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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

{SWD(2020) 87 final}

1 INTRODUCTION

Plant protection products (PPPs), also often referred to as *pesticides*, are used to protect crops against pests, diseases, or competing plants with the aim of optimising food production in conventional or organic farming. Pesticides are also used to maintain food quality (during storage) or to preserve certain areas in the condition needed for their proper use (e.g. railways). 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 on human health or the environment, pesticides are subject to strict rules in the EU, namely Regulation (EC) No 1107/2009[1], hereinafter referred to as 'the PPP Regulation', and Regulation (EC) No 396/2005[2], hereinafter referred to as 'the MRL Regulation'. The objectives of the Regulations are to ensure a high level of protection for human and animal health and for the environment, to improve the functioning of the internal EU market, improve agricultural production in the EU, and facilitate international trade. Implementation of the Regulations is the joint responsibility of the Member States and the Commission, as Member States have key roles for the scientific assessment of active substances and maximum residue levels, where they cooperate closely with the European Food Safety Authority (EFSA). Based on these assessments, the Commission proposes decisions on the approval, renewal of approval and maximum residue levels of active substances, which are subject to a vote in the Standing Committee on Plants, Animals, Food and Feed before formal adoption by the Commission. The responsibility for the assessment of PPPs and their authorisation lies entirely with the Member States.

The PPP and MRL Regulations are embedded in a wider regulatory and policy context, in particular as set by the Sustainable Use Directive[3] and the Common Agricultural Policy[4], which create obligations for the use of authorised pesticides and provide incentives for a more sustainable agriculture and sustainable farming practices. Environmental legislation governing the quality of surface and ground water includes limits for a number of pesticides and the use of pesticides is in general prohibited in areas identified of particular importance to preserve biodiversity.

There is a growing awareness in society around the sustainability of food production, of which the sustainable use of pesticides is an important component, as reflected in the United Nations 2030 Agenda for Sustainable Development[5] and the European Commission's Reflection Paper "Towards a Sustainable Europe by 2030"[6].

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1 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).

2 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).

3 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).

4 Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

5 Available at: https://ec.europa.eu/environment/sustainable-development/SDGs/index_en.htm.

6 Available at: https://ec.europa.eu/commission/files/reflection-paper-towards-sustainable-europe_en.

The Commission is responding to society's concerns regarding sustainability in the European Green Deal[7], more particularly via the Farm to Fork Strategy[8], and the Biodiversity Strategy[9]. These initiatives will promote healthy ecosystems and biodiversity, more sustainable food production systems and healthier diets, while ensuring sustainable livelihood for farmers and access to high quality and nutritious food for consumers. The Green Deal Communication notably commits to reduce the use and risks of chemical pesticides.

However, an EU agriculture entirely without pesticides is not a realistic objective, including in organic farming where a limited number of pesticides may also be used. Use of pesticides is an essential tool to reach the EU's objectives on plant health, food safety and food security, especially in view of the coming increase in global food demand linked to population growth. The aim of EU legislation on pesticides is therefore not to eliminate pesticides but rather to minimise their impact on human health and the environment through reduced dependency on pesticides, alternative methods and through increased use of low risk and non-chemical pesticides.

The Commission has carried out an evaluation of the PPP and MRL Regulations covering the period of their respective entry into application until end 2018 as part of its regulatory fitness and performance programme (REFIT) in order to assess whether the Regulations are fit for purpose and achieve their objectives while keeping EU law simple and remove unnecessary burdens. This report is submitted pursuant to Articles 82 and 62(5) of the PPP Regulation and Article 47 of the MRL Regulation and is accompanied by a Staff Working Document presenting all evidence. This report is published at the same time as the Farm to Fork Strategy and the second report on the implementation of the Sustainable Use Directive. It builds on the evidence collected by an external contractor[10], an opinion from the Commission's Scientific Advice Mechanism[11], audit reports from the Commission services[12], and experience gained from the operation of the Regulations.

In addition, the Commission has given due consideration to two reports by the European Parliament. The first report[13], adopted in September 2018, addressed the implementation of the PPP Regulation and concluded that the PPP Regulation is a significant improvement compared to the past and that it is appropriate to regulate pesticides at the EU level. However, it also concludes that the objectives to protect human and animal health and the environment are not fully achieved and that the implementation of the Regulation is not satisfactory. The European Parliament therefore calls for action from all key players. The second report[14], adopted in January 2019, of the Special Committee on the Union's authorisation procedure for pesticides (PEST Committee), calls for improved transparency, strengthened policies tackling conflicts of interest and reinforced independence of science. It also calls for a strict application of the precautionary principle and of the hazard based approach in the authorisation procedure and argues for more incentives and research for low-risk alternatives,

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7 https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en.

8 COM(2020) 381.

9 COM(2020) 380.

10 External support study published in the EU bookshop.

11 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.

12 E.g. 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.

13 European Parliament (January 2019) Report on the Union's authorisation procedure for pesticides (2018/2153(INI)) - Special Committee on the Union's authorisation procedure for pesticides .

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

as well as the setting up of a negative list of prohibited co-formulants and an approval procedure for safeners and synergists. The Commission has already responded directly to the two European Parliament reports[15,16].

The Commission has also been mindful of the discussions held in the AGRIFISH Council in November 2018 and the Environment Council in December 2018. In particular, Ministers exchanged views on the current developments in the approval and authorisation system and the impacts on European agriculture and farmers of the increasing numbers of non-renewals of approval of active substances. Ministers also discussed the possible launch of a long-term reflection on the possible development of EU measures to complement national actions to reduce and ultimately phase-out the use of hazardous PPPs and stimulate the development of alternatives. The Commission recalled that Member States are not doing enough to reduce dependency on chemical substances for plant protection and that the potential of integrated pest management is not fully exploited. In addition, Member States often do not meet deadlines when they act as rapporteur Member States for the EU approval system and are making increasing use of emergency authorisations of products, which undermine the EU system. The Commission acknowledged the need to find ways to accelerate placing on the market of low-risk active substances and products.

This report outlines the main findings[17] of the evaluation of the implementation and functioning of both the PPP and MRL Regulations in all Member States since their applicability in June 2011 and September 2008. It proposes actions to enhance the implementation of the Regulations in order to simplify or strengthen the current regulatory framework.

While the evaluation has found a number of weaknesses, some of which are divisive among different stakeholders, stakeholders from across the spectrum agree that the current legislation sets an adequate framework of pre-market approval of active substances and authorisation of plant protection products and are not calling for fundamental changes of the PPP Regulation, while views were more divergent as regards the MRL Regulation. The report identifies in the next section sixteen areas where implementation can be improved in the short and medium term.

2 FINDINGS OF THE EVALUATION AND POSSIBLE WAYS FORWARD

2.1 STRENGTHENED PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT

The evaluation found that the PPP Regulation is largely effective in protecting human health and the environment due to the stringency of the approval criteria, although implementation can be further improved. Stakeholders from across the spectrum consider that the regulatory requirements in the EU are among, if not the, strictest in the world. The number of active substances decreased already by more than 50 % under Directive 91/414/EEC, the predecessor to the PPP Regulation, which led to the withdrawal of the market of many substances that would not have met the requirements of the Directive. This means that the level of protection of health and environment was already high before the PPP Regulation came into force. With the PPP Regulation, a process to regularly review the approval of all active substances has been initiated in 2011: active substances approved earlier are reviewed against the strengthened approval criteria to further increase the level of protection in the EU.

[15] The Commission's response to text adopted in plenary SP(2018)829.

[16] The Commission's response to text adopted in plenary SP(2019)355.

[17] Details of the evaluation can be found in the accompanying Commission Staff Working Document.

As a consequence, the number of active substances earlier allowed in plant protection products, is further reduced and the overall number of active substances approved is substantially lower than in third countries with significant agricultural production. The share of active substances with high hazard profiles is low (2%) and will further decrease in the future, while the proportion of active substance with less problematic profiles is relatively large (37%) and is increasing[18]. In fact, in recent years, about half of the applications for the approval of new active substances (of which there are on average 10 per year) are for micro-organisms (non-chemical) or substances that are expected to meet the criteria for low-risk substances. From 2011 to 2018, decisions to not approve, not to renew the approval, or withdraw 22 active substances[19] because of health- or environment-related concerns, have contributed to reducing serious risks for consumers, operators, workers, bystanders and residents in the EU, and for the environment. The protection of human health and the environment is expected to further improve in the coming years when the first review of all existing approvals will be finalised (expected by 2025). However, not all stakeholders agree with the conclusion that the PPP Regulation is effectively protecting human health and the environment - in particular NGOs argue that the implementation of the approval criteria is not sufficiently stringent, and that hazardous active substances are still used in the EU.

While the PPP Regulation has the clear potential to be effective in reaching its objectives, including increasing the share of low risk substances, these have only been partially attained due to efficiency problems. In fact, implementation of the PPP Regulation suffers from significant delays that occur in the approval and renewal of active substances and the (re-) authorisation of PPPs. This leads to the need for the extension of approval periods of active substances for several years in order to conclude the decision-making process, while also delaying market access for low-risk active substances and keeping on the market active substances that ultimately are found to not fulfil the approval criteria anymore.

The costs and workload involved in approving and renewing the approval of active substances and authorising PPPs within the three zones[20] established by the PPP Regulation are not fairly distributed across Member States. This also contributes to the existing delays as certain Member States face a high workload. In addition, the fees raised by some Member States seem to be both insufficient to cover their costs, and, in addition, not all Member States ring-fence the fees for the authorities actually carrying out the work, resulting in insufficient resources being available.

The European Citizens' Initiative[21] on glyphosate, which collected over 1 million signatures in less than 9 months in 2017, called for more transparency in the process for assessing pesticides. In response, and to increase trust in the scientific assessments conducted by Member States and EFSA, the Commission proposed an amendment of the General Food Law[22], which has been adopted by the Council and the European Parliament on 13 June 2019 (Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain)[23] and will become applicable on 27 March 2021. As of that date the full dossier provided by the applicant to support applications for approvals (or renewal of

[18] The methodology to compare the toxicological hazard profiles of active substances approved in 2011 and 2018 is summarised in Chapter 5.1.1. of the accompanying Staff Working Document and set out in detail in its Annex 3.

[19] Decisions not-renewing the approval of another 8 active substances were adopted in 2019.

[20] Article 3(17) and Annex I of the PPP Regulation assign Member States to one of three zones with comparable climatic and agricultural conditions to facilitate cooperation and mutual recognition of product authorisations.

[21] European Citizens Initiative 'Ban glyphosate and protect people and the environment from toxic pesticides'.

22 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).

[23] 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.

approvals) of active substances – except duly justified confidential information will be published early in the risk assessment process. This will give the general public and independent scientists direct access to the underlying data. An EU register of commissioned studies will also be created to guarantee that companies applying for approval submit all relevant information and do not hold back unfavourable studies. The Commission will be empowered to conduct fact finding missions in Member States between 2021-2025 to assess whether testing facilities apply the relevant standards for carrying out tests and studies submitted to EFSA. To improve risk communication, the new Regulation (EU) 2019/1381 sets out certain objectives and general principles of risk communication (e.g. accurate, timely and transparent information, attention to risk perceptions, and accessibility for specialists and non-specialists), based on which the Commission is empowered to adopt in the future a general plan on risk communication by means of an implementing act.

1. Better implementation – addressing delays and increasing transparency

In light of the Green Deal commitment to reduce risks from chemical pesticides and prevent and remedy pollution, the Commission calls on the Member States to significantly increase resources to implement all relevant procedures under the PPP and MRL Regulations within the legal deadlines. In order to have the required resources available, Member States should review the fees they charge, set them at a level fully recovering their costs, and ensure that the fees benefit the authorities conducting the work. The Commission will consider opening infringements proceedings against those Member States that systematically fail to respect the legal deadlines.

In line with the views of the European Parliament to avoid procedural delays leading to inefficiencies, the Commission recommends that Member States only accept complete dossiers of high quality as admissible - both for applications for first or renewed approval of active substance and PPP authorisation applications.

Furthermore, the Commission calls on EFSA and the Member States to implement the actions agreed in the Pesticides Steering Network[24] to improve the peer-review process with a view to avoiding delays. In addition, the Commission will continue to work with EFSA to improve clarity of the EFSA Conclusions as regards uncertainties to facilitate the decision-making process and readability for non-experts.

The Commission will adopt in the second quarter of 2020, a first list of unacceptable co-formulants[25]. The Commission will, thereafter, propose an Implementing Regulation setting out criteria and a procedure for identifying further unacceptable co-formulants. The Commission will also propose a work programme for the assessment of safeners and synergists.

In the course of 2020, the Commission will amend Regulation (EU) 844/2012[26] governing the renewal process to implement the necessary changes flowing from Regulation (EU) 2019/1381. The Commission, will also consider to amend Article 13(5) of Regulation (EU) No 844/2012 to introduce a short window for applicants to submit comments and further information on the draft EFSA Conclusions to address aspects that were raised only late during the peer review process and could not be foreseen by applicants in order to increase

[24] The Pesticide Steering Network is one of EFSA's networks and consist of nationally appointed EU Member State organisations with expertise in the field of pesticides, see https://www.efsa.europa.eu/en/pesticides/networks/.

[25] These will be listed in Annex III to Regulation (EC) No 1107/2009.

[26] Commission Implementing Regulation (EU) No 844/2012 of 18 September 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).

the completeness and robustness of the final EFSA Conclusion. These changes will increase transparency and efficiency throughout the assessment and during the ensuing risk management process.

The human health related cut-off criteria[27] introduced in the PPP Regulation have contributed to removing the most hazardous active substances from the market, mainly through the fact that for most substances for which applicants expect that they meet the criteria no applications for renewal of approval have been submitted. This is contributing to the protection of human health and the environment. Although a step-wise approach was envisaged when evaluating active substances, Member States do not seem to discontinue the risk assessment when an active substance meets the cut-off criteria, resulting in equally high or higher workload as for a normal active substance for the evaluating authorities. Among the reasons to continue the risk assessment are the derogation possibilities for several of the cut-off criteria, for which new procedures and guidance had to be developed but are still not fully complete.

Another identified inefficiency for applying the cut-off criteria has been that not all active substances have a harmonised classification. Member States do not systematically submit a dossier for harmonised classification early in the renewal process. This resulted in delays in the overall assessment and in decision-making. It has decreased the immediate effectiveness of the cut-off criteria.

As a consequence, the expected reduction of the workload for the evaluation of substances meeting (or expected to meet) the cut-off criteria has materialised only for those thirteen active substances for which no applications for renewal were submitted and where no evaluation needed to be carried out[28].

2. Improved implementation of the cut-off criteria

The Commission adopted in the beginning of 2020 an amendment[29] to Regulation (EU) No 844/2012 governing the renewal process to ensure that Member States submit systematically – and early in the evaluation process – proposals for harmonised classification and labelling under the CLP Regulation[30]. This will increase certainty in the use of the cut-off criteria and reduce difficulties and delays during the peer-review and the decision-making process for renewal of approval of active substances.

The Commission recommends that Member States make full use of Article 11(4) of Regulation (EU) No 844/2012 and only continue the full risk assessment if either the active substances do not meet the cut-off criteria or at least one of the derogation possibilities for their approval is invoked.

The Commission will in the 1st half of 2020 re-launch discussions with the Member States to explore possibilities to finalise the guidance document on negligible exposure in order to

27 These are set out in Annex II, points 3.6.2 to 3.6.5, to Regulation (EC) No 1107/2009: substances classified as mutagen, carcinogen or toxic for reproduction category 1A or 1B or having endocrine disrupting properties must not be approved as active substances in plant protection products (PPPs) save for certain limited derogation possibilities.

28 Bromadiolone, carbendazim, carbetamide, difenacoum, glufosinate, molinate, myclobutanil, oxadiargyl, profoxydim, spirodiclofen, tepraloxydim, triflumizole and warfarin.

29 Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (OJ L 19, 24.1.2020, p. 1).

30 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)

accelerate the evaluation of whether this derogation possibility can apply when an active substance meets the cut-off criteria.

The rules for active substances that are candidates for substitution are both ineffective and inefficient. Available evidence show that the comparative assessments for products containing active substances that are candidates for substitution carried out by Member States is complex and requires resources but did not lead to any substitution, mainly due to the lack of alternatives with proven better risk profiles. Thus, the expected benefits for human health or the environment from substituting these more hazardous active substances have not materialised. In addition, comparative assessments have made the authorisation process costlier than for standard authorisations.

3. Simplify the comparative assessment of candidates for substitution

The Commission will by end 2020 make use of its delegation of power to amend Annex IV of the PPP Regulation to improve the effectiveness of comparative assessments of products containing candidates for substitution.

The comprehensive annual monitoring of pesticides residues with more than 80 000 samples analysed per year shows high compliance with the established MRLs, indicating that the food available to consumers is well controlled and safe. By the end of 2018 MRLs were established for 486 substances approved in the EU and 247 non-approved substances on a broad range of agricultural commodities. New MRL applications, including import tolerance requests, undergo a comprehensive risk assessment process and MRLs can only be established if they are safe for consumers. In parallel, a thorough review exercise of existing MRLs started in 2008, which includes existing import tolerances and maximum residue limits established by the Codex Alimentarius Commission[31] and ensures that MRLs are kept up to date and are not retained at levels higher than necessary according to Good Agricultural Practices. However, this review of all existing MRLs was initially delayed because the relevant Article 12 of the MRL Regulation does not set out a clear procedural framework to complete the review of existing MRLs for all approved active substances within one year from the entry into force of the MRL Regulation. Procedures, such as assignment of tasks/responsibilities, deadlines, and the possibility to charge fees to be paid by industry, had first to be developed and agreed with the Member States which led to delays. The review is now progressing well.

Some stakeholders and Member States requested to set up specific MRLs for feed, fish and processed products, an option that is given by the MRL Regulation. The Commission has not yet made use of these possibilities, as there is no indication of potential risks that would point to the need to take priority action in this area. Mechanisms to take enforcement action are already in place in the MRL Regulation and in general food legislation to address situations where specific MRLs have not been established. General provisions for processed products, including processing factors, are also already in place, and in line with related food legislation in other areas (e.g. Regulation (EC) No 1881/2006 on contaminants) those provisions could be clarified and guidance given to Member States (see also box 13).

Developing a methodology for cumulative risk assessment covering simultaneous exposure to multiple chemicals (the ‘cocktail effect’) turned out to be much more complex than initially expected and is still on-going. So far, EFSA has established two groups of chemicals with

[31] http://www.fao.org/fao-who-codexalimentarius/en/

impacts on the nervous system and the thyroid, respectively, and has published draft reports[32] with results of cumulative risk assessment for their residues in food for public consultation in September 2019 followed by a Technical stakeholder event in October 2019[33]. The final reports are expected to be published in April 2020. Work is currently ongoing to further develop the methodology and perform cumulative assessments for other groups of substances, and to eventually use it for regulatory decision-making (e.g. MRL setting and approval of active substances). Substantial resources are required in EFSA and the Member States to advance the further method development. Therefore it will only be possible at a later stage to appreciate the impact of cumulative risk assessment on the protection of human health.

4. Cumulative risk assessment

The Commission, EFSA and the Member States will continue to develop a methodology for cumulative risk assessment in order to further strengthen consumer protection. Faster progress will require EFSA and Member States to allocate sufficient resources to this task.

The Commission and EFSA will develop an action plan by the end of 2020 that would set out priorities for the ongoing work on method development and the subsequent implementation of the methodology. The plan will be based on existing knowledge, and will be flexible to respond to changing scientific developments and experiences gained.

There is a substantial decline in biodiversity in agricultural ecosystems as reflected in a drop of farmland birds and losses of insect populations in parts of the EU. Among other factors, use of pesticides has been identified as an important driver for these developments. The respective restrictions or non-renewal of approvals of active substances with negative impacts on pollinators – such as the neonicotinoids imidacloprid, clothianidin, thiamethoxam and thiacloprid – have contributed to a higher level of environmental protection. Pesticides contribute to the pollution of ground and surface waters. Monitoring data published in 2018 regarding the chemical status of European waters shows that pesticides and their metabolites (often 'legacy substances' that are no longer approved) are the cause of about 6.5% (by area) of groundwater bodies not meeting the good status objective set in the Water Framework Directive[34]. The monitoring data show a reduction in pesticide contamination in surface water over recent years (although only a limited number of substances were monitored), indicating that the PPP Regulation seems to contribute positively to the protection of the aquatic environment. Fewer monitoring data are available for other environmental compartments such as soil, or from animals, plants and humans (biomonitoring). More monitoring data would help to verify whether the model predictions during the risk assessment are correct and/or risk mitigation measures are effective.

5. Environmental- and Bio-monitoring

As part of the Green Deal deliverables, the Commission will intensify the monitoring of environmental concentrations and effects. The Commission will notably, where found relevant, set obligations in approval decisions to monitor the presence of active substances (and/or metabolites thereof) in environmental compartments. In addition, the Commission will explore the possibility to increase monitoring of concentrations in soil by including

[32] https://www.efsa.europa.eu/en/consultations/call/public-consultation-draft-efsa-scientific-reports.

[33] https://www.efsa.europa.eu/en/events/event/technical-stakeholder-event-cumulative-risk-assessment-pesticides-food.

[34] https://www.eea.europa.eu/publications/state-of-water

pesticides in the Land Use, and Coverage Area frame Survey (LUCAS)[35] carried out in the EU.

The Commission is implementing the pilot project agreed by the European Parliament on environmental monitoring of pesticide use through the monitoring of honeybees. A contractor was selected and activities started at the end of 2018[36].

The Commission has proposed active substances for prioritisation in the context of the EU biomonitoring programme HBM4EU[37], and will continue to do so in the future.

When considering impacts on biodiversity, the effects of pesticides use come in addition to effects of the current agricultural production system with large surfaces of monocultures, requiring increased use of pesticides, and other factors affecting landscapes.

Some stakeholders criticise that the current scope of non-target species considered in the risk assessment is too limited to cover all relevant groups.

Further research is necessary, and assessment methods need to be developed to take into consideration cumulative risks to better understand the actual impact of pesticides on populations, diversity within and between species, and relationships between species and ecosystem services.

6. Define Environmental Protection Goals and update Guidance Documents

The Commission and EFSA have made progress with developing a methodology to define specific environmental protection goals to further improve the consideration of biodiversity in the risk assessment process. Through the organisation of workshops with risk assessors and risk managers from the Member States and all relevant stakeholder groups, protection goals will be agreed in an inclusive process that started in 2019.

The Commission will continue efforts to update Guidance Documents on risk assessment methodologies, including the consideration of whether all appropriate non-target species are covered, to keep abreast of scientific advancement and calls on the Member States and EFSA for their cooperation.

The Commission will foresee calls for research projects on methodologies to assess cumulative risks and the impact of pesticides on ecosystems in the context of Horizon Europe.

2.2 COMPETITIVENESS AND THE INTERNAL MARKET

The evidence remains inconclusive on the effects of the PPP Regulation on agricultural production in the EU as this depends on multiple factors. Growers criticise that there is a lack of PPPs in the EU, while the number of approved active substances has actually increased from 427 in 2011 to 484 in 2018, and the number of available PPPs has increased in most Member States.

The number of SMEs producing PPPs and other agrochemical products is decreasing, with the high regulatory requirements being a contributing factor. SMEs consider that the data requirements and assessment procedures are disproportionate, as such companies tend to focus on biopesticides and other potentially low-risk solutions (see also box 11, section 2.5).

35 https://esdac.jrc.ec.europa.eu/projects/lucas/.

36 https://www.insignia-bee.eu/.

37 https://www.hbm4eu.eu/: https://cordis.europa.eu/project/id/733032/.

The zonal system for PPP authorisation has led to some efficiency gains and increased numbers of PPPs being available in most Member States but is not working as well as expected. Authorisation of PPPs through mutual recognition of authorisations from other Member States leads to lower fees for applicants and reduced burden for Member States. Moreover, Member States using mutual recognition have seen larger increases in the number of PPPs available on their markets. However, the actual use of mutual recognition for authorisation of PPPs varies greatly between Member States and zones. The main reasons are specific (or additional) national requirements, lack of harmonisation in the methodologies used for conducting evaluations, lack of cooperation and coordination, as well as sub-optimal efforts spent on commenting on the work carried out by others during the zonal assessment process – all of which leads to the duplication of work and delays. Increased use of zonal authorisations and mutual recognition of authorisations would reduce the duplication of work, release resources and speed up access to market for PPPs.

7. Improve the zonal system for authorisation of PPPs

The Commission recommends that Member States minimise or remove national requirements for PPP authorisations and avoid repetition of assessments already carried out.

The Commission calls on the Member States to increase efforts and resources dedicated to the activities of the respective zonal steering committees to increase cooperation and coordination. The Commission recommends that Member States use the Post Approval Issues working group of the Standing Committee on Plants, Animals, Food and Feed more effectively to resolve divergences, similar to what is done in the coordination group established under the Biocidal Product Regulation[38].

There is insufficient availability of PPPs for minor uses[39] and Member States are not fully using the existing provisions to facilitate authorisation for such uses. Cooperation between Member States, coordination of trials and acceptance of residue data evaluated by other Member States and acceptance of residue trials from outside the EU are insufficient. To overcome the problem, Member States use emergency authorisations instead of extending existing uses of authorised PPPs.

8. Solutions for minor uses

The Commission calls on the Member States to make better use of the existing provisions in the PPP Regulation to extend uses of authorised PPP to minor uses. In addition, the Commission will continue to regularly update the existing Extrapolation Guidelines for MRLs to facilitate MRL setting for minor crops.

The Commission recommends that Member States review the fees charged for minor use extensions and lower them to promote applications from industry or user organisations.

The Commission calls on the Member States to ensure long-term financing of the Minor Uses Coordination Facility in line with the proposal discussed by the Council of Ministers for Agriculture and Fisheries during its meeting of 9 October 2017[40].

2.3 EMERGENCY AUTHORISATIONS

[38] 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.

[39] 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.

40 Agriculture and Fisheries Council, 9/10/2017: https://www.consilium.europa.eu/media/31740/st12959en17.pdf.

Article 53 of the PPP Regulation gives the possibility to Member States to allow the use of PPP without regular authorisation to address dangers to plant health, which cannot be contained by any other reasonable means. There has been a 300% increase in the number of such emergency authorisations since 2011. No data are available on the area on which emergency authorisations are applied. Given that more than 90% of emergency authorisations are granted for PPP containing approved active substances, Member States seem to use emergency authorisations to overcome procedural delays to authorise PPPs and mutually recognise authorisations, in addition to covering minor uses as described in section 2.2. Moreover, some emergency authorisations are granted repeatedly, year after year. Furthermore, the application procedure for setting MRLs for such emergency uses is criticised by stakeholders as being too long.

9. Increase oversight of emergency authorisations

As of 3 February 2020, the Commission publishes[41] all notifications of emergency authorisations received from the Member States on the public interface of the Plant Protection Product Application Management System (PPPAMS[42]) to increase transparency and allow for increased public scrutiny. The Commission will continue work to achieve full implementation of the Plant Protection Product Application Management System (PPPAMS) before the end of 2022 for all authorisations and provide for its mandatory use in an Implementing Regulation.

The Commission will improve the Harmonised Risk Indicator 2 established under the Sustainable Use Directive in order to take account of the area on which PPP under emergency authorisations are applied.

The Commission will continue to work together with the Member States to improve the relevant guidance on emergency authorisations by mid-2020 to clarify the criteria when emergency authorisations can be granted. If found necessary, the Commission will consider adopting an Implementing Regulation setting out such criteria in a legally binding way.

The Commission has further increased oversight of the emergency authorisations granted by Member States by using the provisions of Article 53(2) of the PPP Regulation to request opinions from EFSA on the justification of emergency authorisations. Where appropriate, the Commission will continue to propose Decisions in accordance with Article 53(3) preventing Member States from granting unjustified emergency authorisations[43].

2.4 TESTING ON VERTEBRATE ANIMALS

The sharing of tests and study reports is an important element to reduce animal testing. While the number of shared studies on vertebrate animals has increased, as intended, preliminary data show that overall vertebrate 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 increased evidence will be required in the future to assess substances' effects, e.g. on the endocrine system and metabolites. In addition, the requirement for

[41] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp.

[42] An IT system developed to enable applicant to create applications for PPPs and submit them for evaluation. https://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/pppams_en

[43] The Commission proposed in May 2019 two draft Decisions preventing two Member States from granting again emergency authorisations issued repeatedly for products containing neonicotinoids that were found unjustified by EFSA. The draft Decisions were presented for vote in the Standing Committee Plants, Animals, Food and Feed in October 2019, which led to no opinion in both cases. Subsequent votes in the Appeal Committee also resulted in no opinion. The Commission nevertheless adopted the Decisions on 3 February 2020: Commission Implementing Decision (EU) 2020/152 and Commission Implementing Decision (EU) 2020/153 (OJ L 33, 5.2.2020, p. 16 and p. 19).

periodic re-assessment of all active substances may increase or maintain the need for *in-vivo* testing.

10. Further reduce the need for vertebrate animal testing

The Commission will continue efforts to reduce vertebrate animal testing by promoting the development and validation of testing strategies using alternatives to animal testing through the funding of research projects under Horizon 2020[44] and the European Partnership for Alternatives to Animal Testing (EPAA[45]). The European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) actively supports the protection of animals used for scientific purposes. The Commission is committed to include into the Communications accompanying the data requirements validated alternative test methods when available to phase out the need for animal testing under the PPP Regulation[46].

2.5 SUSTAINABILITY OF PLANT PROTECTION AND LOW-RISK PRODUCTS

The PPP and MRL Regulations contribute to achieving some of the Sustainable Development Goals[47], in particular goal 2 'No Hunger' and goal 3 'Good health', goal 6 'Clean water and sanitation', goal 12 'Responsible consumption and production', goal 14 'Life below water' and goal 15 'Life on land', according to which 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 provisions of the PPP Regulation promoting low-risk active substances and products are particularly relevant. The availability of basic substances, low-risk PPPs, including micro-organisms, has increased but stakeholders consider it as insufficient and approval/authorisation procedures as too lengthy. While the Commission and some Member States have taken action to accelerate the procedures to place low-risk PPPs on the market, their effects are expected to materialise only in the future[48].

Furthermore, new application techniques (e.g. robotics and digitisation) have the potential to strongly reduce risks from the use of pesticides.

11. Promote sustainable plant protection, low-risk solutions and efficient risk mitigation

The European Green Deal and the Farm to Fork Strategy make the reduction of dependency on pesticides and the move towards low-risk substances a priority. The first will be addressed in the context of the Sustainable Use Directive. As to the second, the Commission will speed up the work already started with Member States and EFSA to update, by the end of 2020, the data requirements and assessment methodologies for micro-organisms. Consideration will

44 Examples include the following recently selected projects aimed at developing new methods and testing strategies to identify endocrine disruptors: ATHENA and SCREENED on thyroid hormone disruption, EDCMET and OBERON on metabolic disorders, ENDPOINTS on developmental neurotoxicity, FREIA on female reproductive toxicity.

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

46 Commission Communication in the framework of the implementation of 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 (OJ C 95, 3.4.2013, p. 1).

47 UN Resolution A/RES/70/1.

48 A workplan of 40 actions was endorsed by the Council of Ministers for Agriculture and Fisheries of June 2016 (http://data.consilium.europa.eu/doc/document/ST-10041-2016-REV-1/en/pdf). A progress report was presented to the Council of Ministers for Agriculture and Fisheries in July 2019, which found that actions for Member States had been implemented only partially and with great divergence between Member States (http://data.consilium.europa.eu/doc/document/ST-10238-2019-INIT/en/pdf).

also be given to the specific properties of micro-organisms and other low-risk PPPs when considering more specific rules for pesticides residues (see also box 14).

The Commission will initiate and fund a cycle of Better Training for Safer Food (BTSF) starting in 2020 to strengthen the expertise in Member States for the assessment of applications for micro-organisms and other biopesticides.

The Commission has already followed-up on the implementation of the work plan noted by the Council of Ministers for Agriculture and Fisheries to accelerate the availability of low-risk substances and products, and enhance information sharing on Integrated Pest Management between Member States. The Commission calls on Member States for reinforced commitment to implement the actions assigned to them in the light of the progress report presented to the Council in July 2019.

The Commission will boost the availability of basic substances, e.g. through clarifying procedures and deadlines for their approval and examining possibilities to provide more directly information about their usefulness in plant protection.

The Commission will continue to allocate funding under the research framework programmes[49] to develop more sustainable plant protection methods and technologies to reduce use and risks, such as pest monitoring, prediction models, digitalised farming practices, and new precision application equipment. The Commission strongly encourages Member States to support in their CAP Strategic Plans management commitments and investments aimed at implementing the methods and practices targeting the reduction of pesticides use and the use of alternative methods.

The Commission will continue the work started in 2019, together with Member States and EFSA, to assess the potential of risk mitigation measures including for new application techniques in order to harmonise the assessment of their potential for risk reduction.

2.6 ENFORCEMENT

Enforcement of the PPP Regulation 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.

12. Better enforcement of the PPP Regulation

The Commission calls on the Member States to raise awareness about the risks of illegal and counterfeit products and to increase and broaden enforcement efforts in the sector, including as regards proper use of pesticides, and consider reviewing the level of the penalties for non-compliance. The Commission has started consultations with Member States whether there is a need to set more specific requirements as regards PPPs through the empowerment in the context of Regulation (EU) 2017/625 on official controls.

The MRL Regulation ensures that enforcement action can be taken by Member States for all possible pesticides - commodity combinations. If no specific MRL is set, the so-called 'default MRL' of 0.01 mg/kg automatically applies. This ensures maximum consumer protection, as every pesticide - commodity combination is covered by a MRL. The MRL

49 Ongoing projects under Horizon 2020 include OPTIMA, VIRO-PLANT, SUPER-PEST, INNOSETA, which are focusing on finding new plant protection solutions, including biological (e.g. microorganisms, baculovirus, plant extracts) and non-chemical alternatives (e.g. prevention, monitoring, mechanical) to complement the portfolio of low-risk products available to farmers.

Regulation also covers dual/multiple use substances, i.e. substances that are used for different purposes (e.g. both as pesticides and as veterinary medicines or biocides) and substances that had been used as pesticides in the past, but are no longer used as such. In such cases, the default MRL of 0.01 mg/kg may be applicable and samples may be found to be non-compliant with that level even though the residues in food do not stem from the use of a PPP. This has led to enforcement problems in practice, e.g. in case of biocidal uses for drinking water disinfection, processing, or environmental contamination. The MRL Regulation also established some MRLs that differ from those in other sectoral legislation for the same substance - commodity combination (e.g. veterinary medicinal products legislation). Those issues can be addressed to a certain extent within the existing legal framework, e.g. by setting temporary MRLs based on monitoring data to account for other uses. However, in practice, inefficiencies arose from the fact that the MRL Regulation allows the setting of temporary MRLs in certain exceptional circumstances only, which are however not well defined, leading to lengthy discussions among risk managers before action could be taken. Other solutions are the alignment of MRLs that are safe for consumers in different sectoral legislation and work on harmonised methodologies for e.g. exposure assessments at EU and international level.

General provisions for processed products, including processing factors, are also already in place, but those provisions would benefit from clarification. More guidance could be given to Member States on how to make use of more specific information provided by food business operators. This would be in line with related food legislation in other areas (e.g. Regulation (EC) No 1881/2006 on contaminants).

13. Better enforcement of the MRL Regulation

The Commission will, before the end of 2021, clarify the scope of what is considered 'exceptional circumstances' for setting temporary MRLs to avoid misinterpretations.

The Commission will examine possibilities to allow acceptance of specific MRLs set under a different legal framework (e.g. for substances also used as veterinary medicinal products) and found to be safe for consumers and will support ongoing discussions at EU and at international level to develop a harmonised and coordinated procedure for exposure assessment.

The Commission will clarify before the end of 2021 the provisions of the MRL Regulation and give guidance to Member States how processing factors provided by food business operators could be taken into account for enforcement decisions.

2.7 FASTER RESPONSES IN THE CONTEXT OF THE MRL REGULATION TO EMERGING ISSUES AND TECHNICAL PROGRESS

The current provisions of the MRL Regulation are not sufficiently flexible as regards necessary adaptations to technical progress, for example in case of active substances that are not chemicals such as micro-organisms. It is anticipated that with new scientific and technological progress other emerging issues could arise, e.g. nano-pesticides, MRL setting for large groups of substances following cumulative risk assessment, etc.

14. Faster response to emerging MRL issues and to technical progress

The Commission will in 2020 start to explore practical solutions to integrate new active substances with different properties into the Annexes of the existing MRL Regulation, which was mainly designed for individual chemical substances.

2.8 INTERNATIONAL TRADE

At international level, the strict approach of the EU to pesticides is often criticised by a number of third countries who argue that certain aspects of the EU legal framework and practice are not in line with the World Trade Organisation Sanitary and Phytosanitary (WTO-SPS) Agreement and are too restrictive. At present, our main trading partners rely heavily on the use of pesticides for food production, including for export to the EU, and do not necessarily apply the same standards of protection of the environment as the EU (for example when it comes to the impact on bees).

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. The EU regularly incorporates limits agreed in Codex Alimentarius that are safe for consumers into its MRL Regulation, which facilitates international trade. At the same time, there is criticism from within the EU that MRLs which are safe for consumers are set for non-approved active substances (so-called "import tolerances"), e.g. in cases where the EU non-approval decision was not due to public health reasons, but for instance based on environmental risks. This allows 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. Lastly, as part of these tensions, the cut-off criteria in the PPP Regulation are also often challenged at international level, both bilaterally and in the context of the WTO, as non-EU countries consider that they potentially cause significant trade implications.

To inform business operators and third countries, the Commission and EFSA provide early information about developments related to the approval of active substances that might eventually lead to lowering of MRLs. Despite this early warning, trading partners often submit applications for import tolerances too late to avoid trade disruption and criticise the EU because they consider that the time available for the setting of import tolerances is too short following the lowering of MRLs.

The PPP Regulation contains provisions that allow for the free circulation of treated seeds in the EU if there is at least one authorisation in at least one Member State. However, there is no common view yet on whether it is possible to treat seeds for exports with an active substance that is not approved in the EU - some Member States consider this possible, while the Commission and others do not.

15. Using green diplomacy to promote our green agenda for pesticides

In line with the Green Deal Communication, the EU will use all its diplomacy, trade policy and development support instruments to promote the phasing out, as far as possible, of the use of pesticides no longer approved in the EU and to promote low-risk substances and alternatives to pesticides globally. It is important that efforts made in the EU are also made outside the EU to maximise environmental benefits and ensure a level-playing field for EU operators. In addition, the Commission will reflect on ways to consider environmental aspects when assessing requests for import tolerances for substances no longer approved in the EU while respecting WTO standards and obligations. If found necessary, the Commission will consider a revision of the MRL Regulation in order to strengthen its environmental dimension and make relevant alignments with the pesticides approval process.

The EU will use discussions in international fora, including in the WTO SPS Committee and Codex Alimentarius, to explain the approach followed in the EU for pesticides and encourage third countries to adopt a similar approach.

The EU will look to build green alliances with other regions in the world. This will include a special focus on neighbouring countries. In addition, the Commission will look at the possibility to promote the use of certain development funds to support e.g. Andean and Central American countries that have requested EU support to help them reduce the use of pesticides in fruit production. The EU will use discussions in the context of Free Trade Agreements to promote convergence of approaches in the pesticides area, and include provisions in future Free Trade Agreements with a view to reach equal standards in this area.

The Commission will enhance communication efforts on the impacts of the PPP Regulation on MRLs as well as the timing of the various procedures to make the EU system more predictable for non-EU countries, including for the cut-off criteria.

The Commission will continue contributing to the development at international level of risk assessment and risk management methodologies to facilitate the alignment of MRLs with limits agreed in the Codex Alimentarius and the setting of MRLs following import tolerance requests.

The Commission will continue efforts to find a common understanding among Member States on the possibility to treat seeds for exports with an active substance that is not approved in the EU (see also section 3.1).

The Commission will continue funding Better Training for Safer Food (BTSF) in non-EU countries to inform about the EU Regulations on pesticides, decrease the divergence in farming practices and to promote more selective and less toxic substances as alternatives to older and more toxic substances.

2.9 INTERNAL COHERENCE AND CONSISTENCY WITH OTHER EU LEGISLATION

For the most part, the PPP and MRL Regulations show internal coherence and are consistent with one another. One notable exception are the cut-off criteria which are not reflected in the MRL Regulation. This created uncertainties as regards the consequences for MRLs when the approval of an active substance is not renewed under the PPP Regulation because of the cut-off criteria. This can be addressed by improving clarity on the impacts of the cut-off criteria on MRLs for the substances concerned and the timing of various processes to enhance predictability for non-EU countries (see box 15).

Another exception is the interplay of the review of MRLs with the renewal of approval of active substances, which - due to different timelines - has led to unnecessary administrative burden, duplication of work in the Member States, EFSA and the Commission.

Consistency with other EU policy areas is not always ensured and issues have been identified with the policy on foods for infants and young children (e.g. the definition of 'pesticide residues'), hygiene policy, and chemicals legislation regarding the criteria to identify substances as persistent.

16. Increase internal coherence and consistency with EU legislation

The Commission will continue to work with the Member States and EFSA to improve coordination between the procedure for the renewal of approval of active substances and the MRL review process to gain efficiency and avoid overlaps or contradicting outcomes. This applies to deadlines as well as responsibilities of Member States.

The Commission will align the relevant provisions in the legislation on foods for infants and young children with the MRL Regulation in order to make them consistent and up to date to the latest technical standards.

3 CONCLUSION

Stakeholders from across the spectrum consider that the regulatory requirements for pesticides in the EU are among the strictest in the world. The evaluation, as detailed in the accompanying Staff Working Document, shows that the PPP and MRL Regulation provide for the protection of human health and the environment and are generally effective, although implementation can be further improved. Following on from the reduction of the number of active substances under Directive 91/414/EEC, the PPP Regulation has in particular been effective in further phasing out of high-risk substances and the provisions promoting low-risk substances have started to bear fruit. The Regulations have a recognised added value at EU level and are relevant for the evolving needs of society. Apart from the noted inconsistencies as regards the cut-off criteria coherence is mostly ensured, both internally within and between the Regulations, and externally with other EU legislation and international rules.

Efficiency stands out as the critical area requiring attention. Due to a lack of resources and capacity in the Member States, most of the procedures set out in the Regulations are suffering from severe delays, which in turn negatively affects their effectiveness.

The immediate focus for follow-up of this evaluation will be on improving the implementation of the existing legislative framework. Sixteen areas have been identified where implementation in the short and medium term could be improved. These actions are expected to deliver substantial improvements in the effective implementation of the two Regulations in a short timeframe, which will bring substantial contribution to the achievement of the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy. A swift phasing out of active substances that do not fulfil the approval criteria will promote healthy ecosystems and biodiversity, while promoting low-risk and non-chemical pesticides combined with enhanced implementation of the provisions of the Sustainable Use Directive – in particular as regards Integrated Pest Management, will reduce the dependency on chemical pesticides and contribute to more sustainable food production systems.

In addition, the Commission will reflect on ways to consider environmental aspects when assessing requests for import tolerances for substances no longer approved in the EU while respecting WTO standards and obligations. If found necessary, the Commission will consider a revision of the MRL Regulation in order to strengthen its environmental dimension and make relevant alignments with the pesticides approval process.