency authorisation.

Although the vast majority (91 %) of emergency authorisations are for approved active substances and should not negatively impact human health or the environment, the use of emergency authorisations for PPPs containing non-approved active substances potentially diminishes the positive benefits for human health and the environment.

Comparative assessment of PPPs containing candidates for substitution

Candidates for substitution (CfS) are active substances approved in the EU that meet any of the seven criteria listed in point 4 of Annex II to the PPP Regulation. The criteria are based on the active substances' intrinsic hazard properties, for some in combination with its use pattern. If approved as a CfS, the approval period of the active substance is limited to 7 years (instead of 10 or 15 years). In December 2018, there were ten active substances approved as CfS.

A study carried out in 2013[145] screened the 422 active substances then approved in the EU against the seven criteria. Based on this study, a list of 77 approved active substances identified as CfS was published in January 2015. As of October 2018, the approvals of six of these have been renewed under the PPP Regulation. For 14 CfS[146], the approvals were not renewed, leaving 63 CfS on the list. Another seven active substances[147] on the list are no longer supported by any company and their approval will expire by the end of 2021 at the latest.

The PPP Regulation introduced the concept of CfS to reduce the use of active substances with problematic toxicological profiles. Member States have to carry out comparative assessments before authorising the use of PPPs containing active substances listed or approved as CfS, i.e. the PPP should only be authorised if there is no alternative with a significantly lower risk to human or animal health or the environment. This makes it possible to phase out CfS from the EU market because Member States should substitute them at the authorisation stage.

142 The support study, p. 47.
143 Bulgaria, Estonia, Finland, Hungary, Latvia, Lithuania and Romania.
144 Neonicotinoids: EFSA evaluates emergency uses.
145 European Commission (2013) Ad-hoc study to support the initial establishment of the list of candidates for substitution as required in Article 80(7) of Regulation (EC) No 1107/2009.
146 Amitrole, carbendazim, diquat, fenbutatin oxide, fipronil, glufosinate, imazosulfuron, isoproturon, linuron, mecoprop, molinate, oxadiargyl, tepraloxydim and triasulfuron.
147 Bifenthrin, bromadiolone, difenacoum, lufenuron, methomyl, myclobutanil and profoxydim.

As of January 2018, only 24 Member States and European Economic Area countries reported that they perform comparative assessments. Member States conducted 278 comparative assessments of PPPs containing one or several CfS in 2015 and 2016, but no substitution was made[148]. The main reason for this was a lack of viable alternatives. The general perception of both stakeholders and Member States is that substituting CfS will remain rare in the future. Thus, contrary to what was expected, the introduction of CfS and comparative assessments has not led to any further improvements in the level of protection of human health beyond what is already achieved by the standard approval and authorisation process for active substances and PPP, respectively.

The relationship between the publication of the list and the actual use of CfS could not be further examined as data collected under Regulation (EC) No 1185/2009 on statistics of pesticide use are confidential and were not made available due to restrictions set out in the Regulation.

Setting MRLs to protect consumers

As the MRL Regulation has a strong focus on consumer protection, MRLs set for plant and animal products must be safe for consumers. To ensure that pesticide residues on food do not constitute a health risk to consumers, both acute and chronic risks are assessed by considering a wide range of diets across the EU[149], including those of vulnerable groups such as infants and pregnant women. MRLs must also take into account possible carry-over into animal products from commodities used equally as food and feed. The specific impact of MRLs on animal health is not considered when setting MRLs and specific data on this are not required as animal health considerations are generally part of the approval procedure for active substances.

According to the ALARA[150] principle, MRLs are set at the lowest achievable levels when using good agricultural practices (GAP). Comprehensive field trials are therefore required to determine the amount and application frequency needed for an active substance to achieve the intended plant protection effect. MRLs are only set when it is guaranteed that the concentration of pesticide residues does not have any harmful effects on human health. In particular, a safety factor of at least 100 is applied when deriving toxicological reference values for chronic and acute exposure below which consumers are protected (i.e. the acceptable daily intake (ADI) and the acute reference dose (ARfD)).

The setting of a default value or a specific limit of quantification (LOQ) for pesticide residue-commodity combinations for which there are no authorised uses enables Member States to take enforcement action. Default values generally apply, including for pesticides not listed in the MRL Regulation, e.g. pesticides authorised in non-EU countries which were never assessed in the EU. Table 5 below shows examples of substances for which LOQs were set at lower levels than the default value as for substances with a low ADI, the presence of residues below the default value might still have an impact on consumer safety. In such cases, Member States have to improve the analytical techniques used by their enforcement laboratories to detect the presence of residues at very low levels to further protect consumers.

148 The support study, p. 23.
149 Pesticide Residue Intake Model (PRIMo).
150 'As low as reasonably achievable'.

Table 5. Substances for which lower limit of quantification values than the default apply[151]

Substances	Products	Limit of quantification (LOQ) (mg/kg)	Acceptable daily intake (ADI) (mg/kg bw/day)
Carbofuran	Several fruits and vegetables	0.001-0.005	0.00015
Chlordane	Milk and eggs	0.002-0.005	0.0005
Endrin	Milk and eggs	0.0008-0.005	0.0002
Fipronil	All products	0.005*	0.0002

All parties that show, through adequate evidence, a legitimate interest in health, including civil society organisations, are entitled to submit an application to set or review an existing MRL to protect consumers. In 2018, the Commission asked EFSA to deliver a scientific opinion on the safety of the existing MRLs for acetamiprid[152] and iprodione[153] after lower toxicological reference values were set as part of the renewal process for the active substances. Consequently, the MRLs were lowered for several commodities.

Based on the MRL Regulation, the EU multi-annual coordinated programme for pesticide residues in food is annually re-evaluated to identify the pesticide residue-commodity combinations to be analysed in order to assess human exposure to pesticides and the compliance of food throughout the EEA area. In addition, the MRL Regulation requires Member States to run national control programmes based on their own assessment of risk, thus leading to risk-based sampling schemes. This dual system of monitoring, based on both random and risk-based sampling, is effective in reinforcing the pesticide-residue monitoring framework in the EU.

Based on the data provided by the Member States, EFSA prepares an annual report that assesses consumer exposure to pesticides across the EU. The findings of EFSA's annual reports are reassuring as the level of consumer protection in the EU is high. Overall, the results of 96.2% of the 84 657 samples analysed in 2016[154] as part of the EU-coordinated and national control programmes fell within the legal limits. In total, 50.7% of the tested samples were free of quantifiable residues, while a further 45.5% of the samples analysed contained quantified residues not exceeding the MRLs.

Monitoring results show consistency over the years, since the programme is based on a random sampling plan that takes into account the pesticides and food commodities that are most relevant in terms of the risk that their exposure potentially poses to the public (see Figure 6).

151 EU Pesticides Database.
152 Focused assessment of certain existing MRLs of concern for acetamiprid and modification of the existing MRLs for table olives, olives for oil production, barley and oats, EFSA Journal 2018;16(5):5262.
153 Follow-up assessment of MRLs for the active substance iprodione, EFSA Journal 2018; doi: 10.2903/sp.efsa.2018.EN-1404.
154 The 2016 EU report on pesticide residues in food, EFSA Journal 2018;16(7):5348.

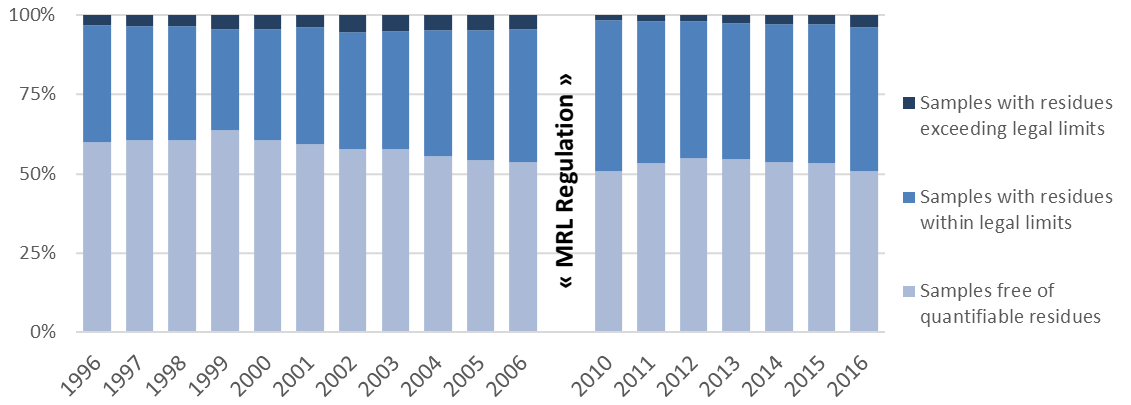


Figure 6. Pesticide residues in the EU, based on monitoring carried out by Member States in the time period 1996-2016[155][156],

The rapid alert system for food and feed (RASFF)[157] makes it possible for control authorities to exchange information on measures taken to respond to serious risks identified in relation to food or feed that are placed on the market in the European Economic Area. In 2017[158], a total number of 3 832 notifications were reported in the system. 186 notifications were submitted for pesticide residues mostly found in fruits and vegetables. 132 notifications concerned products that were rejected at the European Economic Area border and therefore never entered the EU. Note that notifications are made for pesticide residues only when there is a possible health risk.

As mentioned earlier, not all the temporary MRLs were reviewed within the 12-month deadline after the MRL Regulation came into force. To date, EFSA has only reviewed about half of the temporary MRLs. To minimise the impact that this delay may have had on consumer safety, the Commission and Member States have worked together to identify the substances that may have posed a risk to consumers; all temporary MRLs have been reviewed for these.

The Commission has not yet made use of the possibilities given by the MRL Regulation to establish more specific MRLs for feed, processed food and fish as well as a list of specific harmonised processing factors. According to the support study, some Member States indicated that the lack of harmonisation for these products may negatively impact the protection of human health. Conversely, stakeholders considered that the lack of harmonisation has no impact. However, it can be concluded that the lack of specific MRLs for fish, feed and processed products has not had a negative impact, for the following reasons:

- Despite the absence of MRLs specific for feed, feed is already covered in all risk assessments. In practice this means that the risk assessors use a dietary intake calculator to predict the expected residues in animal products resulting from feeding studies.
- For processed food, general provisions are already available in the MRL Regulation allowing Member States' enforcement authorities to consider changes in concentration of residues during processing. While a harmonised and legally binding list of processing factors has not been established, national and EU-level databases

155 1996 to 2006 Annual EU-wide pesticide residue monitoring reports.
156 2010 to 2016, all reports are available on the EFSA webpage.
157 https://ec.europa.eu/food/safety/rasff_en.
158 The Rapid Alert System for Food and Feed, Annual Report (2017).

are available and can be used by Member States' enforcement authorities to inform their decisions. EFSA, by default, makes a very conservative risk assessment using assumptions that rather over-estimate the risk, e.g. by using the processing factor that would lead to the highest possible exposure to ensure maximum consumer protection. Member States requested some more guidance on how processing factors provided by food business operators could be considered when taking enforcement action. Clear provisions exist for example in similar food legislation (Regulation (EC) No 1881/2006 on contaminants) which could serve as reference.

- For fish, a working document with data requirements is still under development. National monitoring results show only very few instances of findings of pesticides residues in fish.

Studies have been carried out to assess how the consumption of organic food, which contain different pesticide residues as only a limited range of approved active substances may be used in organic production, affects human health compared to conventional food. A comprehensive review of such studies was published in 2017[159]. Overall, the evidence is not conclusive as consumers of organic food tend to also lead healthier lifestyles. Moreover, the assessments carried out by EFSA in its annual reports take into account a wide range of consumption data based on different diets.

In view of the above, it can be concluded that the MRL Regulation is to a large extent effective in protecting consumers and that the lack of MRLs for fish, feed and processed products has not negatively impacted consumer protection. The risk assessment conducted to set MRLs is based on strict requirements and is carried out both by the Member States and EFSA. National and EU monitoring programmes show that the rate of MRL non-compliance is overall very low. Moreover, control authorities have a system that detects food which might pose a risk to consumers and that makes it possible to take appropriate enforcement action. However, there are delays in reviewing the existing MRLs, which could make it difficult to take timely action to protect consumers from certain substances.

Cumulative risk assessment of pesticide residues

The assessment of the level of risk for consumer health is currently based on a substance-by-substance assessment of acute and chronic exposure to pesticide residues. Both the PPP and MRL Regulations include provisions for the assessment of the cumulative and synergistic effects (also known as 'the cocktail effect') of multiple pesticide residues during the approval of an active substance and during MRL setting respectively, when a suitable method for doing so is available. Although EFSA and the Commission have been working on an appropriate methodology to conduct cumulative risk assessment for human health, as described below, to date the development and application of a methodology is still ongoing. This task turned out to be much more complex and to require much more resources than expected.

In 2012, EFSA published a guidance document on the use of probabilistic methodology for modelling dietary exposure to pesticide residues[160]. In 2013, it published a scientific opinion[161] that: (i) identified pesticides to be included in cumulative assessment groups

159 Mie, A., Raun Andersen, H., Gunnarsson, S., Kahl, J., Kesse-Guyot, E., Rembiałkowska, E., Quaglio, G., Grandjean, P. (2017) Human health implications of organic food and organic agriculture: a comprehensive review. Environmental Health, 16:111.

160 Guidance on the use of probabilistic methodology for modelling dietary exposure to pesticide residues', EFSA journal 2012; 10(10):2839.

161 Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile, EFSA Journal 2013;11(7):3293 [131 pp.].

based on their toxicological profile; (ii) developed criteria for grouping chemicals with a similar mode of action; and (iii) made further recommendations for developing such a methodology.

The probabilistic approach was a breakthrough change from the deterministic calculations currently used to assess exposure. It can now be used thanks to a specific IT tool developed under the ACROPOLIS[162] research project. EFSA, Member States and the Commission are continuing work on the specific details of the model as regards exposure assessment using monitoring data from the annual EFSA reports mentioned above (retrospective scenario). Work on this retrospective scenario is well advanced and the outcome is expected to be gradually applied for those groups of chemicals with effects on the same target organ (cumulative assessment groups) already established during the annual evaluation of the monitoring data for pesticide residues. For the MRL-setting (prospective) scenarios, work will begin in 2020, building on the experience and the outcomes gained from the retrospective scenario. However, detailed discussions on the parameters to be used for regulatory purposes (approval of substances and MRL setting) have not yet started.

EFSA has published draft reports[163] for two cumulative assessment groups for the thyroid and the nervous system for public consultation in September 2019 followed by a Technical stakeholder event in October 2019.[164] The final reports including risk characterisation are expected to be published in spring 2020. Further scientific reports of the cumulative assessment groups for more organs will be published in the future.

In June 2018, EFSA's Scientific Committee launched an open consultation on a draft guidance document on harmonised methodologies for risk assessment of combined exposure to multiple chemicals for all relevant areas within EFSA's remit, i.e. human health, animal health and ecological areas. In February 2019, the guidance was adopted and is now available in the EFSA Journal[165].

The presence of multiple pesticide residues occurred in 30% of the total food samples analysed by EFSA in 2016[166]. However, EFSA's latest reports on the effects of dietary exposure to pesticide residues on the nervous system and the thyroid, showed that effects of multiple residues on human exposure were mainly driven by high exposures to specific single substances and that the outcome of single residues and multiple residues assessments were very similar. This was supported by reports of Member States that carried out preliminary cumulative risk assessments[167]. Given that so far cumulative assessment groups have been finalised only for two organs (thyroid and nervous system) and that future cumulative assessment groups will focus on effects on other organs, it is currently not possible to draw clear conclusions on the impact of the absence of cumulative risk assessment on human health.

5.1.2. Protecting the environment, including wildlife and water

The use of pesticides has, to some extent, unavoidable impacts on biodiversity, which need to be balanced against the crop protection needs. The PPP Regulation aims to

162 ACROPOLIS — Aggregate and cumulative risk of pesticides: an online integrated strategy.
163 https://www.efsa.europa.eu/en/consultations/call/public-consultation-draft-efsa-scientific-reports.
164 https://www.efsa.europa.eu/en/events/event/technical-stakeholder-event-cumulative-risk-assessment-pesticides-food/.
165 EFSA Scientific Committee (2019) Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals. EFSA Journal 2019;17(3):5634.
166 The 2016 European Union Report on Pesticide Residues in Food. EFSA Journal 2018; 16(7):5348, doi: 10.2903/j.efsa.2018.5348
167 Summary record of the meeting of the Standing Committee on Animals, Food and Feed (PAFF) of 21 November 2017: https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20171121_ppr_sum.pdf.

protect the environment with its strict approval criteria and the introduction of cut-off criteria for active substances. Guidance documents complement these actions by specifying how environmental concerns should be evaluated by Member States during the risk assessment process. Since the PPP Regulation became applicable, 21 active substances[168] have not been approved or approval has not been renewed due to environmental concern. The reasons include risks to groundwater, surface water, soil, aquatic organisms, soil-dwelling organisms, wild mammals, non-target terrestrial plants, and honeybees. This shows that the approval criteria were effectively applied to better address environmental risks.

The Commission has also restricted certain uses of active substances to protect the environment. Since June 2011, 10 active substances have been approved with uses restricted to greenhouses[169], application rate restrictions[170] to protect groundwater, and application frequency restrictions[171] such as '*one application every three years on the same field*'. Member States take further protective measures for the environment when authorising PPPs. To facilitate this, the Commission specifies where Member States should be vigilant and what they should pay particular attention to in the approval process for active substances. This may include potential risks to groundwater, aquatic organisms, non-target terrestrial and aquatic plants, earthworms, birds and mammals, etc. Member States also take regional climatic and environmental differences into consideration when authorising PPPs. Even though it is not possible to link non-approvals or restrictions with specific positive environmental outcomes, it can be assumed that the above-mentioned actions have a positive impact on protecting the environment in the EU. Based on the available evidence, it is, however, not possible to conclude whether this will be sufficient in relation to the significant challenges posed by loss of biodiversity and other environmental impacts.

Stakeholders and Member States alike consider that the PPP Regulation positively contributes to protecting animal health and the environment[172]. However, no studies were identified that show a causal link between the non-approval of active substances and environmental effects[173]. It can also be expected that full implementation of the Sustainable Use Directive would support the objectives of protecting health and the environment by reducing the risks linked to PPPs, through the adoption of non-chemical control methods and a reduction in dependency on PPPs. Sustainability is covered in-depth in section 5.4.1.

Biodiversity and wildlife

The PPP Regulation aims to protect biodiversity and ecosystems by taking into account the impact on populations of organisms, as well as water, soil and air quality during the risk assessment. It does this by assessing the expected environmental exposure, covering a wide range of environmental scenarios which include the application of the PPP for several consecutive years. Based on this exposure assessment and experimental data on expected effects on a variety of different species, the potential risks are calculated. These species serve as indicators for the whole ecosystem and the approach therefore should

168 2-naphthyloxyacetic acid, amitrole, chloropicrin, etoxazole, fenamidone, flufenoxuron, flupyrsulfuron-methyl, iprodione, linuron, orthosulfamuron, oxasulfuron, picoxystrobin, propanil, propargite, propiconazole, Pseudozyma flocculosa ATTC 64874, thiram, tricyclazole, beta-cypermethrin, isoproturon, pymetrozine and quinoxyfen.

169 For the active substances 8-hydroxyquinoline, bifenthrin, pyridalyl and sodium silver thiosulfate.

170 For the active substances acrinathrin, metam, oxyfluorfen, prochloraz and prosulfuron.

171 For the active substances metam, oxyfluorfen, penflufen and prosulfuron.

172 As shown in Figure A.13 of Annex 2: Synopsis report on the stakeholder consultation

173 The support study, p. 60.

ensure the protection of biodiversity in general. Nonetheless, there are still concerns that biodiversity in a wider sense is not fully protected from the use of PPPs, and that pesticides are a threat to terrestrial ecosystems[174,175]. There are also concerns regarding declining trends in insect populations[176] and pesticides use has been mentioned as one of several important factors contributing to this decline[177, 178]. However, it is difficult to distinguish between the effects of PPPs on biodiversity, and the effects of the current agricultural production system and increased surfaces of monocultures, and other factors affecting the landscape. Further research is necessary, and testing, modelling and assessment methods to take into consideration cumulative risks[179,180,181], need to be further developed to better understand the actual impact of pesticides on populations, diversity within and between species, relationships between species and ecosystem services. More specific protection goals can also contribute to effective protection of the environment[182]. EFSA and the Commission are working together to improve environmental protection in the EU of which the first step is to set out the specific protection goals for environmental risk assessment[183,184]. The positive effects of this work are expected to materialise in the future.

Protecting bees and other pollinators

Pollinators provide important ecosystem services, pollinating more than 80 % of crops and wild plants in the EU[185]. Pollinators, including honey bees, bumblebees and wild bees, contribute around EUR 15 billion to EU agriculture each year[186]. To recognise the value of pollinators and protect them, the approval criteria for active substances include specific considerations of honey bees.

A decline in bee populations has been observed in the EU and globally. The decline of bees is multifactorial, with land-use change, intensive agricultural management and pesticide use, environmental pollution, invasive alien species, pathogens and climate change identified as the main threats[187]. Due to the multifactorial reasons behind the decreasing number of bees, and lack of data, it is not possible to directly link decisions taken to protect bees under the PPP Regulation with an increase in bee populations.

174 European Commission (2015) The State of Nature in the EU. Reporting under the EU Habitats and Birds Directives 2007-2012.

175 Sánchez-Bayo, F., Henk A Tennekes, H. A. (2017) Assessment of ecological risks of agrochemicals requires a new framework. ISSN: 2529-8046.

176 Hallmann CA, Sorg M, Jongejans E, Siepel H, Hofland N, Schwan H, et al. (2017) More than 75 percent decline over 27 years in total flying insect biomass in protected areas. PLoSONE 12 (10): e0185809.

177 Ewald JA, Wheatley CJ, Aebischer NJ, Moreby SJ, Duffield SJ, Crick HQ, et al. Influences of extreme weather, climate and pesticide use on invertebrates in cereal fields over 42 years. Global Change Biology. 2015; 21(11):3931–3950. https://doi.org/10.1111/gcb.13026 PMID: 26149473

178 Cardosoa, P. et al. (2020) Scientists' warning to humanity on insect extinctions, Biological Conservation, Volume 242, February 2020, doi.org/10.1016/j.biocon.2020.108426

179 Gustavsson, M., Kreuger, J., Bundschuh, M., Backhaus, T. (2017) Pesticide mixtures in the Swedish streams: Environmental risks, contributions of individual compounds and consequences of single-substance oriented risk mitigation. Science of The Total Environment. Volume 598.

180 Scientific methodologies for the assessment of combined effects of chemicals – a survey and literature review, European Commission, Joint Research Centre, EUR 27471 EN, 2015

181 Bopp et al. (2018) Current EU research activities on combined exposure to multiple chemicals, Environment International, Volume 120

182 European Commission (June 2018) EU Authorisation processes of plant protection products — from a scientific point of view. Group of Scientific Advisors. ISBN 978-92-79-67735-9.

183 EFSA Panel on Plant Protection Products and their Residues (PPR); Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). EFSA Journal 2010;8(10):1821.

184 Nienstedt, K., Brock, T.C.M., van Wensem, J., Montsfort, M., Hart, A. (2012) Development of a framework based on an ecosystem services approach for deriving specific protection goals for environmental risk assessment of pesticides. Science of The Total Environment, Volume 415

185 Europa webpage on honey bees

186 European Commission (2018c). EU Pollinators Initiative. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. COM(2018) 395.

187 See EFSA's bee health webpage

Since 2010, stakeholders such as beekeepers' associations and the European Parliament have criticised the appropriateness of the guidance document that sets out the principles of the risk assessment for bees[188,189]. EFSA concluded in 2012 that the guidance document was not sufficient to protect bees and should be expanded to include exposure routes other than spray applications, a chronic risk assessment and an assessment of the risk to wild species (bumblebees and solitary bees)[190]. In 2013, EFSA developed a new guidance document, but this has not yet received the Member State support necessary for it to be used in the renewal process for active substances. Opponents argue that many substances that do not pose an unacceptable risk to bees would (unnecessarily) fail the risk assessment as the proposed principles and trigger values are too conservative and the proposed options to refine the risk assessment are too difficult to carry out. The Commission is committed to continuing its efforts to get the improved guidance document endorsed in order to reinforce the protection of pollinators in the EU.

In 2013, in response to the availability of new scientific information on toxicity to bees, the Commission reviewed the approval[191] of four active substances[192]. The review resulted in restrictions on the use of the four active substances in 2013[193,194] and further restrictions for three of them in 2018[195]. The approval of the fourth substance, fipronil, expired on 30 September 2017. The applicants concerned challenged the first restrictions in court, but the General Court ruled in favour of the Commission in May 2018. In the light of the last restrictions, the applicants for two of the three active substances[196] have discontinued their support for renewal. As stated above, it is not possible to directly link the restrictions of these substances to potential increases in bee populations because bee decline is multifactorial. Moreover, the repeated granting of emergency authorisations by Member States for many of the restricted uses may reduce the effectiveness of the restrictions for environmental protection. However, as a precautionary approach, the restrictions are expected to improve the environmental situation for pollinators.

Protecting groundwater and surface water

Groundwater provides a major source of drinking water for many EU citizens as well as a steady base flow of rivers and wetlands. Pressures on the chemical quality of groundwater mainly arise from diffuse pollution, which is caused by nitrates in fertiliser or manure and by pesticides, and presents a significant and widespread challenge. The European Environment Agency's reports on the assessment of EU waters and a comparison of the status of groundwater between the report published in 2012[197] (with

188 In particular the EPPO 'Environmental risk assessment scheme for Plant Protection Products — chapter 10: honey bees' (EPPO/OEPP, 2010) revised in September 2010 with ICPBR recommendations.

189 Communication from the Commission to the European Parliament and the Council on Honeybee Health, COM(2010) 714 final

190 EFSA (2012) Panel on Plant Protection Products and their Residues (PPR); Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal 2012; 10(5) 2668.

191 Article 21 of Regulation 1107/2009 allows the Commission to review the approval of an active substance at any time in light of new scientific and technical knowledge and monitoring data.

192 Clothianidin, imdacloprid, thiametoxam and fipronil.

193 Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances.

194 Commission Implementing Regulation (EU) No 781/2013 of 14 August 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance.

195 The Commission Implementing Regulations amending the conditions of approval of the active substances imidacloprid, clothianidin and thiamethoxam were published in the Official Journal on 30 May 2018. These regulations completely ban the outdoor uses of the three substances, and only the use in permanent greenhouses remains.

196 Thiametoxam and clothianidin.

197 The European Environment Agency (2012) European waters — Assessment of status and pressures No 8/2012.

data from 2009) and the report published in 2018[198] (with data from 2015) show little change in the chemical status of groundwater as regards pesticides. In 2009, an estimated 5 % of all groundwater bodies had poor chemical status due to pesticides. In 2015, 6 % of groundwater bodies by area had poor status due to pesticides[199]. The European Environment Agency notes a decline in the occurrence of some pesticides (e.g. atrazine and diuron[200]) as a result of the non-approval of, or restrictions on, their use.

For surface waters, the European Environment Agency's report in 2018 does not specify the extent to which the poor quality of bodies of water is caused by pesticides[201]. However, analysis from a separate 2018 report[202] shows that most individual pesticides causing failure to reach good status do so in fewer than 200 water bodies across the EU[203]. One substance that is reported to be among the top 15 substances causing failure to achieve good chemical status is isoproturon, which caused failure of good status in 199 surface water bodies in eight Member States, i.e. 0.2 % of all surface water bodies in the EU. Future improvements are expected since the approval of isoproturon was not renewed in 2016 because of a high risk to groundwater[204,205]. Another substance reported among the top 15 chemicals is hexachlorocyclohexane, which caused the poor quality of 120 bodies of water in 11 Member States. This active substance has not been approved in the EU since 2004 but is persistent in the environment, which may explain why it is still found during monitoring. The European Environment Agency report concluded that the status of 571 bodies of water improved from 'failing' to 'good' as regards pesticides between the first and second monitoring cycle. If this rate of improvement continues, the number of bodies of water that fail to achieve good status because of the use of priority pesticides, i.e. those listed as priority substances under the Water Framework Directive because of the risk they pose to or via the aquatic environment, may be very small during the next monitoring cycle. AMPA (a breakdown product of glyphosate) is the most frequently occurring pesticide-related substance, causing 185 bodies of water to fail to achieve good status. As AMPA was not specified in earlier reports, it is impossible to assess whether the situation has improved or deteriorated.

Although the monitoring approach envisaged under the Drinking Water Directive does not make it possible to carry out a comprehensive EU assessment of pesticide contamination in drinking water[206], the reported compliance rates are consistently high (a total of more than 99.9 % in 2011-2013 and about 99.6 % for individual pesticides[207]).

Comparisons between the two reporting cycles of the Water Framework Directive, on which the European Environment Agency reports are based, need to be made with caution because of improvements in status-assessment methods and changed threshold values. The expected achievement of good status reported in the second river basin management plans for most of the groundwater bodies by 2027 or beyond 2027 demonstrates the long time lag between the implementation of measures and their

198 The European Environment Agency (2018) European waters — Assessment of status and pressures No 7/2018.
199 See Annex 3 describing the calculation based on figures from the European Environmental Agency reports.
200 The European Environment Agency (2018) European waters — Assessment of status and pressures No 7/2018.
201 In the European Environmental Agency report from 2012, 1 % of surface water bodies had poor chemical quality due to pesticides. However, there was a large number of surface water bodies whose status was unknown.
202 The European Environment Agency (2018) Chemicals in European Waters
203 Of 111 105 surface water bodies and 13 411 groundwater bodies.
204 Commission Implementing Regulation (EU) 2016/872 of 1 June 2016 concerning the non-renewal of approval of the active substance isoproturon (OJ L 145, 2.6.2016, p. 7).
205 Isoproturon is currently being reviewed also under the Biocidal Product Regulation.
206 A comprehensive EU assessment is not possible given that: (a) Member States choose which pesticides and metabolites to monitor in drinking water; (b) only pesticides that are likely to be present in a given water supply need to be monitored.
207 European Commission (2016) Synthesis Report on the Quality of Drinking Water in the Union examining Member States' reports for the 2011-2013 period, envisaged under Article 13(5) of Directive 98/83/EC. COM(2016) 666 final.

effectiveness. Furthermore, a key issue as regards the reporting of pesticides under the Water Framework Directive is that the monitoring is limited both in frequency and number of substances covered and may, therefore, miss pesticides currently approved but not assessed in the environment at EU level.

In conclusion, the PPP Regulation seems to be contributing to the achievement of the objective of protecting EU's bodies of water, but further progress still needs to be made.

5.1.3. Minimising animal testing

The PPP Regulation has a specific objective to minimise the use of animals in testing to approve active substances and authorise PPPs[208]. Data owners and prospective applicants must make every effort to share tests and studies involving animals. This obligation applies both to vertebrate and non-vertebrate animals. In the case of studies on vertebrate animals, if the parties fail to reach an agreement, the Member State concerned is entitled to refer to the studies for the benefit of the prospective applicant. At the same time, the data owner is entitled to lodge a claim in national courts regarding the costs.

It is not possible to compare data on the number of vertebrate animals used in toxicology experiments involving products or substances intended for agricultural use from the pre-2011 baseline period with more recent data. This is because new reporting obligations for 2015 onwards were adopted in 2010[209] and further aligned in 2019[210]. Data presented in Table 6 do not show a clear trend towards reducing the number of animals used. More recent data count only the number of animal uses for tests under the PPP Regulation, while earlier data included animals used for tests of substances 'intended for agricultural use', which is different. Official data for several years is needed to make a more robust analysis possible.

Table 6. Number of animals used in experiments involving products intended for agricultural use in 2008 and 2011. Number of animal uses in testing under the PPP Regulation 2014 to 2017[211]

Year	2008	2011	2014	2015	2016	2017
Number of animals used / Number of animal uses	74 147	81 979	97 879	72 084	61 502	75 205

Furthermore, the numbers in Table 6 only include animals used in experiments in the EU and do not take into consideration the fact that extensive testing of products to be registered in the EU can take place in the context of other regulatory systems like the United States. Such studies can then also be used for regulatory purposes in the EU.

Stakeholders and Member States alike consider that the data-sharing mechanism for studies on vertebrate animals[212] introduced in the PPP Regulation is effective as it increased the number of shared studies in application dossiers[213]. However, this provision is not the only influencing factor and is not sufficient to significantly reduce the number of animals used in testing. In fact, the new data requirements agreed in 2013 require increased testing on vertebrate animals to be carried out for certain toxicological effects, e.g. genotoxicity. Alternative methods are still not considered sufficiently developed to replace animal (*in vivo*) testing for all toxicological effects[214]. Another contributing

208 Which is in addition to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).
209 Directive 2010/63/EU on the protection of animals used for scientific purposes.
210 Regulation (EU) 2019/1010 on the alignment of reporting obligations in the field of legislation related to the environment.
211 For 2008 and 2011, see the support study, p. 15. For 2014, see the support study, p. 42, for the years 2015 to 2017, see official reports available at: https://ec.europa.eu/environment/chemicals/lab_animals/reports_en.htm.
212 Article 62 of Regulation 1107/2009 'Sharing of tests and studies involving vertebrate animals'.
213 The support study, p. 43.
214 Joint Research Centre (2014) Alternative methods for regulatory toxicology – a state-of-the-art review. ISBN 978-92-79-39651-9

factor working against the reduction of animal testing is the increasing amount of information required to conclude the risk assessment for an active substance, in particular for metabolites[215]. Further *in vivo* testing is sometimes suggested during the peer-review process in order to rule out genotoxic potential of metabolites, e.g. in the cases of metsulfuron-methyl[216] and terbuthylazine[217]. Increasing information will also be required to assess the effect of active substances on the endocrine system[218], which will be part of the forthcoming implementation of the new scientific criteria to identify endocrine disruptors. In addition, the requirement for periodical re-assessment of all active substances may mean that *in vivo* testing remains necessary.

There are no specific rules on sharing of studies involving vertebrate animals for cases in which the same studies are performed on the same active substance under different EU legislation (e.g. PPP Regulation and Biocidal Product Regulation). This situation gives leeway for interpretation and in particular for the possibility to accept (or not) studies on vertebrate animals undertaken outside the PPP Regulation. The PPP Regulation also leaves room for interpretation as regards studies on vertebrate animals that have been carried out in other jurisdictions. Member States have noted that increased clarity on how to implement the sharing of data from studies on vertebrate animals and more specific rules related to data protection could help reduce the number of tests on vertebrate animals.

In the light of increasing requirements related to ensuring a high level of protection of human health, the use of animals in tests is not expected to decrease in the future unless: (i) the weight of evidence of available information is better taken into consideration in the risk assessment and related guidance documents; (ii) the data requirements are modified to include more alternative validated testing methods and approaches; and (iii) more clarity is achieved as regards data protection. As regards the second point, more research is needed to make it possible to replace the remaining animal studies with alternative approaches[219]. New Horizon 2020 projects on methods for endocrine disruptors focus on using alternative methods and will ultimately help to gain acceptance of non-animal data in a weight of evidence approach[220]. Beyond the Cosmetics Products Regulation, which already bans animal testing in cosmetics, the Commission and the European Chemical Agency are making significant efforts to minimise animal testing within other regulatory frameworks such as REACH with annual funding of more than EUR 40 million[221]. In addition, the Commission promotes actively the reduction and replacement of animal testing through the European Partnership for Alternatives to

215 Worth, A., Fuart-Gatnik, M., Lapenna, S., and Serafimova, R. (2011) Applicability of QSAR analysis in the evaluation of developmental and neurotoxicity effects for the assessment of the toxicological relevance of metabolites and degradates of pesticide active substances for dietary risk assessment. EFSA Supporting Publications Vol 8, Issue 6.

216 As identified by the comment 'Overall, no firm conclusion can be drawn concerning the gene mutation induction potential of triazine amine and an appropriate *in vivo* study should be performed.' EFSA (European Food Safety Authority), 2017. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for metsulfuron-methyl in light of confirmatory data. EFSA supporting publication 2017:EN-1257. 44 pp. doi:10.2903/sp.efsa.2017.EN-1257.

217 As identified by the data gap 'More information on the repeat-dose toxicity for the groundwater metabolites […] is needed in order to conclude on the relevant reference values to be used for the consumer risk assessment.' EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment for the active substance terbuthylazine in light of confirmatory data submitted. EFSA Journal 2017;15(6):4868, 20 pp. https://doi.org/10.2903/j.efsa.2017.4868.

218 ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority) with the technical support of the Joint Research Centre (JRC) (2018) Andersson N, Arena M, Auteri D, Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J, Terron A and Van der Linden S, 2018. Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311, 135 pp.

219 Focus group on risk assessment

220 European Commission (2018) Funding and tender opportunities: New testing and screening methods to identify endocrine disrupting chemicals.

221 European Commission (2018) Commission General Report on the operation of REACH and review of certain elements Conclusions and Actions. SWD/2018/058.

Animal Testing (EPAA[222]). The EU Reference Laboratory for alternatives to animal testing is working to advance the replacement, reduction and refinement of animal procedures[223,224]. These will ultimately also help to reduce the need for animal testing for regulatory purposes under the PPP Regulation.

In conclusion, the PPP Regulation has led to an increasing number of shared studies being included in application dossiers. However, this has not proven sufficient to achieve the objective of minimising animal testing as tests on vertebrate animals are still required to guarantee the protection of human and animal health and the environment.

5.1.4. Improving the functioning of the single market

Setting MRLs

The MRL Regulation replaced four earlier Directives, thus creating a single legislative framework in the area of pesticide residues. It is directly applicable in all Member States and does not need to be transposed into national legislation. The same provisions and data requirements apply across the EU, as do common principles for conducting risk assessments. Consequently, national competent authorities can rely on a harmonised risk assessment and do not need to re-evaluate the safety of products originating from neighbouring countries. Furthermore, the MRL Regulation extended the list of harmonised food commodities to also cover minor and very minor crops. This reduced trade barriers between Member States and guarantees legal certainty for food-business operators who only have to comply with one set of MRLs.

Under the MRL Regulation, there are provisions that address specific circumstances such as environmental or other contamination, occurrences of pesticide residues in honey, herbal infusions and other products that constitute a minor component of the diet of consumers. In such cases, temporary MRLs may be set based on monitoring data from all Member States, as long as that there are no unacceptable risks to consumers. The maximum duration of such temporary MRLs is 10 years, after which the MRLs need to be reviewed.

Serious risks related to food safety can easily and quickly be addressed by the provisions of the MRL Regulation and the provisions of the General Food Law. However, there is no fast track procedure foreseen in the MRL Regulation to quickly address other issues that are not of consumer health concern, but that arise unexpectedly and require quick action to avoid disturbances of the internal market. Examples in recent years were unexpected residues occurring in food for which harmonised MRLs were either not yet available or set at unrealistically low levels. This was the case for residues in processed foods stemming from use of biocidal products such as DDAC and BAC, residues of chlormequat in mushrooms as cross-contamination from cereal straw, where chlormequat is used. Other examples include residues stemming from emergency authorisations granted by Member States to address plant health risks.

The Commission has used the possibility to set temporary MRLs on the basis of monitoring data in such circumstances. While this speeds up the process somewhat as residue trial data do not always need to be generated to the full extent, the evaluation

222 The EPAA is a private-public partnership between five Directorates-General of the European Commission and 8 industry federations.

223 EU Reference Laboratory for alternatives to animal testing webpage.

224 Zuang et al., (2018) EURL ECVAM Status Report on the Development, Validation and Regulatory Acceptance of Alternative Methods and Approaches, EUR 29455, Publications Office of the European Union, Luxembourg.

procedure as such is not shorter than usual and risk management measures in response to such situations remain slow.

Criticism was raised in particular by Member States on the length of the procedure following emergency authorisations, when a Member State may, in exceptional circumstances, authorise food not complying with MRLs to be placed on its domestic market, as long as such food does not constitute an unacceptable risk to consumers. This is, however, difficult to control and enforce, and disturbs the principles of the single market. The MRL Regulation envisages the possibility to submit an MRL application to address emergency use by setting a temporary MRL. Since there is no fast-track procedure, the Commission requests EFSA to prioritise assessment of these applications to speed up the process. However, this is not sufficient to provide a fast solution.

The MRL Regulation envisages the compiling of a list of active substances for which MRLs are not required to facilitate the free movement of commodities that were treated with substances with a low-risk profile or substances that naturally occur in the environment and are considered safe. Some general principles are set out in the legislation, but there are no clear criteria for selecting these substances which prompted the Commission to draft a guidance document to address this[225]. Overall, since the MRL Regulation came into force, such exemptions have been granted for 130 substances or micro-organisms. However, there are cases where micro-organisms can be human pathogens (e.g. *Bacillus thuringiensis*), meaning that specific MRLs might need to be set. The MRL Regulation covers all active substances by the default level of 0.01 mg/kg where no more specific MRLs are set. However, the default level is not suitable for non-chemicals such as micro-organisms that may require a different type of default level (see also section 5.4.2). The existing data requirements are not fully adapted to the specificities of non-pathogenic micro-organisms, leading EFSA to regularly identify data gaps when evaluating applications, which, in consequence, delays risk management decisions.

Some industry stakeholders claim that the lack of MRLs for feed, processed food and fish may have an impact on the single market, as food-business operators have difficulties in understanding the legal requirements, and believe that national competent authorities do not take a consistent approach. However, there is not sufficient evidence to confirm this[226]. The lack of specific MRLs for feed, fish and processed products is discussed in detail in section 5.1.1. It should be noted that MRLs are already set for feed commodities when they are also consumed by humans. For processed food, there are national and EU-level databases that list the various processing factors that can be used by Member States' enforcement authorities (see also section 5.1.1.)

The zonal system and mutual recognition of authorisations

The PPP Regulation divides Member States into three zones based on comparable agri-environmental conditions to facilitate the granting of authorisations for PPPs, increase access to PPPs for farmers and avoid duplication of work. This feature did not exist in Directive 91/414/EEC (see section 2.1.1).

Dividing the EU into three zones has led to an increase in authorisations granted through the mutual recognition procedure, from 409 in 2011 to 1 109 in 2016[227]. However, there

225 European Commission (2015), Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005 (SANCO/11188/2013 Rev. 2).

226 The support study, p.119.

227 The support study, p. 46.

are large differences, with some Member States mutually recognising more than 100 PPPs per year (Malta and Poland) while some hardly use mutual recognition at all (Germany and Denmark). Each zone has set up a zonal steering committee to distribute work and facilitate cooperation. Depending on how well the steering committee works, those in charge of zonal authorisation have reported that it is working more or less smoothly. The northern zone is reported to work well, the southern zone moderately well, while the central zone is reporting difficulties[228]. However, the number of mutual recognitions per zone does not corroborate this, as the Member States in the northern zone report very few authorisations through mutual recognition[229]. This could possibly be explained by the low number of PPPs used there overall.

Compared with the Biocidal Products Regulation that provides for a coordination group to facilitate authorisations through mutual recognition, no such formalised body exist under the PPP Regulation. In case of disagreements between Member States, there are only the respective zonal steering committees as well as a working group on post-approval issues under the umbrella of the Standing Committee that can provide informal advice. In addition, Member States have identified the need to have secretariat(s) to handle administrative issues and facilitate coordination[230] between zones.

In submission XI.22a. to the REFIT platform, an NGO in Poland criticises the need for national authorisations within zones as 'red tape'. To remedy the situation, the submission suggests that a PPP authorised in one Member State in a specific zone is automatically authorised in all Member States within the same zone. However, in the platform opinion[231], it is clarified that the differences in agricultural and environmental (including climatic) conditions even for the Member States within a zone, justify no automatic mutual recognition. Member States paid particular attention to this during the adoption of the PPP Regulation and the possibility to refuse an authorisation is the result. In the REFIT opinion, it is further recognised that better implementation of the existing system would already address many of the problems encountered and more PPPs would be available in the Member States, preventing illegal trade of non-authorised PPPs.

Introducing a zonal system for authorisation was meant to trigger cooperation, work sharing and reliance on the evaluation work conducted by other Member States of the same zone. However, this has not materialised. The main reasons why Member States fail to use the opportunities for work sharing is their insistence on specific national requirements, the re-evaluation of applications for authorisation, and the lack of harmonisation in the methodologies used for conducting evaluations[232]. This results in structural delays for all authorisation procedures in most Member States (see also section 5.2.2 for further details). When Member States apply additional national requirements, they miss out on the opportunity to accept evaluations carried out by other Member States which would decrease the workload for themselves and speed up PPPs' access to the market. Moreover, the Member States that use mutual recognition benefit from more PPPs available on their national markets (see data and analysis in the next section 5.1.5).

228 The support study, Annex 3.
229 Collected through the Member State survey carried out in the context of the support study.
230 European Commission (2015) Final report, EU Workshop on Zonal Evaluation, Mutual Recognition and Re-authorisation.
231 REFIT Platform Recommendations – Health and Food Safety: XI.22a 'Registration of plant protection'
232 Focus group on PPP authorisation.

There are several underlying reasons leading to a sub-optimal functioning of the zonal system. Member States report[233] some issues that are directly reflecting a lack of trust in one another:

- The quality of the risk assessment performed by other Member States;
- Some Member States do not comment on the risk assessment during the commenting period due to resource constraints (i.e. priorities). This may lead to a situation where their concerns are not known or taken into consideration and ultimately the Member States then refuse the authorisation or re-evaluate the application;
- The zonal rapporteur Member State does not take into consideration comments from the concerned Member States during the peer review, leading to the same situation as described in the previous bullet;

However, there are also other issues that are not related to a lack of trust:

- Different interpretation of the available guidance;
- Different opinions when new endpoints should be applied;
- Different working practices between Member States as regards accepting new data to address concerns that arise during the commenting period;
- Coordination and communication between and within zones, such as the difficulty to reach the co-ordinators in other zones which costs time and turns out to be ultimately less efficient than doing the assessment separately;
- Dossiers are not available in workable electronic format, which effectively diverts the time of the risk assessor from spending time on core tasks which leads to delays;
- Data protection is a national competence which can lead to some studies being available in one Member State and protected and unavailable in another.

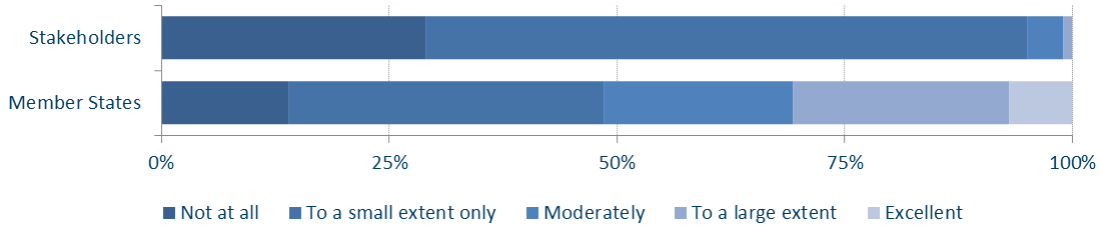


Figure 7. How well is mutual recognition working across zones?

According to stakeholders and Member States, mutual recognition across zones is working even less effectively than mutual recognition within the same zone (see Figure 7). The inter-zonal work is reported to be particularly challenging as there is not much harmonisation or communication between the zones[234].

In conclusion, the zonal system is not working sufficiently well[235,236] and some problems are caused by the absence of basic structures that could facilitate work sharing, communication and arbitration. Nevertheless, compared to the situation under Directive 91/414/EEC, recourse to mutual recognition has improved.

233 European Commission (2015) Final report, EU Workshop on Zonal Evaluation, Mutual Recognition and Re-authorisation.
234 Position paper submitted by the Northern zone – "Input from the Northern Zone on the Review of Regulation 1107/2009"
235 According to the support study, the vast majority of stakeholders (>70 %) consider that the zonal authorisation system is working to a small extent only or not working at all.
236 European Parliament (December 2018) Report on the Union's authorisation procedure for pesticides (2018/2153(INI)) Special Committee on the Union's authorisation procedure for pesticides.

5.1.5. Improving agricultural production and competitiveness of EU agriculture

PPPs are an important factor in agricultural production. All other things being equal, the improved availability and reduced cost of PPPs have a positive impact on productivity[237]. The magnitude of this impact is subject to debate and varies across crops, but some estimates report losses between 5 % and 15 % in the absence of PPPs[238,239].. Sufficient access to PPPs is relevant when comparing the competitiveness of EU farmers versus farmers from non-EU countries.. When productivity of EU agriculture is high, farmers are able to compete with non-EU countries. Conversely, reduced availability or higher cost of PPPs might have a negative impact on yields and productivity if no or only more expensive alternatives are available. This might also negatively affect competitiveness. Nevertheless, the profitability of organic farms, where most chemical pesticides are not permitted is, on EU average, higher than of conventional farms, which is a result of lower input costs and higher CAP support for organic products[240].

There is criticism from stakeholders, farmers and the public[241] that farmers in the EU face unfair competition compared to non-EU countries, because import tolerances can be set for active substances that are not approved in the EU. Farmers in non-EU countries can then use PPPs that are not available to EU farmers while still exporting to the EU, decreasing the competitiveness of EU agriculture and exporting the risks associated with the use of those PPPs to other countries.

The evidence, including a study by the Joint Research Centre on the impact of restrictions on neonicotinoids in the EU[242], remains inconclusive on the potential effects of the PPP Regulation on agricultural competitiveness[243]. Comparing baseline data from 2008-2009 with data from 2015-2016, the input costs for farmers stemming from PPPs increased in some Member States, while they remained stable or decreased in others[244]. Less spending on PPPs may make funds available to spend on something else that may increase productivity. A comparison of the costs of PPPs between the EU and the US does not clearly indicate any competitive advantage or disadvantage as these costs differ depending on the crop that is grown[245]. Any impact of the Regulation on competitiveness is expected to occur only in the short term.[246] In the long run, it can be expected that producers of PPPs and farmers will adapt.

During this evaluation it became apparent that there is a lack of research on the relationship between competitiveness and the PPP Regulation. As mentioned above, there is evidence that the use of PPPs increases yield and productivity, which implies that the availability and use of PPPs is a factor that affects competitiveness. However, there is no clear evidence to link between decisions at EU level and competitiveness.

Availability of PPPs in the EU

237 See for example Popp J., Pető K., Nagy J. (2013). Pesticide Productivity and Food Security. A Review. Agronomy for Sustainable Development 33(1).

238 Hossard L., Philibert A., Bertrand M., Colnenne-David C., Debaeke P., Munier-Jolain N., Jeuffroy M.H., Richard G., Makowski D. (2014). Effects of Halving Pesticide Use on Wheat Production. Science Report 4, 4405. doi: 10.1038/srep04405.

239 Damalas C.A. (2009). Review-Understanding Benefits and Risks of Pesticide Use. Scientific Research and Essay Vol. 4 (10).

240 FADN data reviewed in the Evaluation Study of the impact of the CAP on biodiversity

241 Open public consultation, see responses to the open field questions in Annex 2.

242 Kathage J., Castañera P., Alonso- Prados J.L., Gómez- Barbero M., Rodríguez- Cerezo E. (2017). The impact of restrictions on neonicotinoid and fipronil insecticides on pest management in maize, oilseed rape and sunflower in eight European Union regions. Pest Management Science, Vol. 74, Issue 1, pp. 88-99. https://doi.org/10.1002/ps.4715.

243 The support study, p. 69.

244 The support study, p. 73.

245 The support study, p. 74.

246 The support study, p. 69.

In general, Member States and stakeholders consider the availability of PPPs on the market sufficient or somewhat sufficient, whereas the availability of PPPs for minor uses, organic farming, and low-risk PPPs are considered insufficient. Insecticides have been identified as the group with the lowest availability of products[247].

In most Member States, the number of available PPPs has increased compared to the situation before the PPP Regulation came into force. However, the opposite is true for some of the larger Member States like France and Spain, where the availability of PPPs has decreased. Figure 8 depicts the percentage change in the number of PPPs available in a given Member State between the baseline period 2008-2010 and 2014-2016. The figure shows for example, that Estonia has seen a 62 % increase in the number of available PPPs, while France has seen a 40 % decrease.

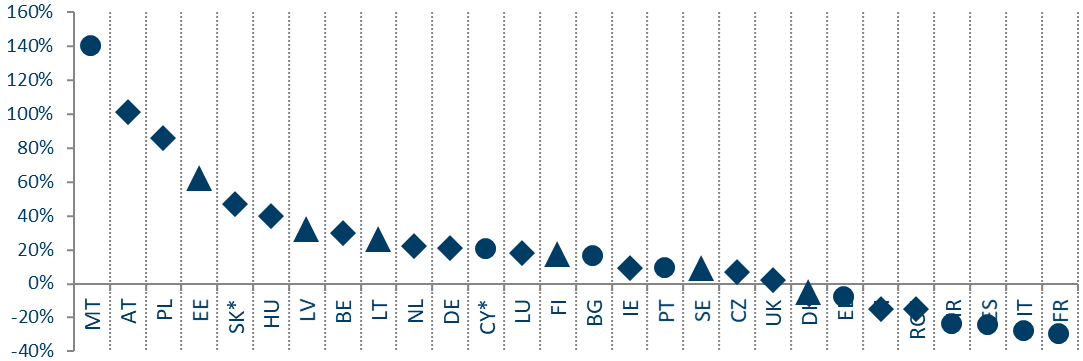


Figure 8. Percentage change in PPP availability in 2014-2016 compared to 2008-2010, based on Member State survey. Triangles represent the northern zone, diamonds represents the central zone and circles represent the southern zone. *Data incomplete for Romania, Slovakia and Cyprus.

The Member States with the largest increase in the number of available PPPs are also the ones who make use of the mutual recognition possibilities provided for in the Regulation. Malta relies entirely on mutual recognition — it is the Member State who mutually recognises authorisations the most. However, Malta started from a very low baseline in 2008 (24 PPPs). Poland was second to Malta in the number of mutual recognitions in 2016, while Austria has granted a high number of authorisations via mutual recognitions since 2012. Note that an increase in the number of PPPs may also reflect an increased number of generic PPPs on the market and not an increase in the uses covered.

A number of smaller Member States reported that one of the main underlying problems for the low availability of PPPs on their market is that industry is not interested in applying for authorisations due to that market's small size.

Stakeholders, especially from the agricultural sector, reported negative effects on competitiveness, citing reduced availability of PPPs due to stricter approval criteria for active substances[248]. However, as the number of approved active substances has increased since 2011 and the number of available PPPs has also increased in most Member States, this statement is not supported by the available data. Indeed, in interviews conducted in the context of the support study, stakeholders acknowledged that the concern is mostly about negative effects expected to materialise in the future because of the expected non-renewal of approval for several substances, which will limit the availability of PPPs for many uses. It is true that the number of non-renewals increased in

247 The support study, p. 55.
248 The support study, p. 69.

2018 and this trend is expected to continue over the next few years. A number of active substances will also be removed from the market as they are no longer supported (see section 5.1.1). As such, farmers' concerns remain[249]: the current approval criteria do not include resistance management and it is therefore possible that in the future resistance to certain modes of action may increase and farmers will be left without efficacious PPPs for certain pests or diseases. At the same time, the full implementation of the Sustainable Use Directive could help address farmers' need for pest management as it promotes integrated pest management and the more widespread adoption of non-chemical pest control techniques and thus, has the potential to reduce dependence on chemical PPPs.

Availability of PPPs for minor uses

A minor use of a PPP is a use on crops that either are not widely grown in a Member State or are widely grown but meet an exceptional plant protection need. Minor uses often have a high economic value for farmers, but usually low economic interest for the industry as their acreage is limited or the exceptional plant protection need cannot be predicted. This leads to a lack of authorised PPPs for such crops, which in turn can lead to illegal uses or to loss of crop production. These crops include most vegetables, fruits, nurseries, flowers and forest trees. It is estimated that overall their value is more than EUR 70 billion per year, which equates to 22 % of the total EU plant production value[250].

To address industry's low interest in applying for authorisations for minor uses, the PPP Regulation includes the possibility to extend an existing authorisation of a PPP for minor uses via a simplified procedure, even without the consent of the authorisation holder. Despite this possibility, Member States and stakeholders consider that there is still insufficient availability of PPPs for minor uses[251] (see Figure 9).

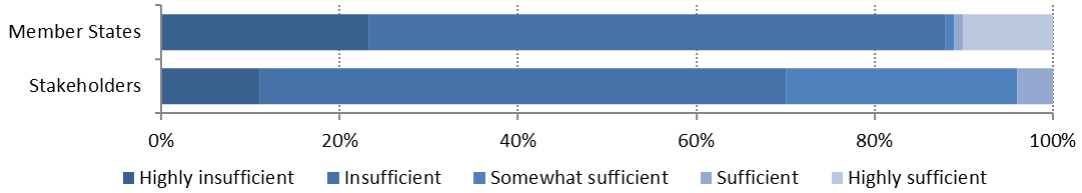


Figure 9. How would you characterise the availability of plant protection products for minor uses on the market?

It is expected that the situation may deteriorate in the future as the availability of traditional broad-spectrum active substances is expected to decrease due to them no longer meeting the approval criteria. It also takes longer to approve an active substance and authorise a product than to withdraw approval and authorisation where a risk is identified. The focus group on PPP authorisation identified the following reasons for the lack of PPPs authorised for minor uses:

- A minor use in one Member State can be a major use in another Member State. As zonal evaluation and mutual recognition do not function perfectly, a minor use is seldom covered by an authorisation. This negatively affects harmonisation as authorisations and extensions need to be granted nationally.

249 The support study, p. 163.
250 Minor Uses Coordination facility webpage.
251 The support study, p. 82.

- It is only possible to grant an extension for a minor use to an existing authorisation. If there is no industry interest in applying for a regular authorisation, it is consequently not possible to extend uses.
- To authorise a PPP under mutual recognition, Member States still need to receive an application, although this can be from official or scientific bodies as well as professional agricultural organisations and professional users.
- There may be liability concerns when it is not the initial authorisation holder who applies for the extension, i.e. it is the authorisation holder who is liable if the PPP is used on another crop (the minor crop) and the crop is destroyed. As each label includes a reference to the liability of the person using the PPP as regards failures concerning the efficacy or phytotoxicity of the product for which the minor use was granted, research institutes, farmers' organisations and national agencies may be reluctant to apply for extensions due to legal concerns.

Member States have established their own national procedures for minor uses and do not cooperate, even within the zones. In addition, the definition of minor uses is not sufficiently clear and is not harmonised. Thus, applicants are not incentivised to apply for uses that could be relevant for minor crops in other Member States[252]. To solve the issue of a lack of PPPs for minor uses, Member States often use emergency authorisations. Over 4 months in 2018, 54 % of all emergency authorisations issued were for minor uses[253]. This is an unintended effect of the PPP Regulation and would not be necessary if Member States extended uses more frequently.

To address the problem of minor uses in a more coherent way, in 2015 the Commission proposed to provide significant financial support and partly funded the EU Minor Uses Coordination Facility for 3 years[254]. Member States have welcomed this initiative as it will create a more level playing field for EU farmers. The Minor Uses Coordination Facility lists Member States' minor use needs online in the European Minor Uses database[255]. The knowledge generated by the Minor Uses Coordination Facility will help to develop a harmonised approach to minor uses in the EU. It must be emphasised, however, that the whole process from identifying a minor use need to the generation of data and the application process generally takes 4-5 years. Therefore, it is expected that the positive effects of the work of the Minor Uses Coordination Facility will only begin to materialise in the coming years, but future funding remains uncertain.

As mentioned before, the Commission is developing the plant protection products application management system (PPPAMS[256]) as a database that in the future will contain information on all PPP authorisations in the Member States. Once fully operational, the PPPAMS will improve the transparency of authorisations and make it easier to identify existing uses in Member States that would also cover minor uses.

Good practices have been identified in France and Ireland, who have taken a proactive approach to addressing critical good agricultural practices (GAP) in PPPs for minor crops. In France, there is an annual programme of residue and efficacy trials, designed to address crop/pest specific problems by generating data to facilitate full authorisation of

252 As reported by the focus group on PPP authorisation.
253 103 of 165 emergency authorisations between April and May 2018 were issued for minor uses. See Annex 3 for methodology.
254 Report from the Commission to the European Parliament and the Council on the establishment of a European fund for minor uses in the field of plant protection products (COM/2014/082).
255 The EMUDA database
256 Information about the PPPAMS is available online on the EUROPA website.

relevant PPPs on these crops. This is a more sustainable alternative to emergency authorisations[257].

Availability of PPPs in the outermost regions

Tropical crops such as bananas, passion fruit, coffee and pineapples are grown in the EU's outermost regions[258]. These minor crops suffer from particularly low access to relevant authorised PPPs. For example, in the French outermost regions, only 30 % of uses are covered by the available authorised PPPs[259].

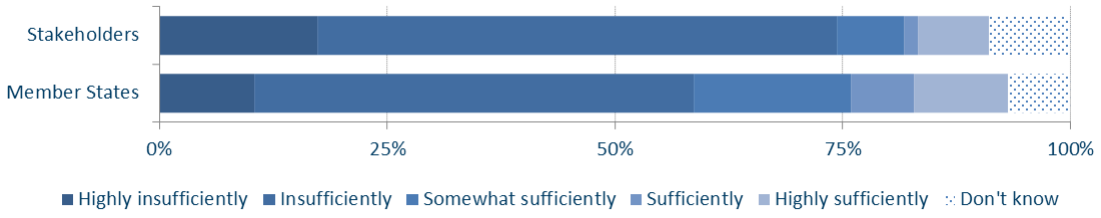
The main reason for this is the low level of applications for authorising PPPs for tropical uses and for pests that only exist in the tropics. The low involvement of PPP producers is due to: (i) the high costs of data generation with uncertain return on investments; (ii) the small size of the market; and (iii) the lack of tropical crop expertise[260]. This is very similar to the situation for minor crops in the main EU regions but taken to another level as there is no major use from which authorisation can be extended.

The situation of the outermost regions as regards minor uses is a national issue relevant for a few Member States, as the main problems relate to the lack of authorised PPPs. One way for Member States to solve the problem has been to grant emergency authorisations. This has been done by Spain for use on mangoes and pineapple, and repeatedly by France for use on sugar cane.

Socioeconomic considerations in decision-making

Although one of the objectives of the PPP Regulation is improving the competitiveness of EU agriculture, socioeconomic considerations are not listed as part of the approval criteria. Other EU legislations such as REACH and the Biocidal Products Regulation can take socioeconomic factors into consideration when deciding to allow the use of chemicals that should in general be substituted. In the PPP Regulation, such considerations only play a role in the possibility to derogate from the cut-off criteria[261] and when Member States grant emergency authorisations.

This was a political choice as PPPs are seen as a specific category of chemicals - they are designed to have effects on living organisms and are deliberately released into the environment. This is not the case for industrial chemicals and, therefore, safety and the protection of human health and the environment are particularly important in the PPP Regulation.



257 European Commission (2017). Overview report on a series of audits carried out in EU Member States in 2016 and 2017 in order to evaluate the systems in place for the authorisation of plant protection products. DG(SANTE) 2017-6250.

258 The EU has nine 'outermost regions': Guadeloupe, French Guiana, Martinique, Mayotte, Réunion and Saint Martin (France), the Canary Islands (Spain) and the Azores and Madeira (Portugal). They are an integral part of the EU and must apply its laws and obligations.

259 The support study, p. 81.

260 The support study, p. 81.

261 Under Article 4(7) of Regulation 1107/2009.

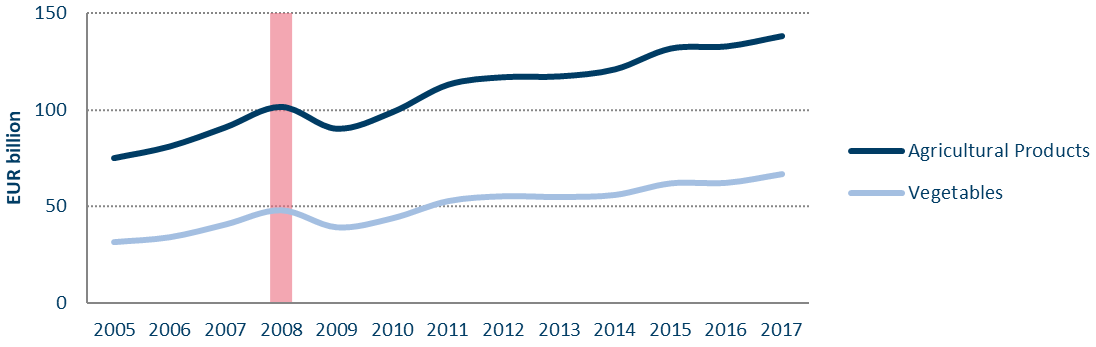
Figure 10. Are economic factors sufficiently taken into consideration in the decision-making of the approval of active substances?

Nevertheless, more than 50 % of Member States and almost 75 % of stakeholders, representing all sectors except NGO's, consider that social and economic factors are insufficiently taken into consideration in decision-making related to the approval of active substances (see Figure 10). Stakeholders consider that having the ability to take economic or social considerations into account as part of the approval criteria means that some active substances of high importance may remain on the market for limited uses, which would positively impact the competitiveness of EU agriculture[262]. However, the inclusion of socio-economic consideration could be seen as a weakening of the approval criteria in particular as regards the protection of human health or the environment.

5.1.6. Facilitating international trade

Academic literature shows that harmonisation of standards, such as MRLs for pesticides, facilitates trade between countries[263]. This implies that different MRLs in the EU and non-EU countries would have a negative impact on international trade. However, a recent empirical study shows that stricter MRLs can have a positive impact on international trade[264]. According to the study, stricter standards positively affect international trade as the demand-enhancing effect of importing food considered safe outweighs the trade-cost effect. Moreover, it can be argued that harmonising EU MRLs has made it easier for food-business operators worldwide to comply with standards. One MRL used throughout the EU makes it possible for trade partners to export products to the Member State of their choice, based on trade interests and partnership, rather than selecting a Member State only because a different MRL applies there. Nevertheless, most stakeholders consulted perceive the MRL Regulation as having had a negative impact on imports, while Member States reported a positive impact both for imports and exports[265].

As shown in Figure 11 below, overall imports of agricultural commodities in the EU steadily increased between 2005 and 2017, with the exception of the 2008-2010 period, which can be explained by the global economic crisis. Given that international trade is affected by many factors such as the existence of trade agreements and economic growth, the trade data do not allow for a clear assessment of any potential effects of the MRL Regulation on trade with non-EU countries.



262 Focus group on risk management and decision-making
263 Support study, p. 109.
264 Anirudh Shingal, Malte Ehrich and Liliana Foletti (2017) 'Re-estimating the effects of stricter standards on trade: endogeneity matters', EUI Working Paper RSCAS 2017/20, European University Institute, Badia Fiesolana. ISSN 1028-3625.
265 Support study, Annex III, consultation activities — surveys and interviews.

Figure 11. EU-28 imports of agricultural products and vegetables from non-EU countries[266]

Setting of import tolerances

For substances for which no MRL exists because there is no use in the EU, operators in non-EU countries can request import tolerances. Since 2008, 94 applications for import tolerances were submitted, among which 80 were assessed positively and 9 received a negative opinion. The remaining 5 applications are still under assessment.

Although import tolerances are clearly mentioned in the MRL Regulation, little guidance is provided on how they should be addressed. The same procedure for setting MRLs applies to EU uses as well as to import tolerance requests, which ensures the same level of protection for consumers regardless of the origin of a foodstuff. However, the procedures are not detailed enough for applicants and the competent authorities of non-EU countries, so a guidance document[267] was developed to provide the necessary information and to set out practicable and workable solutions.

One factor that non-EU countries often mention as hindering international trade is the review of MRLs. For many pesticide commodity combinations, non-EU countries rely on the MRLs that are currently set in the EU. Key examples are haloxyfop-P and thiabendazole[268], for which the MRLs were lowered for linseeds and mangoes respectively due to the lack of data supporting uses on those crops. Although WTO members are informed in advance of the lowering of MRLs via the SPS procedure, the time in which they can react is considered by them to be insufficient to prepare an import tolerance application to prevent the lowering of the MRL. To assist trade partners, the Commission prepared a Communication[269] outlining the overall MRL review process and listing the active substances for which an MRL review is planned.

Implementation of international standards (Codex limits)

The MRL Regulation makes reference to international standards, but does not provide for a clear legal basis for their implementation. A legal basis is, however, included in the General Food Law Regulation[270]. At regular intervals, the Commission drafts a measure to implement CXLs, which are the limits adopted by the Codex Alimentarius Commission. The EU presents reservations to the Codex Committee on Pesticide Residues (CCPR) in cases where EFSA considers that CXLs may pose a risk to consumers in the EU or where a different methodology, different toxicological reference values or different residue definitions are used to derive MRLs. A reservation is also made where a parallel assessment is being carried out in the EU, such as during the approval of an active substance. However, depending on the outcomes of the assessment, the reservation may turn into the adoption of the CXLs at a later stage.

CXLs for which the EU does not make a reservation during CCPR meetings are included in the MRL Regulation, except if they relate to commodities for which MRLs are not (yet) set in that Regulation, such as feed items. Currently, CXLs are set for 208 substances on 20-25 commodities on average[271]. The total number of CXLs implemented is thus much lower than the total number of EU MRLs. Moreover, several CXLs are

266 Eurostat [DS-018995].
267 MRL setting procedure in accordance with Articles 6 to 11 of Regulation (EC) No 396/2005and Article 8 of Regulation (EC) No 1107/2009 (SANTE/2015/10595), Chapter 3.1.
268 See case study in the support study.
269 Committee on Sanitary and Phytosanitary Measures, Communication from the European Union, On-going review of maximum residue levels of pesticides in the European Union (G/SPS/GEN/1494/Rev.1).
270 Articles 5(3) and 13(e) of Regulation (EC) No 178/2002 of the European Parliament and of the Council.
271 Codex Pesticides Residues in Food Online Database

actually based on EU uses, which in the long term may constitute an alternative to import tolerance requests where the uses are withdrawn in the EU. The percentage of EU MRLs harmonised with CXLs in the past years is shown in Table 7.

Table 7. The percentage of EU MRLs harmonised with CXLs

Year	Total number of CXLs for food adopted CAC[272]	EU MRLs set at lower values than CXLs	EU MRLs set at the same or higher values[273] than CXLs
2012	242	22 %	78 %
2013	352	21 %	79 %
2014	301	28 %	72 %
2015	326	25 %	75 %
2016	349	37 %	63 %
2017	417	47 %	53 %
2018	305	21 %	79 %

The EU is criticised by trade partners in relation to the reservations made at CCPR meetings. Trade partners claim that the EU does not comply with international standards (see section 5.3.3). However, only a minor portion of recent CXLs have not been transposed in the MRL Regulation, accounting for 29 % of the total CXLs adopted by the Codex Alimentarius Commission for food between 2012 and 2018. When comparing the percentage of harmonised CXLs accepted by major WTO members, the EU has the highest rate of harmonisation which is facilitating trade (see Figure 12).

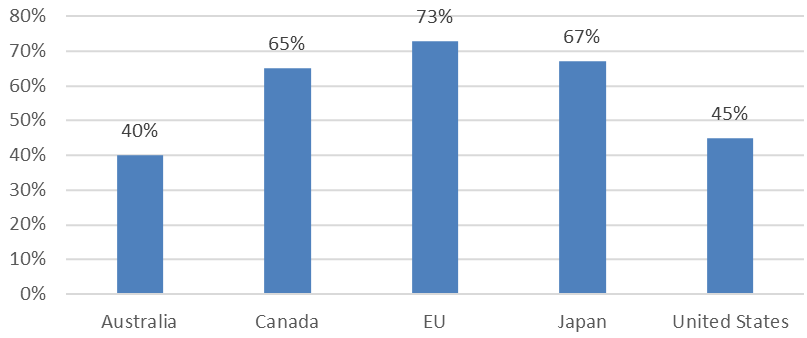


Figure 12. Comparison of harmonised Codex limits adopted between 2012 and 2016 by WTO members

Export of treated seeds

When Directive 91/414/EC was in force, there was a lack of legal provision for treated seeds. The PPP Regulation contains provisions that allow for the free circulation of treated seeds[274] in the EU if there is at least one authorisation in at least one Member State. This clear provision in the PPP Regulation has had a positive harmonising effect within the EU[275]. In the PPP Regulation, it is the treatment of the seeds that constitutes the use of a PPP and requires an authorisation, whereas the sowing of the seeds does not. This has led to two complications. First, Member States are experiencing difficulties in tracing and controlling treated seeds[276]. Second, there is no common view yet on whether

272 Codex Alimentarius Commission.
273 MRLs may be set at a higher level in the EU based on different GAPs than the ones used to establish CXLs. Such MRLs facilitate trade as they cover both international and EU uses.
274 'Seed treatment' is a preventive measure to enhance growth and reduce loss of plant material to pests in early stages of the plant life cycle.
275 The support study, p. 114.
276 The support study, p. 117.

it is possible to treat seeds for exports with an active substance that is not approved in the EU.

5.1.7. Enforcement

Enforcement of the PPP Regulation

All Member States carry out monitoring and official control activities to ensure compliance with the PPP Regulation. A series of audits conducted by the Commission found that controls on users of PPPs are satisfactory. The effectiveness of enforcement activities at national level varies, however, particularly in relation to certain provisions of the PPP Regulation[277]. PPP users have an incentive to comply because of the cross-compliance mechanism under the Common Agricultural Policy[278], where non-compliant PPP users may lose their entitlements to financial benefits.

The Commission's audits reported difficulties with official controls on imports and exports of PPPs and with official controls to verify compliance of PPPs placed on the EU market with the conditions of their authorisation or with parallel trade permits[279]. Not surprisingly, therefore, one of the main issues is the presence of illegal and counterfeit PPPs on EU territory. It is estimated that illegal and counterfeit PPPs represent around 10 % of the EU PPP market[280], while in some Member States this might be up to 25 % of PPPs sold[281]. Member States bordering non-EU countries generally have the highest level of illegal PPPs. The last three operations by Europol, the European Anti-Fraud Office and the Member States targeting illegal and counterfeit PPPs at major seaports and airports and at the land borders seized more than 670 tonnes of illegal or counterfeit PPPs[282].

Sanctions related to marketing illegal PPPs are not always effective at ensuring enforcement as the level of sanctions is too low or infrequent to incentivise compliance[283].

The European Parliament[284] has criticised the poor enforcement of the PPP Regulation and called on the Member States to ensure effective implementation. Stakeholders consistently hold a very negative opinion — more than 80 % consider that the PPP Regulation is not adequately enforced[285].

The Commission's overview audit report recognises that official controls on the use of PPPs and increased focus on enforcing the requirements applicable to the sustainable use of PPPs provide some assurance as to the responsible use of PPPs. However, the report also states that the lack of adequate official controls in the stages prior to use on farms

277 European Commission (2016) Overview report on a series of audits carried out in EU Member States in 2015 and 2016 in order to evaluate the control systems in place for the marketing and use of plant protection products. DG(SANTE) 2016-6004 – MR.
278 Cross-compliance is ensured under Article 55 of Regulation 1107/2009.
279 European Commission (2016) Overview report on a series of audits carried out in EU Member States in 2015 and 2016 in order to evaluate the control systems in place for the marketing and use of plant protection products. DG(SANTE) 2016-6004 – MR.
280 European Commission (2015) Ad-hoc study on the trade of illegal and counterfeit pesticides in the EU — DG Health and Food Safety.
281 Report from the Awareness conference on Fake and Illicit Pesticides held in Alicante in 2012.
282 In 2015, during Silver Axe, 350 inspections of containers were carried out and 190 tonnes of illegal PPPs were discovered entering the EU through seven Member States. In 2018, during Silver Axe II, over 940 shipments of PPPs were inspected in 16 Member States resulting in the discovery of almost 122 tonnes of illegal or counterfeit pesticides. During Silver Axe III, 181 suspicious shipments were inspected and 360 tonnes of illegal or counterfeit pesticides seized.
283 European Commission (2015) Ad-hoc study on the trade of illegal and counterfeit pesticides in the EU — DG Health and Food Safety.
284 European Parliament (September 2018) Report on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009.
285 The support study, p. 107.

(e.g. during manufacturing, distribution and marketing stages) compromise the effectiveness of a system intended to guarantee the safety of PPPs.

Changes introduced by Regulation (EU) 2017/625, which will be applicable at the end of 2019 (see section 3.7), are likely to improve the enforcement of the PPP Regulation, but the final outcome will depend on Member States' action in this area.

Enforcement of the MRL Regulation

Food-business operators placing products on the EU market need to make sure they are safe for human consumption[286], so they must ensure compliance with the MRL Regulation. The results of the EU multi-annual coordinated programme[287] which requires random sampling and analysis of a range of specific substances in certain commodities indicate a high level of protection for the EU citizen (see Figure 6 in section 5.1.1).

Another step forward towards harmonisation concerns the analytical methods used by enforcement laboratories. These methods are validated and the laboratory's overall performance assessed via proficiency tests organised by the EU reference laboratories. Audit results indicate a high degree of harmonisation despite some shortcomings found in a few Member States concerning the range of pesticides analysed, mainly due to lack of resources.

The MRL Regulation covers in its scope also pesticides no longer used as such, residues of biocidal products and of veterinary medicinal products etc. Either a specific MRL or the default value applies to a pesticide-commodity combination under the MRL Regulation, regardless of the source of the residue found. For substances no longer used as pesticides, the default value applies, although the substance may well be lawfully used in veterinary medicine or as a biocide.

Covering all possible sources with one MRL ensures a maximum of consumer protection as Member States can take enforcement action for each and every pesticide – commodity combination. However, in practice this has led to enforcement problems as sometimes the MRLs are not reflecting other uses and are then too low or are different from limits set in other legislation, e.g. on veterinary medicinal products. Different recommendations for MRLs are sometimes given by different agencies for the same substance, e.g. EMA for MRLs of veterinary medicinal products and EFSA for pesticides residues, as the methodology for exposure assessment is different. This has led to confusion for Member States' enforcement authorities and has hampered enforcement action. For example, if low amounts of biocidal active substances (such as those used in cleaning agents that were formerly used as pesticides) are found in foods but do not pose a risk to consumers[288], the default MRLs for the substances continues to apply to the agricultural commodities as the substances are no longer authorised or used as pesticides. Moreover, the substances do not occur in the raw products to which the MRLs apply, but only enter the food chain at a later stage, during processing.

286 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

287 Commission Implementing Regulation (EU) 2018/555 of 9 April 2018 concerning a coordinated multiannual control programme of the Union for 2019, 2020 and 2021 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

288 Reasoned opinion on the dietary risk assessment for proposed temporary maximum residue levels (MRLs) of didecyldimethylammonium chloride (DDAC) and benzalkonium chloride (BAC). EFSA Journal 2014;12(4):3675.

This concern was in particular raised for chlorate, and discussed by stakeholders and governments in the context of the REFIT platform. In its opinion[289] on 'multiple use/multiple source substances-chlorate', the REFIT Platform Stakeholder group recommended changing the definition of 'pesticides residues' and setting limits for multiple use substances under the most suitable legislative framework, including under another legal framework than the MRL Regulation if appropriate. In the REFIT Platform Government group, different opinions were expressed as regards the definition of 'pesticides residues' and the Government group considered that the issues deserved thorough assessments and therefore welcomed the evaluation of the PPP legal framework (see also section 5.3.2). For chlorate, eventually a multi-disciplinary action plan was agreed in May 2017 at a meeting of the Heads of Food Safety Agencies which includes actions on drinking water, food hygiene, foods for infants and young children and the setting of temporary MRLs for chlorate under the MRL Regulation. While the action on food hygiene has been completed, the actions on drinking water and MRL setting in food are currently ongoing.

In the past, the Commission has addressed such situations case by case in the past and always as a reaction to requests of Member States and stakeholders who already experienced problems. The Commission's action consisted often of setting temporary MRLs on the basis of monitoring data to reflect other legitimate uses, or by aligning the MRLs for pesticides with limits set under other legislation. Since the MRL Regulation regards EFSA as the only agency in matters of food safety, direct action on basis of a risk assessment carried out by another agency (e.g. the European Medicines Agency) has not been possible (see also section 5.2.1). Furthermore, in some cases the different methodologies used for consumer exposure assessments of the same substance by different European agencies, which directly mirrors the different methodologies used at international level by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for veterinary medicines lead to different risk assessment outcomes making alignments of legislation difficult.

Setting of temporary MRLs on the basis of monitoring data is limited to "exceptional circumstances" which are not well defined. This regularly leads to delays due to the need to clarify the scope of this provision.

5.1.8. Transparency and risk communication

The PPP Regulation aims to improve the transparency of procedures and access to documents, while trying to balance the need for confidentiality in view of industry's right to keep certain information protected. Compared to Directive 91/414/EEC, it is better defined when and which documents should be made public and what information can be kept confidential[290]. Most of the consulted stakeholder groups (except NGOs) are satisfied with the balance between transparency and confidentiality, noting that this has improved substantially since the previous legislation was in force[291]. Citizens, organisations and businesses can also request access to documents[292].

289 REFIT Platform Opinion on the submission by a member of the REFIT Platform Stakeholder Group on "Multiple use/Multiple source substances – Chlorate", 7 June 2017

290 According to Article 63 of Regulation 1107/2009.

291 The support study, p. 165.

292 According to Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

There is increased public interest in pesticides in general and in the approval of active substances at EU level. To inform the public about decisions taken in the EU, risk communication has to work effectively. The fitness check of the General Food Law recognised the fact that risk communication has not always been effective and has had a negative impact on consumer trust[293]. One particular example is the Commission's and EFSA's unsuccessful risk communication on glyphosate. The public consultation conducted for this evaluation[294], although not statistically significant, confirmed that the public feels insufficiently informed about decisions about pesticides in the EU.

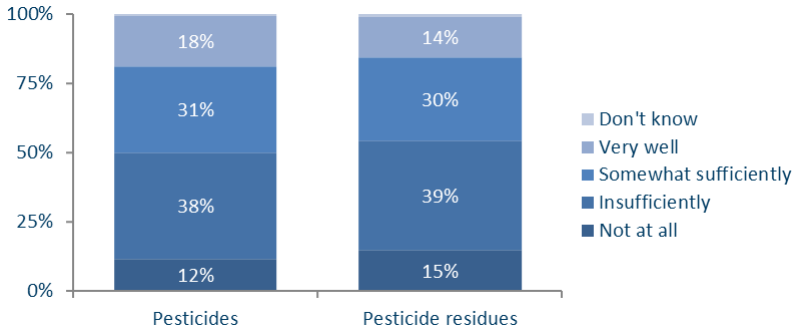


Figure 13. Do you feel well informed about the decisions made in the EU with regard to pesticides and their residue levels?

The following initiatives have been developed to increase transparency:

- The EU Pesticides Database[295] contains information about active substances (approved and not approved) in the EU. The review reports underpinning decision-making are available, as are classifications, information about historical and current MRLs, etc.
- EFSA regularly launches public consultations as part of the risk assessment and peer review of active substances and makes them available on its website[296]. Based on each peer review, EFSA publishes its conclusions and technical reports[297], which later form the basis of decision-making by the Commission and Member States. The public consultation is the right moment to intervene in the risk assessment, but NGOs report that due to lack of resources and the short deadlines to provide input they rarely make use of the opportunity[298].
- Member States are consulted on draft reasoned opinions on MRL reviews, but these are not full public consultations.
- EFSA publishes the upcoming schedule[299] for reviewing MRLs to inform operators and non-EU countries of what is in the pipeline and facilitate early generation of data and applications for import tolerances. However, non-EU countries still criticise the EU for lack of information as regards revisions of MRLs, which they claim lead to negative consequences for international trade.

293 European Commission (2018) Commission Staff Working Document the REFIT Evaluation of the General Food Law (Regulation (EC) No 178/2002). SWD(2018) 38.
294 Open public consultation held as part of the support study.
295 EU Pesticides Database.
296 EFSA's consultations webpage.
297 All EFSA conclusions and reports are published in the EFSA Journal.
298 The support study, p. 165.
299 MRL review progress report.

- EFSA's Register of Questions[300] contains all mandates sent to EFSA, all ongoing procedures, deadlines for EFSA's work, summary dossiers, the rapporteur Member State's review assessment reports, and commenting tables for every active substance. The site contains numerous relevant documents but even experienced users find it difficult to navigate. Furthermore, there is criticism, in particular from NGOs, that the documents are too complex for non-scientists to understand.
- The agendas and summary reports from the Standing Committees on Plants, Animals, Food and Feed are published on the Commission's website[301]. There are also dedicated webpages with detailed information for high profile topics such as endocrine disruptors, glyphosate and neonicotinoids. However, there is criticism from stakeholders that the minutes are too basic and uninformative[302], and that Member State positions are not disclosed - the latter is in fact prevented by the rules governing the comitology process. The Commission has proposed to disclose the votes of Member States at the Appeal Committee level taken in comitology[303], but neither the European Parliament nor the Council have moved the adoption of this proposal forward yet.
- The plant protection products application management system (PPPAMS[304]) will eventually contain information on all PPP authorisations in the Member States. The database is currently used only for emergency authorisations under Article 53 of the PPP Regulation but will be used for all authorisations in the future. However, the full implementation of the system is delayed due to resource constraints both in the Commission and in the Member States. Currently, information on PPP authorisations varies between Member States as some have databases while others provide information through downloadable individual documents. There is currently no EU overview and it is difficult to know which PPPs are available across the EU.
- To access information, anyone can request access to Commission and EFSA documents. Between 2013 and 2018, the Pesticides and Biocides Unit in DG Health and Food Safety released more than 4 000 documents to NGOs, industry representatives, journalists and citizens in response to requests for public access to documents. To increase transparency, in April 2018 the Pesticides and Biocides Unit in DG Health and Food Safety launched a pilot project that involves the online publishing of documents which have been partially or fully released following an 'access to documents' request[305].

The platforms and websites listed above are available, but knowledge about them is low: 37 % of respondents to the public consultation were not aware that any of them existed, while 22 % of respondents were aware that the tools exist but say that they cannot easily find the information they need. Simply having information publicly available does not necessarily translate into a better informed public if the information is difficult to find or understand.

NGOs criticise the regulatory system for PPPs and MRLs, saying that it is opaque, that documents are published too late, that there are conflicts of interest and that industry is

300 EFSA Register of Questions.
301 Standing Committee for Plants, Animals, Food and Feed - section phytopharamceuticals.
302 The support study, p. 168.
303 Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers. COM(2017) 85.
304 Information about the PPPAMS is available online on the EUROPA website.
305 Transparency pilot projects webpage.

too involved in the risk assessment[306]. The risk management process is seen as particularly secretive and it is not clear to stakeholders, NGOs in particular, how negotiations with Member States are carried out in the Standing Committee[307]. All stakeholder groups reported that it is necessary to increase the transparency of the MRL-setting process[308].

Increased transparency and sustainability of the risk assessment in the food chain

In April 2018 the Commission proposed a targeted revision of the General Food Law Regulation[309] in response to the concerns expressed in the European Citizens' Initiative, in order to improve the transparency and sustainability of the risk assessment process in the EU in the food safety area. The proposal was coupled with a revision of eight pieces of sectoral legislation, one being the PPP Regulation. This amendment of the General Food Law has been adopted[310] by the Council and the European Parliament on 13 June 2019 and the majority of the provisions will become applicable on 21 March 2021. The Regulation gives citizens greater access to information submitted to EFSA on approvals. The key elements of the proposal are:

- Ensure more transparency, by allowing citizens to have immediate access to all safety related information submitted by industry in the risk assessment process;
- Create a common EU Register of commissioned studies. This will provide a mechanism by which EFSA will be able to double-check whether all studies commissioned by an applicant in the context of its application for an authorisation, have been submitted and it will guarantee that companies submit all relevant information, and do not hold back unfavourable studies;
- Allow additional studies to be requested, in exceptional circumstances, by EFSA, upon request of the Commission and financed by the EU budget to verify evidence used in its risk assessment process;
- Require consultation of stakeholders and the public on studies submitted by industry to support product authorisation requests;
- Increase the Member States involvement in EFSAs governance structure and scientific panels;
- Strengthening risk communication to citizens, with common actions to enhance consumer confidence by promoting public awareness and understanding and better explaining scientific opinions expressed by EFSA, as well as the basis of risk management decisions.

306 Citizens for Science in Pesticide Regulation.
307 Bozzini E. (2017) Pesticide Policy and Politics in the European Union; Regulatory Assessment, Implementation and Enforcement. Palgrave Macmillan. ISBN 978-3-319-52735-2.
308 The support study p. 168.
309 Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain. COM/2018/0179 final — 2018/088 (COD).
310 Regulation (EU) 2019/1381 of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain, OJ L 231, 6.9.2019, p. 1.

5.2. Efficiency

- To what extent the costs for the Commission including EFSA, Member States, operators involved in the approval of substances and authorisation of plant protection products, in the setting of MRLs have been justified and evenly distributed given the effects achieved?
- Are there issues which pose particular problems for SMEs and micro-enterprises?
- What benefits have been achieved from implementing the legislation?
- Is the legal framework generating unnecessary regulatory burden? Are there any actions that could reduce regulatory burden, or potential alternative policy mechanisms that could improve cost-effectiveness?

MAIN FINDINGS

The PPP and MRL Regulations are only partly efficient: there are significant delays in approving and renewing the approval of active substances, in authorising PPPs, and in the review of all existing MRLs. The deadlines most frequently missed in the renewal process are those for: (i) the admissibility check by the rapporteur Member States; (ii) the assessment of the supplementary dossier by the rapporteur Member State; (iii) the additional assessment needed by the rapporteur Member State during the peer-review process; and (iv) the Commission's decision-making. This leads to repeated extensions of approval periods of active substances in order to finalise decision-making.

There are also delays in the implementation of certain parts of the Regulations due to limited resources available, e.g. a list of unacceptable co-formulants is still not established. When the Regulations were adopted, the estimated amount of work to be carried out and the resources required appear to have been severely underestimated.

The setting of MRLs is considered efficient. However, the MRL Regulation is not flexible enough to address unforeseen circumstances, and this decreases overall efficiency. The MRL review programme is heavily delayed as the workload was much greater than initially expected. As of 2018, only a little over half of the substances have been reviewed.

Due to a lack of data, not all the benefits of the two Regulations could be quantified. The available quantified evidence suggests that benefits linked to the non-renewal of five active substances under the PPP Regulation, even if uncertain and incomplete, amount to about EUR 38.5 million annually.

The costs for industry, Member States, EFSA and the Commission is well accounted for and shows that industry incurs considerable costs to prepare the dossiers and apply for the approval and renewal of approval of active substances, for authorisations of PPPs and for setting MRLs. This particularly affects SMEs as the high upfront costs especially related to the costs of preparing a high quality dossier are a barrier to entering the market.

The fees raised by some Member States are not sufficient to cover their costs, and some Member States do not directly link the fees with the work carried out. For MRLs, the Member States' work on the MRL review is not covered by fees. This results in an insufficient number of staff being available to carry out the necessary work, which contributes to the delays.

In the Member States, the regulatory system for PPPs and MRLs is mostly financed by fees paid by industry to Member States, who use the fees to recover their expenses. The costs of protecting human health and the environment from PPPs are also partly covered by public funds through the work carried out by EFSA and the Commission as this work

is not covered by fees. All costs and benefits are reported in the overview table in Annex 4. In addition, Annex 2 to the support study explains how the costs for Member States and stakeholders have been calculated.

5.2.1. Costs for industry, farmers and SMEs

Industry

Businesses wanting to place a PPP on the market in the EU face considerable costs. The main cost is incurred in discovering and developing new active substances and proving their safety through laboratory and field studies. According to industry, this requires an investment of between EUR 200-250 million[311]. These costs have increased in recent years due to higher demands in the PPP Regulation to prove safety for human health and the environment[312].

Based on stakeholder and Member State data, the support study calculated that industry spends annually around EUR 300 million on preparing dossiers for approvals and renewal of approvals in the EU[313]. Around half of the cost (EUR 122-189 million[314]) relates to new active substance procedures, excluding research and development costs. There are on average 9 new active substance applications per year. The remaining half (up to EUR 196 million[315]) are for the renewal procedures which are more numerous, around 48 per year, but the individual investment is lower than for new active substances. Fees to Member States are a small part (up to 10 %) of the cost of preparing the dossiers at the required standard. Indeed, the main drivers behind the costs for industry, both under Directive 91/414/EEC and the PPP Regulation, are the high study and testing demands to fulfil the data requirements. To put these figures in perspective, the crop-protection market in Europe generated revenue of EUR 12 billion in 2016[316].

The costs estimated for an applicant to obtain authorisation of a PPP in one Member State range between EUR 0.5 million and EUR 1 million. However, as it is possible to apply using the same dossier in several Member States, a simple multiplication would inflate the total cost. The information available is too uncertain to calculate total costs for PPP authorisation in the EU. What has been possible to estimate is the increased costs of EUR 26.7 million in 2016 to obtain authorisation of PPPs containing candidates for substitution compared to regular authorisations. The increase is due to Member States charging higher fees for such authorisations. These higher costs further reduce the efficiency of the authorisation procedure for candidates for substitution as none of the comparative assessments has led to any substitution[317].

For MRLs, the combined annual costs for industry to prepare dossiers are estimated at EUR 55 million. The costs for reviewing MRLs are lower per procedure than the setting of MRLs and import tolerance procedures (see Table 8). No significant administrative costs for companies were identified in the support study[318].

311 McDougal P. (2016). The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010-2014.
312 Ibid.
313 The support study, p. 144.
314 The support study, p. 146.
315 The support study, p. 146.
316 According to InkWood Research.
317 The support study, p. 227.
318 The support study, p. 135.

Table 8. Costs for MRL dossier preparation per type of procedure

	MRL setting	MRL review	Import tolerances
Average costs for dossier preparation per procedure	EUR 500 000	EUR 300 000	EUR 500 000
Average number of applications at the EU level (2008-2016)	76	39	11
Total costs per year for industry	EUR 38 million	EUR 11.7 million	EUR 5.5 million

While industry stakeholders report that the impact of the PPP Regulation on their businesses has been negative, data from Eurostat[319] do not support this claim as the value of PPPs and other agrochemical products increased on average by 22 % between 2014 and 2016 compared to 2008-2010. Also, PPP sales were stable from 2011 and 2016 at EU level and within the three zones. The number of people employed in the pesticides and other agrochemical products manufacturing sector increased by 15 % (+ 6 000 people) between 2008 and 2016[320].

Farmers

For farmers, data from the European Commission Farm Accountancy Data Network indicate that the share of spending on crop protection has not increased since the entry into force of the PPP Regulation[321]. From 2004 to 2010, the share of spending on crop protection out of total specific costs fluctuated between 9.5 % and 10.5 %, and between 9.3 % and 10.3 % from 2011 to 2016. Although there is evidence, based on different data from Eurostat, that the input costs stemming from PPPs have increased since 2010 in the EU[322], farmers in the EU are not at a disadvantage compared with those in the United States. Whether EU farmers or US farmers have the competitive advantage depends on the crop grown[323].

The PPP Regulation has increased uncertainty for farmers as the non-approvals of some active substances have removed solutions and options for pesticide resistance management. Alternatives are sometimes more expensive or harder to find, while non-chemical alternatives and low-risk active substances are often not yet available. When alternatives are available, they may require specific new knowledge and attention to monitor pest cycles in order to efficiently apply solutions more linked to prevention than cure. This implies that farmers need the support of proper integrated pest management advisory services, which is the responsibility of Member States. Overall, no firm conclusions can be made on the PPP Regulation's impact on the costs incurred by farmers, except that the share spent by farmers on PPPs is comparable to what they spent before the PPP Regulation came into application and to what they spend on fertilisers and that these costs are not negligible.

Specific issues related to SMEs

The number of SMEs producing PPPs and other agrochemical products is decreasing. In 2012, there were 413 pesticide manufacturers classified as SMEs, while in 2015 there were 349[324]. The reasons are likely multiple, but the high regulatory requirements are a

319 Eurostat [sbs_sc_ind_r2] and [sts_inpr_a] for volume index of production.
320 23 600 people employed in 2008 and 29 591 people in 2016, see the support study p. 153.
321 The Farm Accountancy Data Network is an instrument for evaluating the income of agricultural holdings and the impacts of the Common Agricultural Policy.
322 The support study p. 74.
323 The support study p. 74.
324 Eurostat, Annual enterprise statistics by size class for special aggregates of activities [sbs_sc_sca_r2].

contributing factor. Smaller firms experience particular difficulties with the high upfront investments necessary to develop and commercialise active substances and the long time to market (on average around 5 years for new active substances[325]) as they have less capital than larger firms. This is further exacerbated by the unpredictable delays in the system (see section 5.2.2). Stakeholders working with biopesticides and in organic farming do not consider the data requirements and procedures in the PPP Regulation to be appropriate or proportionate for potentially low-risk solutions such as micro-organisms. This particularly affects SMEs as they are more often involved in developing such substances than in developing chemical active substances. The Commission is working to improve the situation by drafting guidance documents supporting the assessments of biopesticides, e.g. microbial pesticides and pheromones (see section 5.1.5). In addition, the data requirements on micro-organisms can be updated and modernised (see section 5.4.2).

The PPP and MRL Regulations seem to incur some costs to SMEs in order for the firms to comply. For instance, 24% of the SMEs consulted in the SME panel confirmed that they need to hire an external consultant occasionally or frequently to comply with either the MRL Regulation and/or the PPP Regulation. In the consultation, SMEs stated that 1-5% of all their administrative costs stem from the PPP Regulation.

Some SMEs claim that the data protection granted for studies other than on vertebrate animals is used by the data owners as an anti-competitive tool, limiting SMEs' access to the market. While the PPP Regulation provides for mandatory sharing of tests and studies involving vertebrate animals, this is not the case for non-vertebrate studies. As a result, authorisation holders can refuse access to such studies for generic firms to discourage competition. Generic companies may spend significant time negotiating access to studies. If an agreement is not reached, the company needs to commission its own study, which prolongs the time taken to complete the dossier and submit an application for authorisation, ultimately leading to a delay in accessing the market.

5.2.2. Costs for the Member States, the Commission and EFSA

The overall annual costs for Member States on approval and authorisation procedures for PPPs are estimated at EUR 44 million, with around 930 full-time staff equivalents working as risk assessors and risk managers[326]. Approvals and renewals of approval of active substances are estimated to account for 23 % of these resources, at a cost of EUR 10 million (210 full-time staff equivalents). For MRL procedures, the estimated costs for Member States are EUR 5 million. The costs should be covered by fees paid by industry, the exception being the MRL review programme where fees cannot be raised as an ad-hoc procedure has been established between Member States and EFSA to manage the unexpectedly high workload.

Although fees can be recovered for most procedures, it is not clear if the fees are set at a level that actually covers the costs. There are large discrepancies between the fees charged by Member States: for example, Romania charges EUR 51 000 to be the rapporteur Member State for the approval of a new active substance while Austria charges EUR 350 000; Italy charges EUR 45 000 to be the rapporteur Member State for the renewal of approval of an active substance while Sweden charges EUR 440 000[327]. While the cost of labour is different in the Member States, it seems that not all Member

325 Using data from the support study p, 123 (44 months for the approval of a new active substance) and adding 12 months for the authorisation procedure in the Member States.

326 The support study, p. 144.

327 Annex 2 to the Support Study.

States really charge high enough fees to cover their expenses. Many Member States have also decoupled the work to be carried out from the fees, i.e. the fees paid by industry are channelled to the general state budget rather than earmarked for the authority(ies) carrying out the work. This has several implications, but the main one is the issue of hiring enough staff to handle the workload. This finding is further supported by a recent report of the European Court of Auditors who found that the EU food safety system as regards chemicals (i.e. not only pesticides and pesticide residues) is over-stretched and the Commission and Member States do not have the capacity to implement it fully[328].

The costs for the Member State authorities are not fairly distributed either. This is clearly illustrated by the number of active substances evaluated per Member State. Smaller Member States in terms of population and number of authorised PPPs on their market, such as the Netherlands and Sweden, contribute over-proportionately to the functioning of the system.

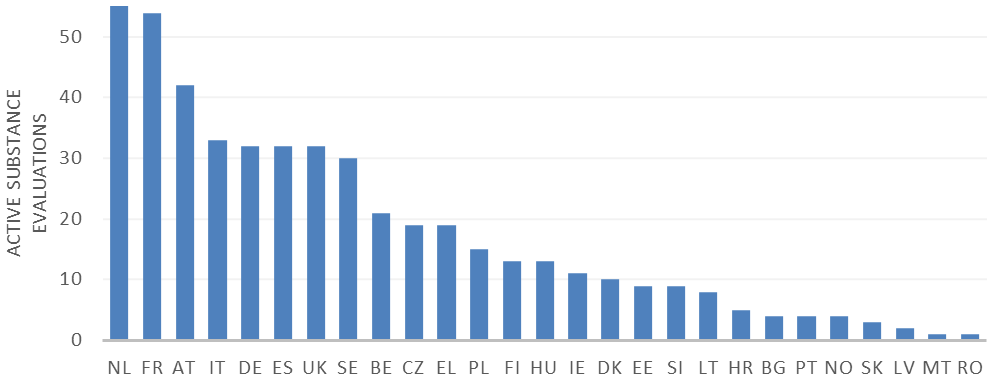


Figure 14. Rapporteur Member State distribution for approvals and renewals of approvals of active substances[329]

There are clear discrepancies in the authorisation of PPPs, with some Member States serving as zonal rapporteur Member State disproportionately often. The United Kingdom, for example, received a high number of applications and was the Member State with by far the highest number of decisions taken when acting as zonal rapporteur Member State. Comparing two Member States from the southern zone clearly illustrates that applicants choose France as zonal rapporteur Member State for evaluation 15 times more often than Spain[330] (see Figure 15). This imbalance in the pattern of applications, and the difficulties which Member States have in cooperating and sharing the work, undermine the PPP Regulation's aim to ensure a fair division of the workload.

328 European Court of Auditors (2019) Special Report No 2: Chemical hazards in our food: EU food safety policy protects us but faces challenges (pursuant to Article 287(4), second subparagraph, TFEU).
329 The Official Journal and summary reports from the Standing Committees on Plants, Animals, Food and Feed.
330 European Commission (2017). Overview report on a series of audits carried out in EU Member States in 2016 and 2017 in order to evaluate the systems in place for the authorisation of plant protection products. DG(SANTE) 2017-6250.

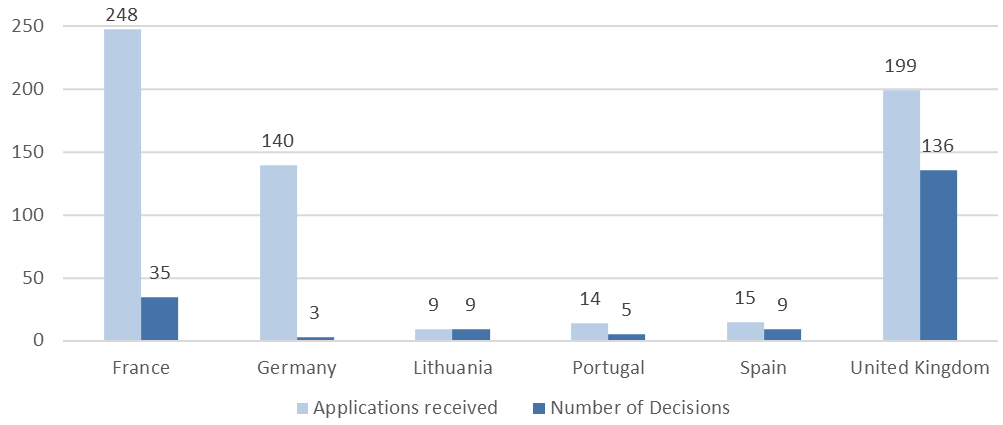


Figure 15. Number of applications received for evaluation (2013-2014) and number of authorisation decisions taken[331]

For approval and renewals of active substances, the cost for EFSA is EUR 3.4 million and for the Commission EUR 2.2 million per year. The combined costs for EFSA and the Commission for MRL procedures are estimated at approximately EUR 3 million per year[332]. None of these costs are covered by fees from applicants. In the financial statement for the PPP Regulation[333] it was expected that 13 full-time staff equivalents (9 administrators and 4 assistants) could carry out the work, but in 2018 there were 18.9 full-time staff equivalents working with the implementation of the Regulation in the Commission. In the financial statement for the MRL Regulation[334], 5 full-time staff equivalents were expected to carry out the work, but in 2018 there were 7.5 full-time staff equivalents working in the Commission with the implementation of the Regulation.

In addition to the work to implement the Regulations, other legally required tasks bind significant resources in the Commission. Such tasks include responding to court cases (25 since 2011) and complaints to the Ombudsman with subsequent investigations (4 since 2011), and access to document requests. In addition, Commission services reply to Parliamentary questions (699 between 2011 and 2017), to objections by Members of Parliament regarding draft Commission Regulations concerning the approval of active substances or amendments of MRLs (11 since 2015[335]), and questions from the special PEST Committee (65 questions between April and June 2018). Finally, Commission departments reply directly to individual letters from citizens and to petitions from citizens, the replies to petitions being published on the Commission's transparency portal[336].

Taken together, all these duties divert Commission resources away from implementing the regulations. This has contributed to delaying the Commission's work on several tasks that were expected to have been implemented by now, such as the adoption of a list of unacceptable co-formulants, a work programme to establish a positive list of safeners and synergists, and MRLs for feed, fish and processed food.

331 European Commission (2016) Overview report on a series of audits carried out in EU Member States in 2015 and 2016 in order to evaluate the control systems in place for the marketing and use of plant protection products. DG(SANTE) 2016-6004 — MR.
332 The support study p. 137.
333 Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market. COM/2006/0388.
334 Proposal for a Regulation of the European Parliament and of the Council on maximum residue levels of pesticides in products of plant and animal origin. COM/2003/0117.
335 This does not include the objection of the European Parliament to the criteria to identify endocrine disruptors in 2017.
336 Transparency portal.

Delays in the procedures for approval and renewal of approval

Decisions on the approval of a new active substance under Directive 91/414/EEC could take more than 8 years[337]. This was because repeated submissions of data were invariably necessary to close data gaps before approval decisions could be issued. To increase efficiency and incentivise speedy evaluations, the possibility to grant provisional authorisations for PPP containing new active substances was removed from the PPP Regulation. To increase efficiency in the procedure for renewal of approvals it was decided to allow submission of new data only during very specific time windows during the evaluation process and only at the request of a Member State or EFSA. The Commission specifically laid down in Implementing Regulation 844/2012 governing the renewal process that any data submitted after the end of the second submission window cannot be taken into consideration[338].

Compared to Directive 91/414/EEC, it takes less time to evaluate and decide on the approval of new active substances under the PPP Regulation: procedures for decisions on the approval of new active substances take on average 3 years and 7 months, with the longest cases taking 6 years[339]. However, the time taken is still slower than required under the PPP Regulation, according to which it is supposed to take 3 years to reach the overall approval decision. Furthermore, an unintended effect of the removal of provisional authorisations has been the use of emergency authorisations for new active substances that are 'in the pipeline'.

The same time frame of three years applies for the procedure for renewal of approval, which breaks down as follows:

- **6 months** between the application for renewal of approval and the submission of the supplementary dossier
- **1 year** for scientific evaluation by the rapporteur Member State when assessing the supplementary dossier for renewal of approvals;
- **11 months** for the peer review and the drafting of a conclusion by EFSA;
- a proposal for a Commission decision through the comitology procedure within **6 months** of receipt of the EFSA conclusion.

In reality, delays occur at almost every step of the process, from the risk assessment by the Member States, during peer review and adopting conclusions by EFSA, to the risk management by the Commission and Member States. Consequently, repeated extensions of the approval periods are necessary to finalise the scientific evaluation and decision-making process for renewals. Extensions of approval were also granted in the transition period between Directive 91/414/EEC and the PPP Regulation to enable applicants to prepare their applications according to the new format and data requirements. These extensions are heavily criticised by NGOs and the European Parliament[340], and the Ombudsman has opened an inquiry following a complaint by an NGO. As a result of the delays, as of October 2018, not a single active substance has been renewed within the initial 10-year approval period.

337 The support study p. 7.
338 Article 13(5) of Regulation (EU) No 844/2012.
339 The support study p. 123.
340 European Parliament (September 2018) Report on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009.

The four most difficult deadlines to meet for renewals are:

(i) The 30-day deadline for the rapporteur Member State to check the admissibility of application(s) and supplementary dossier(s). The result is an administrative check where Member States accept poor quality and sometimes data-deficient dossiers and later accept additional studies to make up for the data gaps encountered during evaluation.

(ii) The 12-month period for the rapporteur Member State to assess the supplementary dossier and draft the renewal assessment report. During this period, Member States may ask for additional information but the period cannot be extended. About 10 % of the active substances are evaluated on time (see Figure 16), while the rest have varying degrees of delays, with some being severe. Figure 16 below presents the delays by the rapporteur Member States for completing the risk assessment for the renewal of approval of active substances. It shows for example that 10 active substances have been evaluated with a nine-month delay, i.e. the time for those Member States to finalise the scientific assessment took in total 21 months. For 6 active substances Member States are 30 months or more late in delivering the draft renewal assessment report.

Since 2016, the Commission has repeatedly reminded Member States of their obligations to keep to the legal deadlines for assessing active substances. Despite these reminders, no improvement has occurred; on the contrary, the delays continue to increase.

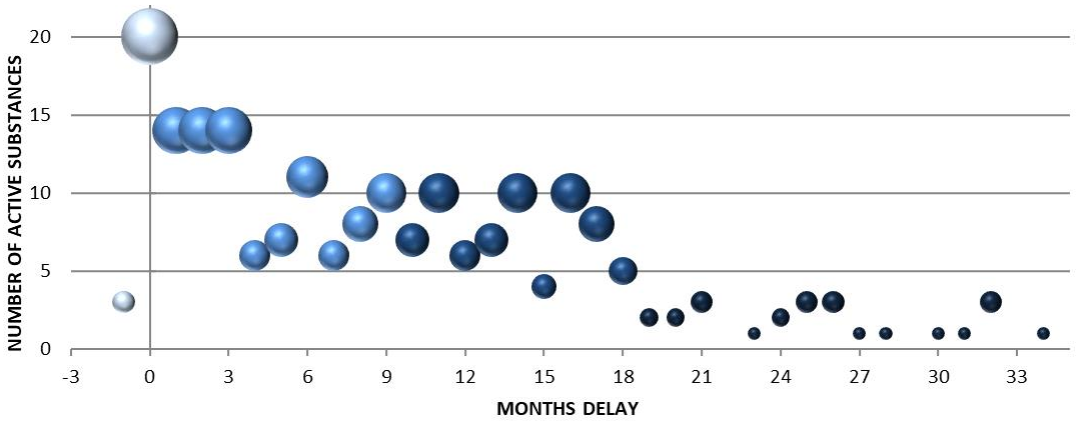


Figure 16. Number of months delay as of October 2018 for Member States to deliver the draft renewal assessment report. Data on 205 active substances for which the supplementary dossier was submitted between 2012 and 2017. The size of the bubbles is proportionate to the number of active substances concerned; the darker the colour, the longer the delay. Calculations made by the European Commission.

In February 2017 the Commission sent a letter to all Member States that were behind schedule, asking for explanation as to why the draft renewal assessment reports were not delivered on time. In response, Member States reported the following reasons contributing to the delays. These show that there is no one single factor behind the delays, but rather a systemic failure:

- The 12-month assessment period to prepare a draft renewal assessment report of a high standard is insufficient without a 'stop-the-clock'[341] possibility. The data requirements have been updated and the expected level of details in the assessment reports is considerably higher than in the past. Recent additional requirements,

341 The stop-the-clock procedure refers to the possibility for the Member State to 'pause' the legal time and ask the applicant for more data.

updated through guidance documents, include the following areas: metabolites, residue definition, impurities, technical specification, endocrine effects, water treatment processes, bees, genotoxicity, assessment of open literature and increasingly complex higher tier environmental studies. Furthermore, there are several cross-cutting areas where EFSA has produced scientific opinions, such as those on weight of evidence and biological relevance that may also have an impact on the complexity of assessments. As a result, the workload per assessment report has increased but the timelines for the assessments have not been adapted to reflect this. Some very large dossiers, such as for glyphosate, demand extraordinary resource requirements.

- Dossiers are sometimes of low quality and studies are missing or not reported to the required standard. Applicants then submit additional studies during the assessment, which delays the process. In some cases the applicant does not have access to the original dossier for the first approval and therefore cannot provide a fully updated assessment for the active substance in question.
- The necessity to re-assess old studies was not laid down in the Renewal Regulation[342]. EFSA requests in-depth re-evaluation of almost all old data in line with new data requirements and international protocols, plus an updated presentation of the results. Re-opening previously submitted studies is sometimes indispensable in order to conclude on the risk assessment, but should not always be required.
- Supplementary dossiers submitted for renewal of approvals were expected to be 'lighter' as they were only an update on top of the original dossier. In reality they have proven to be of similar size, or sometimes larger and more complex, than dossiers for new active substance approvals. The assessment of relevant open literature and datasets greatly increases the time the Member State needs to complete the process.
- Multiple applicants who submit separate dossiers significantly increase the workload, while the timeline laid down for preparing the draft renewal assessment report anticipates only a single application.
- The risk assessment requires expertise, which is not easy to find. This is a considerable challenge, especially for small Member States. Training experts is costly and time consuming, while outsourcing is not a viable short-term solution due to the very specific expertise required. Moreover, new developments make continuous training necessary to ensure that experts can perform assessments that reflect the latest scientific and technical knowledge. Also, since the number of active substances allocated to some Member States tends to fluctuate, those Member States find it difficult to manage the human resources working on the assessments.
- Aligning the risk assessment process with the Classification, Labelling and Packaging Regulation is a significant additional burden and is affecting an increasing number of substances.

(iii) The two-month period for the rapporteur Member State to evaluate additional information during the peer-review process. During the peer-review process, EFSA may, following consultation with the rapporteur Member State and the co-rapporteur Member State, request additional information from the applicant, setting a deadline of 1 month for the applicant to provide such information. The rapporteur Member State then has 2 months to evaluate the additional information and update the renewal assessment report.

342 Commission Implementing Regulation (EU) No 844/2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances

In many cases, the number of additional requests is significant. For example, for the active substance chlorpyrifos there were 162, 98 and 90 points of additional information requested from 3 applicants. The additional information submitted to the Member States is extensive and requires far more time than the two-month period allowed for by the legislation. In some cases, entire sections need to be re-written and the risk assessments completely re-performed. This leads to severe delays.

(iv) The six-month deadline for the Commission covers preparation of the draft renewal report and a draft Regulation deciding on the renewal (or not) of the approval of an active substance. While the Commission presents a review report within the 6 months in 75 % of cases[343], adoption of the implementing Regulations to renew (or not) the approval of active substances takes between 7.5 months and 3 years, with an average of 15 months[344]. This leads inevitably to the extension of the approval periods. To avoid this it would be necessary to conclude the entire process including the adoption of the decision within 6 months. This has proven to be unrealistic given that the internal Commission procedures for preparing a formal draft Regulation and adopting it after the vote in the Standing Committee take already about 3 months. For many substances, extensive discussions are necessary in the Standing Committee to secure the necessary support for the draft Regulation. In a growing number of problematic cases, Member States' positions (or absence of positions) have led to the votes resulting in 'no opinion', which makes it necessary for the Appeal Committee to meet, causing further delays.

As described at the beginning of this section, the decision to only allow submission of new data during very specific time windows in the renewal process was well intended for historical reasons, but the unintended negative consequences have proven to outweigh the benefit of having a streamlined process. There have been several cases, such as flurtamone and fosetyl, where the rapporteur Member State has accepted a complete dossier and performed a scientific assessment recommending renewal of approval, only for EFSA to identify data gaps following the peer review. At that moment in time, such data gaps cannot be addressed by the applicant — even though the relevant studies may exist. If the uncertainties are significant, the approval of the active substance may not be renewed, the only option for the applicant being to re-apply to have the active substance approved as a new active substance. This would create considerable (unnecessary) work for the Member States, EFSA and the Commission and come at significant cost to the applicant. Analysis of the workflow shows that the problems relate to:

- the late involvement by EFSA and sometimes by other Member States, who identify more data gaps than the rapporteur Member State;
- the rigidity of the system, which does not allow information to be accepted at a late stage to close data gaps identified late in the process or outside the permitted submission period during the peer-review process. The fact that new information cannot be taken into consideration even when it could solve a critical area of concern for an active substance is then a source of delays in the decision-making process described before.

The problem with regulating PPPs efficiently is not unique to the EU. Canada experiences similar problems due to limited resources coupled with the requirement to periodically review the registration of active substances and products. This has become increasingly demanding and unsustainable in the long term in view of the resources

343 Calculated for 60 active substances where data were available.
344 Calculated for 52 active substances where data were available.

required. The workload pressures are impacting the performance of the evaluating authority, as well as the ability of the authority to respond to stakeholders' expectations and react to emerging issues. To manage the situation, the Canadian authorities are prioritising the evaluation of the most hazardous active substances and have started a process to review the activities relating to the pesticide re-evaluation programme with a view to increasing both the efficiency and the effectiveness.

Another point of comparison is the United States (see section 2.3 on the baseline — other points of comparison), as the US system is considered by industry in the EU as more efficient and predictable. The US system seems to allow for a more narrow and focused renewal assessment in which it is determined if new data are needed and what data are needed upfront, in US parlance this is called 'data-call in'. As identified above, one of the reasons for the delays in the EU is that the rapporteur Member States often needs to re-assess at least parts of old dossiers during the risk assessment; in the US the Environmental Protection Agency decides earlier whether this is necessary. In addition, while in the EU system the need for further data often only emerges during the peer-review process and the time available at that stage often does not allow the applicant to submit all the required additional information to alleviate possible concerns, in the United States it is decided upfront what new data are needed from the applicant. Indeed, one of industry's main criticisms of the EU system is that it is unpredictable.

Considering available data for re-registration process, the US system is not necessarily a more efficient way of evaluating active substances. According to a report in 2007, in the US, the median time for the re-registration process was 30 months and the average 54 months indicating that the distribution is skewed with some assessments being relatively straightforward while others require considerable resources[345]. More recently, the US EPA estimated[346] that the average review period is 6 years. In the EU, the renewal of approval of the active substance has taken on average 43 months and in addition it takes 12 months for re-authorisation of the PPP, i.e. a minimum of 55 months. Also in the EU, there is high variability between active substances due to their complexity. Similar to the EU, the US struggles with considerable backlog and severe delays during the re-registration process. One of the sources of delay are the responses to the data call-in, which require a lot of time for the registrants to prepare and submit, as well as for the Agency to receive, track, review, and respond to (if required). These are the same problems as identified in the EU. Another issue is also the quality of data from registrants, and in order to fill data gaps additional time is required for the registrant to prepare and submit studies and for the Agency to review them. Thus, considering the problems identified and looking at available data, it is difficult to give a definitive answer as to how much more efficient the US system is, if at all. Moreover, several of the inefficiencies identified in the EU system can be solved by better cooperation between the Member States and EFSA. Earlier involvement by EFSA (in e.g. pre-submission meetings) could also solve certain issues — some which are already addressed by the proposal to amend the General Food Law Regulation.

When comparing to the Biocidal Products Regulation in the EU, it emerges that the evaluating authorities are facing similar or even more severe delays in the work to implement the Biocidal Product Regulation. In fact, originally, the review programme of all existing active substance on the market was intended to be completed in 10 years

345 Environmental Protection Agency (2007) Evaluation of the U.S. EPA Pesticide product Reregistration Process: Opportunities for Efficiency and Innovation.
346 Estimate provided by the US EPA during a meeting with the Commission services on 2-3 April 2019.

(from 2004 to 2014), but had to be extended by 10 years when the Biocidal Products Regulation was adopted. So far, it is not assured that the new deadline will be met as the delays for evaluating Member States to submit the assessment reports keep growing. For new active substances, the procedure for approval takes on average 44 months, again longer than foreseen in the Regulation. This is far better than under the previous Biocidal Products Directive were dossiers for new active substances were assessed on average within 62 months with a minimum of 35 months and maximum up to 122 months.

However, the Biocidal Products Regulation is more efficient during the risk management phase. One reason is that the risk assessment results in a single opinion by the Biocidal Products Committee of the European Chemicals Agency (ECHA) composed of Member States experts, rather than dual outputs of a rapporteur Member State Assessment Report and EFSA Conclusions under the PPP Regulation. While there are often lengthy discussions in the Standing Committee for Plants, Animals, Food and Feed on approvals of active substances, in general under the Biocidal Products Regulation, most of the decisions on the approval of active substance proposed by the Commission were swiftly and unanimously supported by the Member States in the Standing Committee on Biocidal Products.

In conclusion, this comparison is intended to demonstrate that complex and demanding legislation such as the PPP Regulation is challenging to manage in view of the limited resources available – but similar problems exist for other comparable legislation in the EU and also in other jurisdictions.

Efficiency of the cut-off criteria

The cut-off criteria were introduced with the PPP Regulation to increase the protection of human health and the environment (see section 5.1.1 for an in-depth discussion of these). The cut-off criteria were also expected to reduce the workload for the evaluating authorities by reducing the need for full assessments since such substances would be identified early and the assessment would be limited. However, this efficiency gain has materialised only for the 13 active substances for which no applications for renewal were submitted and where no evaluation needed to be carried out. For the other eight active substances meeting the cut-off criteria, the workload for Member States was the same as when Member States conduct full risk assessments, or higher, although a step-wise approach was envisaged[347].

Derogations[348] can be applied for several of the cut-off criteria. In combination with the absence of initial harmonised classification, this has led to increased workload and delays in the assessment of active substances. To illustrate this, in the case of bromoxynil there was no harmonised classification for any of the cut-off criteria in place when the applicant submitted the dossier, and the rapporteur Member State did not propose a new harmonised classification. However, after the peer review, EFSA considered a classification according to which the substance would fall under the cut-off criteria (as toxic for reproduction category 1B) to be more appropriate. Consequently, the applicant had to be given the possibility to demonstrate whether the derogation possibilities could apply, and the evidence submitted had to be assessed. This made an additional peer review necessary before EFSA could publish a conclusion on the outcome of the peer

347 According to the second subparagraph of Article 4(1) of Regulation (EC) No 1107/2009.

348 Very limited derogation possibilities exist for active substances where the applicant demonstrates that exposure is negligible (Annex II to the PPP Regulation), or where the active substance is needed in order to control a serious danger to plant health which cannot be contained by other available means (Article 4(7) of the PPP Regulation). No derogation possibilities exist for active substances that are classified as mutagenic 1A or 1B, or for active substances that are POP, PBT or vPvB.

review. Naturally, this process took longer than initially envisaged and more resources were required than first expected. Similar delays were incurred for pymetrozine and flupyrsulfuron-methyl.

In addition, the decision-making on the renewal of approval of the active substance flumioxazin was affected by delays owing at least in part to the absence of agreed guidance to assess negligible exposure and the delayed finalisation of the protocols to assess a serious danger to plant health[349].

Rather than simplifying the scientific evaluation by the Member States, the cut-off criteria have thus led to an increase in the workload and delays in the system, which have increased the costs of the procedure.

Delays in authorising PPPs

The authorisation process for PPPs in Member States is also affected by severe delays, with legal deadlines in the PPP Regulation for granting authorisations for PPPs being exceeded for all types of authorisations. Mutual recognition is particularly affected, with the compliance rate with legal deadlines in some Member States being below 5 %. This results in delayed or reduced access to pest-control tools for growers, while the availability of PPPs varies among Member States, even for those in the same zone. Such delays clearly reduce efficiency and might also affect the effectiveness of the Regulation in reaching its objectives as PPPs may remain on the market under earlier authorisations although the conditions of authorisations would need to be tightened. The legal requirement for systematic re-authorisation of all PPPs following a renewal of approval of an active substance increases the pressure on an already overloaded system[350].

The most problematic delays are those in mutual recognitions and when authorising PPPs as concerned Member State within a zone. There is consensus among Member States that more time is needed. The envisaged deadline is 4 months but in reality Member States take on average 10 months. In some Member States there are cases where it has taken more than 2 years to authorise a PPP through mutual recognition or as a concerned Member State. Another particularly problematic procedure is the re-authorisation of PPPs after the renewal of approval of their active substance. This is because the re-authorisation should be granted 9 months following the application for authorisation which needs to be submitted at the latest 3 months following the renewal of approval of the active substance. It is difficult for the Member States to plan their work because it is unpredictable when the re-approval decision will be made at EU level. As with the renewal of active substances, re-authorisation is more burdensome than expected because of the need to consider requirements on additional new information or higher tier tests that are not available at the time of the first authorisation. On top of the problems with the procedure per se, Member States also fear that with the increasing number of renewals in the pipeline they will be overloaded with work and unable to deal with other procedures.

Delays also occur in situations where, following an initial negative conclusion on an evaluation, applicants are allowed multiple opportunities to submit further studies to satisfy the requirements[351]. Member States explained that they request additional

349 The guidance document on the derogations for 'negligible exposure' has not been finalised (as of October 2018). The EFSA protocols for the evaluation of active substances to control a serious danger to plant health were finalised in July 2016 for herbicides, in April 2017 for insecticides and in December 2017 for fungicides.

350 European Commission (2017). Overview report on a series of audits carried out in EU Member States in 2016 and 2017 in order to evaluate the systems in place for the authorisation of plant protection products. DG(SANTE) 2017-6250.

351 Ibid.

information during mutual recognition because the quality of the dossier is poor or because it is outdated when the application is submitted. This is despite mutual recognition applying to all existing authorisations, including those based on approvals under Directive 91/414/EEC, as confirmed by a national court in Germany[352].

This failure to fully use the possibilities offered by the zonal system and mutual recognition is all the more deplorable given that: (i) in 56 % of cases, the authorisation granted by the concerned Member State or through mutual recognition remained identical to that granted in the Member State of origin; and (ii) in 27 % of cases, the PPPs were authorised with different risk mitigation measures. As a result, in most cases authorisation is delayed beyond the deadlines, even though the outcome of the extra evaluation conducted by the concerned Member States is either the same or very similar to the original authorisation[353].

As described in section 5.1.4, there are particular difficulties with mutual recognition reported in the central zone. This has been somewhat counterbalanced by the United Kingdom, which is the Member State with by far the highest number of decisions taken when acting as zonal rapporteur Member State. This offsets to some extent the problems in the central zone by allowing applicants to apply for mutual recognition of the authorisations in other Member States of the central zone[354]. In fact, benefits do materialise for those Member States, as seen in section 5.1.5: Member States who use mutual recognitions to a large extent have also increased the number of available PPPs on their national market the most.

Efficiency of the MRL procedures

Overall, stakeholders and Member States consider that the procedure to establish MRLs is efficient and that the benefits outweigh the costs. On average, an application to establish MRLs is addressed (i.e. the MRLs become applicable) within 24 months from its submission. However, the length of the process varies greatly depending on how fast the evaluating Member State assesses the application. While the MRL Regulation specifies clear deadlines for EFSA and the Commission, it does not set out a timeline for the evaluating Member State. This makes the overall process unpredictable. Moreover, applications are often submitted incomplete and the assessment is put on hold either by the evaluating Member State or by EFSA pending the submission of the missing data. In this case also, no deadline for submission is specified. To address these issues, the Commission has recommended that the evaluating Member State complete the evaluation of an application within 12 months (plus 6 months if the applicant has to submit additional data). Where it is clear that the applicant cannot fulfil the data requirements within a reasonable period, the evaluating Member State should contact the applicant, requesting that it withdraws the application.

As the MRL Regulation does not provide means to promote minor uses, the Commission and Member States have developed a guideline on the extrapolation of MRLs[355]. An example of how the extrapolation of MRLs works is presented in Table 9. For minor crops, the applicant must perform four residue trials only, whereas for major crops a minimum of eight trials is required.

352 Summary of the two judgments in German. (Aktenzeichen: 9 A 27/16; 9 A 28/16).

353 European Commission (2017). Overview report on a series of audits carried out in EU Member States in 2016 and 2017 in order to evaluate the systems in place for the authorisation of plant protection products. DG(SANTE) 2017-6250.

354 Ibid.

355 European Commission (2017), Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (SANCO 7525/VI/95 Rev. 10.3).

Table 9. Example of extrapolation alternatives from major to minor crops

Bulb vegetables	onions	→	garlic
			shallots
	leeks	→	spring onions/green onions and Welsh onions
	onions	→	Whole group of bulb vegetables

The Regulation does not offer any guidance or flexibility in cases where an application is made to set an MRL for a minor crop on the basis of extrapolation from a major crop; to remedy this, a fast-track procedure was agreed with the Member States ad hoc. In this simplified procedure, neither a thorough evaluation report nor an EFSA reasoned opinion is needed. Overall, the above described measures were introduced to ensure that MRLs could be set faster for minor uses.

In exceptional cases, MRLs can be set on the basis of monitoring data. However, there are no provisions outlining how this should be carried out, so decisions are taken on a case-by-case basis. Furthermore, such situations are addressed by setting temporary MRLs, which have a maximum validity of 10 years. This may be inappropriate for addressing certain cases of environmental contamination for persistent substances where only a permanent MRL would provide for a solution in the long term and where no reductions are expected in a time span of 10 years. The automatic lowering of the temporary MRLs may cause difficulties where new monitoring data are submitted at a late stage to extend the validity of the MRL. This is because the overall MRL-setting process takes time and the lowering of the temporary MRL needs to be prevented by applying retroactive application dates in an MRL measure[356]. The Commission recently started setting deadlines for the submission of new data by the applicants concerned rather than applying an expiry date to the temporary MRL.

The current provisions are somewhat inflexible since the MRL-setting process is always triggered by the submission of an application. This prevents the Commission from taking the initiative, even in cases where new information is available that points to the need for a review of an existing MRL related to a public health concern and an EFSA opinion confirms such a concern. Legal clarifications became necessary, delaying the procedures and thus decreasing overall efficiency.

Moreover, even when immediate action is needed, EFSA still has to issue a thorough scientific opinion. In fact, the MRL Regulation considers EFSA as the only competent authority in matters of food safety. It does not provide for the possibility to consider assessments carried out by other European agencies such as the European Medicines Agency . This causes duplication of work when setting MRLs for substances used both in plant protection products in and veterinary medicinal products (see also section 5.1.7. on enforcement) [357].

The procedure to review MRLs is considered by stakeholders and Member States to be less efficient than the procedure to establish MRLs and the main reasons of this lower

356 See Article 2 of Commission Regulation (EU) No 241/2013 of 14 March 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole, fludioxonil and prohexadione in or on certain products (OJ L 75, 19.3.2013, p. 1).

357 Commission Regulation (EU) 2017/623 of 30 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, amitraz, coumaphos, diflufenican, flumequine, metribuzin, permethrin, pyraclostrobin and streptomycin in or on certain products (OJ L 93, 6.4.2017, p. 1).

efficiency are the delays in the procedure and the insufficient alignment with the PPP Regulation[358].

The MRL review is a tool to:

- take stock of the authorised uses in plant protection of a given active substance per crop across the EU;
- ensure that all critical uses are supported by data according to the pertinent data requirements;
- align the legislation with international standards, where appropriate; and
- ensure that all MRLs are sufficiently protective for European consumers.

The implementation of the MRL review was initially hampered by a number of factors: (i) the formal lack of involvement of Member States in the review process; (ii) the need to establish a working procedure to collect and assess the relevant information; (iii) the absence of empowerment of the Commission to put in place implementing Regulations in this regard; and (iv) the unrealistic timeline to complete the review of all MRLs existing at the time when the Regulation became applicable. The first two issues have since been addressed through voluntary involvement of the Member States and pragmatic arrangements between Member States, EFSA and the Commission. However, the Member States cannot request fees to cover their resource needs and the lack of such an incentive further delays the overall process. Also the resources attributed to EFSA are not sufficient to meet the tight deadlines. Currently, MRL reviews for about 24 substances are completed per year and overall about half of all MRLs have been reviewed so far.

A major cause of inefficiency of the MRL review procedure is the lack of integration with the periodic renewal of the approval of active substances under the PPP Regulation. The toxicological reference values agreed in the peer review of the approval/renewal of approval assessment are an important input for the MRL review, and revisions to the approval conditions may affect the authorisations of PPP for use on certain crops. Therefore, the timing of the MRL review relative to the various procedures under the PPP Regulation is crucial to maximise the benefit from the MRL review and to prevent MRL review results becoming obsolete. Here also, the absence of empowerment of the Commission to put in place implementing Regulations addressing the interplay between the PPP Regulation and the MRL Regulation hampers more efficient implementation. A pragmatic approach was agreed between the Commission, EFSA and the Member States to minimise inconsistencies: MRL reviews are now scheduled after the renewal process so as to take into account the possible new toxicological reference values and new residue definition recommended by EFSA after the peer review of the renewal assessment. This, however, obviously further delays the MRL review process.

5.2.3. Benefits to human health and to the environment

A full, comprehensive quantification of the health and environmental benefits of applying the approval criteria in the PPP Regulation was not possible due to problems in assessing causality (see sections 5.1.1 and 5.1.2[359]). Nevertheless, the non-approval of substances on health-based criteria has contributed to avoiding risks, e.g. from genotoxicity, toxicity to reproduction, carcinogenicity or acute poisoning. Similarly, the

358 The support study, p. 138.

359 A cost-benefit analysis of the kind carried out for the REACH Regulation could not be carried out for the PPP and MRL Regulations as data on actual use are not accessible. For REACH, the health benefits were estimated at EUR 700 million per year due to a reduction of exposure to e.g. mercury and lead. However, that report also acknowledged that a number of benefits could be qualitatively assessed only. Ref: ECHA (2016) Cost and benefit assessments in the REACH restriction dossiers. doi: 10.2823/57600.

non-approval of substances due to environmental concerns has led to the avoidance of risks to groundwater, soil and wildlife.

Several economic studies have tried to quantify the costs of using PPPs on healthcare and on the environment, e.g. due to loss of biodiversity. The problem in relying on these studies for this evaluation is that they are either old or use old data which actually capture the effect of Directive 91/414/EEC. Compared to the time when Directive 91/414/EEC was in force, i.e. the baseline, more than 50 % of all active substances have been removed from the market. Thus, the expected economic benefits such as reduced healthcare costs and reduced costs for remedying environmental damage started already under Directive 91/414/EEC. The PPP Regulation is sustaining and fostering those benefits through the implementation of strict approval criteria. A (rough) estimate of the health benefits has been made based on one study[360] assessing the health impact and damage costs of pesticides in the EU (see section 5.1.1 for further details). According to our calculations (see Annex 3), the non-approval and withdrawal of five active substances[361] under the PPP Regulation has contributed to annual cost savings of about EUR 38.5 million for human health. These are the benefits that could be quantified and covers only a few active substances non-approved in the EU since 2011. The overall benefits are expected to be considerably larger. To give a flavour of the magnitude of costs versus benefits, the quantified benefits of EUR 38.5 million can be compared with the costs spent on the renewal of approval of the five active substances which is calculated at EUR 6.6 million[362]. This comparison shows that the benefits in these cases outweigh the costs incurred by the PPP Regulation for non-renewals of approvals.

The setting of MRLs at safe levels is also expected to have generated positive monetary benefits for human health, but these could not be quantified. Quantification of these benefits was not possible as there is a very high number of different possible combinations between substances, crops, and MRLs. An aggregation of the effects of the different MRLs on human health cannot be performed, and exploring the health effects of single substance residues on specific crops would not provide a complete picture.[363]

As described in section 5.1.2, the use of PPPs has been identified as one of the contributing factors to the decline in bee populations, although the magnitude of its role is unknown and most likely varies between regions. The multiple reasons behind the decline in bees make it impossible to estimate the benefit of restricting the use of pesticides harmful to bees, such as the three neonicotinoids imidacloprid, clothianidin and thiamethoxam. However, the restrictions can be expected to contribute to an improvement in pollination services, which overall are estimated to generate economic benefits of around EUR 15 billion per year in the EU[364].

The impact assessment accompanying the proposal for the PPP Regulation estimated costs of treating drinking water at EUR 30 million in the Netherlands[365] and EUR 184 million in the United Kingdom[366]. Recent estimations of the costs of treating drinking water in the EU are scarce and this evaluation did not identify any relevant studies

360 Fantke, P., Friedrich, R., and Jolliet, O., (2012) Health impact and damage cost assessment of pesticides in Europe. Environment International Vol 49, p 9-17. https://doi.org/10.1016/j.envint.2012.08.001.

361 amitrole, glufosinate, linuron, methomyl and propineb.

362 See Annex 3 for calculation and further explanation.

363 The support study, p. 136.

364 European Commission (2018c). EU Pollinators Initiative. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. COM(2018) 395.

365 Kiwa N.V Water Research 2004: Door drinkwaterbedrijven gemaakte kosten als gevolg van bestrijdingsmiddelgebruik, Nieuwegein, p 3.

366 DEFRA 2003, Partial Regulatory Impact Assessment: Groundwater Proposals under Article 17 of the Water Framework Directive, p12.

published after 2011. However, as reported in section 5.1.2, monitoring the occurrence of pesticides in surface water suggests that implementation of the PPP Regulation has brought some improvements, and this trend is expected to continue. As a result, the cost of removing pesticides from drinking water is likely to have decreased in the EU since the baseline period, i.e. before 2011.

5.2.4. Societal and agricultural benefits and costs related to PPPs in the EU

The agricultural sector provides benefits in the EU, some of which accrue from the use of PPPs. The quantity and quality of food produced in the EU may be dependent on the use of effective PPPs. There is a high demand for fresh produce free of marks, spots and dents and with a long shelf-life. PPPs contribute to higher yields and are used to prevent rot and moulds of harvested produce.

The EU agricultural sector also provides employment opportunities in rural areas. PPPs affect the competitiveness of EU agriculture as the availability or not of PPPs may influence decisions to move to cultivating less human-resource-intensive crops. Furthermore, there are certain crops that are of cultural importance, e.g. rice in Portugal and Italy, where it is important to have access to certain PPPs to protect this crop.

As the PPP Regulation has been effective in ensuring sufficient availability of PPPs, at least for major crops (see section 5.1.5), it has generated benefits for the EU agricultural sector. However, it is difficult to quantify these short-term benefits and to estimate the PPP Regulation's contribution to making PPPs available for use in the EU agricultural sector. Agricultural productivity and profitability are indeed affected by multiple factors, including significant subsidies through the Common Agricultural Policy.

In the long term, a high level of environmental protection through the PPP Regulation can ensure sustainability of farming (e.g. through preserved biodiversity and soil fertility) and therefore lead to food security.

The availability of PPPs generate other benefits that are not related to the agricultural sector: for instance, weed control on railways. In these situations, weeds are often controlled using broad-spectrum herbicides and the availability of such PPPs is important for public safety needs. In the United Kingdom, manual weeding and other maintenance of the railway network could increase costs by as much as EUR 99 million[367] a year if it were not possible to use glyphosate.

Another benefit not related to agriculture is landscape management, in particular in controlling invasive species. The control of bracken (a type of fern) on hills in the United Kingdom is one example where the active substance asulam is the only efficacious alternative[368]. Since the active substance was not approved in 2011, the only viable method has been for the United Kingdom to issue emergency authorisations for asulam, which is not a long-term sustainable solution. This shows the benefit of having emergency authorisations in the PPP Regulation, while highlighting deficiencies in the system, as the active substance asulam actually does not meet the strict approval criteria.

5.2.5. Benefits from the single market and international trade

Cost savings from the zonal system

367 Oxford Economics (2017) Economic impact of a glyphosate ban — Impact on the rail network.
368 Article in the Guardian, Uplands protest over ban on bracken spray.

The cooperation of Member States during the zonal evaluation of an application to authorise a PPP creates somewhat higher upfront costs. This is because the reference Member State has to consult the concerned Member States on the draft assessment report and the concerned Member States should review and comment the draft assessment report. However, these should be more than compensated by gains later on thanks to lighter procedures when authorising PPPs through mutual recognition as the concerned Member State. Mutual recognition across zones should also lead to cost savings both for industry and Member States.

It has been estimated that authorisations for a concerned Member State are 2.6 times less resource-intensive than for reference Member State authorisations, while mutual recognitions are 4 times less resource-intensive than reference Member State authorisations[369]. Monetising these benefits gives a figure of EUR 15 000 for each concerned Member State per PPP authorised. For mutual recognition procedures across zones, the authorisation cost is almost EUR 20 000 lower for Member States. Moreover, the fees for industry mirror the costs: for zonal authorisation the fees are, on average, EUR 30 000 in the reference Member State, EUR 10 000 for mutual recognition and EUR 6 000 for authorisation in a concerned Member State[370]. In other words, concerned Member State authorisations and mutual recognitions offer efficiency gains in lower fees for applicants and reduced burden for Member States. Overall, during the five-year period between 2012 and 2016, Member States (and also applicants as they pay fees) saved EUR 13-17 million compared to what they would have spent if they had issued standard authorisations only[371]. There was no estimation of the number of expected mutual recognitions in the impact assessment accompanying the proposal for the PPP Regulation, meaning that comparison with an 'ideal' situation is unfortunately not possible.

Benefits of international trade

In 2017, the EU maintained its position as the largest global exporter and importer of agri-food products, reaching a total value of EUR 255 billion[372]. Of this figure, EUR 117 billion can be attributed to imports. This shows how important it is to set clear provisions in the MRL legislation for the setting of import tolerances and for the adoption of Codex limits. The EU is compliant with international standards, and the MRLs based on EU uses can also accommodate import tolerances for the crops concerned if these are grown inside and outside of the EU. The EU also benefits from trade facilitation through import tolerances as this allows for the import of crops not grown in the EU, while increasing the availability of the entire range of food products throughout the year.

The export of agri-food products accounts for EUR 138 billion. The global demand for food is likely to increase with population growth and changes in consumer preferences. The EU's agri-food sector stands to gain from this demand growth. Non-EU countries are attracted by food produced in the EU because of its reputation as offering safe, sustainably produced, nutritious and quality products. In particular, non-EU countries rely on the stringent assessment provided for by the MRL Regulation in relation to consumer protection.

The MRL Regulation is therefore contributing positively to promoting international trade both by allowing imports as well as by attracting markets in non-EU countries. However,

369 The support study p. 132.
370 The support study, table 5.2, p. 131.
371 The support study, p. 132.
372 European Commission (2018), Monitoring Agri-trade Policy 2018-1, Agri-food trade in 2017.

an aspect which might harm trade is the timeline for the setting of import tolerances, which is considered by trade partners as being too long to prevent the lowering of MRLs following the withdrawal of an EU use.

5.3. Coherence

- To what extent have the MRL Regulation and PPP Regulation put in place a coherent policy on pesticides?
- To what extent is the legal framework consistent with agricultural policies, food policies, environmental policies and policies on chemicals and biocides?
- To what extent is the legal framework consistent with international rules and agreements related to trade, food, environment and chemicals?
- Where coherence is not achieved, what factors or elements have hindered its achievement? Which are the main differences, overlaps and inconsistencies? How do these shortcomings impact the compliance level?

MAIN FINDINGS

For the most part, the Regulations show internal coherence and are consistent with one another. The exceptions are the interplay of the review of MRLs with the renewal of approval of active substances leading to unnecessary administrative burden. The fact that the cut-off criteria in the PPP Regulation are not reflected in the MRL Regulation is another inconsistency leading to potentially significant trade implications with non-EU countries.

Consistency with other EU policy areas is moderate as the interactions with policies on foods for infants and young children, hygiene policy, and chemicals legislation regarding persistency may all require attention.

The cut-off criteria in the PPP Regulation are controversial at international level in the framework of the WTO. On the other hand, the EU regularly incorporates Codex limits that are safe for consumers into its MRL legislation (see Figure 12).

The definitions of 'plant protection product' and 'pesticide residue' could be updated to increase clarity in relation to substances used also for other purposes.

5.3.1. Pesticides policy area

The PPP and MRL Regulations are considered to be overall internally coherent. However, the following areas have been identified as not fully coherent by the Member States and the Commission during their work as risk managers and lead to problems in implementing the Regulations.

Internal coherence of the PPP Regulation

- Article 4(1) provides for a step-wise approach in the scientific evaluation for cut-off criteria, i.e. if an active substance meets at least one of the cut-off criteria, the Member State can stop the assessment. This simplification of the safety assessment of an active substance has not yet happened, as described in section 5.2.2 above. This is already an inconsistency in itself: the provision was meant to simplify the process with a step-wise approach, but in fact the Regulation requires a full risk assessment to allow for the evaluation of the derogation possibilities based on negligible exposure and/or essential use under Article 4.7. Furthermore, the cut-off criteria mentioned in Article 4(1) are not consistent with Annex II, which contains more cut-off criteria

(e.g. endocrine disrupting properties). This results in difficulties at implementation stage.

- Grace periods for sale and use of stocks of PPPs following non-renewals of approvals of active substances are covered by both Article 20(2) and Article 46; the wordings in the two articles differ, leading to questions about their respective scope of application.
- PPPs containing exclusively basic substances are not subject to the EU rules on authorisations (Article 28(2)(a)). Consequently they may not be marketed as PPPs nor labelled as such. In light of the growing importance of alternatives to PPPs, this creates questions regarding the availability and the transmission of appropriate user information to consumers and workers using basic substances. Moreover, uncertainties arise where a producer applies for approval of an active substance that is already approved as a basic substance – or vice versa.
- The provisions related to authorisations (Article 31) and labelling of PPPs (Article 65) are currently not fully aligned as regards the use of Integrated Pest Management.

Internal coherence of the MRL Regulation

- Article 49 provides for the possibility to grant transitional measures in several circumstances to allow for the normal marketing, processing and consumption of products. However, the procedure for modifications of MRLs following revocation of authorisations of PPPs (Article 17 of the MRL Regulation) is not explicitly covered by this Article, despite the fact that this is currently the most frequent case where transitional measures would be needed to give trade partners the possibility to adapt to the lowering of EU MRLs.

Definitions

Some definitions in the PPP and MRL Regulations are identified as problematic and lacking clarity. A majority of the Member States and stakeholders (in particular from the agricultural, food and feed, and PPP/chemical industry)[373] have identified that there is a need for changes to the definitions of **plant protection product**[374] and **pesticide residues**[375]. For PPPs, Member States and stakeholders consider that there is a need for clarification on dual and multiple-use substances as well as for naturally occurring substances[376], e.g. active substances used in plant protection products and in growth stimulants and biocides. The definition should also include the possibility to use 'product in bulk' and a definition of '*in situ* production', in order to cover innovative modes of action of formulations. For pesticide residues, Member States argue that the definition should be clarified to ensure that appropriate enforcement action can be taken for multiple source substances. As regards the scope covered by the MRL Regulation, some Member States proposed that the definition of pesticide residues should also cover unacceptable co-formulants, adjuvants, safeners and synergists, and that some flexibility would be needed to exceptionally remove from the scope very specific active substances (e.g. substances such as chlorate that have not been used in PPP for a long time, but occur due to other legitimate uses) in order to regulate them under another more appropriate legal framework.

373 The support study, pp. 175 and 176.
374 The scope of what is a plant protection product is provided in Article 3(1) of Regulation 1107/2009.
375 Article 3(2)c of Regulation 396/2005.
376 REFIT Platform Opinion on the submission by a member of the REFIT Platform Stakeholder Group on "Multiple use/Multiple source substances – Chlorate", 7 June 2017

Consistency between the PPP and the MRL Regulations

Consistency between the MRL Regulation and the PPP Regulation is ensured by a logical sequence starting with the active substance approval. The application[377] for approval of an active substance has to include, where relevant, an application for a MRL[378]. This pre-requisite for MRL application avoids approving active substances for which no safe MRL can be set and therefore ensures good resource management.

Authorisations of PPPs cannot be granted until the relevant MRLs are in place[379], so the process is sequential. To minimise delays, the Commission prepares a draft measure setting MRLs as soon as the approval decision under the PPP Regulation is made. This approach is also supported by the Ombudsman[380].

Consistency issues have arisen between the review of MRLs[381] and the renewal of approval of active substances. The procedures are currently not sufficiently aligned and have resulted in duplication of work and unnecessary updates of EFSA opinions on MRL reviews that became obsolete after the renewal process. As mentioned in section 5.2.2, in the absence of any provisions in the Regulations, a pragmatic approach was agreed between the Commission, EFSA and the Member States to minimise inconsistencies by scheduling MRL reviews after the renewal process so as to take into account the possible new toxicological reference values and new residue definition recommended by EFSA after the peer review of the renewal assessment.

The support study identified that the PPP Regulation and MRL Regulation have different definitions of vulnerable groups (see page 179 of that study). The MRL Regulation defines vulnerable groups as 'children and the unborn' while the PPP Regulation extends this definition to also include 'nursing women, the elderly and workers and residents subject to high pesticide exposure over the long term'. No issues have been reported to date as a result of this, although the existence of different definitions potentially could have an effect on the risk assessment when setting MRLs.

The MRL Regulation divides the EU into two zones for the evaluation of residue behaviour and the setting of MRLs, a northern European and a southern European zone. This is inconsistent with the PPP Regulation, which has established three zones for the purpose of granting authorisations for PPPs. The number of zones is an obvious difference, but there is no evidence that this difference has created any problems as the zones have no correlated purpose. While the two zones for MRL setting were established based on climatic considerations and different residue behaviour under different climatic conditions, the three zones for authorisation purposes were established based on climatic, agricultural (practices) and biological (pests) considerations. The establishment of the three zones also included other elements, such as already existing collaboration between Member States.

Differences in required scientific assessments are also a source of difficulties, particularly in managing import tolerances. While the PPP Regulation introduced human health and environmental cut-off criteria, the MRL Regulation, which was adopted before the PPP Regulation, is based solely on risk assessment. Non-compliance of a substance with the cut-off criteria leads in principle to its non-approval, meaning that no

377 Under Article 8(1)(g) of Regulation (EC) No 1107/2009.
378 Referred to in Article 7 of Regulation (EC) No 396/2005.
379 Following Article 29(1)(i) of Regulation (EC) No 1107/2009.
380 Decision of the European Ombudsman in case 2000/2015/ANA on the European Commission's compliance with the rules on the approval of plant protection products.
381 Under Article 12 of Regulation (EC) No 396/2005.

PPPs containing that active substance are authorised in the EU. Following the MRL Regulation, import tolerances can, however, still be requested for such substances and the subsequent risk assessment may conclude that no risk for human health is identified, which could lead to the granting of the import tolerances. While the same level of consumer protection is always ensured (i.e. the same set of safe MRLs apply equally to imported and EU produced food), this discrepancy may have a negative impact on the competitiveness of EU agriculture.

5.3.2. Other EU policy areas

The PPP Regulation and MRL Regulation interact with other EU policies on agriculture, food, environment and chemicals. While the overall consistency is considered adequate, some inconsistencies have been identified, as described below.

Consistency with other chemicals legislation

The PPP Regulation and other chemicals legislation in the EU create categories of substances, e.g. endocrine disruptors or substances that are persistent, and these categories are subject to different regulatory consequences. The consistency of the PPP Regulation with other EU chemicals legislation is covered in depth in the fitness check on the chemicals legislation (except REACH)[382]. On endocrine disruptors, the fitness check concluded that 'horizontal' criteria for endocrine disruptors i.e. criteria applicable across all EU legislation, have not been set. The same criteria to identify substances with endocrine disrupting properties have been adopted under the PPP Regulation and the Biocidal Products Regulations. Other pieces of legislation referring to endocrine disruptors have different wordings, creating uncertainty as to which chemicals are considered by the respective legislative provisions and what level of evidence is required to identify such chemicals. To increase consistency across EU policy as regards endocrine disruptors, the Commission presented in November 2018 a strategy entitled 'Towards a comprehensive European Union framework on endocrine disruptors', which includes the commitment to carry out a cross-cutting fitness-check. The fitness-check will analyse how the different provisions/approaches on endocrine disruptors interact, identify any possible gaps, inconsistencies or synergies, and assess their collective impact in terms of costs and benefits for human health and the environment, the competitiveness of EU farmers and industry, and international trade[383].

The PPP Regulation includes criteria to identify substances that are persistent organic pollutants (POP), active substances that are persistent, bioaccumulative and toxic (PBT), and active substances that are considered to be very persistent and very bioaccumulative (vPvB). These criteria are substantially the same as those in REACH and in the Biocidal Products Regulation. However, the guidance on how to assess such criteria is different. For instance, there are substantial difference in the consideration of the POP, PBT and vPvB properties of metabolites and the temperature to which key degradation studies are normalised. This can lead in some cases[384] to a substance being identified as a PBT under REACH and the Biocidal Products Regulation and as 'not PBT' under the PPP Regulation. Scientifically it makes no sense that the properties of a substance differ depending on the regulatory sector. The reasons are historical, as agricultural activities

382 European Commission (2019) Commission Staff Working Document Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries. SWD/2019/199 final

383 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Towards a comprehensive European Union framework on endocrine disruptors. COM(2018) 734.

384 Such as in the case of acetamiprid.

take place when it is warm, and because a higher normalisation temperature was also used until recently for industrial chemicals. In addition, the PPP Regulation has very strict regulatory consequences for POP, PBT and vPvB substances, i.e. non-approval with no possibility of derogation while under REACH the regulatory consequence is not necessarily as severe (i.e. the use of such substances can be authorised if the relevant conditions set out in REACH are met). The fitness check on chemicals concluded that additional benefits of introducing PBT and vPvB substances as new hazard classes need to be further assessed. Such assessment is one of the priority areas for future improvement of the current EU legislative framework for chemicals.

Consistency between the MRL Regulation and the legislation on foods for infants and young children

Directive 2006/125/EC[385] and Directive 2006/141/EC[386] require that the food they cover must not contain residues of individual pesticides at levels exceeding 0.01 mg/kg and establish levels lower than 0.01 mg/kg for several very toxic pesticides. These specific rules on pesticides in food for infants and young children are not fully in line with the MRL Regulation, as the definition of 'pesticide residues' is outdated and comprises only residues of plant protection products, whereas the MRL Regulation also includes residues of biocides.[387]. This has led to legal uncertainty about the coverage of residues of biocidal products by the legislation on foods for infants and young children, making legal interpretations necessary. Furthermore, the lack of a cross reference with the MRL Regulation prevents the automatic update of the specific residue definitions of active substances. For example, when EFSA identifies a metabolite the toxicity of which requires its inclusion in the residue definition, the residue definition of the active substance at stake has to be updated both in the MRL Regulation and in the legislation on foods for infants and young children.

Consistency between the MRL Regulation and hygiene policy

At EU level, food hygiene is regulated by Regulations (EC) No 852/2004, 853/2004 and 854/2004, which set rules and criteria covering all stages of the production, processing, distribution and placing on the market of food intended for human consumption. However, rules ensuring compliance with food hygiene criteria on the use of chemical decontaminants in food processing are laid down only in national legislation, with the EU issuing only guidelines on this issue. Certain chemical decontaminants can lead to residues in foods. The MRL Regulation comes into play when these chemicals are also residues of active substances currently or previously used in PPPs. For example, the use of chlorinated solutions in food processing (e.g. as processing aids authorised by Member States' national legislation) can lead to chlorate residues in foods, while the use of chlorate as an active substance in PPP is no longer approved and chlorate MRLs are set at the default value. Levels higher than the default levels that can be found in foods are then due to the legal use of disinfectant solutions and not to the illegal use of a pesticide. However, this leads to systematic non-compliances with the chlorate MRLs currently in place. This concern over multiple source substances is not limited to chlorate, as similar concerns were identified for other substances (see also section 5.1.7).

385 Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p. 16).

386 Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401, 30.12.2006, p. 1). Directive 2006/141/EC will be replaced by Commission Delegated Regulation (EU) 2016/127.

387 According to Article 3(2)b) of Regulation 396/2005.

Consistency between the PPP Regulation and environmental policy

There are concerns that the PPP Regulation is not fully consistent with the EU's biodiversity strategy to 2020[388], in particular as regards the scope of the risk assessment. While the biodiversity strategy covers the full variety of life (diversity within species, diversity between species/communities and diversity of ecosystems), the risk assessment conducted under the PPP Regulation evaluates effects on the populations of individual species (see also section 5.1.2). In addition, the range of non-target indicator species is limited and some stakeholders consider that these do not cover all animal taxa that could be affected by PPP use. Pesticides policy is not sufficiently consistent with EU climate policy. While the EU's climate policy aims to minimise greenhouse gas emissions, no such considerations are made when approving or not approving active substances. This relates most prominently to herbicides as their use may reduce the need for mechanical tillage. Tillage releases carbon emissions both through the use of machinery and by releasing carbon stored in the soil[389].

The PPP Regulation relates to the Water Framework Directive and its daughter directives, as the objective of good status (surface and groundwater) should be taken into account when approving and renewing active substances. A more coordinated link between the risk assessments and monitoring carried out under the Directive and Regulation could improve the decision-making.

Consistency between the PPP Regulation and Fertilising Products Regulation

Some economic operators have tried to register substances that are approved for use in PPPs as fertilisers. Such attempts have been unsuccessful and all active substances that fall under the PPP Regulation have been evaluated as such. To increase clarity in the future, the Commission proposed amending the relevant definition in the PPP Regulation as part of its proposal for a new Regulation on fertilising products[390]. The new Regulation was published in the Official Journal in June 2019[391].

The new legislation defines a new product category called plant biostimulant, which concerns substances, mixtures or microorganisms that, in principle, fall in the scope of the PPP Regulation, although their function relates to plant nutrition and not to plant protection. By amending the PPP Regulation, to exclude plant biostimulants from the scope, the new legislation creates a clear demarcation line between the two pieces of legislation and keeps products influencing plant nutrition outside the scope of PPP Regulation. The new legislation is maintaining, however, the authorisation obligation for products with dual claims, relating to both plant protection and plant nutrition features.

5.3.3. International agreements

Consistency of the Regulations and WTO, OECD and Codex Alimentarius

The EU regulatory system for pesticides is to a large extent consistent with international rules and agreements. OECD guidance documents are applied when evaluating studies under the PPP Regulation and the MRL Regulation.

388 EU Biodiversity strategy to 2020.

389 Fitness check on chemicals legislation (excluding REACH), http://ec.europa.eu/growth/sectors/chemicals/ec-support.

390 Proposal for a Regulation of the European Parliament and of the Council laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009. COM/2016/0157 final — 2016/084 (COD).

391 Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003, OJ L 170, 25.6.2019, p. 1–114.

The EU is a Party to the Sanitary and Phytosanitary Measures (SPS) Agreement and the Technical Barriers to Trade (TBT) Agreement. The MRL Regulation is considered to be coherent with the requirements of the SPS Agreement. The EU's trading partners are systematically informed within the WTO about proposed amendments to MRLs and all non-renewals or restrictions are notified to the WTO allowing for comments during a period of 60 days. Observations by trading partners are taken into account before risk management decisions are adopted.

A problematic issue identified is the potentially significant trade implications of the cut-off criteria, which is the subject of continuous concerns raised by trading partners in the WTO. Non-EU countries often remind the Commission that non-approval decisions need to respect WTO principles and be risk-based[392]. The cut-off criteria, including the criteria to identify endocrine disruptors, have been the subject of discussion in the WTO-TBT and WTO-SPS Committees since 2013[393]. Between 2015 and 2017, in the WTO Committees, non-EU countries raised specific trade concerns on pesticides 208 times against the EU. During the same time, the EU raised only two specific trade concerns on pesticides against other countries[394]. Although decisions under the MRL Regulation are based on assessments of risk only, the effects of the cut-off criteria, i.e. the non-approval of active substances with subsequent lowering of MRLs, is claimed to result in inconsistency between the EU approach and WTO obligations. However, so far no active substance has not been approved based solely on the cut-off criteria, as there have always been other issues identified as well during the risk assessment, and it remains possible to request import tolerances for such substances. See also section 5.1.6 for the impacts of MRLs on international trade.

The EU is a member of the Codex Alimentarius. Under the MRL Regulation[395], Codex limits (CXLs) are taken into account when MRLs are set, which means that MRLs are progressively aligned with international standards. Where the EU deviates from CXLs due to concerns for consumer protection, different data requirements or extrapolation rules, it explains these in a transparent manner to Codex members and observers, trading partners, stakeholders and the general public. For more details see section 5.1.6. While data requirements and the risk assessment methodology are overall consistent between the Codex and the EU, a few differences persist. The EU is actively working with the relevant bodies[396] to address such divergences.

5.4. Relevance

- Are the objectives of the Regulations pertinent to the evolving needs, problems and issues in the fields of pesticide residues and the placing on the market of PPPs?

MAIN FINDINGS

The Regulations make a relevant contribution towards meeting the Sustainable Development Goals. Major threats to the primary production of food must be mitigated and at the same time food and feed must be kept safe and free from biological and chemical threats - the PPP Regulation and MRL Regulation contribute to achieving those goals.

392 In particular Article 5 of the SPS Agreement.
393 European Commission (2016) Impact assessment defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation.
394 Data from the WTO-SPS Committees' summary reports, compiled by the Commission.
395 In line with Article 14(2)(e) of Regulation 396/2005.
396 Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and Codex Committee on Pesticide Residues (CCPR).

There is increased demand for more sustainable agriculture in the EU. In this regard, the objective of protecting the environment is still relevant and the PPP Regulation provides for the proper use of PPPs, which includes the application of good plant protection practice and compliance with the principles of integrated pest management. The PPP Regulation is also complemented by the Sustainable Use Directive and by the Common Agricultural Policy, which create additional incentives for a sustainable agriculture.

The availability of low-risk active substances, including micro-organisms, has increased but is still considered by stakeholders as insufficient and procedures are considered lengthy. While the Commission and the Member States have taken action to accelerate the procedures to place low-risk PPPs on the market, the effects of these efforts are expected to materialise only in the future. Furthermore, the MRL Regulation only offers limited flexibility to address the specificities of non-chemical active substances, e.g. micro-organisms or other biopesticides.

The PPP and MRL Regulations are relevant to the Sustainable Development Goal on innovation. The PPP Regulation has the potential for continuous adaptation to scientific progress as the data requirements and risk assessment methods laid down in implementing Regulations or guidance documents can be adapted to take into consideration new concepts such as nanopesticides, micro-organisms and new application techniques (e.g. robotics). However, the MRL Regulation offers less flexibility to adapt to evolving technology and future needs (e.g. nanopesticides, integration of large cumulative assessment groups)

5.4.1. Sustainability

Sustainable Development Goals (SDGs) and sustainable agriculture in the EU

The PPP and MRL Regulations contribute to achieving the 2030 Agenda for Sustainable Development[397]. Sustainable agriculture has been and is a priority for the EU which has made a commitment to fully implement the SDGs in its policies and set out the way ahead in a Commission Communication in November 2016[398]. The approach set out in the Communication upholds the principle of subsidiarity as many actions can only be successfully implemented through national legal frameworks and non-legislative action at Member State level. The objective of the PPP and MRL Regulations are mainly relevant for the following SDGs:

Figure 17. Sustainable Development Goals related to the PPP Regulation and MRL Regulation

Food security is one of the most fundamental among basic needs. Major threats to primary production of food must be mitigated. Food and feed must also be kept safe and free from biological and chemical threats. While the use of PPPs reduces losses to pests during food production, it is essential that it does not result in residues of pesticides in food that are harmful for consumers. The MRL Regulation ensures that consumers can eat safe food and that food exceeding the MRLs for pesticides cannot be placed on the market.

The PPP Regulation makes sure that professionals using PPPs in their daily work and bystanders and residents are not exposed to unacceptable levels. With its extensive environmental protection provisions, the PPP Regulation ensures that groundwater, surface water, and drinking water quality are not jeopardised by the use of PPPs in agriculture, as substances not complying with the relevant criteria cannot be approved. The PPP Regulation contributes to preserving the quality of natural resources due to strict requirements on the protection of water, wildlife, pollinators, soil and air, which must be met before an active substance can be approved and a PPP authorised by a Member State.

There is demand in the EU for more sustainable agriculture with less impact on the environment, including increased demand for organic food. In a European Parliament survey, stakeholders across all categories found the objectives of the PPP Regulation relevant, while noting that the PPP Regulation should better promote the use of integrated pest management[399].

While it is clear that the PPP and MRL Regulations contribute to a more sustainable agriculture in the EU, they cannot achieve this alone. The Sustainable Use Directive introduced for the first time clear principles at EU level for integrated pest management and a range of measures to achieve sustainable use of pesticides to reduce the impacts of

397 UN Resolution A/RES/70/1.

398 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committees and the Committee of the Regions: Next steps for a sustainable European future,- European action for sustainability (COM(2016) 739 final of 22.11.2016.

399 European Parliament Research Service (April 2018) European Implementation Assessment. Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market. ISBN: 978-92-846-2734-9.

the use of PPPs on human health and the environment. These measures cover: (i) national action plans to reduce the dependency on the use of pesticides and promote integrated pest management; (ii) actions to improve information, training, control and the upgrade of application techniques and the handling and storage of pesticides; and (iii) monitoring of outcomes. The link between the Sustainable Use Directive and the PPP Regulation is through the proper use of PPPs, including compliance with integrated pest management principles laid down in the Sustainable Use Directive[400]. The Commission's report in 2017 on the implementation of the Sustainable Use Directive concluded that the Directive offers the potential to greatly reduce the risks of pesticide use. However, more rigorous and ambitious implementation by Member States would be needed to achieve the environmental and health improvements sought[401].

Another complementary policy instrument is the Common Agricultural Policy. In a recent Communication[402], the Commission reflected on the future of food and farming and on the need of the Common Agricultural Policy[403] to address citizens' concerns on sustainable agriculture, including the sustainable use of pesticides. The current Common Agricultural Policy (since 2013) already includes measures which promote proper sustainable use of PPPs as an environmental cross-compliance obligation, under which farmers may face a reduction in direct payments if they do not comply with the rules set for use of PPPs. In the proposal for a new Common Agricultural Policy (2018)[404], the Commission has further prioritised the sustainable use of PPPs via the objectives detailed in the proposal and via the proposed indicators.

Availability of low-risk active substances and basic substances

To support the implementation of integrated pest management, the PPP Regulation introduced the categories of *basic* and *low-risk* substances to promote the development of less harmful PPPs; these are acknowledged as an integral part of integrated pest management and the implementation of the Sustainable Use Directive. The number of basic and low-risk substances approved in the EU is steadily increasing (see Table 4, section 5.1.1). As of December 2018, there were 13 low-risk active substances and 20 basic substances approved.

Despite the intended promotion of low-risk active substances, most Member States[405] consider that the provisions of the PPP Regulation do not facilitate placing low-risk active substances on the market. There is consensus among stakeholders and Member States that the availability of low-risk PPPs is insufficient. Many stakeholders, including the European Parliament[406,407], are critical of the fact that progress is slow and that not enough is being done to promote low-risk active substances. Stakeholders working with biopesticides and organic farming also complain that there is no 'lighter' fast-track procedure to approve low-risk active substances and to place low-risk PPPs on the

400 According to Article 55 of Regulation 1107/2009.

401 European Commission (2017) Report from the Commission to the European Parliament and the Council on Member State National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides. COM/2017/0587 final.

402 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. The Future of Food and Farming COM(2017) 713 final. Brussels, 29.11.2017.

403 https://ec.europa.eu/info/food-farming-fisheries/key-policies/common-agricultural-policy/cap-glance_en.

404 Proposal for a Regulation of the European Parliament and of the Council establishing rules on support for strategic plans to be drawn up by Member States under the Common agricultural policy […] SEC(2018)305

405 20 out of 27 Member States consider that the provisions are working 'not at all' or 'to a small extent only'.

406 European Parliament (September 2018) Report on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009.

407 European Parliament (December 2018) Report on the Union's authorisation procedure for pesticides (2018/2153(INI)) Special Committee on the Union's authorisation procedure for pesticides.

market. In fact, confirming whether an active substance can be approved as low-risk is only possible at the end of the risk assessment and risk management process, as for all substances subject to the PPP Regulation. Only then can it be demonstrated that the substance meets the very demanding low-risk criteria. The approvals of several active substances that are presumably low-risk are in the process of being renewed and the benefits will only materialise once the renewal assessment is finalised. The delays in the renewal process negatively affect also the renewal of low-risk substances (see section 5.2.2).

In view of the above, while the PPP Regulation and the Sustainable Use Directive are seen as mostly consistent with one another, a slight inconsistency relates to the delays and the long time it takes to bring low-risk PPPs and non-chemical control techniques to the market. This complicates the effective implementation of the Sustainable Use Directive as in order for such methods to contribute to a more sustainable agriculture they need be made available to farmers.

To promote low-risk active substances and PPP, the Commission has worked together with the Member States[408] to identify short- and long-term actions that could accelerate the procedures involved in bringing low-risk products to the market. A plan of 40 actions was endorsed by the AGRIFISH Council of June 2016[409]. All actions identified for the Commission are either in progress, close to finalisation, or finalised. This includes the compilation of a list of 57 potentially low-risk active substances[410] approved in accordance with the former Directive 91/414/EEC, which allows Member States to inform users about products whose use should be encouraged. Such awareness-raising is expected to translate into more interest from manufacturers in applying for national authorisations pushed by the sector's demand for such products. Furthermore, Member States are expected to become more familiar with the concept of low-risk and the potential portfolio of low-risk PPPs. In turn, it is expected that Member States will process the re-authorisations faster for the low-risk PPPs following their renewal of approvals in the coming years. Unfortunately, these assumptions cannot be verified yet as the active substances in question will only be reviewed in the coming years under the AIR 4 programme.

Many presumed low-risk active substances are microbial pesticides and pheromones and the Member States, EFSA and applicants are still acquiring experience in assessing them. The Commission has developed a guidance document on low-risk criteria and has started drafting guidance documents supporting the assessments of biopesticides, e.g. microbial pesticides and pheromones. The guidance documents will address key concerns and increase clarity on how to conduct the assessments. This should result in faster and more accurate scientific evaluations.

Some stakeholders and Member States consider that the current data requirements are neither appropriate (as they derive from requirements imposed on chemicals in the case of micro-organisms) nor proportionate to low-risk substances for which the risk assessment should in principle be less data consuming. The findings of the European

408 Within the Expert Group on Sustainable Plant Protection.
409 Outcome of the Council meeting available online: https://www.consilium.europa.eu/en/meetings/agrifish/2016/06/27-28/.
410 Commission notice concerning a list of potentially low-risk active substances approved for use in plant protection. C/2018/4828, (OJ C 265, 27.7.2018, p. 8).

Parliamentary Research Service study highlight the limited use of low-risk PPPs because they generate low profits due to often being marketed as niche products[411].

As to basic substances, there are procedural problems that lead to delays. In the absence of clear provisions in the PPP Regulation, the Commission and Member States have agreed on a Guidance Document[412] setting out an ad-hoc procedure for the approval of basic substances, which is lighter and sets out fewer requirements compared to the approval of active substances. The Commission is responsible for the first step, which is the admissibility check of the application. Due to resource constraints, there have been delays in completing the admissibility verifications. As of December 2018, the Commission performed an admissibility check for 40 out of 58 applications (not counting extension of uses). On average it takes about 4 months for the Commission to take an admissibility decision on a basic substance application. Following the completion of a Technical Report by EFSA, it takes on average 7 months until a draft Regulation on the approval (or not) is submitted to the Member States for vote in the Standing Committee for Plants, Animals, Food and Feed. These delays are heavily criticised by the applicants of basic substances. In addition, it is fair to recognise that it can be difficult for users to identify the usefulness of products containing basic substances for purposes of plant protection as these may not be labelled as PPPs. Several Member States have indicated this as a limit on the full exploitation of the marketing potential of such products, because their labels cannot include information on the crop-protection uses allowed.

5.4.2. Innovation and scientific progress

Scientific knowledge on substances and testing methods is continuously evolving. In parallel, new substances are developed, possibly raising new concerns and risks to human health and the environment. Since the PPP and MRL Regulations have to work in this evolving context it is important that they can adapt to this changing environment quickly and efficiently.

The REACH review identified combination effects and endocrine disruptors as emerging issues; both of these are already conceptually addressed in the PPP and MRL Regulations, although their implementation is still under development. The work to include cumulative risk assessment (the 'cocktail effect' of simultaneous exposure to multiple substances) is under development and described in depth in section 5.1.1. In a European Parliament survey, stakeholders across all categories found that the PPP Regulation should better reflect the need for innovation[413].

Although innovation is not explicitly among the objectives of the Regulations, both the PPP and MRL Regulations can, in general, be adapted to new scientific concepts by adapting data requirements and risk assessment methods laid down in implementing Regulations or guidance documents. To update guidance documents, the Commission and EFSA work together with the Member States and stakeholders. There are currently 49 technical guidance documents[414] available and additional guidance documents are under development. While guidance is essential to adapt to new scientific concepts relatively easily, they make the assessments more complex. Outdated guidance on the other hand, may not provide the protection of human health and the environment that is

411 European Parliament Research Service (April 2018) European Implementation Assessment. Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market. ISBN: 978-92-846-2734-9.
412 Guidance Document available online on the Europa webpage.
413 European Parliament Research Service (April 2018) European Implementation Assessment. Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market. ISBN: 978-92-846-2734-9.
414 Europa webpages on guidance documents for PPPs and for MRLs.

endeavoured. In general, there is a good level of harmonisation and coherence among guidance for active substance approval, while some cases of incoherence exist[415] and some existing guidance documents have not been updated for a considerable time due to resource constraints.

Micro-organisms and biopesticides

Micro-organisms and substances of biological origin are often identified as more sustainable alternatives to chemical active substances. However, these also need to be proven safe by an appropriate risk assessment relying on a suitable set of data. The current data requirements and assessment principles are often criticised as being too costly and unsuitable for developers of innovative micro-organisms or substances of biological origin that often find only niche markets.

Pertinence of the current data requirements is questioned as regards micro-organisms as well as innovative modes of action, such as RNA-dependent gene silencing where the mode of action against pests is not through any of the currently common routes, e.g. with a chemical, a toxin/metabolite or an infection of the targeted pests. To overcome these barriers for micro-organisms, the European Parliament adopted a Resolution in February 2017[416] calling for a new and separate legal framework for such products. At the same time, the report from the PEST Committee calls for an assessment of such products that is equally stringent as that for chemical active substance[417].

The support study concluded that the PPP Regulation does not provide a sufficient possibility to adapt to scientific and technical progress as regards the scope of the legislation[418]. However, the framework created by the PPP Regulation actually offers flexibility to accommodate specific needs. This includes accommodating innovative technologies through the adaption of data requirements and the relevant assessment methodologies. There is already a specific set of data requirements for micro-organisms, which can be adapted to technological progress. The OECD guidance for the risk assessment of micro-organisms has been expanded by a working group of Member States experts on bio-pesticides as regards metabolites of concern and anti-microbial resistance.

The MRL Regulation, on the other hand, lacks some flexibility to address MRLs for non-chemical active substances, e.g. micro-organisms, due to the default MRL of 0.01 mg/kg which applies to all actives substances. Although specific MRLs for micro-organisms could in principle be set under the MRL Regulation already now (e.g. by using specific footnotes in the Annexes to change the expression of measurement units from "mg/kg" to another more appropriate expression, e.g. "colony forming units") in Annex V, an exemption of micro-organisms from the general default level of 0.01 mg/kg or the setting of another more appropriate default level for micro-organisms is not possible within the current legal framework.

Furthermore, as discussed in section 5.1.4. the existing data requirements are not fully adapted to the specificities of non-pathogenic micro-organisms, leading EFSA to regularly identify data gaps when evaluating applications, which, in consequence, delays

415 Nganga, J., Bisonni, M., and Christodoulou, M. (2018) Guidelines for submission and evaluation of applications for the approval of active substances in pesticides. Study requested by the European Parliament's Special Committee on the Union's authorisation procedure for pesticides (PEST Committee).

416 European Parliament (2017) Biological low-risk pesticides European Parliament resolution of 15 February 2017 on low-risk pesticides of biological origin (2016/2903(RSP)).

417 European Parliament (December 2018) Report on the Union's authorisation procedure for pesticides (2018/2153(INI)) Special Committee on the Union's authorisation procedure for pesticides.

418 The support study, p. 172.

risk management decisions. It is also doubtful whether potential new needs that may arise in future from new technologies (e.g. nanopesticides, MRLs for whole cumulative assessment groups instead of single substances) can be sufficiently addressed within the current MRL framework.

Application techniques — robotics, GPS and digital agriculture

Diffuse and point-source pollution in the environment have been significantly reduced thanks to constant innovation improving the accuracy of spraying equipment. Low-drift nozzles, deflectors and shields are reducing spray drift and incidental spillages, and result in improved handling and pre- and post-application procedures (such as loading and rinsing). Similar progress has been observed for personal protective equipment. Innovative tools are made available on the market but practical implementation highly depends on whether these techniques are perceived as effective and efficient by users.

Precision farming techniques have also advanced, enabling PPPs to be applied only to plants that are actually attacked by pests. Combined with GPS technologies, this also improves record-keeping on crop spraying, which facilitates enforcement. Once digitalisation is made affordable for the 'average farmer', this will continue to improve the performance and accuracy of PPP application, thus significantly reducing the applied quantities of PPP. Such advances could potentially allow for more hazardous active substances to be approved considering that where the exposure is minimal, the risk would become acceptable.

These innovative techniques' potential to mitigate risk for operators has not been fully exploited to date and they are not being considered in the risk assessment procedures. However, future revisions of the 'uniform principles' to assess PPPs and develop agreed guidance on the efficacy of the various methodologies could enable refined application techniques to be considered as risk reduction tools.

Nanopesticides

Nanotechnology is offering new methods for formulating and delivering pesticide active ingredients, as well as novel active ingredients collectively referred to as 'nanopesticides'[419]. While some concerns have been expressed about the altered risk profile of these new products, many see them as offering great potential to support the necessary increase in global food production in a sustainable way[420]. As the application of nanotechnology in agriculture is still in the early stages, there is limited information on the impact on humans, animals and the environment. This makes it challenging for scientists and government officials to improve knowledge in this field[421].

The PPP Regulation currently contains no specific provisions or even a definition for nanomaterials. However, data requirements and risk assessment methods can be adapted to take on board such new technologies, and in the near future this may even become necessary.

419 Hayles, J., Johnson, L., Worthle, C., Losic, D. (2017) Nanopesticides: a review of current research and perspectives. New Pesticides and Soil Sensors, p 193-225. https://doi.org/10.1016/B978-0-12-804299-1.00006-0.

420 Kah, M., Kookana, R.S., Gogos, A., and Bucheli, T. D. (2018) A critical evaluation of nanopesticides and nanofertilisers against their conventional analogues. Nature Nanotechnology. Volume 13, pages 677-684.

421 Villaverde, J.J., Sevilla-Morán, B., López-Goti, C., Sandín-España, P., Alonso-Prados, J.L. (2017) 6 — An overview of nanopesticides in the framework of European legislation. New Pesticides and Soil Sensors. p 227-271. https://doi.org/10.1016/B978-0-12-804299-1.00007-2.

5.5. EU added value

- What is the added value of regulating plant protection products and pesticide residues at EU level?
- To what extent have the MRL Regulation and the PPP Regulation resulted in added value with regard to the objectives pursued that could not be achieved at national/international level?

MAIN FINDINGS

All stakeholders and Member States acknowledge the added value of the Regulations. Their added value are: (i) the EU-wide protection of human health; (ii) the generation of data and scientific knowledge, and the public availability of such data; (iii) increased cooperation among Member States; and (iv) a harmonised system for trading partners.

The costs of achieving the objectives to protect human health and the environment were lower than in a system where each Member State conducts the risk assessments on its own. There have been attempts to conduct the risk assessment for active substances at international level, but they proved to require more time and more resources for coordination with the same results.

Increased added value could possibly be achieved by introducing EU-wide authorisations for low-risk PPPs which do not require risk mitigation, and for PPPs which have similar conditions of use throughout the EU, e.g. in greenhouses.

There is wide consensus among all Member States and stakeholder groups that regulating PPPs and MRLs at EU level adds value[422]. The European Parliament Research Service also concluded from stakeholders' views that regulating pesticides at EU level has added value[423]. Some stakeholders call for even greater harmonisation and for the authorisation of PPPs at EU level or further international harmonisation. This evaluation has identified EU added value stemming from: (i) the data and scientific knowledge generated; (ii) the increased capacity to perform assessment work in many Member States; (iii) EU-wide protection of human health; and (iv) a harmonised system for trading partners. Despite the inefficiencies and delays described in section 5.2.2, EU added value also stems from the cost-effectiveness of the system compared to a situation where each Member State were to regulate PPPs on its own.

Although the EU system for approving active substances is very comprehensive and costly, it benefits from economies of scale as it achieves higher total output while keeping the individual input relatively lower. In a system where each Member State creates a similar system on its own, the combined total costs would be higher and duplication of work inevitable. Approving active substances at EU level is thus more cost-effective and allows for work sharing where each Member State performs assessments on behalf of the others. This is all the more important as there is a limited number of scientific experts in the EU in general and in some Member States in particular. Cooperation via the peer-review system has also boosted capacity in many Member States due to knowledge exchange between them.

The data generated to support approvals of active substances and authorisations of PPPs are considerable and could not have been collected on the same scale by a Member State

422 The support study, p. 213.

423 European Parliament Research Service (April 2018) European Implementation Assessment. Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market. ISBN: 978-92-846-2734-9.

operating individually. This is in particular true for areas such as endocrine disruptors and cumulative risk assessment, in which the science is still not mature. Where there is a demand for increased knowledge for regulatory purposes in specific areas such as genotoxicity, investments are made collectively. Since the outcome of the risk assessment is published, the system also contributes to the general availability of information about agrochemicals.

The system provides for equal EU-wide protection of human health. First, through harmonised MRLs, which provide for the same protection of everyone from pesticide residues in food. Second, the risk assessment for active substances and approval at EU level ensure the same level of protection of operators, bystanders and residents. This may not have been achieved were there no legislation at all in the EU. It may also not have been achieved if there were legislation at Member State level only as the protection goals could have had varying stringency in the Member States, resulting in varying protection levels. Of course, the final protection of human health also depends on the conditions of authorisation laid down by the Member States and on the respect of these by users and the level of enforcement in the Member States, which has been shown to vary (see section 5.1.7 on enforcement).

In view of the frequent amendments to the MRL Regulation, the Commission has set up the EU Pesticides Database to facilitate the work of food-business operators, national competent authorities and laboratories. The database can be consulted in 23 official languages of the EU. Having a single MRL throughout the EU enhances the free movement of food and enables trade partners to export products to the Member State of choice, based on trade interests and partnership.

To assess the full added value of the PPP and MRL Regulations it is necessary to look beyond the EU. The capacity of the EU and the ability to set up a comprehensive scientific system to evaluate active substances has positive effects in non-EU countries. For example, EFSA conclusions are used to support regulatory decisions in the countries participating in the Permanent Interstate Committee for Drought Control in the Sahel (CILSS), i.e. Burkina Faso, Cape Verde, Chad, The Gambia, Guinea-Bissau, Mali, Mauritania, Niger, Senegal and Togo. The publicly available information in the EU provided by EFSA and the Commission is known to assist risk managers in those countries in their decision-making. Consequently, the PPP Regulation is supporting the protection of human and animal health and the environment also in Western Africa.

While most developed countries have their own regulatory system, it seems that some countries, also make use of scientific assessments and regulatory decisions in the EU. For instance, the outcome of the risk assessment or decisions to not approve or to restrict active substance in the EU may trigger early reviews of active substances in other countries, such as Australia. This saves resources in non-EU countries and facilitates focused assessments on specific issues.

As regards MRLs, the limits set for crops in the EU apply also to imported products. For active substances that are not approved, the MRLs are set at the 'limit of quantification' (LOQ), which means no residues are allowed. This encourages substitution of the active substance also in non-EU countries to avoid the need for requesting an import tolerance. Thus, the PPP and MRL Regulation contribute to the protection of human health and the environment for more people than just those living in the EU.

Should authorisations of PPPs be made at EU level?

Authorisation of PPPs are made at Member State level because of subsidiarity — national agencies have historically been in the best position to evaluate PPPs and decide on appropriate risk mitigation measures due the very specific agricultural and climatic conditions in their home country. However, in June 2018, the Commissions' Scientific Advice Mechanism questioned the added value and efficiency of the current two-step process consisting of approving active substances at EU level then authorising the PPP at national level. The Scientific Advice Mechanism, as well as EFSA[424], argues that PPPs should be authorised at EU level[425]. The European Parliament on the other hand would like to see an assessment whether it would be appropriate to make EFSA responsible for the risk assessment of PPPs, while leaving the actual decision on the authorisation of plant protection products at national level, in order to take account of country-specific situations[426].

However, the added value of introducing a single-step risk management decision on PPPs including all ingredients at EU level is not clear. Aside from the significant differences in agricultural and environmental conditions in the Member States, there are several thousand PPPs compared to less than 500 active substances, meaning that the number of assessments and decisions taken at EU level would have to increase strongly, requiring a significant increase in resources for EFSA and the Commission, but also in the Member States as they would have to participate in significantly more peer-review processes.

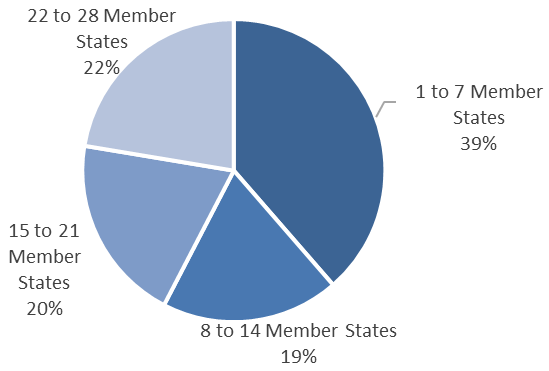


Figure 18. Share of active substances that are authorised in a PPP in Member States

Moreover, as shown in Figure 18, only for 22 % of the active substances approved in the EU PPPs containing them are authorised in more than 22 Member States, while for almost 60 % of active substances PPPs containing them are authorised in 14 or fewer Member States. EU authorisations of PPPs would therefore seem to be useful only for a limited number of PPPs. Another argument in favour of the current two-step process is that it keeps technical and scientific capacity in Member States.

Although it is true that by leaving authorisation of PPPs at the national level Member States duplicate work and spend a lot of resources on product evaluations, much can already be done within the current system to reduce duplication. If fully exploited, the zonal system and mutual recognition allow for cooperation and work sharing, as well as

424 EFSA (European Food Safety Authority) (2018) Scientific risk assessment of pesticides in the European Union (EU): EFSA contribution to on-going reflections by the EC. EFSA supporting publication 2018:EN-1367. 17 pp.
425 European Commission (June 2018) EU Authorisation processes of plant protection products — from a scientific point of view. Group of Scientific Advisors. ISBN 978-92-79-67735-9.
426 European Parliament (December 2018) Report on the Union's authorisation procedure for pesticides (2018/2153(INI)) Special Committee on the Union's authorisation procedure for pesticides.

avoidance of duplicative work. As to improved knowledge about all PPPs authorised in the Member States, the full implementation of the plant protection products application management system (PPPAMS) will remedy the lack of a complete overview of all the products available in the Member States.

Increased added value could possibly be achieved with a system similar to the Biocidal Product Regulation where authorisations of products can be made at both national and EU level. EU authorisations can be granted for products which have similar conditions of use in the entire EU, e.g. hand disinfectants. For PPPs, this approach could be taken for uses in greenhouses. This approach could also be taken for low-risk PPPs which do not require risk mitigation measures. A clear advantage of an EU authorisation is that it is directly applicable in all Member States and therefore reduces the administrative burden for applicants. The challenge for the Commission and EFSA, however, would be, in view of the limited resources available, to manage not only the approval of active substances, but also the authorisation of such products.

Should pesticides be regulated internationally?

International cooperation could potentially add even more value as more countries would share the risk assessment work. However, international reviews have been tried under the auspices of the OECD in the global joint reviews, where the EU, US and Australia have worked together to jointly review some new active substances[427]. The outcome was mixed, with a good risk assessment coming at the cost of an inefficient process where increased coordination efforts and the inflexibilities of each regulatory system worked against effective work sharing. It therefore seems that the EU system has higher added value than conducting the risk assessment in a global context. However, this could change in the future if the right institutions and work sharing mechanisms were to be created.

6. CONCLUSIONS

This evaluation assessed the effectiveness, efficiency, relevance, coherence and EU added value of the PPP Regulation and the MRL Regulation. The assessment compared the current situation against conditions before the Regulations applied, i.e. pre-2008 for the MRL Regulation and pre-2011 for the PPP Regulation. Additional points of comparison were used in the evaluation, as appropriate, including a comparison with the US and Canadian regulatory systems for PPPs and the EU's Biocidal Products Regulation.

The Sustainable Use Directive is a complementing piece of legislation that was not in scope of the evaluation. As the Directive does not cover the risk assessment and management framework, it is unlikely that the conclusions in the current evaluation would be different as regards the robustness of the risk assessment at EU level if the Directive had been included in the evaluation. However, it could be expected that full implementation of the Sustainable Use Directive would support the objective of protecting health and the environment by reducing the risks linked to plant protection products, through the adoption of non-chemical control methods and a reduction in dependency on plant protection products.

427 See case study for cyantraniliprole in the support study.

The analysis was constrained by some limitations. First, the difficulty in establishing a clear causal link between the two Regulations and health and environmental impacts, due to the fact that such impacts are determined by a multitude of factors. Second, the process for reviewing the approval of all active substances and their MRLs has not yet been completed and the full effects of the Regulations can therefore not yet be captured. Finally, data at national level in particular as regards the actual use of pesticides in spatial and temporal dimensions are not available, which does not allow for the assessment of the scale of the impacts. The evaluation, nevertheless, is based on an extensive literature review and data collection through desk research, as well as a wide consultation, which allowed incorporating the opinions of a broad range of stakeholders. To ensure reliability of the data collected, different sources of data were compared and opinions from stakeholders were examined against other evidence (i.e. triangulation) to the extent possible. This approach mitigates the effect of the limitations described above.

The **objectives of the Regulations were found to be relevant** for the evolving needs and problems identified in the field of pesticides, although the demand for more sustainable agriculture should be better taken into account.

The Regulations are mostly coherent and consistent, both internally and with one another. The exceptions are the interplay of the review of MRLs with the renewal of approval of active substances and the fact that the cut-off criteria in the PPP Regulation are not reflected in the MRL Regulation. Consistency with other EU policy areas is moderate, with the policy on foods for infants and young children, hygiene policy, and chemicals regarding persistency possibly requiring attention. The cut-off criteria in the PPP Regulation are often challenged at international level in the context of WTO. On the other hand, the EU regularly incorporates Codex limits that are safe for consumers into its MRL Regulation, which facilitates international trade.

The PPP Regulation was found to be **effective to a large extent in protecting human health and the environment** due to the stringency of the approval criteria, which led to non-approval or non-renewal of approval of active substances that are harmful for human health and/or the environment. Currently, there are very few (2 %) active substances with high hazard profiles compared to a large share (37 %) of active substances with low hazard profiles. Further benefits are expected in the future once the full review cycle of all approved active substances is finalised (expected by 2025). However, not all stakeholders agree with this conclusion, in particular NGO's. It has to be recognised also, that while the Regulations have the clear potential to be effective in reaching their objectives, these have only been partially attained due to the delays and efficiency problems, and implementation can be improved.

The cut-off criteria remove the most hazardous active substances from the market and therefore **contribute to protecting human health and the environment.** In particular, for less than 40% of the few active substances that meet the criteria and are still on the market companies apply for the renewal of approval. However, the absence of harmonised classification for many active substances and the need to evaluate whether the foreseen derogation possibilities can apply resulted in delays in the overall assessment and in the decision-making. New procedures and guidance had to be developed which are still not fully complete. Thus, some active substances that meet the cut-off criteria are still approved under the conditions from Directive 91/414/EEC instead of having been restricted or not having their approval renewed. This has decreased the immediate effectiveness of the cut-off criteria.

The rules on **active substances that are candidates for substitution are ineffective and inefficient** and did not deliver the expected results. The comparative assessments for products containing active substances that are candidates for substitution carried out by Member States in 2015 and 2016 did not lead to any substitution, mainly due to the lack of alternatives with proven better risk profiles. Thus, the expected benefit for human health or the environment from substituting these hazardous substances has not been achieved. In addition, comparative assessments were found to be costlier (in total EUR 26.7 million) than standard authorisation procedures.

Emergency authorisations allow Member States to address unexpected dangers to plant health where other viable alternatives do not exist, although these derogations are often used to address other issues. In fact, the number of **emergency authorisations has increased** by 300 % since 2011. Member States seem to use emergency authorisations to mitigate the consequences of the delayed processes to authorise PPPs, the failure to mutually recognise authorisations, and to cover minor uses. The application procedures for setting MRLs for such emergency uses were also considered by stakeholders to be too long. Moreover, there is concern that emergency authorisations issued for non-approved or restricted active substances can negatively affect the protection of human health and the environment.

The MRL Regulation has contributed to **protecting human health by setting safe MRLs,** including MRLs based on import tolerances and CXLs. The EU's comprehensive annual monitoring showed high compliance with the established MRLs, indicating that the food available to consumers is safe. Although the Commission has not yet made use of the possibilities given by the MRL Regulation to establish specific MRLs for certain product groups (fish, feed, processed foods) as well as a harmonised processing factors, this has not decreased consumer protection. Developing a method for cumulative risk assessment turned out to be much more complex and required more resources than initially expected and therefore is still ongoing.

The results from monitoring the status of European waters show a **reduction of pesticide contamination in surface waters**, at least in relation to priority pesticides under the Water Framework Directive, which indicates that the PPP Regulation contributes positively to the protection of the aquatic environment.

The number of shared studies on vertebrate animals has increased, as intended, although preliminary data show that overall animal testing has not decreased. This is due to the increased scientific evidence required to approve active substances. The situation is not expected to improve because increasing evidence will be required in the future to assess substances' effects on the endocrine system. In addition, the requirement for periodic re-assessment of all active substances may increase or at least maintain the need for *in-vivo* testing.

Having harmonised MRLs across the EU has meant that the functioning of **the single market for food and feed has improved considerably**. The overall MRL setting procedure is working well, although it lacks sufficient flexibility to provide quick responses to newly emerging issues, such as unexpected findings of pesticides in food (e.g. through environmental contamination) or residues arising from emergency uses or from substances coming from multiple sources.

The **zonal system for product authorisation is not working as well as expected**. The use of mutual recognition for authorisation of PPPs varies greatly between Member States and zones. The main reasons for this are additional national requirements, the re-evaluation of applications, and the lack of harmonisation in the methodologies used for

conducting evaluations, leading to duplication of work. Authorisation of PPPs by concerned Member States and mutual recognition of authorisations from other Member States were found to lead to lower fees for applicants and reduced burden for Member States. It was estimated that between 2012 and 2016 Member States using mutual recognition saved EUR 13-17 million compared to what they would have spent had they issued regular authorisations. Furthermore, Member States using mutual recognition have seen larger increases in the number of PPPs available on their markets. The lack of trust will probably be gradually overcome by growing experience in collaboration between Member States. In a more substantial change - as also called for by the European Parliament - moving the scientific assessment of PPP authorisations to the EU level could further enhance mutual trust, but would have significant resource implications both for Member States and EFSA.

International trade is facilitated by harmonised MRLs at EU level that allow imports into the entire EU at the same standards. Nevertheless, trading partners continue to express their dissatisfaction that MRLs in the EU are often set at lower levels than those applying in non-EU countries or set internationally, thus creating trade barriers. At the same time there is criticism from within the EU that MRLs are set for non-approved active substances which allow imports of products treated with those active substances that are not available to EU farmers, decreasing the competitiveness of EU agriculture.

The overall process **for setting import tolerances** takes on average about 2 years instead of 1 year due to poor quality dossiers and lack of resources in Member States and EFSA. Moreover, the time available for the setting of import tolerances is criticised for being too short to avoid the lowering of MRLs in the EU following the non-renewal of approval of an active substance. However, applications are often submitted too late in the process, although information about a forthcoming lowering of MRLs is announced to trading partners significantly in advance.

The evidence remains inconclusive on the effects of the PPP Regulation in improving the **competitiveness** of EU agriculture as this depends on multiple factors. There is criticism on the lack of PPPs in the EU, while the number of approved active substances has actually increased since 2011 (from 427 to 484) and also the number of products available has increased in most Member States. Evidence shows that EU sales of PPPs were stable during the 2011-2016 period and that the value of PPPs and number of persons employed in the sector has increased. The number of SMEs producing PPPs and other agrochemical products is decreasing, with high regulatory requirements being a contributing factor. Data requirements and assessment procedures are considered disproportionate for SMEs, who tend to focus on biopesticides and other potentially low-risk solutions. As regards farmers, the information available does not offer a clear picture as data on spending on crop protection suggest that their share in farm expenditure has been stable, while costs for PPPs show an increasing trend since 2010, i.e. from before the applicability of the PPP Regulation. At the same time, farmers expressed concerns regarding the future availability of PPPs, following the expected non-renewal of approval of several active substances. Although such concerns are legitimate, farmers' needs for pest management can be addressed also by the full implementation of the Sustainable Use Directive and the promotion of non-chemical alternatives. To assess or monitor the relationship between competitiveness, the use of PPPs and regulatory changes, it would be necessary to establish relevant indicators and collect data over time on a sufficiently granular level.

There is **insufficient availability of PPPs for minor uses** and Member States are not fully using the existing provisions to facilitate authorisation for such uses. Cooperation

between Member States, acceptance of residue data evaluated by other Member States and acceptance of residue trials outside the EU are insufficient. To overcome the problem, Member States are using emergency authorisations instead of extending existing uses of authorised products. Minor crops in outermost regions face similar issues in terms of availability and emergency authorisations have been used also there to overcome this problem.

The **availability of low-risk active substances**, **including micro-organisms, has increased** but is still considered by stakeholders as **insufficient** and procedures are considered lengthy. While the Commission and the Member States have taken action to accelerate the procedures to place low-risk PPPs on the market, the effects of these efforts are expected to materialise only in the future. Furthermore, the MRL Regulation only offers **limited flexibility to address non-chemical active substances**, e.g. micro-organisms or other biopesticides. Similar issues may arise with evolving technology and future needs (e.g. nanopesticides, integration of large cumulative assessment groups).

The **quantifiable benefits of the two Regulations** are only a share of the overall health and environmental benefits, while **the costs** are well accounted for. The costs incurred by industry for PPP authorisation were found to have increased compared to the baseline (i.e. Directive 91/414/EEC) due to more stringent criteria and stricter data requirements. The available quantified evidence suggests that benefits linked to the non-renewal of five active substances under the PPP Regulation, even if uncertain and incomplete, amount to about EUR 38.5 million annually and are higher than the costs related to the evaluation procedures.

There is wide agreement among Member States and stakeholders that **both Regulations have an EU added-value** in achieving their objectives. The added-value includes achieving EU-wide protection of human health, offering economies of scale in generation of data and scientific knowledge, increasing cooperation among the Member States, and simplifying the system for trading partners.

The PPP and MRL Regulations are only partly efficient due to the significant delays that occur in the approval and renewal of approval of active substances, the authorisation of PPPs, and the review of all existing MRLs. The deadlines missed most often in the renewal process are those for: (i) the admissibility check by the rapporteur Member States: (ii) the assessment of the supplementary dossier by the rapporteur Member State; (iii) the additional assessment needed by the rapporteur Member State during the peer-review process; and (iv) the decision-making by the Commission. The re-authorisation of PPPs after the renewal of approval of the products' active substance is also identified as problematic. This is because the delays at the approval stage have reduced predictability of the timing of the approval decisions, which in turn does not allow for good resource management in the Member States. The MRL review process started with several years of delay since the MRL Regulation does not establish the necessary procedural framework. Working procedures and arrangements had first to be agreed between the Commission, EFSA and Member States and rely on voluntary support from the Member States. As of 2018, the MRLs of a little over half of the substances have been reviewed and completion of the review for the remaining ones cannot be accurately predicted.

The free circulation of treated seeds has had a positive harmonising effect within the EU, although there have been some **enforcement difficulties** in the Member States for tracing and controlling treated seeds. Weaknesses were also found as regards official controls on imports and exports of PPPs, as well as on compliance of PPPs placed on the EU market with the conditions of their authorisation, or with parallel trade permits. This

has resulted in the presence **of illegal and counterfeit PPPs** on the EU market which may harm human health and the environment. The MRL Regulation ensures that effective and timely enforcement action can be taken, however, some problems have been experienced in practice by enforcement authorities, in particular with multiple source substances. The new Regulation on official controls and enforcement in the agri-food chain, which will become applicable in 2019 will give Member States a strengthened toolkit to detect fraudulent and deceptive practices, including in the areas covered by the PPP and MRL Regulations.[428]

The main cause of delays is the **lack of sufficient staff in Member States** to carry out the necessary work within the deadlines set in the Regulations. Member States argue that finding the expertise for the risk assessment is a challenge, especially for small Member States. When the Regulations were adopted, the estimated amount of work to be carried out and the resources required appear to have been severely underestimated, resulting in too short and unrealistic deadlines. Such constraints are not expected to be solved in the near future and might worsen as additional requirements during the renewal procedures for active substances and re-authorisation of PPPs are expected. The **costs and workload** involved in approving and renewing the approval of active substances and authorising PPPs within zones are not fairly distributed across Member States. This also contributes to the existing delays as certain Member States face a large workload. In addition, **the fees** raised by some Member States seem to be insufficient to cover their costs, and not all Member States link the fees to the actual work carried out, resulting in fewer resources being available. Furthermore, the work carried out by the Member States on the MRL review is not covered by fees.

In summary, the Regulations are generally effective, in particular with regard to the protection of human health and the environment, but are not entirely efficient and in several areas burdens can be reduced. Coherence is mostly ensured, both internally (within and between the Regulations) and externally with other EU legislation and international rules. The objectives of the Regulations are relevant for the evolving needs, although the demand for a more sustainable agriculture may need to be better addressed. The Regulations are complemented by the Sustainable Use Directive and the Common Agricultural Policy that create additional strong incentives for a sustainable agriculture. The Regulations have a recognised added-value at EU level but also beyond the borders of the EU. This conclusion is further supported by the European Court of Auditors who found that the EU food safety model related to chemicals, including PPPs and MRLs, is soundly based and respected worldwide. However, it is currently over-stretched, as the Commission and Member States do not have the capacity to implement it fully[429].

To reduce the above-mentioned inefficiencies, margins for improvement exist. This Staff Working Document is accompanying a Commission report to the European Parliament and the Council, which contains a number of proposals for action to enhance implementation in order to simplify or strengthen the current regulatory framework.

428 Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products

429 European Court of Auditors (2019) Special Report No 2: Chemical hazards in our food: EU food safety policy protects us but faces challenges (pursuant to Article 287(4), second subparagraph, TFEU)

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Annex 1: Procedural information

Lead DG, Decide Planning/CWP references

DG Health and Food Safety led the REFIT evaluation of EU legislation on plant protection products and pesticide residues. It was item 24 of the Commission REFIT initiative in the Commission's work programme for 2016[430] and item 6 in 2019[431]. This initiative is linked to REFIT action 43 on the Commission's work programme for 2015[432], 'Fitness check on the General Food Law', which was carried out in 2017.

Organisation and timing

The inter-service group was set up in June 2015 to steer and provide input into the evaluation of the legal framework in the field of pesticides. It included representatives from five directorates-general — Agriculture; Environment; Health and Food Safety; Internal Market, Industry, Entrepreneurship and SMEs; and Trade — and from the Legal Service and the Secretariat-General. In addition, a representative of the Directorate-General for Regional Development contributed to the meetings from January 2018. The group met nine times during the evaluation process; see Table A.1.

Table A.1. Inter-Service Steering Group meetings and discussion topics

Dates	Topics for discussion
20 November 2015	Agreement in principle on the mandate, scope and strategy of the evaluation. Discussion on the Roadmap.
18 October 2016	Discussion on the draft terms of reference of the support study — final endorsement through email consultation on 2 March 2017.
3 July 2017	Kick-off meeting for the support study with the contractor.
3 October 2017	Discussion on the inception report and consultation strategy of the support study — final endorsement through email consultation on 8 November 2017.
14 February 2018	Discussion on the interim report on the support study — final endorsement through email consultation on 23 March 2018.
23 May 2018	Discussion on the draft final report on the support study — final endorsement through email consultation on 28 September 2018.
12 September 2018	Discussion on the structure and content of the staff working document.
16 November 2018	Discussion on the draft final staff working document.
11 December 2018	Discussion on the draft final staff working document.

External expertise

The analysis of the evaluation is based on an external support study conducted by Ecorys Brussels from June 2017 to October 2018. This support study answered 28 evaluation questions linked to the five evaluation criteria[433].

Several other reports and studies have been published recently on the implementation of the PPP Regulation and the way in which the system for regulating pesticides and chemicals in the EU operates. The findings of the reports listed below have been carefully considered for the analysis in this staff working document:

430 Commission Work Programme for 2016. No time for business as usual. COM(2015) 610.
431 Commission Work Programme for 2019. Delivering what we promised and preparing for the future. REFIT initiatives.
432 Commission Work Programme for 2015. A New Start. COM(2014) 910.
433 Support study published in the EU bookshop.

- The European Commission reports on audits and overview reports of a series of audits in Member States. These include overview reports on the authorisation of plant protection products[434], and on checks on pesticides in food of plant origin[435].
- Following a request from the College of Commissioners, led by Commissioner Andriukaitis, the Group of Chief Scientific Advisors published a scientific opinion on EU processes for the authorisation of plant protection products in June 2018[436].
- In April 2018 the European Parliament's Research Service published an implementation report on the PPP Regulation on the placing of plant protection products on the market[437]. The report was requested in May 2017 by the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI).
- The European Parliament adopted in September 2018 an own-initiative report on the implementation of the PPP Regulation which had been prepared by the ENVI committee, with MEP Pavel Poc as rapporteur[438]. The report is based on the external study by the European Parliament's Research Service.
- On 6 February 2018 the European Parliament adopted a decision on setting up a special committee on the EU's procedure for the authorisation of pesticides (the PEST Committee), its responsibilities, its numerical strength and its term of office. In January 2019, the Parliament adopted the report of the PEST Committee which had been prepared by MEPs Norbert Lins and Bert Staes as rapporteurs[439].
- The REFIT evaluation of the General Food Law[440], the REACH review[441], the fitness check on chemicals legislation other than REACH[442] and the report on the implementation of the Sustainable Use Directive[443].

Consultation of the Regulatory Scrutiny Board

The Commission's Regulatory Scrutiny Board assessed a draft version of this evaluation and issued a positive opinion on 4 February 2019[444]. The Board made recommendations to improve the report further. These were addressed as follows in the revised report.

To better take into account the interactions with related pieces of legislation, section 5.4 on relevance brings together all issues related to sustainability and low-risk active substances in a more comprehensive discussion. In addition, section 1.2 on the scope of the evaluation has been expanded to clarify why an evaluation encompassing also the Sustainable Use Directive was not possible to carry out at this point in time. The

434 European Commission (2017). Overview report on a series of audits carried out in EU Member States in 2016 and 2017 in order to evaluate the systems in place for the authorisation of plant protection products. DG(SANTE) 2017-6250.
435 European Commission (2012). Overview Report of a Series of Audits in Member States in Order to Assess the Official Control Systems in Place for Pesticide Residues in Food of Plant Origin, DG(SANCO)/2012-6631.
436 European Commission (June 2018) EU Authorisation processes of plant protection products — from a scientific point of view. Group of Scientific Advisors. ISBN 978-92-79-67735-9.
437 European Parliament Research Service (April 2018) European Implementation Assessment. Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market. ISBN: 978-92-846-2734-9.
438 European Parliament (September 2018) Report on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009.
439 European Parliament (January 2018) Report on the Union's authorisation procedure for pesticides (2018/2153(INI)) Special Committee on the Union's authorisation procedure for pesticides.
440 European Commission (2018) The REFIT Evaluation of the General Food Law (Regulation (EC) No 178/2002) SWD(2018) 38.
441 European Commission (2018) Commission General Report on the operation of REACH and review of certain elements Conclusions and Actions. SWD/2018/058.
442 Fitness check on chemical legislation (excluding REACH)
443 European Commission (2017) Report from the Commission to the European Parliament and the Council on Member State National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides. COM/2017/0587.
444 Regulatory Scrutiny Board opinions on evaluations and fitness checks.

Sustainable Use Directive will be evaluated in the near future and the findings are expected to complement this evaluation.

In section 5.1.4, the part on the zonal system has been deepened to provide for a more thorough analysis of the underlying reasons for the reported lack of trust in the zonal system that hampers mutual recognition. In section 5.1.8 on transparency and risk communication, a text box has been inserted describing more details of the Commission's proposal on transparency and sustainability of EU risk assessment in the food chain to clarify how the proposal already addresses some of the concerns raised by stakeholders. The difficulties related to residues of chlorate are brought together and discussed in section 5.1.7 on enforcement, further expanding on the opinion delivered by the REFIT platform.

The description of the findings has been nuanced on some occasions to reflect better divergent views among stakeholders (e.g. in section 5.1.1 on effectiveness).

All recommendations for simplification and burden reductions are contained in the report to the European Parliament and the Council which this Staff Working Document accompanies. The report contains an expanded discussion about future actions for the Commission, Member States and EFSA that are expected to improve implementation of the Regulations.

Annex 2: Synopsis report on the stakeholder consultation

This synopsis summarises the consultation activities carried out, the stakeholders who contributed, and their opinions. The roadmap for the evaluation was published in November 2016. 21 stakeholders sent in feedback on the roadmap via a dedicated webpage. Responses received in the first four weeks after the roadmap was published fed into the design of the evaluation, influencing the terms of reference of the support study[445]. The support study then collected data from stakeholders through consultation activities.

Consultation strategy

The consultation strategy was drawn up in January 2017 together with the terms of reference of the support study, and data were collected on all five evaluation criteria. Stakeholders that have contributed to one or more consultations are: national public authorities; EFSA; the Commission services; the pesticide industry, the food industry, NGOs working on the environment, health, animal protection and transparency; members of the public, consumers and farmers, and authorities and other stakeholders from non-EU countries.

Table A.2. Consultation activities carried out

Consultation	Target/participants	When?	Contributions
Open public consultation	Consumers, citizens and farmers.	13 Nov 2017 - 12 Feb 2018	9 847
SME consultation panel	Distributed via the Europe Enterprise Network to target: small, medium and micro-sized companies.	14 Nov 2017 - 15 Jan 2018	294
Stakeholder survey	Trade and industry associations covering the chemical industry; retail and wholesalers; food and feed industry; environmental, health and consumer NGOs; and farmer associations.	14 Nov 2017 - 12 Jan 2018	240
Member State survey	Member States and EEA countries.	16 Nov 2017 - 19 Feb 2018	30
Focus groups	Member State authorities, EFSA, the Commission, stakeholders working with risk assessment.	24 Jan 2018 28 Feb 2018 5 Mar 2018 9 Mar 2018	8 9 7 8
First workshop	Member State authorities, the Commission, trade and industry associations, and NGOs at EU level.	12 Sep 2017	40
Second workshop	Member State authorities, the Commission, trade and industry associations, and NGOs at EU level.	16 May 2018	50
In-depth interviews	Trade and industry associations, NGOs at EU level, Member States, non-EU countries, EFSA and the Commission.	10 Jan 2018 - 25 Apr 2018	60

445 The feedback can be accessed via the Europa webpage.

Analysis of the data

The data collected from the surveys was downloaded in spreadsheets. The contractor of the support study was responsible for the first analysis of the data and to take into consideration the opinions of the public, stakeholders and Member States. 17 position papers were sent by non-EU countries[446], stakeholder organisations[447] and Member States[448]. These were all read and taken into account in the analysis. Once the support study had been finalised, all data were sent to the Commission who conducted a second analysis for the preparation of the staff working document. The open field questions in the surveys and the position papers were reanalysed.

The answers to the questions to all four surveys are available in tabular form in Annex 3 of the support study.

Online public consultation

The public consultation opened on 13 November 2017 and closed on 12 February 2018. A total of 9 879 responses were submitted (including 32 duplicates, which were removed). The remaining **9 847 responses** were analysed.

The public consultation was designed to collect the views of the public on plant protection products and pesticide residues in the EU. In particular, it sought to gather information on how well informed the public feel about pesticides, pesticide residues and EU decision-making. The survey focused on public perceptions of how pesticides and pesticide residues are regulated. It comprised 24 questions and was available online (via 'EU survey') in the EU's 23 official languages. It could be accessed via the European Commissions' public consultation website[449]. Contributions received by post were also considered as input into the EU survey.

65 % of respondents lived in Germany or France
4 % were from non-EU countries
77 % were aged 30-64
76 % were employed or self-employed
55 % lived in a rural area
20 % worked in farming
56 % said the PPP or MRL Regulations were relevant to their professional work

446 Argentina, Australia, Brazil, Canada, India, Kenya, Malaysia, New Zealand, Peru, Thailand and the USA.
447 ECPA, Syngenta and Wine Institute.
448 From Sweden, Belgium and the Netherlands and from the northern zone steering group.
449 Online Public Consultation

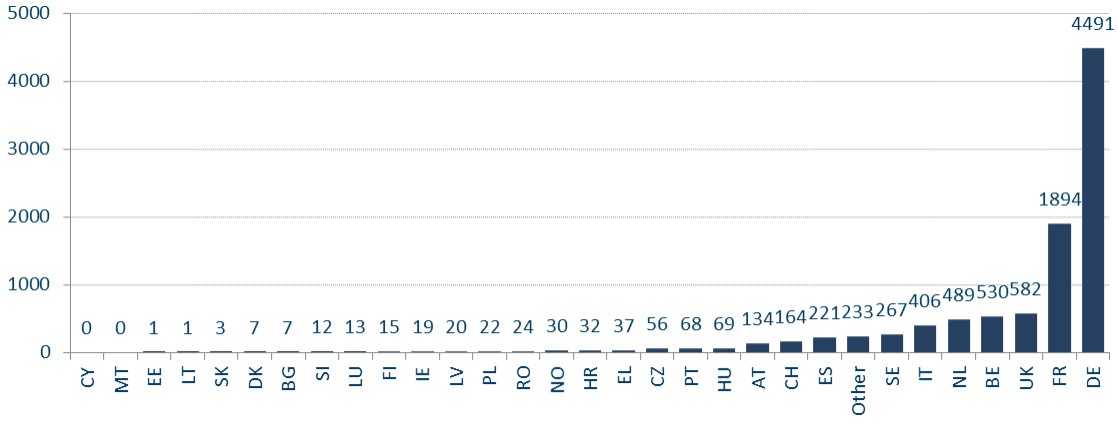


Figure A.1. Distribution of replies by country in absolute numbers

The vast majority (99 %) of respondents knew that the EU regulates pesticides and pesticide residues. However, the public does not think that the PPP Regulation provides sufficient protection for human health, animal welfare and the environment.

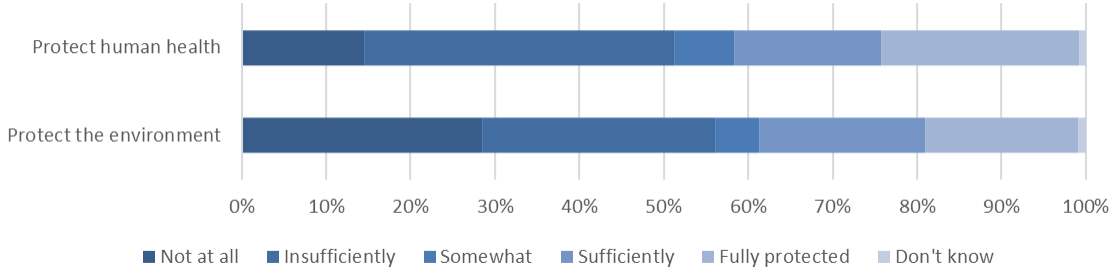
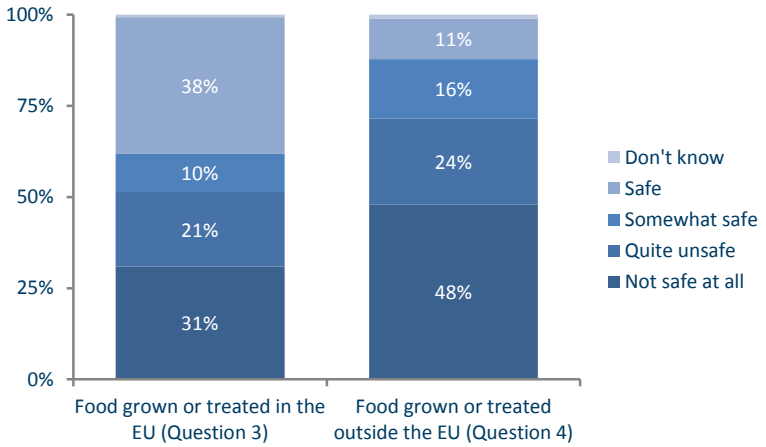


Figure A.2. In your opinion, are human health and the environment protected from the use of pesticides in the EU?

One of the main concerns identified is that consumers do not feel safe eating food that has been treated with pesticides, even though MRLs are set at safe levels and, according to the annual residue monitoring reports, are complied with to a large extent[450]. The proportion of consumers who feel unsafe increases when they are asked if they feel safe eating imported food treated with pesticides.



450 See all reports on EFSA's webpage.

Figure A.3. Do you feel safe consuming food that has been grown or treated with pesticides in the EU and outside the EU?

Responses are influenced by whether or not the respondents' work has any link with the Regulations. People whose work has some connection with the Regulations feel safer about eating food treated with pesticides than those whose work does not. The same pattern recurs in other questions, such as:

- whether it is necessary to use PPPs to meet existing demand for food (see Figure A.4);
- whether human health is protected from pesticides in the EU;
- whether the environment is protected from pesticides;
- whether MRLs in the EU are sufficiently stringent.

In all these questions, those who stated that the Regulations were relevant to their work had a more positive view of their effects. Better knowledge of the regulatory system thus goes hand in hand with a more positive view of benefits and safety.

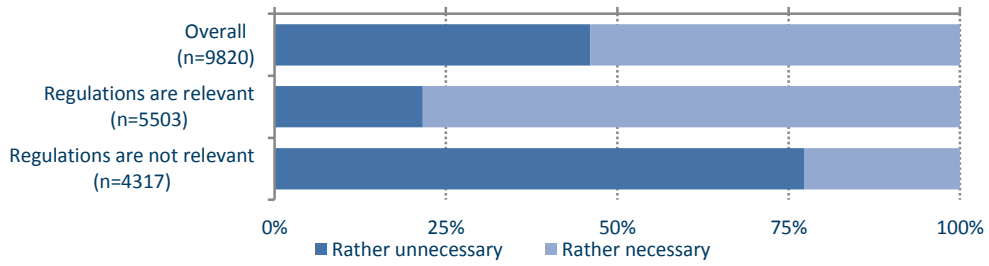


Figure A.4. Do you believe pesticides are necessary to meet the current demand for food?

Respondents are clearly divided on whether pesticides are necessary to meet the existing demand for food (see Figure A.4). About 70 % of respondents for whom the Regulations are relevant to their work say pesticides are necessary or crucial to meet demand. Among them, 75 % of farmers consider plant protection products and pesticides (PPPs) necessary or crucial for this purpose. Farmers who use PPPs themselves were also asked about the availability of pesticides. The majority (64 %) said the PPPs they need were 'mostly' or 'very' available, while a minority (4 %) said they were not available at all. 69 % of farmers also said they were at a competitive disadvantage compared with farmers outside the EU.

The public were asked for their opinion about the level of MRLs in the EU. While 28 % thought the MRLs were about right, 50 % thought them too high (see Figure A.5). Of the respondents for whom the Regulations were not relevant to their work, 82% were of the opinion that MRLs are too high in the EU. Most respondents working in the food/feed industry said the harmonisation of MRLs had had a positive effect on the single market.

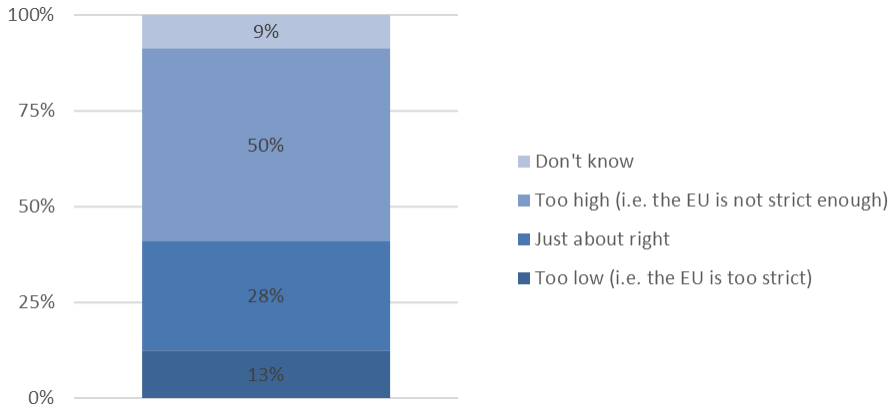


Figure A.5. What do you think about MRLs in the European Union?

Half of respondents feel they are not well enough informed — or completely uninformed – about decisions taken in the EU on PPPs and pesticide residues. There are several platforms and webpages with information about pesticides and pesticide residues in the EU. However, awareness of these is low; 37 % of respondents were not aware that any such sources existed. One issue is that 22 % of respondents know the tools exist, but cannot easily find the information. Just having information publicly available thus does not necessarily mean the public is better informed, if that information is hard to find.

The public was asked about the level at which pesticides and pesticide residues should be regulated. 35 % thought they should be regulated at national level to some extent, 55 % thought they should be regulated at EU level to some extent, and 61 % thought they should be regulated at international level to some extent.

DG Health and Food Safety has analysed the position papers submitted in the course of the consultation. Of the 186 documents sent in that were in a readable format (e.g. .pdf, .doc, .txt), 18 files were corrupted and could not be opened. A total of 168 documents were therefore analysed. Most of them were critical of the PPP Regulation and MRL Regulation, with only 2 % taking a positive view of the current regulatory system.

The main concerns expressed had to do with adverse effects on the environment — particularly the declining insect and bee populations — and human health. Many concerns about human health had to do with cumulative exposure to multiple pesticide residues and the long-term exposure of workers and bystanders to pesticides. 24 % made a link between the active substance glyphosate and inadequate protection of human health and the environment. Several submissions about glyphosate referred to growing concern about its impact on biodiversity, but most expressed concern that it might cause cancer. 11 % of submissions contained references to scientific literature or scientific articles. 4 % included references to the UN special report on the right to food[451]. Some submissions contained suggestions for improving the current system to take more account of innovation in application techniques or for reforming the VAT system to support more sustainable farming. Many referred to the environmental and human health benefits of organic farming. 5 % of submissions criticised the survey itself and the wording of the questions.

The Commission read all the 4108 submissions to the open field question. The responses were submitted in German (2145), French (797), English (713), Dutch (177), Swedish (107), Italian (89), Spanish (42), Polish (16), Czech (7), Latvian (6), Greek (3),

451 United Nations (2017) Report of the Special Rapporteur on the right to food. A/HRC/34/48.

Hungarian (3), Croatian (2), Danish (1), Estonian (1), Lithuanian (1), and Romanian (1). Comments fall into one of two contradictory groups: (i) those in favour of pesticides and (ii) those opposing them. However, both sides agree that EU agriculture faces unfair competition, as imports are not subject to the same strict rules as farm produce from within the EU. Farmers would therefore like to see more harmonisation of PPPs in the EU. The issues most frequently raised are as follows:

(i) Arguments for pesticides

- Pesticides are necessary to produce enough food at affordable prices.
- Media reporting and public opinion are biased, alarmist and one-sidedly negative.
- Decision-making is no longer based on science and facts, but is politicised.
- Decision-making is biased towards protecting health and the environment, and fails to take account of the needs of agriculture. The result is fewer types of PPPs. Farmers lack the tools they need, especially for minor uses, while resistance problems are growing.
- Innovation is declining.
- MRLs provide full protection for consumers.
- PPPs have not been harmonised enough across the EU, nor are they sufficiently available. National authorities insist on applying extra rules and deadlines to the various processes.

(ii) Arguments against pesticides

- Pesticides are unnecessary or can be used far less without jeopardising adequate food production, as organic farming shows.
- All farming should go organic. Existing 'industrial' farming is unsustainable. EU subsidy policy must be altered so as to stop supporting industrial farming and instead support organic production instead.
- Decision-making is biased towards the economic interests of industry and agriculture; the precautionary principle is not applied as it should be.
- Assessments cannot be trusted, as studies provided by industry cannot be trusted, there is not enough transparency, and the evaluating authorities are not genuinely independent.
- Pesticides are poisonous and adversely affect soils and water, leading to decreased fertility.
- Pesticides are responsible for insect and bird population decline.
- Overall assessments of active substances are not stringent enough and MRLs do not provide sufficient protection for consumers, as they fail to take account of the cocktail effect.
- More research is needed into alternatives to pesticides.

SME consultation panel

The SME survey was launched on 14 November and closed on 15 January 2018. A total of 296 responses were submitted, of which two were duplicates. **294 responses** were therefore available for analysis.

The survey was designed to collect the views of micro, small and medium-sized enterprises (SMEs). Its main purpose was to gat her information on how the existing rules governing the approval of active substances, authorisation of PPPs and the setting of MRLs of pesticides are working. The focus was on administrative burden and costs. Responses were collected via the Europe Enterprise Network.

The survey, which comprised 19 questions, was available in all official EU languages. The Europe Enterprise Network's regional partners translated responses to the survey into English where necessary.

50 % were from either Poland or Portugal.
46 % were involved in farming or businesses to do with farming.
73 % were micro-enterprises with a turnover of less than EUR 2 million.
15 % had a turnover of less than EUR 10 million.

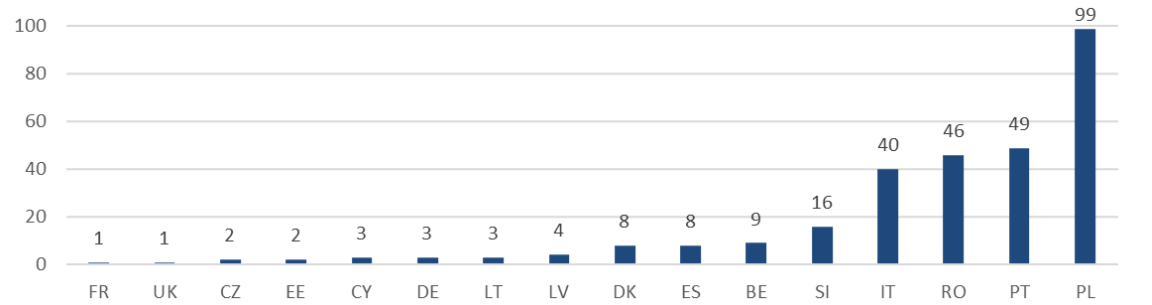


Figure A.6. SME respondents by Member State

The largest single group of SMEs responding (136) are involved in agricultural business. The others work in the following areas: processing food and feed (50), retail and logistics (38), manufacturing PPPs (11), and manufacturing agricultural inputs (9). The 49 SMEs in the category 'other' classified themselves as working in fields including consultancy, importing seeds, scientific work and research, and breeding.

The main issue the survey addressed was the administrative burden and costs which the two Regulations impose on SMEs. This is covered by several questions, such as whether businesses have difficulties complying with the Regulations, or whether they need to hire external consultants to advise them or help them comply with the Regulations. Respondents were also asked to estimate the share of administrative costs stemming from the Regulations on pesticides as a percentage of all the administrative costs incurred by their business.

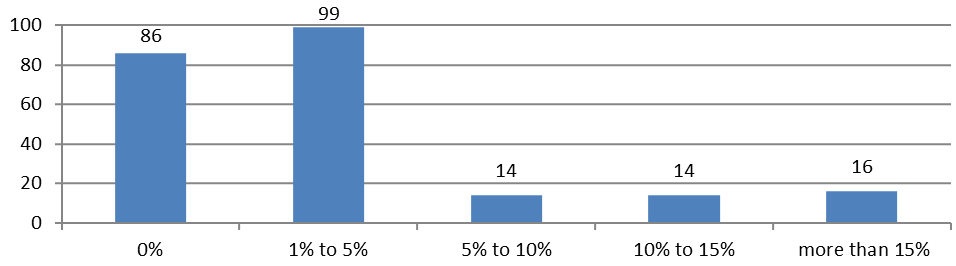


Figure A.7. What is the share of administrative costs stemming from the Regulations on pesticides as a percentage of all the administrative costs incurred by your business?

Overall, businesses report that the administrative costs arising from the Regulations are fairly low. Most businesses that responded to the question about impacts on their business reported that the MRL Regulation had had no impact on their production (76 %), competitiveness (61 %), or sales (64 %). Similarly, the majority responded that the PPP Regulation had not affected their investments (74 %), production (69 %) or competitiveness (59 %).

Most SMEs (86 %) reported that they had had no serious difficulty in complying with MRLs set in the EU. Only 5 respondents (2 %) reported frequent difficulties in complying with MRLs. To comply with the MRL Regulation or the PPP Regulation,

24 % of respondents hire an external consultant, either frequently or occasionally, to advise them or help them comply.

SMEs were asked their views on the level of MRLs in the EU. While 36 % thought they were about right, 26 % thought them too high.

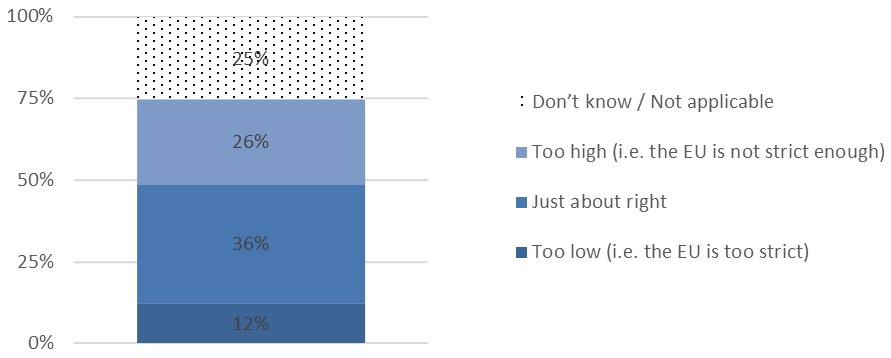


Figure A.8. What do you think about MRLs in the European Union?

Respondents are concerned mainly by the complexity of the rules and the administrative burden, especially as they are relatively small. When asked if their needs were sufficiently taken into consideration, half the respondents were satisfied and half dissatisfied with the Regulations. In the open field questions, SMEs expressed concerns about the difficulties of developing and commercialising new active substances. Meeting the requirements for research and development and bearing the high costs involved are particularly difficult for smaller firms. SMEs say the data requirements and procedures in the PPP Regulation are not considered appropriate or proportionate for low-risk solutions.

Stakeholder survey

The stakeholder survey ran from 14 November 2017 to 12 January 2018. It comprised 136 open and closed questions, and was made available to all stakeholders affected directly or indirectly by the Regulations. The aim was to collect data and views on how the system was working.

Stakeholders from all key groups responded to the questionnaire. Of the 240 respondents, 185 were listed in the EU Transparency Register. Responses from organisations not registered were grouped in the 'Other' category. Stakeholders listed in the transparency register were grouped into six categories (see Figure A.9).

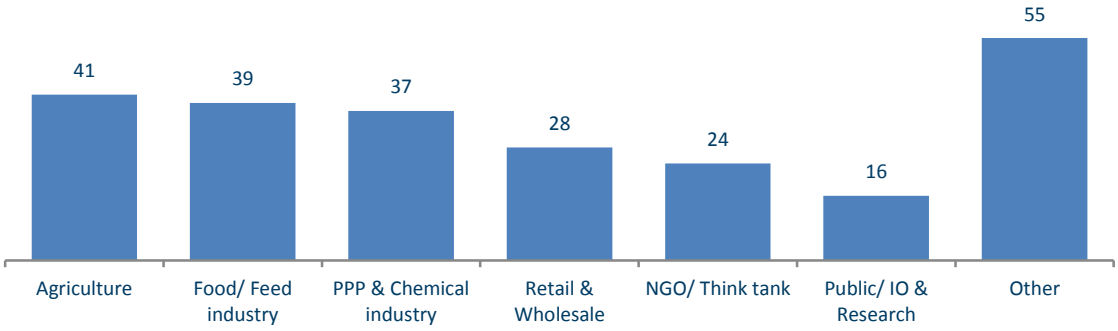


Figure A.9. Overview of types of stakeholders who submitted responses to the stakeholder survey

A majority of stakeholders think the PPP Regulation achieves the aim of protecting users, bystanders and residents, at least to a large extent, as well as the environment (see Figure A.10). A majority do not think it achieves the aim of ensuring that EU agriculture is competitive. Almost 50 % think the MRL Regulation improves international trade to a small extent only, or not at all.

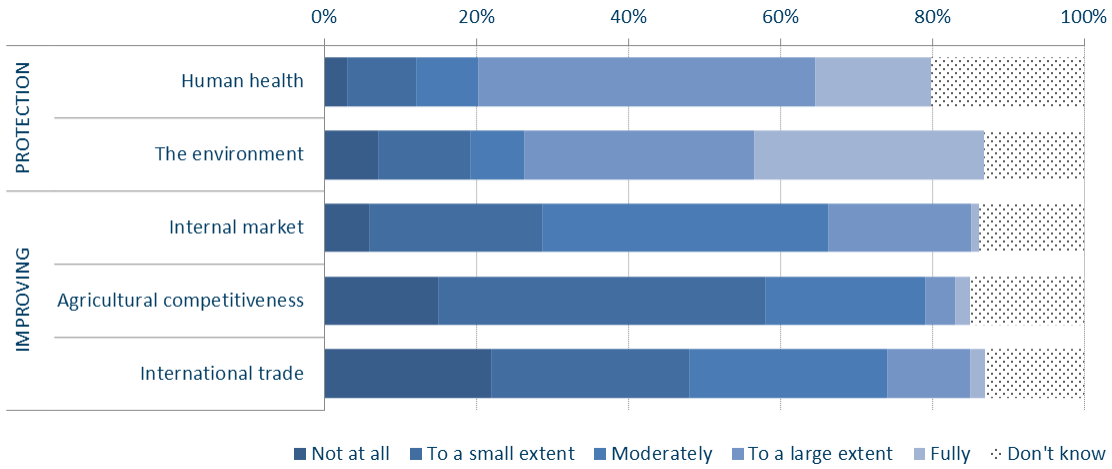


Figure A.10. To what extent have the PPP and MRL Regulations reached the following objectives?

NGOs and think tanks are more critical of the Regulation's benefits. 75 % of them say it does not achieve the objective of protecting human health, or only to a small extent. 25 % say it totally fails to protect the environment.

There is agreement across stakeholder groups that the provisions of the PPP Regulation are not working very well. As regards the approval of new active substances, most respondents from the food and the crop-protection industries say the provisions work to a small extent only. NGOs are even more critical: 77 % say the provisions work to a small extent only. Respondents are similarly critical of how the provisions on the renewal of approval of active substances work in practice.

As regards the implementation and enforcement of the approval procedure, there are differences of opinion among different stakeholder groups. Most NGOs and think tanks say the provisions are implemented to a small extent only. Representatives of the crop-protection industry and associated industries, on the other hand, say the provisions have been implemented, at least to a large extent. Over three quarters of NGOs say the cut-off criteria have not been implemented correctly. The crop-protection industry, on the other hand, criticises them as too restrictive.

With similar response patterns across all stakeholder groups, respondents say that the authorisation of new PPPs and the zonal system work better than the procedures to renew an authorisation and inter-zonal mutual recognitions.

Organisations with a vested economic interest mostly rate the risk assessment and risk management of the approval process as moderately or sufficiently transparent. Again, NGOs take a different view. In their opinion, the processes involved are not at all transparent. All stakeholder groups agree that the MRL-setting process needs to be made more transparent. 86 % of respondents say this could be done by defining clearly which documents should be made publicly available.

As regards the MRL Regulation, many respondents from the industry say the MRLs for food and feed set at EU level are too strict. NGOs, on the other hand, say the levels at

which they are set are too high. About a third of respondents think existing MRL levels are just about right. Consequently, respondents from the food industry say the Regulation has had an overall negative impact on imports of products from non-EU countries into the EU.

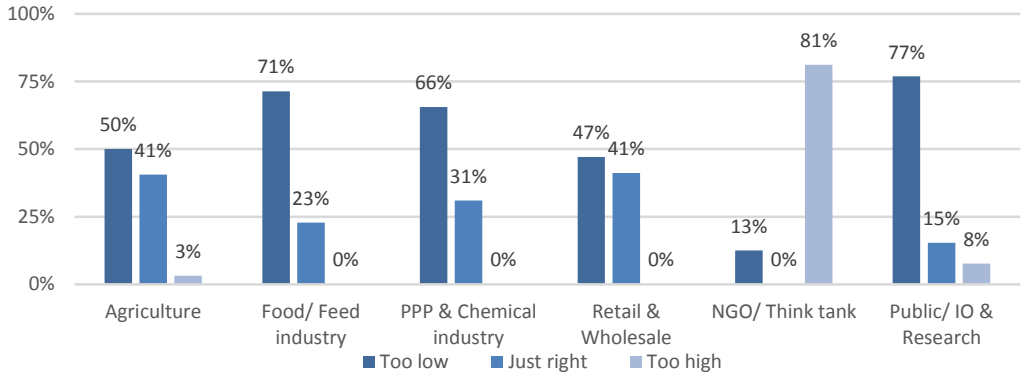


Figure A.11. What do you think about MRLs in the European Union?

Respondents across stakeholder groups say the MRL Regulation is achieving the benefits it is supposed to provide; most think it achieves the aim of protecting consumers to a large extent, or even fully. Respondents have similar opinions on the objective of improving the workings of the single market.

Member State survey

All 28 Member States and two European Economic Area countries (Iceland and Norway) gave input through a targeted survey, which was online from 16 November 2017 to 19 January 2018. Respondents had the option of completing the survey online or of emailing their responses. The questionnaire had 126 questions of two kinds (open and closed). The northern-zone steering committee and 3 EU countries submitted additional position papers.

The Member States take a positive view overall of the effects the PPP Regulation has had. They rate its impact on the objectives of protecting human health and the environment and improving the workings of the single market as 'very positive' or 'positive'. As regards agricultural production, however, 40 % of Member States think the Regulation has had a 'negative' or 'very negative' impact (see Figure A.12).

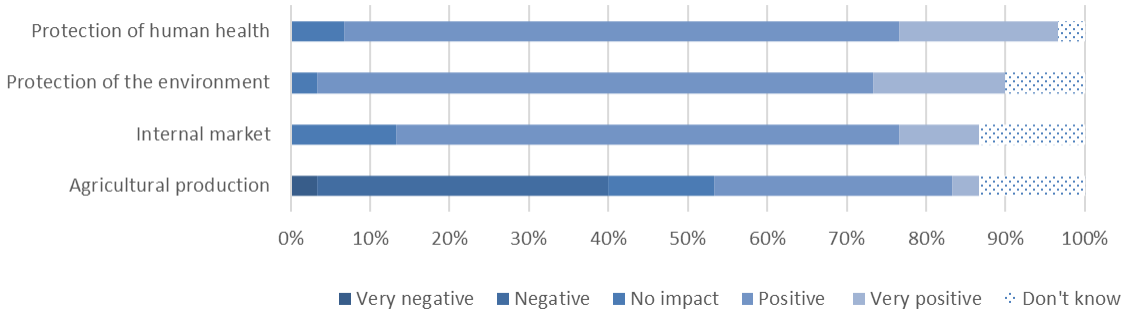


Figure A.12. What impact has the PPP Regulation had on the following objectives?

The Member States say the MRL Regulation has had either a positive or a very positive impact on all objectives (see Figure A.13).

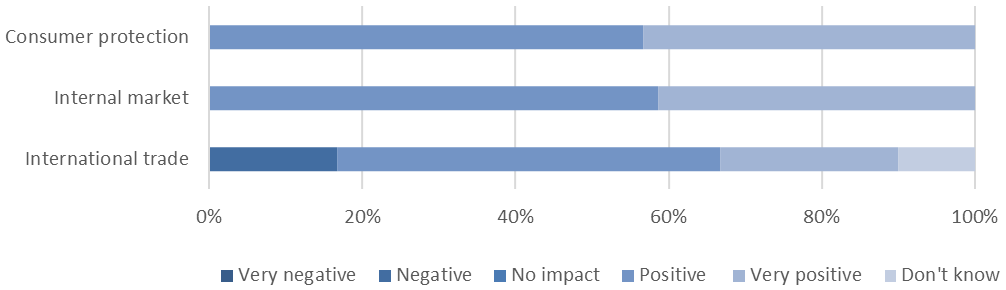


Figure A.13. What impact has the MRL Regulation had on the following objectives?

The Member States seem satisfied with the procedure for approving active substances. However, they voice greater concern about the procedure for renewing approvals. Only five of them say the provisions on the renewals work, at least to a large extent. Four say they work to a small extent only. The majority of Member States also think the approval criteria appropriate. The cut-off criteria, however, appear to be controversial. Fewer than half of the Member States think they are appropriate. Three prefer stricter cut-off and risk-based criteria (see Figure A.14).

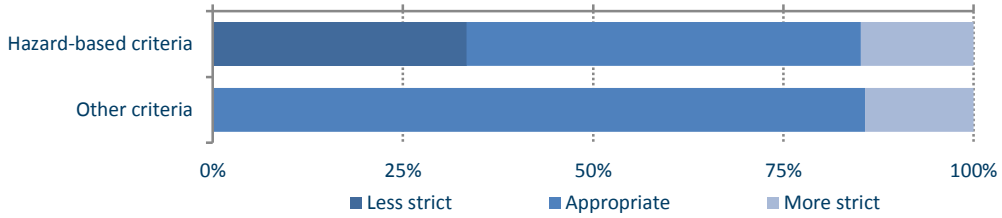


Figure A.14. Are the criteria for approving an active substance appropriate? If not, should they be stricter or less strict?

A majority of Member States say the benefits of the PPP Regulation outweigh its costs. In general, they say the procedures are more efficient today than before the Regulation was implemented (Figure A.15). They say the partial harmonisation of the authorisation procedures was successful.

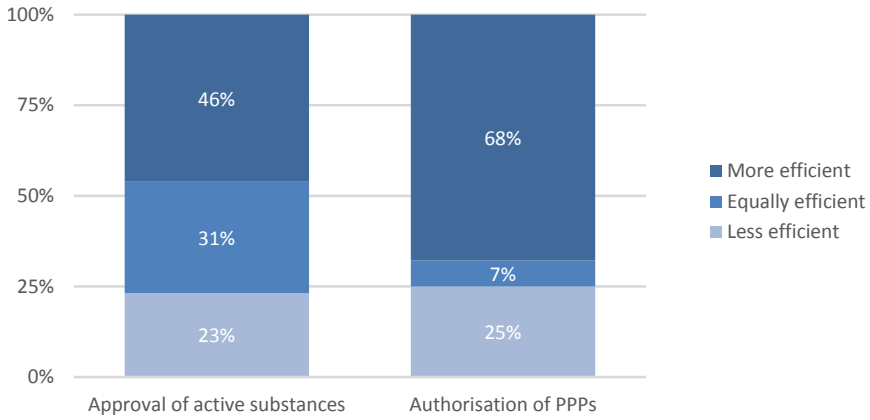


Figure A.15. Do you think procedures today are more efficient or less efficient than before the entry into force of the PPP Regulation?

Member States say they approve of the default limit of 0.01 mg/kg set out in the MRL Regulation. Only one says the limit is not strict enough. Member States say the provisions on setting and reviewing MRLs work well in practice. Greater problems are

reported on the review of existing MRLs; four Member States say the provisions work to a small extent only.

Most Member States consider the benefits of the MRL Regulation to outweigh the costs. About half of them say the benefits outweigh the costs, at least to a large extent. However, perceptions of the efficiency of the MRL-setting and reviewing procedures vary somewhat. Overall, the Member States see the setting procedure as more efficient than the review procedure.

The Member States were asked what level pesticides and their residues should be regulated at. They still favour the current system, with approval of active substances and MRLs at EU level and authorisation of PPPs at national level. Several would welcome more international cooperation.

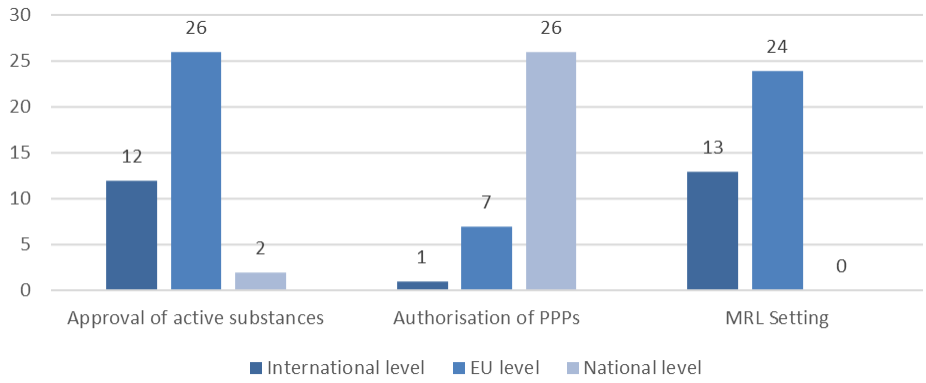


Figure A.16. What level of governance is most appropriate for regulating pesticides and their residues? (Multiple responses possible)

Focus groups

Four focus groups were convened between January and March 2018 to collect additional information from experts from Member States, EFSA, the Commission, the Minor Uses Coordination Facility, and from consultants advising on the submission of dossiers. The Member States represented at each of the focus groups were selected to reflect geographical coverage and the size of the countries. The topics examined by the focus groups were: 1) risk assessment; 2) risk management and decision making; 3) MRL setting; and 4) PPP authorisation.

1. *Risk assessment*

Participants: NL, UK, FR, DE, BE, EFSA, JSC International, Exponent International Limited.

Participants in the focus group identified reasons for the delays in the course of the risk assessment procedure. One particular issue is the amount of information to be processed by the relatively tight deadlines for responding to applications. Participants were very satisfied with the cooperation between Member States and EFSA. It was also generally agreed that there should be a formalised forum to discuss general risk assessment issues where Member States could have a say.

Although the cut-off criteria were supposed to speed up the process, participants reported that in practice, there is too little time to first conduct an evaluation on the cut-off criteria, then a full evaluation. There is a general consensus among the Member States that the cut-off criteria do not speed up the process.

As alternative methods to animal testing are becoming increasingly prominent, it was agreed that the risk assessment should be improved to allow taking those new methods also into consideration. It was reported that the reduction of animal testing is difficult to enforce at European level, and that a register of earlier studies conducted would be needed to avoid the duplication of studies involving animals. Participants also discussed the transparency of the process and civil society participation in it. They appreciated the fact that EFSA has published a good deal of information on the assessment of active substances and acknowledged that the process has become more transparent over the years. At the same time, although some stakeholders are actively involved, it is often difficult to engage the scientific community.

2. *Risk management and decision-making*

Participants: EL, SE, LU, SK, PL, EFSA, and the Commission.

Participants noted that one of the key objectives of the PPP Regulation was to harmonise and streamline procedures across the EU, and that further streamlining processes could help boost cooperation, particularly in terms of enabling risk managers to take more decisions. It was suggested that EFSA conclusions should allow for some flexibility, underpinned by sufficient information on how risks can be managed. It was further suggested that involving risk managers in the drafting of guidance documents for risk assessment could improve understanding of the procedures while also strengthening the link between the two stages of the process. All of this could help reduce delays, as risk managers sometimes think the risk assessment lacks sufficient depth and completeness for sound decision-making, and file additional data requests.

The timeframe for risk management was generally reported to be appropriate. However, one key problem was the lack of a stop-the-clock option (during the risk management process) which could provide more predictability as regards timelines and reduce the use of confirmatory information procedures. Application of the precautionary principle is thought to be one of the least well understood concepts in the PPP Regulation. This leads to differences in understanding among stakeholders as to how the principle should be applied, and there are calls for it to be better defined.

It is generally agreed that scientific progress is taken into account in the risk management process. However, other factors (socioeconomic and agronomic) are not taken into account sufficiently and should be more clearly included in the Regulation for this to be improved. There is a parallel with the participants' opinion on risk assessment; while they think the PPP Regulation has improved transparency, they highlight a need to do more to include the scientific community — widely perceived as disengaged – in the process, to improve scientific scrutiny.

3. *PPP authorisation*

Participants: BE, ES, DK, PT, HU, the Minor Uses Coordination Facility and the Commission.

This group focused on aspects related to the authorisation of PPPs at Member State level. Participants described the renewal procedures as burdensome, as the legal deadlines are too tight and resources are in short supply. One specific example is the need to provide all the information required in both the national language and English, which binds resources and time. Coordination within the zonal system was reported to vary across zones. For example, participants stressed the role of meetings and knowledge exchange in the Northern zone in enabling proceedings to run smoothly. In the central zone, on the other hand, harmonisation and zonal cooperation were thought to pose particular

challenges. The reasons for this are the size of the zone and the diversity of the Member States belonging to it.

Participants said the number of national requirements was rising rather than falling, as Member States generally believe national requirements provide additional protection. This creates obstacles for mutual recognitions. Emergency authorisations are considered by Member States to be helpful in solving some of the problems thought to have been created under the current legislative framework. Participants pointed to a lack of PPPs available in their country, partly due to delays in re-authorisations, with smaller countries, in particular, seeing emergency authorisations as an important mechanism to provide agriculture with the tools needed. The focus group also discussed low incentives for industry to apply for authorisations as one of the reasons why few alternatives are available. As there is no common definition of minor uses, Member States apply the rules differently, which is a further obstacle to placing these products on the market and hinders zonal authorisations. An EU-wide minor uses database would be welcomed.

4. *MRL setting*

Participants: EL, UK, DE, FR, EFSA, EFSA and the Commission

As regards procedures and timelines, the participants identified several problematic elements. The main concern relates to the review of existing MRLs under Article 12. In practice, EFSA is dependent upon Member States' support for this procedure, yet Article 12 does not have the same priority for Member States as, for instance, Article 6 of the MRL Regulation. It was suggested that a guidance document for Article 12 could help support the work. Participants also agreed that legal deadlines are too short for more complex applications. Different Member States handle incomplete dossiers in different ways; some make use of the stop-the-clock procedure and request additional data, while others do not allow additional submissions.

Participants highlighted inconsistency between the OECD and EFSA guidance documents as one of the problems, as it was not always clear which guidance applied. Another element that was highlighted was the fact that cumulative risk assessment is not adequately accounted for when MRLs are set or reviewed. Inconsistency between the PPP Regulation and legislation on genetically modified organisms was also highlighted; this could be solved by updating the definition for residues. According to the participants, there is also a need to improve the transparency of the MRL-setting process. One Member State said that although stakeholders had the option of reacting, the process was difficult. Overall, participants agreed that the MRL Regulation had helped achieve a harmonised approach, and that overall the Regulation had also been effective in achieving closer cooperation between Member States and EU-level authorities.

Workshops

Two workshops were held on 12 September 2017 and 16 May 2018, respectively, to engage with stakeholders and Member States. The minutes are available on the Commission's REFIT webpage[452].

Interviews

The contractor of the support study conducted around 60 interviews. The information was used in the answers to the evaluation questions in the support study.

452 Pesticide REFIT webpage

The stakeholders and Member States interviewed were: European Seed Association, European Crop Protection Association, European Crop Care Association, IBMA, Pesticide Action Network, FDE, Greenpeace, PROFEL, COPA-COGECA, UK Pesticides Campaign, Bee Life, Coceral, IFOAM, Freshfel, SNE, Health and Environment Alliance, Clientearth, FEFAC, COE, Austria, Belgium, Croatia, Denmark, Estonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and United Kingdom. Representatives of the European Commission and EFSA were also interviewed.

Annex 3: Methods and analytical models

External support study

The support study was carried out by Ecorys Brussels for the Commission. The study answered 28 evaluation questions. The evaluation questions were derived from the questions in the roadmap but with higher level of detail combining the questions with the scope of the evaluation.

In the structuring phase, the contractor set out the strategy for the study and sequence of tasks. The structuring ended with the delivery of the inception report, which included the methodology and analytical methods to be used together with the questionnaires to be used in the data collection. Based on the consultation strategy, the contractor carried out the data collection, which included surveys, interviews, focus groups, case studies and workshops. An interim report was delivered following the data collection to take stock of the progress made. The final report was published on 18 October 2018[453].

Toxicological profile of approved active substances

To compare the toxicological hazard profile of active substances approved in the EU in 2011 and 2018, a dataset was created based on an extract from the EU Pesticides Database. The substances approved in 2011 were mapped with the help of Regulation 540/2011 and implementing Regulations on approvals, renewal of approvals, non-approvals, non-renewal of approvals and withdrawals. Following the mapping of approved active substances, the hazard classification as reported on the European Chemical Agency's website[454] was added. This was done using a step-wise approach:

1. harmonised classification;
2. proposed classifications yet to be reviewed;
3. notified (self-reported) classifications;
4. EFSA views on appropriate classifications from the most recent EFSA conclusion.

Based on the hazard classifications for human health, the substances were divided into 10 categories (see Table A.3). Based on the 10 groups, 3 larger groups were created. The high hazard group represents the active substances meeting the cut-off criteria. The active substances which had no classification were placed in the low-hazard group. One caveat with this approach is that active substances that should have a harmonised classification but have no proposed or notified classification are placed in the low hazard category. However, it is not expected that this concerns a significant number of active substances, distorting the analysis. Micro-organisms are considered low-hazard, although it is acknowledged that they can still exhibit skin-sensitising properties, despite not being classified.

Figure A.17 shows the comparison. In the graph there is also the projection for 2022 which is based on the application for renewal of approval of active substances. For more than 56 active substances, there is no longer support at EU level. The projection for 2022

453 The support study published in the EU Bookshop
454 https://echa.europa.eu/

does not include applications for new active substances, as it is not possible to predict what new active substances will be approved in the future and how they will be classified.

To account for the larger number of active substances available in the EU in 2018 compared to 2011, the share of active substances falling within a group was calculated and compared over the years instead of comparing just the numbers or active substance.

Table A.3. Hazard classifications related to human health.

Classification, proposed classification or notified classifications: C&L inventory				
HAZARDOUSNESS	Mutagenic Cat. 1			Cut-off
	Carcinogenic Cat. 1	Reprotoxic Cat. 1		
	Carcinogenic Cat. 2	Reprotoxic Cat. 2	Mutagenic Cat. 2	Intermediate
	Acute toxic Cat. 1			
	Acute toxic Cat. 2	Resp sensitiser Cat. 1	STOT Cat. 1	
	Acute toxic Cat. 3	Skin sensitiser Cat. 1	STOT Cat. 2	
	Acute toxic Cat. 4	Eye damage/irrit. Cat. 1		
	STOT Cat. 3	Eye damage/irrit. Cat. 2	Skin corrosive Cat. 1	
	Skin Irrit Cat. 2			
	Micro-organisms			Low
	No classification			

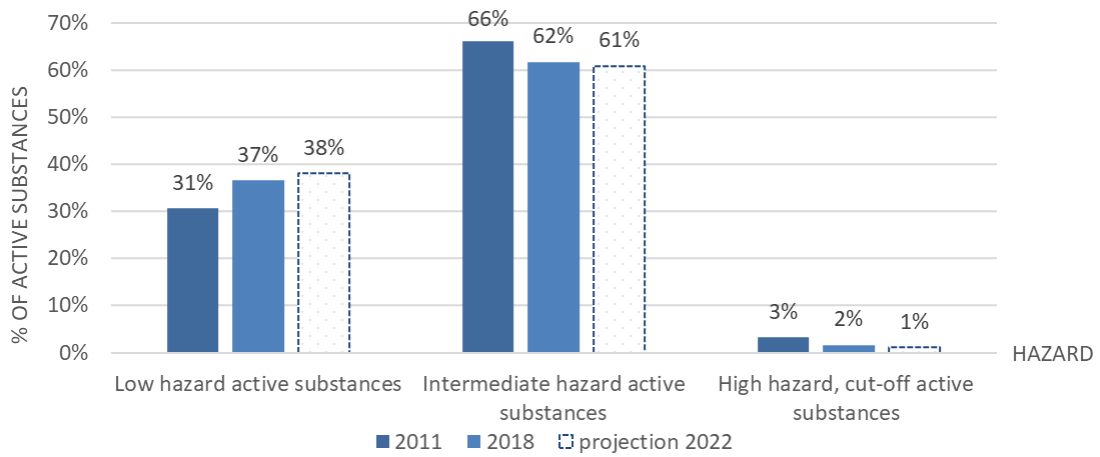


Figure A.17. Distribution of toxicological profile of active substances from 2011, 2018 and 2022.

Emergency authorisations for minor uses

The share of emergency authorisations that are issued for minor uses was estimated at 54%. The calculation is based on all emergency authorisations registered in the PPPAMS for four months in 2018: January, February, April and May. The four months were selected to contain a peak in submissions (April-May) and a trough in submissions (January-February).

Table A.4. Emergency authorisations issued by Member States for minor uses

Month	Emergency authorisations	for minor uses	%
January 2018	36	12	33 %
February 2018	56	24	43 %
April 2018	91	50	55 %
May 2018	74	53	72 %
Total / Average	**257**	**139**	**54 %**

The information is retrieved from the PPPAMS, from the information in the good agricultural practice table where Member States state whether the use is major or minor. In the four months analysed, 257 emergency authorisations were issued, of which 139 were for minor uses, i.e. 54 %. The share of minor uses increases in the months with the highest number of granted authorisations (Table A.4).

Calculation of health benefits — cost savings

The calculations of health benefits are based on data from a scientific study and rely on several assumptions, therefore allowing only for a very rough estimate. The study concluded that in the EU, 13 active substances[455] account for 90 % of health damage costs (EUR 78 million annually, based on 2003 data). Using Eurostat data on the harmonised index of consumer prices (HICP[456]), these costs were inflated to 2017 values, amounting to about EUR 100 million per year.

Annual costs at 2003 price level: EUR 78 million

HICP in 2003: 79.49

HICP in 2017 (latest year available): 101.97

Annual costs at 2017 price level: (78 000 000*101.97)/79.49 = EUR 100 058 624

Of those 13 active substances, 10 are no longer on the market in the EU. 5 of those active substances were already non-approved under Directive 91/414/EEC. The cost savings attributed to the PPP Regulation could therefore only refer to 5 of the active substances that were still approved in 2011 when the PPP Regulation became applicable. To simplify calculations, it is assumed that each of the 13 active substances contributed proportionately to health damage. The non-approvals and withdrawals of the 10 active substances have contributed to cost savings of:

(10/13=0.769)*100 058 624=76 968 172 (about EUR 77 million).

As only half of the costs are directly related to the PPP Regulation, it follows that EUR 76 968 172/2 = 38 484 086. Thus, **annual health benefits amount to about EUR 38.5 million.**

Calculation of the costs of the (non) renewal of approval of five active substances

To allow for a comparison of the benefits reported, the cost for the review of the approval of the five active substances have been estimated. These are reported in section 5.2.3. The calculation concerns the active substances amitrole, glufosinate, linuron, methomyl and propineb that were approved in 2011 when the PPP Regulation became applicable.

The applicants supported the renewal of approval of amitrole, linuron and propineb and prepared the dossiers and paid fees to the rapporteur Member States. The cost for dossier preparation for the renewal of approval of a conventional active substance is approximated at around EUR 2 million[457]. Glufosinate was initially supported by the applicant but the support was withdrawn in December 2017. It is therefore assumed that the cost of the dossier, as well as the fee to the Member State was paid in full. For

455 The 13 active substances are: 1.3-D, amitrole, dazomet, diazinon, glufosinate, linuron, mancozeb, methomyl, parathion, propineb, simazine, terbuthylazine and trifluralin.

456 Eurostat, Harmonised index of consumer prices (HICP) [prc_hicp_aind], accessed on 9 November 2018.

457 The support study, page 146.

methomyl, the applicant did not apply for renewal of approval and the active substance expired without a renewal assessment. The cost is therefore assumed to be zero.

Information on the fees were retrieved from Annex 3 in the support study as the fees varies between Member States. France was the rapporteur Member State for amitrole and charges according to the support study EUR 200 000. Germany was the rapporteur Member State for glufosinate and charges EUR 189 000. Italy was the rapporteur Member State for propineb and linuron and charges EUR 45 000 for a renewal of approval.

As EFSA and the Commission do not charge fees it is difficult to estimate the exact costs for the work on one individual active substance. However, combining the costs for EFSA and the Commission for approvals and renewals (EUR 3.4 million + EUR 2.2 million = EUR 5.6 million) and dividing with the approximate number of procedures per year (9 new active substances and 48 renewals = 57 procedures) the cost is around EUR 100 000 per active substance. As the support for glufosinate was discontinued during the Member State assessment, the costs for EFSA and the Commission is not taken into account for that active substance.

In total the costs to review the approvals of the active substances are (2 000 000*4) + 189 000 + 200 000 + (45 000*2) + (100 000*3) = 8 779 000 ≈ **EUR 8.8 million**

Calculation of the number of the MRLs currently set under the MRL Regulation

As of October 2018, 486 approved and 247 non-approved substances were reported in the Annexes to the MRL Regulation. These substances were notified or an application for approval was submitted under either the PPP Regulation or its predecessor Directive 91/414/EEC. All other substances that are used worldwide, but were never notified at EU level, are not considered in the calculation, although the default value of 0.01 mg/kg applies to them. Among the MRLs included in the MRL Regulation, no MRLs are required for 130 substances. These substances need to be subtracted from the calculation. For each substance considered in the calculation, MRLs are set for the 315 commodities of plant and animal origin, which are listed under the MRL Regulation. This also includes MRLs that are set at the limits of quantification.

MRLs set under the MRL Regulation: (486 + 247 -130) * 315 = 189 945 ≈ **190 000**

Comparison of harmonised CXLs

The calculation of the CXLs that were transposed in the EU and other major countries was carried out for the purpose of estimating the level of harmonisation with international standards. Australia, Canada, Japan and the United States were selected for comparison because of the availability of data in English and because they are OECD members with developed regulatory systems in place. The timeframe 2012-2016 ensures that these countries had sufficient time to transpose CXLs in their national legislation and update the relevant databases. As the MRL Regulation does not report specific MRLs for feed items, only food was considered in the comparison.

Between 2012 and 2016, a total of 1570 pesticide CXLs for food commodities were adopted by Codex, for 103 different pesticides. This information can be retrieved from the Codex Alimentarius Commission reports. When assessing the level of harmonisation, the following was considered: i) national MRLs that are set at the same level of the CXLs ii) national MRLs that are set at higher levels than the CXLs for the same food products. This is because products that are compliant with the CXLs can also be marketed in

countries where higher MRLs apply. The various national databases were consulted and compared to the CXLs listed in the Codex Alimentarius Commission reports to assess the percentages of harmonisation.

Table A.5. CXLs transposed in the MRL Regulation.

Year	Total number of CXLs for food adopted	Share of EU MRLs set at the same or higher values than CXLs	Number of EU MRLs set at the same or higher values[458] than CXLs
2012	242	78 %	189
2013	352	79 %	278
2014	301	72 %	217
2015	326	75 %	245
2016	349	63 %	220
TOTAL	**1570**	**73 %**	**1149**

1 149 MRLs / 1 570 CXLs = 0,7318 = **73%**

A similar comparison per year for the number of transposed CXLs was made for Australia, Canada, Japan and the United States to allow for a comparison between jurisdictions. The result of the comparison is visualised in Figure A.18 and shows that the EU transposed the highest share of CXLs, while Australia and the US transposed less than 50% of CXLs.

Sources, with hyperlinks:

- Codex Alimentarius Commission meeting reports
- Australian Government Federal Register of Legislation
- Health Canada MRL Database
- EU Pesticides Database
- The Japan Food Chemical Research Foundation Search Engine for MRLs
- US Government Publishing Office - Electronic Code of Federal Regulations

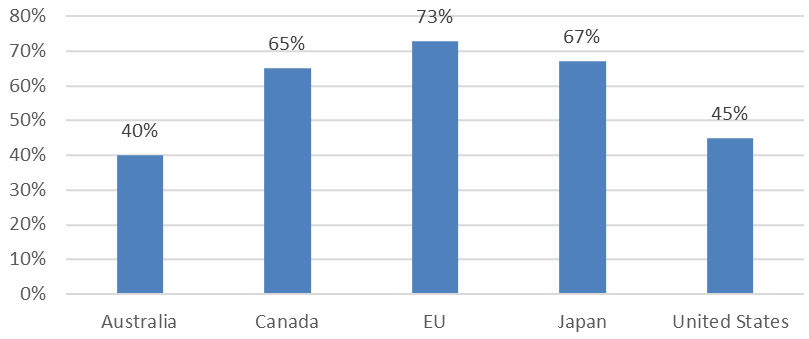


Figure A.18. Comparison of harmonised Codex limits adopted between 2012 and 2016 by WTO members

Currency converter

To facilitate comparisons, all currencies in publications have been converted into EUR. The online currency converter fxtop.com was used for this purpose. The exchange rate on 1 January was used for any given year.

458 MRLs may be set at higher level in the EU to address more critical GAPs than the ones used to establish CXLs. Such MRLs facilitate trade as they cover both international and EU uses.

Environmental impacts — groundwater

In section 5.1.2 on the environmental impacts of the PPP Regulation, two figures are reported to compare the chemical status of groundwater. They are calculated as shown in Table A.6 on the basis of data reported in the following European Environment Agency reports:

- European waters — Assessment of status and pressures, 2012
- European waters — Assessment of status and pressures, 2018

Table A.6. Comparison of chemical status of groundwater in the EU – 2012 and 2018 reports

<table>
<tr><td rowspan="6">Groundwater</td><td colspan="2">European Environment Agency report, 2012</td><td>European Environment Agency report, 2018</td></tr>
<tr><td>Chemical status by area</td><td>Pesticides</td><td>Pesticides in groundwater by area</td></tr>
<tr><td>72 % good status</td><td rowspan="3">In 20 % of groundwater bodies with poor status, pesticides are responsible for the poor status</td><td rowspan="3">In 6 % of groundwater bodies (by area), pesticides are responsible for the poor status</td></tr>
<tr><td>25 % poor status</td></tr>
<tr><td>3 % unknown</td></tr>
<tr><td colspan="2">25 % * 20 % =</td></tr>
<tr><td colspan="2">5 % of groundwater bodies have poor chemical status as a result of pesticides</td><td>6 % of groundwater bodies (by area) have poor chemical status as a result of pesticides</td></tr>
</table>

Annex 4: Costs and benefits

This annex provides a table giving an overview of all costs and benefits. Annex 3 explains how the health benefits were calculated. Annex 2 to the support study explains in detail the methodology for quantifying costs.

OVERVIEW OF COSTS AND BENEFITS IDENTIFIED IN THE EVALUATION[459]							
		Citizens/Consumers/Environment		Businesses		Administrations	
		Qualitative	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative
Cost: Approval of active substances	**Economic cost** for businesses (regulatory charges and compliance costs) in preparing a dossier, application fee etc. Cost for administrations in carrying out the risk assessment and risk management. **Expected.**	**Indirect costs** for citizens and consumers as they are not directly involved in the approval process but as taxpayers they are covering the remaining costs that are not covered by fees for the Commission, EFSA and the Member States.			Approx. per year: New active substances EUR 122-189 million. Renewal of active substances EUR 196 million.		Member States: cost for approval and re-approvals of active substances approx. EUR 10 million (210 Full-Time Equivalents). This cost can be recovered by the fees paid by industry to the Member State EFSA: cost for approval and re-approvals of active substances approx. EUR 3.4 million. Commission: costs approx. EUR 2.2 million.
Cost: Delays in the renewal of approval of active substanc	**Unexpected costs** **Unexpected**				Benefits for businesses from retained profits of existing PPPs on the market	The cost for administrations investing more resources than	

459 All costs for industry and the Member States are from the support study. The costs were reported by the Member States and stakeholders through the online consultations. Other sources are reported separately in the table.

OVERVIEW OF COSTS AND BENEFITS IDENTIFIED IN THE EVALUATION[459]							
		Citizens/Consumers/Environment		Businesses		Administrations	
		Qualitative	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative
es **Benefit:** Delays in non-renewal decisions	**benefits**				are estimated between EUR 10 million and 100 million per active substance per year.	expected**.**	
Cost: Authorisation of PPPs	**Economic cost** for businesses (regulatory charges and compliance costs) in preparing a dossier, application fee etc. Cost for administrations in carrying out the risk assessment and risk management**.** **Expected.**				The cost for dossier preparation for authorisation of new PPPs range between EUR 1-2 million. For renewal of authorisation on between EUR 0.2-0.4 million. As the same dossier can be used in several Member States it was not possible to calculate the total cost as an additive approach would inflate the cost. For other		Member States: cost for authorisations approx. EUR 34 million per year for all Member States. The Full-Time Equivalents associated with PPP authorisations ranges from 1 to more than 100 depending on the Member State. These costs should be covered by fees paid by industry.

OVERVIEW OF COSTS AND BENEFITS IDENTIFIED IN THE EVALUATION[459]							
		Citizens/Consumers/Environment		Businesses		Administrations	
		Qualitative	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative
					procedures, the approx. cost per year: Minor uses extension EUR 43-80 million. Parallel trade permit EUR 3 million.		
Cost: Comparative assessment of CfS	**Economic cost** for businesses (regulatory charges) due to higher fees. Cost for administrations in carrying out the comparative assessment. **Unexpected.**				Approx. per year: Renewal of authorisation with CfS EUR 120 million. Increased costs for applicants for comparative assessment procedures amount to EUR 26.7 million in 2016.		Member States: the Full-Time Equivalents associated with comparative assessments ranges from less than 1 to 3.
Benefit: Cost savings by using mutual recognition	**Reduced economic cost** for administrations when re-assessing dossiers			The cost savings from using mutual recognition also benefit			Between 2012 and 2016, Member States have saved EUR 13-17 million

OVERVIEW OF COSTS AND BENEFITS IDENTIFIED IN THE EVALUATION[459]							
		Citizens/Consumers/Environment		Businesses		Administrations	
		Qualitative	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative
	against national requirements. **Unexpected.**			industry (applicants) as they are the ones paying the fees.			compared to a situation where they would have issued only standard authorisations.
Cost: Setting and reviewing MRLs	**Economic cost** for businesses (regulatory charges and compliance costs) in preparing a dossier, application fee etc. Cost for administrations to carry out risk assessment and risk management. **Expected.**				The combined annual costs for the industry for MRL procedures are estimated at approximately EUR 55 million of which the costs stem from: MRL setting: EUR 38 million MRL Review: EUR 11.7 million Import tolerances: EUR 5.5 million	The costs for the Member States of reviewing MRLs were unexpected as the related activities were not foreseen in the MRL Regulation. The ad hoc procedure created to manage the work implied less work for EFSA but more work for the Member States without the possibilities to raise fees.	The Commission and EFSA: costs for MRL procedures are estimated to EUR 3 million per year. Member States: cost for MRL procedures are approximately EUR 5 million per year.
Cost: Enforcement and monitoring	**Economic costs** for administrations (enforcement costs				For SMEs, 1-5 % of all administrative costs stem from	There are costs for the Member States to enforce the	

OVERVIEW OF COSTS AND BENEFITS IDENTIFIED IN THE EVALUATION[459]							
		Citizens/Consumers/Environment		Businesses		Administrations	
		Qualitative	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative
	and administrative costs) monitoring, reporting and enforcing. **Expected.**				the MRL Regulation.	Regulations and monitor. They were not quantified separately in the framework of the support study but are expected to be moderately high.	
Cost: Impact from PPP Regulation on the price of PPPs.	**Economic costs** for farmers due to supply of PPPs. **Unexpected.**			No firm conclusions can be made on the impact of the PPP Regulation on the costs incurred by farmers. The share spent by farmers on PPPs are comparable to what they spend on fertilisers and these costs are not negligibl	From 2011 to 2016, the share of spending on crop protection over total specific costs fluctuated between 9.3% and 10.3%.[460]		

460 The Farm Accountancy Data Network is an instrument for evaluating the income of agricultural holdings and the impacts of the Common Agricultural Policy.

OVERVIEW OF COSTS AND BENEFITS IDENTIFIED IN THE EVALUATION[459]							
		Citizens/Consumers/Environment		Businesses		Administrations	
		Qualitative	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative
				e.			
Benefit: Health benefits from reduced exposure[461]	**Health benefits** due to reduced exposure of pesticide residues. **Expected**		EUR 38.5 million, see calculation in Annex 3.				
Costs: Removing pesticides from drinking water **Benefit:** Avoidance of cost of removing pesticides from drinking water	**Environmental costs** to reduce pollutions levels. **Expected**					There is a cost of removing pesticides from drinking water as pesticides may be present in surface waters used for drinking water. Benefits for national water utilities in terms of cost savings to remove pesticides from drinking water are expected to decrease due to the improved chemical status of	

461 Fantke, P., Friedrich, R., and Jolliet, O., (2012) Health impact and damage cost assessment of pesticides in Europe. Environment International Vol 49, p 9-17. https://doi.org/10.1016/j.envint.2012.08.001.

OVERVIEW OF COSTS AND BENEFITS IDENTIFIED IN THE EVALUATION[459]							
		Citizens/Consumers/Environment		Businesses		Administrations	
		Qualitative	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative
						surface waters with respect to pesticides.	
Cost: Hiring an external consultant to comply with the Regulations.	**Economic cost** for businesses (compliance costs).				24 % of SMEs consulted need to hire an external consultant occasionally or frequently to comply with either the MRL Regulation and/or the PPP Regulation.		
Benefit: Avoidance of acute poisoning of operators or neighbours	**Direct health benefits** for operators due to increased safety from labelling, equipment and less hazardous PPPs.			Active substances that are scientifically demonstrated to be dangerous for human health are not approved or not renewed, ensuring the safety of operators.			
Benefit: reduced threats to pollinators	**Direct economic benefits** from pollinators	There are multifactorial reasons behind the decline in					

OVERVIEW OF COSTS AND BENEFITS IDENTIFIED IN THE EVALUATION[459]							
		Citizens/Consumers/Environment		Businesses		Administrations	
		Qualitative	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative
	on orchards and crops dependent on pollination. **Expected**	bees, therefore, the annual benefit from restricting the use of some neonicotinoids is a share of EUR 15 billion[462].					
Benefit: Food security in the EU	**Indirect societal benefits** from ensuring a sustainable food supply in the EU.	Restricting the approval and renewal of active substances that are dangerous for the environment allows to better preserve soil and insects that are essential for long-term productivity.					
Benefit: A thriving agricultural sector	**Indirect social benefits** from providing opportunities in rural areas.	PPPs remain available to ensure pest management and support agriculture in the EU. Agricultural activities translate into employment opportunities in rural areas.					

462 European Commission (2018c). EU Pollinators Initiative. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. COM(2018) 395.

OVERVIEW OF COSTS AND BENEFITS IDENTIFIED IN THE EVALUATION[459]							
		Citizens/Consumers/Environment		Businesses		Administrations	
		Qualitative	Quantitative	Qualitative	Quantitative	Qualitative	Quantitative
Benefit: Access to high quality of fresh produce year round	**Indirect social and individual benefits** from eating a variety of food.	Consumers value food variety and fresh food products that are ensured by the use of PPPs.					

Annex 5: Court cases and complaints to the Ombudsman (Status as of December 2018)

OVERVIEW OF COURT CASES BROUGHT TO COURT CONCERNING THE APPLICATION OF REGULATION 1107/2009				
CASE[463]	**Parties**	**Active Substance**	**Subject**	**Pending/outcome**
C-499/18 P	Bayer Cropscience and Bayer AG v Commission	clothianidin and imidacloprid	Appeal, by Bayer Cropscience and Bayer AG against the judgment in case T-429/13 of 17 May 2018 by which the general court dismissed the appellants' action for annulment of Regulation 485/2013 as regards the conditions of approval of the appellants' active substances.	Pending
C-445/18	n/a Reference for preliminary ruling Vaselife International and Chrysal International	n/a	Parallel trade	Pending
T-574/18 T-574/18 R	Agrochem-Maks vs Commission	oxasulfuron	Suspend the application (interim) and Annul (main case) the Commission Implementing Regulation (EU) 2018/1019 of 18 July 2018 concerning the non-renewal of approval of the active substance oxasulfuron	Pending
T-393/18	Mellifera eV vs. Commission	Internal Review Aarhus Regulation: Glyphosate	Annul Commission decision to not carry out an internal review of Commission Implementing Regulation (EU) No 2017/2324 on the renewal of approval of the active substance glyphosate	Pending
C-115/18 (suspended until a judgment is rendered in case C-616/17 which concerns nearly identical issues)	n/a Reference for preliminary ruling	n/a (indirect: Glyphosate — national criminal proceedings against individuals destroying glyphosate containing products in stores)	Validity of Regulation (EC) No 1107/2009 in the light of the precautionary principle	Pending

463 T: General Court, C: Court of Justice, R: interim measures, P: appeal.

OVERVIEW OF COURT CASES BROUGHT TO COURT CONCERNING THE APPLICATION OF REGULATION 1107/2009				
CASE[463]	**Parties**	**Active Substance**	**Subject**	**Pending/outcome**
T-25/18	Pesticide Action Network Europe (PAN Europe) vs Commission	n/a	Annul Commission decision C(2017) 7604 final of 9 November 2017, partially refusing to grant the applicant access to documents relating to the drafting of Delegated Regulations on scientific criteria for the assessment of endocrine disrupting substances	Pending
T-178/18	Région de Bruxelles-Capitale v Commission	glyphosate	Annul Commission Implementing Regulation (EU) 2017/2324 renewing the approval of the active substance glyphosate	Pending
T-125/18	Associazione — GranoSalus vs Commission	glyphosate	Annul Commission Implementing Regulation (EU) 2017/2324 renewing the approval of the active substance glyphosate	Pending
T-67/18	PROBELTE SA. vs Commission	8-hydroxyquinoline	Annul Commission Implementing Regulation 2017/2065 confirming the conditions of approval of the active substance 8-hydroxyquinoline, as set out in Implementing Regulation 540/2011 and modifying Implementing Regulation 2015/408 as regards the inclusion of the active substance 8-hydroxyquinoline in the list of candidates for substitution (The applicant had applied for an amendment of the approval — to lift the restrictions to greenhouse applications)	Pending
C-616/17	n/a: Reference for preliminary ruling	n/a (indirect: Glyphosate — national criminal proceedings against individuals destroying glyphosate containing products in stores)	Validity of Regulation (EC) No 1107/2009 in the light of the precautionary principle	Pending
T-719/17 T-719/17 R	DuPont & FMC vs Commission	flupyrsulfuron-methyl	Annul Commission Implementing Regulation 2017/1496 of concerning the non-renewal of approval of the	The main application is still pending. The application for

OVERVIEW OF COURT CASES BROUGHT TO COURT CONCERNING THE APPLICATION OF REGULATION 1107/2009				
CASE[463]	**Parties**	**Active Substance**	**Subject**	**Pending/outcome**
			active substance DPX KE 459 (flupyrsulfuron-methyl)	interim measures was rejected by Order of President of the General Court on 22 June 2018.
T-476/17 T-746/17 R	Arysta vs Commission	diflubenzuron	Annul Commission Implementing Regulation 2017/855 as regards the conditions of approval of the active substance diflubenzuron (restriction to greenhouse uses) — based on the assessment of confirmatory information required in the earlier approval	The main application is still pending. The application for interim measures was rejected by Order of President of the General Court on 22 June 2018.
T-12/17	Mellifera eV vs Commission	Internal review (Aarhus Convention) — glyphosate	Annul Commission Decision Ares (2016) 6306335 of 8 November 2016. Order the Commission to adopt a new decision on the merits of the applicant's request for internal review of Implementing Regulation (EU) 2016/1056 on the extension of authorisation for glyphosate	Pending
T-476/16	Adama vs Commission	isoproturon	Annul Commission Implementing Regulation 2016/872 concerning the non-renewal of approval of the active substance isoproturon	No decision — Action withdrawn by the applicant
T-746/15	BIOFA vs Commission	sodium hydrogen carbonate	Annul Commission Implementing Regulation (EU) 2015/2069 approving the basic substance sodium hydrogen carbonate. The annulment was not about Article 4 approval criteria but regarding the use of data for approving sodium hydrogen carbonate as a basic substance	Action dismissed as inadmissible (Order of the General Court of 9 November 2016)
T-600/15	Pesticide Action Network Europe (PAN Europe) and Others vs Commission	sulfoxaflor	Action for annulment of Implementing Regulation No 2015/1295, approving the active substance sulfoxaflor	Action was dismissed as inadmissible — Order of the General Court of 28 September 2016
T-310/15 Appeal C-	European Union Copper	copper compounds	Partial annulment of Commission Implementing	The Appeal brought by the

OVERVIEW OF COURT CASES BROUGHT TO COURT CONCERNING THE APPLICATION OF REGULATION 1107/2009				
CASE[463]	**Parties**	**Active Substance**	**Subject**	**Pending/outcome**
384/16 P	Task Force vs Commission		Regulation (EU) 2015/408 establishing a list of candidates for substitution — for copper compounds	Taskforce was dismissed. (Judgment of the Court of 13 March 2018) The application was judged inadmissible (Article 263 (4) TFEU)
T-296/15 and appeal C-244/16 P	Industrias Químicas del Vallés vs Commission	metalaxyl	Partial annulment of Commission Implementing Regulation (EU) 2015/408 establishing a list of candidates for substitution — for metalaxyl	The Appeal was dismissed. (Judgment of the Court of 13 March 2018) The application was inadmissible (Article 263 (4) TFEU)
C-442/14	n/a: reference for preliminary ruling	Several plant protection and biocidal products	National Court case (NL) — Bayer CropScience SA-NV Stichting De Bijenstichtig vs College voor de toelating van gewasbeschermingsmiddelen en biociden: Interpretation of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information — concept of emissions into the environment; overriding public interest: Underlying national case — request to the Netherlands authority responsible for authorising the marketing of plant protection products and biocidal products (the College voor de toelating van gewasbeschermingsmiddelen en biociden, CTB) for disclosure of 84 documents concerning marketing authorisations issued by that authority for certain plant protection products and biocides.	Judgment of the Court 23 November 2016 Wide interpretation of the expression 'information on emissions into the environment' by the Court
T-671/13	Pesticide Action Network	clothianidin, thiamethoxam	Annul the Commission decision of 9 October 2013 in which the Commission	Action withdrawn in 2015 by the

OVERVIEW OF COURT CASES BROUGHT TO COURT CONCERNING THE APPLICATION OF REGULATION 1107/2009				
CASE[463]	**Parties**	**Active Substance**	**Subject**	**Pending/outcome**
	Europe (PAN Europe) (and Syndicat agricole Confédération paysanne vs Commission)	and imidacloprid	declared inadmissible the request for internal review of Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid	applicant
T-578/13	Luxembourg Pamol (Cyprus) and Luxembourg Industries vs Commission	potassium phosphonates (case still governed by Directive 91/414/EC)	Annulment of EFSA Decision of 8 October 2013 concerning the publication of certain parts of the Peer Review Report and Final Addendum on Potassium Phosphonates in respect of which the Applicants claimed confidentiality pursuant to Council Directive 91/414/EEC and Commission Regulation (EU) No 188/2011	Judgment of the General Court of 3 June 2015: Action dismissed as inadmissible
T-584/13	BASF AGRO vs Commission	fipronil	Annul Commission Implementing Regulation 781/2013 amending the conditions of approval for fipronil and the sale and use of treated seeds	Judgment of the General Court of 17 May 2018: - Commission decision partially annulled (amendment of conditions of approval of the active substance) - Action on sale and use of treated seeds dismissed (inadmissible)
Joined casesT-429/13 and T-451/13 (C-499/18 P)	Bayer CropScience and Syngenta Crop protection vs Commission	neonicotinoids	Annul Commission Implementing Regulation 485/2013 amending the conditions of approval for imidacloprid, chlothianidin and thiametoxam (neonicotinoids) and the sale and use of treated seeds	Judgment of the General Court of 17 May 2018: The action was dismissed. The Appeal was submitted by Bayer see entrance with Reference C-499/18 P.
T-545/11 Appeal C-673/13 P T-545/11 RENV	Stichting Greenpeace Nederland and PAN Europe vs Commission	Access to documents — glyphosate	Declare that the Commission's decision of 10 August 2011 is in violation of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice	Judgment of 23 November 2016 on the Commission's appeal: Judgment of the

OVERVIEW OF COURT CASES BROUGHT TO COURT CONCERNING THE APPLICATION OF REGULATION 1107/2009				
CASE[463]	**Parties**	**Active Substance**	**Subject**	**Pending/outcome**
			in Environmental Matters, Regulation (EC) No 1049/20012 and Regulation (EC) No 1367/2006 (see also C-442/14 on substance)	General Court of 8 June 2013 was set aside and case referred back to the General Court where the case is still pending (hearing took place in March 2018). The criteria developed in the appeal judgment have now to be applied to the specific situation underlying the case.

OVERVIEW OF COMPLAINTS TO THE EUROPEAN OMBUDSMAN CONCERNING THE APPLICATION OF REGULATION 1107/2009 AND REGULATION 396/2005			
Case	**Complaint**	**Subject**	**Pending/Outcome**
678/2018/TE	PAN	Extension of the approval period for active substances in plant protection product	Pending
2000/2015/ANA	ECPA	MRLs and compliance with the rules on the approval of PPPs.	The Ombudsman concluded in the sense that the practice is acceptable and there was no maladministration from the Commission side. The Commission must act diligently when the approval is done
1869/2013/AN	Bayer CropScience AG	Access to documents	The Ombudsman concluded that there had not been any maladministration on the part of the Commission.
12/2013/JN	ECPA	Confirmatory data Procedure	Ongoing. Commission submitted to Ombudsman a detailed report in February 2018.

OVERVIEW OF COURT CASES BROUGHT TO COURT CONCERNING THE APPLICATION OF DIRECTIVE 91/414/EEC				
CASE	**Parties**	**Active Substance**	**Subject**	**Pending/outcome**
T-232/11	Stichting Greenpeace Nederland, Pesticide Action Network Europe (PAN Europe) vs Commission	glyphosate	Internal review and access to documents	Case withdrawn in 2015 by the applicant.
T-362/11	Stichting Greenpeace Nederland, Pesticide Action Network Europe (PAN Europe) vs Commission	glyphosate (still under Directive 91/414/EEC regime)	Action for annulment of the Commission's decision of 6 May 2011, refusing to grant the applicants full access to certain documents concerning the first authorisation to place the active substance glyphosate on the market under Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market	Case withdrawn in 2012 by the applicant
T-232/11	Greenpeace NL & PAN Europe vs European Commission	n/a	Aarhus. 31substances (including glyphosate) (refusal by the Commission of internal review)	The applicant informed the General Court that they wished to discontinue the proceeding. Therefore, the case was removed from the register of the General Court.
T-446/10	Dow AgroSciences Ltd and Dintec Agroquímica — Produtos Químicos, Lda v European Commission	trifluralin	Non-inclusion in Annex I to Directive 91/414/EEC — Regulation (EC) No 33/2008 — Accelerated assessment procedure — Manifest error of assessment — Principle of non-discrimination — Proportionality	Judgment of the General Court (Sixth Chamber) of 10 September 2015. Favourable for the Commission
T-71/10 T-71/10R (I) T-71/10 R (II) C-149/12 P	Xeda International SA and Pace International LLC v European Commission	Diphenylamine (I)	Non-inclusion in Annex I to Directive 91/414/EEC — Withdrawal of authorisations of plant protection products containing that substance — Action for annulment — Locus standi — Admissibility — Proportionality — Article 6(1) of Directive 91/414/EEC — Rights of the defence — Article 3(2) of Regulation (EC) No 1095/2007.	Judgment of the General Court (Fifth Chamber) of 19 January 2012. Favourable for the Commission.

OVERVIEW OF COURT CASES BROUGHT TO COURT CONCERNING THE APPLICATION OF DIRECTIVE 91/414/EEC				
CASE	**Parties**	**Active Substance**	**Subject**	**Pending/outcome**
T-95/09 T-95/09 R	United Phosphorus Ltd v Commission of the European Communities	napropamide	Decision concerning the non-inclusion of napropamide in Annex I o Directive 91/414/EEC. Request for interim measures and main case.	Interim Measures were grated. Judgment on the main Case favourable for the Commission.
T-338/08 C-405/12	Stichting Natuur en Milieu and Pesticide Action Network Europe v European Commission		Internal review of temporary MRLs	Judgment of the General Court (Seventh Chamber), 14 June 2012. Not favourable for Commission. This Judgment was appealed, Judgment of the Court (Grand Chamber) of 13 January 2015.
T-475/07 T-475/07 R C-391/08 PR C-584/11 P	Dow AgroSciences Ltd and Others v European Commission	trifluralin	Active substance trifluralin: Non-inclusion in Annex I to Directive 91/414/EEC Action for annulment; Evaluation procedure; Concepts of 'risk' and 'hazard'; Manifest error of assessment; Draft review report; Legitimate expectations; Principle of proportionality.	Judgment of the General Court (Third Chamber) of 9 September 2011. Order of the Court (Fifth Chamber) of 7 May 2013. Outcome favourable for the Commission.
T-467/07 T-467/07 R C-228/08 PR	Du Pont de Nemours (France) and Others v Commission	methomy	Annulment of Commission Decision 2007/628/EC of 19 September 2007 concerning the non-inclusion of methomyl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance	The applicant informed the General Court that they wished to discontinue the proceeding. Therefore, the case was removed from the register of the General Court. Order — 01/07/2009 The interim were not granted.
T-470/07	Dow Agrosciences and Others v Commission	1.3-dichloropropene	Action for annulment of Commission Decision 2007/619/EC of 20 September 2007 concerning the non-inclusion of 1.3-dichloropropene in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant	The applicant informed the General Court that they wished to discontinue the proceeding. Therefore, the case was removed from the register of the

OVERVIEW OF COURT CASES BROUGHT TO COURT CONCERNING THE APPLICATION OF DIRECTIVE 91/414/EEC				
CASE	**Parties**	**Active Substance**	**Subject**	**Pending/outcome**
			protection products containing that substance	General Court. Order — 30/09/2008
T- 403/07	Union nationale de l'apiculture française and Others v Commission of the European Communities	fipronil	Action for annulment — Directive 91/414/EEC — Plant protection products — Directive 2007/52/EC	The Order of the Court of First Instance (Fourth Chamber) of 3 November 2008 dismissed the action as inadmissible.
T-367/07 T-367/07 R C-99/08 P (R)	Cheminova A/S and Others v Commission of the European Communities	malathion	Active substance 'malathion' — Non-inclusion in Annex I to Directive 91/414/EEC — Action for annulment — Locus standi — Admissibility — Evaluation procedure — Assessment by EFSA — Plea of illegality — Article 20 of Regulation (EC) No 1490/2002 — Submission of new studies — Article 8(2) and (5) of Regulation (EC) No 451/2000	Judgment of the Court of First Instance (Eighth Chamber) of 3 September 2009, favourable for the Commission. The interim Measures were not grated (Order of the President of the Court of First Instance of 4 December 2007). The Appeal on the interim measures was dismissed.
T-31/07 T-31/07 R	Du Pont de Nemours (France) SAS and Others v European Commission	flusilazole	Active substance flusilazole — Inclusion of flusilazole in Annex I to Directive 91/414/EEC — Actions for annulment — Partial annulment — Non-severability — Inadmissibility — Non-contractual liability — Limiting the inclusion for a period of 18 months and for four crops — Precautionary principle — Principle of proportionality — Right to be heard — Equal treatment — Statement of reasons.	Judgment of the General Court (First Chamber) of 12 April 2013. Favourable for the Commission. The interim measures were granted and the act was suspended (Order of the President of the Court of First Instance of 19 July 2007).
T-30/07	Denka International BV v Commission	dichlorvos (MRLs)	Action for annulment — Directive 2006/92/EC — Maximum levels for dichlorvos residues.	Lack of individual concern, the application was dismissed as considered inadmissible (Order of the Court of First Instance (Seventh

OVERVIEW OF COURT CASES BROUGHT TO COURT CONCERNING THE APPLICATION OF DIRECTIVE 91/414/EEC				
CASE	**Parties**	**Active Substance**	**Subject**	**Pending/outcome**
				Chamber) of 27 June 2008).
T-416/06 T-416/06 R C-236/07 PR	Sumitomo Chemical Agro Europe v Commission	procymidone	Annulment in part of Commission Directive 2006/132/EC of 11 December 2006 amending Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, with a view to include procymidone as an active substance	The applicant informed the General Court that they wished to discontinue the proceeding. Therefore, the case was removed from the register of the General Court (Order — 21/01/201). The interim measures were not grated.
T-393/06 T-393/06 R(I) T-393/06 R(II) T-393/06 R(III) C-277/07 P(R) C-69/09	Makhteshim-Agan Holding BV, Makhteshim-Agan Italia Srl and Magan Italia Srl v Commission of the European Communities	azinphos-methyl	Action for annulment — Action for failure to act — Directive 91/414/EEC — Plant protection products — Active substance azinphos-methyl — Inclusion in Annex I to Directive 91/414/EEC — Absence of a new Commission proposal after opposition by the Council — Article 5(6) of Decision 1999/468/EEC — Non-actionable measure — Absence of a request to act — Inadmissibility.	Favourable outcome for the Commission.
T-454/05 T-454/05 R	Sumitomo & Philagro France v Commission	procymidone	Active substance procymidone — Directive 91/414/EEC — Action for annulment — Action for failure to act — No need to adjudicate — Action for damages	Order of the Court of First Instance (Third Chamber) of 17 October 2007, The case was dismissed as considered manifestly unfounded.
T-420/05 T-420/05 R(I) T-420/05 R(II) T-380/06 C-459/06 P (R)	Vischim Srl v Commission of the European Communities	chlorothalonil	Inclusion in Annex I to Directive 91/414/EEC — Assessment procedure — Directive 2005/53/EC — Application for annulment — Application for a declaration of failure to act — Application for damages.	Judgment of the Court of First Instance (Sixth Chamber) of 7 October 2009, favourable for the Commission.
T-34/05 R C-258/05 P(R)	Bayer CropScience and Others v	endosulfan	Endosulfan as an active substance — Withdrawal of marketing authorisations —	Interim measures were dismissed. Order of the Court

OVERVIEW OF COURT CASES BROUGHT TO COURT CONCERNING THE APPLICATION OF DIRECTIVE 91/414/EEC				
CASE	**Parties**	**Active Substance**	**Subject**	**Pending/outcome**
T-75/06 (integrating T-34/05) C-517/08P	Commission Commission officially supported by Rapporteur Member State (ES)		Evaluation procedure — Time-limits — Rights of the defence — Principle of proportionality	(Second Chamber) of 15 April 2010 favourable for the Commission.
T-229/04	Sweden v Commission	paraquat	Directive 91/414/EEC — Plant protection products — Paraquat as an active substance — Marketing authorisation — Authorisation procedure — Protection of human and animal health.	Judgment of the Court of First Instance (Second Chamber, extended composition) of 11 July 2007. The Commission act was annulled.
T-158/03	Industrias Químicas del Vallés, SA v Commission of the European Communities.	metalaxyl	Directive 91/414/EEC — Plant protection products — Active substances — Metalaxyl — Authorisation procedure — Summary dossier and complete dossier — Time-limits — Principle of proportionality — Misuse of powers	Judgment of the Court of First Instance (Second Chamber) of 28 June 2005. The Commission act was annulled.