TECHNICAL REPORT

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Scientific risk assessment of pesticides in the European Union (EU): EFSA contribution to on-going reflections by the EC

European Food Safety Authority (EFSA)

Abstract

This document summarises the input that EFSA has provided to the European Commission in the context of the REFIT process of the EU pesticides legislation and that EFSA has provided to the EC Scientific Advice Mechanism in response to questions about the scientific assessment of pesticides. It provides a number of reflections about the process for the scientific assessment of Plant Protection Products in the EU, including considerations about the strengths of the current system and areas for possible improvement. The paper considers the separation between scientific risk assessment and risk management decision making as a strength of the system, as well as the direct involvement in the process of the network of Member State (MS) risk assessment organisations coordinated by EFSA. The paper explores options to extend the EU-level assessment of active substances to include Plant Protection Products and relevant co-formulants. This could be done through a system that allows the integration of national requirements and the consideration of the agricultural and environmental diversity of the EU and its Member States. These reflections are provided solely on the basis of EFSA's experience of implementing – at a technical level – the scientific assessment of Plant Protection Products in the EU and do not take into account other policy or decision-making factors that may be relevant in ongoing discussions by policy makers about possible changes to the EU pesticide legislation.

Key words: pesticides, scientific risk assessment, peer review process, REFIT, pesticides legislation

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Summary

This document presents EFSA's reflections on the scientific assessment of pesticides according to its technical experience in implementing the current legislative framework and through the EFSA peer-review process. It includes the outcome of a dedicated workshop of the EFSA Pesticides Steering Network (PSN) on improving the EU peer review on pesticide active substances. In addition, Section 6 presents the results of internal EFSA discussions on how the scientific risk assessment of pesticides at EU level might be enlarged and benefit from technological developments. These discussions are connected to ongoing activities such as the EFSA project on the electronic submission of dossiers for pesticides and other regulated products (MATRIX), or the development of an electronic database containing the List of Endpoints Validated for the Risk Assessment, which are currently presented as annexes to the EFSA Conclusions and Reasoned Opinions. The document also touches on the possibility of extending the scientific risk assessment at EU level to include not only the assessment of active substances but also of the scientific assessment of Plant Protection Products (PPP) in relation to risks to human health, animal health and the environment. It is recognised that some scientific and technical assessments are better suited for national evaluations, such as the assessment of the efficacy of pesticides or the integration of the use of pesticides with other plant protection alternatives for ensuring sustainable use, and these are not addressed in this document.

Regarding the possibility to extend the EU level assessment to include PPP, the paper focuses on the pre-market scientific review process described under Regulation (EC) No 1107/2009. For dietary risk assessments, Regulation (EC) No 396/2005 already requires harmonised scientific assessments at EU level covering all uses, as well as specific provisions for updating the risk assessment to account for the authorised uses of PPPs by the MS, while in other areas the harmonisation among MS is handled at zonal level. Options for extending both concepts – meaning an EU assessment of all uses and an update of the risk according to the MS authorisations – to the non-dietary human health assessments and to environmental risks are explored. Considering that new technological developments and EU efforts in collecting environmental information offer new possibilities, e.g. for addressing the zonal and regional variability within a single but spatially explicit assessment at EU level, it is concluded that this option could be implemented technically if considered feasible by EU policy makers.

This document is intended as a presentation by risk assessors of options to feed into the broader thinking by policy makers about scenarios for a future model for pesticide risk assessment. The document does not include considerations on feasibility, alternatives and possible implementation plans, resources or cost/benefit analysis, as those aspects fall outside EFSA's remit and sphere of competence. Furthermore, this document covers exclusively the process of scientific risk assessment, which is part of EFSA's remit. Risk management and regulatory decision-making processes are not addressed in this document as these are the responsibility of the European Commission and the Member States, based on the principle of subsidiarity.

The document has been elaborated by EFSA and submitted to the European Commission (EC) in relation to the REFIT process of the pesticides legislation, covering Regulation (EC) No 396/2005 and Regulation (EC) No 1107/2009. An advanced draft was presented for information to the Scientific Panel on Plant Protection Products and its Residues (PPR Panel) and to DG SANTE and the MS through the Pesticides Steering Network. The comments received were considered by EFSA during the finalisation of this document. The document has been also included in the information submitted to the Scientific Advisory Mechanism of the European Commission in relation to the ongoing activity of the High Level Group of Scientific Advisors on the scientific assessment of pesticides.

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1. Background and introduction

The scientific assessment of pesticides in the EU is described by Regulation (EC) No 396/2005[1] and Regulation (EC) No 1107/2009[2]. Both regulations allocate scientific tasks to the European Food Safety Authority (EFSA) and both have been taken into consideration as part of the REFIT process.

There is a fundamental difference regarding the level of EU coverage for the risk assessments conducted under Regulation (EC) No 396/2005 and Regulation (EC) No 1107/2009 governing the scientific evaluation of pesticides.

Regulation (EC) No 1107/2009 includes, as a first step, the scientific assessment of the active substances (a.s.) present in pesticide formulations. This is done at an EU level through a peer-review conducted by EFSA in close cooperation with the Member States (MS). For each a.s. that is proposed for market authorisation in the EU, EFSA and the MS review a draft assessment report prepared by a Rapporteur MS (RMS). The scope of the assessment is limited to some uses, considered as the "representative uses", which are proposed by the applicant as the Good Agricultural Practices (GAP) under which the pesticide should be used.

The second step concerns the assessment of the actual Plant Protection Products (PPP), consisting of the active substance(s), safeners, synergists, and co-formulants. For these, Regulation (EC) No 1107/2009 stipulates that the risk assessment be carried by MS, where the "actual uses" of each PPP proposed for registration is evaluated at a zonal or national level i.e. without an EU-wide scientific evaluation and involvement of EFSA. An interzonal evaluation is conducted for uses in greenhouses and for seeds. The zonal and interzonal assessments include a commenting period with the concerned MS.

A different approach has been implemented by Regulation (EC) No 396/2005, which covers the process for setting Maximum Residue Limits (MRL) and the risk assessment for consumers regarding pesticides residues in food. In this case, all scientific assessments are handled at EU level, with involvement of both MS and EFSA, and they cover all relevant intended uses through the selection of the uses resulting in the higher level of residues expected for each food commodity (critical Good Agricultural Practices). There are also clear post-marketing provisions, with an MRL review process that considers all authorised uses and an extensive EU-level post-marketing monitoring programme with annual assessments of the actual risk for consumers of pesticide residues in food.

This document focuses on the process under Regulation (EC) No 1107/2009, and in particular actions with regard to the pre-market scientific review process. For dietary risk assessments, Regulation (EC) No 396/2005 already requires harmonised scientific assessments at EU level covering all uses, as well as specific provisions for updating the risk assessment accounting for the authorised uses of PPP by the MS. Options for extending both concepts - an EU assessment of all uses and an update of the risk according to the MS authorisations – to the non-dietary human health assessments and to the environmental risks are specifically explored.

2. Current system

The current process requires a complex interaction of tasks and responsibilities between the European Commission, Member States and EFSA. A simplified summary for risk assessment (RA) and risk management (RM) tasks is presented in Table 1 for a.s. and PPP. It should be noted that in some cases the roles are different depending on the process, thus the Table is a simplified version and does not address every single process and workflow.

[1] 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. No L 70, 16.3.2005, p. 1-16.

[2] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council 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. 1-50.

Table 1. Simplified "as-is" situation: current distribution of RM and RA responsibilities and resources (human and financial) for pesticide a.s. (first step) and PPPs (second step, *in italics*).

	Risk management processes & procedures	Decision process for individual applications	Risk assessment processes & guidance	Risk assessment for individual applications
European Commission Origin of resources: Community budget	Lead role for a.s. and MRL at EU level	Approval of a.s. Setting MRLs	Role as developer or sponsor at EU level for a.s. and MRL	For a.s. and MRL, no role for some processes, sponsor role for others
	Different role for PPPs at zonal and national level depending on the process	*Role regarding PPP authorisations is limited to some processes*	*No specifically defined role for PPP at zonal and national level*	*Role as developer and sponsor at zonal and national level for PPP*
Member States Origin of resources: National budget and may request industry contribution through fees	Contributing role for a.s. and MRL at EU level	Contributing role for a.s. Contributing role for MRLs	Contributing role for a.s., MRL and general principles at EU level	Lead (RMS) or contributing (others) role for the assessment of a.s. Initial role (EMS) or no role (others) for MRL applications. Initial (RMS) or contributing (others) role for the MRL review
	Exclusive role for PPP at national level	*Lead role for PPP authorisations*	*Exclusive responsibility for PPP at MS level Joint responsibility for PPPs at zonal level*	*Exclusive/shared role for PPPs (national and zonal assessments) Exclusive role for PPP exceptions, PPP mutual recognition and other processes.*
EFSA Origin of resources: Community budget	--	--	Role if mandated for RA guidance, lead role for MRL and consumer risks, lead role for scientific updates and RA methods	Mandatory or optional role for a.s., mandatory role for MRL, Possible role regarding identification of concerns
			If mandated, the risk assessment methodology covers also the assessment of PPPs	*No role for PPPs unless mandated by MS*

3. Reflections on strengths of the current system

The current system offers, in general, a good collaboration model for the scientific assessment of the active substance, involving MS and EFSA. The basic principles are summarised below:

- Collaborative model involving EU and MS experts, allowing the consideration of national conditions and creating a link between national-level risk assessors and risk managers with respect to the MS decision-making process but without compromising the division of responsibilities that is central to the EU risk analysis paradigm (e.g. the separation between risk assessment and risk management).
- Pre-market assessment with periodic renewals for each active substance and each PPP, with direct involvement of experts both in EFSA and in all MS for a.s.
- Extensive guidance at EU level for pre-marketing and renewal assessments of a.s., PPP, and for MRL setting, covering key issues related to the scientific assessment[3]
- In depth assessment by a RMS of the a.s., supported by a co-RMS in some cases. The assessment is then strengthened through a peer-review process at EU level, handled by EFSA in close cooperation with experts from the other MS, resulting in an updated RMS assessment and the EFSA Conclusion.
- Transparent EU assessment for the a.s., including a public consultation and the publication of the full scientific assessment before the risk management decision-making process for approval/re-approval of the a.s. begins. This comprises publication of the EFSA Conclusion, the updated RMS assessment, and the Peer Review Report.
- For dietary risk assessment and MRL setting, full harmonisation of the scientific assessments at EU level involving MS and EFSA. For the other areas, non-dietary and environmental risks, the EU assessment is limited to the a.s. and the representative uses indicated by the applicant in the dossier.
- For dietary risk assessment and MRL setting, a comprehensive review process is implemented to assess which uses are finally authorised by the MS, involving MS and EFSA for the scientific assessment.
- For dietary risk assessment and MRL setting there is an extensive post-market monitoring programme with clearly defined roles for MS and EFSA.

4. Reflections on aspects of the overall risk assessment framework

The current regulatory system for pesticide risk assessment is clearly a step up from the system that preceded it (Council Directive 91/414/EEC[4]). As indicated below, there are, nevertheless, some elements that may benefit from further consideration. Some are related to the basic principles of the review process, while others refer to the way the system is implemented.

Those elements under EFSA's remit in the current regulatory frame have been recently addressed by EFSA. An Action Plan for improving the current peer-review process is under implementation (EFSA, 2017).

The EFSA peer-review process

The initial assessment conducted by the RMS, often supported by a co-RMS, is peer-reviewed through a set of commenting rounds and expert meetings. The peer-review is conducted by EFSA in close cooperation with the MS organisations responsible for the risk assessment. Following this peer-review process, the RMS updates the assessment and EFSA finalizes the evaluation and produces an EFSA

[3] Although some guidance documents have not been updated with new scientific developments for over 10 years

[4] 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. 1–32

Conclusion, summarising the key elements and endpoints to be considered in the approval of the active substance and in the national risk assessments for the authorisation of Plant Protection Products at MS level.

General points for consideration identified by EFSA and the PSN in relation to the peer review process are as follows:

- In most food sectors, the role of risk managers is limited to establishing the policy framework for the risk assessment and the setting of protection goals. In the case of pesticides, the role of risk managers extends to defining the risk assessment methodology that must be applied for a.s. and MRLs, including how to implement the conceptual model and how to conduct the assessment. Proposals for updating the risk assessment methodology must also be approved by risk managers.
- The capacity and capability of the Rapporteur MS to fulfil its tasks is sometimes challenging when resources and/or scientific expertise in specific areas are lacking. In addition, EFSA does not have a mandate to conduct an accordance check of the RMS' risk assessment before starting the peer review (c.f. 'accordance check' by ECHA foreseen in the biocides product regulation). Some examples are listed below:
    - SANTE has requested to re-start the assessment and peer-review of an active substance after publication of the EFSA Conclusion due to insufficient quality of the RMS assessment. This was highlighted by EFSA and several MS from the beginning of the peer-review consultation process.
    - Some RMS, following discussion with EFSA and EC, have decided to withdraw their assessments (DAR/RAR) due to insufficient quality, leading to postponements and additional efforts from those involved in the peer-review.
    - During some assessments the RMS did not include additional information, requested by EFSA under the clock stop procedure and provided by the applicant, in an updated assessment. This then led to an inconclusive assessment even though the information had in the meantime been provided by the applicant.
- Lack of clarity on guidance documents and models used throughout the EU for risk assessment of PPP. This leads to lack of coherence among zones and MS which may rely on different guidance not discussed at EU level. In addition, not all pesticide guidance documents are included in the EFSA repository on applicable guidance, as some risk assessment guidance documents on a.s. and MRLs are produced by EC (DG SANTE)[5] and not by EFSA. Consequently, there is no single repository that includes all guidance.
- This may lead to a lack of harmonisation for the assessment of PPPs between different MS. For example, the same study may be assessed differently by different zones or MS. There is also no scientific arbitration mechanism at EU level nor a central database of submitted studies. This is relevant as some studies may only be submitted at national/zonal level and thus may not ever have been assessed at EU level.
- Alternatively, it may also lead to a duplication of work when the representative uses and crops selected by industry in their a.s. application do not offer sufficient coverage of the EU uses or when additional information is provided in the PPP application, which is frequently the case. This then requires re-assessment of the same studies and data at several levels: EU, zonal and national.
- Currently co-formulants are not specifically covered except by some MS national decisions. The process for inclusion of co-formulants in Annex III of Regulation (EC) No 1107/2009 listing the co-formulants which are not accepted for inclusion in PPPs is still under

[5] See http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en, and Commission Communications in the framework of the implementation of Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, and Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products

discussion. Furthermore, there is no harmonised approach towards the assessment of synergistic/antagonistic effects between the different components of a PPP. DG SANTE is currently preparing a regulation on co-formulants to cover this gap. As far as possible, it would be beneficial to ensure coherence and effectiveness in the assessment of a.s., PPP and co-formulants.

- In summary, the EU assessment of the a.s. may lead to a situation which provides an incomplete view on the actual uses of the a.s., except in the case of risk of pesticides residues for consumers which is complete and fully harmonised at EU level. The a.s. risk assessment is conducted based on an initial industry proposal, but, except for MRL and consumer risks, is not updated once the MSs have decided which uses to authorise for each PPP and under which conditions and risk mitigation options.
    - For example, the list of uses assessed at EU level for the neonicotinoid insecticide imidacloprid (approval and post-approval assessments for bees and for aquatic organisms) highlights limitations in restricting the EU assessment to only a few "representative" uses. Even if in this case the uses selected by the applicant are representative, the MS authorisation process has to rely on a large number of new risk assessments.
    - To note, DG SANTE is creating a centralised database of all PPP authorised in the MS. Once ready, this database can be used to identify the considerable number of uses that have not been assessed at EU level.
    - Risk communication may also be challenging if the risks of the a.s. are not fully reflective of actual use and if the risks of PPP are not updated following the MS evaluations and authorisations. The risk at the EU level also depends on the actual uses and market penetration (total volume and geographical distribution). This information will be available to the MS through the implementation of the National Plans under Directive 2009/128/EC[6] on sustainable use of pesticides, but currently there are no activities at EU level for linking the risk assessment of a.s. and PPP with the implementation of this Directive in order to assess the overall risk of each a.s. according to the approved PPP authorisations, market penetration, and actual use (total and regional distribution) by the farmers.
- It is noteworthy that while the monitoring of pesticide residues in food provides good information on the real exposure of consumers, non-dietary and environmental risks are not covered by such monitoring schemes.

5. Reflections on the scientific risk assessment process

For dietary risk assessments, Regulation (EC) No 396/2005 requires harmonised scientific assessments at EU level covering all uses, as well as specific provisions for updating the risk assessment to account for the authorised uses of PPPs by the MS. This section explores the technical feasibility for extending both concepts, EU assessment of all uses and update of the risk according to the MS authorisations, to the non-dietary human health assessments and to the environmental risks.

The last decade has been characterised by new technological developments regarding massive data handling, including spatially explicit environmental data. The combination of new technologies with the EU achievements following significant efforts in collecting environmental information offer new possibilities for addressing the agricultural and environmental differences among EU Member States. Technically, it could be possible to address regional variability within a single but spatially explicit assessment at EU level, if this option is considered feasible by EU policy makers.

It is EFSA's understanding that the suggestions put forward by EFSA in this section are compatible with the current regulatory system, e.g. the proposed centralised risk assessment platform will

[6] 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. 71–86

increase efficiency and provide benefits for MS assessments within the current zonal authorisation system, and the current system allows the European Commission and Member State to request support from EFSA through specific mandates on issues on which EFSA contribution is not explicitly mentioned in the regulation.

However, it should be noted that this section is intended as a presentation by risk assessors of options to feed into the broader thinking by policy makers about scenarios for a future model for pesticide risk assessment and does not include considerations on feasibility, alternatives and possible implementation plans, resources or cost/benefit analysis, as these aspects fall outside EFSA's remit and sphere of competence.

The section is structured in three consecutive levels, providing the views of EFSA at different levels of granularity, according to the reader's needs. The first level proposes the general goals for enhancing the scientific risk assessment process in the area of pesticides. The second level describes options regarding the general principles for the scientific risk assessment of pesticides. The third level goes a step further, and presents a proposal on how these general principles could be implemented using modern technologies. The reflections presented are based on two fundamental concepts. First, that the strengths of EU level scientific pre- and post-marketing assessments, already implemented for dietary risks and MRL setting under Regulation (EC) No 396/2005, can be extrapolated to non-dietary and environmental risks. Second, technology is now ready for the development of integrative IT tools (digital collaboration platforms, data standards for inter-operability, accessibility of data repositories). These tools offer the possibility for addressing regional conditions and for the automatic update of the risk outcomes following the risk management decision. In this way, the scientific assessment can be conducted at EU level and accommodate MS needs being informative for decisions at national level.

5.1. Considerations for enhancing the EU scientific risk assessment of pesticides and expected benefits

Possible improvements could focus on:

a) further enhancing consumer and environmental protection, providing outputs (risk characterisation) that are more relevant for decision making at MS level (e.g. possibility for addressing national agricultural, environmental and landscape characteristics) and a system whereby assessments can be updated rapidly.

b) increasing efficiency that would reduce the risk of backlogs and facilitate risk management decisions by including risk mitigation measures that address the (agri)cultural and environmental conditions of different MS and territories.

c) allowing the early introduction of innovative and more sustainable substances and products, fostering the potential for companies to expand their markets across the EU, which is particularly relevant in the case of low risk products where SME play a key role.

Following these objectives, and based on the experience from the dietary risk assessment involving the MSs and EFSA, the current system might be enhanced as follows:

1. The assessment would be harmonised but also consider cultural (e.g. food diets), agricultural, and environmental differences within the EU.

2. The scientific efforts would be focused on:

    - harmonising the process for a.s., PPP and co-formulants at EU level; assessing the scientific evidence for each a.s., co-formulant and PPP; setting the "input values for risk assessment", meaning a list of validated endpoints for conducting the risk assessment.

- a single IT frame, integrating all current calculators and future updates. This requires developing and keeping updated the individual modules of an IT based EU pesticide risk assessment tool which implements the guidance documents, and presents in an automated way the risks outcomes, to be interpreted by risk assessors, based on the intended uses and the verified values selected for risk assessment.
- developing risk communication support tools that generate in an automated way EU risk assessment characterisations for each pesticide use, providing information to risk managers, stakeholders and the public.

3. New scientific methodologies such as cumulative and mixture assessment would be incorporated into the guidance and the IT based EU pesticide risk assessment tool as soon as available and agreed by risk assessors and risk managers

4. All a.s., PPP and relevant co-formulants would be assessed in one process coordinated at the EU level and organised in close cooperation with Member States, covering all relevant parts of the EU territory in which they may be marketed according to the intended uses.

The expected benefits from a centralised, integrated, collaborative EU risk assessment process are linked to a further increase in the level of protection for citizens and the environment, as well as major efficiency gains. In particular, it might enable:

- A further strengthening of the EU assessment process by enhancing predictability, consistency, and transparency; providing outputs (risk characterisation) that are more relevant, and assessments that could be updated rapidly (new data, more efficient process), helping prioritisation and identification of public health and environmental concerns.
- Higher flexibility for risk managers at EU and national level to take science-based decisions for human health and environment protection, including risk mitigation measures, addressing the (agri)cultural and environmental conditions of different MS and territories.
- The process for PPPs and co-formulants could be harmonised at EU level and more evidence based, increasing consistency, predictability and transparency. All studies would be assessed at EU level using the same scientific criteria and principles as well as agreed EU methodologies.
- Improving efficiency, once the input values (list of endpoints) are set for a particular substance or PPP, EU risk assessment calculations could be done and updated for each use in an automated way. The increased efficiency might reduce the risk for backlogs, allowing the early introduction of innovative and more sustainable substances and products.
- Better differentiation between roles of risk assessors and risk managers. The risk assessors would be responsible for the risk assessment methodology/guidance including definition of the information required for a state of the art science based assessment.
- Offers a single point of contact for industry, facilitating market access across the EU for SME and low risk products, and for third countries in view of trade issues.
- Improved risk communication offering specific tools for risk managers and citizens.

5.2. Proposed general principles for the scientific risk assessment of pesticides

Based on the accumulated experience under Council Directive 91/414/EEC, Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005, a set of renewed options are proposed below. They cover all aspects of the risk assessment of pesticides (hazard assessment, hazard characterisation, exposure assessment and risk characterisation) to protect human health and the environment.

- To maintain a collaborative system with a centralised EU risk assessment body (e.g. EFSA) and risk assessment organisations in each MS.

- The key role of the EU risk assessment body would be the coordination and distribution of the scientific tasks within the MS risk assessment bodies, the peer-review of the MS assessments ensuring consistency, and the coordination of capacity building projects for ensuring sufficient expertise in all MS.
- Risk assessment bodies in the MS would contribute directly to the EU risk assessment on human health, animal health and the environment (as lead/rapporteur tasked by the EU risk assessment body or through the peer-review) and to the methodological developments; and would ensure that national conditions and scientifically based requirements are incorporated in updated assessments.
- The centralised EU risk assessment body would act as a hub for EU, MS and international organisations, would be responsible for producing guidance for risk assessment of pesticides, developing the data requirements for the a.s. (including chemical substances and micro-organisms), the relevant co-formulants contained in a PPP, and PPPs at EU level.
- The EU risk assessment body would develop the methodology to integrate the cumulative assessment of different a.s., a.s. with co-formulants, and different PPP applied either simultaneously or consecutively.
- The EU risk assessment body would implement the relevant parts of the risk assessment guidance into an IT-based EU pesticide risk assessment tool which would cover three processes, leading to three complementary assessments:
    - i) *initial* EU risk assessment for pre-assessment of the intended uses of each a.s., relevant co-formulant and PPP, to support the risk management decision (supports process *I.- Pre-marketing assessment*),
    - ii) *realistic* predictive risk assessment for marketed PPP based on the market authorisation conditions which have been decided by risk managers (EU or MS level). Cumulative risk assessment considering several substances (a.s. and/or co-formulants) and PPP will be performed if the respective methodology is available (supports process *II.- Risk actualisation for marketed products*),
    - iii) *actual* risk assessment refined using actual monitoring data according to "post-marketing vigilance principles" (supports process *III.- Post-marketing risk monitoring).* Monitoring data when available, e.g. required in the approval/authorisation process or obtained from other EU activities such as the Water Framework Directive, national activities, research activities, or other sources is considered. In addition MS and other actors may consider using this system in the design of their monitoring activities and report back the results to the EU risk assessment body, to be included in risk refinements.
- The IT-based EU pesticide risk assessment tool would cover European diversity/variability such as cultural (e.g. food diets) and environmental conditions and would integrate risk mitigation measures. Risks could be assessed at EU, MS or regional (if required) level. The technical specifications and implementation for such a system should be developed with full involvement of MS and should consider the risk management needs of the European Commission and MS. Some elements to be considered are mentioned below as examples:
    - incorporation of EU-harmonised as well as national/regional tools/scenarios.
    - sufficient flexibility in implementing new data (e.g. new national consumption data) or models, as well as decisions taken at MS level, such as which risk mitigation measures are accepted by each MS.

- capacity for addressing the EU agricultural and environmental variability considering landscape differences among and within MS.
- possibility to include expert judgements for the final outcome.
- availability to MS authorities for supporting their assessments and decision making processes, e.g. the evaluation of efficacy and adequacy of the proposed Good Agricultural Practices (GAPs) for the national conditions, and provide interfaces with national systems when required.
- clear rules on the accessibility by the different actors, in particular authorities in the EU and MS, applicants, other interested parties and the public.

- The IT based EU pesticide risk assessment tool might allow the EU assessment to focus on the scientific evaluation of the studies/evidence for each substance (a.s. or relevant co-formulant) or PPP, focusing on the validation of the input values to be used in the risk assessment. Once the input values are established, the IT-based EU pesticide risk assessment tool should allow, in an automated way, the estimation of risk outcomes for each intended use at EU level, using as a source the input values and each use (as defined by the GAP). The input values could be updated if new information is submitted, and the risk assessment outcome would be updated automatically after the agreement on the new input values. This system will streamline the work of risk assessors focussing the scientific assessment on the evaluation of the scientific evidence and selection of input values and the interpretation of the risk characterisation outputs, while the calculations will be automated
- Hazard based assessments are not specific to the use as a pesticide and in some cases are also covered by other EU bodies (e.g., ECHA under CLP and REACH). The information generated by other EU bodies will be integrated in the EU risk assessment of pesticides, in particular the ECHA-RAC opinions on harmonised classification.
- A centralised integrated EU system needs to attract and maintain a pool of experts in the relevant areas within the EU risk assessment body and at MS level. This also includes sharing of knowledge and developing the competencies of experts.

5.3. Implementation of an EU level collaborative scientific risk assessment of a.s., PPP and co-formulants

The general principles proposed above could be implemented through a collaborative effort of EFSA and MS supported by an IT-based EU pesticide risk assessment tool. In terms of the risk assessment, the European variability, national requirements and (agri)cultural variability can be fully covered by integrating landscape characteristics in the risk assessment methodology, as proposed in the EFSA 2020 strategy. Depending on risk management needs, risks can be expressed regarding acceptability, if previously defined by risk managers (e.g. clear indication of the specific protection goals by risk managers), or expressed in terms of the likelihood and magnitude of the expected adverse effects supporting the trade-off by risk managers. A single IT framework should also lead to improvements in efficiency, transparency and predictability. A cooperative effort including EFSA, MS and the European Commission is needed for implementing this approach and to develop and validate this IT system in the regulatory context. An IT framework cannot replace the need for expert judgement, particularly at higher tier levels, but will facilitate the process for gathering and presenting the evidence and for reporting the expert outcome. Once the input values (list of endpoints) are set for a particular substance or PPP, EU risk assessment calculations could be done and updated for each GAP in an automated way. It is recognised that the level of knowledge and harmonisation is higher for the assessment of chemical pesticides and on-going improvements in structuring the data and in modelling practices will offer new possibilities in the future. The possibilities for automation of the risk

assessment process are currently much more limited for microbial pesticides, which require a different kind of expertise by risk assessors.

The proposed implementation of an integrated process for EU scientific risk assessment of pesticides at EU level is summarised in Figure 1 and outlined below.

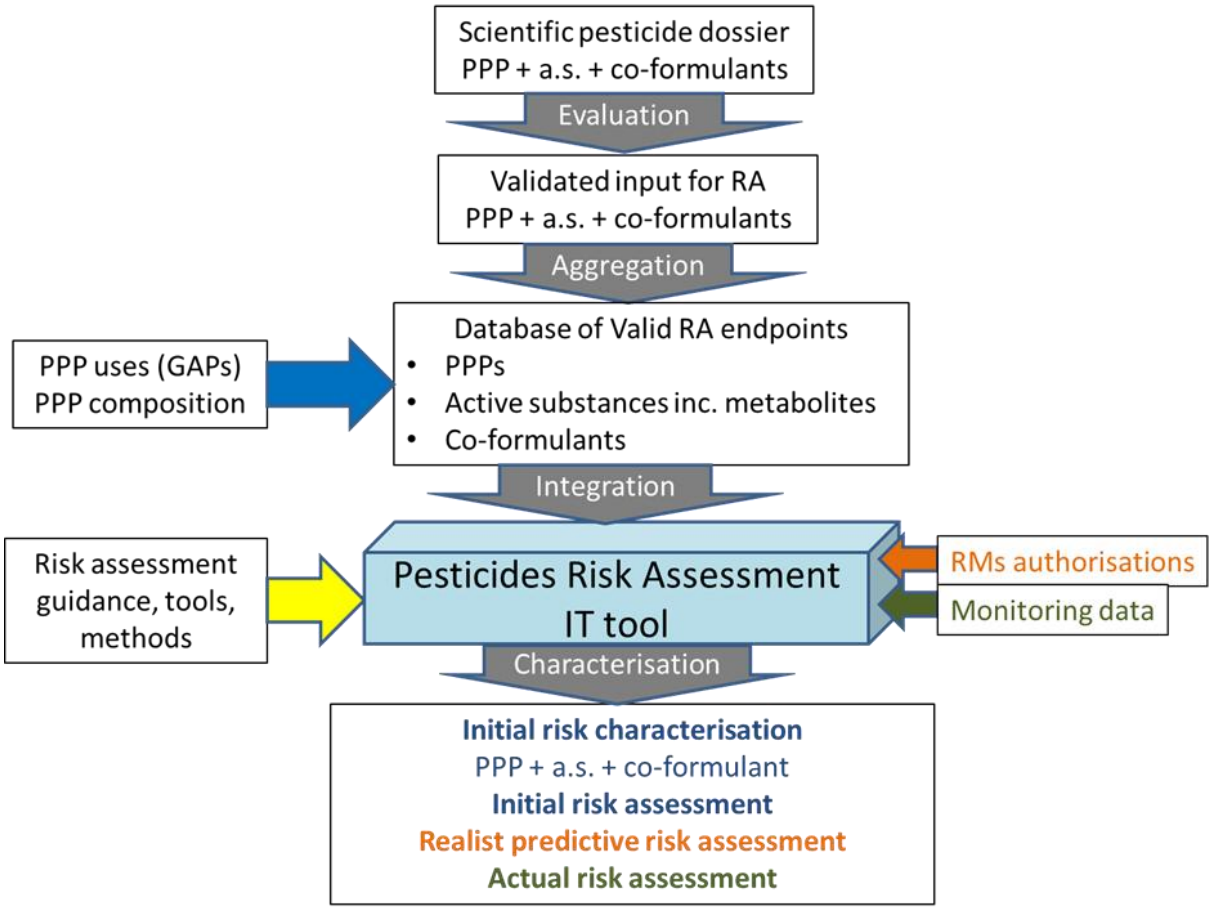

Figure 1. Proposal for an enhanced process for pesticide risk assessment at EU level.

I.- Pre-marketing assessment of pesticides (products, active substances, and other ingredients) at EU level: INITIAL RISK ASSESSMENT

Covers three complementary steps:

a. First submission (PPP containing a new a.s. or first renewal of PPP for a currently approved a.s.)

- Applicant (manufacturer) submits to EU risk assessment body (e.g. EFSA) a dossier in electronic format for a PPP with all relevant uses (incl. information on the a.s., metabolites, co-formulants, and the PPP according to guidance issued by the EU risk assessment body). All uses, not just a few representative uses, are included. The application may contain several PPP, if needed.
- Scientific check and quality assessment of submitted data by EU risk assessment body.

- Public call for data and literature search carried out by EU risk assessment body to ensure transparently a consideration of all data.
- The EU risk assessment body acts as hub for the EU risk assessment, coordinates the work of MS risk assessment bodies (e.g. possibly through a form of grant system to MS RA bodies) and produces the EU risk assessment.
- The EU risk assessment body, in close collaboration with MS risk assessors, identifies the input values (list of endpoints) to be used in the risk assessment for each a.s., relevant co-formulant, and PPP. If the a.s. or some co-formulants have been previously assessed by the EU risk assessment body, the previous assessment is updated with the new information. The proposal includes the applicable classification of the PPP according to the principles for the classification of mixtures under Regulation (EC) No 1272/2008.[7]
- The results of the EU risk assessment are presented to EU risk managers for decision making; these results identify and quantify the risks and indicate the uncertainties, but do not conclude on the acceptability of the identified risks except when specific protection goals and acceptability criteria have been already established by risk managers. Proposed risk mitigation measures are included.
- The EU risk assessment is presented to stakeholders and the public using risk assessment communication tools that allow integration of different a.s. and different co-formulants and PPP.

b. Submission of new information

Any new information (updated dossier or new dossier containing information on the same a.s., metabolites, co-formulant or PPP) is assessed by the EU risk assessment body in collaboration with the MS, and added to the list of input values for risk assessment (list of endpoints) of the a.s./PPP and is processed automatically in the risk assessment tool, updating the previously performed risk assessment. Risk assessors in the MS inform MS risk managers on the possible needs for reviewing national authorisations.

c. Submission of a new use or new PPP containing an a.s. or relevant co-formulant already assessed

For any new use of a PPP or for a related PPP the process will re-start. As above, if the dossier includes new information this will also trigger the re-assessment for currently authorised uses as relevant, which will be efficiently performed by processing the existing and the new information on the a.s, co-formulant and PPP; the outcome of the risk assessment is made available electronically in an easy-to-use form. The applicant should use the agreed input values for risk assessment (list of endpoints) or present a request for change based on scientific evidence.

II.- Risk actualisation for marketed products following the assessment and authorisation: REALISTIC PREDICTIVE RISK ASSESSMENT.

1. The EU risk assessment body publishes (database) the input values for risk assessment (list of endpoints) for each assessed a.s., relevant co-formulants, and PPP.
2. Risk managers consider additional elements, including the national assessments on efficacy and agricultural needs, and take the decision on the authorisation of pesticides, including the

[7] 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. 1–1355

authorised GAPs, mandatory risk mitigation measures, and communicate the decision to the European Commission, the applicant and the EU risk assessment body.

3. Additional information on actual use and market penetration (including the information submitted under Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides, REACH, or by applicants and other stakeholders) is considered for the realistic predictive risk assessment.

4. The EU risk assessment body develops the IT based EU pesticide risk assessment tool presenting the realistic predictive risk assessment integrating the authorisation conditions and additional information (point 3). The results are analysed by the EU risk assessment body supported by the risk assessment organisations in the MS, and possible recommendations are communicated to the European Commission and MS. The tool allows stakeholders and the public to conduct realistic risk assessments in a transparent manner including cumulative risk assessments for several substances (a.s. and/or co-formulants) and several PPP, if respective methodology is available.

III.- Post-marketing monitoring and control – assessment of actual level of risk: ACTUAL RISK ASSESSMENT

1. Monitoring data, including post marketing vigilance by applicants, are generated and/or compiled by MSs and transmitted to the EU risk assessment body.

2. The data are used to refine the exposure estimates and the hazard assessment, if needed, using the realistic predictive risk assessment (see section II) based on actual residue findings and information from post marketing vigilance. The results are analysed by the EU risk assessment body supported by the risk assessment organisations in the MS, and possible recommendations are communicated to the European Commission and MS. A module within the IT based EU pesticide risk assessment tool facilitates a retrospective actual risk assessment.

3. The IT based EU pesticide risk assessment tool also allows a comparative assessment of the realistic predictive (see section II) versus the actual risks; leading to the identification of possible needs for further improvement of the tools, parameters and models in risk assessment. It also provides risk managers with relevant information and evidence assisting risk managers to revisit approval conditions.

References

EFSA (European Food Safety Authority), 2017. Action plan for improving the peer review process. EFSA supporting publication 2017:EN-1349. 9pp.

Abbreviations

a.s.	Active substance
CLP	classification, labelling and packaging
DAR	Draft Assessment Report
EC	European Commission
EFSA	European Food Safety Authority
EMS	Evaluating Member State
GAP	Good Agricultural Practice
MRL	Maximum Residue Level
MS	Member States
PPP	Plant protection product
PSN	Network on Pesticide Steering
RA	risk assessment
RAR	Renewal Assessment Report
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RM	risk management
RMS	Rapporteur Member State
SME	small and medium enterprise