7 October 2020

# EFSA

## Guidance on ERA for GM animals 2013

**Reinhilde Schoonjans**

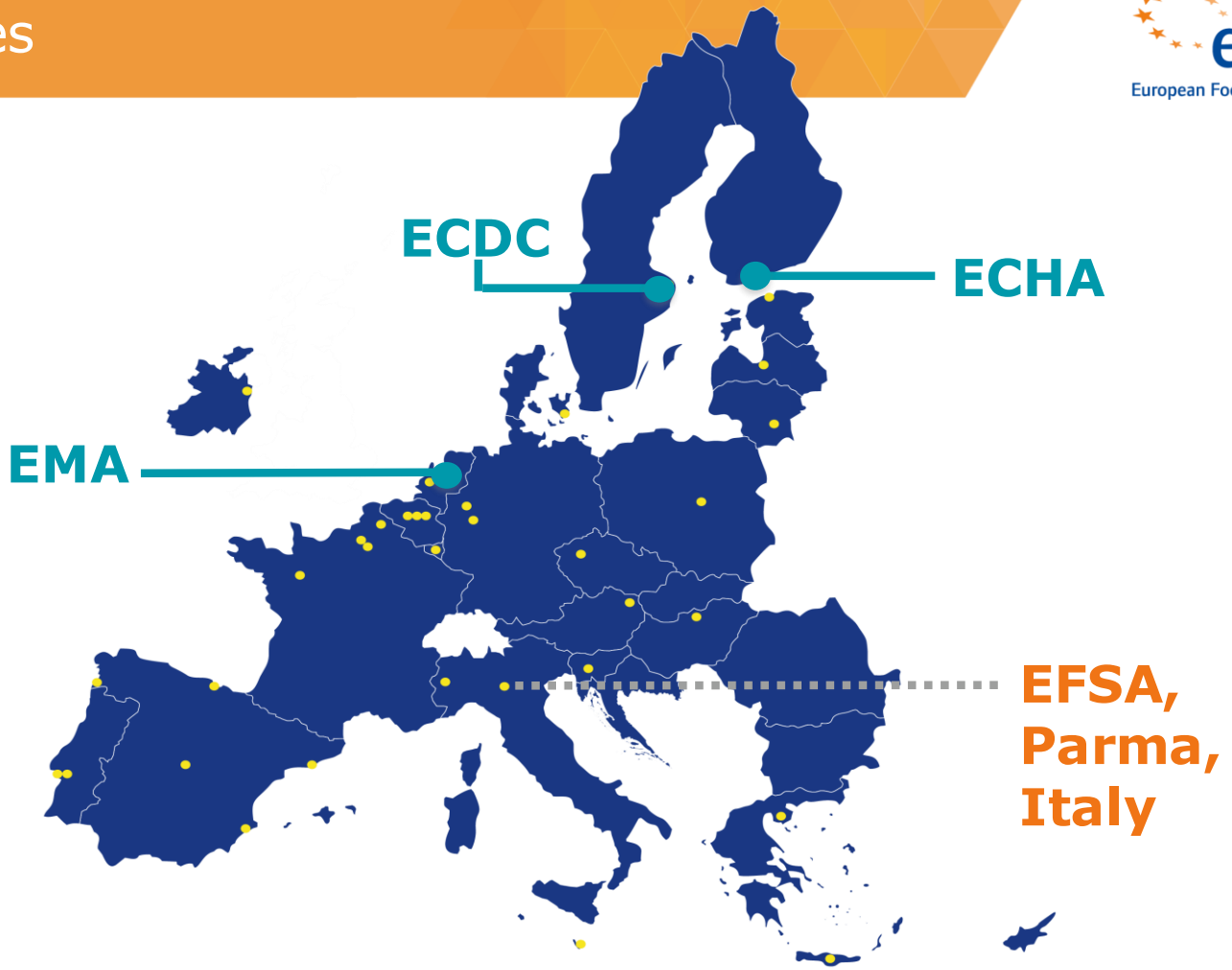
Yann Devos and Elisabeth Waigmann

Senior Scientist

Trusted science for safe food

efsa
European Food Safety Authority

# EU agencies



# Keeping food safe in the EU

# What EFSA does not do

# Genetically modified organisms

SCOPE:

Deliberate release into the environment (not contained use).

For Food/Feed use mainly (excl. Medicinal use).

Main GMOs: from microorganisms to plants to animals

European Food Safety Authority

EFSA Journal 2013;11(5):3200

SCIENTIFIC OPINION

# Guidance on the environmental risk assessment of genetically modified animals[1]

**EFSA Panel on Genetically Modified Organisms (GMO)[2,3]**

European Food Safety Authority (EFSA), Parma, Italy

## ABSTRACT

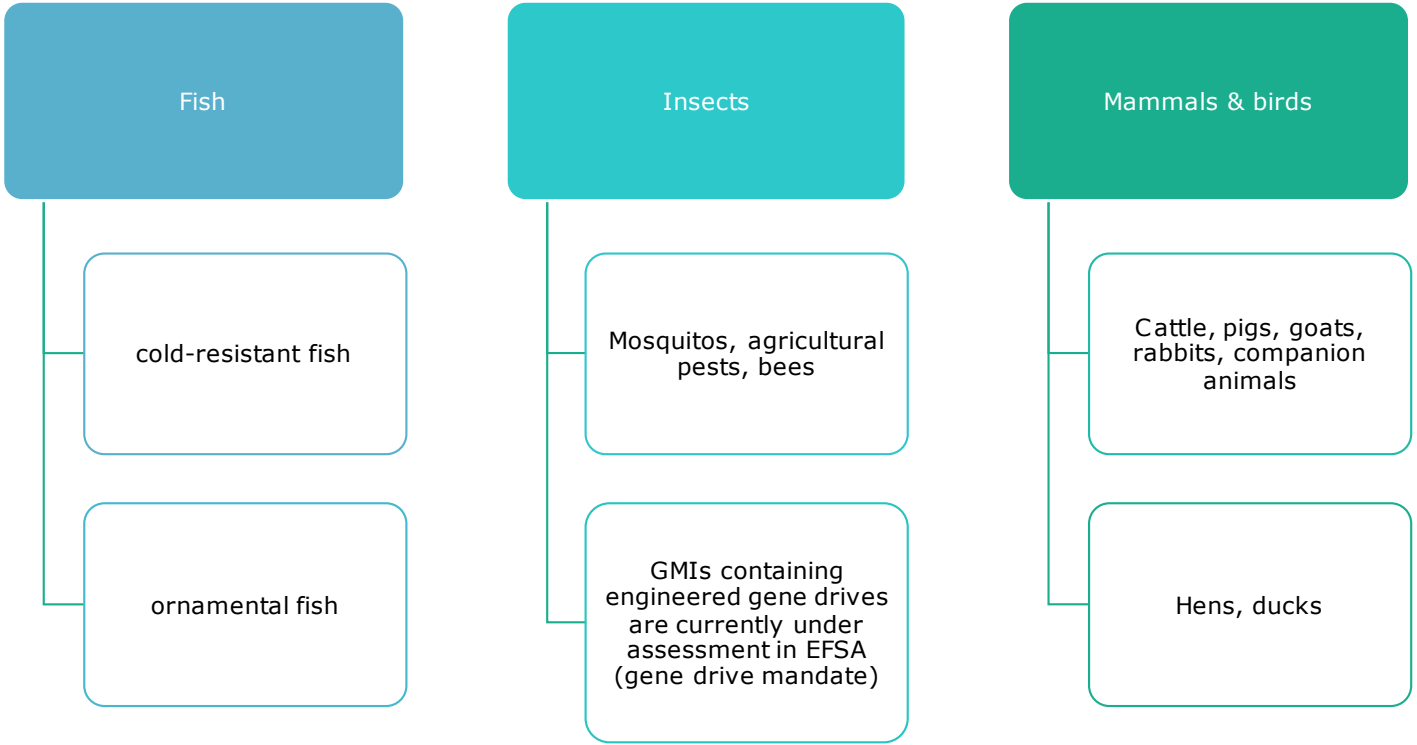
This document provides guidance for the environmental risk assessment (ERA) of living genetically modified (GM) animals, namely fish, insects and mammals and birds, to be placed on the European Union (EU) market in accordance with Regulation (EC) No 1829/2003 or Directive 2001/18/EC. It provides guidance for assessing potential effects of GM animals on animal and human health and the environment and the rationales for data requirements for a comprehensive ERA. The ERA should be carried out on a case-by-case basis, following a step-by-step assessment approach. This document describes the six sequential steps for the ERA of GM animals, as indicated in Directive 2001/18/EC: (1) problem formulation including hazard and exposure identification; (2)

Previous presentation on Food/Feed safety of GM Animals (EFSA, 2012), by Antonio Fernandez Dumont in workshop of 8 September

Guidance produced upon request from the European Commission

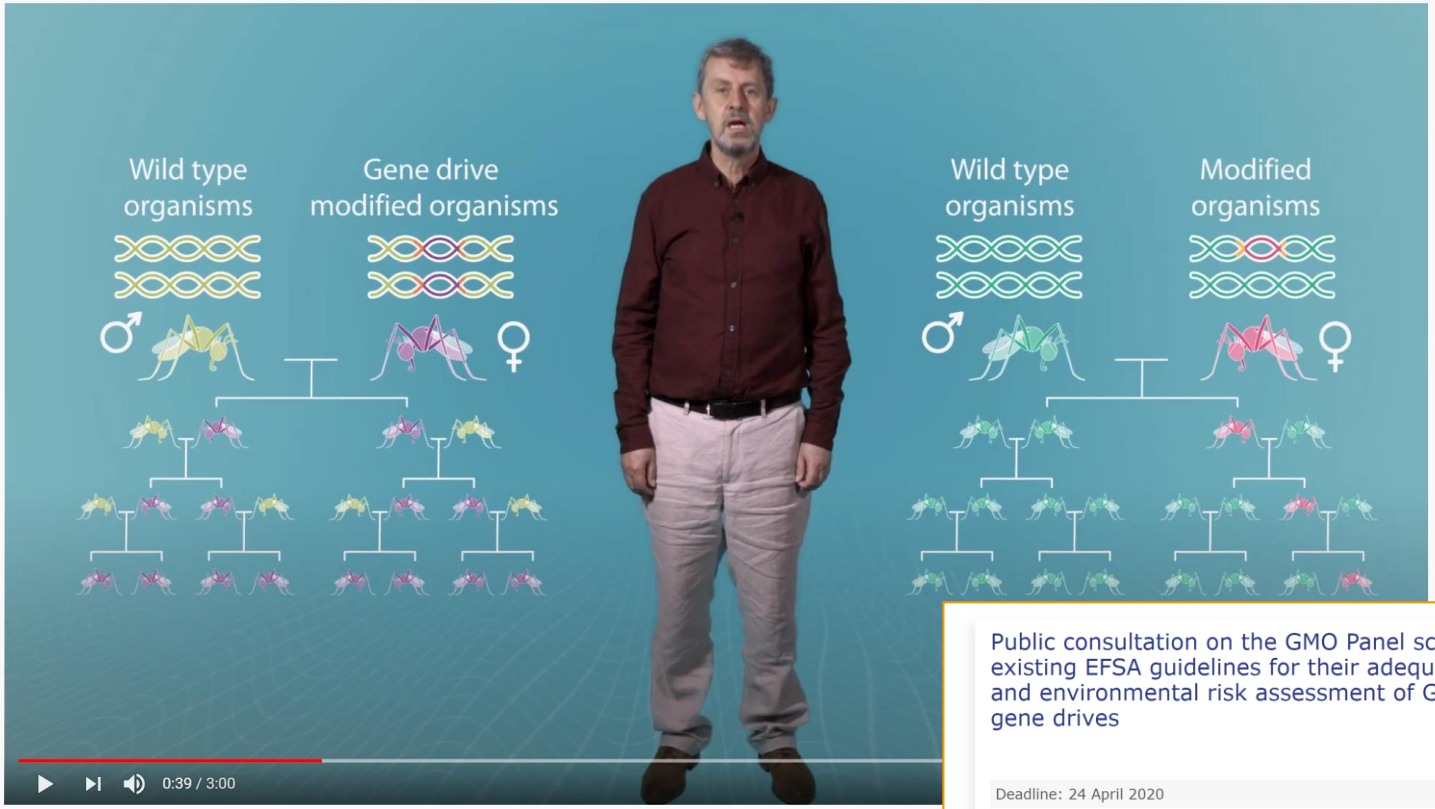
# Scope | Animal groups, examples mentioned

- Living genetically modified (GM) animals to be placed on the European Union (EU) market in accordance with Regulation (EC) No 1829/2003 or Directive 2001/18/EC.



YouTube IT

Zoeken




What is gene drives about?

1.372 weergaven • 17 feb. 2020

EFSAchannel
12,3K abonnees

efsa
European Food Safety Authority

https://youtu.be/cqr1dicd_fw

## Public consultation on the GMO Panel scientific opinion on the evaluation of existing EFSA guidelines for their adequacy for the molecular characterisation and environmental risk assessment of GM insects with synthetically engineered gene drives

Deadline: 24 April 2020

Document (1.09 MB)

Privacy Statement (129.85 KB)

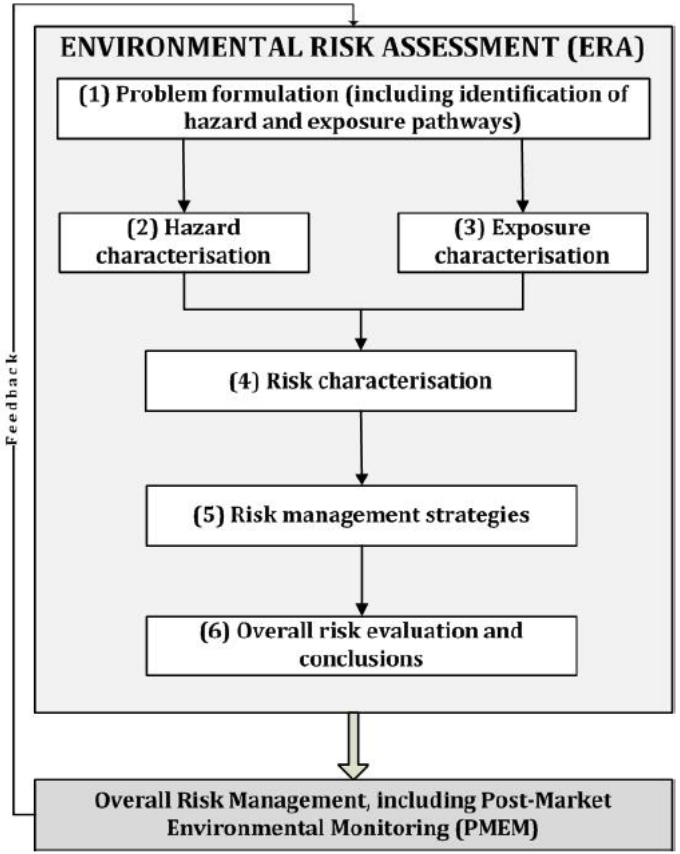
EFSA's GMO Panel has launched an open consultation on its draft scientific opinion on the evaluation of existing EFSA guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified insects with synthetically engineered gene drives. In line with the mandate of the European

**Subject area**

GMO

New advances in biotechnology

# Risk assessment | 6 steps




- PROBLEM FORMULATION: difference that may have consequences for the environment needs to be assessed. Others not.
- FEEDBACK mechanisms needed from real life experiences with the product
- UNCERTAINTY is to be reported at each step

# Risk assessment | Problem formulation

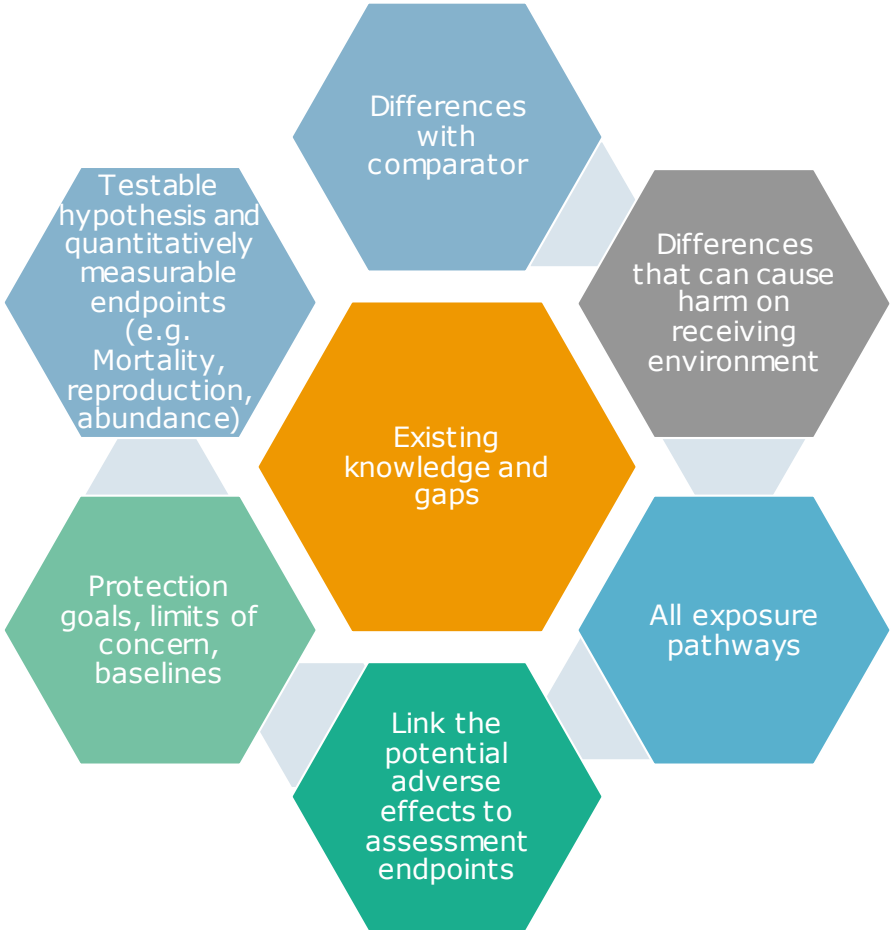


**Table 1:** Examples of environmental protection goals in EU. Directive 2001/18/EC specifically applies to GMOs. Other legally binding and non-regulatory documents, as listed below, could also be considered by applicants, even though GM animals may not be specifically mentioned

| Examples of protection goals | | | |
|---|---|---|---|
| **Areas of protection** | | **Background** | **Scope** |
| **Biodiversity conservation** | Species of conservation or cultural value | Directive 2004/35/EC (EC, 2004) | Environmental liability |
| | | Directive 92/43/EEC (EC, 1992) | Conservation of natural habitats and of wild fauna and flora |
| | | Directive 2009/147/EC (EC, 2009d) | Conservation of wild birds |
| | | Regulation (EC) 338/1997 (EC, 1997) | Protection of endangered wild fauna and flora |
| | | Action plan for biodiversity | Conservation of biodiversity |
| | | Biodiversity strategy (e.g. EC, 2011) | Conservation of biodiversity |
| | Protected habitats | Biodiversity action plan for the conservation of natural resources | Conservation of natural resources |
| | | Biodiversity action plan for agriculture | Conservation of biodiversity |
| | | Bern convention | Conservation of European wildlife and natural habitats |
| | | Convention on biological diversity | Conservation of biological diversity |
| **Ecological functions** | Land | Directive 2004/35/EC (EC, 2004) | Environmental liability |
| | | Thematic strategy for soil protection | Preservation of soil functions |
| | Water | Directive 2000/60/EC (EC, 2000) | Water protection |
| | | Directive 2008/56/EC (EC, 2008) | Strategy for the marine environment |
| | Production systems | Regulation (EC) 708/2007 (EC, 2007) | Use of alien and locally absent species in aquaculture |
| | | Biodiversity strategy | Sustainable use of biodiversity |
| | | Thematic strategy on the sustainable use of natural resources | Sustainable use of natural resources |

These are the policy targets to consider when defining protection goals

# Risk assessment | Cross-cutting issues (1)

## Determining the receiving environment

- wild/feral populations of the animal species, ecological requirement of the animal species, wild relatives
- Accessible ecosystems
- Management systems and farm practices

## The choice of adequate comparator

- Conventional counterpart if available
- Alien species?
- Wild type of the GM Animal living in the environment
- For fish
- For insects

## The use of non-GM surrogates

- Indigenous surrogate that lives in the receiving environment

# Risk assessment | Cross-cutting issues (2)

## Experimental design, statists and modelling

- Limits of concern, scaling up

## Uncertainty analysis

- EFSA work on uncertainty
- Interplay between ERA and PMEM to deal with uncertainties

## Long term effect

- direct or indirect, immediate or delayed, including cumulative long-term effects
- Chronic exposure; increased spatial ant temporal complexity
- Behaviour, climate…

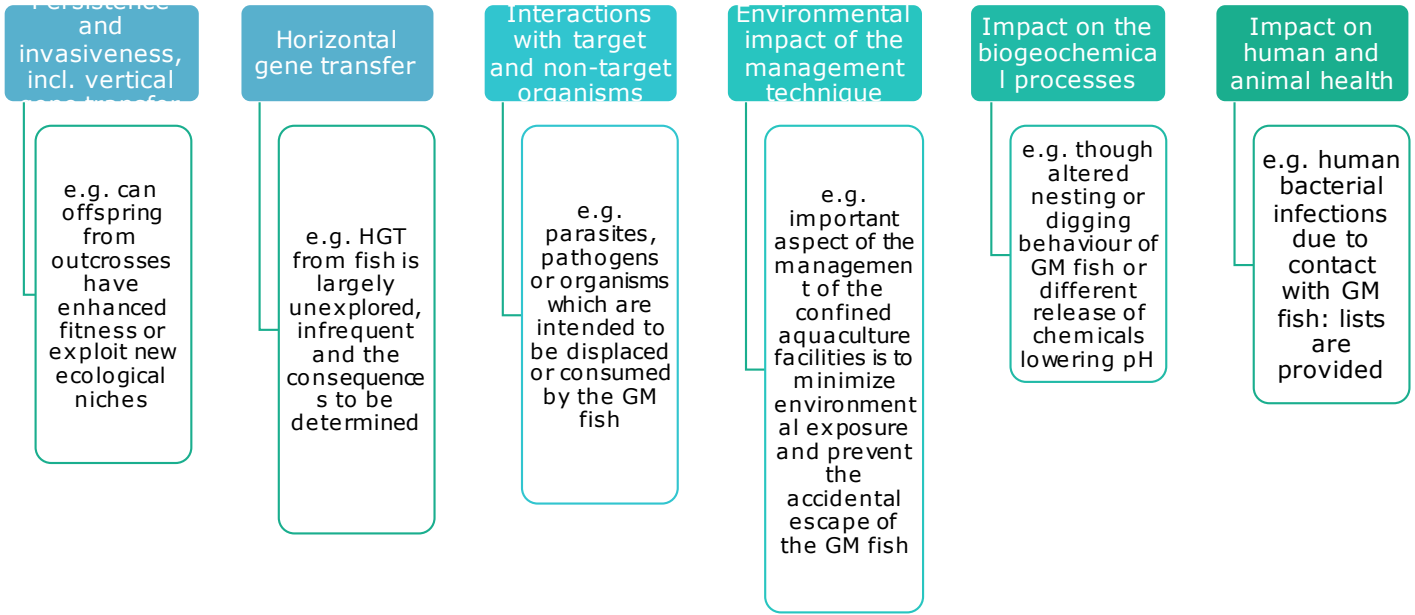
## Animal health and welfare

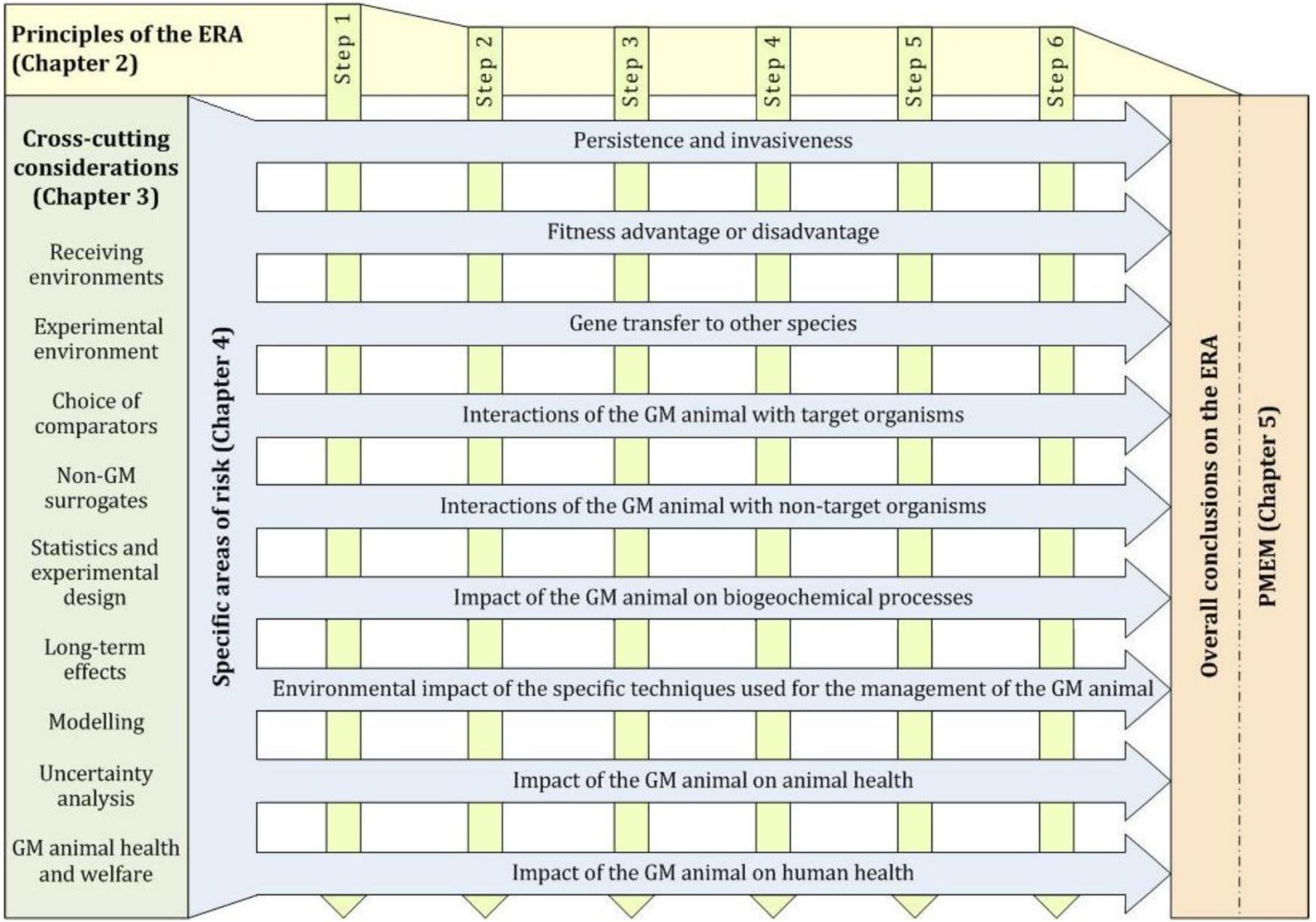
**Table 2:** Examples of biotic and abiotic factors important in identifying and characterising receiving environments.

| Resources and functions required from the ecosystem by the animal | |
|---|---|
| ***Biotic ecosystem factors and attributes*** | ***Biotic ecosystem sub-factors interacting with GM animal*** |
| Food sources | Prey, host, food materials |
| Mates | Conspecifics (both sexes) and other species in case of hybridisation |
| ***Abiotic ecosystem factors and attributes*** | ***Abiotic ecosystem sub-factors interacting with GM animal*** |
| Feeding, mating and breeding territory/sites | Space use and requirements for different life stages, migratory requirements |
| Climate | For example, temperature, wind, sunlight, precipitations |
| Chemical and physical properties | For example, $O_2$, salinity, turbidity, temperature, water flow |
| Security | For example, shade, shelter, refugia |
| **Resources and functions contributed to the ecosystem by the animal** | |
| ***Biotic ecosystem factors and attributes*** | ***Biotic ecosystem sub-factors interacting with GM animal*** |
| Conspecifics | Population characteristics (Genetics, demographics, etc.) |
| Predators, consumers | Species which may use the GM animal as a prey/food item |
| Pests (e.g. pathogens, parasites) and diseases | Pathogen abundance and distribution |
| ***Abiotic ecosystem factors and attributes*** | ***Abiotic ecosystem sub-factors interacting with GM animal*** |
| Organic waste products | Faecal and respiratory outputs (e.g. $CH_4$, $NH_4$, $CO_2$); post-mortem decomposition; toxic compounds |
| Habitat restructuring | For example, stream bed structure, habitat alteration, nest building |

# Risk assessment |: 7 areas of risk

The areas of risk are set in Directive 2001/18/EC and its Annex III A (information required in notifications concerning releases of genetically modified organisms other than higher plants




Principles of the ERA (Chapter 2)
Step 1
Step 2
Step 3
Step 4
Step 5
Step 6
Cross-cutting considerations (Chapter 3)
Receiving environments
Experimental environment
Choice of comparators
Non-GM surrogates
Statistics and experimental design
Long-term effects
Modelling
Uncertainty analysis
GM animal health and welfare
Specific areas of risk (Chapter 4)
Persistence and invasiveness
Fitness advantage or disadvantage
Gene transfer to other species
Interactions of the GM animal with target organisms
Interactions of the GM animal with non-target organisms
Impact of the GM animal on biogeochemical processes
Environmental impact of the specific techniques used for the management of the GM animal
Impact of the GM animal on animal health
Impact of the GM animal on human health
Overall conclusions on the ERA
PMEM (Chapter 5)

# Conclusions

EFSA provided up request a very detailed guidance document

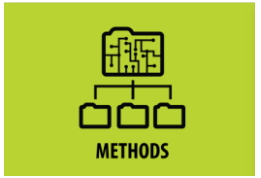
Draft opened for public consultation and input before finalization

Communications to the public foreseen: https://youtu.be/HdilG2aEYSg

This guidance prepared for the future, though never practiced yet in full at EU/EFSA level

This guidance is useful for activities in other jurisdictions (personal communication)

This adequacy and sufficiency of this frame is now being assessed for gene drive modified insects, and soon for synbio animals





# Stay connected

European Food Safety Authority

**Subscribe to**

efsa.europa.eu/en/news/newsletters
efsa.europa.eu/en/rss

**Receive job alerts**

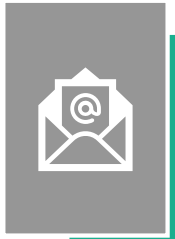
careers.efsa.europa.eu – job alerts

**Follow us on Twitter**

@efsa_eu
@plants_efsa
@methods_efsa
@animals_efsa

**Follow us Linked in**

Linkedin.com/company/efsa



**Contact us**

efsa.europa.eu/en/contact/askefsa