DRAFT SCIENTIFIC OPINION

Scientific Opinion on the temporal and spatial ecological recovery of non-target organisms for environmental risk assessments[1]

Scientific Committee[2, 3]

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ABSTRACT

The European Food Safety Authority (EFSA) performs environmental risk assessments for single potential stressors such as plant protection products, genetically modified organisms and feed additives and for invasive alien species that are harmful for plant health. In this risk assessment domain, the EFSA Scientific Committee recognises the importance of more integrated environmental risk assessments considering both the local and landscape scale, as well as the possible co-occurrence of multiple potential stressors that fall under the remit of EFSA, which are important when addressing ecological recovery. In this Scientific Opinion, the Scientific Committee gathered scientific knowledge on the potential for recovery of non-target organisms for further development of environmental risk assessments. Current EFSA guidance documents and opinions were reviewed on how ecological recovery is addressed in environmental risk assessment schemes. In addition, this Scientific Opinion is based on expert knowledge and data retrieved from the literature. Finally, the information presented in this opinion was reviewed by experts from the relevant EFSA Panels, European risk assessment bodies and through an open consultation requesting input from stakeholders. A conceptual framework was developed to address ecological recovery for any assessed products, and invasive alien species that are harmful for plant health. This framework proposes an integrative approach based on well-defined specific protection goals, scientific knowledge derived by means of experimentation, modelling and monitoring, and the selection of focal taxa, communities, processes and landscapes to develop environmental scenarios to allow the assessment of recovery of organisms and ecological processes at relevant spatial and temporal scales.

KEY WORDS

Recovery, resilience, trait-based assessment, semi-field experiments, mechanistic models, field monitoring, focal species and landscapes

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SUMMARY

At EFSA's 10th anniversary conference (EFSA, 2012), it became apparent that EFSA's environmental risk assessment (ERA) schemes have evolved independently in the different areas within its remit (see EFSA, 2011), and that further harmonisation is possible on specific topics. EFSA, therefore, mandated the Scientific Committee (under mandate M-2013-0098) to harmonise EFSA's environmental risk assessment schemes with regard to: (1) accounting for biodiversity and ecosystem services to define protection goals for environmental risk assessment; (2) coverage of endangered species as non-target organisms in single-stressor environmental risk assessment; and (3) temporal and spatial recovery of non-target organisms for environmental risk assessments. The Scientific Committee prepared three separate scientific documents to address the above mentioned issues and this scientific opinion is specifically about (3) temporal and spatial recovery of non-target organisms for environmental risk assessments.

The EFSA Scientific Committee collected and discussed relevant information from the diverse areas of environmental risk assessment conducted by EFSA and from the scientific literature. From these discussions, a draft Scientific Opinion was proposed for public consultation and further adoption by the EFSA Scientific Committee (see section 1). For this assessment, the Scientific Committee proceeded in four steps.

First, the Scientific Committee provided clarification on terminology and concepts that are needed when addressing ecological recovery (see section 2). In particular, definitions were provided for environmental stressors (i.e. physical, chemical and biological) including pulse and press disturbances (section 2.1); direct and indirect effects (section 2.2) and ecological recovery (section 2.3), comprising actual and potential recovery (section 2.3.1), recovery at the population level, including internal and external recovery (section 2.3.2) and resilience at the ecosystem level (section 2.3.3).

In the above clarifications, an analogy was made between the terms stress, disturbance and perturbation. Also, it was highlighted that multiple environmental stressors can act simultaneously or sequentially. It was concluded that, independently of the type(s) of stressor(s) and duration of stress, the normal operating range of individuals, populations, communities and ecosystems becomes disrupted when the environmental stressors exceed a threshold of exposure. The actual recovery is related to the return to this normal operating range, whereas the potential recovery was defined as the disappearance of the stressor to level and/or concentration in which it no longer has an adverse effect on the ecological entity (endpoint) and after which recovery theoretically can start. However, it is challenging to define and measure the normal operating range. Under field conditions, adverse effects of a stressor can remain unnoticed if the measurement endpoints show a relatively large variability due to effects of natural factors. For indirect effects, it was noted that they may persist longer than direct effects. Furthermore, clarifications were provided on the concept of metapopulations, which is necessary to understand recovery in a landscape context, and on population stability. To predict recovery of populations of non-target organisms it is necessary to understand actual population fitness during the period of stress.

Second, the Scientific Committee developed a conceptual framework for the assessment of ecological recovery (section 3) and gathered knowledge on the key parameters that need to be considered when assessing ecological recovery, in particular (i) the properties of the types of potential stressors of concern that fall under the remit of EFSA (herafter mentioned potential stressors), i.e. plant protection products, genetically modified organisms, feed additives and invasive alien species that are harmful to plant health (see section 4 and Appendices A and B); (ii) the species and their traits, e.g. related to demography, dispersal and foraging behaviour as well as adaptation to potential stressors (see section 5); and (iii) the specific features of the landscape, i.e. variations in land use, and the types, spatial distribution and connectivity of habitats (see section 6).

Regarding the properties of the plant protection products, genetically modified organisms, feed additives and invasive alien species that are harmful to plant health (described in sections 4.1, 4.2, 4.3

and 4.4, respectively), the Scientific Committee summarised information on their patterns of use, or presence in the case of invasive alien species that are harmful to plant health, in space and time, and on how ecological recovery is tackled for each of these potential stressors in the EU legislation. In addition, when available, studies providing data on ecological recovery from exposure to these stressors were described. Finally, impacts on food-web interactions and ecological recovery from these stressors were addressed.

Regarding the species traits that may affect ecological recovery, demographic (life-history traits), recolonisation (dispersal traits) and other traits such as foraging behaviour are identified as being of utmost importance (section 5.1). To illustrate this, some examples of specific traits for focal taxa are described (section 5.2). The contribution of genetic diversity to recovery is discussed in the context of adaptation to stresses (i.e. in the sense of the selection and genetic inheritance of resistant genotypes) (see section 5.3). According to the ecological insurance hypothesis, the more genetically diverse a population or community, the better they can withstand potential stressors and can continue providing ecosystem services. It is worth noting that adaptation to stress may or may be not associated with fitness costs.

Some specific features of agricultural landscapes that may affect ecological recovery (section 6) are described for the terrestrial and aquatic (i.e. for surface waters that drain agricultural landscapes) compartments. For the terrestrial compartment (section 6.1), the spatial distribution and connectivity of treated fields in relation to non-treated areas and the variety of possible land uses in Europe are known to influence the likelihood of concurrent events (i.e. treatments in multiple fields) and therefore the level of exposure to potential stressors in the landscape. These features are all important to consider when selecting the spatial scale at which recovery needs to be assessed. It is also highlighted that these features are important for influencing recovery of organisms that move between in-field and off-field areas (due to the concept of “action at a distance” – i.e. effects of potential stressors may occur outside of the spatial area occupied by these stressors). For the aquatic compartment (section 6.2), the surface area drained by streams overall is considerably larger than that of ponds, while ditches have an intermediate position. In reverse, the retention time of water (i.e. the average length of the time that water spends in the system) increases when going from streams to ditches to ponds. In theory, both the potential of fastest recovery following exposure to a potential stressor and the chance to suffer multiple potential stressors will be ranked in the order streams > ditches > ponds. Given the spatial and temporal variability of the European landscapes and also given the diversity of the datasets and classifications used to assess and record the landscape structure in Europe, it may be challenging to incorporate such variations when conducting an environmental risk assessment and assessing ecological recovery (section 6.3).

Third, taking into account the complexity of ecological systems comprising multiple variables (see section 7), the Scientific Committee examined the pros and cons of experimental (section 7.1) and modelling (section 7.2) approaches to address ecological recovery of the appropriate focal species. Experimental studies allow replication so that treatment-related effects on, and recovery of, populations, communities and functional endpoints can be evaluated statistically, but are limited in the ecological realism that can be investigated. The minimum detectable difference is suggested as an indicator of the statistical power of a semi-field test. For modelling approaches, pros are mostly linked to the ability of models to simulate accurately complex ecological systems where potential stressors may cause multiple outcome changes due to feedback mechanisms. This requires a good understanding of the ecological processes influencing the responses of the assessed entity within its environmental context and a clear definition of the domain of the applicability of the model. Potential disadvantages are the high demand for data and expert skills for both the development and validation of models. However, in prospective risk assessment (e.g. in the case of invasive alien species that are harmful to plant health), neither experimental nor modelling approaches can provide complete information. In such cases, expert opinion elicitation is required. Finally, it is concluded that experimental and modelling approaches need to be linked to appropriately predict recovery processes at the appropriate spatial and temporal scales, while field monitoring is required as a reality check.

Fourth, from the information collected and described above, the conceptual framework as given in section 3 is revisited and discussed, and an integrated approach for addressing ecological recovery for any potential stressor, and invasive alien species that are harmful to plant health, is proposed (see section 8). Initially, the factors affecting ecological recovery of vulnerable non-target organisms after exposure to different types of potential stressor (section 8.1) and the relationships between recovery of structural and functional endpoints (section 8.2) are clarified. Then, the integrated approach is described (sections 8.3) based on the conceptual framework described earlier and information is provided on how to select appropriate focal taxa and/or processes (section 8.3.1) and appropriate spatial scales (section 8.3.2) to address exposure, effects and ecological recovery. Finally, clarifications are provided to address specifically ecological resilience for systems impacted by invasive alien species that are harmful to plant health (section 8.3.3).

This Scientific Opinion makes several conclusions and identifies key challenges for assessing ecological recovery of non-target organisms in environmental risk assessment of potential stressors (see section 9.1), followed by a series of recommendations (see section 9.2).

Conclusions

Recovery can be assessed at the levels of individuals, populations, communities, or functions. In broad terms, recovery can be thought of as the return of an ecological entity (e.g. structure such as abundance, or function such as an ecosystem service) to its normal operating range (sometimes referred to as baseline properties), having been perturbed outside of that range by a stressor (or multiple stressors). In order to assess recovery, it is first necessary to define what the normal operating range of the ecological entity and/or process is.

The appropriate point in a risk assessment at which the assessment of recovery should be considered and planned is at the problem formulation step, when specifying the specific protection goal(s). Ecological recovery should be considered at the relevant level of biological organisation and relevant spatial and temporal scales for each specific protection goal. In a following step, focal taxa, focal communities and/or focal landscapes should be identified, based on relevant traits.

The extent to which recovery is considered in current risk assessments relevant to EFSA varies with the risk assessment area. In environmental risk assessment schemes, specific protection goals are defined in terms of a “threshold option” (no effects permitted, so assessment of recovery is not relevant) or a “recovery option” (effects are inevitable and permitted within specified spatial and temporal frames, and recovery assessment is therefore important). For plant protection products, both threshold and recovery options apply, depending upon the protection goal. For genetically modified organisms and feed additives, the recovery option may be selected on a case-by-case basis. For invasive alien species that are harmful to plant health, the focus of environmental risk assessment is different to that of the potential stressors but ecological recovery is part of the scenario assumptions. In general, regulatory guidance documents and their supporting legislation provide very little specific information on how to assess recovery.

The introduction of potential stressors may be followed by stress-periods of limited duration (pulse disturbances) or in prolonged stress periods (press disturbances). The recovery option in environmental risk assessment is in theory feasible if the potential stressors cause pulse disturbances, but short-term exposures may result in long-term effects if impacted organisms are not able to re-colonize the stressed habitat.

Trait-based assessment is a valuable approach for recovery assessments. Traits can be viewed from the perspective of the assessment endpoint or the landscape. Key ecological traits that govern recovery time are life-history traits (i.e. fecundity, voltinism and lifespan), dispersal ability (i.e. active or passive), diet and foraging behaviour, and presence of life stages resistant to the potential stressor(s). Key landscape traits that govern recovery are the proportions, configuration and connectivity of exposed and non-exposed habitats. Recovery can be classified into two main types, depending upon whether it occurs *in situ* (internal recovery) or via dispersal (external recovery). Both types of recovery may be exhibited by the same ecological entity (e.g. at different stages in a species' life-history).

As with effects assessments, the main approaches to assess recovery are experimentation, prediction, monitoring and expert elicitation. The main tools for prediction of recovery are mechanistic models whilst experimental approaches involve semi-field and field studies. Both modelling and experimental approaches have strengths and weaknesses. For experimental studies, a key difference between effects assessment and recovery assessment is that the studies of recovery may require larger spatial and/or temporal scales, particularly if the organisms move between exposed and non-exposed habitats and if external recovery is key. Large-scale field monitoring studies are required as a reality check and to improve prospective environmental risk assessment procedures. In scenario development and prospective environmental risk assessment, rigorous expert opinion elicitation is usually required.

A number of theoretical concepts relate to the assessment of recovery (e.g. action at a distance, alternative stable states and metapopulation dynamics). The importance of these concepts varies with the stressor and risk assessment being conducted but in general they are more difficult to identify for more complex levels of ecological organisation. Depending upon the potential stressor(s) and ecological entities and/or processes being assessed for a specific protection goal, genetic adaptation may have an important bearing both on susceptibility to these stressors and recovery from stressor-induced effects.

Indirect effects may be especially pronounced if relatively large and long-term direct effects on non-target organisms are allowed (e.g. in-field effects of potential stressors like pesticides) and/or these effects cannot be avoided (e.g. the spread of an invasive alien species that are harmful to plant health). Indirect effects may persist longer than direct effects. In principle the magnitude and the duration of indirect effects at the ecosystem-level can be studied in (semi-)field experiments and by means of food-web models. The occurrence of persistent indirect effects at the landscape-level might be detected by conducting large-scale monitoring programmes, but the identification of causal relationships between different potential stressors and their direct and indirect effects will be difficult and probably requires the development of landscape-specific ecological interaction models.

As with effects assessment, the assessment of recovery is easier when stressors are considered in isolation in relatively simple ecological systems but this does not reflect those real-life situations which typically involve multiple stressors in more complex systems in which non-target organisms move between exposed and non-exposed habitats. These multiple stressors may affect the fitness of the ecological entity. Thus, it should be borne in mind that at the landscape-level both multiple natural stressors as well as the presence of non-exposed refuge areas may influence the recovery ability of an ecological entity, in addition to the potential stressors that are the subject of the environmental risk assessment.

Due to the complexity of ecological systems and the need to evaluate effects and recovery in spatial and temporal dimensions, a systems approach is required. The current Scientific Opinion brings together the above considerations in a conceptual framework to guide risk assessors and risk managers on how to integrate recovery assessments into environmental risk assessment. For a given specific protection goal, the conceptual framework links together the key parameters (i.e. focal taxa or communities, focal landscapes, and potential stressors), the environmental risk assessment tools (i.e. system modelling and semi-field or field experiments) and the supporting information, which includes the societal perspective as well as ecological monitoring and the scientific evidence base.

While the protection goals for plant protection products, feed additives, genetically modified organisms and invasive alien species (i.e. those species that are harmful to plant health) are fundamentally similar, harmonization of procedures to assess recovery is currently difficult to implement pragmatically because of the differences in the nature and impacts of invasive alien species as compared to the other potential stressors.

Assessing ecological recovery needs a systems-based approach and the assessment of ecological recovery needs to be integrated into the full risk assessment. In order to adopt a systems approach, several challenges were identified as follows:

- To define the normal operating range of ecological entities (bearing in mind that this may vary in time and between different ecosystems);
- To identify focal taxa, focal communities and/or focal landscapes;
- To appropriately assess recovery in cases where the recovery option only applies in-field but not off-field, even though (according to action at a distance) effects might also occur off-field (this would be relevant, for example, to plant protection products or genetically modified organisms);
- To predict the role of indirect effects on ecological recovery at the landscape level;
- To select appropriate spatial and temporal scales and key landscape traits for the assessment of impact and recovery of different organism groups and therefore to determine the right management and/or mitigation decisions (trade-off);
- To operationalize links between experimentation, modelling and monitoring, and between prospective and retrospective studies, to consolidate risk assessments;
- To parameterize population and food-web models including uncertainty;
- To establish predictive food-web and/or ecological interaction models that can be used in prospective environmental risk assessment;
- To develop good mechanistic effect models which are both manageable and realistic enough;
- To integrate systems approaches and multiple (potential) stressors into environmental risk assessment.

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1. INTRODUCTION

The European Food Safety Authority (EFSA) conducts environmental risk assessment (ERA) for potential stressors which are plant protection products (PPPs), genetically modified organisms (GMOs), feed additives and invasive alien species (IAS) [4] that are harmful to plant health. A potential stressor, as used in this opinion, means an assessed product or an IAS related to the food and/or feed chain in all areas falling within the EFSA remit (see Appendix B for further description on those potential stressors). The concept "assessed products" as used herein means " claims, materials, organisms, products, substances and processes" submitted to EFSA for evaluation in the context of market approvals and/or authorisation procedures[5].

The ERAs are conducted within EFSA's remit to ensure the safety of the food and/or feed chain. When an effect on ecosystem functioning or on non-target organisms (NTOs) is expected and/or observed, ecological recovery becomes relevant and therefore needs to be considered in the ERA.

In the legal framework, ERA is a mandatory part of the market registration procedure of PPPs[6,7], GMOs[8,9] and feed additives[10,11,12]. In the case of IAS, there is a legal requirement[13] to assess potential consequences on the environment of the inadvertent introduction and spread of harmful organisms with trade as well as risk reduction options in order to provide the risk manager and the European Commission (EC) with information that supports the formulation of appropriate measures to reduce the risk of unacceptable impacts[14]. The regulation providing this legal requirement is currently under revision (EC, 2013). In the current regulations, ecological recovery is not explicitly mentioned and not

[4] Invasive alien species (IAS) are plants, animals, pathogens and other organisms that are non-native to an ecosystem, and which may cause economic or environmental harm or adversely affect human health (Convention on Biological Diversity, 2015; http://www.cbd.int/idb/2009/about/what/). The EFSA plant health panel assesses risks posed by invasive alien species that are harmful to plant health. Therefore, within the context of this opinion, the term IAS refers to invasive alien species that are harmful to plant health. Strictly, the term "invasive" refers to the tendency of a species to disperse and extend the spatial range, or colonize systems from which it was previously absent. An organism is "alien" if it does not naturally occur in a system or area.

[5] For an official list of the relevant legal acts identifying all the "products" subject to EFSA's scientific evaluation see: In managed areas, such as agricultural areashttp://www.efsa.europa.eu/en/apdesk/docs/apdeskhow.pdf

[6] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 209,24.11.2009.

[7] 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.309/1 24.11.2009.

[8] Directive 2001/18/EC of the European Parliament and of the Council of 12 march 2001 on the deliberate release into the environment of genetically modified organisms and repealing council directive 90/220/EEC (O.J. l 106, 17.4.2001, p. 1).

[9] Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council. OJ L 268, 18.10.2003.

[10] Commission Directive 2001/79/EC of 17 September 2001 amending Council Directive 87/153/EEC fixing guidelines for the assessment of additives in animal nutrition, O.J. L 267, 6.10.2001, p. 1.

[11] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition, O.J. L 268, 18.10.2003, p. 29.

[12] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives, O.J. L133, 22.5.2008, p.1.

[13] Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community O.J., L.169, 10.7.2000, p. 1, as last amended.

[14] ISPM No. 11: Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms (2004), Rome.

mandatory, although the assessment and monitoring of any potential undesirable long-term effect on the environment from the use of PPPs and GMOs and from the introduction and spread of IAS is required.

When conducting an ERA, the problem formulation is the appropriate starting point to consider the concept of ecological recovery. A key part of problem formulation is the description of protection goals. In the respective legislative frameworks, these protection goals cover human, animal and plant health and the environment. However, for the development of a robust risk assessment scheme, these protection goals are broadly defined and need to be further translated into more specific protection goals (SPGs) (EFSA PPR Panel, 2010). These SPGs need to be made specific, testable and measurable to enable the collection of pertinent data that may be assessed by risk managers. Key issues are what to protect, where, and over what period of time.

To derive SPGs, EFSA developed a methodology (EFSA PPR Panel, 2010; EFSA PLH Panel, 2011) that is based on the ecosystem services concept (Nienstedt et al., 2012). According to this methodology, for each of the ecosystem service providing key drivers, also referred to as service providing units (SPUs) (Gilioli et al., 2014) to be protected, the following dimensions of the SPG need to be defined: the ecological entity (e.g. individual, population, functional group, ecosystem), the attribute of that entity (e.g. behaviour, growth, abundance, biomass, processes), the magnitude of effects (i.e. negligible, small, medium, large), the temporal scale of effect for the attribute (e.g. duration, frequency) and the spatial scales (e.g. in- and off-field patches of landscapes, see EFSA SC, 2016a). In addition it is also necessary to set exposure assessment goals which, together with the SPGs, determine the overall level of protection. Risk managers need to take into account the overall level of protection when choosing a SPG and a related exposure assessment goal (EFSA SC, 2016a).

In ERA schemes for PPPs, SPGs are defined in terms of a "threshold option", where an impact on relevant endpoints is not tolerated (recovery is not relevant), and a "recovery option", where an impact is considered unavoidable and an "acceptable" degree of impact is tolerated (recovery is relevant); the magnitude and spatial and temporal scales of the "acceptable" impact are operationalised (EFSA PPR Panel, 2010, 2013a). For GMOs, the recovery option may be selected under certain conditions, although the magnitude, spatial and temporal scales of the acceptable impact are operationalised in SPGs but assessed on a case-by-case basis (EFSA GMO Panel, 2010a, 2011). Recovery is not taken into account in the current EFSA Guidance for ERA of feed additives (EFSA FEEDAP Panel, 2008). For IAS, the focus of the ERA is different from the other potential stressors, but ecological recovery is part of the scenario assumptions. Its concept is related to that of resilience of an ecosystem (EFSA PLH Panel, 2010a). According to the Plant health (PLH) Panel, a scenario assumption is an attempt to explore what future developments may be triggered by a driving force that cannot or can only partly be influenced by decision makers (Henrichs et al., 2010; Gilioli et al., 2014). A scenario analysis includes explicitly the combination of qualitative and quantitative information and estimates (EEA, 2001). Most of the work on IAS is based on qualitative evaluation that can be translated into quantitative assumptions on the final state of the system (Henrichs et al., 2010).

The way ecological recovery and the five dimensions (ecological entity, attribute, magnitude, temporal scale and spatial scale) of the SPGs are determined for PPPs, GMOs, feed additives and IAS, are further detailed in Appendix A.

In ERA, when addressing ecological recovery, different spatial scales may apply, from the field (e.g. a pesticide-sprayed crop and its immediate surroundings) to the continental (if an IAS enters the EU territory and has the capacity to spread over and impact the whole of the EU territory). In addition, different levels of biological organisation need to be considered in ERAs. For example, due to the nature of IAS, ERAs for these species usually focus on the resilience at the ecosystem level, whereas in the case of PPPs and GMOs, protection of populations is usually the focus of attention, not *per se* excluding the recovery option. Ecological recovery should therefore be considered at the relevant level of biological organisation.

As a general rule, a regulation that considers ecological recovery could potentially allow impacts on populations of NTOs and possible consequences on ecosystem properties as long as they are reversible within an acceptable temporal and spatial frame. When, locally and temporarily, an effect on communities or some given populations of NTOs is allowed as for the use of PPPs in treated fields, ecological recovery, becomes an issue and needs to be considered to ensure that effects on NTOs are of acceptable duration and reversible. Also for the effect of PPPs on aquatic organisms in edge-of-field surface waters, ecological recovery was proposed to risk managers as an alternative to the threshold option (where no impact on populations is allowed) (EFSA PPR Panel, 2013a) whereas for feed additives, the focus is on the threshold option (EFSA FEEDAP Panel, 2008).

A final decision by risk managers on the overall level of protection is needed to determine whether ecological recovery should be taken into consideration in the risk assessment or not. However, in this Scientific Opinion, independently of this decision on SPGs and the type of assessed products and/or species of concern, it will be assumed that ecological recovery is relevant and that a conceptual framework is required to support risk managers in making the best decisions based on informed options and current scientific knowledge.

In this framework, the potential for ecological recovery needs to be considered in space and time. This task is complex and remains a challenge because of the diversity of agricultural landscapes and, in the case of IAS, of non-agricultural landscapes across Europe, the variability in species vulnerabilities under different climatic conditions, the uncertainty linked to the lack of data on e.g. species life-history traits, species sensitivity and multi-generation effects, and the current gaps in knowledge on indirect effects from species interactions (see section 2 for terminology).

An extra layer of complexity in ERA would be the inclusion of realistic exposure scenarios where populations are most likely exposed to multiple stressors (anthropogenic and/or natural) at the same time or in a sequential order rather than to single stressors and where effects may accumulate over time. In the context of ecological recovery, these scenarios are highly relevant and deserve further attention. To accomplish this, a systems perspective needs to be developed (EFSA, 2014a) and this is the objective of this Scientific Opinion. Therefore, the Scientific Committee proceeded in four steps. First, the Scientific Committee provided clarification on terminology and concepts that are needed when addressing ecological recovery (i.e. definitions on ecological, internal, external, actual, potential and population recovery; pulse and press disturbances; direct and indirect effects; population stability, resistance and resilience; and the concept of metapopulations). Second, based on these clarifications, the Scientific Committee developed a conceptual framework for addressing ecological recovery for any potential stressor and gathered knowledge to determine the key parameters to be considered, in particular properties of the potential stressors of concern (i.e. PPPs, GMOs, feed additives and IAS) including knowledge on how ecological recovery is currently addressed for each of these stressors, the species traits (i.e. demographic, recolonisation and other traits such as foraging behaviour and adaptation) and the specific features of the landscape (i.e. variations in the composition, structure and management of exposed and unexposed areas). Third, to assess both spatial and temporal ecological recovery taking into account the complexity of the system comprising multiple variables, the Scientific Committee examined the pros and cons of experimental and modelling approaches for the development of this system perspective approach. Fourth, from the information collected and described above, the Scientific Committee developed an integrated approach for addressing ecological recovery for any potential stressor.

1.1. Background and Terms of Reference as provided by EFSA

In EFSA's context, ERA considers the impact on the environment caused by, for example, the use of certain substances in food and feed, the application of PPPs, the introduction and spread of non-endemic plant pests or the introduction of a GMOs.

For those products falling within its remit, EFSA is responsible for ERA in accordance with the various relevant legislations (EFSA, 2011). More detailed descriptions of ERA have been developed in a number of guidance documents from individual EFSA Scientific Panels: e.g. EFSA Panel on Plant Protection Products and their Residues (PPR) (2009, 2013a); EFSA Panel on Plant Health (PLH) (2010a, 2011); EFSA Panel on Genetically Modified Organisms (GMOs) (2010a, 2013a); EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) (2008) and EFSA Panel on Biological Hazards (BIOHAZ) (2010a, b); and it is envisaged that other EFSA Panels (e.g. the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)) will perform ERA on applications submitted to EFSA.

To keep up with new regulatory and scientific developments, such guidance documents require updating as appropriate and are therefore considered as "living documents" (EFSA SC, 2015a). Against this background, the Scientific Committee continues to identify opportunities to harmonize best practices for ERA.

From the EFSA 10th anniversary conference (EFSA, 2012) it was evident that there is a clear need for making protection goals operational for use in ERA. A need for more harmonised ERAs was also recently pointed out in a letter titled "*Environmental health crucial to food safety*" to the editors of Science (Hulme, 2013).

Protection goals are only briefly mentioned in the respective legislative frameworks of the different Panels and could be further specified e.g. by the use of the ecosystem services concept (EFSA, 2010; EFSA PPR Panel, 2010; Nienstedt et al., 2012). Moreover, following a harmonised approach across ERAs of different potential stressors[15] would ensure that environmental protection goals are considered consistently, irrespective of the type of innovation (EFSA SC, 2016a).

Many of the overarching elements that exist in ERA of respective EFSA areas are related to protection goals. Guidance is needed on methodologies to implement biodiversity and ecosystem services as protection goals. Two specific items have been identified recently as requiring more detailed scientific consideration from a working group of the Scientific Committee: coverage of endangered non-target species and recovery of non-target species. Such specific considerations could further complement the currently existing practices for risk assessment, as described in the existing EFSA guidance documents.

EFSA, therefore, requested the Scientific Committee to establish a working group, including experts from the relevant EFSA Panels, to provide separate opinions on harmonising the approach to setting protection goals and the two specific elements of ERA within the remit of EFSA, i.e. "Coverage of endangered non-target species " and "Recovery of non-target species".

EFSA requested to consider and involve during the preparation of the opinions the experience and guidance developed by other EU and Member State agencies and scientific bodies (e.g. Scientific Committee for Environmental Health Risks (SCEHR), European Environmental Agency (EEA), European Medicines Agency (EMA), European Chemicals Agency (ECHA), Joint Research Centre (JRC)), international bodies (e.g. World Health Organisation-International Programme on Chemical Safety (WHO/IPCS), Organisation for Economic Co-operation and Development (OECD)) and other international agencies (e.g. United-States Environmental Protection Agency (US-EPA)).

For the task of developing an opinion on recovery, the Scientific Committee was requested to consider common approaches and the specific questions to be addressed for this topic including the following:

[15] As described in the interpretation of the terms of reference and scope, "stressor" is used herein as "environmental stressor" and means any physical, chemical, or biological entity that can induce an adverse response in the environment. Products/species, i.e. stressors that fall under the remit of EFSA, can be considered as potential stressors. The concept "potential products" as used herein is meant to include "claims, materials, organisms, products, substances and processes" submitted to EFSA for evaluation in the context of market approvals/authorisation procedures.

- Which are the relevant traits of different organism groups and what are their respective quantifiable and/or non-quantifiable parameters that characterise recovery, for examples:
    - genetic diversity, needed for populations to adapt to new selective pressures of the environment,
    - potential for internal recovery by the exposed population, determined by life-cycle and reproduction characteristics,
    - potential for external recovery (immigration) from unexposed populations, determined by dispersion ability and mobility.
- How to take into account the potential of recovery in ERA under real field conditions assuming repeated exposure? The above traits of different organism groups relevant for recovery could be used for comparison to e.g. the pesticide application patterns or other exposure patterns relevant for other units of EFSA.
- How to describe the parameters relevant for the recovery of different organism groups in a generic way i.e. which would allow their use in other (or all) relevant areas within EFSA's remit.

For the two other opinions to be developed by the Scientific Committee, the Terms of Reference are specified in the respective parallel opinions (EFSA SC, 2016a, b).

1.2. Interpretation of the Terms of Reference

In accordance with the various relevant legislations in place (EFSA, 2011)[16] EFSA performs ERA on the application of PPPs, the deliberate release into the environment of GMOs, the use of certain substances in food and feed (e.g. feed additives) and the introduction and spread of IAS that are harmful to plant health. The purpose is to evaluate their potential adverse effects on the environment. In this document such agents are considered as potential environmental stressors but for pragmatic reasons (of abbreviation) are collectively referred to as "potential stressors" throughout the text of this document and as defined in the glossary[17]:

Potential stressor: used as " potential environmental stressor" and meaning any physical, chemical, or biological entity resulting from the use of a regulated product or the introduction of an invasive alien plant species related to the food/feed chain that is assessed in any area of EFSA's remit and that can induce an adverse response in a receptor (Romeis et al. 2011). Potential stressors may adversely affect specific natural resources or entire ecosystems, including plants and animals, as well as the environment with which they interact (http://www.epa.gov/risk_assessment/basicinformation.htm).
When stressors are assessed within the remit of EFSA, these are referred to in this Scientific Opinion as potential stressors. Although this Scientific Opinion deals with potential stressors assessed by EFSA, the principles of this opinion may also be valid for other stressors assessed by other agencies such as EMA or ECHA, or for other stressors of natural origin.

[16] While an overview table is given in EFSA (2011), more detailed guidelines for ERA have been developed in a number of guidance documents from individual EFSA Scientific Panels (Panel on Plant Protection Products and Residues (PPR), 2009 and 2013; Panel on Plant Health (PLH), 2010 and 2011; Panel on Genetically Modified Organisms (GMO) 2010 and 2013, Panel of Feed Additives (FEEDAP), 2008 and Panel on Biological Hazards (BIOHAZ), 2010a,b). Moreover, it is envisaged that other Panels (e.g., the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)) will perform ERA on applications submitted to EFSA.

[17] It is recognized that particular terms apparently have different meanings when used in the different areas of the EFSA's remit. In the context of the harmonization of the ERA procedures across the different areas, defining a common glossary is also important. The glossary of this guidance provides the definition of the terms as they are used in this document.

The overall aim of this opinion is to investigate how to address ecological recovery in the ERA schemes of potential stressors like PPPs, GMOs, feed additives, and also IAS that fall under the remit of EFSA.

Recovery is used in a number of different ways in risk assessments. For example, these include physiological recovery with a focus on the individual level, and population recovery focused at the population level. However, for the purposes of this opinion we use the general concept of *ecological recovery* since this represents the range of levels of organisation addressed by the SPGs for populations, communities and ecological functions and ecosystem services. We define ecological recovery as the return of an ecological entity to a defined reference state after a disturbance (e.g. return to its pre-disturbance state). Ecological recovery can thus be defined at all levels of biological organisation from populations to ecosystems, and including both structural and functional attributes.

EFSA Panels' ERA schemes and corresponding applicable sectoral legislations are reviewed in the "*Review of current practices of environmental risk assessment within EFSA*" (EFSA, 2011). EFSA performs prospective ERA for PPPs, GMOs, and feed additives, before being placed on the market. For IAS, EFSA's ERA can be both prospective and retrospective. The protection of the environment is also envisaged by the risk assessment of certain biological hazards in certain products (e.g. animal by-products) and can be envisaged for more products of relevance to EFSA Scientific Panels (e.g. for food contact materials).

Specific objectives

Following the EFSA 10th Anniversary Scientific Conference (EFSA, 2012), wherein experts from various EFSA areas provided details and exchanged experiences on their current schemes for ERA, the Scientific Committee explored the differences and similarities across EFSA areas when addressing ecological recovery. In response to the Terms of Reference, this opinion will therefore formulate "*specific steps for achieving harmonisation of how to address ecological recovery in ERA*".

The main advantage of harmonisation is to have a common and easy-to-understand communication tool for the full range of stakeholders, risk assessors and risk managers involved in the ERA. The present opinion will also aid when detailing the problem formulation and the required evidence base for risk assessments that address recovery, thus contributing to **transparency**, as requested by EFSA. Harmonisation also contributes in setting the ERA on a more solid **scientific foundation** and can be a first step to future guidance development (within the respective EFSA areas).

Scope

In line with EFSA's responsibilities regarding the food and feed chain, the scope of this opinion includes the risk assessment of products **for use in, or threatening, plant and animal production**, including their impact on the wider environment, as well as IAS that are harmful to plant health. This opinion, however, **does not cover the intentional introduction of PPPs, GMOs and feed additives outside of agriculture**, aquaculture or forestry.

Those products and/or species in scope are termed hereafter as "potential stressors"[13]. The concept "**potential stressors**" as used herein means "claims, materials, organisms, products, substances and processes" submitted to EFSA for evaluation in the context of market approvals and/or authorisation procedures[18].

Other stressors, such as habitat destruction or environmental contamination and products associated with uses and activities covered by other regulations, such as those on pharmaceuticals, biocide products or the "Registration, Evaluation, Authorisation and Restriction of Chemicals" (REACH), are

[18] For an official list of the relevant legal acts identifying all the "products" subject to EFSA's scientific evaluation see: http://www.efsa.europa.eu/en/apdesk/docs/apdeskhow.pdf

not considered explicitly in this opinion, as they fall outside the remit of EFSA. Furthermore, the scope covers the risk assessments of **single potential stressors** as currently foreseen in the specific regulatory frameworks, while the Scientific Committee recognises that a more holistic assessment considering multiple potential stressors (in and outside of the remit of EFSA, assessed and non-assessed) essential for ensuring the viability and protection of the environment in the long-term. In this sense, this opinion could be also of interest for other organisations such as EEA.

In managed areas, such as agricultural areas (and also, where relevant, aquaculture areas), typically a whole range of protection goals can be set and one has to prioritise what to achieve and what to protect. Regarding such managed areas, and the biodiversity therein, trade-off decisions have to be made as one cannot protect everything, everywhere, at the same time in agriculture and aquaculture. Biodiversity is a common and prominent legal protection goal for all ERAs performed by EFSA and it is noted that agricultural systems are highly disturbed habitats with food production as one main goal[19]. However it is also noted that agricultural areas can form quite large proportions of the area of some Member States and therefore protection of the biodiversity as another common good might strongly depend on the implementation of biodiversity goals in these areas (e.g. farmland birds as one prominent systematic group). EFSA is not responsible for trade-off discussions, as this falls under the domain of risk management.

[19] this goal is heavily impacting on biodiversity through necessary agricultural management practices such as tillage, ploughing, harvesting etc. Greenhouse gas emissions are also stressors related to agricultural practices, but not further discussed herein.

Data and Methodologies

1.3. Data

The types of evidence used in the current opinion are:

- The evidence base used for this mandate stems primarily from expert knowledge gathered by a working group of the EFSA Scientific Committee dedicated to the work of this opinion, consultations with members of the EFSA PPR, GMO, FEEDAP and PLH Panels, from published EFSA Scientific Opinions, Guidance Documents and an external scientific report requested by EFSA on ecological recovery (Kattwinkel et al., 2012) and from data retrieved from the literature.

- Established approaches as described in existing EFSA Guidance Documents and Scientific Opinions from the FEEDAP, GMO, PLH and PPR Panels (i.e. EFSA FEEDAP Panel, 2008; EFSA GMO Panel, 2010a, 2013a; EFSA PLH Panel, 2010a, 2011, 2014; EFSA PPR Panel, 2009, 2013a) and in the Guidance Document on Terrestrial Ecotoxicology (EC/SANCO, 2002).

1.4. Methodologies

The methodology used for this opinion was to aggregate the information from the diverse EFSA areas and external experts, discuss them in a working group of the EFSA Scientific Committee and extract from such discussions principles and proposals for adoption by the EFSA Scientific Committee. EFSA followed its specific standard operating procedure detailing the steps necessary for establishing, updating or closing the working group of the Scientific Committee that prepared this opinion. The standard operating procedure implements the Decision of the Executive Director on the selection of experts of the Scientific Committee, Panels and working groups[20].

Wide consultation prior to the adoption of this opinion took place as follows:

- Prior to the first operational meeting of the working group, the topics of the mandate were openly discussed with experts representing a wide variety of stakeholders. The summaries and outcomes of the discussions from the 19th EFSA Scientific Colloquium on "*Biodiversity as Protection Goal in Environmental Risk Assessment for EU agro-ecosystems*", are published on EFSA's website (EFSA, 2014a).

- Letters of invitation to participate in this activity were sent to other EU risk assessment bodies (ECHA, EEA, EMA, JRC, SCENIHR and SCHER), and to WHO, OECD and US-EPA. All invited risk assessment bodies and the OECD have appointed a contact point or an observer to the working group meetings.

- Public consultations (including international Institutions) were held online between mid-June and mid-September 2015. The report of this public consultation will be published together with this opinion.

[20] See http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

2. TERMINOLOGY RELATED TO ECOLOGICAL RECOVERY

2.1. Environmental stressors and pulse and press disturbances

An environmental stressor is a chemical, physical or biological agent to which organisms are exposed in the environment, and that acts on and causes an adverse response in these organisms. Different combinations of stressors may act simultaneously or sequentially (multiple potential stressors). Environmental stress can be defined as the change in environmental conditions caused by natural stressors (e.g. nutrient depletion, natural toxins, drought, floods, avalanches, grazing, and parasites) and/or anthropogenic environmental stressors (e.g. pollution, agriculture, fishing, deforestation). In this document the term stress is considered synonymous with the frequently used terms disturbance and perturbation. Above certain thresholds of exposure, environmental stressors disrupt the normal operating range (NOR) of the structural and functional properties of individuals, populations, communities or ecosystems. For example, application of a pesticide may greatly reduce the density of carabid beetles in a crop field; thus, the population density of these species is pushed out of its NOR by the disturbance. Note that the NOR of e.g. the population density of a species may be different in different types of ecosystems and in different periods of the year. According to Bender et al. (1984), a specific environmental stressor might result in a stress-period of limited duration (pulse disturbance) or in a prolonged stress-period (press disturbance), dependent on the environmental persistence and/or frequency of occurrence of the environmental stressor of concern. A pulse disturbance may cause a relatively instantaneous but short-term alteration of the densities of certain sensitive species, after which the population system may return to its NOR. Note, however, that short-term localized exposures to a environmental stressor may result in long-term effects if the impacted organisms are not able to repopulate the stressed habitat by reproduction and/or recolonisation. In addition, if short-term exposures to environmental stressors repeatedly occur, and the period between exposure events is shorter that the recovery time of impacted populations, the cumulative impact may resemble that of a press disturbance. A sustained alteration of the density of certain species may shift the system to a new configuration (alternative stable state), particularly if populations of key species are severely impacted (see section 2.3.3).

2.2. Direct and indirect effects

Direct and indirect effects are defined as follows:

- A direct effect on an ecological entity (such as a specified NTO species) refers to an effect that is mediated solely by the interaction between the specified receptor and the environmental stressor, i.e. the receptor is exposed directly to the environmental stressor and as a result the receptor exhibits a response.

- An indirect effect involves effects being transmitted to the specified receptor through an indirect route involving one or more other, intermediary, receptors. A predatory NTO for example could be affected indirectly by a environmental stressor in several ways, including effects of the environmental stressor reducing the abundance of its prey species, its intra-specific or inter-specific competitors, its pathogens or its parasites.

The same ecological receptor may experience both direct and indirect effects from an environmental stressor. Given the myriad multi-trophic interactions that take place between individuals in ecosystems there is potential for some indirect effects to be complex and it may not always be known which intermediary receptors and pathways are involved. Where there are several intermediary receptors, each with its specific life-history and resilience characteristics, it may be difficult to predict the overall effects, including the ecological recovery of impacted entities or processes.

2.3. Ecological recovery and resilience

2.3.1. Definitions of recovery and normal operation range

Cyclic (e.g. diurnal, seasonal) and other fluctuations in environmental conditions are normal phenomena in nature. Ecosystems are self-regulating systems that have evolved mechanisms of self-repair and their biological populations are adapted to resist and recover from fluctuations in environmental conditions, at least when fluctuations are limited to restricted spatial and temporal scales. According to Lahr (2000), strategies that organisms apply to survive unfavourable periods comprise dormancy (escape in time) and dispersal (escape in space). These mechanisms to cope with natural stressors may also apply to disturbances of anthropogenic origin, particularly if they concern pulse disturbances.

When defining ecological recovery, a distinction between *actual* and *potential* recovery can be made (van Straalen et al., 1992; Brock and Budde, 1994). Actual recovery implies the return of the perturbed ecological entity or process (e.g. species composition, population density or ecosystem services) to the NOR observed in the undisturbed state of the ecosystem of concern (e.g. before the environmental stressor event took place), or to a level that is not significantly different from that in control or reference systems. Potential recovery is defined as the point in time at which the environmental stressor diminishes to a level at which it no longer has adverse effects on the ecological entities of interest and after which recovery of impacted populations theoretically can start if there is a ready supply of propagules (e.g. offspring of surviving individuals or recolonisation). Within this context, a distinction should be made between (1) effect period: the time-window that the environmental stressor-related effect on the ecological entity or process is observed, from the moment that the effect of the environmental stressor on the ecological entity or process starts until the time that its effect can no longer be observed, (2) recovery time: the time period from when the environmental stressor has dropped to a level and/or concentration at which it no longer has adverse effects until the moment that the ecological entity or process has returned to its NOR and (3) positive recovery phase: the time period during which an ecological entity or process is returning from the maximum stressed level to a level within its NOR (Figure 1:).

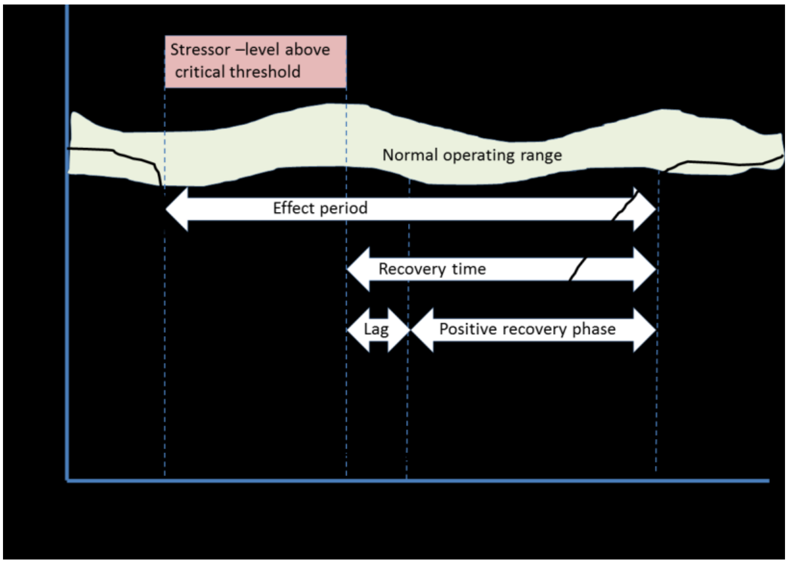


Figure 1: Schematic illustration of the effect period of a stressor-population response and related recovery times. t_1 = start of stressor pressure and start of effect period; t_2 = end of stressor pressure and start of recovery time; t_3 = start of positive recovery phase (lag phase and positive recovery phase sum up the recovery time); t_4 = moment of actual recovery (i.e. end of the effect period and end of the actual recovery time)

2.3.2. *Population resilience and recovery*

In general terms the stability of a population will determine the extent to which it can withstand and recover from a perturbation. Population stability can be defined to have two components. The first is *resistance*, defined as the magnitude of environmental perturbation a population can tolerate without being pushed out of its NOR. The second component of stability of a population is *resilience*. Population resilience is related to the return time to equilibrium following a perturbation (Pimm, 1984). A population with high resilience has a short return time to its NOR after disturbance outside this range. A population with low resilience has a long return time. Population resilience depends on the ecological context and is related to the degree to which induced fluctuations in the population density are buffered by density-dependent feedback mechanisms and competition with other species (Knillmann et al. 2012).

The capacity for population growth affects the rate at which a population may return to normal pre-exposure densities after a stress factor has been removed (Berryman and Kindlmann, 2008; Gotelli, 2008). Species with high potential rates of population growth are better predisposed to recover rapidly from impact than species with low potential rates of population growth. When a population is at equilibrium, its net rate of population growth is by definition zero, however, underlying this zero net rate of growth may be high gross rates of reproduction and immigration, compensated by high gross rates of death (e.g. due to short life-history) and emigration, effectively cancelling each other out. These gross rates are likely to show density dependence, e.g. the relative death rate or probability of emigration increases with density, or the relative birth rate decreases with density), resulting in a stable level, usually called “carrying capacity”. If the gross rates at equilibrium are high, recovery may be quick, and the population may be resilient to stress. If, on the other hand, these underlying gross rates at the equilibrium are small with no or weak density dependence, return to equilibrium will be slow, and the population will not be resilient to stress. Effectively, this reasoning shows that the rate and density dependence of birth and death at the equilibrium determine the capacity for recovery from stress. The level of the equilibrium in itself gives insufficient information to assess potential for rapid recovery. Therefore whether a population is found at high or low densities does not necessarily indicate its ability to recover.

The stability or fitness (in terms of high resistance and/or high resilience) of a population is therefore an intrinsic feature of the population in the current ecosystem, and cannot be inferred by its density. To assess the scope for recovery, insight is needed on the density at which populations find themselves, which will also depend upon the abiotic and biotic properties of the environment that the populations experience, as well as a previous history of perturbation. To predict recovery, it is therefore necessary to understand population fitness.

Population recovery has two components: internal recovery and external recovery. Internal population recovery depends upon surviving individuals in the stressed ecosystem or upon a reservoir of resting propagules (e.g., seeds and ephippia) not affected by the environmental stressor. In contrast, external population recovery depends on the immigration of individuals from neighbouring areas by active or passive dispersal. Both the internal and external rates of recovery of affected populations depend on the life-history characteristics of the affected species. Important life-history properties are the number of generations per year and related life-history strategies (r-K), the presence of relatively insensitive (dormant) life stages and the capacity of organisms to actively migrate from one site to another (Barnthouse, 2004; Liess and von der Ohe 2005; Solomon et al., 2008; Kattwinkel et al., 2012). Voltinism (pertaining to the number of broods or generations per year) may be an important property determining rates of population recovery of invertebrates in particular. Multivoltine organisms have more than two generations per year, bivoltine organisms have two generations per year, univoltine organisms one and semivoltine organisms less than one, i.e. generation time is longer than a year. Note that the number of generations per year of species may vary with temperature and consequently with latitude and the length of the growing season (Niemi et al., 1990). Consequently, when recovery is taken into account in ERA, differences between latitudes may be of importance, particularly when extrapolating data from temperate to colder regions.

Since the spatial distribution of both organisms and environmental stressors in landscapes tends to be patchy or aggregated, external population recovery cannot be evaluated without considering the landscape in which biological populations and environmental stressors occur. To address spatial and temporal scales, modelling is required, and there is a range of conceptual approaches to deal with spatially structured populations. Three major characteristics can be varied: i) the basic unit, which can be abundance-based (sub-population), site-based (locality, grid cell) or individual-based; ii) implicit or explicit spatial representation; iii) discrete or continuous representation of space. To evaluate external recovery in patchily-distributed populations the metapopulation concept may be helpful. A metapopulation is a "population of populations" of the same species where individual populations are connected through immigration and emigration (Levins 1969; Hanski and Gilpin, 1991). Metapopulations are often specified as abundance-based models with discrete, implicit spatial representation (see Figure 2)[21]. To represent species with an aggregated distribution not based on specific landscape patches, models that represent space explicitly and continuously would be preferred, such as individual-based models. In all cases sub-populations within the larger population may serve as sinks or sources (Pulliam, 1988).

Sink populations in landscapes are populations which receive more individuals (immigrants) than they lose (emigrants), whereas for source populations it is the reverse. To protect populations in landscapes, it is of utmost importance to maintain areas with viable source populations that can serve to replenish populations recovering from stresses. In landscapes characterised by intensive use by man (e.g. agricultural landscapes), and in which introduced stressors may locally eliminate populations, refuge areas with viable source populations are essential to facilitate external recovery.

Therefore, if external recovery plays an important role in the re-establishment of a sub-population, mortality due to an anthropogenic stressor in one patch of an agricultural landscape (e.g. stressor exposure in a specific area) may have ecological effects on sub-populations of the same species in non-exposed patches of landscape, at least if these populations are connected through dispersal and therefore part of the same larger population network. The decline in the size of a source population (local dilution due to net emigration) is also referred to as action at a distance (Figure 2:).

Combining the spatial and temporal distributions of environmental stressors and the spatially-varying characteristics of populations illustrates that an understanding of the arrangement and connectivity of habitats, resources and environmental stressors in the landscape (ecological infrastructure) is critical for assessing the effects of environmental stressors and external recovery processes on populations (see e.g. Thomas et al., 1990; Sherratt and Jepson, 1993; Spromberg et al., 1998; Brock et al., 2010b), Topping and Lagisz, 2012). Considering the phenomenon of action at a distance of environmental stressors on populations, it is thus important to make a distinction between the stressor-receiving area and the stressor-impacted area. In the stressor-receiving area the actual exposure to the environmental stressor(s) of concern takes place (e.g. agricultural fields treated with pesticides, including edge-of-field habitats that become exposed above critical thresholds of effects by spray drift, surface run-off and/or leaching). The stressor-impacted area may be larger than the stressor-receiving area due to action at a distance by different mechanisms, i.e. depletion of individuals due to net movement to the stressor-impacted areas, without a reverse flow from the impacted area, or at least a reduced flow from this area (Figure 2:).

[21] Given the difficulty to characterize most microbial species because of the inability to distinguish microorganisms at high resolution (species and strains) and to track them in situ (Pace, 1997), the concept of metapopulation for microorganisms can only be considered at low resolution (genus, family) or functional level.

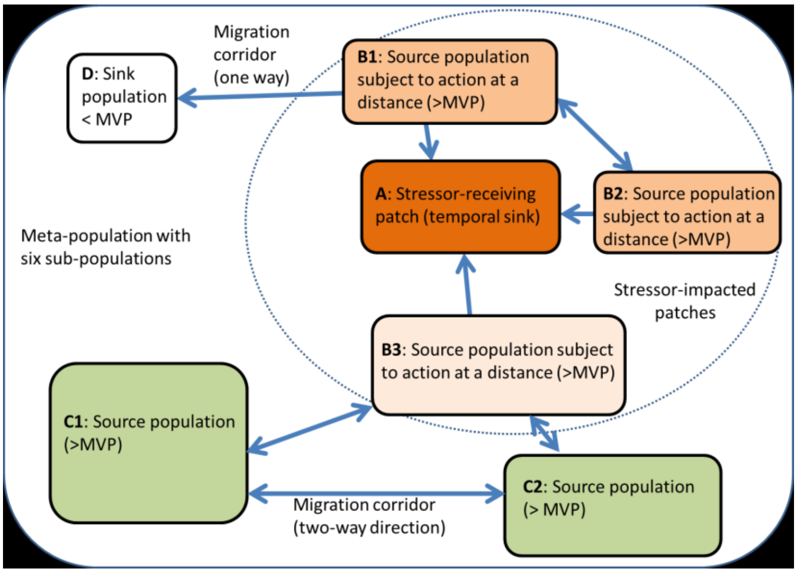
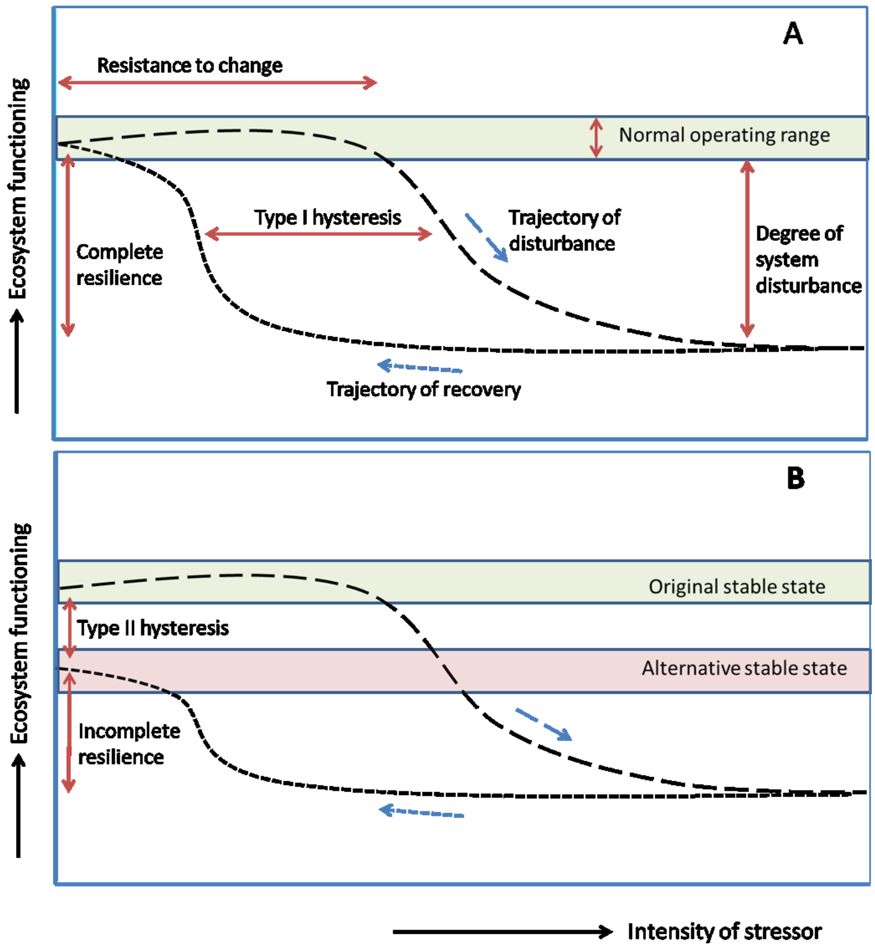


Figure 2: Schematic illustration of a metapopulation with six sub-populations to exemplify the concept of action at a distance. A= Sub-population stressed by an assessed product (e.g. pesticide); B1-3 = Sub-populations not exposed to the assessed product but subject to dilution of abundance due to net migration of individuals to the stressor-receiving patch; Sub-population B3 is less impacted than B1 and B2 due to connections with C1 and C2; C1-2 = Sub-populations that are not exposed and hardly subject to action at a distance; D = Sub-population characterised by a size that is smaller than the minimum viable population

2.3.3. *Ecosystem resilience and recovery*

Multiple equilibria (i.e. multiple possible stable states) are a common observation in ecological systems (Holling, 1973; Scheffer, 1998; Scheffer et al., 2001; Scheffer and Carpenter, 2003). Once a system makes a transition to a new stable state, e.g. a shift from a macrophyte dominated system to an algae dominated ecosystem as a result of pesticide use (see e.g. Stansfield et al., 1989), it is often very difficult to reverse this, or it may not be possible at all (Prigogine, 1997). Ecosystem resilience has been defined in various ways, but usually refers either to the amount of disturbance that can be absorbed by an ecosystem before the system redefines its structure (i.e. deviates from its NOR), or the time it takes for the ecosystem to return to a stable state within the NOR following the disturbance (Gunderson, 2000). When considering recovery it should be borne in mind that the ecosystem might not necessarily return to the same stable state that it exhibited before the disturbance. The extinction of key species for example may alter the trajectory of ecological recovery and functioning of the ecosystem in such a way that an alternative equilibrium (steady state or stability domain) is reached.

A concept relevant to ecological resilience is “hysteresis”. If the impact of the environmental stressor exceeds the ecological resistance, the trajectory of ecological recovery after removal of the environmental stressor may not be the same as the trajectory of ecological deterioration, the difference being termed hysteresis. Elliot et al. (2007) make a distinction in two types of hysteresis, viz. the lag in recovery trajectory (type I hysteresis) and the difference between the NOR of the original ecosystem and that of the alternative stable state of the system when there is not complete ecological recovery (type II hysteresis). Within this context a distinction can be made between complete resilience, resulting in a complete ecological recovery, and incomplete resilience, a return to an alternative stable state with type II hysteresis being the difference between the original and new stable state (Figure 3:).

823 

824 **Figure 3:** Schematic illustration of changes to the state of a system with increasing disturbance
825 caused by one or multiple environmental stressors. In the illustrations both the trajectories of
826 disturbance and recovery are presented, which often do not follow the same route. In panel A the state
827 of the stressed system returns to its original stable state as a result of recovery. In panel B, the changes
828 caused by the environmental stressor(s) are not reversible and the trajectory of recovery results in
829 another stable state of the system (revised from Elliot et al., 2007)

830 Where disturbances lead to shifting stability domains, management options fall into one of three
831 general classes of response (Gunderson, 2000). The first is to do nothing and wait to see if the system
832 will return to some acceptable state. The second option is to actively manage the system and try to
833 return the system to a desirable stability domain (which may be the aim in an ecological risk
834 assessment). The third option is to admit that the system is irreversibly changed, and hence the only
835 strategy is to adapt to the new, altered system.

836

3. A CONCEPTUAL FRAMEWORK TO ASSESS ECOLOGICAL RECOVERY FROM EFFECTS OF POTENTIAL STRESSORS IN AGRICULTURE

If the problem formulation phase of the ERA reveals that recovery of NTOs is an issue for a potential stressor and has to be addressed, a conceptual framework can guide the process to increase the realism in the assessment of ecological recovery of populations of vulnerable NTOs in agricultural landscapes. The conceptual framework of this approach is presented in Figure 4.

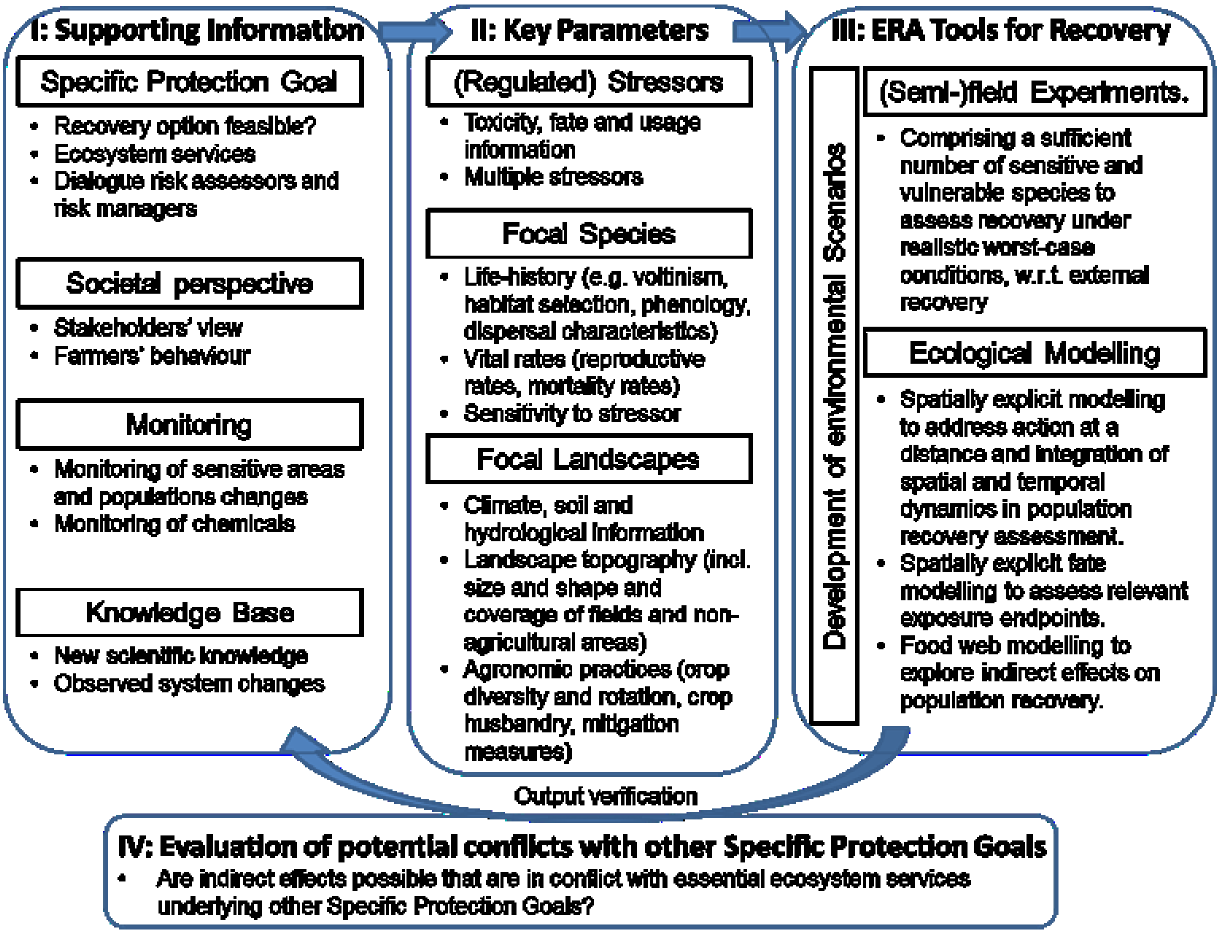


Figure 4: Conceptual framework for the assessment of ecological recovery in prospective ERAs for potential stressors

First of all, this approach requires well defined SPGs. Secondly, to perform an ERA that includes the recovery option, the decision schemes and the ERA tools should have a sound scientific basis. This requires the following information:

- Environmental exposures to potential stressors in relevant environmental compartments as affected by physical, chemical and/or biological properties of these stressors, agricultural land-use, climate, soil type and hydrological conditions (a general requirement for ERA, irrespective of the recovery option);

- Sensitivities of focal NTOs to potential stressors as derived under standard laboratory conditions (a general requirement for ERA, irrespective of the recovery option);

- Climate zone specific data on demographic and mobility traits of (focal) species dwelling in agricultural landscapes (to select focal taxa and communities to address ecological recovery in ERA);

- Geographic Information System (GIS) data to analyse the relevant properties of (focal) agricultural landscapes of concern such as the spatial configuration of fields, crops and off-field refuge areas (to select focal agricultural landscapes to address ecological recovery in ERA);

- Population- and community-level responses of exposure to potential stressors as derived from (semi-)field experiments (to study the rate of recovery of affected endpoints, to evaluate possible indirect effects on ecological recovery and to inform mechanistic effect models to address recovery in ERA);

- Appropriate modelling approaches, in line with the principles of good modelling practice, for spatial-temporal extrapolation of experimental data;

- Evaluation of potential conflicts with essential ecosystem services underlying other SPGs;

- Field monitoring data on (a) exposures of potential stressors to identify unexpected exposure routes and landscape specific exposure to multiple potential stressors and (b) population dynamics of NTOs in agricultural landscapes;

- A retrospective reality check of prospective ERAs is desirable. Prospective ERAs will not be able to always ensure an adequate protection of NTOs since the spatial and temporal scale of their use (e.g. PPPs, GMOs and feed additives) in Europe usually is not known in advance while also unexpected effects may become apparent later and stakeholders' views on the acceptability of effects may change in time. A retrospective reality check uses multiple lines of evidence including novel scientific knowledge published in the literature and information on changes in the ecological and chemical status of ecosystems and landscapes obtained from monitoring programmes.

Ideally the above information should be organised in databases. These databases would be important to select focal communities, species, processes and landscapes that may be necessary to inform the design of (semi-)field experiments and for the construction of environmental scenarios to use in conjunction with mechanistic effect models that aim to address the ecological recovery option.

The overall structure of the conceptual framework (Figure 4) is therefore that the SPGs define the overall scope of the recovery assessment and provide the spatial, temporal and biological reference level to be considered (e.g. functional groups in specific systems for microbes or regional populations for most invertebrates). Within the bounds specified by the SPG the recovery assessment framework comprises of the tools identified for usage in ERA (i.e., experiments and models) which are used to implement an assessment within an environmental scenario. This scenario is in turn fed by input parameters defining focal landscapes, environmental factors, biological entities and potential stressor properties. The input parameters are informed by supporting information from scientific knowledge, social information (such as farmer behaviour) and ongoing monitoring. Results of the recovery assessment should be verified with reference to the supporting information as this will change with time. This means that there should be a formalised iterative link between ERA and monitoring to ensure that ERA methods are up-to-date, but also to evaluate and improve the modelling tools used for ERA.

The feedback loop from assessment to monitoring is a critical component of this framework, and will need to be implemented. Both the state of knowledge and the state of the environment are in flux, and as more complex assessment procedures are developed, these dynamic aspects need to be formally considered, as does a procedure for iterative testing and improvement of the tools used to support the recovery framework.

Guidance on how to derive specific protection goals for potential stressors is given in EFSA Scientific Committee (2016a), while an overview of how the recovery option applies for the different potential stressors is provided in Appendix A. The following describes in detail the main building blocks of the concepual framework presented in Figure 4:

- ***Potential stressors***: In section 4 information is provided on the patterns of use of assessed products, and the presence of IAS, in space an time. In addition this section describes how ecological recovery is taken into account in EU legislation underlying different potential stressors and discusses the current knowledge base on ecological recovery from exposure to different potential stressors.
- ***Focal species***: In section 5, species traits affecting internal and external ecological recovery are discussed. This information is important for selecting the focal taxa on which ERA should focus when addressing the ecological recovery option.
- ***Focal landscapes***: In section 6, the specific features of landscapes that affect ecological recovery are discussed for both populations of terrestrial and aquatic NTOs. This information is particularly important when selecting focal landscapes for developing environmenal scenarios that are used to assess external recovery.
- ***(Semi-)field experiments and monitoring***: In section 7.1, the pros and cons of experimental approaches and landscape scale monitoring studies to address ecological recovery are discussed.
- ***System modelling***: In section 7.2, the pros and cons of modelling approaches to address ecological recovery are discussed.

In section 8, the conceptual framework presented above in Figure 4 is revisited and used to illustrate the importance of developing an integrative approach for addressing recovery for potential stressors. In addition, in section 8, the relationship between recovery of structural and functional endpoints is described and general guidance is provided on the selection of focal taxa and/or processes and the selection of the appropriate spatial scales to address exposure, effects and ecological recovery.

4. PROPERTIES OF POTENTIAL STRESSORS AND HOW ECOLOGICAL RECOVERY IS ADDRESSED

4.1. Plant protection products (PPPs)

Pesticides are chemical or biological (e.g. bacterial) substances, or a mixture of substances, intended for preventing, destroying, or controlling any pest. The most common agricultural use of pesticides is as PPPs, which in general protect crops from damaging influences of pests such as weeds, plant diseases or insects. Since many non-pest species are taxonomically related to pest organisms, and a relatively large part of the PPPs applied reaches a destination other than their target pest species, the use of PPPs also results in exposure and effects on NTOs. Information on trends in the use of PPPs in Europe and on exposure and effect assessment in ERA is provided in Appendix B, section 1.

4.1.1. Patterns of use in space and time

As noted above, the spatial pattern of PPP application and exposure will interact with the stressed population to affect recovery time, depending upon the spatial dynamics of the potential stressor and of the individuals in the population. There are three important application factors which need to be considered as contributing to the impacts of PPPs and subsequent recovery. These are (1) the timing of applications relative to life-history stage, (2) the number and frequency of applications of the same PPP and (3) the cumulative risks of exposure to multiple PPPs.

Timing of application: Since exposure is a function of the ecology and behaviour of the organism, and internal toxicokinetics, the life-stage or physiological condition that the organism is in when exposed to the PPP can be very important. For example, in a damselfly both spatial and temporal co-occurrence of the pesticide and insect, as well as differential sensitivity of different life-stages were found to be important in determining pesticide impacts (Takamura, 1996). Clearly organisms with a sessile stage that occurs in an unexposed micro-habitat will not be affected by pesticide application (e.g. beetle eggs in soil will not be exposed to a foliar spray). Hibernating life stages (e.g. tubers and seeds of aquatic macrophytes) may be less sensitive to PPPs exposure in winter time when the organisms are metabolically less active.

Number and frequency of applications of the same PPP: Effects on NTOs of repeated applications of the same PPP in a crop are taken into account in ERA, but the time-frame considered usually is limited to one growth season. Population-level effects of a few applications of the same PPP may be subtle and remain unnoticed, but a gradual increase in impact from year to year applications may occur. This suggests that also a long-term evaluation of ecological recovery may be required (EFSA PPR Panel, 2015; Liess et al. 2013).

Cumulative risks to different PPPs: Currently in prospective ERA the exposure and effect assessment is predominantly conducted one PPP at a time. In the current European registration procedure, the number of applications of the same pesticide in the crop is taken into account but not the cumulative stress of the different pesticides used in the crop protection programme or in agricultural landscapes characterised by different crops. An important question is whether the chemical-by-chemical approach in the current prospective ERA for PPPs is sufficient to also prevent cumulative risks from exposure to different PPPs, as well as to predict ecological recovery at realistic spatial and temporal scales. Chemical monitoring data and model calculations, however, seem to indicate that in individual edge-of-field surface waters usually a limited number of pesticides (seldom exceeding 2 to 3) dominate the mixture in terms of toxic units (see e.g. Belden et al., 2007; Liess and von der Ohe 2005; Schäfer et al., 2007; Verro et al., 2009). Consequently, when addressing cumulative stress of pesticides in ERA, it seems cost-effective to focus on those pesticides that dominate the exposure in terms of toxic units (> 90%). Information on the distribution of crops in agricultural landscapes and frequently occurring pesticide combinations may be derived from existing databases (e.g. databases under the EU subsidies scheme and databases from EU pesticide usage as collected within the frame of the Sustainable Use Directive). This information may be important input for population models to evaluate effect periods and recovery times following pesticide stress in a realistic agricultural landscape context. For example, Focks et al. (2014b) demonstrated that simulated exposure in edge-of-field surface water to a combination of pesticides typical for tuber and orchard crops may lead to increased mortality probabilities and effect sizes for a vulnerable aquatic invertebrate but would not lead to longer recovery times than when exposed to the individual compounds.

4.1.2. Ecological recovery in European guidance documents

An overview of SPGs for PPPs and the recovery option is presented in Appendix A. For vertebrates (birds, mammals, fish, amphibians) the recovery option is void since individual mortality and effects on reproduction are not allowed. For other groups of organisms recovery is assessed through semi-field (e.g. mesocosms) or field studies, but population models are not excluded.

Terrestrial organisms: For soil micro-organisms the Guidance Document on Terrestrial Ecotoxicology (EC/SANCO, 2002) specifies that change in activity should be no greater than 25% after 100 days. For terrestrial non-target arthropods (NTAs) current practice is based on Escort 2 (implemented in EC/SANCO, 2002), where in-field recovery shown within one season is considered acceptable. However, new information suggests that whilst this approach will probably be relevant for non-mobile in-field arthropods, the prediction of the effect in space and time for populations of mobile arthropods requires a landscape-scale assessment (EFSA PPR Panel, 2015); here recovery is implicitly part of this landscape-level impact assessment. According to EFSA PPR Panel (2012), effects on colony size of bees should never exceed 7%, bee forager mortality can be increased for a certain period (e.g. a factor of 3 over 2 days). For in-soil macro-organisms, currently there is no guidance on how to assess ecological recovery, but the PPR panel is in the process of drafting a Scientific Opinion on the ERA for soil-organisms exposed to PPPs.

Aquatic organisms: For aquatic organisms, guidance on ecological recovery is available in the EFSA Aquatic Guidance Document (EFSA PPR Panel, 2013a) which gives several criteria for higher-tier micro-/mesocosm studies to derive Regulatory Acceptable Concentrations on basis of the recovery option, viz.;

- The exposure regime studied in the micro-/mesocosm test system should be realistic to worst case relative to the exposure profile predicted for the relevant edge-of-field aquatic ecosystem (threshold and recovery option);
- At least eight different populations of the potentially sensitive taxonomic group (informed by lower tiers and read across) should be present in the test systems with an appropriate Minimum Detectable Difference (MDD) to demonstrate possible treatment-related effects on population abundance (threshold and recovery option);
- A few representatives of the potentially sensitive populations mentioned above should also be vulnerable with respect to recovery (recovery option);
- The accepted total effect period for the most sensitive population in aquatic micro-/mesocosms is not longer than eight weeks (as a result of consultation with risk managers) (recovery option);
- The duration of the population-level effects should be statistically underpinned by considering appropriate statistical techniques and information on MDDs (recovery option).

4.1.3. Studies and data on ecological recovery from exposure to plant protection products

Terrestrial organisms: a recent EFSA-commissioned external review "Ecological recovery of populations of vulnerable species during the risk assessment of pesticides" (Kattwinkel et al., 2012) investigated ecological recovery following PPP use among vertebrates and invertebrates. In total, 55 different pesticides were investigated in 55 studies on terrestrial invertebrates, although many of them are no longer authorized in Europe (e.g. pentachlorophenol and 2,4,5-T). Thirty three (60%) of the studies were published since 2000 and 12 (22%) were published in the last two years before the review (i.e. before 2012). The designs included laboratory studies (12 on microbes), 2 semi-field and 37 field studies. The size of the investigated areas in the field varied considerably: subplots (< 10 m²) were used in 10 studies, plots (10 m² - 1 ha) in 11 studies, sites (1-10 ha) in seven studies, landscape level (≥ 10 ha) in five studies, and the area was not reported in four studies. The studies were conducted in a wide range of countries globally but it is notable that in countries with a long tradition in pesticide studies (e.g. France, Germany and The Netherlands) almost no field relevant terrestrial field study was found published in the open literature. Overall, there were too few comparable data from the included studies for a formal quantitative analysis. No clear pattern was evident between a taxon's generation time and the time for recovery. However this probably reflects the limitations of the data rather than lack of a relationship.

Whilst the aim of the review was to evaluate the recovery process of populations and communities after pesticide exposure in a systematic way with regard to the investigated taxa groups, substance classes, modes of action and additional environmental conditions, it was not possible to derive general, reliable recovery times out of the available literature.

A number of studies provide insights into factors that influence the recovery of terrestrial invertebrate populations following adverse effects of pesticide use. Among the carabid ground beetles, for example, life-history characteristics including the number of generations per year, overwintering site, timing of reproduction and dispersal in relation to the timing of pesticide applications, and overwintering strategy (e.g. whether as an adult or larva) are known to influence the persistence of pesticide effects and the likelihood of recovery (Vickerman, 1992). In the large-scale Boxworth project (Greig-Smith et al., 1992), Burn (1992) classified predatory arthropods into groups according to their dispersal ability (poor, moderate, high), principal overwintering stage (adult or larva) and overwintering habitat (mid-field or non-crop habitat). The most vulnerable species to direct and indirect effects of insecticides, and least able to recover in abundance within the same season, were those with poor dispersal ability which overwintered within arable fields as adults in the soil surface. Conversely, the least affected and fastest-recovering species were those that had moderate or high dispersal ability and either over-wintered as adults in non-crop habitats or within fields as subterranean larvae. Hedgerows in crop edges are potentially important sources of recovery of predatory arthropods (Burn, 1992; Vickerman, 1992) and other soil invertebrates such as Collembola (Alvarez et al., 1997; Frampton, 2002; Frampton et al., 2007). However, it should be noted that hedgerows (as with other source habitats) do not necessarily act as a continuous source of recolonisation since the timing of dispersal from hedgerows is governed by a species' life-history. For example, effects of an insecticide on the predatory carabid beetle *Agonum dorsale* were found to depend on the exact time of the insecticide application in relation to the beetle's time of dispersal from hedgerows and both these events varied from year to year (Burn, 1992). Year-to-year variation in abundance patterns can make interpretation of recovery difficult, e.g. for linyphiid spiders in wheat fields in the Boxworth project, in most years abundance increased through the summer (April to August), but in some years abundance was roughly similar across months whilst in one year a clear decline occurred from April to August (i.e. opposite to the usual pattern) (Vickerman, 1992). Heterogeneity of species' spatial distribution is another factor that can complicate the assessment of recovery following pesticide effects. For Collembola and other soil invertebrates individual species may be present in one field but not the next adjacent one (Frampton, 1999), or may be restricted to only part of a field (Frampton, 2001a, b), or may exhibit distributions that do not appear to correspond to field and field boundary layouts.

Aquatic organisms: Gergs et al. (2015) reviewed the scientific literature on ecological recovery potential of freshwater organisms and demonstrated that pesticide applications might have characteristics of both pulse and press disturbances. Particularly, frequent and long-term use of pesticides may result in press disturbances, and associated long-term community shifts, as was demonstrated for ditches in the fruit orchard region Altes Land in Germany (Heckman, 1981; Schäfers et al., 2006) and in streams in the agricultural regions of Braunschweig, Germany (Liess and von der

Ohe, 2005) and Brittany, France (Schäfer et al., 2007). In these cases, many aquatic species were presumably tolerant or became resistant, whereas others were eliminated from the habitat over a multi-year period of pesticide use. However, pesticide exposure in edge-of-field surface waters of agricultural landscapes often coincides with other types of environmental stressors (e.g. habitat destruction due to “clearing” of macrophytes; eutrophication; hydro-dynamic stress), thus, it may be difficult to distinguish the impact of pesticide exposure and other confounding environmental stressors in field monitoring programmes. To study the impact of multi-stress by pesticide while avoiding confounding factors controlled mesocosm experiments may be used that focus on realistic application rates of the total package of pesticides used in crops (e.g. van Wijngaarden et al., 2004; Arts et al., 2006; Auber et al., 2011). These studies demonstrated that reducing exposure concentration by mitigation measures may shift a press disturbance into a pulse disturbance, allowing ecological recovery to take place.

4.1.4. Impact on food-web interactions and ecological recovery

Plant protection products can cause direct toxic effects on NTOs when applied in agro-ecosystems and spilling over to edge-of-field surface waters. These direct toxic effects may initiate a shift in food-web interactions within communities that may lead to responses in more tolerant species. While the direct effects of pesticides usually reduce population abundance of sensitive NTOs, such indirect effects may increase or decrease abundances of more tolerant species. Indeed, pesticide-induced changes in, for example, competition and predation/grazing rate can alter abundances of populations not suffering direct toxic effects, in this way changing community structure and functioning (trophic cascades). For example, application of the insecticide chlorpyrifos in experimental freshwater ecosystems simulating the community of drainage ditches caused a decline in arthropod populations due to direct toxic effects, a decrease in abundance of Turbellaria (indirect effect due to a decline in prey populations), an increase in abundance of some Rotifera (indirect effect due to release of competition), an increase in biomass of periphytic algae (indirect effect due to release from grazing) and a decrease in macrophyte biomass (indirect effect due to shading by periphyton) (Brock et al., 1992).

Indirect effects and shifts in food-web interactions may enhance, mask or spuriously indicate direct effects caused by pesticide exposure, including pesticide mixtures (see e.g. Fleeger et al., 2003; Halstead et al., 2014). Declines in bird, butterfly and soil invertebrate populations in agro-ecosystems correlate well with agricultural intensification, including increased pesticide use, indicating that indirect effects of pesticides in agricultural landscapes cannot be ignored (Köhler and Triebskorn, 2013; Gibbons et al., 2014; Hallmann et al., 2014; and literature cited therein). Studies have shown that in experimental aquatic ecosystems with similar exposure regimes, no observed effect concentration (NOEC) values for the most sensitive endpoints were quite similar, irrespective of whether the studies were conducted with different nutrient contents or in different seasons. However, when exposed to similar, higher, concentrations , ecological recovery times were sensitive to nutrient status and season (Roessink et al., 2005; van Wijngaarden et al., 2006). Furthermore, indirect effects may (i) persist longer and (ii) be delayed in comparison to direct effects from which they originate (e.g. Brock et al., 2004; Butler et al., 2010). These studies illustrate that the rate of recovery is clearly context-dependent.

Indirect pesticide effects may have implications for ecological recovery of pesticide-impacted populations. Experimental studies in aquatic microcosms have demonstrated that manipulated intraspecific (Liess and Foit, 2010) and interspecific competition (Foit et al., 2012; Knillmann et al., 2012) and predation (Beketov and Liess, 2006) affected population recovery of sensitive crustaceans after pesticide exposure. Van Wijngaarden et al. (2005) showed that insecticide application in plankton-dominated microcosms resulted in more pronounced indirect effects (algal blooms) and in longer recovery times of sensitive cladocerans under warm “Mediterranean” conditions than under cool “temperate” conditions, probably because of altered food-web interactions between cladocerans, rotifers (competitor) and algae (food). In a river contaminated by pesticides, Dorigo et al. (2010) showed that algae and microbes successfully colonised artificial substrates in pesticide-polluted stretches and when moved to clean stretches, these pesticide-tolerant periphyton communities resisted invasion of non-tolerant algae. This phenomenon was reported to be more pronounced in mature biofilms than in pioneer biofilm communities. Furthermore, pesticide-stressed invertebrates and vertebrates have been reported to be more prone to infectious diseases and parasites (Köhler and Triebskorn, 2013) and, if this occurs, it would likely hamper their ecological recovery.

The rate of recovery of ecological entities or processes is therefore context-dependent. It is influenced by (among other things) the degree to which the physicochemical environment and ecologically important food-web interactions are directly or indirectly altered by pesticide exposure, either alone or in combination with other (potential) stressors. The implications of this are discussed in greater detail below.

In conducting outdoor (semi-)field experiments with pesticides (and other stressors) it is not possible to fully control *a priori* the test community and food-web interactions because of unpredictable environmental conditions not controlled by the experimenter (e.g. weather). The natural decline in exposure to a potential stressor may not always lead to an immediate start of ecological recovery, e.g. if more persistent indirect effects occur. So far, however, pronounced indirect effects and their possible impacts on ecological recovery of sensitive populations in experimental ecosystems stressed with pesticides have predominantly been observed in ecologically relatively simple microcosm test systems (Brock et al., 1992; van Wijngaarden et al., 2005; Foit et al., 2012; Knillmann et al., 2012). Brock (2013) argues that in ecologically more complex and diverse field communities, indirect effects due to exposure to a similar level of pesticide may be more efficiently dampened. In these structurally more complex communities the higher number of taxa may provide a larger functional redundancy in that less sensitive organisms (partly) take over the ecological role of the affected species. In relatively simple ecological systems indirect effects are more pronounced due to lack of functional redundancy. This became apparent in studies comparing responses of a similar exposure regime of the same insecticide (chlorpyrifos) in experimental test systems of different ecological complexity (see e.g. the following studies in order of increasing ecological complexity of test system used: Daam and van den Brink (2007), Van Wijngaarden et al. (2005), Brock et al. (1992), Zafar et al. (2011), van den Brink et al. (1996).

Most studies that have linked indirect effects with increased recovery times have been in experimental aquatic systems. For terrestrial systems most of the published links between indirect effects and recovery times are for bird populations (see e.g. Bright et al., 2008). For example, sawfly larvae (a key food item for some insectivorous birds) are susceptible to some insecticides and modelling suggested sawfly recovery from insecticide effects could take seven years. In fact, sawflies (along with other herbivorous insects important in the diet of birds) are also themselves sensitive to availability of host food plants which can be affected by herbicides. So, indirect effects could occur at different trophic levels (plant-insect and insect-bird) leading to delayed recovery at one trophic level affecting recovery at the next one up. However, proving whether lack of recovery is due to indirect and/or direct effects is challenging (Boatman et al., 2004).

Community ecology theory and modelling may help to predict the cascade of indirect and direct effects of potential stressors on biodiversity and ecosystem properties (see e.g. Relyea and Hoverman, 2006; Rohr et al., 2006), including the context-dependency of ecological recovery on impacted food-web interactions. Mechanistic effect modelling, for example using food-web models (e.g. Baird et al., 2001; Traas et al., 2004; De Laender et al., 2011) and population models (see e.g. Baveco et al., 2014; Gabsi et al., 2014; Galic et al., 2014; Kattwinkel and Liess, 2014) may be appropriate tools to evaluate the context-dependency of ecological recovery. Mechanistic effect modelling may not only help to better define the experimental setup of (semi-)field experiments for assessing the ecological recovery of impacted populations but, more importantly, it can be used for spatial-temporal extrapolation of the concentration-response relationships and recovery rates observed in these test systems. An important pre-requisite for the use of mechanistic models in prospective RAs is the selection of appropriate environmental scenarios. These scenarios should represent, as far as possible, the complexity of agro-ecosystems that are stressed by realistic application suites of pesticides and other assessed products.

4.2. Genetically modified organisms (GMOs)

According to Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (EC, 2001) and Directive 2009/41/EC on the contained use of genetically modified (GM) micro-organisms (EC, 2009a), GMOs mean “organisms, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.” To date, the most well-known application of GMO technology is related to food/feed and fiber crops. GMO technology is also used for animals (e.g. fish, insects) and for biological and medical research, production of pharmaceutical drugs, vaccines, and experimental medicine.

Single and stacked herbicide tolerant and insect resistant genetically modified plants (GMPs) are well-known applications of GM technology in crop plants. However, also other properties of crop plants have been modified with GM technology. As a successful example, drought tolerant GM maize can be mentioned. Other important traits under development and presently tested in field trials are GM crops which are specially tailored for improved nutritional values such as improved amino acid composition, micronutrients and fatty acids. Examples of GM crops with improved properties for industrial processing are potatoes with modified starch, with low acrylamide potential for chips and reduced Black Spot Bruise, and apples with non-browning qualities when sliced or bruised. The few examples cited show that such GMPs may play a more important role in the near future.

Information on GMP technology, trends in the use of GMOs in Europe and on exposure and effect assessment in ERA is provided in Appendix B, section 2.

4.2.1. Patterns of use in space and time

The period of exposure to potential GMP stressors depends upon the GMP crop type, the growing period of the crop (i.e. the time from sowing to harvest), physiological characteristics of the GMP (e.g. which parts of the plant express the potential stressor), and the ecology, behaviour and life-stage of the exposed organisms. Since there is very little practical experience with commercial cultivation of GM crops in the EU, there is no literature available addressing the pattern and use of GMPs in space and time in the EU as a whole. The only EU country where farmers grow Bt maize on a considerable percentage of the total maize area is Spain, which serves as an example for the EU in this context. In Bt maize, protection against insect pests is achieved by expressing insecticidal Cry toxins of the soil bacterium *Bacillus thuringiensis* (Bt) by means of GM technology. While the overall area of Bt maize remains insignificant in the EU, Bt maize covers approximately 30% - 40% of the total maize acreage in Spain (information based on Gomez-Barbero et al., 2008). The total maize area in Spain has varied between years and regions (e.g. it was 353 600 ha in 1998 and 512 500 ha in 2006), but there is no indication that the distribution pattern and acreage of maize have changed with the adoption of Bt maize. Also, there is no indication that the cultivation techniques have changed with Bt compared to conventional maize, except that fewer insecticides are used by Bt maize farmers (Gomez-Barbero et al., 2008). In Spain, adoption by farmers, and hence the spatial distribution of Bt maize, is strongly influenced by economic factors (Gomez-Barbero et al., 2008), by insect pest pressure and by the efficacy of Bt maize to prevent damage compared to other protection methods.

4.2.2. Ecological recovery in European legislation

Effects of GMPs on humans, animals and the environment must be assessed case-by-case according to Directive 2001/18/EC. Questions about potential effects of GMPs on NTOs including long-term effects - and as such on recovery in space and time - must be elucidated prior to licensing GMPs in the EU. Recovery is not explicitly taken into account in the present EU GMO legislation (EC, 2001, 2002). However, since monitoring of “potential long-term effects” of GMOs is mandatory (EC, 2001), the need to assess recovery is implied. Routine monitoring is considered necessary as a precaution and to detect unexpected and unwanted effects. All applications for marketing GMOs, or releasing them into the environment must include a monitoring plan. This plan is part of the authorisation decision. Consent holders must present annual post-market monitoring reports to the competent authority (EC, 2001, 2009a; EFSA GMO Panel, 2011), and EFSA peer reviews the reports (EFSA GMO Panel, 2013b). Monitoring should be able to uncover environmental effects which could include long-term population and community effects on target and NTOs. Should monitoring indicate adverse long-term effects, regulatory authorities would have opportunities to request mitigation measures to allow recovery from effects.

Recovery of NTOs is addressed indirectly by the mandatory management of resistance of target organisms. Target resistance prevention and management plans are an integral part of the monitoring plan submitted to the competent authority. One element of the present monitoring plan of commercial Bt maize growing in the EU is the obligatory establishment of non-Bt maize refuges by each grower. Maize fields should have 20% of the surface planted with non-Bt maize (refuge) that serves the target pest insects to maintain Bt sensitive sub-populations that will mate randomly with the few remaining resistant individuals from Bt fields. It is recommended that target populations in refuges should not be managed with insecticides to keep the Bt sensitive population as abundant as possible (EuropaBio, 2012). With this strategy, refuges also maintain non-target populations and community structures and would contribute to the recovery of potential ecological effects.

4.2.3. Impact on food-web interactions and ecological recovery

According to Directive 2001/18/EC and Commission Decision 2002/623/EC[22] on the deliberate release of GMOs (EC, 2001, 2002), the objective of an ERA is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment. Adverse effects can occur directly or indirectly through mechanisms which may include, among others, interactions with other organisms (for definitions see section 2.2). The general principles of assessing adverse effects as stipulated in the Directive and Commission Decision apply across all GMOs, including microorganisms, plants and animals.

Typical indirect adverse effects of GMPs may occur due to food-web interactions. Potentially, organisms of higher trophic levels (e.g. birds, insect predators and parasitoids) can suffer from host and prey shortage if herbivorous arthropods are killed, or sub-lethally affected by intoxicated or otherwise affected food sources with low nutritional quality (e.g. Romeis et al., 2004; Naranjo, 2009). The reduction of pests is the obvious goal of any crop protection method and often induces food shortage, mainly to specialist organisms (e.g. host-specific parasitoids) (Romeis et al., 2006). As an example, meta-analyses from field studies have shown that populations of the specialist parasitoid of the European corn borer, *Macrocentrus grandii*, is strongly reduced in *Bt* maize (and in insecticide treated maize) (Naranjo, 2009). Non-target herbivorous arthropods that exploit the crop may be partially sensitive to the GMP and can sub-lethally be affected which in turn may translate into altered nutritional quality for higher trophic level organisms. A case that demonstrates such food-web interactions is the adverse impact of *Bt* toxin-affected lepidopteran larvae on fitness of the Green lacewing, an important predator in maize (Romeis et al., 2014).

Long-term effects and ecological recovery from effects of Bt crops on NTAs are commonly assessed in multi-year and multi-site field studies comparing abundance and community structures inside of Bt and non-Bt crops either treated or not with insecticides currently used in conventional insect control. Significant impacts of Bt crops on NTAs have been attributed by most studies to reductions of the target pest populations causing food shortages, and to partially-sensitive non-target herbivores exposed to the Bt toxin being of a lower nutritional quality (e.g. Dively, 2005; Head et al., 2005; Torres and Ruberson, 2005; Naranjo, 2009). Slightly reduced natural enemy abundance or slight changes in community structure were not reported to have caused any negative impact on biological control functions (Naranjo, 2005; Wolfenbarger et al., 2008; Comas et al., 2014).

[22] Commission decision establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC(2002/623/EC), O.J. L 200/22, 30.7.2002.

4.3. Feed additives

According to Commission Regulation (EC) No 1831/2003[9], feed additives are substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions: satisfy the nutritional needs of animals with essential nutrients such as amino acids, trace elements and vitamins, favourably affect the characteristics of feed or animal products, favourably affect the colour of ornamental fish and birds, favourably affect animal production, performance or welfare and, have a coccidiostat or histomonostatic effect (Article 5(3)). Information on the types of feed additives, trends in their use in Europe and on exposure and effect assessment in ERA is provided in Appendix B, section 3.

4.3.1. Patterns of use in space and time

Given the usage and physical properties of some feed additives, their concentration in the various compartments of the environment, where the manure is disposed may be considerable. Indeed, they are used over extended periods of time, for large numbers of animals (terrestrial and aquatic organisms) and many additives, such as some trace elements, are poorly absorbed and therefore largely excreted in the environment. Fertilisation by manure is an important factor for agricultural systems and also for the adjacent natural aquatic and terrestrial ecosystems. For agricultural systems, spatial and temporal exposures to feed additives vary with environmental storage capacity (which is influenced by climatic variations across the EU and national regulations), the quantity of manure applied to land (which depends on the animal density and maximum threshold allowed for manure/slurry applications in fields and these thresholds are defined by national legislation, usually based on nitrate), and the type and number of applications (which vary across the EU depending on manure/slurry availability and cropping time).

In fish farming systems, exposure to feed additives varies with the aquaculture regime (i.e. extensive, semi-intensive and intensive farming systems) and production methods (e.g. cages, raceways, ponds, tanks and recirculation systems) which are directly related to the fish species and the stage of its life-history (EFSA FEEDAP Panel, 2007). Therefore, to calculate Predicted Environmental Concentrations (PECs) in the aquatic compartment, representative systems are selected (EFSA FEEDAP Panel, 2008). For mariculture systems, exposure varies with various environmental factors (e.g. water depth, water renewal, sedimentation rate, etc.) which are themselves highly variable in space. Such site-specific conditions of the surroundings of the aquaculture facility are generally not taken into account as product registrations do not have local restrictions.

4.3.2. Ecological recovery in the EU legislation

Recovery is not taken into account in the current legislation on the risk assessment of feed additives (Regulation (EC) No 429/2008[10]) and it is not described in the EFSA Guidance on ERA of feed additives (EFSA FEEDAP Panel, 2008). An overview on recovery and SPGs for feed additives is presented in Appendix A. In ERA schemes for feed additives (EFSA FEEDAP Panel, 2007, 2008), the recovery option may be selected under certain conditions, although the magnitude and spatio-temporal scale of the acceptable impact are not operationalised in SPGs but assessed on a case-by-case basis.

4.3.3. Studies and data on ecological recovery from exposure to feed additives

Feed additives appear in the environment through excreta from the animals to which they were fed. For aquaculture, this means that exposure of the environment may be constant and in that case no recovery is possible. In marine fish farm operations, sea cages are regularly moved to allow the sediment underneath to recover from the deposition of organic material excreted by the animals. For feed additives used in mariculture, it is considered that bioturbation and faunal ingestion may account for recovery in the sediment (i.e. physical removal of settled particles and enhancement of bacterial action in seabed sediments).

Manure from terrestrial farm animals is spread on land and farmers may apply manure at various times during the growing season provided that on individual fields they do not exceed the nitrogen or phosphorus standards. Therefore, there is little room for recovery periods. Furthermore, over 1 000 feed additives are registered in the EU[18,19,20] ranging from microbes to xenobiotics. Although the experimental information available to assess the safety to the environment is often limited, most compounds used as feed additives are not expected to be of ecotoxicological concern. Most additives are degraded in the animal and do not reach the environment. Other additives are natural compounds which are already present in the environment so that the use of the additives will not substantially increase environmental concentrations. Only a minority of the additives will end up in the manure and will have the potential to pollute the soil, groundwater or surface water. Most feed additives have a limited toxicological potential.

4.3.4. *Impact on food-web interactions and ecological recovery*

Manure stands at the basis of terrestrial and aquatic food-webs. Adverse effects from feed additives on non-target species should not occur because the assessment of safety to the environment accepts no effects, based on PECs falling below thresholds of concern or effect data from a prescribed set of standardised ecotoxicity tests. It follows that if this protection goal is achieved there should also be no impact on food-web interactions and ecological recovery should not be an issue.

4.4. Invasive alien species (IAS) that are harmful to plant health

According to the definition proposed by the EC, IAS are "species that are initially transported through human action outside of their natural range across ecological barriers, and that then survive, reproduce and spread, and that have negative impacts on the ecology of their new location as well as serious economic and social consequences". When IAS are of phytosanitary concern, the assessment of their harmfulness falls within the remit of the EFSA PLH Panel. In the impact assessment for IAS, ecological recovery is addressed through the concept of resilience of the ecosystem which is defined in the PLH Panel practice as the ecosystem capacity to cope with environmental change, through buffering, adaptation and re-organisation and maintenance of key ecosystem functions. Such adaptation may include changes in the species composition of ecosystems (EFSA PLH Panel, 2011, 2014). Information on trends in the extent of IAS in Europe and on exposure and effect assessment in ERA is provided in Appendix B, section 4.

4.4.1. *Patterns of presence in space and time*

Invasice alien species are very different from other classes of potential stressors assessed by EFSA such as PPPs, GMOs and feed additives in that their occurrence in ecosystems is usually not planned and intentional, but is an unintentional and undesirable, but hard to avoid, side-effect of trade in plants and plant products. Hence, the entry of such IAS into the European territory occurs at haphazard places that are unpredictable because the rates of entry are very low, and any realization of entry is the outcome of a chance process with very low probabilities for any given location, despite non-zero probabilities for the continent as a whole over a chosen time frame. From 1975 till 2000, the average yearly number of newly established alien species in Europe was 13 invertebrate species and 7 plant species per year (Hulme, 2009). The rate of entry of new organisms has increased over time, supposedly due (mostly) to increase intracontinental trade as well as changes in land use and climate (Hulme, 2009). Locations of entry are related to the size of the trade.

From initial entries, an invasive organism may spread over the European territory by natural dispersal mechanisms, e.g. aerial dispersal of plant spores or long distance flight of insects, but usually intra-European trade is a much more important mode of spread within the EU territory. Ultimately, organisms will end up establishing in areas where the living conditions are suitable, primarily influenced by climate and presence of host plants. The time needed for the spread of an IAS over the continent may vary from a single year (e.g. the historic invasion and major impact of the pathogen causing potato late blight in Europe in 1845; Fry, 2008) to decades of years (e.g. the Colorado potato beetle, *Leptinotarsa decimlineata* (Grapputo et al., 2005) or the corn root worm *Diabrotica virgifera virgifera*).

An exception to the rule that locations of initial entry and establishment are unintentional and therefore hard to predict is the release of alien species to control invasive plants (Hoddle, 2004; Seastedt, 2015). One insect and one pathogen have to date been used against invasive weeds in the EU (iBiocontrol catalogue based on Winston et al., 2014; http://www.ibiocontrol.org/catalog/, online). This contrasts with 176 insects used against insect pests in the same region according to Greathead and Greathead (1992). The practice of so-called “classical” biological control by release of natural enemies from the area of origin of IAS provides a cost-effective way to control invasive plants, resulting in a potential for recovery of ecosystems impacted by IAS. The benefits of classical biological control of IAS in natural ecosystems have recently been summarized by van Driesche et al. (2010).

All in all, IAS occur across the continent in a wide variety of ecosystems, and their presence is an example of a “press disturbance”. That is: after initial entry and establishment, an invasive organism will usually stay. However, the impacts may decrease over time as native species respond to the new species as a target for feeding due to population increase, while genotypes of native species may be selected that can cope (e.g. compete) better with the new invader. These adaptations of ecosystems will result in a reduction of population densities of the invader over time, and, hence, to a reduction of impacts (Strayer et al., 2006).

4.4.2. Ecological recovery in the EU legislation

In the EU plant Health regime (Council Directive 2000/29/EC[11]) currently under revision only few IAS are addressed as harmful organisms to plants and plant products. With regards to animal health, pests and diseases are also covered only partially by the various regulations and directives of the Animal Health regime. Other EU legislations also take IAS partially into consideration. This is the case of the Wildlife Trade Regulation (338/97)[23] (restricting imports of endangered species including IAS), the Regulation on the use of alien and locally absent species in aquaculture (708/2007)[24], the Birds Directive (2009/147/EC)[25], the Habitats Directive (92/43/EEC)[26], the Water Framework Directive (2000/60/EC)[27] and the Marine Strategy Framework Directive (2008/56/EC)[28]. The last 4 legislative acts require the restoration of ecological conditions and refer to the need to take IAS into consideration. Nevertheless, most IAS remain unaddressed by this legislative framework.

With regards to the measures taken by the Member States against the IAS, the efforts are often fragmented with gaps in species coverage. The preventive measures including early detection and the response to new threats are often insufficient. Measures taken at national level are not always effective considering the potential spread of an IAS through trade from one Member State to another.

In this context and as part of the target 5 of the EU biodiversity strategy to 2020, in order to fill policy gaps in combating IAS a dedicated legislative instrument was developed with the EU IAS Regulation

[23] Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein. O.J., No L61/1, 3.3 .97.

[24] Council Regulation (EC) No 708/2007 of 11 June 2007 concerning use of alien and locally absent species in aquaculture. O.J. L 168/1, 28.6.2007.

[25] Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds. O.J. L 20/7, 26.1.2010.

[26] Council Directive 92 /43 /EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora. O.J. No L 206/7, 22.7.92

[27] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. O.J. L 327/1, 22.12.2000.

[28] Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive). O.J. L 164/19, 25.6.2008.

that came into force on 1 January 2015[29]. The regulation should ensure appropriate prevention, early detection and rapid eradication of IAS and to provide legal basis for the management of IAS that are widely spread.

In Article 18 of this regulation on the prevention and management of the introduction and spread of IAS, it is indicated that the Member States shall take proportionate restoration measures to assist the recovery of an ecosystem that has been degraded, damaged, or destroyed by IAS of Union concern. The measures should include (a) measures to increase the ability of an ecosystem exposed to disturbance to resist, absorb, accommodate to and recover from the effects of disturbance; and (b) measures ensuring the prevention of reinvasion following an eradication campaign.

4.4.3. Studies and data on ecological recovery from exposure to invasive alien species that are harmful to plant health

Ecological recovery is explicitly taken into account in the scenarios that are developed to assess IAS impacts on ecosystem functioning (Gilioli et al., 2014). Broadly, the assessment defines future times at which impacts on ecosystem entities and associated ecosystem services are quantified. Expert elicitation is used to assess the extent to which ecosystem functioning is likely to be affected over different time horizons and how ecological recovery mechanisms may mitigate the impact (Figure 5:). This approach addresses uncertainty about the extent to which ecosystem resilience will mitigate or reverse environmental impact of IAS. At the one extreme, the trend in ecosystem modification may be irreversible (low or no resilience) (Figure 5: A), at the other extreme, it may be completely reversible (high resilience) (Figure 5: C). Assumptions about the resilience of the invaded environment are required to evaluate the impacts and the strength and type of resilience (ecological recovery at species, community or ecosystem functioning level) which need to be taken into account when setting an appropriate time horizon and estimating ecological recovery.

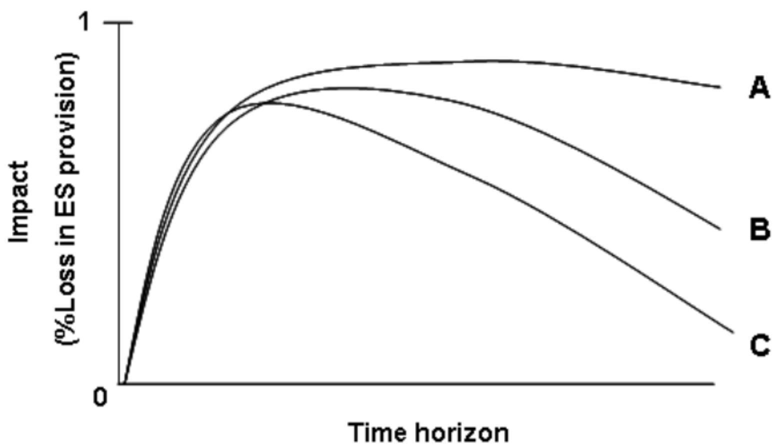


Figure 5: Possible trends in the development of environmental impacts (in terms of percentage of loss in ecosystem service provision) of an IAS over time related to three levels of resilience. A: In low resilience systems, the impact increases up to a maximum after which only little or no recovery from impact is observed. B: In medium resilience systems, a decrease of the impact is expected over time after the maximum impact has been reached. C: In highly resilient systems, a strong reduction of the impacts is expected (from: EFSA PLH Panel, 2011)

[29] Regulation of the European Parliament and of the Council on the prevention and management of the introduction and spread of invasive alien species. Available online at http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2014-0425+0+DOC+XML+V0//EN&language=EN#BKMD-44

4.4.4. *Impact on food-web interactions and ecological recovery*

One of the key concerns about IAS is how they may affect native species, and how these effects may percolate through ecosystems via feeding relationships and competition. To assess effects on other species in an ecological network requires food-web modeling (De Ruiter et al., 2005). However, food-web modeling has to our knowledge not been used for impact assessment of IAS, except in theoretical cases (e.g. Chalak et al., 2010). The use of food-web models would require that they are predictive, and that their predictive quality has been proven in independent experiments. Much remains to be done to make food-web models useful for assessing impacts of IAS.

5. SPECIES TRAITS AFFECTING ECOLOGICAL RECOVERY

A species trait is a well-defined, measurable, phenotypic or ecological character of an organism, generally measured at the individual level, but often applied as the mean state of a species (McGill et al., 2006; Rubach et al., 2011). Traits reflect the morphological, physiological, behavioural, ecological or life-history expression of an organism's adaptations to its environment that may also be regarded as properties of the taxon or population to which the organism belongs (Frimpong and Angermeier, 2010). A functional trait is one that strongly influences the organism's performance (McGill et al., 2006) in terms of response to pressures (response trait) and/or its effects on ecosystem processes or services (effect trait). "Trait state" refers to a species' or population's modal tactic of a given trait, i.e. the mean state of the trait for a species.

The EFSA PLH Panel used in its ecological risk assessment of the apple snail (EFSA PLH Panel, 2014) the concept of "traits" of SPUs. This is a more abstract usage of the term trait, and is not so much related to recovery as to the provision of ecosystem services by ecological entities in the impacted ecosystem.

5.1. Generic properties of species traits influencing internal and external recovery

Van Straalen (1994) illustrated with a conceptual model how population vulnerability is driven by a combination of external exposure, intrinsic susceptibility, and population sustainability. "Population sustainability" refers to the potential for a population to recover from any toxic effect, and can be characterised by two types of traits – traits that are related to demography and traits related to recolonisation. Liess and von der Ohe (2005) and Rubach et al. (2011) elaborated on van Straalen's conceptual model (van Straalen, 1994), providing lists of demographic and recolonisation traits relevant to the risk assessment of chemicals. For field data a combination of traits was successfully applied to link exposure to community composition with the SPEAR approach (Liess and vd Ohe, 2005; Schäfer et al. 2012) and to link exposure to biodiversity (Beketov et al. 2013).

Demographic traits are those that influence the population growth rate and ultimately drive population densities and age distributions. These are relevant to external recovery as well as internal recovery, since source populations with adequate densities and age structures would be required for initiation of recolonisation; and, following recolonisation, (potential) stressor-receiving patches would need to be fully repopulated. The following demographic traits are relevant to the assessment of population recovery (Liess and von der Ohe 2005; Rubach et al., 2011):

- Life span;
- Survival to reproduction;
- Generation time (i.e. the interval between reproductive events);
- Voltinism (i.e. the number of reproductive events per year);
- Number of offspring (i.e. clutch size per reproductive event).

Recolonisation traits are traits that govern the ability of an organism to reach a new habitat. The following recolonisation traits are relevant to the assessment of external population recovery (Liess and von der Ohe 2005; Rubach et al., 2011, with additions):

- Dispersal capacity (i.e. the ability of a species to disperse to a new area, including the timing of dispersal periods);
- Distribution patchiness (i.e. degree of connectedness or fragmentation of the populations);
- Territorial behaviour (e.g. intraspecific competition) – limits a species' ability to move freely in the available space;
- Trophic level;
- Diet specialisation;
- Dispersal mode (i.e. active or passive);
- Reproduction mode (e.g. sexual or parthenogenetic);

Other traits: The classifications proposed by Liess and von der Ohe (2005) and Rubach et al. (2011) are useful, but there are other traits which are also important for recovery which are not easily classified as recolonisation or demographic traits. These primarily include local movement and foraging behaviour. A particular example is pollinators that may seek out nectar sources on a daily basis, and may select areas treated with potential stressors as a result. Similarly, species with wide home ranges may come into contact with multiple stressors in space and time, potentially influencing impacts of the potential stressors and recovery. Other examples of behavioural traits that might increase or decrease exposure to potential stressors are burrowing and canopy foraging. A resistant life-stage is an example of a physiological trait that may influence exposure to potential stressors.

5.2. Some examples of specific traits for focal taxa

In the context of ecotoxicological risk assessment, focal bird species have been defined by EFSA as bird species that represent others in a crop resulting from their potential higher level of exposure to pesticides (Dietzen et al., 2014). Because in the example provided by Dietzen et al. (2014) focal taxa are selected according to exposure rather than recovery, it is, within the context of this Scientific Opinion, important to consider the traits of focal taxa likely to determine their recovery.

Species which are the least able to recover following use of a potential stressor may possess multiple traits that predispose them to poor recovery. For example, among carabid beetles, species which have poor dispersal ability (are flightless), have only one generation per year (univoltine), and spend their entire life-history in pesticide-treated fields (i.e. have limited opportunity for external recovery) are the least able to recover from annually repeated insecticide applications (Vickerman, 1992). Similarly, aquatic invertebrates with a relatively long generation time, low dispersal ability and that complete their whole life-history in water have been identified as potentially vulnerable taxa in isolated chemically-stressed aquatic ecosystems (Liess and Von der Ohe, 2005; Gergs et al., 2011; Galic et al., 2012). In contrast, in the tiered approach to ecological risk assessment, standard test species often have multiple traits that would favour more rapid recovery. For example, the aquatic invertebrate *Daphnia* and the soil invertebrate *Folsomia candida* have high intrinsic rates of increase, short generation times, and a short time interval for first offspring, which makes these species easy to rear and large amounts of data can be gathered quickly. However, such “r-selected” species are much less susceptible to stress at the population level than species with different life-history variables (Stark et al., 2004).

When interpreting traits, it should be borne in mind that some traits may be correlated and that they cannot be combined at random (Culp et al., 2011).

5.3. The contribution of genetic diversity to recovery

Genetic diversity in populations allows them to adapt to stresses. Adaptation may lead to the enhancement of a species’ fitness to a certain potential stressor by increasing, for instance, its ability to withstand exposure to a toxicant. Tolerance can be acquired by physiological acclimation or by genetic inheritance. The latter is a process of genetic adaptation of the population occurring under the selection pressure exerted by the exposure to a potential stressor. It takes multiple generations and involves the gradual replacement of sensitive genotypes within the population as a result of their reduced survival and reproductive output under stress by more tolerant or resistant genotypes. As a result the population as a whole will be better able to withstand the same stress if it occurs again. In ecotoxicology, this process is the basis of the pollutant-induced community tolerance concept (Blanck et al., 1988). There are numerous examples in the literature of such resistance development through selection, e.g. the development of resistance in insects, mites and plant pathogens to the pesticides used to control them (Hardman et al., 2000; Hoy, 2011). Likewise, following their exposure, plant populations can adapt to heavy metals. In populations which are more resistant to stress, recovery may be faster because the initial impact of the stress is smaller, and the individuals may be better able to cope with the environmental stressor at an individual level. As a result, a population may return to its NOR faster, and ecological functions may be also restored. Genetic diversity does not guarantee that a species will be able to adapt as it depends on the presence of resistance-conferring genes in the gene pool. However, ecological insurance[30] (Loreau et al., 2001) implies, as a general rule, that the more genetically diverse a population is, then the better will be its capability to adapt to (potential) stressors.

When a population has been reduced in size by exposure to a potential stressor, some important genetic resources necessary to cope with environmental fluctuations and multiple exposures to other types of (potential) stressors may be removed. Adaptation to multiple (potential) stressors through selection is therefore much more difficult for species than adaptation to a single potential stressor, and it takes much more time for such selection to multiple stresses to occur (Vinebrooke et al., 2004). Adaptation of a population to multiple toxicants is much less likely to occur because the energy budget demanded for the different mechanisms of detoxification decreases the fitness of the adapted species. However, adaptation to different toxicants having similar chemical structure and mode-of-action is more likely to occur by sharing genetic processes responsible for co-tolerance (Blanck, 2002).

In vertebrates, to avoid adverse consequences of genetic drift and inbreeding and for maintenance of self-sustaining and genetically viable populations, the minimum effective breeding population size is estimated to be between 500 and 5 000 individuals, depending on a range of demographic and environmental factors. Many vertebrate populations do not meet this minimum effective population size (Brown et al., 2009). In these cases populations would be considered endangered and, if exposed to potential stressors, then the ability to recover may be affected by inbreeding. In conservation management of endangered species which already occur in small populations, population viability analysis is a common tool to investigate species extinction risk or recovery potential (Lindenmayer et al., 1993), although the actual implementation of population viability analysis is critizised and could be improved (Beissinger and Westphal, 1998; EFSA SC, 2016b).

An example of adaptation occurs when organisms such as microbiota are selected to specifically deal with a potential stressor such as a chemical through metabolism. Bacterial populations may develop a capacity towards rapid biodegradation of pesticides which are used as nutrients and energy sources for their growth (Udikovic-Kolic et al., 2012). This genetic adaptation results in a faster microbial breakdown of the pesticides, thereby diminishing their environmental persistence, and accordingly faster recovery of other species and ecological functions.

Adaptations to stress may be costly, but not in each and every case. Examples for both cases abound in the literature; the acquisition of resistance of natural populations of *Daphnia longispina* exposed to heavy metals was not associated with fitness costs (Ribeiro et al., 2012). On the contrary, the acquisition of tolerance of *Daphnia galeata* to the pyrethroid insecticide fenvalerate was shown to cause a decrease in intrinsic population growth rate revealing the fitness cost of this adaptation (Tanaka and Tatsuta, 2013). If an adaptation is costly, the fitness of an adapted population in the absence of the (potential) stressor would be less than of a population that has not been exposed to the (potential) stressor and has not been under selection for resistance. It is worth noting that the lower fitness of adapted populations can lead to counter-selection, i.e. selection pressure against the genetic adaptation, which leads to loss of the adaptation and its associated cost, and restoration of the population fitness (Changey et al., 2011).

Laboratory studies and simulation modelling of interactions between two species of aquatic invertebrates (*Culex quinquefasciatus* and *Daphnia magna*) have suggested that genetic adaptation to toxicants is affected by predation and competition. According to these findings, interspecific interactions could delay the development of pesticide resistance (Becker and Liess, 2015). However, further studies on a wider range of species, in both aquatic and terrestrial compartments, would be

[30] The ecological insurance hypothesis suggests that biodiversity supplies an "insurance" buffering the effect of environmental changes on ecosystem services. This hypothesis considers that functionally redundant species respond differently to these changes but overall the functional community which they formed, continue to provide the ecosystem service (Loreau et al., 2001).

needed to clarify the wider relevance of these findings and help to determine how information on biotic interactions could support assessment of the recovery potential of ecological entities.

6. Specific features of agricultural landscapes that affect ecological recovery

Some biological populations may be largely dependent on agricultural landscapes. Agricultural landscapes, for a large part consist of patches of landscape (fields) directly used for agriculture, but include surrounding natural or semi-natural landscape elements (e.g. field margins, hedgerows, drainage ditches, streams) that may also be impacted by agricultural activities.

6.1. Terrestrial components of agricultural landscapes

In terms of risk assessment of assessed products (e.g. pesticides) in agricultural landscapes, it is important to make a distinction between the area of treated fields and different types of non-treated areas, as well as the spatial configuration of these areas (and any temporal change in these), since this may vary considerably in different parts of Europe. Potential stressors may occur in landscapes which range structurally from very homogenous with few non-agricultural habitats to highly heterogeneous with multiple habitat types (e.g. Figure 6:). Even within the same structural habitat type the land use can vary, for example it may comprise a monoculture or multiple crops. Such spatial variation influences the likelihood of concurrent events (e.g. pesticide spraying in multiple fields) which in turn affects the exposure to potential stressors of the ecological populations and communities which are present.

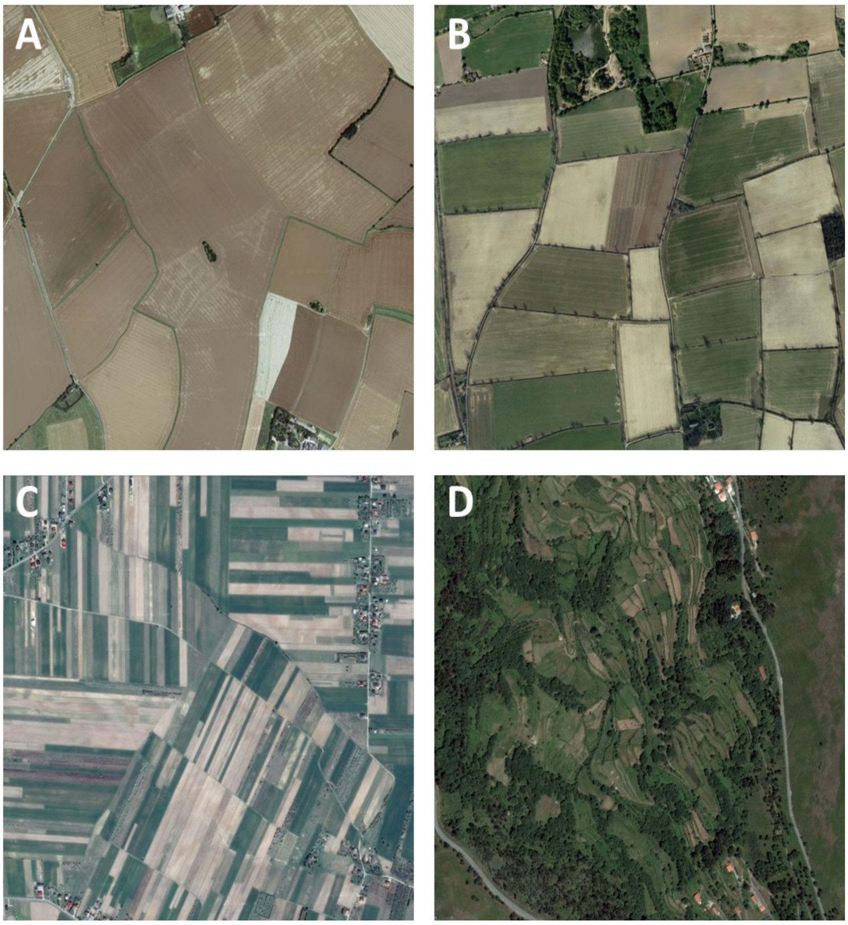


Figure 6: Four different European agricultural landscapes (Google Earth 2006 a, b, 2013 a, b). All landscapes shown cover the same area (1 x 1 km), but heterogeneity in field sizes, crop diversity, and area and structure of non-cultivated areas differs greatly. A-B) East Anglia, UK from the same period of time showing different crop diversity and very large fields; C) Krakow, Poland showing intensively managed small fields of regular shape; D) northern Portugal showing extensively managed landscapes with irregular arable fields and high proportion of off-field habitats

In terrestrial agricultural landscapes the non-target populations for which recovery is to be assessed may be wholly or partly present in the fields where and when the assessed product is applied. Individuals of these populations are therefore exposed directly, or may be in locations where resources are directly affected (e.g. birds eating insects that have been killed by insecticides or removed by herbicides (Boatman et al., 2004)).

The scale at which the evaluation of recovery takes place will depend upon the definition of the population used, but will also be influenced by the landscape composition, structure, and management. If within-field impacts are being assessed (e.g. for soil-dwelling Collembola), then the relevant spatial scale is the micro-habitat variation within a field, but for most organisms a larger scale is needed. Non-target organisms comprise an extremely diverse assemblage of taxa with very different life-histories, ecologies and behaviours, which affect their distribution in, and use of, the landscape. As individuals, some species, such as birds, exploit habitats at a very large spatial scale, whereas others are more restricted, e.g. spiders. For species that do not move between field and off-field as individuals, and where dispersal at scales greater than the size of treated field is not a feature of their ecology, then traditional approaches to separation of in-field and off-field assessment of recovery are useful. However, the majority of species do not fit this profile. The scale at which recovery should be considered will depend upon the species and the regulatory question assessed (see section 8.3.1). Key terrestrial landscape aspects are the size of fields, the landscape heterogeneity (e.g. many or few semi-natural habitats between fields, variation in semi-natural habitat types), crop diversity, and the heterogeneity in space and time of farming activities.

The precise nature of the landscape structure is also important when considering recovery of organisms that move between in- and off-field areas. Fields are typically surrounded by narrow strips of non-cropped habitats (ditch banks, hedges and grass banks). These habitats are subject to action at a distance but may also be exposed to assessed products. Manipulation of habitats can be used to facilitate recovery. For example, Dalkvist et al. (2013) evaluated the impact of an endocrine disruptor on vole populations and found that placing source habitats near treated orchards reduced population impacts within the orchard.

Many of the terrestrial organisms present in agricultural habitats have good dispersal abilities and other life-history characteristics that allow them to cope with anthropogenic disturbances. This results in complex spatial dynamics, but also means that the timing and spatial extent of the potential stressors is important in determining population level impacts and recovery. Calculations with a basic metapopulation model indicate that to maximise impact on a pest, fields should be treated simultaneously over a large area (Levins, 1969). Conversely to minimise impact on NTOs and their ecological functions, the opposite may apply (Ives and Settle, 1997). The impact of a particular potential stressor is not easy to assess since there are confounding effects of multiple stressors which may dramatically alter the system state. Synchronised management (e.g. soil cultivation, pesticide treatment) may occur on a larger or smaller scale within a particular agricultural landscape, and this can be of vital importance to the impact on and recovery of non-target populations when a potential stressor is also introduced. There is therefore important interplay between homogeneity of agricultural practices over spatial scales, and the potential for recovery from stresses. Landscape features therefore may need to be assessed when assessing the potential for external recovery. This is clearly problematic as it indicates that not the assessed product or species *per se* may be decisive for the recovery from impact, but the properties of the environment in which these products or species are having an effect. This is challenging from a regulatory perspective.

6.2. Surface waters in agricultural landscapes

Agriculture requires the availability of freshwater resources and permanent and/or ephemeral drainage ditches, ponds and streams are typical aquatic habitats of European agricultural landscapes. The densities and types of surface waters in agricultural landscapes, however, differ considerably between different agricultural landscapes of Europe. For example, in the undulating agricultural landscape of the Dutch province of Limburg, the estimated surface area of more or less permanent water courses is approximately 500 m^2/km^2 (for a large part streams, but also ditches), while the proportion of surface water is approximately 73 000 m^2/km^2 (mainly ditches) in the fen area of the province of Zuid-Holland (van der Gaast and van Brakel, 1997) (Figure 7).

Figure 7: Illustration of the variation in densities and types of surface water occurring in Dutch agricultural landscapes. Left: Agricultural landscape in the higher undulating area of the province Zuid-Limburg with the river Geul. Right: Water courses, mainly drainage ditches, in a low-lying fen area polder landscape (copy rights at http://www.geobronnen.com/cms/wp-content/uploads/stock-footage-river-geul-meanders-through-geul-valley-in-the-most-southern-part-of-limburg-the-netherlands-300x240.jpg and http://www.adammandelman.net/wp-content/uploads/2013/09/Burtynsky-Polders-Grootschermer-The-Netherlands-2011-1024x767.jpg, online)

The land-use of terrestrial components of agricultural landscapes drained by streams, ditches and ponds not only impacts species composition but also life-history characteristics of aquatic species in these systems. For example, in Dutch drainage ditches located in landscapes with a land-use dominated by nature conservation, the percentage of individuals of aquatic macro-invertebrates with a semi- and/or univoltine life-history (generation time ≥ 1 y) is higher than in ditches in landscapes dominated by agricultural fields. In contrast, in ditches bordering agricultural fields where environmental stress (e.g. fertilizers, pesticides, clearance regimes) is likely higher, the bivoltine (2 generations per year) and multivoltine (more than 2 generations per year) organisms have a larger share in the aquatic communities, indicating that they are adapted to an overall higher level of disturbance (e.g. Brock et al., 2010a). This phenomenon has also been observed when comparing biological traits of stream invertebrates between landscapes that differ in intensity of agricultural practices (e.g. Liess and Von der Ohe, 2005; Schäfer et al., 2007).

Although not often directly applied in aquatic ecosystems, assessed products used in agriculture may be emitted to edge-of-field surface waters, e.g. by means of spray drift, surface run-off, drainage and accidental spills. Within this context it is important to note that the area of agricultural landscape that is drained by different types of edge-of-field surface waters varies considerably. The surface area drained by streams overall is considerably larger than that of ponds, while ditches have an intermediate position. In contrast, the retention time of water (i.e. the average length of the time that water spends in the system) increases when going from streams to ditches to ponds. The implications are that stream communities may become exposed for shorter periods to individual potential stressors (which would tend to decrease impact), but also may suffer a larger number of assessed products applied in the area (which would tend to increase impact). In contrast, pond communities may become exposed for longer periods but to fewer assessed products since they drain a relatively small surface area. Ditches have an intermediate position, dependent on the surface area that they drain and the water flow in these systems. Furthermore, in interconnected larger surface waters such as streams and ditches it is easier for mobile aquatic organisms to avoid local exposure or to re-colonise previously impacted stretches than in ponds. Consequently it will be easier to make a distinction between internal and external recovery in isolated lentic (still water) ecosystems like ponds than in interconnected lentic (e.g. drainage ditches) and lotic (e.g. streams) ecosystems. In theory, both the potential of fastest recovery following exposure to a potential stressor and the chance to suffer multiple potential stressors will be ranked in the order streams > ditches > ponds.

Gergs et al. (2015) conducted a literature review on the ecological recovery of aquatic organisms following the exposure to chemical and physical environmental stressors in both field and semi-field studies. They demonstrated that organisms within the same taxonomic group had overall faster ecological recovery in lotic (streaming water) than in lentic (still water) aquatic ecosystems (Figure 8:).

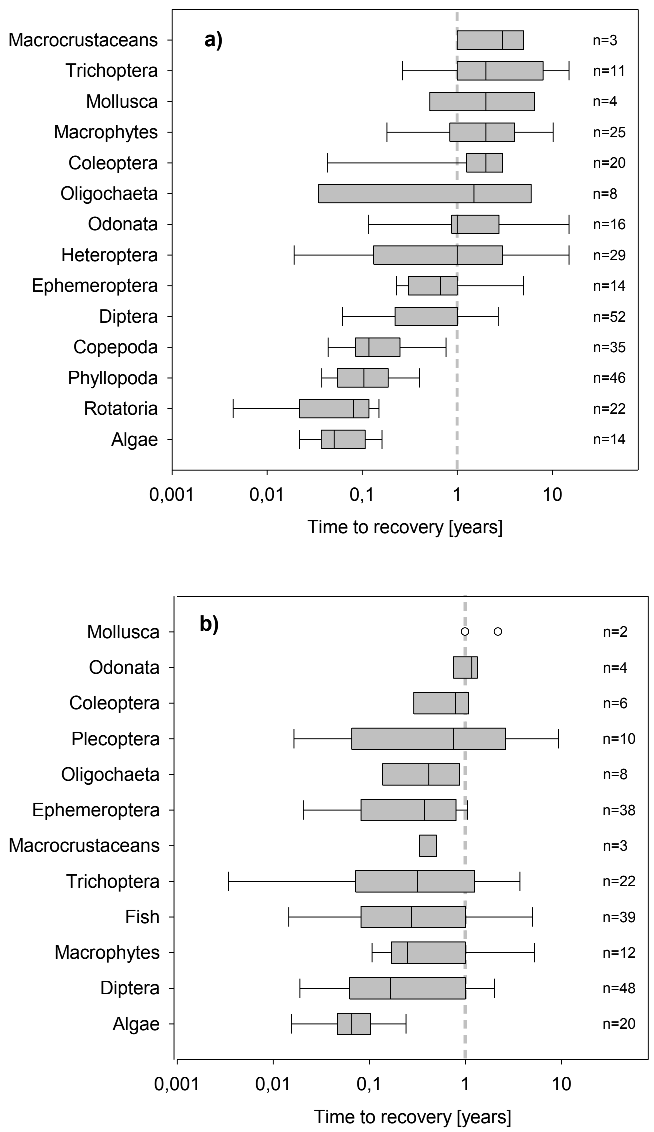


Figure 8: Recovery times for selected taxonomic groups in lentic (i.e. still water; panel a) and lotic (streaming water; panel b) freshwater ecosystems following exposure to chemical and physical environmental stressors as reviewed by Gergs et al. (2015). Boxes represent quartiles and whiskers indicate 95% confidence limits. Dots represent data n < 3. Taxonomic groups are sorted according to their median time to recovery

Gergs et al. (2015) also included the colonization of newly constructed freshwater ecosystems, since this was considered a worst-case scenario with no possibility of internal recovery. The variability in recovery times within taxonomic groups shown in Figure 8: is high. This can be explained by differences in species traits (related to voltinism and dispersal abilities) and also by the specific differences in modes-of-action of the different environmental stressors, the spatial and temporal scales of the exposure regimes studied, the landscape properties relating to buffer strips bordering agricultural fields, the connectivity of aquatic ecosystems, and the presence of nearby refuge areas. The importance of the presence of buffer strips and forested upstream in mitigating effects and facilitating recovery of stream invertebrates was demonstrated recently by Bunzel et al. (2014).

6.3. Spatial and temporal characterisation of agricultural landscapes

The above shows that the spatial and temporal scales cannot be ignored in ERA. When considering recovery in a European context, it must be realized that landscape structures differ enormously both within and between different EU countries (e.g. see Hazeu et al., 2011). These differences manifest themselves in the composition, arrangement and grain of heterogeneity. Landscapes across Europe have been classified and mapped in many ways (e.g. Mücher et al., 2010), and in many countries national or regional GIS data are available (e.g. see the EU agri-environmental indicator landscape[31] and related databases to assess landscape structure in the EU[32]). For example, in Denmark the "Animal, Landscape and Man Simulation System" (ALMaSS) project (http://ccpforge.cse.rl.ac.uk/gf/project/almass/, online) uses a number of national datasets together with information on agricultural subsidy claims to map landscapes in sufficient detail to be used for large scale landscape population modelling (e.g. Dalkvist et al., 2009; Topping, 2011). These data allow modelling of land cover in high resolution (1-m), and also enable land management to be classified according to farm typologies. Landscapes across the EU have been classified in various ways and with different levels of resolution but this may present some limitations, in particular regarding the accessibility of data at regional/national scales.

[31] http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Agri-environmental_indicator_-_landscape_state_and_diversity

[32] CORINE land cover map (100-m resolution), CAPRI agro-economical model (disaggregated data from regional NUTS2-level to 1km cells; see http://d-nb.info/1045345814/34), data on irrigable and irrigated areas (see irrigation http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Agri-environmental_indicator_-_irrigation); farm typologies (see http://www.capri-model.org/dokuwiki/doku.php?id=capri:concept:farmtypes); riparian dataset (25-m resolution; see http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/16201/1/lb-na-24774-en-c.pdf)

7. USEFULNESS OF EXPERIMENTAL AND MODELLING APPROACHES TO ADDRESS ECOLOGICAL RECOVERY

7.1. Experimental approaches

Ecological risk assessment generally aims to preserve the long-term viability of populations, i.e. population sustainability (Rubach et al., 2011), although approaches emphasizing ecosystem functioning and ecosystem services also exist (EFSA PLH Panel, 2011). An assumption is made in the risk assessment of chemicals that short-term population effects on invertebrates will have no long-term consequences if population sustainability is not reduced (Hommen et al., 2010). Higher-tier approaches for assessing sustainability have been developed, including semi-field or field studies at population or community level, such as aquatic micro-/mesocosm studies and terrestrial model ecosystem studies and NTA and earthworm field studies. Each of these approaches has limitations, however, and there is no “perfect approach” (Table 1:). A key reason for this is that ecosystems are spatially heterogeneous and it is very difficult to capture all relevant ecological elements, including sources of external recovery, unless a large spatial scale is employed which is very costly.

Table 1: Pros and cons of experimental approaches to address ecological recovery. The different experimental approaches are presented in order of increasing ecological complexity

Tier of testing	Pros	Cons[33]
Laboratory population tests	Relatively simple, quick and less demanding on resources; Easy to replicate; Minimum Detectable Differences (MDDs) to demonstrate treatment-related effects may be relatively small.	Typically employ easily-cultured single species which may not be ecologically representative; Cannot assess external recovery; Limited inter-species interactions; Population densities artificial.
Model ecosystem and semi-field studies	Enable standardisation of exposure and habitat conditions; Allow replication and statistical evaluation; Can include some ecological interactions; Larger aquatic mesocosms likely to be more ecologically realistic than aquatic microcosms and terrestrial model ecosystems.	Limited external recovery (particularly in terrestrial model ecosystems); Organisms with a complex life-history may be under-represented; Do not capture all ecological interactions that may occur; terrestrial model ecosystems and aquatic microcosms usually cannot assess multi-season effects of chemicals; MDDs for treatment-related effects may be relatively large.
Field studies	Realistic spatial unit; Can assess multi-season effects of chemicals if of sufficient duration.	Sampling methods may be selective with regard to traits (e.g. pitfall sampling does not catch aerially-dispersing species); Difficult to replicate fields or to find reference systems; Difficult to statistically underpin treatment-related effects; May not include all relevant source habitats.
Landscape scale monitoring studies	The most realistic spatial scale of ecological recovery assessment available; Likely to include relevant source habitats.	Resource intensive; Rarely conducted, so do not routinely support ecological risk assessments; Due to resource requirements may be limited in temporal scale; Difficult to replicate; Difficult to statistically underpin treatment-related effects.

[33] Long-term interactions, such as genetic changes as a result of environmental conditions, cannot be assessed by short-term or small-scale experimentation.

It is easier to sample populations of typical water organisms in a non-destructive way, meaning that aquatic mesocosms can often be larger and more realistic than terrestrial model ecosystems. Since terrestrial model ecosystems usually need to be sampled destructively to study treatment-related effects on soil populations, more replicates may be required. These then need to be smaller for logistic reasons. In smaller test systems the detection of treatment-related population responses is often practically possible only for smaller organisms with a relatively short generation time. Furthermore, external recovery may be captured more easily in larger aquatic mesocosms (e.g. flying adults of aquatic insects may colonise the test system) than in smaller aquatic microcosms or terrestrial model ecosystems; however, in general, aquatic mesocosms do not capture passive drift of organisms from upstream sources, which is one of the key routes of external recovery in lotic systems.

A challenge in terrestrial field studies is that some organisms that are vulnerable to agricultural chemicals have spatially disjunct populations meaning that they may not be adequately represented even in a replicated field study (e.g. Collembola; Frampton, 1999). Soil microorganisms are known to be diverse and heterogeneously distributed making it difficult to use as a potential indicator to estimate the ecotoxicological impact of potential stressors. However, this difficulty might be tackled at a higher level of taxonomic resolution or at functional level (Imfeld and Vuilleumier, 2012; Philippot et al., 2012). Where assessment of recovery is of interest, the agricultural chemical regime may be specifically manipulated at a site where the species is known to be present (e.g. Frampton, 2001a). Manipulative studies can also be designed to assess whether invertebrate recovery in a field occurs from internal or external sources (Frampton et al., 2007). However, these specific types of recovery studies are relatively uncommon and not employed routinely in risk assessments.

The reliability of the conclusions drawn from an experimental ecosystem study (micro-/mesocosm or terrestrial model ecosystem experiments) depends on the statistical power of the test that is used to demonstrate treatment-related effects. It is possible to estimate an indicator of the statistical power of a semi-field test *a posteriori*: viz. the minimum detectable difference (MDD). The MDD defines the difference between the means of a treatment and the control that must exist in order to conclude that there was a significant effect (see e.g. Environment Canada, 2005). The MDD is affected by three factors, viz., (1) the number of replicates, (2) the variance of the measurement endpoints, which can be separated into the inherent variability between the replicates and the variability caused by the sampling methods, and (3) the selected type I error level (an error level of 0.05 is usually selected as default). The statistical power of semi-field tests can to a large extent be increased by improving the sampling and quantification methods rather than by increasing the number of replicates only. A proposal on how to evaluate treatment-related effects and recovery of populations in aquatic micro- and/or mesocosm tests using the MDD classes given in EFSA PPR Panel (2013a) is provided in Brock et al. (2014).

When considering the analysis of data on ecological recovery it is important to distinguish between statistical significance and biological relevance (EFSA SC, 2011). It is recommended that the nature and size of biological changes or differences that would be considered relevant should be defined in advance.

In its scenarios for apple snail impacts on ecosystems, the EFSA PLH Panel used temporal scales of the impact (and recovery) extending from 5 to 30 years. Evidently, in this example, experimental approaches are not useful for prospective risk assessments. In such a case, the assessment must be made either by using models (if validated models are available) or by eliciting expert opinion. A rigorous approach to the elicitation of expert opinion is essential (EFSA, 2014b).

7.2. Modelling approaches

7.2.1. Pros

There is a growing realisation that in complex ecological systems (including agricultural landscapes) potential stressors may cause multiple outcome changes due to feedback mechanisms within the system (e.g. Blaustein and Kiesecker, 2002; Didham et al., 2005; Harmon et al., 2009; Salice et al., 2011). This means that empirical results need to be considered carefully in terms of the precise context under which they were gathered. Developing system models allow a better understanding of the framework in which recovery operates. Thus, modelling, if able to simulate accurately the feedback mechanisms and context, can provide predictions of changes in systems properties for a range of environmental contexts and therefore can warn of potential causes of concern, by covering a much wider scope than is possible with experimental approaches.

A clear advantage of modelling is that there is no requirement for additional field work if the input data are adequate and the model sufficiently verified. Under these conditions logistical and temporal issues can be dealt with more easily. This is particularly the case if weather or other variables that may alter the outcome are important, since experimental work will always be subject to the prevailing environmental conditions at the time field work is undertaken. A secondary temporal effect is the history prior to experimentation. In the case of recovery the state of the system prior to the experimental management will be dependent upon the history of events up to this point. These are rarely known, and cannot be separated entirely from the treatment effects. However, in models these issues do not present a problem if the appropriate states of the population/communities of concern are defined by the modeller.

Similar to the historical context, the resilience of the overall population before treatment is critical to determine if the impact of a treatment is to be realistically evaluated (see section 2.3.2). This can be assessed by modelling, if explicitly addressed either by simulation of the actual population state in the environment under consideration or by evaluating a range of potential resilience states. However, simple population dynamics, considering populations under density-dependent control as a single entity, are only part of the issue that modelling needs to address. As stated earlier (see section 2.3.2), populations in agricultural systems are often fragmented, and will often be subjected to spatio-temporally varying potential stressors (e.g. assessed products applied to different fields). In fact there are a number of issues that affect populations that can only realistically be assessed by models or by very long-term and large scale monitoring. These are all related to spatio-temporal variation in potential stressor and/or population state in space and time. Chief among these is the "action at a distance" concept, or source-sink phenomenon. This will occur when an ecological trap is caused by repeated mortality (e.g. repeated pesticide exposure), interspersed by immigration from source habitats. This in turn will lead to impacts in the source habitat, and depending upon dispersal and reproductive rates may even result in source-population decline (Holt, 1993). If, however, non-treated source habitats are numerous enough in agricultural landscapes and only slightly influenced by "action at a distance", these source habitats may guarantee a successful external recovery of populations in areas of landscape directly exposed to assessed products. Similarly, patch-dynamics or metapopulation dynamics may also result in complex long-term population trajectories which can result in overall population declines, even though local effects appear to be small (e.g. Bulman et al., 2007) or in population increases, even when local effects are large. Here spatial modelling can be used to project the population dynamics into the future when the properties of the actual agricultural landscape of concern are taken into account.

Another major advantage of modelling is the descriptive power of defining the model itself. During this process uncertainties, processes and data needs can be explicitly defined, providing description of what we currently know, but also identifying weaknesses in current knowledge. Sensitivity analysis can be used to identify processes and parameters that require closer study or data generation to improve the ERA (e.g. Parry et al., 2013). In this way the system model can help direct future research into areas of most concern for better evaluation of recovery.

There are five major advantages of population modelling:

- The state of the population before the introduction of the potential stressor can be defined;
- Wide geographical, spatial and temporal scales can be incorporated;

- Multiple stressors, including integration of spatial, potential and other environmental stressors, can be assessed (e.g. Dalkvist et al, 2009);
- Uncertainties, inclusions and exclusions in the model can be explicitly defined, and the model can be used to identify areas requiring data generation;
- The method is relatively inexpensive compared to data generation.

Ecological recovery of populations may also depend on stressor-related shifts in community composition and food-web interactions. For example, the replacement of a vulnerable population by a less vulnerable one with a similar niche may hamper recovery of the original vulnerable species. Indirect effects of potential stressors may be more persistent than the direct effects on the impacted populations of concern, and, consequently, might affect recovery potential of these populations. Food-web models are in principle appropriate tools to address stressor-induced shifts in population interactions. First of all, food-web (or food chain) models are useful to trace the fate of contaminants through the food chain and assess impacts at higher trophic levels than those initially impacted by a contaminant. Secondly, food-web (or food chain) models can help assessing cascading effects mediated by ecological interactions between species such as predation or competition. While food-web models are conceptually suitable and appropriate, parameterization and uncertainty of predictions are challenges in their application in risk assessments (see e.g. Baird et al., 2001; Traas et al., 2004; De Ruiter et al., 2005; De Laender et al., 2011).

7.2.2. *Cons*

Modelling is a data hungry process. Models which consider larger spatio-temporal scales will need data not only regarding the (focal) species being considered but also the state of the environment and the way it might change. This requires a good understanding of all relevant ecological processes influencing the responses of the entity to be assessed within its environmental context and of the feedback mechanisms. All this data also needs to be incorporated into a model which requires specialist skills, but more importantly the result needs to be assessed in terms of function and reliability (see EFSA PPR Panel, 2014). This evaluation is a rather resource demanding endeavour for both the modeller and assessor.

It is important to consider all aspects of the domain of the validity of the models (EFSA PPR Panel, 2014). The evaluation process also requires data, but this data may be difficult to obtain. “Validation” of models is considered necessary, but in the case that we want models for prediction of novel system states we cannot expect model predictions for these states to be verified in the short-term. Hence, assessment of models requires considerable insight into the system and considerable modelling expertise from the assessor. This is a practical difficulty if this expertise is in short supply.

Although usually less costly than the generation of experimental data, some systems models can be very large encompassing a wide range of aspects. Therefore, costly model development, testing and documentation are of particular concern for large models with many components. As a result, larger models are likely to become long-term projects, requiring standardised set-up and usage conditions to be specified for regulatory use. Currently these do not exist and therefore evaluation procedures will be costly and difficult to assess objectively for these models. These are not costs that have been traditionally associated with ecological modelling, but come with steadily increasing expectations of model documentation and performance (e.g. EFSA PPR Panel, 2014).

Limiting factors to the use of models can therefore be identified as follows:

- Insufficient data to create the model;
- Technical inability to represent the necessary processes at the correct scales;
- Difficulty in assessing whether a model is useful;
- Development, testing and documentation of models can be resource demanding;
- Educating regulators and other end-users of model outputs in the possibilities and limitations of complex mechanistic models is a time demanding activity;

- Model outcomes are reasoned hypotheses, not facts;
- Difficulties in including the full range of variable influences operating in the real world.

7.2.3. Overall evaluation of pros and cons of models

Although mechanistic effect models have the advantage that they can be controlled by the modeller and in this sense have no spatial-temporal limitations, there are some important lessons learned from semi-field (mesocosm) experiments with respect to the occurrence and persistence of indirect effects. In semi-field experiments that contain a limited number of interacting populations and a relatively simple food-web, and most likely also in relatively simple food-web models that depict the interaction of a limited number of populations, the observed or simulated indirect effects of stress may be unrealistic if essential feedback mechanisms that may dampen responses, in both space and time, to potential stressors in agricultural landscapes are not taken into account. So, in order to predict population and community recovery with computer simulation models, they should represent the complexity of agricultural landscapes (or edge-of-field surface water habitats) in a realistic way. For example, regular geometry in spatial models introduces bias to simulation results and should be avoided (Holland et al., 2007). Furthermore, the size of the simulated landscape scene may affect results if there is a net loss of individuals over the outer edge of the scene (e.g. Skelsey et al., 2005). Such artificial spillovers in spatial models may be avoided for example by connecting the edges of the simulated scene, using the torus representation to create "periodic boundaries" (e.g. Liu et al., 2013). The challenge for mechanistic effect modelling is then to be simple enough to keep the required input data manageable, and complex enough to realistically capture the complexity of the agricultural landscape under evaluation. Managing this trade-off will be a matter of compromising in the foreseeable future.

It is clear that modelling in combination with experimental data can more accurately represent the systems and processes required for the assessment of ecological recovery than experimental data in isolation. The ability to integrate dynamics over time, space and different environmental contexts results in modelling being able to represent a much wider range of potential causes of concern than would be possible with experimental approaches. Here it is useful to consider different error avoidance strategies and their aims. Experimental approaches attempt to avoid Type I errors, thus will evaluate whether a condition can be shown to occur under a specific set of circumstances (i.e. in this case recovery). However, for recovery and risk assessment in general we need to avoid Type II errors, i.e. we should not fail to warn of circumstances where problems may occur. For example, a field experiment may document with 95% confidence that recovery occurred (a Type I error avoidance test), but what is more interesting is to know under what circumstances recovery would not occur. This means we should place more emphasis on breadth of environmental conditions in our analysis, something that is only possible with modelling.

However, uncertainty related to the accuracy of predictions makes models intrinsically less attractive than empirical data. The Scientific Committee is currently developing a scientific opinion on guidance on uncertainty in risk assessment (EFSA SC, 2015b). This uncertainty is partly related to lack of knowledge identified in the modelling process and so is also a result of the rigorous approach now required for model development and documentation (i.e. knowledge gaps often are made explicit for modelling but often not for field experiments); this should not be considered a drawback of modelling. Lack of data to build models is however, a real problem often excluding modelling as a viable approach. The corollary to this is that experimental evidence is also often gathered without adequate understanding of the context in which it is generated, and the fact that it does not directly represent the real system (e.g. see Schwartz et al., 2000). Both models and experiments are proxies for the real world application of the potential stressors and subsequent population recovery. In both cases it is therefore necessary to carefully define the question(s) which the model or experiment need to answer. The framework of knowledge and uncertainty surrounding these questions also needs to be defined to be sure that the information used for recovery assessment is based on sound scientific principles.

8. AN INTEGRATIVE APPROACH FOR ADDRESSING ECOLOGICAL RECOVERY FOR POTENTIAL STRESSORS

8.1. Factors affecting ecological recovery of vulnerable non-target organisms after exposure to a potential stressor

From the information presented in the previous sections, it can be concluded that ecological recovery of structural endpoints (e.g. population densities) in ecosystems may be hampered due to factors/conditions mentioned in Table 2: . Following careful consideration, the Scientific Committee concluded that each of the criteria, as listed in Table 2, appears to be applicable to all four of the regulatory risk assessment domains.

Table 2: Factors hampering ecological recovery of ecosystem structure and population abundance and relevant for potential stressors such as. PPPs, GMOs, feed additives and IASs

Criteria defining circumstances under which recovery may not be expected to occur
Long duration of exposure relative to life-history
Large spatial scale exposure relative to organism spatial characteristics
High probability of exposure of sensitive life stage
Lack of exposure avoidance behaviour
Lack of physiological ability to reduce the sensitivity to the potential stressor
High probability of indirect effects of the potential stressor
Low fecundity and long generation time
Low recolonisation ability
Lack of, or inadequately connected, source populations
Population viability already threatened by other (potential) stressors

However, this list of criteria is restrictive due to the complex nature of landscapes. The spatial distribution of NTOs is governed by both niche-assembly and dispersal-assembly rules. In addition, the spatial distribution of potential stressors tends to be patchy. Consequently, besides the species traits that affect internal and external recovery, the spatio-temporal arrangement of habitats, resources and exposure to potential stressors is critical for the evaluation of population dynamics in landscapes. Within agricultural landscapes, the traditional approach of the separation of in-field and off-field assessment of ecological recovery is only useful for terrestrial non-target species that do not move between in-field and off-field habitats as individuals, and when dispersal at scales greater than the size of the treated field is not an important feature of their ecology. For many terrestrial non-target species that occur in agricultural landscapes this is typically not the case. For example it is known that agricultural landscapes favour highly dispersive species of carabid beetles (Holland, 2002). Furthermore, the distinction between in-field and off-field is particularly relevant for those potential stressors that are specifically applied in the field, in particular pesticides or, e.g., manure which may result in exposure to residues of feed additives. In the case of IAS, a distinction between in-field and off-field will usually not be helpful because IAS are not intentionally applied, except when they are introduced with planting material.

For those aquatic non-target species that mainly depend on internal recovery processes for their sustainability in edge-of-field surface waters (e.g short-cyclic organisms with many offspring and/or resistant life stages) a local risk assessment may suffice to address their ecological recovery. For many aquatic species with a more complex life-history, population recovery usually cannot be evaluated without considering the landscape context. Therefore, small-scale experimental semi-field studies can only be used to address the ecological recovery option in the aquatic risk assessment if (1) in lower-tiers aquatic organisms with a short-generation time, in which internal recovery is relevant, are identified to be at risk (e.g. algae at risk from herbicides), or (2) the test systems also contain representatives of vulnerable populations of the taxonomic groups at risk (see e.g. EFSA PPR Panel, 2013a).

Figure 9: schematically illustrates the importance of species traits, landscape properties and exposure characteristics on extinction risk and internal and external recovery processes of NTOs in a landscape context. Acting in concert, species traits, landscape properties and exposure characteristics may determine the potential for populations of NTOs to escape the stress event in space (x-axis in Figure 9:) or time (y-axis in Figure 9:). Note that the potential for NTOs to recover from an effect of a potential stressor is multi-factorial. External recovery depends on the spatial pattern of exposure, the home range of individuals, habitat or food preferences, and the availability and connectivity of refuges. The potential for internal recovery depends on generation time, the number of offspring, the presence of resistant life stages, and the persistence of the potential stressor.

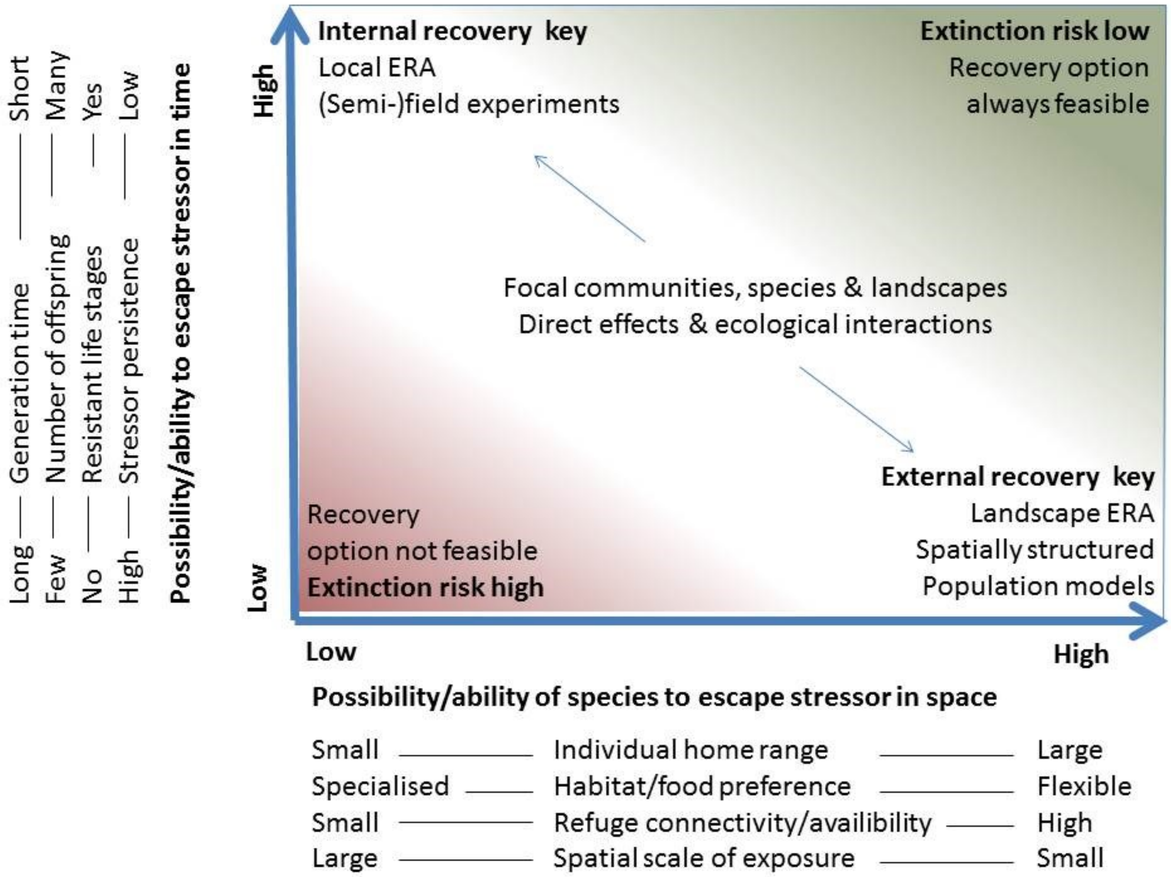


Figure 9: Schematic illustration of the importance of species traits, landscape properties and exposure characteristics on extinction risk and internal and external recovery processes of NTOs in agricultural landscapes as well as the role of (semi-)field experiments and spatially structured population models to assess ecological recovery of stressed populations of NTOs.

As illustrated in Figure 9: , relatively small-scale semi-field and field experiments may be appropriate tools to conduct local risk assessments suitable to address the ecological recovery of non-target species that mainly depend on internal recovery processes. These (semi-)field experiments may also demonstrate the possible routes and potential impacts of indirect effects on the ecological recovery of populations of interest. However, if ecological recovery is mainly dependent on landscape properties and recolonisation traits of the affected non-target species, either large-scale field studies (which are very expensive to conduct) or spatially explicit population models (which are costly to develop, and have validation issues on top of this) may be the appropriate tools.

Not all non-target species and communities can be appropriately assessed always and everywhere. Therefore, the selection of focal taxa, communities or landscapes is an important prerequisite for prospectively addressing the impact of potential stressors and the potential for ecological recovery of non-target species. Focal taxa are relevant for both experiments and models; focal landscapes are relevant for spatially explicit population models; and focal communities are relevant for semi-field and field experiments and food-web models (see also the conceptual framework presented in Figure 4).

8.2. Relationship between recovery of structural and functional endpoints

Besides the structural recovery of ecosystems, the recovery of ecosystem functions and ecosystem services needs to be considered and assessed. In the recovery of ecological functions we can consider the recovery of species populations in terms of numbers and biomass, and in terms of the diversity of the species populations, taking into account evenness. Both abundance and diversity may be important for assessing recovery of ecosystem functions and ecosystem services. For instance, ecosystem services provided by beneficial insect species, such as pollinators and pest natural enemies depend on species numbers (Cardinale et al., 2012); hence a recovery of functions along with the recovery of numbers is plausible. They also depend on the diversity of the insect groups. Different natural enemy groups together may provide better biological control than a single species (but not necessarily) (Tscharntke et al., 2005).

The relationship between taxa richness and function is generally non-linear, e.g. due to functional redundancy. Based on the generally non-linear saturating relationship between species richness and ecological functions, it may be the case that ecological functions are (largely) recovered at diversity levels that have not fully returned to the NOR (Cardinale et al., 2011, 2012). Different species may provide the same function in somewhat different ways, e.g. pollinators pollinate at different times of day or different times of the season, and natural enemies forage on different parts of the plant (this is referred to as complementarity, e.g. Tscharntke et al., 2005); Plant species with complementary traits may together capture a greater portion of the available resources and thus improve productivity and, in the long term, nutrient cycling (Cong et al., 2014). Tscharntke et al. (2005) discuss that with a greater species pool, the probability for high levels of ecosystem service provisioning is increased as the probability of presence of species that are good at providing services increases with species richness. As environmental conditions vary, different species may perform best; hence, a diverse community provides likely more robust levels of services (insurance hypothesis). Redundancy is the contrary of complementarity, indicating that functions of different species cannot be distinguished. This means that species loss will not result in loss of function. Redundancy thus provides insurance against service loss when there is species loss. Overall, ecological functioning and ecosystem services may recover before species abundance and species diversity have fully recovered, but further empirical evidence is needed to confirm this.

8.3. The need for an integrative approach

The information presented in the previous sections, and summarised in the conceptual framework (Figure 4) and Figure 9, shows that in principle experimental (e.g. semi-field experiments) and modelling tools (e.g. spatially explicit population models) could be used to address the recovery option in ERAs for potential stressors that fall under the remit of EFSA and for which the exposure is a consequence of application in agricultural settings, e.g. PPPs, GMOs and feed additives. The information presented in sections 8.3.1 and 8.3.2 mainly concerns the selection of focal taxa, processes and landscapes for the prospective ERA of pesticides, feed additives and GMOs, with a focus on the recovery option. Section 8.3.3 presents the IAS-specific approach to address ecological resilience in ERA.

8.3.1. Selection of focal taxa and/or processes

In agro-ecosystems and related landscapes there is usually a high number of NTOs and ecological processes that may be affected by potential stressors. Considering that only some of these species and processes can be tested and/or evaluated in ERA, a representative subset of relatively vulnerable NTOs and ecological processes (referred to as "focal taxa" and "focal processes") that allow a realistic worst-case higher-tier ERA needs to be selected. Within this context, it is important that the selection of focal taxa and/or processes is done in the broader context of ERA that may or may not consider the recovery option. The steps described in Figure 10 for the selection of focal taxa and/or focal processes to assess ecological recovery may be used.

Before starting with the stepped procedure depicted in Figure 10, it is important to emphasise that the selection of focal taxa and/or processes must be done separately for each SPG. Note that the focal taxa and/or processes may be different for different ecosystem services underlying a SPG. For example, the protection of populations of terrestrial NTAs may be important in agro-ecosystems for the ecosystem services "pest control" and "pollination", but the important taxa that provide these ecosystem services will usually be different for different services. Likewise, for the ecosystem services "nutrient cycling" and "decomposition of organic matter", microbes play a crucial role, but different functional groups of microorganisms in soils and sediments are responsible for different functions. Furthermore, it is important to collect information on the intended use of the potential stressor, e.g. the application of a pesticide or GMO in a certain crop. This information sheds light on the types of (agro-)ecosystems that potentially become exposed to the potential stressor. In addition, when the recovery option is offered, it is important to consider that essential ecosystem services may not be provided by the impacted populations until they are recovered. Due to the complex and complementary relationships between interacting populations, particularly when and where functional redundancy is low, a risk assessment offering the recovery option must also address the potential consequences for other NTOs and the ecosystem services they provide. This assessment may require repeating the process described in Figure 10 for the selection of a complementary set of focal taxa and focal processes, as the assessment of these effects requires a selection of focal taxa and processes based on their dependency on ecosystem service(s) that will not be provided during the recovery period.

A first step in the selection of species and processes to address in ERAs is the identification of SPG-relevant sensitive taxa and/or processes vulnerable to exposure. For this, traits determining the chance of exposure and traits determining the intrinsic sensitivity to the assessed stressor of concern should be used. Within this context, information on the mode-of-action of the assessed stressor is also needed (particularly relevant for pesticides and GMO traits with a specific toxic mode-of-action). This first step outlined in Figure 10 is essential for all ERAs, irrespective of whether the threshold option or recovery option is selected. Within the context of this Scientific Opinion, the part of the decision scheme addressing the recovery option is most relevant. The SPGs for certain taxa (e.g. for vertebrates such as birds, mammals, amphibians, and fish, in ERA of pesticides) may not allow the recovery option, so that the part of the decision scheme addressing the threshold option is most relevant for these taxa.

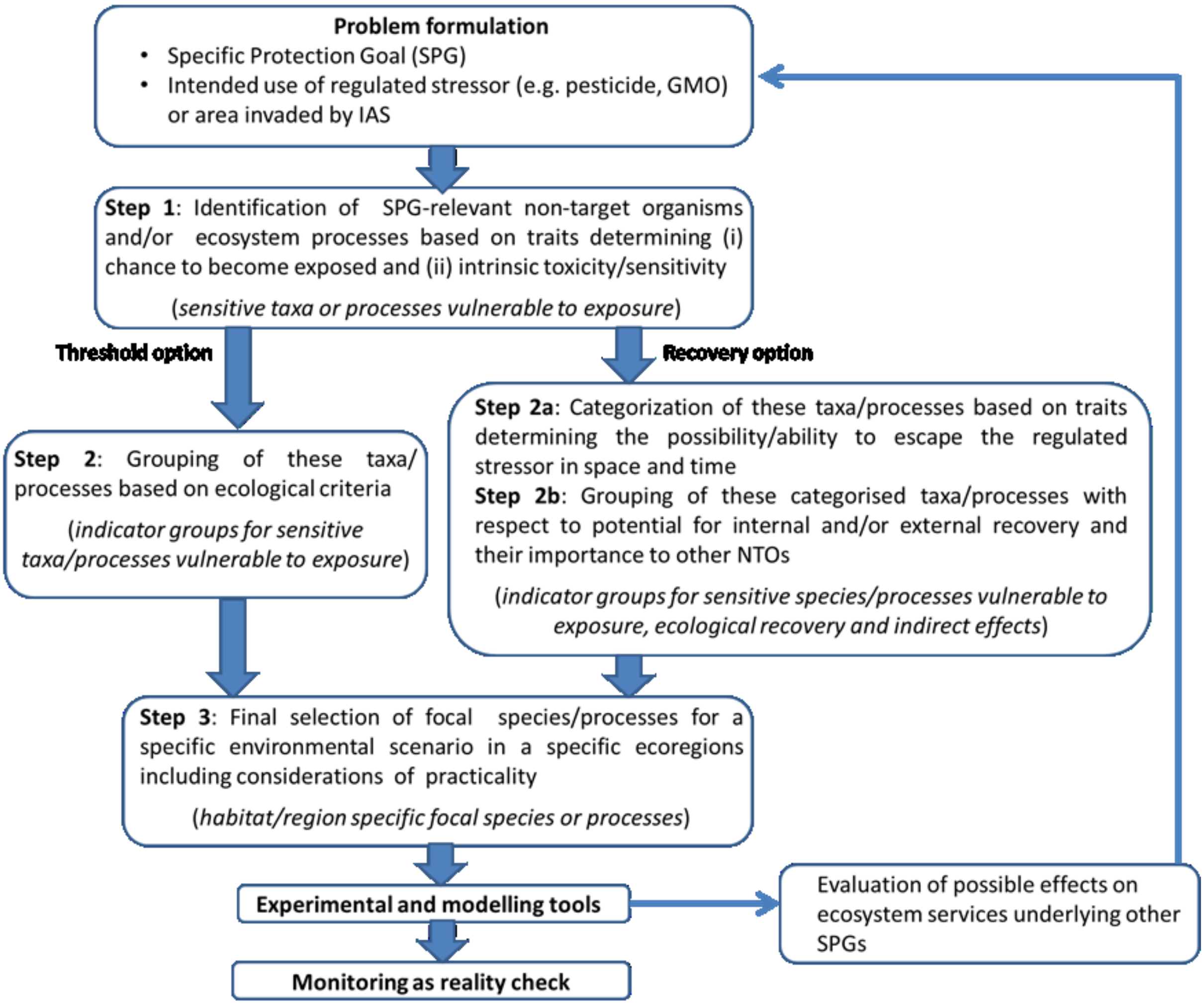


Figure 10: Steps for selecting focal taxa and/or processes for conducting ERAs that address the threshold and recovery options (adapted after EFSA GMO Panel, 2010a)

In cases where the recovery option is not in conflict with the defined SPG, steps 2a and 2b of the decision scheme (Figure 10) illustrate the importance of categorising the potentially stressor-sensitive taxa or processes based on their ability to escape the assessed stressor in space and time (see also Figure 8). Within this context, a grouping of vulnerable taxa and/or processes based on traits that determine internal and/or external recovery is required, as well as information to identify the chance that their temporal decline causes indirect effects. Criteria for this grouping are: demographic and recolonisation traits, as well as information on the ecological roles these taxa play in communities. This grouping will result in indicator groups for recovery of susceptible species and/or processes that are relevant for local or landscape-level ERAs (see section 8.3.2 below).

Step 3 in the decision scheme (Figure 10) refers to the final selection of focal taxa and/or processes for a specific environmental scenario in a specific ecoregion. Note that the selection of focal taxa and/or processes should be based on ecological criteria (e.g. spatial distribution in Europe; habitat preference; ecological significance with respect to the ecosystem services considered) and practicality (testability, available ecological and/or ecotoxicological information) so that their stressor-response relationships (including recovery) can be studied in experimental ecosystems (e.g. mesocosms), in field experiments and/or by means of mechanistic population and ecological interaction (e.g. food-web) models.

The recovery option requires the assessment of potential consequences for other NTOs of not providing some ecosystem services during the recovery period of the selected focal taxa and/or process. Within this context, it should be borne in mind that: non-target organisms suffering indirect effects may not necessarily be sensitive to the potential stressor; populations that suffer direct and/or indirect effects may be affected by action at a distance; and variability among ecoregions and ecotypes may be important (since the ecological role of selected focal taxa and their links with ecosystem services may differ between different ecosystems and among different spatial scales).

Although the prospective ERA of assessed products is usually based on a realistic worst-case approach with respect to parameter selection, it cannot be excluded that, for example, a large-scale use of the assessed stressor(s) will result in unexpected effects on NTOs and processes and/or that the rate of recovery initially predicted deviates from reality. For this reason, a reality check of prospective ERA procedures by means of field monitoring programmes is recommended (see also Figure 4). Furthermore, note that (endangered) species considered insensitive to direct effects of a potential stressor may be susceptible to indirect effects (see e.g. EFSA SC, 2016b). These indirect effects may, for example, concern a decline in essential food resources and/or habitat caused by direct effects of potential stressor(s) on sensitive taxa and/or processes (see e.g. section 4). Due to unexpected interactions and cascade effects, the magnitude and duration of indirect effects are not possible to predict with total accuracy using ERA procedures. These effects may, however, be detected using large-scale field monitoring studies. Linking this monitoring as an iterative procedure to improve modelling approaches is therefore very important. The resulting improved spatially explicit ecological interaction models may then be used to investigate possible mitigation and management measures to avoid the newly observed indirect effects.

8.3.2. Selection of appropriate spatial scales to address exposure, effects and ecological recovery

From the above, it appears that when conducting ERAs for assessed stressors the selection of focal taxa and/or processes cannot be disconnected from selecting an appropriate spatial scale to address exposure, effects and ecological recovery. Significant differences exist in the climatological, physical, chemical and biological properties of agricultural landscapes among different areas in Europe. Consequently, for EU-level risk assessments, different environmental scenarios need to be developed that reflect these differences (see also EFSA PPR Panel, 2014).

The possible consequences of the combination of direct and indirect effects of assessed stressors on ecological recovery processes are difficult to address with simple approaches. Therefore, ecosystem-level scenarios that incorporate physical and chemical ecosystem properties (e.g. for in-field, edge-of-field and off-field terrestrial habitats; ponds, ditches and streams) and focal taxa that have been selected on the basis of demographic and dispersal traits, should form the basis for designing appropriate semi-field tests and food-web models. Landscape-level scenarios that incorporate landscape properties and focal taxa selected on the basis of both demographic and dispersal traits form the basis for spatially-explicit modelling approaches to address internal and external ecological recovery processes of populations.

Development of environmental scenarios should include integral linkage of exposure and effects; this is necessary since the appropriate linking of exposure to effects is crucial in ERA and more complicated when addressing effects and ecological recovery for ecological entities subject to variable exposures in space and time. Environmental (ecosystem- and landscape-level) scenarios and effect models (i.e. spatially explicit population and food-web models) in principle can be used to evaluate: (1) the effects and ecological recovery potential following exposure to individual assessed stressors; (2) the cumulative effects and ecological recovery potential resulting from realistic combinations of assessed stressors; (3) the relative contributions of different stressors (assessed and non-assessed); (4) the importance of landscape properties and refuge areas on recovery potential of NTOs; and (5) the consequences of mitigation measures and landscape management on possible impacts of assessed stressors.

As described in sections 2.3.2 and 4, non-target taxa may occur in both exposed and non-exposed patches of landscape. A local scale ERA (informed, for example, by means of semi-field experiments) may suffice for focal NTOs if the individuals do not move between exposed and non-exposed habitats and ecological recovery is largely dependent on internal recovery processes (see top-left corner of Figure 9) and/or when the conditions for external recovery represented in the semi-field experiment are realistic worst-case. For a mobile species with individual ranges larger than the local scale of the exposed habitat (e.g. a treated field or edge-of-field site), however, a local scale ERA in most cases is not sufficient, since in semi-field experiments a high enough abundance of focal taxa in combination with realistic worst-case conditions for their external recovery usually are not realised. To sufficiently address phenomena like action at a distance and external recovery processes as influenced by landscape properties (e.g. spatial configuration and connectivity of exposed and un-exposed habitats), a landscape-level ERA is required. Therefore, in both mobile and non-mobile focal taxa, specification and consideration of the temporal pattern of stressors is necessary in addition to the spatial distribution of stressors.

The EFSA PPR Panel described a procedure for ERAs of assessed stressors at the local and landscape scales for mobile (focal) NTAs (EFSA PPR Panel, 2015). The NTA opinion demonstrates that, in addition to a local scale ERA, also a landscape scale ERA (represented by means of spatially explicit population models) would need to be conducted for focal taxa which move between exposed and non-exposed sites (i.e. species for which external recovery processes are key). Note that it may be easier to design realistic worst-case conditions for external recovery of invertebrates in aquatic semi-field experiments (e.g. experimental ponds) than in terrestrial semi-field experiments. Experimental ponds, usually, are isolated test systems approximating realistic dimensions and surrounded by non-aquatic habitats. In experimental terrestrial ecosystems (e.g. experimental plots), the size of the test systems considerably influences external recovery processes since the scale of the experimental plot rarely matches the scale of fields or landscapes where the stressor is applied. In this case, both the size of the plot and habitat composition of the surroundings is likely to alter rates and scales of external recovery (Thacker and Jepson, 1993; Topping et al, 2014).

In landscape-scale population modelling, we need rules of thumb and associated criteria to determine the size of the focal landscape, as well as the spatial configuration of different habitats within that focal landscape, at which effects and ecological recovery potential should be assessed. This is because the smaller the scale of the simulated landscape, the more local effects dominate; while the potential for significant edge effects may also increase (the results of what individuals do when reaching the edge of the simulated landscape). Some useful criteria are that the landscape scale should be large enough, and the spatial configuration of the different landscape elements complex enough, to contain a viable long-term population of the species. In addition to this, the spatial dynamics of the species and their life-histories need to be taken into account. Landscapes that are so small that an average individual can travel from one side to the other are too small to generate long-term spatial dynamics associated with source-sink phenomena. A size for a focal landscape whereby the average individual or its progeny of the focal taxa of concern could not traverse it within 10 generations, could be a reasonable rule of thumb. Experience with the ALMaSS model system (Topping, pers. comm.) suggests that a 10 x 10 km landscape works well for the majority of terrestrial species (e.g. carabid beetles, small mammals and skylarks), but that larger areas are needed for large mammals (e.g. roe deers). Smaller areas can be used for low-mobile terrestrial species, but scales of less than 5 x 5 km generally introduce unwanted edge effects. Similar rules of thumb need to be developed for mobile aquatic species that inhabit interconnected surface waters like streams and ditches.

The conceptual framework presented in Figure 4 and further discussed in this section requires appropriate ERA tools to address recovery (i.e., experiments and models). Whilst field and semi-field approaches are already well developed, standard environmental scenarios for prospective ERA that allow integrated fate and effect modelling to address ecological recovery of populations of vulnerable non-target species are in their infancy. Nevertheless, experience with the application of mechanistic effect models in the ERA for assessed stressors has recently increased and examples of this can be found in recent issues of the scientific journals “Ecological Modelling” (Grimm and Thorbek, 2014) and “Environmental Toxicology and Chemistry” (Galic and Forbes, 2014). The landscape features incorporated in the environmental senarios for spatially explicit population modelling of potentially vulnerable NTOs may range from relatively simple to complex. Ideally, the modelling approach should be as simple as possible (easier to apply, input parameters less demanding) on the condition that the model outputs are sufficiently valid to support decisions (e.g. see reservations regarding artificial landscape configurations in section 7.2.3) (Topping, pers. com.; Skelsey et al., 2005; Bianchi et al., 2007). If the landscape features that are addressed in the environmental scenario are relatively simple it should be demonstrated that the adopted scenario in the modelling approach is a realistic worst-case with respect to exposure and effects, including ecological recovery. To demonstrate this, for a representative number of potentially vulnerable taxa and potential stressors, spatially explicit population modelling approaches linked to realistic landscapes including stressor dynamics (e.g. the ALMaSS approach developed by Topping et al., 2003) may be used to "calibrate" the modeling approaches based on simpler environmental scenarios. In all cases, an important scientific criterion that needs to be fulfilled for population models to assess risks for assessed products and NTOs is that they have to follow the principles of good modelling practice (e.g. EFSA PPR Panel, 2014).

As indicated above, the recovery option requires a complementary assessment regarding the consequences of not providing some ecosystem services during the recovery period. An example is the functional role of the aquatic pelagic invertebrate community. According to the PPR Panel guidance for pesticides (EFSA PPR, 2013a), aquatic invertebrates in edge-of-field surface waters are to be protected at the population level by considering their abundance and/or biomass. The recovery option allows small effects for a few months, medium effects for weeks and large effects for days on the abundance and/or biomass of vulnerable populations of invertebrates, as long as their reduction does not result in more persistent indirect effects. An important ecosystem service provided by freshwater invertebrates is the control of algal blooms (EFSA PPR, 2010) and this role is particularly relevant in freswater ecosystems of the Mediterranean region (higher temperatures and nutrient levels). Microcosm studies on the fate and effects of an insecticide have confirmed that allowing the recovery option for invertebrates that graze algae under Mediterranean conditions may result in more pronounced algal blooms (indirect effect) and a slower recovery of affected daphnids than under temperate test conditions (Van Wijngaarden et al. 2005). Other experimental pond studies with insecticides confirmed that under different environmental conditions and at exposure levels above the threshold of direct effects, secondary consequences of not providing some ecosystem services by the affected populations may result in clear differences in type and mangnitude of indirect effects and rate of recovery of affected endpoints (López-Mancisidor, 2008a, b; Knillmann et al., 2012 ; Liess et al., 2013).

8.3.3. Conceptual approach of ERA for invasive alien species that are harmful to plant health

The conceptual approach of ERA for IAS has been documented by the plant health Panel (EFSA PLH Panel, 2011) and was recently revised in the ERA of the apple snail for the EU (EFSA PLH Panel, 2014). The ERA framework applied by the EFSA PLH Panel is shown in Figure 11.

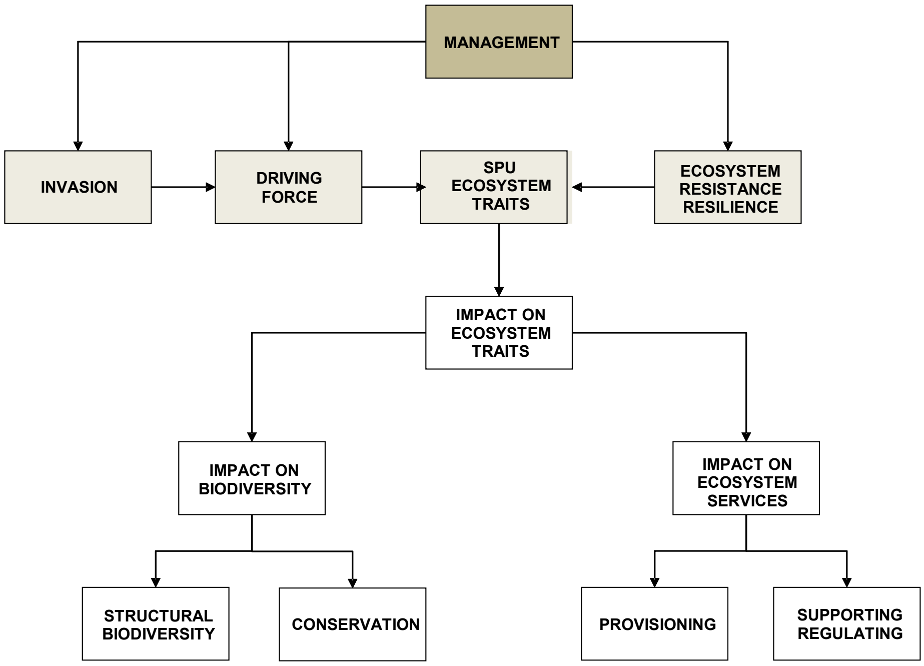


Figure 11: Scheme of the procedure for assessing the environmental risk posed by apple snails (EFSA PLH Panel, 2014). The scheme is derived from the one proposed in the ERA Guidance (EFSA PLH Panel, 2011)

The IAS is considered the driver of ecosystem change. The driving factor, also called driving force, is a factor directly or indirectly causing ecosystem changes. A direct driver unequivocally influences ecosystem processes by itself, while an indirect driver operates by altering one or more direct drivers. The indirect drivers are underlying (root) causes that are formed by a complex of social, political, economic, demographic, technological, and cultural variables. Collectively, these factors influence the level of production and consumption of ecosystem services. The causal linkage is almost always mediated by other factors (Tomich et al., 2010). The driving force is expressed in terms of density or abundance of the IAS.

The definition of impact relates to the specific SPU, a functional unit whose components (individuals, species or communities) are characterised by functional traits defining their ecological role (Vanderwalle et al., 2008).

The impact depends on (i) the resistance of the system defined as the ability of the ecosystem to continue to function without change when stressed by a disturbance that is internal to the system (Harrington et al., 2010); the resilience of the system defined as an ecosystem's ability to recover and retain its structure and function following a transient and exogenous shock event (Harrington et al., 2010); and (iii) the management measures in place to control the IAS.

Scenario analyses are performed for the impacts to be assessed under specific assumptions defining the scenarios of the assessment. The scenario analysis are attempts to explore what future developments may be triggered by a driving force, in this case an exogenous driving force, i.e. a driving force that cannot or can only partly be influenced by decision makers (Henrichs et al., 2010). Scenario analysis includes explicitly combination of qualitative and quantitative information and estimates (EEA, 2001). Most of the work is based on qualitative evaluation that can be translated into quantitative assumptions on the final state of the system (Henrichs et al., 2010).

The density of the driver of the ecosystem service change is introduced in the scenario analysis together with the spatial and temporal dimensions.

The impacts are assessed on:

- The Ecosystem traits or functional traits. A functional trait is a feature of an organism which has demonstrable links to the organism's function (Lavorel et al., 1997; Harrington et al., 2010). Thus, a functional trait determines the organism's response to pressures (response trait) and/or its effects on ecosystem processes or services (effect trait). Functional traits are considered to reflect adaptations to variation in the physical and biotic environment and trade-offs (ecophysiological and/or evolutionary) among different functions within an organism. In plants, functional traits include morphological, ecophysiological, biochemical and regeneration traits, including demographic traits (at population level). In animals, these traits are combined with life-history and behavioural traits (e.g. guilds: organisms that use similar resources/habitats). To evaluate the impact on the traits, the relationships between the driver of the ecosystem change and the ecosystem traits are assessed. Then the clusters traits–biodiversity and traits–Ecosystem services are identified. The clusters correspond to the multiple associations between traits and services (De Bello et al., 2010).

- The Ecosystem services: benefits that humans recognise as obtained from ecosystems that support, directly or indirectly, their survival and quality of life; ecosystem services include provisioning, regulating and cultural services that directly benefit people, and the supporting services needed to maintain the direct services (MA, 2005; Harrington et al., 2010).

- The Biodiversity: the variety of living organisms and the ecological complexes of which they are part (Harrington et al., 2010). It covers genetic, structural and functional components, which are represented at different organisational levels, from within-organism to individual organism, species, population, community and ecosystem levels (adapted from Secretariat of the CBD (2002), MA (2003) and extended according to Noss (1990)).

Only the negative impacts of IAS on the traits, ecosystem services and biodiversity components are assessed.

There are important similarities in the approach outlined for IAS and the approach outlined above for PPPs, GMOs and feed additives, but there are also some important differences. The key differences are:

- IAS are usually (with the exception of biological control agents of invasive plants) not intentionally applied in agricultural areas to achieve production goals, as is the case for PPPs, GMOs and feed additives, but they come as uninvited invaders at their own accord;

- As a result, the spatial distribution of these IAS is the outcome of natural and (usually inadvertent) human-assisted dispersal processes, rather than a spillover outside the area of intended application as for the other types of potential stressors above. The distinction between in-field and off-field is less relevant for IAS;

- The consequences of IAS are the result of ecological relationships with other species in the invaded ecosystems, such as herbivory or pathogenesis, and further interactions in the ecological network. While such ecological interactions are also relevant for other stressors, in the case of IAS, they are the primary impact, whereas for other stressors, they are indirect impacts, following from initial impacts on sensitive species.

- As the interaction between IAS and ecosystems is very long-term, the time scale of assessment is usually much longer (years to decades of years) than in the case of stressors that have toxic effects; hence the concepts of ecological recovery, while still relevant, apply to very different temporal scales.

- Selection of focal taxa in the case of impacts of IAS focuses on SPUs, while there is much focus in the initial phases of assessment on the ecosystem services that are to be protected. The choice of ecological entities for which the impacts are addressed follows from the identification of, first, the ecosystem services, and, second, the ecological entities that support these services. In the case studies that are currently available (EFSA PLH Panel, 2010b, 2013), these ecological entities are mostly at the supra-species level.

- Resilience is not defined according to the time scale of the life time of individuals, but according to the time scale of the overall ecosystem response.

While the protection goals for PPPs, GMOs, feed additives, and IAS are fundamentally similar, harmonization of procedures to assess recovery is currently difficult to implement pragmatically because of the differences in the nature and impacts of IAS as compared to other potential stressors.

9. CONCLUSIONS AND RECOMMENDATIONS

9.1. Conclusions

Recovery can be assessed at the levels of individuals, populations, communities, or functions. In broad terms, recovery can be thought of as the return of an ecological entity (e.g. structure such as abundance, or function such as an ecosystem service) to its normal operating range (sometimes referred to as baseline properties), having been perturbed outside of that range by a stressor (or multiple stressors). In order to assess recovery, it is first necessary to define what the normal operating range of the ecological entity and/or process is.

The appropriate point in a risk assessment at which the assessment of recovery should be considered and planned is at the problem formulation step, when specifying the specific protection goal(s). Ecological recovery should be considered at the relevant level of biological organisation and relevant spatial and temporal scales for each specific protection goal. In a following step, focal taxa, focal communities and/or focal landscapes should be identified, based on relevant traits.

The extent to which recovery is considered in current risk assessments relevant to EFSA varies with the risk assessment area. In environmental risk assessment schemes, specific protection goals are defined in terms of a "threshold option" (no effects permitted, so assessment of recovery is not relevant) or a "recovery option" (effects are inevitable and permitted within specified spatial and temporal frames, and recovery assessment is therefore important). For plant protection products, both threshold and recovery options apply, depending upon the protection goal. For genetically modified organisms and feed additives, the recovery option may be selected on a case-by-case basis. For invasive alien species that are harmful to plant health, the focus of environmental risk assessment is different to that of the potential stressors but ecological recovery is part of the scenario assumptions. In general, regulatory guidance documents and their supporting legislation provide very little specific information on how to assess recovery.

The introduction of potential stressors may be followed by stress-periods of limited duration (pulse disturbances) or in prolonged stress periods (press disturbances). The recovery option in environmental risk assessment is in theory feasible if the potential stressors cause pulse disturbances, but short-term exposures may result in long-term effects if impacted organisms are not able to re-colonize the stressed habitat.

Trait-based assessment is a valuable approach for recovery assessments. Traits can be viewed from the perspective of the assessment endpoint or the landscape. Key ecological traits that govern recovery time are life-history traits (i.e. fecundity, voltinism and lifespan), dispersal ability (i.e. active or passive), diet and foraging behaviour, and presence of life stages resistant to the potential stressor(s). Key landscape traits that govern recovery are the proportions, configuration and connectivity of exposed and non-exposed habitats. Recovery can be classified into two main types, depending upon whether it occurs *in situ* (internal recovery) or via dispersal (external recovery). Both types of recovery may be exhibited by the same ecological entity (e.g. at different stages in a species' life-history).

As with effects assessments, the main approaches to assess recovery are experimentation, prediction, monitoring and expert elicitation. The main tools for prediction of recovery are mechanistic models whilst experimental approaches involve semi-field and field studies. Both modelling and experimental approaches have strengths and weaknesses. For experimental studies, a key difference between effects assessment and recovery assessment is that the studies of recovery may require larger spatial and/or temporal scales, particularly if the organisms move between exposed and non-exposed habitats and if external recovery is key. Large-scale field monitoring studies are required as a reality check and to improve prospective environmental risk assessment procedures. In scenario development and prospective environmental risk assessment, rigorous expert opinion elicitation is usually required.

A number of theoretical concepts relate to the assessment of recovery (e.g. action at a distance, alternative stable states and metapopulation dynamics). The importance of these concepts varies with the stressor and risk assessment being conducted but in general they are more difficult to identify for more complex levels of ecological organisation. Depending upon the potential stressor(s) and ecological entities and/or processes being assessed for a specific protection goal, genetic adaptation may have an important bearing both on susceptibility to these stressors and recovery from stressor-induced effects.

Indirect effects may be especially pronounced if relatively large and long-term direct effects on non-target organisms are allowed (e.g. in-field effects of potential stressors like pesticides) and/or these effects cannot be avoided (e.g. the spread of an invasive alien species that are harmful to plant health). Indirect effects may persist longer than direct effects. In principle the magnitude and the duration of indirect effects at the ecosystem-level can be studied in (semi-)field experiments and by means of food-web models. The occurrence of persistent indirect effects at the landscape-level might be detected by conducting large-scale monitoring programmes, but the identification of causal relationships between different potential stressors and their direct and indirect effects will be difficult and probably requires the development of landscape-specific ecological interaction models.

As with effects assessment, the assessment of recovery is easier when stressors are considered in isolation in relatively simple ecological systems but this does not reflect those real-life situations which typically involve multiple stressors in more complex systems in which non-target organisms move between exposed and non-exposed habitats. These multiple stressors may affect the fitness of the ecological entity. Thus, it should be borne in mind that at the landscape-level both multiple natural stressors as well as the presence of non-exposed refuge areas may influence the recovery ability of an ecological entity, in addition to the potential stressors that are the subject of the environmental risk assessment.

Due to the complexity of ecological systems and the need to evaluate effects and recovery in spatial and temporal dimensions, a systems approach is required. The current Scientific Opinion brings together the above considerations in a conceptual framework to guide risk assessors and risk managers on how to integrate recovery assessments into environmental risk assessment. For a given specific protection goal, the conceptual framework links together the key parameters (i.e. focal taxa or communities, focal landscapes, and potential stressors), the environmental risk assessment tools (i.e. system modelling and semi-field or field experiments) and the supporting information, which includes the societal perspective as well as ecological monitoring and the scientific evidence base.

While the protection goals for plant protection products, feed additives, genetically modified organisms and invasive alien species (i.e. those species that are harmful to plant health) are fundamentally similar, harmonization of procedures to assess recovery is currently difficult to implement pragmatically because of the differences in the nature and impacts of invasive alien species as compared to the other potential stressors.

Assessing ecological recovery needs a systems-based approach and the assessment of ecological recovery needs to be integrated into the full risk assessment. In order to adopt a systems approach, several challenges were identified as follows:

- To define the normal operating range of ecological entities (bearing in mind that this may vary in time and between different ecosystems);
- To identify focal taxa, focal communities and/or focal landscapes;
- To appropriately assess recovery in cases where the recovery option only applies in-field but not off-field, even though (according to action at a distance) effects might also occur off-field (this would be relevant, for example, to plant protection products or genetically modified organisms);

- To predict the role of indirect effects on ecological recovery at the landscape level;
- To select appropriate spatial and temporal scales and key landscape traits for the assessment of impact and recovery of different organism groups and therefore to determine the right management and/or mitigation decisions (trade-off);
- To operationalize links between experimentation, modelling and monitoring, and between prospective and retrospective studies, to consolidate risk assessments;
- To parameterize population and food-web models including uncertainty;
- To establish predictive food-web and/or ecological interaction models that can be used in prospective environmental risk assessment;
- To develop good mechanistic effect models which are both manageable and realistic enough;
- To integrate systems approaches and multiple (potential) stressors into environmental risk assessment.

9.2. Recommendations

- Develop approaches to address and interpret uncertainty of recovery in environmental risk assessment (e.g. in assessing boundaries in model predictions);
- Develop approaches to address multiple potential stressors (occurring simultaneously and/or sequentially);
- Develop long-term predictions and assessments (following exposure to multiple potential stressors simultaneously and/or sequentially) which should be based on a realistic spatial scale, reflecting the landscape context, rather than single potential stressors assessed at a local scale;
- Organise information on species traits of non-target organisms and landscape properties in databases, to assist the selection of focal communities, species, processes and landscapes;
- Develop environmental scenarios that can be used in prospective environmental risk assessments to inform the design of (semi-)field experiments and to apply mechanistic effect models that aim to address the ecological recovery option;
- Consider whether a decision scheme would be useful to assist dialogue among stakeholders, when deciding for SPGs, whether the recovery option is appropriate.

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APPENDICES

Appendix A. Overview on recovery and specific protection goals for plant protection products, genetically modified organisms, feed additives and invasive alien species

Plant Protection Products (PPPs) Environmental risk assessment (ERA) is a standard part of the application procedure of active substances to place PPPs on the European Union (EU) market. Background documents include: Regulation (EC) No 1107/2009[5], Regulation (EC) No 546/2011[4], EC/SANCO (2002) (Guidance document on Terrestrial Ecotoxilogy), the Guidance Document of EFSA on Aquatic organisms (EFSA PPR Panel, 2013a) and the Guidance Document of EFSA on the risk assessment of PPPs on bees (EFSA PPR Panel, 2013b)					
Recovery	**Ecological entity**	**Attribute**	**Magnitude**	**Temporal scale**	**Spatial scale**
For vertebrates (birds, mammals, fish) **recovery** option is void since individual mortality and effects on reproduction are not allowed. **For other groups of organisms recovery** is assessed through semi-field (e.g. mesocosm) or field studies when a population or trait group reaches back the control level with a certain statistical power.	Aquatic organisms: Populations (for invertebrates, algae and macrophytes), individuals (acute) to populations (chronic) (vertebrates) to functional groups (microbes). Risks to aquatic microbes currently not assessed Non-target terrestrial invertebrates: Colonies for honeybees, populations for other non-target arthropods (NTAs); In-field populations for earthworms and soil dwelling arthropods Non-target terrestrial plants: Populations	Aquatic organisms: Diversity and abundance in numbers (for invertebrates) and/or biomass (for algae and macrophytes) Non-target terrestrial invertebrates: Survival, growth, reproduction, abundance, biomass, colony size for bees; Behaviour is not assessed as a separate endpoint but integral part of field studies and some first tier tests (e.g. by measuring parasitisation rates) Non-target plants: Germination (seedling emergence), biomass, vegetative vigour Microbes:	Aquatic organisms: Ecological threshold option: For all organism groups: negligible effects. Recovery option: Focus on vulnerable species of the sensitive taxonomic groups. The magnitude and duration of acceptable effects in (semi-)field studies is integrated in effect classes. Non-target terrestrial invertebrates: Bees 7% effect on colony size, increase of background mortality of foragers by a factor of 1.5, 2 or 3 depending on the duration of the increased mortality. The actual magnitude of acceptable effects on populations is not quantified. It is tolerated that NTAs are	Aquatic organisms: Recovery option: The total period of the effect due to (repeated) application of the PPP should not be longer than weeks to months (the recovery option in the new Guidance Document is based on recovery within 8 weeks of the most sensitive measurement endpoint) Non-target terrestrial invertebrates: Effects on colony size of bees should never exceed 7%, forager mortality can be increased for a certain period of time (e.g. a factor of 1.5 over 6 days, 2 over 3 days and 3 over 2 days), recovery within 1 year for in-field populations of NTAs and earthworms	Aquatic organisms: Small permanent water bodies (stream, pond, ditch) at the edge-of-field. Non-target terrestrial invertebrates: Honeybee colonies at the edge of treated fields; Treated fields and the immediate off-field for NTAs; Treated fields for in-soil organisms Non-target plants: The immediate off-field area of treated fields Microbes: Treated fields

	Terrestrial Microbes: Functional groups	Processes	exposed in-field to applied rates which are two times greater than the rates which lead to 50% effects on mortality and reproduction and in the off-field to rates which are 5 times lower than the rates which lead to a 50% effect.. Non-target plants: The actual magnitude of acceptable effects on populations is not quantified. It is tolerated that plants and seeds are exposed to concentrations which are 5 times lower than the EC_{50}. Microbes: +/-25% effect on nitrogen and carbon mineralisation	Non-target plants: No temporal scale defined Microbes: 100 days	
Genetically Modified Organisms (GMOs) - ERA is a mandatory part of the EU market registration procedure of GMOs					
Recovery	**Ecological entity**	**Attribute**	**Magnitude**	**Temporal scale**	**Spatial scale**
Potential adverse effects (including direct, indirect, immediate, delayed and cumulative long-term effects) on the environment are assessed on a case-by-case basis. However, there is no systematic	Case-specific. EFSA GMO Panel (2010a) specifies a number of risk areas and protection goals and EFSA GMO Panel (2010b) gives specific names of non-target organism (NTO)	The selection of Assessment and/or measurement endpoints depends on the GMO/trait/use combination and therefore is determined on a case-by-case basis during	Potential adverse effects (environmental harm) are quantified, using a comparative approach. Limits of concern are set on a case-by-case basis, in order to assess the biological relevance of observed differences between the	No predetermined guidance/agreement/proposals for allowed temporal scale of the effect nor for recovery. However, some of the temporal scale options used by the GMO Panel in its risk assessment relate to the potential for recovery, (case	No predetermined guidance/agreement/proposals for allowed spatial scale of the effect nor for recovery. Some of the spatial scale options used by the GMO Panel include: landscape,

analysis of the characteristics to estimate actual **recovery**. However, **recovery** is explicitly mentioned in EFSA GMO Panel (2010a, b), EFSA GMO Panel (2011) and Commission Decision 2002/623/EC. When a potential risk is identified, then the implementation of risk mitigation measures is advocated in order to reduce the identified risk to an acceptable level. In addition, post-market environmental monitoring is put in place to reduce remaining scientific uncertainties and to identify the occurrence of unanticipated adverse effects.	species.	problem formulation	GMO, the isolines (the same non-modified plant) and conventional counterpart	specific) management systems and to the assessment of long-term effects.	region, Member State, adjacent habitat and field. The GMO Panel advocates to reduce damage in the field, while other stakeholders might tolerate more damage in-field. The GMO Panel uses often and defines the term “receiving environment” in which genetically modified plants (GMPs) are deliberately released.
Feed Additives - Requirement of an ERA as part of the authorisation process (no mention of **recovery)**					
Recovery	**Ecological entity**	**Attribute**	**Magnitude**	**Temporal scale**	**Spatial scale**
Recovery is not considered	Populations in the terrestrial and aquatic environment as defined in Regulation (EC) No	Populations in the terrestrial and aquatic environment as defined in Regulation (EC) No	Not defined	Not defined	Not defined

	429/2008.	429/2008.			
Invasive alien pests (IAS) that are harmful to plant health - Council Directive 2000/29/EC provides the legal basis for the EU's plant health regulations (EFSA PLH Panel, 2011). Though it does not lay down specific requirements for an ERA, the assessment of potential consequences on the environment of introduction and spread of harmful organisms is included in the internationally recognised standards for pest risk assessment (IPCC, 2014). The assessment of consequences is not normative as it is for PPPs and GMOs, but the PLH Panel assesses impacts to support risk management decisions by the European Commission (EC). In the guidance for ERA (EFSA PLH Panel, 2011), the term "recovery" is used nor defined, but the opinion makes ample use of the concept of "resilience". In the context of this opinion, resilience is defined as the ability of an ecosystem to recover and retain its structure and function following a transient and exogenous shock. In the ecological risk assessment of the apple snail (EFSA PLH Panel, 2014), the effects of resistance, resilience and management on snail population dynamics in the short (5 years) and the long term (30 years) were estimated.					
Recovery	**Ecological entity**	**Attribute**	**Magnitude**	**Temporal scale**	**Spatial scale**
Recovery is explicitly accounted for in the PLH approach to ecological risk assessment for plant pests, by considering ecosystem resilience at different time scales. Ecosystem resilience is defined by the ecosystem capacity to cope with environmental change, through buffering, adaptation and re-organisation and maintenance of key ecosystem functions.	The ecological entity is identified in accordance with the expected impacts of the alien species. In the case of the apple snail, shallow fresh water areas were identified as the ecological entity at risk.	Attributes of the ecological entity at risk are identified ad hoc, using expert elicitation, in consideration for the effects on biodiversity and ecosystem services. In the case of the apple snail, three classes of attributes ("traits" in the idiom of the PLH Panel) were identified: attributes related to the macrophytes, attributes related to water quality, and attributes related to biodiversity.	The PLH Panel uses in its assessment of impact ratings on a five-point ordinal scale: minimal, minor, moderate, major, and massive (EFSA PLH Panel, 2014, p 74). Specific guidance is given to assist the risk assessor in determining the rating score. Based on ratings by multiple assessors, an average risk rating and an uncertainty score are determined. The PLH Panel does not compare the assessment outcome to normative endpoints, which is the remit of the risk manager.	The temporal scale is in the order of years to decades of years.	The spatial scale corresponds to the extent to which the pest has an impact within the selected timeframe.

Appendix B. Properties of the potential stressors regarding their trends in use in EU and their exposure and effects

1. Plant protection products (PPPs)

1.a. Types of PPPs

Plant protection products can be classified by target organism such as herbicides (affecting algae and vascular plants), insecticides (affecting insects and other arthropods), and fungicides (affecting fungi and Oomycetes), nematicides (kill nematodes), acraricides (control mites) amd molluscidides (affecting snails and slugs).

1.b. Trends in use

Agricultural land covered 44% of the EU's territory or 137 million hectares in 1997[34]. Depending on the crop and production system different amounts of pesticides are applied. The total amount of PPPs used in the EU was more than 200 000 tons in Europe (Eurostat, 2007). The use of pesticides increased steadily in the 1990s, stabilising in the late 90s and then declining continuously from 1999 onwards. The trend of declining volumes of pesticides use after 2003 is confirmed by industry sales data from the European Crop Protection Association (ECPA)[35] for the years 2009 and 2010. Reasons for the declining amounts of pesticides may be due to the review, at EU level, of authorisations of PPPs on the market which has led to the withdrawal of products used in large amounts, and their replacement by products used at lower doses (i.e. pesticides applied at a few grammes per hectare instead of kilogrammes per hectare). This decrease, since the end of the 1990s, is mainly due to the reduction in the use of fungicides which represent the bulk of all PPPs used in the EU. In contrast to fungicides, there was an increase in the use of herbicides, mainly applied to arable crops. The amount of insecticides applied doubled from 1996 to 2000 and has slightly reduced since then. The amounts of pesticides used differ depending on the crop. In some crops such as fruits and vegetables greater amounts of pesticides (in particular fungicides) per hectare are applied compared to arable crops. The sustainable use directive (Directive 2009/128/EC)[36] aims at further reduction and safer use of pesticides including training of pesticide users, awareness raising, minimising or banning the use of pesticides in critical areas for environmental and health reasons, and promoting the principles of integrated pest management.

Note that a decrease in the amounts of pesticides used may not imply a decrease in the risk to the environment, since many active compounds which are used nowadays present a higher toxicological potential than compounds used in the past. However, many current pesticides have a higher specificity to target species than compounds used in the past.

1.c. Exposure and effect assessments

When considering exposure to PPPs and exposure conditions that influence population-level effects and recovery it is important to note that the term exposure may be used differently in fate/exposure modelling and in effects modelling. The result of fate/exposure modelling is the spatial and temporal distribution of the predicted environmental concentration (PEC) of the PPP in a relevant environmental compartment, also referred to as the exposure profile (see e.g. EFSA PPR Panel, 2013a). In current exposure assessments on the basis of e.g. FOCUS models and scenarios (http://focus.jrc.ec.europa.eu/, online), however, the focus is on predicting peak (PEC_{max}) and time-weighted average exposure concentrations (PEC_{twa}) as well as temporal exposure profiles for a limited

[34] http://ec.europa.eu/agriculture/envir/report/en/terr_en/report.htm

[35] http://www.ecpa.eu/page/industry-statistics

[36] European Commission 2009, Directive 2009/128/EC, establishing a framework for Community action to achieve the sustainable use of pesticides OJ L 309, 24.11.2009, p. 71

number of in-crop and off-crop situations, and less on spatially explicit exposure modelling at the landscape-level. Since environmental concentrations of a PPP may vary both in time and space, the spatial-temporal statistical distribution of exposure concentrations together with the percentile to be taken from this spatial-temporal distribution are essential parts of exposure assessment goals underlying ERA. The selection of the appropriate statistical population of exposure concentrations of course should also depend on the spatial-temporal configuration (e.g. related to home range) of the (most vulnerable life-stage of the) taxon/functional group at risk (see e.g. EFSA PPR Panel, 2013a; Appendix A). If an exposure estimate is computed as an average of multiple data points (over time, space, or both), there is uncertainty in the resulting estimate of the mean. Therefore, it is customary to select a certain percentile as a conservative estimate of the true PEC. In pesticide exposure assessment in the EU it is common practice to select the overall 90th percentile PEC_{max} for a limited number of selected in-crop and off-crop situations as defined in current FOCUS exposure scenarios.

In effects modelling, “exposure” ideally is the concentration that the organism is exposed to internally at the relevant target-sites. This internal exposure results from a combination of external exposure concentrations in relevant environmental compartments/patches of habitat where the organisms dwell (PECs provided by fate/exposure modelling), ecology and behaviour of the organism that affect uptake of the PPP, and internal toxicokinetics. In practice, however, available toxicity data are expressed in terms of external exposure concentrations (e.g. in water, soil, food) determined under more or less standardised test conditions, particularly in lower tiers. Since spatial and temporal variability in exposure concentrations of PPPs is more the rule than the exception for the majority of organisms in agricultural landscapes and edge-of-field surface waters, the appropriate linking of external exposure concentration to internal exposure concentrations in organisms is an important exercise for which toxicokinetic/toxicodynamic models (e.g. Jager et al., 2011) may be used.

As mentioned above, in current ERA for PPPs the exposure assessment is based on selected models and scenarios with a limited spatial resolution (e.g. FOCUS) and the approach followed is presumed to be realistic-worst case, particularly with respect to PEC_{max} calculations for individual active ingredients. Whether the selected exposure scenarios are realistic-worst case as well for assessing long-term exposure concentrations remains to be evaluated. Furthermore, to appropriately address external recovery potential for potentially vulnerable populations, information on the spatial and temporal dynamics of PPPs exposure in the agricultural landscape under evaluation may be required. The results of fate/exposure modelling as currently used may work well for individuals or populations that are stationary and/or where internal recovery mechanisms play an important role (where only temporal dynamics matter). In this case, pesticide fate and effects are investigated in separate modelling to predict recovery. However, there are difficulties in implementing the approach where individuals are mobile and external recovery processes play an important role, or if the potential stressor is mobile in the environment. Populations can extend over large areas (e.g. individuals of some bird species can visit different areas in Europe). When individuals are mobile the spatial aspect of exposure becomes particularly important in determining the time-variable internal concentration of exposed organisms. If the potential stressor is applied to fragments of the whole population then, unless the population is completely sedentary and the proportion of the population exposed easily calculated, it is not possible to separate effects and exposure in determining recovery.

Abiotic, biotic and agronomic parameters describing the environmental scenario and the behaviour of organisms form complex interactions. Currently, there is no agreed procedure on how to derive a distribution from all these factors and choose a certain percentile from that due to the overwhelming number of potential factors involved (EFSA PPR Panel, 2014). The alternative is to develop standard environmental scenarios in such a way that the realistic extremes are taken into account. Such scenarios would consider both the spatial and temporal profile of potential stressors as the spatio-temporal context of the landscape with its land uses and non-crop habitats and other potential refuges that may act as sources for recovery. It is suggested that to achieve this, a dynamic modelling of exposure in space and time is carried out and linked directly with the effects modelling (EFSA PPR Panel, 2015). For example, this type of approach has been used in aquatic systems to study population-level risks of pesticide exposure in an interconnected system of edge-of-field surface waters (Focks et al., 2014a), and in terrestrial systems in animal, landscape and man simulation system (ALMaSS) models (e.g. Topping et al., 2014).

2. Genetically modified organisms (GMOs)

2.a. GMO technology

Techniques used to produce GMOs and techniques, not considered to result in genetic modification when used, are defined in the respective Annexes 1A of Directives 2001/18/EC and 2009/41/EC. Since the introduction of the first commercially cultivated genetically modified plants (GMPs) in the mid-1990’s in the USA and Canada, novel breeding and genetic modification techniques have evolved in rapid pace with the result that in some instances it is as yet unclear whether they give rise to novel plants pursuant to the EU GMO legislation or whether such plants may be exempt of the current GMO market approval procedure. A clarification of what techniques will be considered to result in a GMO is of special interest for crop plants as some of these new techniques have been subject to field trials only during the last few years, and it is to be expected that such plants will reach the market very soon. With the objective to verify the adequacy of EFSA guidelines to perform a risk assessment of plants developed through a number of new techniques, the EFSA Panel on GMOs released a Scientific Opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis (EFSA GMO Panel, 2012). For definitions it is recommended to consult the Scientific Opinion (EFSA GMO Panel, 2012). The EFSA GMO Panel compared the hazards associated with plants produced by cisgenesis and intragenesis with those obtained either by conventional breeding techniques or by transgenesis. The Panel concluded that similar hazards can be associated with cisgenic and conventionally bred plants while novel hazards can be associated with intragenic and transgenic plants. The Panel is of the opinion that all of these breeding methods can produce variable frequencies and severities of unintended effects that cannot be predicted and thus, need to be assessed case by case. Independent of the breeding method, undesirable phenotypes are normally removed and discarded during selection and testing programs by breeders. The risks to the environment, and in particular to NTOs, will depend on the new characteristics of the plant, exposure factors, the extent of the cultivation, and the receiving environment in which the crop is grown.

“Stacked events” are defined as GMPs that are derived from conventional crossing of GMPs with one or more GMP events (EFSA GMO Panel, 2007). To date, stacked event GMPs are not licensed for commercial cultivation in Europe but they are favored over single event GMPs by farmers in other countries. Stacked events combining herbicide tolerance and insect resistance are deployed in cotton, soybean and maize. For example for maize, six different Cry toxins of the soil bacterium *Bacillus thuringiensis* (Bt) are expressed in one plant and combined with two herbicide tolerant genes that code for tolerance against the herbicides Gluphosinate and Glyphosate, i.e. eight single events are stacked in the same maize plants. This eight-event stack combining herbicide tolerance and insect resistance was launched in the USA and Canada in 2010 (James, 2013). The trend for increased use of stacks will continue and intensify as more traits become available to farmers. Stacking has become an important feature of GM technology to reduce the risk of build-up of resistant target populations of insects and weeds. Also, GMPs are stacked to enlarge the activity spectrum against multiple targets. As a consequence of this, multiple potential stressors may act simultaneously against NTOs and recovery may become more critical.

2.b. Trends in use

In 2014, GMPs were commercially cultivated worldwide, over a total area of 181.5 million hectares (James, 2014) which accounts for approximately 12% of all arable land presently in use for agricultural crop production. Major GM crops commercially grown are soybean, maize, cotton, oilseed rape, sugar beet and alfalfa with either herbicide tolerant or insecticide resistant, and both traits combined (stacked) in the same plants. During the 19 years of commercial GM crop cultivation

(1996-2014), herbicide tolerant has consistently been the dominant trait representing, in 2014, 57% of the total GM crop acreage, whereas insecticide resistant crops and stacked products (herbicide tolerant/insecticide resistant) were grown on 15% and 28%, respectively, of the total GM crop acreage.

In the EU, the only approved GM crop for commercial cultivation is the insect resistant maize MON810 that expresses an insecticidal protein from the soil living bacterium Bt. Bt maize is protected in Europe mainly from attack by two lepidopteran key pests, the European corn borer (*Ostrinia nubilalis*) and the Mediterranean corn borer (*Sesamia nonagrioides*). In Spain, maize MON810, which expresses a single Bt Toxin (Cry1Ab), has been cultivated since 1998, and in 2014 the acreage was over 131 000 hectares of the total 143,000 hectares of Bt maize grown in the EU. The total GM Bt maize acreage grown in the EU in 2014 corresponds to roughly 1% of the total maize area of approximately 13 million hectares cultivated in the EU (Meissle et al., 2011). However, in certain areas of Spain with high corn borer infestations (e.g. in Catalonia), Bt maize adoption reached 84% in 2010 (James, 2010).

Currently, no GM animals or derived products are on the EU market, nor have any application for GM animals been received in the EU. However, scientific developments suggest submissions may be made in the future across a range of species. Therefore EFSA has developed comprehensive risk assessment guidelines for GM animals (EFSA GMO Panel, 2013a).

2.c. Exposure and effect assessments

The guiding principle of assessing exposure and effects arising from genetic modification consists of comparing, in a case-by-case approach, the genetic, physiological, ecological and agronomic characteristics of the GMP with those of the non-modified plant under comparable conditions. Differences in effects are a function of the plant characteristics, the introduced trait, intended use and the quality of the receiving environment (Roberts et al., 2013). Pathways and levels of exposure will vary accordingly, and it may not be possible to estimate the exposure precisely without detailed knowledge of these characteristics. Likelihood of exposure can be expressed either qualitatively using an ordered categorical description (such as “high”, “moderate”, “low” or “negligible”) or quantitatively as a relative measure of probability (from zero to one) (for details see EC, 2002). However, if qualitative terms are used to express such likelihoods, then the link between likelihood and probability should be accounted for. Thus, whatever term is chosen, an indication of the range should be given, within a numeric scale of 0 to 1, to which the term is intended to refer. For example, “the likelihood of exposure of a non-target lepidopteran species to Bt toxin (Cry1Ab protein) in field margins was estimated to be moderate, where "moderate" in this context means within the probability range of 0.1 to 0.4” (EFSA GMO Panel, 2010a).

Based on the above mentioned information, a list of potentially exposed NTOs (plants, animals, microorganisms) in-crop and off-crop is established case-by-case. Conceptual models with worst-case scenarios are proposed that will guide the assessment of effects on selected NTOs in different ecosystems (terrestrial, aquatic) belonging to the receiving environment (Sears et al., 2001; Garcia-Alonso et al., 2006; Romeis et al., 2008; Carstens et al., 2010, 2012). Hypotheses of exposure and effects on populations of selected organisms are then formulated and tested in a stepwise approach.

Exchange of genes between crops and their wild relatives has occurred ever since the first plants have been domesticated (Connor et al., 2003). However, exposure of wild relatives to gene flow of crop plants has received major attention only in the context of GMPs. Environmental concerns of hybridization of GMPs with wild relatives include the potential for altered fitness of the crop plant itself and of its wild relatives. An increased fitness may enable plants with the GM trait to become more invasive of semi-natural and natural habitats with unwanted effects on biodiversity and ecosystem services (Sanvido et al., 2007), or to be more persistent in agricultural crops, exacerbating a weed problem (EFSA GMO Panel, 2010a) and possibly induce an increase in herbicide use

(Mortensen et al., 2012). Alternatively, gene flow to wild relatives may decrease the fitness of hybrid offspring (Devos et al., 2012).

Genetically modified herbicide tolerant (GMHT) oilseed rape is not licensed in the EU for commercial growth. However, some Member States have concerns that traits of GMHT oilseed rape would alter fitness, persistence and invasiveness, and induce adverse ecological effects. Field studies have though confirmed that herbicide tolerant traits in oilseed rape do not confer a fitness advantage, unless the herbicides for which tolerance is obtained are applied. Devos et al. (2012) conclude that GMHT oilseed rape is neither more likely to survive, nor to be more persistent or invasive than its conventional counterpart in the absence of the herbicides for which tolerance is conferred. The ability of oilseed rape to successfully invade ruderal habitats appears to be limited by the availability of seed germination sites and interspecific plant competition, and there is no evidence that genes conferring herbicide tolerance significantly alter its competitive ability.

3. Feed additives

3.a. Types of feed additives

Article 6 of Commission Regulation (EC) No 1831/2003 defines the five categories of feed additives as follows: (i) Technological (preservatives, antioxidants, emulsifiers, thickners, stabiliser, gelling agents, binders, radionuclide control, anticacking agents, acidity regulators, silage additives, denaturants), (ii) Sensory (colourants and flavourings), (iii) Nutritional (vitamins, trace elements, aminoacids, urea), (IV) Zootechnical (digestibility enhancers, gut flora stabilisers, favourably affecting the environment, other zootechnical additives), (v) Coccidiostats and Histomonostats.

3.b. Trends in use

Feed additives used in the EU are those that have been granted an authorisation as requested under Regulation (EC) No 1831/2003. Those additives are granted authorisation for specific animal species, defined conditions of use and for a period of 10 years. In accordance with Article 17 of Regulation (EC) No 1831/2003, the Commission has established the EU Register of feed additives[37], which is divided into two parts. The first part contains the list of modifications to the Register and the current authorisations[38] and the second contains the list of additives for which no application for re-evaluation was submitted before the deadline of 8 November 2010[39].

Most data on the volumes of feed additives used in the EU are held by private companies and treated as confidential. The data available in the open literature are scarce and scattered, making it difficult to determine spatial and temporal patterns of use.

3.c. Exposure and effect assessments

The amounts of feed additives that may potentially reach the environment depend on the quantity of manure/slurry produced by livestock, techniques used in (in- or outdoor) animal husbandry, and are limited by the legislated maximum amounts of nitrogen that can be applied to arable land.

For the terrestrial and aquatic compartments, the ERA of feed additives (and their metabolites) to non-target species is conducted following a stepwise approach (Commission Regulation (EC) No 429/2008[10]). The first phase aims at characterising the risk from exposure by calculating PECs in the respective compartment of concern. It is assumed that if the PEC does not exceed a pre-set trigger value during the time of the application, it will not be of concern for the rest of the year when the

[37] http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm
[38] http://ec.europa.eu/food/food/animalnutrition/feedadditives/docs/comm_register_feed_additives_1831-03.pdf
[39] http://ec.europa.eu/food/food/animalnutrition/feedadditives/docs/comm_register_feed_additives_1831-03_annex2.pdf

additive is not in use. Therefore, unless the FA is persistent, there is no build-up over time and recovery is not relevant since there was no expected effect in the first place. If a risk is highlighted during the first phase, additional information is collected to assess the potential for feed additives to affect non-target species in the environment (i.e. PEC/PNEC ratios, which are used as indicators of risk and also called risk quotients, are calculated to determine whether the risk is acceptable or not. The FOCUS tool developed for the risk assessment of PPPs has been adopted for the refinement of PECs of feed additives (EFSA FEEDAP Panel, 2007).

To determine a meaningful exposure assessment for a FA originating from terrestrial farm animals, realistic worst case scenarios based on typical manure/slurry management strategies are made. For example, additional information on agricultural practice and metabolism and/or degradation (e.g. the metabolic fate of the additive in fish, and other processes that may change its bioavailability) are collected to refine the PEC assessment. However, in most cases, toxicity data for relevant species are missing (see EFSA FEEDAP Panel, 2007 for a review of the strategies used in the EU and the gaps and lack of detailed information on this topic). Therefore, final decisions are usually made on a PEC falling below pre-specified (although arbitrary) threshold values. Because of the limited toxicological potential of most feed additives these threshold levels are believed to indicate negligible risks (although for many feed additives, it is not checked experimentally).

Copper and zinc accumulation in sediments underneath sea cages has been highlighted as being of potential toxicological concern that could attenuate recolonisation of biota following cessation of fish farming in an area (Champeau, 2013). Whilst copper in sediments comes primarily from antifouling treatment of the net pens, the accumulation of zinc is mostly caused by zinc supplementation of fish feeds. Using the maximum allowed concentration in feed in the EU and the simple exposure models recommended by FEEDAP in its technical guidance, it was calculated that zinc concentrations in sediment under sea cages would not exceed 182 mg/kg sediment, which is below the PNEC (Monteiro et al., 2010). However, measurements of sediments collected near salmon farms in Canada and New Zealand showed that zinc in sediments are in reality often above PNEC even though zinc contents in feeds were similar to those in the European market (Morrisey et al., 2000; Brooks and Mahnken, 2003; Champeau, 2013). This is clearly an issue that deserves further attention.

Supplementation of animals with trace elements, such as copper and zinc, presents problems in that farm animals have requirements that need to be satisfied, but high levels of trace elements in excreta can potentially be unsafe to the environment. For this reason maximum contents have been set for trace elements in animal feeds. When used in terrestrial livestock, trace elements will be excreted by the animal in the faeces and will enter the soil environment when the faeces are applied, as a fertiliser to land, or in the form of manure, slurry or litter. During the farming of fish in sea cages, it is unavoidable that copper and zinc are deposited in the sediment underneath the cage.

EFSA commissioned a study on the environmental impact of copper and zinc used in animal nutrition (Monteiro et al., 2010). In this particular study, it was concluded that the use of zinc as a FA does not pose direct concern for the agricultural soil compartment, but that there is a potential environmental concern related to drainage and run-off of zinc to surface water. Most vulnerable to these processes are acid sandy soils. The use of zinc as a FA at currently authorised levels in marine aquaculture was predicted not to be an appreciable risk to the environment. Due to the concerns rose in the report (Monteiro et al., 2010), EFSA published an Opinion in which it proposed reducing maximum authorised levels of zinc in animal feeds (EFSA FEEDAP Panel, 2014). It was estimated that introducing newly-proposed total maximum contents, provided they are applied in feeding practices, would result in an overall reduction of zinc emissions from animal production of about 20%.

In the study by Monteiro et al. (2010), copper was implicated to pose a potential risk to soil organisms specifically as a result of the application of piglet manure. Levels of copper in other types of manure were deemed too low to create a risk. There might also be a potential environmental concern related to contamination of sediment due to drainage and the run-off of copper to surface water. The use of copper-containing additives in aquaculture, up to the maximum authorised copper level in feeds, was not expected to pose an appreciable risk to the environment.

Zinc and copper are also used as veterinary drugs for piglets to prevent diarrhoea and are in this application administered orally at doses an order of magnitude higher than those of feed additives. This use is not assessed by EFSA but falls under the European Medicines Agency (EMA) responsibility.

Two classes of parasiticides (i.e., coccidiostats and histomonostats) which can be administered as feed additives are stable and may remain active long (for months) after being excreted by the animals that fed upon them. It has been highlighted that some veterinary drugs aimed at controlling endoparasites, in particular macrocyclic lactones, can potentially have detrimental effects on manure-decomposing communities such as dung beetles and flies (Beynon 2012a, b; Beynon et al., 2012; Wall and Beynon, 2012). The loss of dung colonisers was shown to delay pat decomposition, a significant ecosystem service (Wall and Beynon, 2012). The Scientific Committee noted that the EFSA ERA of feed additives focusses on collected manure spread on land and does not directly address the potential impact on manure-decomposing communities in pats from livestock on pastures. Likewise, the standard OECD tests on earthworms, proposed by the FEEDAP Panel to assess the potential of effects to organisms living in soil, does not fully address impacts on communities living in the manure itself. Although experimental studies to date have not examined effects of feed additives (including coccidiostats and histomomostats) on colonisers of manure and the resulting impacts on dung decomposition, effects on these communities cannot presently be excluded.

4. Invasive alien plant pest species (IAS) that are harmful to plant health

4.a. IAS in Europe

The total number of IAS currently identified in Europe amounts to 12 122 species (DAISIE, 2014), part of which are pests[40] of plants, either cultivated or wild.

4.b. Trends of extent in Europe

The combined effects of the increased human impacts on the environment imposed by the Industrial Revolution, and the globalisation of trade, have favoured the introduction of IAS to new territories (Hulme, 2009). As a result, in the last two centuries numerous non-native species have become successfully established over large parts of Europe (Hulme, 2007). Partly due to climate change, the rate of biological invasions keeps increasing in the EU and worldwide, representing one of the major, and growing, causes of biodiversity loss and species extinction (Caffrey et al., 2014), with an estimated cost for the EU of at least € 12 billion per year and damage costs continuing to rise. These impacts vary greatly across IAS and the affected ecosystems. There is therefore an urgent need to develop standardized methods to assess the impacts of IAS taking into account traits of the IAS and the characteristics of the receiving environment (Dick et al., 2014). The EFSA PLH Panel proposed a framework to establish a standardised methodology to assess such impacts of IAS (EFSA PLH Panel, 2011).

4.c. Exposure and effect assessments

The concept of exposure is interpreted as the potential pest density (or prevalence) over time. The pest population density represents the most important state variable necessary to describe current and predicted trophic relationships between a pest and its host and therefore between a pest and the ecosystem that it affects over time (EFSA PLH Panel, 2011, 2014).

[40] Within this Scientific Opinion, "pest" is used as a synonym for an invasive alien species, detrimental to plant health.

Pest population density can be expressed in terms of number of individuals or amount of biomass per unit area or volume. In the case of phytophagous pests, the option to consider biomass can be even more informative than number of individuals when assessing the population pressure on the environment. In the case of plant pathogens, the population density can be considered equivalent to the prevalence of the disease/symptoms in a given plant population per unit of area or volume (EFSA PLH Panel, 2011). The EFSA Plant Health Panel assesses the effects of an alien species on an ecosystem as:

- Effects on ecosystem attributes. Here a very broad range of attributes can be considered, e.g. biomasses of functional groups in the ecosystem, chemical properties of surface water (e.g. phosphorus concentration, oxygen concentration, pH).

- Effects on ecosystem services and biodiversity: as the percentage of reduction (i) in the provision level of the ecosystem services, and (ii) in each biodiversity component, in relation with the alien species density.

In the assessment of impacts of IAS on the environment, not only the effects of the species itself have to be assessed, but also those of control measures that are carried out to mitigate pest impacts. Mitigation efforts following the introduction of alien species affecting plants are likely to result in intensified control efforts, especially in agriculture, but also in natural habitats. Any control effort, but in particular increased use of pesticides, will cause further impacts (Chalak, 2009; Chalak et al., 2010). Alternative control methods, such as biocontrol by introduction of an alien natural enemy species, also carry risks, in particular the attack of native species (Messing and Wright, 2006).

GLOSSARY

Actual recovery: The return of a perturbed ecological entity or process (e.g. species composition, population density or ecosystem service) to its normal operating range, or to a level that is not significantly different from that in control or reference systems.

Adaptation: 1. The process of adjustment of an individual organism, population or community to environmental stress. 2. Process of evolutionary modification which results in improved survival and reproductive efficiency. 3. The enhancement of fitness of an organism by any morphological, physiological, developmental or behavioural trait (Lincoln et al. 1982).

Adverse (environmental) effects: Any effect that causes harm to the normal functioning of plants or animals. Establishing what an adverse effect is and which effect is regarded as environmental harm is a complex process of also analysing and implementing policy objectives taking into account broader societal and relevant stakeholder values. It requires that risk managers define what is important to protect and the magnitude of the effect that is to be regarded as harmful or unacceptable.

Alien species: According to the EU Directive on Invasive Alien Species an 'alien species' means any live specimen of a species, subspecies or lower taxon of animals, plants, fungi or micro- organisms introduced outside its natural range; it includes any part, gametes, seeds, eggs or propagules of such species, as well as any hybrids, varieties or breeds that might survive and subsequently reproduce, (see also invasive alien species).

Assessment endpoint: An explicit expression of the environmental value to be protected, operationally defined as an ecological entity and its attributes (Suter et al., 1993).

Biodiversity: The variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

Carrying capacity: The maximum number of organisms that can be supported in a given area or habitat; usually denoted by *K*; the upper asymptote of the logistic equation (Lincoln et al. 1982).

Cisgenesis: The genetic modification of a recipient organism with a gene from a crossable – sexually compatible – organism (same species or closely related species). This gene includes its introns and is flanked by its native promoter and terminator in the normal sense orientation. Cisgenic plants can harbour one or more cisgenes, but they do not contain any parts of transgenes or inserted foreign sequences. To produce cisgenic plants any suitable technique used for production of transgenic organisms may be used. Genes must be isolated, cloned or synthesized and transferred back into a recipient where stably integrated and expressed.

Community (biocenosis): An association of interacting populations, usually defined by the nature of their interactions, by their combined ecological functions, or by the place in which they live (adapted from Ricklefs and Miller, 1999).

Direct effect: An effect that is mediated solely by the interaction between the specified receptor and the environmental stressor, i.e. when the receptor is exposed directly to the stressor and as a result the receptor exhibits a response or an ecological effect.

Demographic trait: A trait that influences the population growth rate and ultimately drives population densities and age distributions (Rubach et al., 2011). Also referred as a life-history trait.

Dormancy: A state of relative metabolic quiescence in which viable propagules (e.g. seeds, spores, winter or dry-season eggs) do not germinate.

Ecological entity: Any biological and/or ecological unit able to provide an ecosystem service (e.g. individual, population, functional group, community).

Ecological recovery: The return of the perturbed ecological endpoint (e.g. species composition, population density) to its normal operating range.

Ecosystem: A dynamic complex of plant, animal and microorganism communities and their nonliving environment interacting as a functional unit (MA, 2003).

Ecosystem function: See ecosystem process.

Ecosystem process: Ation or event that results in the flow of energy and the cycling of matter (Ellis and Duffy, 2008). Examples of ecosystem processes include decomposition, production, water and nutrient cycling (MA, 2003).

Ecosystem service: The benefit people obtain from ecosystems. Ecosystem services include provisioning services such as food and water; regulating services such as flood and disease control; cultural services such as spiritual, recreational, and cultural benefits; and supporting services such as nutrient cycling that maintain the conditions for life on Earth.

Ecosystem structure: Attribute related to the instantaneous physical state of an ecosystem. There are several characteristics to describe ecosystem structure. For example, species population density, species richness or evenness, and standing crop biomass.

Environmental risk assessment (ERA): The evaluation of the probability and seriousness of harmful (or adverse) effects to human health and the environment, whether direct or indirect, immediate or delayed, following exposure to a potential stressor.

Exposure assessment goal: An explicit expression of the type of exposure, as well as the spatial and temporal characteristics of the exposure, that has to be assessed for a specific potential stressor, and that needs to be defined in a dialogue between risk assessors and risk managers so that it can be linked to the specific protection goal.

External recovery: Recovery governed by the immigration of individuals by active or passive dispersal.

Feed additive: According to Commission Regulation (EC) No 1831/2003 feed additives are substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions: favourably affect the characteristics of feed or animal products, favourably affect the colour of ornamental fish and birds, satisfy the nutritional needs of animals, favourably affect animal production, performance or welfare and, and have a coccidiostat or histomonostatic effect (Article 5(3)).

Fitness (population fitness): The relative ability to survive and reproduce of a given genotype or phenotype conferred by adaptive morphological, physiological or behavioural traits.

Focal species, taxa, process, landscape: Those species, taxa, processes and landscapes focused on in ERA. Focal species/taxa are indicative for specific habitats as well as vulnerable to the potential stressor of concern and in this way represent a larger group of other species/taxa to be protected. A focal process is indicative for an essential ecological process vulnerable to the potential stressor of concern and in this way representative for other ecological processes. A focal landscape concerns the type of landscape that has to be considered in the environmental scenario in order to allow a realistic worst-case ERA for the focal species/taxa of concern.

Food web: A representation of the various paths of energy flow through populations in the community (Ricklefs, 1990).

Functional group: A collection of organisms with similar functional trait attributes, and that are likely to be similar in their response to environmental changes and effects on ecosystem functioning (Hooper et al. 2002).

Functional redundancy: A characteristic of species within an ecosystem where certain species contribute in equivalent ways to an ecosystem function such that one species may substitute for another. Note that species that are redundant for one ecosystem function may not be redundant for others.

Functional trait: A measurable property (e.g. mobility, feeding behavior, trophic level, and place in the food web) of an organism, which has demonstrable links to the organism’s function (Lavorel et al., 1997; Harrington et al., 2010).

Genetically modified organism (GMO): An organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination (EC, 2001).

Hazard (harmful characteristics): The characteristics of a potential stressor that can cause harm to or adverse effects on human health and/or the environment.

Hysteresis: The time-based dependence of an ecosystem function on current and past levels of stressor. The dependence arises because the history of the system affects the state of the ecosystem function.

Indirect effect: An indirect effect involves effects being transmitted to the specified receptor through an indirect route involving one or more other, intermediary, receptors. A predatory non-target organism for example could be affected indirectly by a stressor in several ways, including effects of the stressor reducing the abundance of its prey species, its intra-specific or inter-specific competitors, its pathogens or its parasites.

In-field area: The in-crop area and its boundaries that are managed by the farmer in the context of the crop management.

Internal recovery: The population recovery facilitated by the survival of individuals or resting propagules (e.g., seeds or ephippia), and their subsequent growth and/or reproduction, depends upon surviving individuals within the area affected (previously or currently) by a stressor (i.e., excluding population recovery facilitated by immigration – see also external recovery).

Intragenesis: A genetic modification of a recipient organism that leads to a combination of different gene fragments from donor organism(s) of the same or a sexually compatible species as the recipient. These may be arranged in a sense or antisense orientation compared to their orientation in the donor organism. Intragenesis involves the insertion of a reorganised, full or partial coding region of a gene frequently combined with another promoter and/or terminator from a gene of the same species or a crossable species.

Invasive alien species (IAS): Plants, animals, pathogens and other organisms that are non-native to an ecosystem, and which may cause economic or environmental harm or adversely affect human health. The EFSA plant health panel assesses risks posed by invasive alien species that are harmful to plant health. Therefore, within the context of this opinion, the term IAS refers to invasive alien species that are harmful to plant health. Strictly, the term “invasive” refers to the tendency of a species to disperse and extend its spatial range, or colonize systems from which it was previously absent. An organism is “alien” if it does not naturally occur in a system or area.

Landscape: An area comprising a system of interest (e.g. agricultural system) at a relatively large scale resulting in heterogeneity in space such as fields or habitat patches.

Life-history trait: See demographic trait.

Measurement endpoint: Measurable quality related to the valued characteristics chosen as the assessment (Suter et al., 1993). Within the context of ERAs that fall under the remit of EFSA this concerns a quantifiable response to a potential stressor that is related to the assessment endpoint.

Metapopulation: Populations of the same species connected through immigration and emigration (Hanski and Gilpin, 1991).

Minimum viable population: An estimate of the lower bound in number of individuals required for a high probability of survival of a population over a given period of time.

Non-target arthropod (NTA): An arthropod species that is not intended to be affected by the potential stressor under consideration.

Non-target organism (NTO): An organism that is not intended to be affected by the assessed stressor under consideration.

Normal operating range (NOR): The acceptable bounds or range in values of a measurement endpoint that is normally observed during a pre-defined period in the undisturbed ecosystem of concern.

Off-field area: Area outside the managed “in-field area”.

Plant Protection Product (PPP): A substance (or device) used to protect (crop) plants from damage by killing or reducing pest organisms or by mitigating its effects.

Potential recovery: The disappearance of the stressor to a level/concentration at which it no longer has adverse effects on the ecological entities of interest and after which recovery of impacted populations theoretically can start if there is a ready supply of propagules (e.g. offspring of surviving individuals or recolonisation).

Population: A group of individuals of the same species.

Potential recovery: The point in time at which the stressor diminishes to a level at which it no longer has adverse effects on the ecological entities of interest and after which recovery of impacted populations theoretically can start if there is a ready supply of propagules (e.g. offspring of surviving individuals or recolonisation).

Potential stressor: used as “ potential environmental stressor” and meaning any physical, chemical, or biological entity resulting from the use of a regulated product or the introduction of an invasive alien plant species related to the food/feed chain that is assessed in any area of EFSA’s remit and that can induce an adverse response in a receptor (Romeis et al. 2011). Potential stressors may adversely affect specific natural resources or entire ecosystems, including plants and animals, as well as the environment with which they interact (http://www.epa.gov/risk_assessment/basicinformation.htm).

Press disturbance: Relatively long-term disturbance due to gradual or cumulative pressure on a system. In ERA it concerns a long-term response of an endpoint following a single or repeated exposure to one or more stressors.

Protection goal: The objectives of environmental policies, typically defined in law or regulations (Romeis et al., 2011).

Pulse disturbance: Disturbance that occurs as a relatively discrete event in time. In ERA it concerns a response of an endpoint following exposure to a stressor in which both the exposure and effect periods are relatively short-term.

Recovery option: Specific protection goal option accepting some population-level effects of the assessed stressor if ecological recovery takes place within an acceptable time-period.

Recovery time: The time period from when the stressor has dropped to a level/concentration at which it no longer has adverse effects until the moment that the ecological entity or process has returned to its normal operation range.

Refugia: An area in which an ecological entity can survive through a period of unfavourable conditions.

Resilience: The amount of disturbance that can be absorbed by an ecosystem before the system redefines its structure (i.e. deviates from its normal operation range), or the time (recovery time) it takes for the ecosystem to return to a stable state, within the normal operation range following, the disturbance (Gunderson, 2000).

Resistance: 1. A genetic adaptation allowing an organism to cope with the effect of exposure to a stressor to which it once was susceptible. 2. The property of an ecosystem to resist change when exposed to a stressor.

Risk: The combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequences occur.

Service providing unit (SPU): The systematic and functional components of biodiversity necessary to deliver a given ecosystem service at the level required by service beneficiaries (Luck et al., 2003; Vanderwalle et al., 2008).

Sink population: A local sub-population within a spatially-structured populationthat does not produce enough offspring to maintain itself through future generations without immigrants from other populations.

Source population: A local sub-population within a spatially-structured population that produces an excess of offspring above those needed to maintain itself through future generations. The excess offspring provide a source of immigrants to other sub-populations.

Species trait: A species trait is a well-defined, measurable, phenotypic or ecological character of an organism, generally measured at the individual level, but often applied as the mean state of a species (McGill et al., 2006; Rubach et al., 2011). Traits reflect the morphological, physiological, behavioural, ecological or life-history expression of an organism's adaptations to its environment that may also be regarded as properties of the taxon or population to which the organism belongs (Frimpong and Angermeier, 2010).

Specific protection goal (SPG): An explicit expression of the environmental value to be protected, operationally defined as an ecological entity and its attributes (Suter et al., 1993).

Stressor: Any physical, chemical, or biological entity that can induce an adverse response in a receptor (Romeis et al. 2011).

Threshold option: Specific protection goal option accepting no to negligible population-level effects of exposure to an assessed stressor.

Trait: A well-defined, measurable, phenotypic or ecological character of an organism, generally measured at the individual level, but often applied as the mean state of a species (McGill et al., 2006).

Voltinism: A trait of a species pertaining to its number of broods or generation per year or per season.

Vulnerable species: A vulnerable species is a species with a relatively high sensitivity for a specific stressor, a high chance to become exposed and/or high risks of indirect effects plus a poor potential for population recovery.

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ALMaSS	Animal, Landscape and Man Simulation System
BIOHAZ Panel	EFSA Panel on Biological Hazards
Bt	*Bacillus thuringiensis*
CBD	Convention on Biological Diversity
CEF Unit	Food Ingredients and Packagings Unit
DAISIE	Delivering Alien Invasive Species Inventories for Europe
EC	European Commission
ECx	Concentration where x % effect was observed/calculated
ECHA	European Chemicals Agency
ECPA	European Crop Protection Association
EEA	European Environmental Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EPA	Environmental Protection Agency
ERA	Environmental Risk Assessment
EU	European Union
FEEDAP Panel	EFSA Panel on Additives and Products or Substances used in Animal Feed
FOCUS	FOrum for the Co-ordination of pesticide fate models and their USe
GIS	Geographic Information System
GM	Genetically modified
GMHT	Genetically modified herbicide tolerant
GMO(s)	Genetically modified organism(s)
GMO Panel	EFSA Panel on genetically modified organisms
GMP	Genetically modified plant
IAS	Invasive alien species (that are harmful to plant health for this opinion)
IPCS	International Programme on Chemical Safety

JRC	Joint Research Centre
MDD	Minimum detectable difference
NOR	Normal operating rage
NTA	Non-target arthropod
NTO	Non-target organism
OECD	Organisation for Economic and Co-operation Development
PEC	Predicted environmental concentration
PEC_{max}	Maximum predicted environmental concentration
PEC_{twa}	Time-weighted average predicted environmental concentration
PLH Panel	EFSA Panel on plant health
PNEC	Predicted no effect concentration
PPP(s)	Plant protection product(s)
PPR	Plant protection residue
PPR Panel	EFSA Panel on plant protection residue
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCEHR	Scientific Committee for Environmental Health Risks
SPG	Specific protection goal
SPU	Service providing unit
UK	United Kingdom
US	United States
USA	United States of America
WHO	World Health Organisation