

Three **proposals** for operational protection goals for GMO risk assessment: Lepidoptera; Laursilva in Macaronesia; Field marginal habitat in arable cropping systems

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Environmental Risk Assessment for GMO plants



European Food Safety Authority

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SCIENTIFIC OPINION

Guidance on the environmental risk assessment of genetically modified plants¹

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 genetically modified (GM) plants submitted within the framework of Regulation (EC) No 1829/2003 on GM food and feed or under

Unknown Zone | Protected Mode: On



European Food Safety Authority

EFSA Journal 2010; 8(11):1877

SCIENTIFIC OPINION

Scientific Opinion on the assessment of potential impacts of genetically modified plants on non-target organisms¹

EFSA Panel on Genetically Modified Organisms (GMO)^{2,3}

Applications for the cultivation of GM plants within the EU are submitted within the framework of EC Directive 2001/18.

Guidance was revised and two documents on environmental risk assessment for such applications were issued by EFSA in 2010.

Since then, no new applications for cultivation have been received.



Harmonisation not innovation

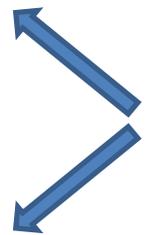
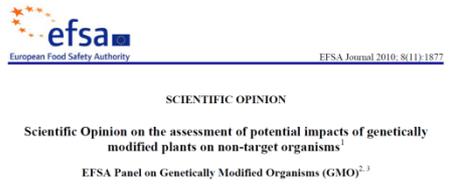
2016 GD section 3.3

For each SPU ... parameters of the SPG options should be specified, using ... five interrelated dimensions: **ecological entity, attribute, magnitude, temporal scale and spatial scale.**

These dimensions have been ... considered implicitly by the EFSA GMO Panel (2010a,b).

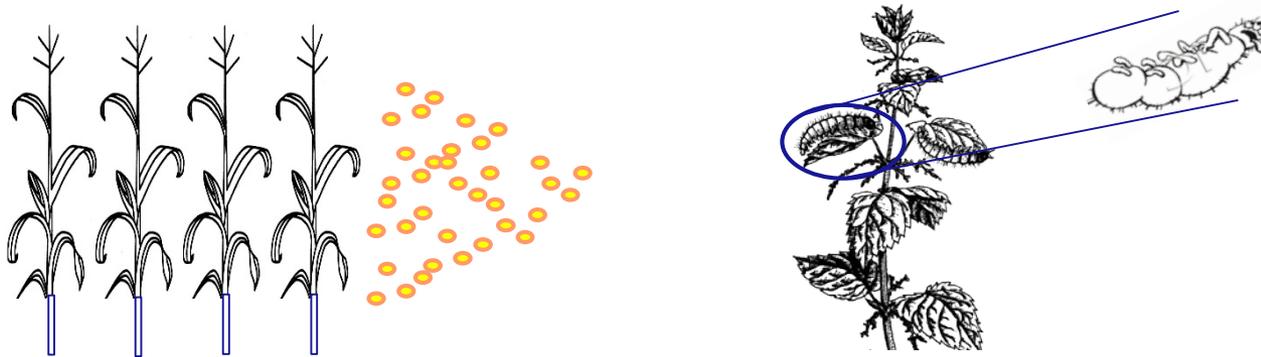
For GMOs, the sustainability of land use (for agriculture and forestry) and of management systems is considered a primary environmental general protection goal per se. They have been made operational by defining the five dimensions for the main ecosystem services affected, which are:

- cultural services: e.g. species of conservation concern
- provision of habitat
- regulating services for pests
- supporting services of nutrient cycling / soil formation / soil retention / water and erosion regulation



'Proposal' 1:

Modelling to quantify the risk to valued non-target Lepidoptera by *Bt*-maize pollen deposited on their host plants



A well-established model, in the absence of specific field data on mortality:

Perry, J.N. et al. (2010) *Proceedings of the Royal Society of London series B*, **277**, 1417-1425.

<http://rspb.royalsocietypublishing.org/cgi/content/abstract/277/1686/1417>.

Perry, J.N. et al. (2011) *Proceedings of the Royal Society of London series B*.

<http://rspb.royalsocietypublishing.org/content/early/2011/01/04/rspb.2010.2667.full>

Perry, J.N. (2011) *Outlooks on Pest Management*, **22**, 199 - 205. DOI: 10.1564/22oct02

Perry, J.N. et al. (2011) *Journal of Applied Ecology*, **49**, 29–37.

Perry, J.N. et al. (2013) *Ecological Modelling*, **268**, 103–122.

Perry, J.N. et al. (2017) *Environmental Sciences Europe*, **29**:21.

<https://enveurope.springeropen.com/articles/10.1186/s12302-017-0119-8>

Assessment of the EFSA GMO Panel on potential adverse effects resulting from the exposure of non-target Lepidoptera to Bt maize pollen

Item	Choice
Ecosystem service	Cultural services: species of conservation concern; aesthetic values
Service providing Unit (SPU)	Lepidoptera
Legal considerations	Directive EC 2001/18; Directive 92/43/EEC on conservation of habitats, wild fauna and flora

Dimension	Choice
Ecological entity	Metapopulation (stressor acts on larvae)
Attribute	Abundance: direct mortality + indirect sub-lethality; Between-species diversity
Magnitude of effects	1% global mortality (maximum tolerable effect below which no explicit management conditions for mitigation are necessary). Ideally modulated through key-factor analysis + sensitivity analysis
Temporal scale	Seasons; Generations
Spatial scale	Landscape; Region
Example of a Specific Protection Goal (SPG)	< 1% reduction in abundance of larvae of any non-target species over a single year in a region.

Measurable Endpoints for Proposal 1

In the field

- host plant abundance,
- larval abundance per host plant,
- time period of maize anthesis,
- time period of instar exposure
- pollen grains per host plant leaf area.

In the laboratory

- sensitivity of instar per unit dose of Bt toxin.

In models

- Population dynamics
- Sublethal effects
- alternative sources of mortality

'Proposal' 2:

Habitat: Laurel forests in Macaronesia

The Laurisilva of Macaronesia is a form of mountain cloud forest. It constitutes a UNESCO World Heritage Site (<http://whc.unesco.org/en/list/934>) **and is explicitly protected under the EU Habitats Directive** (Natura 2000 code 9360).

Introduced Eucalyptus is already an invasive weed and has degraded biodiversity in some natural and semi-natural habitats, requiring eradication programmes. A cold-tolerant genetically modified (GM)-Eucalyptus would be a potential stressor if introduced into certain areas not previously colonised by eucalyptus, such as Macaronesia . As a cold-tolerant GM-Eucalyptus would survive in temperatures below those normally experienced by the species concerned, it has a greater potential to become established and invasive of habitats not normally exposed to these species of Eucalyptus. Areas particularly at risk could be mountainous parts of the Macaronesian Islands with a generally cooler climate and higher rainfall such as the Azores and Madeira.



Assessment of the EFSA GMO Panel on potential adverse effects resulting from the exposure of Macaronesian habitat to cold-tolerant GM Eucalyptus

Item	Choice
Ecosystem service	Provision of habitat; Provision of natural medicines; Cultural services
Service providing Unit (SPU)	<i>Laurus novocanariensis</i> ; Particular plant species with medicinal potential; Species of conservation concern
Legal considerations	Directive EC 2001/18; Directive 92/43/EEC

Dimension	Choice
Ecological entity	Habitat (what requires protection is the area itself, the abiotic environment and the biota in the habitat)
Attribute	Biomass; Process; Within- & between-species diversity; Landscape structure
Magnitude of effects	Negligible tolerable effect
Temporal scale	Seasons
Spatial scale	Protected area; Region
Example of a Specific Protection Goal (SPG)	Ban on and eradication of any cold-tolerant GM-Eucalyptus in the Macaronesian region

Measurable Endpoints for Proposal 2

In Macaronesia

- monitoring of forests for GM Eucalyptus
- the abundance, biomass and diversity of native species;
- soil characteristics

Elsewhere

- the reproductive biology and invasive potential of the GMO (seed dormancy, phenotypic plasticity, etc.)

'Proposal' 3:

Non-crop, in-field and field marginal habitat in arable cropping systems

Non-cultivated habitats, including landscape features (e.g. hedgerows, grassy field margins, beetle banks, conservation headlands) provide essential resources (prey and shelter) for natural enemies of pests. Such habitat plays a critical role in integrated pest management programs underpinning EU Directive 2009/128/EC. The maintenance of connectivity (spatially and temporarily) of these habitats, and avoidance of fragmentation (see e.g. <http://biodiversity.europa.eu/topics/fragmentation>) is vital to stabilise and maintain populations of biocontrol agents.



Examples of potential stressors for such habitat include genetically-modified herbicide-tolerant (GMHT) cropping systems, e.g. an HT soybean. Here, the potential indirect effect on the entity 'habitat' specifically relates to weed populations and sustainable agricultural systems. Further details are in EFSA GMO Panel (2012) (EFSA Journal 2012;10(6):2753) which recognises that the protection of species and of the agricultural systems that depend upon them cannot be achieved without protection inter-alia of their habitat.

Assessment of the EFSA GMO Panel on potential adverse effects from a GMHT soybean system affecting non-crop, in-field and field marginal habitat in arable cropping systems

Item	Choice
Ecosystem service	Provision of habitat; Pest regulation; Cultural services
Service providing Unit (SPU)	Habitat (for natural enemies, including soils, plants, hedgerows); Natural enemies; Iconic flowering plant species & invertebrates; agricultural landscape features.
Legal considerations	Directive 2001/18; Directive 2009/128/EC24; Regulation (EU) No 1305/2013 on support for rural development

Dimension	Choice
Ecological entity	Habitat
Attribute	Habitat and landscape structure; Biodiversity of plant community; Process (weed resistance to herbicides)
Magnitude of effects	Small tolerable effect
Temporal scale	Rotations
Spatial scale	In crop/field; edge of field/field margin; nearby off-crop
Example of a Specific Protection Goal (SPG)	Reversal of decline in abundance of song-birds, over a five-year period, on a per-farm basis, whilst retaining farm profitability. (Herbicides used within an agreed environmentally-sensitive management scheme.)

Measurable Endpoints for Proposal 3

Arable plants

- Heard et al. (2003)
- Roy et al. (2003)

Insects in arable ecosystems

- Brooks et al. (2003)
- Roy et al. (2003)

Farmland birds

- Gibbons et al. (2006)

Modelling

- Crop rotation models (e.g. EFSA Journal 2012;10(6):2753; Heard et al. (2005) *Weed Research*, **45**, 331-338)

most references from
Farm Scale Evaluations
of GMHT crops.
UK Government
£9m Euros

Will such risk assessments
of GMHT systems
be done in the future?