Scientific Committee mandate on Environmental Risk Assessment

21 June 2016, Brussels, Roundtable with NGOs

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Environmental risk: harmonising assessment, protecting biodiversity

EFSA has published two Scientific Opinions on environmental risk assessment (ERA), with a third to follow shortly. Reinhilde Schoonjans explains the issues at the heart of this major project.

How is ERA relevant to EFSA's work?

Environmental risk assessment is central to much of what we do. EFSA performs ERA as part of its evaluations of "regulated products" – pesticides, genetically modified organisms, and additives in food and animal feed – and of invasive alien species that are harmful to plant health. So as well as assessing the potential risks to human health from such products, we also look at the harm they may cause to the environment.

Why have you produced these opinions?

It has become apparent in recent years that because of the different requirements laid

Subject area

Cross-cutting science

Related topics

Environmental Risk Assessment
Pesticides
Plant health
Genetically Modified Organisms

Related News

Cooperating in times of crises

Corporate, Cross-cutting science

published: 03 Dec 2015

Register for the open Scientific Committee plenary meeting

Cross-cutting science

published: 25 Sep 2015

AIM OF THE MANDATE

Regardless of **the type of potential stressor**

- Plant Protection Products (PPP),
- Genetically Modified organisms (GMO),
- Invasive Alien Species (IAS),
- Feed Additives (FA)

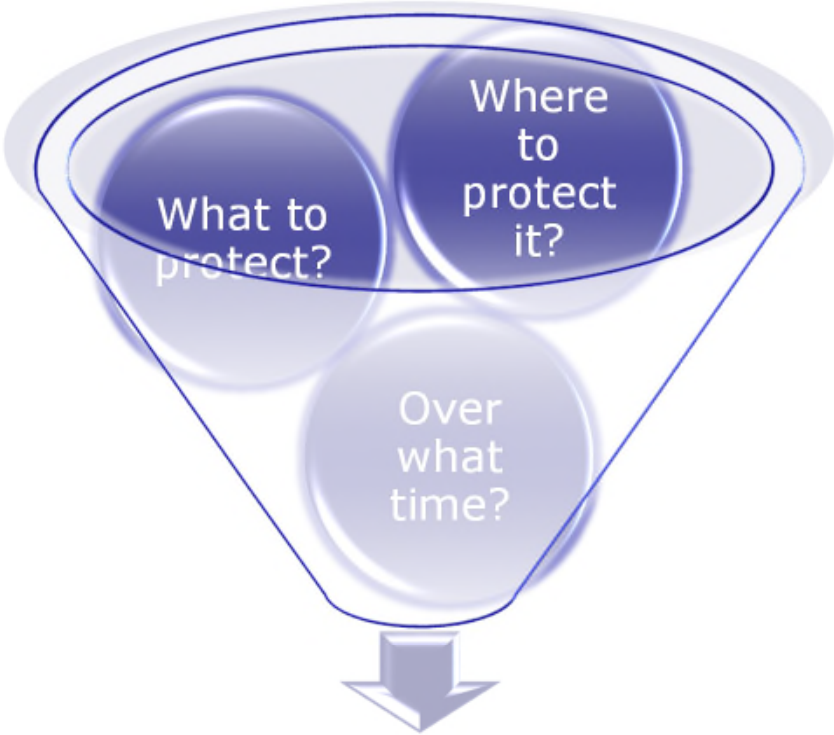
harmonise approaches when:

Proposing specific environmental **protection goal options** (SPGs)

Considering **endangered species** (or species of conservation concern) as potential non-target organisms

Integrating the temporal/spatial **recovery** of non-target organisms

01 Deriving specific environmental protection goal options (SPGs) for use in ERAs



SPG based on ecosystem service/SPU combination

GUIDANCE FOR SPECIFIC PROTECTION GOALS FOR ERA

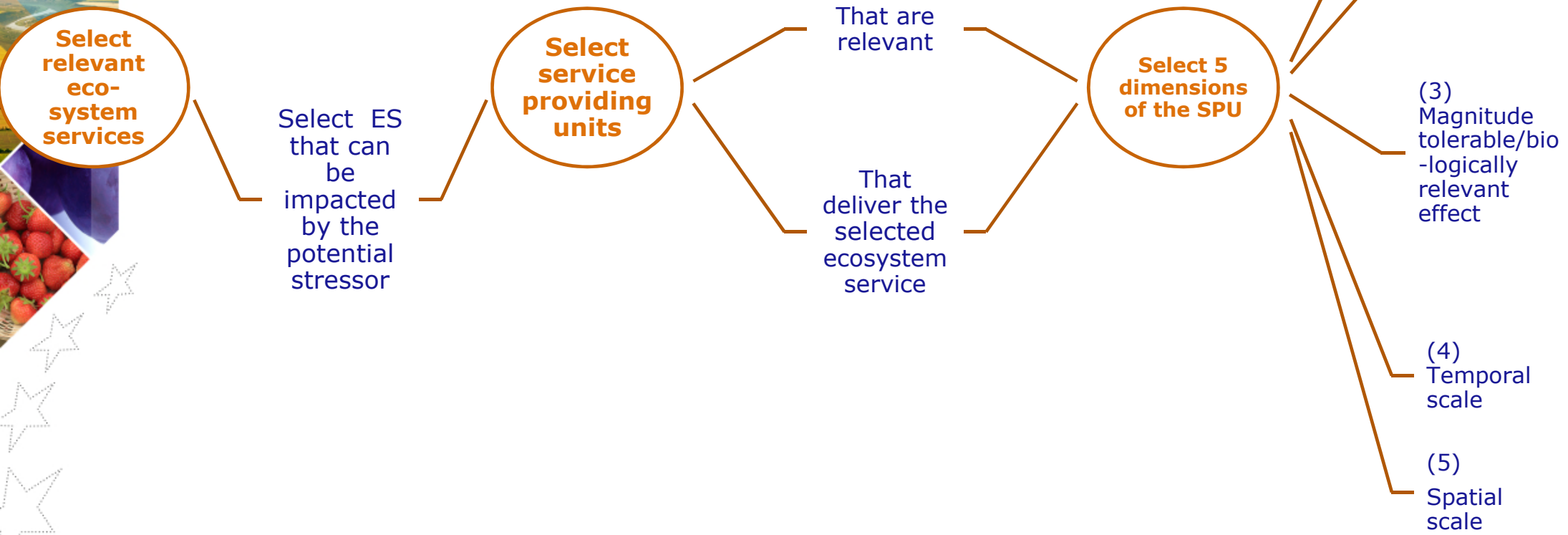
Harmonised **framework**, **accounting for biodiversity and ecosystem services**, to make broad/vague policy protection goals operational

Extends prior work by PPR Panel in 2010 to **a wider range of potential stressors** under EFSA's remit

Implementation by risk assessors during **the problem formulation** at the start of ERA

THE METHOD

Three Steps



EXAMPLE

Soil organisms exposed to feed additives: SPG proposal

ES: All services applicable to soil microorganisms, soil invertebrates, plants
SPU: Soil microorganisms, soil invertebrates, plants

Dimensions	Options
Ecological entity	Individual – [(meta)population] – functional group – community – ecosystem – habitat
Attribute	Behaviour – [survival] – [growth] – [reproduction] – abundance – biomass – [process] – biodiversity – landscape or habitat structure
Magnitude	[Negligible] – small – medium – large
Temporal scale	[Not applicable] – Days – weeks – months – seasons – years – decades – generation – rotation
Spatial scale	[In crop/field] – edge of field/field margin – [nearby off-crop] – protected area – watershed – landscape – region – continent

SPG = No additional effect on survival, growth, reproduction and nitrogen transformation processes, beyond those caused by farming practices themselves, of soil microorganisms, soil invertebrates and plants in the first 5–20 cm soil in the field and nearby off crop

The proposed approach supports the protection of biodiversity

- Source of many ecosystem services, plays an essential role in sustaining ecosystem functioning
- Conservation value as a «cultural service»
- Attribute to protect

DEVELOPMENT AND STATUS OF THE DOCUMENT

Steps of development

Scientific Colloquium November 2013

- Mandate discussed with all stakeholders
- Colloquium report published

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Draft amended after panel consultation & public consultation (2015)

- Stakeholders, observers from RA bodies
- Individual comments & answers published

↓

Draft discussed & finetuned with the EC on 11 April 2016

See following slides

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Adopted by the SC on 21 April 2016

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Published on 17 June 2016

Context and examples

- 1.3 (Aim of the Guidance): Clarifies in detail the purpose of the document and the respective role of RM and RA
- section 1.7 (Biodiversity in an agricultural context): Illustrates (a) that the proposed SPG framework is also applicable for potential stressors in non-pristine environments impacted by anthropogenic activities, and (b) explains the role of biodiversity in an agricultural context
- Appendix A (Examples of how SPUs and their five dimensions can be used to define SPG options in problem formulation): Examples serve to explain how SPG options can be proposed by risk assessors of EFSA on the basis of the methodological framework provided in the document.

PURPOSE AND ROLE DIVISION

Method to derive SPG options	Selection of SPG
SC document is about **method harmonisation** between EFSA Panels in deriving SPGs options for ERA	SC document does **not propose SPGs as such** (needs RM involvement)
The role of RAs is to propose possible SPG **options** based on scientific criteria, acknowledging existing general protection goals	**Selecting SPG** is a RM responsibility (involving cost – benefit analysis based on environmental, economical and political criteria)
The method was discussed and involved **RM consultations**	**Continuous** RA - RM dialogue needs to be optimised

GENERAL ADVANTAGES OF THE PROPOSED METHOD

We do not have all the detail of its implementation in each case now, but

The method itself is found to be a robust, systematic and transparent tool

It is applicable to all potential stressors and ecosystems

The method offers the same (easy to understand) language over different areas, allows to compare and facilitates trade-off decisions

SPG definition as part of the ERA problem formulation

Agreed SPGs beforehand render the problem formulation and ERA more efficient

SPGs enhance transparency when

- Comparing to SPGs for other potential stressors
- Separating scientific elements from other RM considerations
- Structuring the (public) debate on risk assessments

EFSA panel can demand fit-for-purpose datasets that

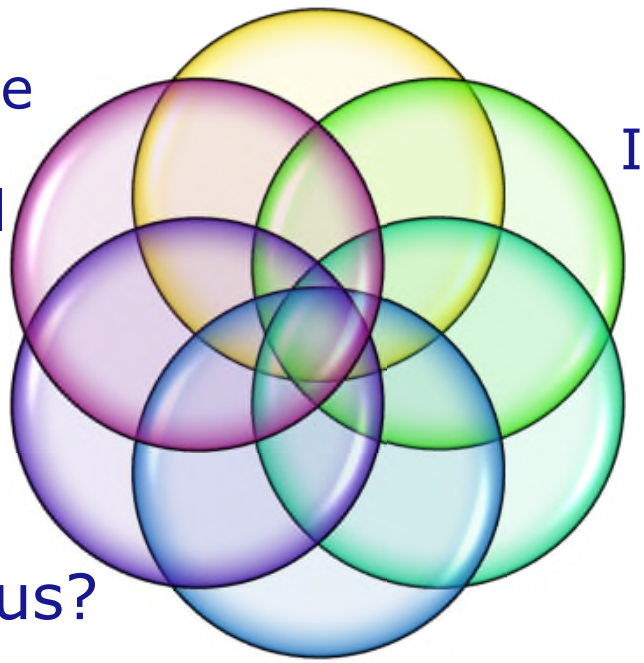
- Show to consider biodiversity in a comprehensive manner
- Are calibrated to appropriate tier and against a predefined benchmark (limits of concern)

02

Covering endangered species as potential non-target organisms in ERA

What is the spatial/termporal scale of endangerment?

Indirect effects from the application of the stressor in agricultural context?



Is there co-occurrence with the stressor?

Do they have poorer recovery?

Population viability status?

Are they more toxicological sensitive?

Discussion of the extent to which endangered species are covered in the current ERA schemes (= in an agricultural context)

Analys of the **legal basis** and the relevant ecological and biological features used to classify a species as endangered

Review of the characteristics that determine **vulnerability** and whether endangered species can suffer more than non-endangered species from potential stressos

DEFINITION ENDANGERED SPECIES

Endangerement is related to spatio-temporal scale

- Listed in one or more ‘red lists’ as threatened (i.e. EU, global IUCN Red List or national/regional red lists
- Rare based on the classification of Rabinowitz’s seven classes of rarity (including ‘endemics’, ‘classic rarity’, ‘habitat specialists’ and ‘truly sparse’ species)

Compared to standard test species

- Not enough data to generalise, but examples show that they can be due to
  - Slow life-history traits, low population size
  - Habitat destruction, low genetic variation
  - Differences in TK/TD mechanisms and traits: food and habitat specialists with phylogenetic loss of certain detoxification pathways
  - Lack of evolutionary experience in interacting with invasive species

GMO and Invasive alien species

- The protection of endangered species is explicitly mentioned during problem formulation

- ERA schemes allow a tailor-made assessment and selection of one or more endangered species
  - 5 GMO scenarios further explained: exposure to transgene product, altered interaction between GM plant and associated fauna, altered persistence and invasiveness, introgressive hybridisation potential, altered farm management practice
  - Invasive apple snail example

Mitigation and monitoring

Plant Protection Products

- General guidances based on the selection of vulnerable non-target species and assessment factors
  - Probably covering many endangered species
  - Only exceptionally mentioning of some rare plants and amphibian larval stages
- Tier 1 acute toxicity further analysed for 4 organism groups:
  - Testing closely related species: little gain in protection (95%)
  - Laboratory single species tox tests show high variability for birds, insects and crustacea; lower variability for fish

Feed Additives

- ERA does not tolerate any population effect on any species in the environment
  - Endangered species implicitly covered

CHALLENGES AHEAD

RA + RM

- Make specific protection goals for endangered species
- Opinion gives examples of SPG options

RA - EFSA Panels

- Use the check-lists of traits that influence vulnerability
- Check assessment factors to cover endangered species in ERA
- Justify use of surrogate species: trait-based

Others + EFSA

- Centralised trait database to group risk assessment information
- Ecological modelling – multiple stressors
- Local scale assessments

THANKS FOR YOUR ATTENTION

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