SPECIAL ISSUE

EFSA Journal

doi: 10.2903/j.efsa.2016.s0508

Advancing environmental risk assessment of regulated products under EFSA's remit

Yann Devos[1], Helmut Gaugitsch[2], Alan J. Gray[3], Lorraine Maltby[4], Jock Martin[5], Jeffery S. Pettis[6], Jörg Romeis[7], Agnès Rortais[1], Reinhilde Schoonjans[1], Joe Smith[8], Franz Streissl[1] and Glenn W. Suter II[9]

Abstract

The pre-market environmental risk assessment (ERA) of regulated products such as genetically modified organisms, plant protection products and feed additives is an important process to safeguard the desired level of protection of the environment and biodiversity. ERA evaluates the potential adverse effects on the environment of certain actions, and is an important analytical scientific tool to support regulatory decision-making. Significant advances have been made in the field in recent years. Potential avenues to the further advancement of ERA of regulated products under EFSA's remit were discussed during the breakout session 'Advancing environmental risk assessment' held at the EFSA 2nd Scientific Conference 'Shaping the Future of Food Safety, Together' (Milan, Italy, 14–16 October 2015). The value of ERA and its relevance to decision-making can be increased by: (1) using the ecosystem services approach to make protection goals operational; (2) relying on problem formulation to enhance the relevance of ERA studies; (3) complying with quality standards to warrant the reliability of ERA studies; (4) making ERA more contextual by accounting for multiple stressors and environmental benefits; and (5) acknowledging the strengths and limitations of post-market environmental monitoring as a tool to resolve scientific uncertainties.

Keywords: biodiversity, data quality, ecosystem services, genetically modified organisms, multiple stressors, plant protection products, problem formulation, protection goals

Correspondence: editor-in-chief.efsajournal@efsa.europa.eu

Author affiliations: [1] European Food Safety Authority (EFSA); [2] Unit Land Use & Biosafety, Umweltbundesamt (Environment Agency, Austria); [3] Centre for Ecology and Hydrology; [4] Department of Animal and Plant Sciences, The University of Sheffield; [5] Integrated Environmental Assessments, European Environment Agency; [6] US Department of Agriculture (USDA), Agricultural Research Service; [7] Institute for Sustainability Sciences, Agroscope; [8] Advisor in Regulation, Science and Government (formerly Office of the Gene Technology Regulator); [9] National Center for Environmental Assessment, US Environmental Protection Agency.

Acknowledgements: The European Food Safety Authority (EFSA) thanks the participants of the breakout session 'Advancing environmental risk assessment' held at the EFSA 2nd Scientific Conference 'Shaping the Future of Food Safety, Together' (Milan, Italy, 14–16 October 2015) for their active and valuable contribution to the discussion. We also thank Kirsten Haupt, Sylvie Mestdagh and Elisabeth Waigmann for carefully proofreading this publication.

Disclaimer: The views expressed in this publication are those of the authors and do not necessarily represent the official views or policies of EFSA or the other author institutions. EFSA assumes no responsibility or liability for any errors or inaccuracies that may appear.

Suggested citation: Devos Y, Gaugitsch H, Gray AJ, Maltby L, Martin J, Pettis JS, Romeis J, Rortais A, Schoonjans R, Smith J, Streissl F and Suter GW II, 2016. Special issue: advancing environmental risk assessment of regulated products under EFSA's remit. EFSA Journal 2016;14(S1):s0508, 14 pp. doi:10.2903/j.efsa.2016.s0508

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

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1. Introduction

Genetically modified plants (GMPs), plant protection products (PPPs) and feed additives (referred to hereafter as regulated products) are subject to a risk analysis and regulatory approval before entering the market in the European Union (EU). In this process, the role of the European Food Safety Authority (EFSA) is to assess and provide scientific advice to risk managers on any possible risk that the deployment of regulated products may pose to human health, animal health and the environment. The decision on the level of acceptable risk is taken by risk managers who weigh policy options to accept, minimise or reduce characterised risks.

Pre-market environmental risk assessment (ERA) is an important analytical scientific tool that helps regulatory decision-making. Robust ERAs begin with an explicit problem formulation, where plausible and relevant exposure scenarios and the potential adverse effects from those exposures are identified. Risk is then characterised by testing specific hypotheses about the likelihood and severity of adverse effects.

Although significant advances have been made in the field in recent years, ERA still faces a number of challenges. Potential avenues to overcome some of these challenges and advance ERA are explored here, including:

- an approach to make protection goals operational for use in pre-market ERAs of regulated products under EFSA's remit;
- the relevance and reliability of scientific studies to support ERAs;
- the broadening of the scope of ERAs to account for multiple stressors and environmental benefits; and
- the interplay between pre-market ERA and post-market environmental monitoring to resolve scientific uncertainties.

This publication builds upon presentations made and discussions held during the breakout session 'Advancing environmental risk assessment' at the EFSA 2nd Scientific Conference 'Shaping the Future of Food Safety, Together' (Milan, Italy, 14–16 October 2015).[1]

2. Using the ecosystem services approach to make protection goals operational for use in ERAs

The first part of problem formulation establishes the context for the assessment by identifying which of the potentially exposed and susceptible components of the environment (species, habitats, services, etc.) are valued by civil society and/or protected by relevant laws or policies. This exercise establishes the so-called environmental policy protection goals: environmental components that should be protected and taken into account when conducting ERAs to support regulatory decision-making. These protection goals can vary between jurisdictions, although their overall aim is to limit harm to the environment, including biodiversity and ecosystems, caused by human activities.

However, policy protection goals, such as protecting biodiversity, are often too generic and vague to be useful for ERA, and need to be translated into specific, operational ones (also termed assessment endpoints or specific protection goals) (USEPA, 1998; Nienstedt et al., 2012; Sanvido et al., 2012; Devos et al., 2014, 2015; Garcia-Alonso and Raybould, 2014). Because protecting everything, everywhere, forever, is rarely, if ever, tenable, operational protection goals have to delineate the environmental components that need to be protected, where and over what time period, and the maximum impact that can be tolerated.

One way to translate policy protection goals into operational protection goals for the ERA of regulated products is to use an ecosystem services approach (EFSA, 2010a,b, 2014c; Nienstedt et al., 2012; Herman et al., 2013; Maltby, 2013; Garcia-Alonso and Raybould, 2014; Gilioli et al., 2014; Devos et al., 2015; Munns et al., 2015). Ecosystems support human societies through functions and processes known as ecosystem services. Although biodiversity is usually not explicitly mentioned as an ecosystem service, it is the source of many ecosystem services and plays an essential role in sustaining ecosystem functioning and the ability to provide benefits to humans (Mace et al., 2012; Duncan et al., 2015; SEP, 2015a). Loss of biodiversity can therefore affect the functioning of ecosystems and their ability to provide society with the goods and services needed to prosper (Potts et al., 2010; Cardinale et al., 2012; Wratten et al., 2013).

[1] The scientific programme of the conference is available at http://www.efsaexpo2015.eu/programme/. All the conference material of the breakout session (including briefing notes, presentations and videos) is available at http://www.efsaexpo2015.eu/show-session/?idsession=10

The ecosystem services approach has gained wide acceptance within the international scientific and risk assessment community, and is currently widely applied by policy-makers to protect biodiversity and safeguard the sustainability of ecosystems (Olander and Maltby, 2014; Devos et al., 2015; SEP, 2015a; EFSA, 2016; Maltby et al., 2016; Mulder et al., 2016; Munns et al., 2016). In the EU, the 2020 Biodiversity Strategy, for example, aims to halt the loss of biodiversity and improve the state of Europe's species, habitats, ecosystems and the services they provide over the next decade.[2] Under Action 5 of the 2020 Biodiversity Strategy, EU Member States are called to map and assess the state of ecosystems and their services in their national territory, assess the economic value of such services, and promote the integration of these values into accounting and reporting systems at EU and national level by 2020.[3] In the USA, the US President recently issued an executive memorandum directing that ecosystem services be incorporated in federal decision-making (EOPUS, 2015).

Investigating the environment through the framework of ecosystem services enables us to recognise the wide range of benefits to humans provided by ecosystems and biodiversity, to identify how changes in these environmental components influence human well-being, and to account for both economic and environmental considerations. However, putting the ecosystem services concept into practice can entail challenges due to the complexities of ecosystem components and their interactions, and a lack of understanding of how regulated products may impact ecosystem service delivery across different spatial scales (Maltby, 2013; Wratten et al., 2013; Gray, 2014; Olander and Maltby, 2014; Duncan et al., 2015; Maltby et al., 2016; QUINTESSENCE Consortium, 2016).

Since 2010, EFSA has been developing a science-based framework to make protection goals operational by accounting for the importance of ecosystems and biodiversity in providing benefits to humans (EFSA, 2010a,b, 2014c, 2016). EFSA's ecosystem services approach to define operational protection goals follows three sequential steps: (1) identifying relevant ecosystem services potentially impacted by the use of regulated products; (2) identifying service-providing units (structural and functional components of biodiversity) that provide or support these ecosystem services; and (3) specifying the level of protection for these service-providing units. The level of protection is defined by five dimensions: the ecological entity of the service-providing unit and its attribute, as well as the maximum magnitude and spatial/temporal scale of tolerable impact (EFSA, 2010a,b, 2012, 2013a,b, 2014b,c, 2015a, 2016; Nienstedt et al., 2012; Devos et al., 2015). Setting the level of protection necessitates a dialogue between risk assessors and risk managers because it involves normative considerations, which cannot be accounted for by risk assessors and scientists alone (Sanvido et al., 2012; Raybould, 2013; Devos et al., 2014, 2015; Wickson, 2015).

The five dimensions are closely interrelated and the choice made for one specific dimension directly influences others. It is therefore important that the relationship between the various dimensions is presented to risk managers in a concise and transparent manner. Moreover, the rationale to justify specific choices for each dimension should be made explicit, using relevant criteria whenever possible. Based on life-history characteristics/traits and the potential for recovery, for example, it can be justified to require a higher level of protection for an important species within a service-providing unit that has a long life cycle and few offspring and which is restricted to a small geographical area, compared to a globally distributed, mobile species that has many offspring and a short recovery time (Nienstedt et al., 2012; Devos et al., 2015; EASAC, 2015).

The ecosystem services approach provides an easy-to-understand tool and a common language, which facilitates communication among stakeholders (including citizens, academia, EU Member States, risk assessment bodies, industry and non-governmental organisations). Improved communication will help to clarify the often divergent positions on what is of value and why, and reveal the underlying values and ideals held by the different actors. Communication among stakeholders will also be essential to reach agreement on operational protection goals, which must be set before ERAs are conducted because they define the framework in which scientists and risk assessors operate when performing ERAs. If what constitutes environmental harm is not defined at the beginning of the ERA, then one cannot discover harmful effects by scientific research. Natural sciences may improve the quality and relevance of the scientific information used to support ERAs and make scientific uncertainties explicit. But they offer little to resolve disagreement about the acceptability of risks, which is primarily a dispute over normative values (Sarewitz, 2007; Raybould and Poppy, 2012; Sanvido et al., 2012; Raybould, 2013; Devos et al., 2014, 2015; Gray, 2014; Pollock and Hails, 2014).

[2] http://ec.europa.eu/environment/nature/biodiversity/policy/index_en.htm

[3] Action 5 is implemented by the working group MAES on Mapping and Assessment of Ecosystems and their Services. Further information is available at http://biodiversity.europa.eu/maes

Thus, agreement on operational protection goals and criteria to derive such protection goals will increase the value of ERAs by providing information necessary for effective decision-making. Collected data and their interpretation can then be directed towards evaluating the impact of any observed effect on what is desirable to protect. Ideally, generic operational environmental protection goals valid for all regulated products should be defined to ensure consistency between regulated products when protecting the environment from harm (Suter, 2000; Suter et al., 2004).

The approach also helps to identify and account for synergies and trade-offs between ecosystem services. Not all ecosystem services can be safeguarded at the same level in the same place at the same time. Enhancing the provision of one service may have consequences for other services. Such trade-offs may lead to conflicts of interest because decisions made by risk managers may favour one group of beneficiaries over another. Hence, communication and stakeholder consultation/involvement can contribute to informed and transparent choices on which ecosystem services to protect and prioritise in agro-ecological landscapes, so as to find a good balance between the ecosystem services provided.

In conclusion, EFSA's ecosystem services approach may offer a practical framework that can be used to derive operational protection goals in a systematic, comprehensive and transparent manner for different regulated products under EFSA's remit. It requires the identification of service-providing units of relevant ecosystem services that may be harmed by regulated products, and the specification of their ecological entity and attribute, as well as the maximum magnitude and spatial/temporal scale of tolerable impact. The approach is considered a promising one to making (environmental) policy protection goals operational for regulated products under EFSA's remit.

3. Paying greater attention to the relevance and reliability of studies supporting ERAs

When performing or appraising ERAs, it is important to consider the quality of the evidence, including how much and what type of data are needed to support ERAs (EFSA, 2015c). Studies should be relevant to the risk hypotheses addressed, and reliable in terms of the inherent quality and validity of the results. Some information available in the wider literature is, at best, irrelevant to ERAs and, at worst, scientifically flawed and misleading (Waltz, 2009; Romeis et al., 2013). The use of clear and internationally agreed criteria will enable a systematic, predictable, comprehensive and transparent approach for the quality appraisal of ERA studies. It will also allow risk assessors and scientists to determine how much reliance can be placed on ERA studies (OGTR, 2013). A better understanding of the strengths and limitations of ERA studies reduces scientific uncertainty in ERAs, and clarifies the extent to which they can contribute to regulatory decisions.

3.1. Relying on problem formulation to enhance the relevance of ERA studies

The evidence used in ERAs is key to their effectiveness, and also to ensuring that they remain clearly focused on identifying and realistically evaluating possible risks. The type and extent of the data that are useful (rather than merely of interest) in conducting ERAs are determined by problem formulation. Problem formulation is the critical first step of ERA, which helps to frame the process. It identifies protection goals, asks what harm may occur by the deployment of a regulated product, and defines what information is genuinely needed to assess the likelihood and seriousness of the harm occurring. It enables a structured, logical approach to identifying harmful effects requiring characterisation, at the same time as excluding non-harmful effects as irrelevant. It also helps to identify available and missing information, and scientific uncertainties that may limit the assessment. Problem formulation has therefore proved adequate to maximise the usefulness of ERA studies for decision-making (USEPA, 1998; Raybould, 2006, 2007, 2010; Wolt et al., 2010; Gray, 2012).

Problem formulation involves several elements: (1) the definition of operational protection goals, which are explicit and unambiguous targets for protection extracted from legislation and public policy goals (see Section 2); (2) the identification of characteristics of the regulated product capable of causing potential adverse effects (hazards) and pathways of exposure through which the deployment of the regulated product may adversely affect human health, animal health or the environment; and (3) outlining specific hypotheses to guide the generation and evaluation of data in the subsequent risk assessment steps. Problem formulation also requires: (4) the identification of methods (through a conceptual model and analysis plan) that will help to direct the risk characterisation and produce

information that will be relevant for decision-making. If relevant and reliable information is available, then the ERA can reduce the number of hypotheses to test for risk characterisation.

Information considered in problem formulation can come from many sources, including published scientific literature, expert opinions, research data and relevant data gathered during product development. However, not all information on the ecology of regulated products available in the scientific literature is equally relevant to ERA. This is because ecological research and ERA differ with respect to the sources of problems, the nature of hypotheses under testing and even the methods for testing hypotheses (Gray, 2004, 2014; Raybould, 2006, 2007, 2010; Layton et al., 2015). It is therefore important to demarcate ERA studies from ecological research, and to explain how an ecological study has relevance to the ERA of a regulated product (Raybould, 2006, 2007, 2010; Johnson et al., 2007). The provision of a conceptual model will underpin the usefulness of scientific information to ERA. It would explain how the deployment of the regulated product could lead to adverse effects on something of value through a chain of events taking account of both hazard and exposure (Tepfer et al., 2013).

3.2. Complying with quality standards to warrant the reliability of ERA studies

Testing of relevant risk hypotheses in ERA studies should be as rigorous and objective as hypothesis testing in any other branch of science. This testing needs to comply with quality standards to increase confidence in the results and add certainty to the conclusions. Moreover, any study should be carried out in such a way that it minimises the probability of erroneous (i.e. false negatives and false positives) or inconclusive results (Begley, 2013; Romeis et al., 2013). Adhering to quality standards will facilitate study reproducibility and peer review of tests. It will also benefit regulatory authorities by enhancing the quality of information generated for use in ERAs. Furthermore, high confidence in the study results is a precondition for the acceptance of data across regulatory jurisdictions and should encourage risk assessors to share useful information and thus avoid redundant testing.

In the frame of the assessment of potential adverse effects of GMPs on non-target organisms, Romeis et al. (2011) indicated that the reliability of test systems is optimised if the following conditions are met: (1) the purity of the test substance is well characterised and described; (2) the bioactivity of the test substance, as provided to the test organisms, is established; (3) test organisms are exposed to high concentrations of the test substance relative to predicted exposures in the field; (4) ingestion of the test substance by the test organisms is confirmed; (5) endpoints are measured that are likely to indicate the possibility of adverse effects on the abundance of non-target organisms or other assessment endpoints; (6) the number of replicates in the study is such that defined effect sizes can be detected with sufficient statistical power; (7) negative control treatments are included to assess the suitability of the test system; and (8) positive control treatments are included, where feasible, to demonstrate that the test system is able to detect treatment effects.

4. Making ERA more contextual to account for multiple stressors and environmental benefits

Another avenue to advance ERA is to make ERAs more contextual by broadening their scope. This would require a paradigm shift from the current practice to a more holistic assessment that accounts for the presence of multiple (anthropogenic and/or natural) stressors, and that considers environmental benefits.

4.1. Moving towards integrated ERAs to account for multiple stressors

ERAs typically address specific regulated products in isolation according to the relevant legislation. They do not necessarily consider cumulative effects arising from the exposure to different regulated products, or simultaneous or sequential exposures to different natural stressors. However, at the landscape level, species can be exposed to multiple natural stressors, in addition to (multiple) regulated products. Some of these natural stressors may interact with regulated products resulting in effects on exposed organisms that may be either lower or higher (in the case of antagonistic, additive and/or synergistic effects) than the effect of one stressor alone. The overall level of exposure of individuals to stressors and the impact on populations of those species will vary in space and time,

depending on species characteristics (e.g. foraging behaviour, adaptation, demographic and recolonisation ability) and landscape features (e.g. structure, composition and land management).

The answer of how to test and assess multiple stressors, including regulated products, is not clear cut. EFSA has already identified the need for more sophisticated methodologies to account for multiple lines of evidence (EFSA, 2014a). The assessment of effects from single stressors in simple ecological systems is easier than the assessment of effects from multiple stressors at the landscape level. Yet, it does not reflect real-life conditions, which involve multiple stressors in more complex systems. There is a need for long-term predictions and assessments following exposure to multiple co-occurring stressors to reflect this complexity.

Honeybees (*Apis mellifera* spp.) represent an excellent model and case study for the implementation of an integrated ERA of multiple stressors. They provide important ecological functions, sustaining basic ecosystem services and human food production (Potts et al., 2010). Many crops depend directly on insect pollination and the honeybee is considered to be one of the most important pollinators, although other insect taxa contribute to pollination (Rader et al., 2016). Honeybees are typically used as a surrogate species for other bees in ERAs, but they cannot be considered representative of all bee taxa because populations of wild bees usually comprise different functional and life-history characteristics and exhibit different sensitivities (Arena and Sgolastra, 2014; Thompson, 2015).

Managed honeybee colonies are exposed to a wide range of regulated (e.g. veterinary products and PPPs) or natural (e.g. infectious agents, climatic and habitat changes, resources, etc.) stressors, some of which contributed to honeybee colony losses in many parts of the world (van Engelsdorp and Meixner, 2010; Potts et al., 2010; Laurent et al., 2015). There is still a lack of good knowledge of the potential interactions and effects of these multiple stressors at the colony level and in field conditions. It is therefore difficult to predict how the stressors change colony dynamics separately and in combination (Thompson, 2012; ANSES, 2015). Moreover, honeybee colonies function as a superorganism where, similar to the cells of an organism, individuals having specific and complex tasks ensure essential functions within the colony (nutrition, excretion, thermoregulation, respiration and reproduction) (Seeley, 1989). Feedback mechanisms in honeybee colonies make it challenging to extrapolate effects measured at the individual level mostly under laboratory conditions to potential adverse effects on colony processes and population dynamics observed under field conditions (Rumkee et al., 2015). In addition, determining the colony level impact of an individual effect is difficult because stressors can affect individuals in a number of ways (Rumkee et al., 2015).

There are some useful approaches for understanding interdependent biological processes, and interpreting and relating sublethal measurement endpoints to assessment endpoints (e.g. colony strength and survival, quantity of hive products). They include holistic approaches such as ecological modelling combined with the results of mechanistic studies, and semi-field and field studies were identified as useful approaches (EFSA, 2013c, 2015b; Rumkee et al., 2015; SEP, 2015b; Volani et al., 2015). Ecological modelling enables the disentanglement of interactions and their exploration, both separately and in combination, in fully controlled simulations (Rumkee et al., 2015). Modelling could also inform the design of higher Tier studies (e.g. timing, scale, replication, duration); assist interpretation of Tier II and III study results; account for observed variability in endpoints (e.g. season); consider other non-chemical factors (e.g. landscape and weather); incorporate data from multiple assessment Tiers; and integrate chemical and non-chemical stressors. Such assessments and developments are currently underway at the EFSA level in the frame of the 'MUST-B: EU efforts towards the development of a holistic approach for the risk assessment on MUltiple STressors in Bees' project (EFSA, 2015b; Volani et al., 2015).

4.2. Weighing the potential for environmental benefits

The main objective of most risk-based legislation regulating the use of a specific product is to ensure a high level of protection of human health, animal health and the environment. The focus therefore is on the assessment of risks only. Legislation does not explicitly consider whether the deployment of regulated products fulfils wider socio-economic and ecological aspirations, or meets other policy objectives (Tait and Barker, 2011; Raybould and Poppy, 2012; Masip et al., 2013). In some jurisdictions, however, broad policy goals also aim to promote improvements in human health and sustainable agriculture. For example, the EU's Sustainable Use Directive provides a framework to consider the best use and options for PPPs (European Commission, 2009). Another example is the

Australian gene technology regulation, which recognises the potential of genetically modified organisms to contribute to society (OGTR, 2013).

Protection is often seen as preserving a baseline condition; it is not seen as improving the environment. In other words, a missed opportunity to improve the environment (e.g. by minimising negative side effects of agriculture) is not regarded as an environmental risk. Ideally, regulated products should be assessed not only for their risks to human health, animal health and the environment, but also for their potential benefits. Balancing potential risks and benefits of regulated products, and putting these into the context of risks and benefits of current agricultural systems, could contribute to achieving greater environmental sustainability in agricultural and land management systems (ACRE, 2007; EFSA, 2008; Pollock and Hails, 2014), provided that clear policy objectives for sustainable agriculture are set.

Weighing the potential for environmental harms and their associated costs against the potential for environmental benefits may enable risk managers and decision-makers to place risks and scientific uncertainties into context. ERA and cost–benefit analysis can offer transparent ways to assemble and integrate relevant evidence to support complex decision-making (Fischhoff, 2015). Cost–benefit analyses may facilitate a proper evaluation of the options available for regulatory decision-making by comparing cost and benefit estimates associated with possible decisions with cost estimates of inaction (Deblonde and du Jardin, 2005; Eckerstorfer and Gaugitsch, 2013). Cost–benefit analyses can also guide the selection of those options that have limited impact on ecosystems and their services at the landscape level because trade-offs across ecosystem services, among beneficiaries and between time periods are expected (see Section 2) (Carpenter et al., 2009; Daily et al., 2009).

There is value in considering the potential benefits and costs of regulated products (Binimelis and Myhr, 2016). Although the assessment of risks is separate from assessment of costs and benefits, the latter can rely on the ERA for quantification of benefits. This paper does not seek to discuss the features and merits of different approaches to cost–benefit analysis, apart from noting that they should be sufficiently rigorous and scientific to be useful in regulatory decisions. Information from ERAs and the ecosystem services approach could provide valuable input to such cost–benefit analysis.

5. Acknowledging the strengths and limitations of post-market environmental monitoring as a tool to resolve scientific uncertainties

Scientific uncertainties are inherent in the scientific process and ERAs. Indeed, ERA can be considered the structured process by which uncertainty is analysed and addressed (OGTR, 2013). ERAs should list identified scientific uncertainties clearly and unambiguously, and clarify their impact on the overall assessment outcome. Explicit information on the premises underlying the ERA, and the nature and magnitude of scientific uncertainties associated with characterised risks, helps risk managers in regulatory decision-making.

Applicants seeking market approval for a regulated product may need to gather additional data to resolve identified scientific uncertainties. In addition, risk managers may request environmental monitoring to be carried out after the placing on the market of a regulated product to provide data on scientific uncertainties identified in the ERA. The latter is typically the case when addressing uncertainties that are considered non-critical, or when potential harm can only become evident in the large-scale deployment of the regulated product. Data gathered through environmental monitoring could feed back into ERA. They could also indicate whether environmental harm to a specific protection goal has occurred, initiating remedial measures or sustaining claims of redress linked to environmental liability (Sanvido et al., 2005, 2011; EFSA, 2011).

However, it has to be recognised that environmental monitoring could become very resource intensive due to ecological complexities. Any environmental monitoring therefore needs to clearly focus on parameters which are readily measurable, and can be linked to and unambiguously interpreted as a consequence of the regulated product.

Risk managers should acknowledge the strengths and limitations of environmental monitoring programmes as a tool to resolve remaining scientific uncertainties after market introduction. Hence, they should consider whether remaining uncertainties related to adverse environmental effects of a regulated product would be assessed in a more efficient and rigorous way during pre-market ERA, or via post-market environmental monitoring.

6. Conclusions

ERA should further increase its value and relevance to decision-making on regulated products under EFSA's remit. This can be achieved by being precise about operational protection goals, formulating relevant risk hypotheses, and collecting relevant and reliable information/conducting studies to test those hypotheses.

- Defining more clearly and precisely what constitutes environmental harm independently from the regulated product under consideration. This will facilitate a more structured approach to ERA, ensure a common approach on how to derive operational protection goals across different regulated products under EFSA's remit, and increase the value of ERAs by providing information necessary for effective regulatory decision-making.
- Relying on problem formulation will ensure that resources are spent to gather need-to-know information instead of unnecessary data that might be scientifically interesting but may obscure the risk assessment.
- Complying with quality standards will minimise the probability of erroneous or inconclusive results, increase confidence in the results and add certainty to the conclusions.
- Taking into consideration multiple stressors and landscape-specific features in ERAs will inform about differences in risks under different environmental conditions and agricultural practices. This would lead to better informed decision-making and enable targeted risk mitigation measures. Knowledge about the real risks under different agro-environmental conditions is a prerequisite to determining an optimal balance between environmental protection and food production.

It is important to emphasise that ERA is only a part of the regulatory decision-making process. ERA for regulated products needs to be broader in scope so it can tackle the bigger questions regarding environmental impacts. To achieve this, two main issues need to be addressed. Future regulatory decision-making needs to balance putative risks against potential benefits. Furthermore, questions about the safety of regulated products need to consider all the frequently emphasised, but entirely contingent harms associated with current agricultural and land management systems.

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Abbreviations

ERA environmental risk assessment
GMP genetically modified plant
PPP plant protection product