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COLLABORATIVE PROJECT

Assessing and Monitoring The Impacts of Genetically Modified Plants on Agro-ecosystems

D 2.1 Regional Protection Goals In Different European Regions

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Disclaimer: The results as presented in Chapter 3 of this report are based on expert opinions. The mentioning of the Member State serves the purpose to show differences and similarities and does by no means imply that the answers to the survey reflect the official positions of the respective Member State.

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1 INTRODUCTION

1.1 The AMIGA project

Under the seventh framework programme “Food, Agriculture and Fisheries, Biotechnology” the project AMIGA (Assessing and Monitoring Impacts of Genetically Modified plants on Agro-ecosystems) has several major aims: it seeks to provide baseline data on biodiversity in agro-ecosystems in the EU and to translate regional protection goals into measurable assessment endpoints. Additionally suitable bioindicators for various European regions are to be defined and the knowledge on potential long term environmental effects of genetically modified plants (GMPs) should be improved. Also post market environmental monitoring, integrated pest management and economical aspects of GMPs are covered by AMIGA. Last but not least, the efficacy of the new EFSA Guidance Document for the Environmental Risk Assessment of GMPs will be tested.

Work Package 2 “Biogeographic regions and protection goals” of the AMIGA project aims to develop a selection matrix for identifying relevant biogeographical zones to be considered. Hereby, a case-specific approach is chosen. Environmental protection goals and potential bioindicators are selected to characterize the receiving environment.

Task 2.1. “Survey of regional protection goals in the different regions ”aims at providing an overview on existing protection goals in EU Member States on different levels. This should provide the basis for a decision system for selecting regions for field trials.

1.2 Environmental protection policies – an overview

The protection of the environment is established in different legislative and non-legislative sources and at different administration levels – from the international and supra-national level to the subnational or regional level. The environmental objects to be protected by the different regulatory and non-regulatory frameworks differ considerably, covering not only a range of organisms and habitats but also biotic and abiotic functions and services. Last but not least also the instruments used to protect these objects differ significantly.

Environmental policies and goals at different administrative levels

At the international level the International Union for Conservation of Nature and Natural Resources (IUCN) is the world’s first global environmental organization and a leading institution on the environment and sustainable development. The conservation of nature and biodiversity as well as sustainable development is the core vision of the IUCN’s programme (www.iucn.org). At the level of multilateral environment agreements the Convention on Biological Diversity (CBD) has 3 main objectives: the conservation of biological diversity, the sustainable use of the components of biological diversity and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (www.cbd.int). As a supplementary agreement to the Convention on Biological Diversity the Cartagena Protocol on Biosafety is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity. Its aim is to “protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology” (www.cbd.int).

At the European level the European Union has established a regulatory system for different environmental issues. European environmental law covers different subjects, such as air, water, waste, nature, GMOs and chemicals, all governed by sectoral legislation. Examples are the Ambient Air Quality Directive, the Water Framework Directive, the Waste Directive, the Birds and Habitats

Directives, the REACH Regulation for chemicals and the Directive on deliberate release and placing on the market of GMOs.

The definition of environmental protection goals at the national level has started long before efforts were made at the European level. Historically, the concept of e.g. protected areas has existed in Europe for at least hundreds of years. The designation of areas conserved for particular resources such as timber or hunting goes back to medieval times. In Europe, privately funded organisations and in the early 20th century also the states acted as creators of protected areas (EEA 2012a). Due to this historical context in European countries legal protection status of protected areas varies depending on their historical development and depending on the administrative structures in the respective country.

Also for the protection of species, efforts are different in the European countries. The national red lists of species provide countries with key information about species status regarding their endangerment within their borders. Their status depends on the regional efforts to develop such lists and the subjective assessment on the national or even regional level. In addition, in some countries there may exist, beside national red lists, also sub-national red lists for particular taxa. Although red list species are not necessarily assigned a protection status, they serve as indicators for environmental quality and are used as a multi-functional instrument in environmental control.

Harmonization efforts of protected areas and species at the EU level have been made by the establishment of the Birds and Habitats Directives. Also for Red List species harmonization efforts exist on the international level by the development of IUCN guidelines for Regional Red Lists which are available since 2003, laying out a clear, repeatable protocol that can be used by any country. Also on the European level red list taxa exist (van Swaay et al. 2010).

However, not only supra-national or international policies and national policies define environmental protection goals but these are also set on a regional level in certain cases. For example, certain protection goals are not outlined in one particular legislative act but can be found in different regulatory acts and legal ordinances within a particular country. For example, in Austria the protection of soil is not covered by a national “soil protection act” but soil protection goals are laid down in different legislative acts relating to soil, such as the ordinance for compost, the ordinance for sludge and refuse composting, the plant protection ordinance and other regulations for the protection of water and air. In addition there are five different soil protection acts in five of the nine Austrian regions, specifically focussing on soil protection (www.umweltbundesamt.at). The reason for this is, apart from the historical context, the division of competences for these topics between the national and the regional level.

Environmental protection goals using different instruments

The most common form of environmental protection in European environmental law is the directive but regulations are used as well, mainly when the harmonization of the internal market is concerned (Beijen 2009). In these directives and regulations different regulatory instruments are used, depending on the goal that must be achieved. Examples are emission standards, environmental quality standards, procedural requirements like public participation, product standards, the obligation to set up plans and programmes, permit regimes or authorisation systems (e.g. for chemicals, plant protection products and GMOs), subsidy programmes and requirements regarding the designation and use of areas (Beijen 2009).

In addition to the sectoral legislation of EU environmental law, there are also rules governing procedure, such as the Environmental Impact Assessment Directive (EIA Directive), the Integrated Pollution Prevention and Control Directive (IPPC Directive) and the Access to Environmental Information Directive (Beijen 2009). The Directive on Environmental Liability (Directive 2004/35/EC) establishes a framework for environmental liability with a view to preventing and remedying environmental damage resulting from certain occupational activities.

Environmental strategies and Action Plans complement the sectoral legislation and procedural rules in the European Union. For instance the Thematic Strategy for Soil Protection adopted by the European Commission (European Commission 2006) explains why action is needed to ensure a high level of soil protection, what kind of measures must be taken, and sets the overall objective of the Strategy. The EU's biodiversity strategy to 2020 aims at halting the loss of biodiversity and ecosystem services in the EU by 2020 (European Commission 2011). Both strategies do not have legally binding status but EU Member States are encouraged to integrate the strategy in their own national plans, programmes or strategies by implementing the six main targets. Many EU Member States are currently in the process of developing or updating their national biodiversity strategies.

Different objectives of environmental protection

What to protect is one of the basic questions in environmental protection. In some cases the objective of environmental protection is exactly defined, e.g. when a certain species or habitat is to be protected. Different levels of biological organisation (individual species to population) can be concerned. While in one case a particular species is subject to conservation efforts, e.g. by including it in a red list or by assigning a protection status for its habitat, in other cases a species community or a particularly valued ecosystem is core of the protection efforts. In sectoral issues or when environmental media are concerned (air, soil, water), the protection of populations, communities, or even ecosystems can also be considered (e.g. plant protection products; Directive 91/414/EEC). Most recently the protection of ecological functions and services, such as ecosystem services is gaining more attention. Although a clear common understanding of ecosystem services is not fully developed yet they are useful for extrapolation of protection goals across levels of biological organization and across spatial and temporal scales (Galic et al. 2012). In addition they are powerful tools linking measurement endpoints with relevant protection goals (Galic et al. 2012). This has led to the discussion whether to use them in ecological risk assessment for soils (e.g. Faber et al. 2012), for plant protection products (EFSA 2010c, Nienstedt et al. 2012) and for genetically modified organisms (EFSA 2010).

Apart from the protection of specific environmental objects such as animal and plant species, habitats and ecosystems, or ecological functions or services, there are other objectives of environmental protection that are less precise and need translation into more specific protection goals.

One of the most prominent but largely imprecise environmental protection goal is the protection of biodiversity. Almost all environmental regulatory acts and regulation on all administrative levels – from international to regional – include biodiversity as major protection goal (e.g. "helping avert global biodiversity loss"; European Commission 2011). However, in most cases there is no clear definition of biodiversity and there are several different possibilities: plant or animal species diversity, habitat and ecosystem diversity, genetic diversity, functional diversity, agricultural biodiversity, etc. Additionally, further objectives to be protected are mentioned in different environmental laws, provisions or strategies at different administrative levels which need further specification. In the following some examples are listed :

- reduction of chemical plant protection products
- reduction of eutrophication (e.g. Swedish National Environmental Quality Objectives)
- preservation of the agricultural landscape
- preservation of food production
- preservation genetic integrity of nature (Precautionary law of Vienna)
- preservation of the diversity, the character and the recreation value of nature and landscapes (German Nature Protection law)
- preservation of the ability of sustainable use of natural goods
- preservation of the development of natural ecosystems
- reduction of greenhouse gas emission
- maintaining and restoring ecosystem and their services (EU 2020 strategy)

- increasing the contribution of agriculture and forestry to maintaining and enhancing biodiversity
- Ensuring the sustainable use of fisheries and resources
- Combating invasive alien species

1.3 Protection goals in the ERA of GMOs

The authorization of GMOs in the EU is guided by principles which are laid down in Directive 2001/18/EC. Beside the obligation to apply the precautionary principle in the decision making step of the risk analysis and the obligation for a gradual increase in the scale of release (step-by-step principle) the basic element of the authorization system is the case-by-case evaluation of potential risks to human health and the environment. The general principles of environmental risk assessment (ERA) require the identification of potential adverse effects the GMO might have on the environment and their potential consequences. Detailed principles for the ERA are laid down in the Guidance Notes to Annex II of the Directive (2002/623/EC). Further guidance on the ERA has been elaborated (EFSA 2006) and recently been updated (EFSA 2010a, EFSA 2010b).

The main environmental objective of Directive 2001/18/EC and Regulation (EC) No. 1829/2003 is the "protection of the environment from harm caused by the deliberate release or the placing on the market of GMOs". However the Directive does not specifically define this protection goal, but merely refers to the avoidance of "unacceptable damage" or "risks to the environment" which a particular GMO may pose.

In the EFSA Guidance Document on environmental risk assessment (EFSA 2010a), protection goals are addressed more specifically: "Aspects of the environment that need to be protected from harm according to environmental protection goals set out by EU legislation" need to be identified during the problem formulation step in the ERA (EFSA 2010a). In order to finally be able to translate environmental protection goals into measurable assessment endpoints in the ERA process (EFSA 2010a), it is necessary to further define those protection goals which so far exist as general concepts. A first step in this direction was made in the new EFSA Guidance Document (EFSA 2010a) which put a clear focus on the protection of biodiversity and ecosystem functions, but also opened up the ERA process to the potential consideration of species of conservational importance as well as protection goals such as sustainable land use and ecosystem services.

1.4 Challenges in the selection of protection goals in the ERA of GMOs

The overall goal of the protection of the environment against human activities or hazardous substances is laid down in numerous legislative and non-legislative provisions (see above). General protection goals outlined by the existing provisions are the starting point for the definition and selection of specific protection goals and assessment endpoints suitable for the environmental risk assessment of human activities which may adversely affect the environment, hence, also for the cultivation of GMOs.

When addressing and selecting protection goals with relevance for the ERA of GMOs several challenges arise:

Protection goals differ depending on the administrative level on which they are set

Protection goals defined by legal or non-legal provisions may differ depending the level at which they are set (European level, EU Member State Level or regional level). This is for example the case if European legislation is supplemented by national laws. For plant protection products the protection goals set by the regulation of the active ingredient at EU level may differ from the environmental protection goals set at national level where the plant protection product is registered and conditions for its use are defined by a particular Member State.

Also regionally there may be differences in the formulation of protection goals. In EU member states with autonomous regions (e.g. Spain) or where the administrative competence for nature protection is on the regional level (e.g. Belgium, Austria) protection goals may differ even between regions of a particular country.

Protection goals for the environmental risk assessment of GMO at EU level (Directive 2001/18/EC and relevant Annexes) and at the national level, e.g. in Austria (Austrian Gene Technology Act), are defined only in a very general way (e.g. avoidance of adverse effects on human health and the environment) and differ from those outlined in e.g. the precautionary laws of the Austrian regions which contain more specific formulations for the protection of the environment when GMOs are cultivated. The precautionary laws refer to the protection of wild species of animals and plants and their natural habitats or to the protection of the genetic integrity of nature. In addition, the protection of the biological diversity in protected areas is emphasized. The precautionary laws specifically list the protected areas in the particular regions which have to be taken into consideration when a GMO is cultivated (Dolezel et al. 2007).

A range of protection goals (e.g. protection of biodiversity, genetic diversity or protection of ecosystem services) is not specifically represented by specific laws but they are outlined in a range of different legislative documents of a specific Member State. These may be national but also subnational acts and regulations. In other cases, specific acts referring to a particular environmental matter may exist at national level in some Member States only (e.g. Federal Soil Protection Act in Germany). In contrast, in other Member States like Austria soil protection is not covered by a specific national law but rather covered by a range of laws at national and regional level, where it is mostly linked to the respective hazard source (e.g. clean air act, fertilizer act, forest protection act etc.). In addition some of the Austrian regions also have specific soil protection acts.

For the protection of species and habitats differences at supra-national, national and regional levels are evident. EU Member States have developed their own systems in order to protect species and habitats in their territory (EEA 2012a). Due to this fact there are difficulties in harmonizing habitat protection at EU level due to differences in definitions and protection status categories between the different Member States. The protection goals for protected areas are mostly specified by particular legislative provisions enacted for the designation of the protected area in the particular country. For example, the conservation goals of specific species, habitats or landscapes occurring in national parks are defined in the national park laws or regulations of each Member State.

Also species protection has developed in EU Member States before the harmonisation of the legislation started on EU level. Many Member States have species protected in their national laws or even regionally (e.g. in case of the federal nature protection laws in Austria). Red List species may not have a legislative protection status but are still considered as important protection goals in the Member States. They may be defined at national or subnational level, depending on the individual efforts in the respective Member States. Although at EU level species protection is harmonized by defining species of community interest which cover some of the nationally protected or endangered species there are

still species left which – at a national or even subnational level – are of conservation concern in the different EU Member States.

Protection goals are vaguely defined

The protection goals defined by environmental policies are mostly normative concepts or statements which are formulated too vaguely and too broadly to be scientifically considered. They need translation into operational and specific protection goals and, finally, assessment and management endpoints (Garcia-Alonso 2013). The policy documents listed in the EFSA ERA Guidance Document (EFSA 2010a) are also general policy goals set at EU level which need specification for the respective risk assessment issue concerned. General protection goals outlined in EU legislation such as e.g. “avoidance of adverse effects on the environment” and “protection of human health and the environment” (in case of GMOs or chemicals) leave room for interpretation as to which specific environmental protection goals need to be addressed. For GMOs, several effect categories (e.g. direct, indirect, long-term effects, adverse effects to target or non-target species) which need to be considered in the ERA are mentioned in Directive 2001/18/EC; however, the specific protection goals may differ depending on the GMO, its exposure pathways, the risks identified in the ERA and the receiving environment. The problem of translating general environmental protection goals into manageable assessment units has been recognised by EFSA. In a recent Scientific Opinion on a GMO to be authorized for cultivation, protection goals were specifically addressed (EFSA 2012). The herbicide tolerant soybean and its related non-selective herbicide glyphosate may pose risks to the environment by changing weed communities or promoting weed resistance under certain circumstances (EFSA 2012). It is recognized that protection goals are diverse and depend on the environmental policies in the respective Member States. In addition, they are not always clearly defined leaving it in the responsibility of risk managers to decide upon risk mitigation measures that are consistent with the environmental protection goals and biodiversity action plans pertaining to their regions (EFSA 2012).

More specific goals and qualification of protection goals at EU level have been set by other regulatory provisions than those for GMOs, e.g. for plant protection products in Directive 91/414/EEC and its guidance documents on Aquatic Ecotoxicology where unacceptable impacts for consideration for freshwater organisms are described. One decision criterion therein is the recovery from short-term effects, although no acceptable values are given for particular species (Hommen 2010).

As another example, the Water Framework Directive (WFD, Directive 2000/60/EC) demands a “good ecological status for natural waters and defines environmental quality standards (EQS) for 33 priority substances, thus defining the environmental objective of “good surface water chemical status” (Hommen 2010). The WFD does not only cover the chemical state of the water body but also defines the “good ecological status” explicitly defining targets for certain ecosystems (Hommen 2010).

Also the Environmental Liability Directive (Directive 2004/35/EC) defines environmental damage for protected species and habitats based on the “polluter pays principle” providing criteria for the determination of the significance of any damage to protected species and natural habitats listed in the FFH Directives (Directive 79/409/EEC and Directive 92/43/EEC), although specific goals and thresholds are also lacking.

The aims of Directive 79/409/EEC (Birds Directive) and Directive 92/43/EEC (Habitats Directive) are the protection of biodiversity by the way of conservation of natural habitats of wild fauna and flora and of naturally occurring birds, respectively, in the European territory. Measures must be taken to maintain or restore natural habitats and species of wild fauna and flora of Community Interest “at favourable conservation status”. Criteria for the assessment of a “favourable conservation status” of species and habitats as well as criteria for selecting sites eligible for identification as sites of community importance and designation as special areas of conservation are given in the Habitats Directive. Habitats and species listed in the respective annexes listed in the two directives are subject

to strict conservation measures, including the creation of an ecological network of special areas of conservation (Natura 2000).

1.5 Selection of protection goals for the ERA of GMOs

As shown above a comprehensive tracking of protection goals across EU Member States is factually impossible. Accessing the relevant legislative acts and regulations of the respective Member States, which are written in the respective Member State languages and which are spread across the administrative levels of the particular Member State is hardly feasible.

Therefore, though recognizing that the nationally and regionally defined protection goals are very important and that limiting the study to EU-wide available data is only covering part of the legally defined protection goals, in this report the focus of the analysis is on protection goals for which Member State data are aggregated at the EU level and that can be easily and quickly accessed. This is the case for species and habitats listed in the Habitats Directive. In addition, the relevance for the GMO risk assessment is given by focussing on lepidopteran and coleopteran species listed in the Habitats Directive. These species are of conservation concern throughout the European Union and are highly relevant for the environmental risk assessment of GM maize expressing lepidopteran or coleopteran-specific Cry-toxins. However, not in all cases FFH Lepidoptera or Coleoptera would be relevant for the ERA of a specific GMO. Their selection depends on the specific traits expressed by the GMO and the cultivation area of the plant (e.g. maize, potato etc.). If the plant and the trait are considered, a selection procedure of lepidopteran or coleopteran FFH species can start leading to relevant species which may be addressed in more detail in the ERA. As example, in this report, four lepidopteran species listed in the Habitat Directive were selected for a GIS-based analysis whether they could be subject to selection for the ERA of a particular GMO depending on their distribution in different biogeographic regions in Europe. Relevant coleopteran and lepidopteran species of the Habitats Directive are grouped according to their biogeographical relevance (Chapter 2).

In addition, the consideration of relevant protection goals for the GMO risk assessment in EU Member States was evaluated by an online questionnaire and personal interviews with relevant stakeholders reflecting an informed expert opinion at Member State level (Chapter 3).

2 NATURE PROTECTION GOALS IN THE EU

2.1 Species and habitats protection at EU level

The basic legal instrument with the purpose of preserving biodiversity in the EU is the Habitat Directive (Directive 92/43/EEC) and the Birds Directive (Directive 79/409/EEC, updated by Directive 2009/147/EC). Both Directives commit the Member States of the EU to set up a coherent European ecological network of protected areas, named "Natura 2000". While the Birds Directive requires Member States to designate "Special Protection Areas" (SPAs) for more than 190 bird species, the designation of "Special Areas of Conservation" (SACs) are required under the Habitats Directive for the conservation of more than 1100 species and more than 230 habitats of special European conservation concern.

The Habitats Directive lists natural habitat types of Community interest (Annex I) as well as animal and plant species of Community interest (Annex II) for the conservation of which special areas need to be designated. In addition, also "priority species/habitats" are listed for which the European Community has a particular responsibility for protection. Annex IV of the Habitat Directive contains animals and plant species for which a strict protection regime must be applied across their entire natural range within the EU, both within and outside Natura 2000 sites.

Both Directives provide an EU-wide ecological network of protected areas comprising more than 26 000 sites (EEA 2012a). About 18 % of the land territory of the 27 EU Member States is covered by the terrestrial component of the Natura 2000 network (Status: end of 2011, EEA 2012a).

Article 17 of the Habitats Directive requires Member States to report on the implementation of the conservation measures undertaken, to evaluate the impact of those measures on the conservation status of the habitat types and species of Community interest and to report the main surveillance results. The first Article 17 report covered the period 2001-2006, the second will cover 2007-2012 and is due in 2013. Member States reports are available in the central data repository of the EIONET (**http://cdr.eionet.europa.eu**) as well as the Member States assessments of the conservation status of habitats and species of Community interest (**http://bd.eionet.europa.eu/article17**). The data submitted by the Member States are harmonized by the European Topic Centre on Biodiversity in order to produce a biogeographical assessment.

In the first round of reporting by EU Member States only about 17% of the species or habitats covered by the Habitats Directive showed favorable conservation status (EEA 2010b). Hence the pressure on the European biodiversity is still considerable.

The Natura 2000 viewer was created by the European Environment Agency as an interactive tool enabling people to locate Natura 2000 sites and access related information (**http://Natura 2000.eea.europa.eu**). Beside information on Natura 2000 sites also information on nationally designated areas (see Chapter 2.2), biogeographical regions, Corine land cover and EU life projects is available.

2.2 Nationally designated areas

Beside the European obligations to protect biodiversity in specially designated habitats, nationally protected areas exist in all EU Member States. The EU Member States provide regular information on their nationally designated areas, collected in the "Common Database on Designated Areas" (CDDA) at the European Environment Agency (EEA). This database holds information about protected sites and about the national legislative instruments, which directly or indirectly created the protected areas. It contains also sites which, under national legislation, were designated for the purpose of nature

protection including e.g. national parks and nature reserves, but which are not part of the Natura 2000 Network. The inventory is updated on a yearly basis and each category of protected area is assigned the respective IUCN category for comparative purposes. The CDDA database includes spatial information on each protected area, so that spatial overlaps of designated areas can be taken into account (http://www.eea.europa.eu).

However the data contained in this database have some deficiencies:

- No information on the protection goals of the individual protected areas is included
- Protected areas designated by regional authorities are not included
- Voluntarily designated areas (e.g. by conservation trusts) are not included
- There are data gaps due to missing data of the boundaries of protected sites (spatial data)
- There are data gaps due to missing assignments of IUCN categories to the protected areas
- There are data gaps due to incomplete reporting by EU Member States

Nearly 8 % of EU land is covered by nationally designated areas only. On 8 % of the EU land territory Natura 2000 areas overlap with nationally designated areas (EEA 2012a). However, the overlap of Natura 2000 boundaries with the boundaries of nationally designated areas shows different patterns across the EU. There are some countries where Natura 2000 overlaps almost completely with national designations (e.g. Austria, Germany) while in other countries there often is no overlap (e.g. Greece, Hungary).

2.3 Protection of species and habitats independent of their location or occurrence

The Habitats Directive protects species in different ways. Species listed in Annex II are protected via the designation of SCIs under the Natura 2000 network. For animal and plant species listed in Annex IV a strict protection regime is required across their entire natural range within the EU, both within and outside the Natura 2000 network. Similarly, in some EU Member States there are ecosystem types which are protected by law throughout the national territory without being mapped. This is the case, e.g. for dry grasslands in Denmark or bogs in Hungary (EEA 2012a).

2.4 Protected habitats and agriculture

An important characteristic of the European continent is that land in Europe often has multiple purposes and is managed simultaneously with different aims (EEA 2012a). About half of land in EU Member States is dedicated to agricultural activities. Due to its history of settlement a large number of wildlife species and semi-natural habitat types in Europe are dependent on continuing low-intensity agricultural practices (EEA 2012a). An area where farming is associated with high biodiversity is often qualified as “High Nature Value” (HNV) farmland. It is characterized by semi-natural vegetation, low intensity agriculture and structural elements such as field margins or hedgerows as well as farmland supporting rare species (Anderson et al. 2003, cited in EEA 2010a).

Land abandonment and agricultural intensification are the two greatest pressures on biodiversity in European agro-ecosystems (EEA 2010a). Agricultural production and biodiversity are therefore strongly interlinked. For example, of the 231 habitat types of Annex I of the EU Habitats Directive, 55 depend on extensive agricultural practices. Similarly, 7 butterfly species of Annex II of the Habitats Directive depend directly on extensive agriculture (EEA 2010a). Altogether, agro-ecosystems account for more than one-third of the land surface of Natura 2000 areas (SPAs and SCIs together; EEA 2012a).

In addition, FFH habitat types linked to agro-ecosystems have a poorer conservation status (only 7% favorable assessments) than FFH habitat types with no relation to agro-ecosystems (17%; EEA 2010a). This latter trend is particularly relevant for the Atlantic biogeographic region where pressure on agricultural land and farming intensity is highest.

Similar to Natura 2000 habitats, also in nationally designated areas agro-ecosystems take the second largest share of land, making up about 28% of nationally protected areas (EEA 2012a).

2.5 Biogeographic regions and EU protection goals

A major characteristic of the European continent is its high diversity in climatic and geological conditions leading to differences in biodiversity. The ecological differences within and between EU Member States have been recognized by the classification of the European geographic area into biogeographic regions (EEA 2012b). Nine biogeographic regions can be distinguished: Alpine, Atlantic, Black Sea, Boreal, Continental, Macaronesian, Mediterranean, Pannonian and Steppic.

The proportion of designated areas under the Habitats Directive (SCIs and SACs) differs depending on the biogeographic region. The highest coverage of terrestrial land is achieved in the Black Sea, the Alpine and the Macaronesian regions while the lowest coverage is in the Atlantic, Continental and Boreal region (EEA 2012a).

An assessment of the conservation status of habitat types and species of Community interest according to Article 17 of the Habitats Directive (see Chapter 2.1) is also made at the biogeographic level by the European Topic Centre on Biological Diversity (ETC/BD) based on the data and assessments reported by the Member States.

2.6 Case study: Distribution of FFH Lepidoptera and Coleoptera in the European Union: biogeographic differences

2.6.1 Methods

Species listed in Annex II and Annex IV of the Habitat Directive linked to agro-ecosystems (Halada et al. 2010) were chosen in order to select relevant lepidopteran and coleopteran species using agricultural habitats either preferentially, occasionally or for which agricultural habitats are suitable. These species were then grouped according to their distribution and biogeographical criteria. In addition as a case study, 4 lepidopteran species were selected for which GIS analyses were made. Their occurrence was mapped together with the maize cultivation area in the EU and grouped biogeographically.

Maize cultivation data

From the EUROSTAT online Database (**http://epp.eurostat.ec.europa.eu**) the areas of maize cultivation (green maize + corn maize) were queried for NUTS2 and NUTS 1 regions, using the latest available data entry between 2003 and 2012 for each country or region. If available the maize area of NUTS2 was used, otherwise the proportion of NUTS1 maize area was used for those regions not covered by NUTS2 data. Data coverage is EU 27+1 (Croatia), without Greece and Cyprus (no data available). As the NUTS1 and NUTS2 regions are not equal in size the absolute maize area has been normalized by the regions area, resulting in the density of maize cultivation (area maize/total area of region).

Biogeographical regions

The biogeographical regions (BGR) dataset (**http://www.eea.europa.eu/data-and-maps/data/biogeographical-regions-europe**; version of 25. Apr 2011) contains the official

delineations used in the Habitats Directive (92/43/EEC) and for the EMERALD Network set up under the Convention on the Conservation of European Wildlife and Natural Habitats (Bern Convention). If aggregated to the Biogegraphical regions of Europe (BGR) the internal differences within the Biogeographical regions are covered largely. If accounting for the area of the reference region the density of maize for each biogeographical region is calculated. As the BGR cover the geographical Europe, data have been clipped to the area of available maize data, corresponding to the borders of EU 27+1. The Macaronesian and the Steppic regions are not represented in this evaluation due to a lack of data from these regions in the first Article 17 reports.

The biogeographic regions used for the analyses are different from those used in the AMIGA project. A particular AMIGA country can be attributed to different biogeographic regions. For example, Spain consists of three different biogeographic regions, the largest being the Mediterranean, but the northern part belonging to the Atlantic and the Alpine region.

Table 1: Comparison of biogeographic regions of the AMIGA project and the FFH categories. Abbreviations: MED = Mediterranean, CON = Continental, ATL = Atlantic, BOR = Boreal, ALP = Alpine, STEP = Steppic, BS = Black Sea, PAN = Pannonian

AMIGA Project partner	AMIGA Classification	GMO/non-GMO trials	FFH Classification
Spain	MED	x	MED, ATL, ALP
France	MED	x	ALP, ATL, CON, MED
Italy	MED	x	ALP, CON, MED
Romania	BALKAN	x	CON, ALP, STEP, BS
Bulgaria	BALKAN	x	CON, BS
Slovakia	CON	x	CON, ALP, PAN
Germany	CON	x	CON, ATL, ALP
Austria	CON		ALP, CON
Hungary	CON	x	PAN
Denmark	ATL	x	ATL, CON
Netherlands	ATL	x	ATL
Ireland	ATL	x	ATL
Belgium	ATL		ATL, CON
United Kingdom	ATL		ATL
Sweden	BOR	x	ALP, BOR, CON
Finland	BOR	x	ALP, BOR

FFH data

All Member States are requested by the Habitats Directive to monitor species and habitats of Community interest. Article 17 of the Habitats Directive requires that every 6 years Member States prepare reports to be sent to the European Commission on the implementation of the Directive. In the first reporting period 2001-2006 assessments on the conservation status of the habitat types and species of Community interest have been made (http://bd.eionet.europa.eu/article17).

Data on the distribution of FFH species were retrieved from the Article 17 Report Database by the EEA (www.eea.europa.eu/data-and-maps/data/article-17-database-habitats-directive-92-43-eec). GIS files are gridded to 10km grids (or equivalent) due to the heterogeneity of the data sets received from EU Member States. There is no information on population size or density of the species in the GIS files, they give only an indication on the distribution of the species. Coverage is EU 25, data on FFH Lepidoptera and Coleoptera from Romania and Bulgaria were not available in the first reporting period.

Each FFH lepidopteran species represents a protection goal that possibly needs evaluation in the ERA of the GM maize. For this purpose the occurrence and distribution of the butterflies in maize growing areas within the EU needs evaluation in order to select the relevant species for the ERA. Four species of butterflies have been selected as cases for the ERA of GM maize expressing a lepidopteran-active Cry-toxin. The species have been selected from the Annexes II and IV of the Habitats Directive as

examples for species with differing distribution patterns across the EU, covering different biogeographical regions.

- 1065: *Euphydryas aurinia* (EupAur): Annex II
- 4037: *Lignyoptera fumidaria* (LigFum): Annex II / IV
- 1059: *Maculinea teleius* (MacTel): Annex II / IV
- 1056: *Parnassius mnemosyne* (ParMne): Annex IV

2.6.2 Results

2.6.2.1 FFH species linked to Agro-ecosystems

The following table shows the lepidopteran species listed in the Annexes of the Habitats Directive which can be linked to Agro-ecosystems (Halada et al. 2010).

In total 31 species have their habitats preferred, occasionally or suitable in agro-ecosystems (Table 2). Of these, 25 are listed in Annex II, 28 are listed in Annex IV of the Habitats Directive. For 16 species agro-ecosystems are suitable habitats, for 9 species they choose their habitats occasionally in agro-ecosystems and for 5 species agro-ecosystems are preferentially chosen. For one species the classification relates to preferred and suitable (*Parnassius memnosyne*).

Table 2. FFH Lepidoptera linked to Agroecosystems. o = occasional, p = preferential, s = suitable (Categorization by Halada et al. 2010).

FFH LEPIDOPTERA	**Annex II**	**Annex IV**	**Habitat**
Agriades glandon aquilo	x		o
Arytrura musculus	x	x	o
Catopta thrips	x	x	s
Coenonympha oedippus	x	x	s
Colias myrmidone	x	x	p
Cucullia mixta	x	x	o
Erebia calcaria	x	x	o
Erebia christi	x	x	o
Erebia sudetica		x	s
Eriogaster catax	x	x	s
Euphydryas aurinia	x		s
Glyphipterix loricatella	x	x	s
Gortyna borelii lunata	x	x	s
Hesperia comma catena	x		s
Leptidea morsei	x	x	o
Lignyoptera fumidaria	x	x	s
Lycaena dispar	x	x	p
Lycaena helle	x	x	s
Maculinea arion		x	p
Maculinea nausithous	x	x	p
Maculinea teleius	x	x	p
Melanargia arge	x	x	s
Papilio alexanor		x	o
Papilio hospiton	x	x	o
Parnassius apollo		x	o
Parnassius mnemosyne		x	p/s
Phyllometra culminaria	x	x	s
Plebicula golgus	x	x	s
Polymixis rufocincta isolata	x	x	s
Proserpinus proserpina		x	s
Pseudophilotes bavius	x	x	s

Only few FFH Coleoptera can be linked to agro-ecosystems (5 species). Of those 3 are additionally listed in Annex IV and one (*Osmoderma eremita*) is additionally listed as priority species. 4 species are found occasionally in agro-ecosystems, for one species agro-ecosystems are suitable (Table 3).

Table 3. FFH Coleoptera linked to Agroecosystems. o = occasional, p = preferential, s = suitable (Categorization by Halada et al. 2010).

FFH COLEOPTERA	**Annex II**	**Annex IV**	**Habitat**
Carabus hungaricus	x	x	s
Cerambyx cerdo	x	x	o
Lucanus cervus	x		o
Morimus funereus	x		o
Osmoderma eremita	x	x	o

2.6.2.2 FFH species grouped according to biogeographic regions

The lepidopteran and coleopteran species selected above were then regionally grouped according to biogeographic criteria (Tables 4 and 5). For FFH Lepidoptera most species occur in the Alpine region, the fewest in the Boreal region. There are species occurring across a many biogeographic regions (e.g. *Maculinea* sp.) while others are restricted to one region (e.g. *Agriades glandon aquilo,* only Alpine). For FFH Coleoptera most species occur in many biogeographic regions, one species (*C. hungaricus*) occurs in two regions only.

Table 4. FFH Lepidoptera linked to agro-ecosystems and grouped according to their occurrence in biogeographic regions in the European Union

ALPINE	ATLANTIC	BOREAL	CONTINENTAL	MEDITERRANEAN	PANNONIAN
Agriades glandon aquilo	*Coenonympha oedippus*	*Euphydryas aurinia*	*Coenonympha oedippus*	*Catopta thrips*	*Arytrura musculus*
Coenonympha oedippus	*Eriogaster catax*	*Lycaena dispar*	*Colias myrmidone*	*Eriogaster catax*	*Catopta thrips*
Colias myrmidone	*Euphydryas aurinia*	*Lycaena helle*	*Erebia sudetica*	*Euphydryas aurinia*	*Coenonympha oedippus*
Erebia calcaria	*Gortyna borelii lunata*	*Maculinea arion*	*Eriogaster catax*	*Gortyna borelii lunata*	*Colias myrmidone*
Erebia christi	*Lycaena dispar*	*Maculinea teleius*	*Euphydryas aurinia*	*Lycaena dispar*	*Cucullia mixta*
Erebia sudetica	*Maculinea arion*	*Parnassius apollo*	*Gortyna borelii lunata*	*Maculinea arion*	*Eriogaster catax*
Eriogaster catax	*Maculinea nausithous*	*Parnassius mnemosyne*	*Leptidea morsei*	*Maculinea nausithous*	*Euphydryas aurinia*
Euphydryas aurinia	*Maculinea teleius*	*Proserpinus proserpina*	*Lycaena dispar*	*Melanargia arge*	*Glyphipterix loricatella*
Hesperia comma catena	*Parnassius apollo*		*Lycaena helle*	*Papilio alexanor*	*Gortyna borelii lunata*
Leptidea morsei	*Proserpinus proserpina*		*Maculinea arion*	*Papilio hospiton*	*Leptidea morsei*
Lycaena dispar			*Maculinea nausithous*	*Parnassius apollo*	*Lignyoptera fumidaria*
Lycaena helle			*Maculinea teleius*	*Parnassius mnemosyne*	*Lycaena dispar*
Maculinea arion			*Parnassius apollo*	*Plebicula golgus*	*Maculinea arion*
Maculinea nausithous			*Parnassius mnemosyne*	*Proserpinus proserpina*	*Maculinea nausithous*
Maculinea teleius			*Proserpinus proserpina*	*Pseudophilotes bavius*	*Maculinea teleius*
Melanargia arge					*Parnassius mnemosyne*
Papilio alexanor					*Phyllometra culminaria*
Parnassius apollo					*Polymixis r. isolata*
Parnassius mnemosyne					*Proserpinus proserpina*
Proserpinus proserpina					

Table 5. FFH Coleoptera linked to agro-ecosystems and grouped according to their occurrence in biogeographic regions in the European Union

ALPINE	**ATLANTIC**	**BOREAL**	**CONTINENTAL**	**MEDITERRANEAN**	**PANNONIAN**
Cerambyx cerdo	*Cerambyx cerdo*	*Cerambyx cerdo*	*Carabus hungaricus*	*Cerambyx cerdo*	*Carabus hungaricus*
Lucanus cervus	*Lucanus cervus*	*Lucanus cervus*	*Cerambyx cerdo*	*Lucanus cervus*	*Cerambyx cerdo*
Morimus funereus	*Osmoderma eremita*	*Osmoderma eremita*	*Lucanus cervus*	*Morimus funereus*	*Lucanus cervus*
Osmoderma eremita			*Morimus funereus*	*Osmoderma eremita*	*Morimus funereus*
			Osmoderma eremita		*Osmoderma eremita*

2.6.2.3 Case studies: FFH Lepidoptera relevant for the ERA of GMOs

As example on how a selection procedure of EU harmonized protection goals for the ERA of GMOs could work specific analyses were made for four lepidopteran species, assuming a GMO expressing a lepidopteran-active toxin and maize as a crop plant. Overlaps of the selected species with maize cultivation areas in the EU were calculated and categorized according to biogeographic criteria. The selection of the taxa and crop species for such an analysis is case-specific depending on the GM plant and the trait. Such an analysis can be made for different taxa and depending crop plants if data availability is ensured. A similar analysis can be made for FFH habitats and nationally designated areas. As indicated above (Chapter **Errore. L'origine riferimento non è stata trovata.**) harmonized data on the distribution of FFH species and also habitats as well as on nationally designated areas are available. However, a preliminary analysis of FFH habitats which occur in or near agricultural landscapes shows that these habitats are distributed widely throughout Europe (data not shown). Hence, a GIS-based analysis according to biogeographical criteria will not be successful at this scale. In addition, a selection of protected areas for risk assessment purposes of GMOs at EU level would, however, be very complex, as the protection aims and goals depend on the individual protected area.

Distribution of maize cultivation in Europe

Figure 1 shows the density of maize cultivation in the bio-geographical regions of Europe. Coverage is EU 25 (no data from Greece and Cyprus). The area of maize cultivation is not equally distributed within the Biogeographical regions (BGR); usually maize cultivation is clustered in certain parts of the BGR. In case the border of the BGR separated a NUTS2 region, the maize cultivation area of the NUTS2 region was split between the two neighbouring BGRs in proportion to the BGR area share assuming equal distribution of maize in the NUTS2 region). The BGRs with the highest maize cultivation density is the Steppic region, followed by the Pannonian region (see also Table 6). The smallest share of maize cultivation is found in the Boreal and the Mediterranean region.

Table 6: Area of the region and area/share of maize cultivation per Biogeographic region. Figures are summed up on the basis of NUTS2 data for maize (see Methods). Areas are given in ha and in percentage of the regions total area. NUTS regions of BG, CY, GR, HR, and RO are not included because either data on maize or on the species were not available from the queried data sources (see Methods).

Biogeographic Region	**Area (ha)**	**Maize area (ha)**	**% maize of region area**
Alpine	28.654.416	1.002.442	3,50%
Atlantic	68.333.438	2.993.326	4,38%
Black Sea	1.130.161	68.915	6,10%
Boreal	79.133.495	31.210	0,04%
Continental	108.317.860	4.660.523	4,30%
Mediterranean	67.780.641	620.140	0,91%
Pannonian	7.677.937	903.768	11,77%
Steppic	3.713.086	451.104	12,15%
total	**364.741.035**	**10.731.429**	**2,94%**

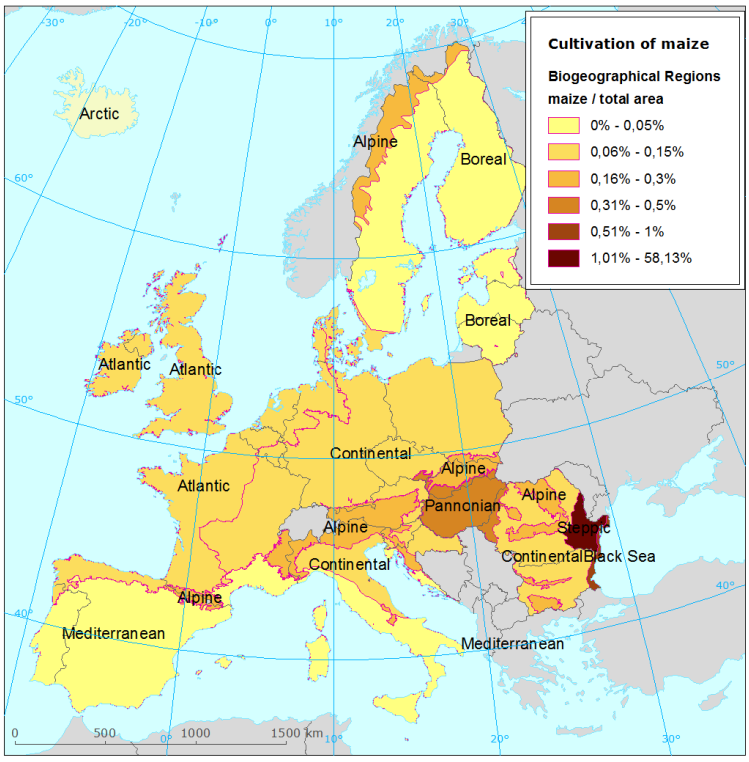

Figure 1: Maize cultivation density per Biogeographical region (EAA 2011, Eurostat, calculation: Umweltbundesamt)

Distribution of FFH Lepidoptera in maize cultivation areas in Europe

The distribution of the four selected FFH Lepidoptera differs considerably.

Figure 2, Figure 3, Figure 4 and Figure 5 show the distribution of *E. aurinia, P. Mnemosyne, M. teleius and L. fumidaria* in Europe over the maize cultivation density.

Example 1: *Euphydryas aurinia*

E. aurinia occurs mainly in grasslands. It occurs across Europe covering six biogeographical regions: ALPINE, ATLANTIC, BOREAL, CONTINENTAL, MEDITERRANEAN and PANNONIAN with a focus on the Atlantic and Continental Region. In AMIGA countries it occurs in Spain (all three regions), France (all four regions), Italy (all three regions), Slovakia, Germany, Austria, Hungary, Denmark, United Kingdom, Ireland, Sweden and possibly Finland (data not available yet).

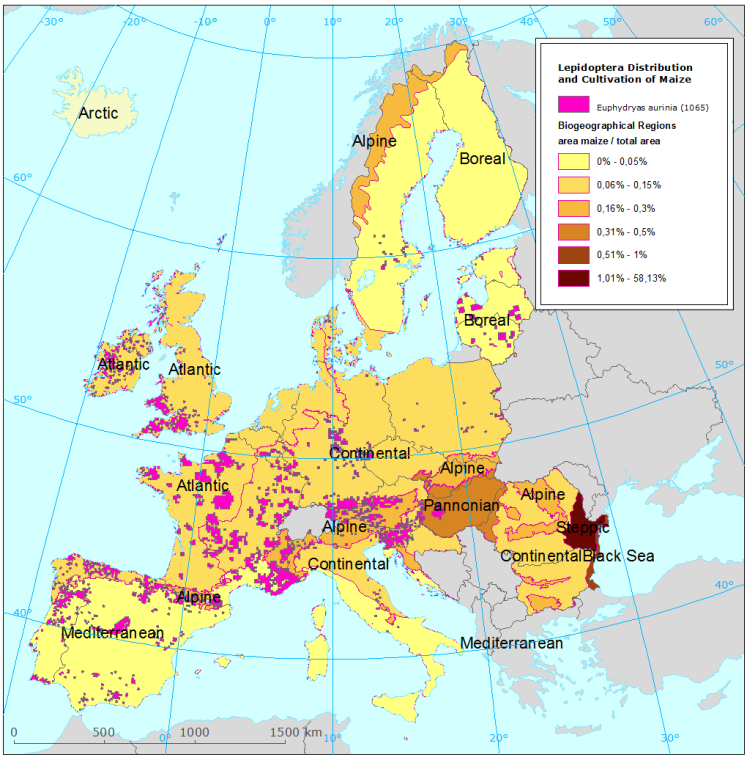

Figure 2: Distribution of Euphydryas aurinia, over Maize cultivation density per Biogeographical region (EAA 2011, Eurostat, calculation: Umweltbundesamt)

Example 2: *Parnassius mnemosyne*

Parnassius mnemosyne is occurring throughout Eurasia, inhabiting many European countries. It prefers woodland clearings and flower-rich meadows. It is recorded in the bio-geographical regions ALPINE, BOREAL, CONTINENTAL, PANNONIAN and MEDITERRANEAN. In AMIGA countries it occurs in Spain (only Alpine region), France, Italy, Germany (restricted to few locations in the continental and the alpine region), Austria, Hungary, Slovakia, Sweden (restricted to a few locations along the coast) and possibly Finland (data not available yet). Its distribution focus lies in Austria, Slovenia, Slovakia, Hungary and the north of Italy. It cannot be found in the Atlantic region.

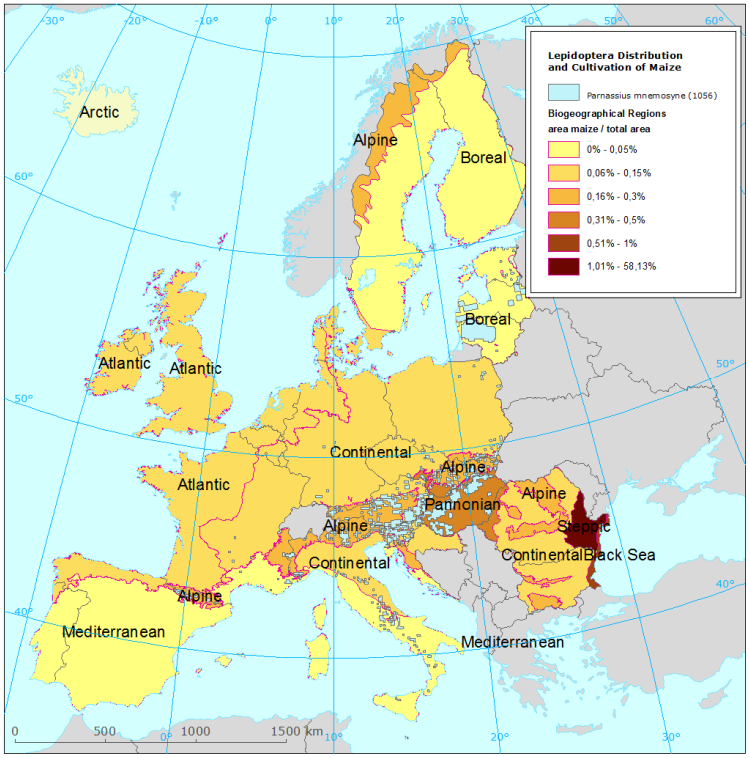

Figure 3: Distribution of Parnassius mnemosyne, over Maize cultivation density per Biogeographical region (EAA 2011, Eurostat, calculation: Umweltbundesamt)

Example 3: *Maculinea teleius*

Maculinea teleius is widely spread across Europe. It is depending on its host plant *Sanguisorba officinalis*. It is recorded in the bio-geographical regions ALPINE, ATLANTIC, BOREAL, CONTINENTAL, and PANNONIAN but it lacks from the MEDITERRANEAN region. In AMIGA countries it occurs in France (all three regions), Italy (alpine and continental), Germany (alpine and continental), Slovakia (alpine and pannonian), Austria (alpine and continental), Hungary, and the Netherlands. In Germany it is widespread while in the Netherlands its distribution is very restricted.

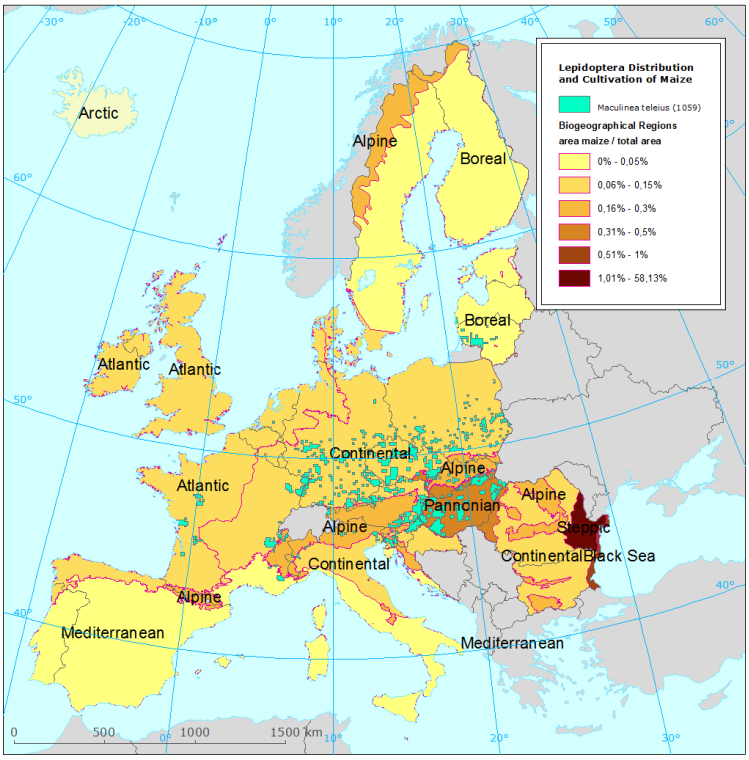

Figure 4: Distribution of Maculinea teleius, over Maize cultivation density per Biogeographical region (EAA 2011, Eurostat, calculation: Umweltbundesamt)

Example 4: *Lignyoptera fumidaria*

Lignyoptera fumidaria is recorded only from Hungary (PANNONIAN region) where it occupies grasslands and steppes and saline flats.

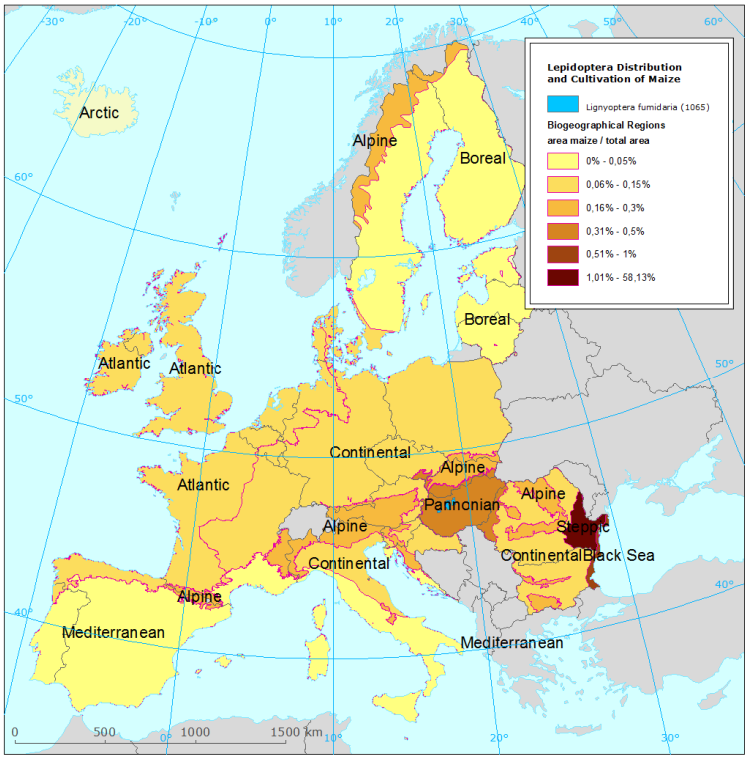

Figure 5: Distribution of Lignyoptera fumidaria, over Maize cultivation density per Biogeographical region (EAA 2011, Eurostat, calculation: Umweltbundesamt)

Table 7 summarizes the distribution area of four FFH lepidopteran species and the area and share, respectively, of maize cultivation in the distribution area of the Lepidoptera broken down for each biogeographic region (BGR). Comparing the share of maize in the total BGR (see Table 6) with the share of maize in the distribution area of the respective species, an overlap of maize cultivation and the species habitat in the BGR is indicated.

The highest share of maize area in the distribution area of the Lepidoptera is represented by the Pannonian BGR reaching 11,4 to 13,7 % which corresponds approximately to the average maize share in the Pannonian BGR of 11,7 % (see Table 6). Three species (*M. teleius*, *E. aurinia* and *L. fumidaria*) have a higher share of maize in their distribution area than the average of the Pannonian BGR (11,7 %). This indicates that their distribution overlaps with maize cultivation in the Pannonian BGR.

In the Atlantic BGR the average maize area corresponds to 4,4 %. The species *P. mnemosyne* and *L. fumidaria* do not occur in this BGR. *M. teleius* has a much higher share of maize in its distribution area than the average maize area in this BGR indicating a concentration of maize in its region of occurrence. In contrast, *E. aurinia* has a less than average maize area in its distribution area, hence it may be occurring less frequently in regions where maize is cultivated in this BGR.

In the Continental BGR with a maize share of 4,3% one species does not occur (*L. fumidaria*), the three other species have maize share values less than the average, hence, there may be no strong overlap between their distribution and maize cultivation in this BGR.

In the Alpine BGR with an average maize share of 3,5 %, two species have a more than average maize share in their distribution area (*P. Mnemosyne* and *M. teleius*), one species has a less than average maize share (*E. aurinia*), L. fumidaria is not recorded from the Alpine BGR.

In the Boreal and the Mediterranean BGR the share of maize cultivation is generally low, with 0,04 % and 0,9 %, respectively. Three of the four lepidopteran species which occur in the Boreal BGR have a higher maize share than the average, indicating that the maize cultivation may concentrate in their distribution area. For the Mediterranean BGR *P. mnemosyne* and *E. aurinia* have a slightly higher maize share, *M. teleius* a lower average maize share in its distribution area. L. fumidaria can be found neither in the Boreal nor in the Mediterranean BGR.

Considering all BGR *P. mnemosyne* and *M. teleius* have slightly higher maize share values (4,6 % and 5,7 %, respectively) than the average (2,9 %; see Table 6). The maize share in the distribution area of *E. aurinia* (2,9%) corresponds to the average value of maize area calculated over all BGRs. In contrast, the maize share of 12,7% in the distribution area of *L. fumidaria* is much higher than the average value. This species which has a very restricted distribution in the EU concentrates in the maize hot spots areas of Hungary.

Table 7: Area of distribution and area/share of maize in distribution area of 4 different FFH Lepidoptera. Figures have been summed up on the basis of NUTS2 data for maize and the 10km-gridded distribution data for the species (see Methods). Areas are given in ha and in percentage of the regions total area, respectively for the species distribution area. NUTS regions of BG, CY, GR, HR, and RO not included because either data on maize or on the species were not available from the queried data sources.

Lignyoptera fumidaria	**Area of distribution (ha)**	**Area maize (ha) in distribution area**	**Maize in % of distribution area**
Alpine	0		
Atlantic	0		
Boreal	0		
Continental	0		
Mediterranean	0		
Pannonian	209.026	26.615	12,7 %
total	209.026	26.615	12,7 %
Maculinea teleius	**Area of distribution (ha)**	**Area maize (ha) in distribution area**	**Maize in % of distribution area**
Alpine	1.891.316	74.024	3,9 %
Atlantic	531.933	46.466	8,7 %
Boreal	586.270	2.449	0,4 %
Continental	10.093.390	420.251	4,2 %
Mediterranean	111.860	408	0,4 %
Pannonian	3.065.366	380.455	12,4 %
total	**16.280.134**	**924.054**	**5,7 %**
Parnassius mnemosyne	**Area of distribution (ha)**	**Area maize (ha) in distribution area**	**Maize in % of distribution area**
Alpine	6.418.780	256.944	4,0 %
Atlantic	0		
Boreal	3.092.294	8.735	0,3 %
Continental	3.172.932	108.895	3,4 %
Mediterranean	745.411	9.308	1,3 %
Pannonian	3.342.300	382.336	11,4%
total	**16.771.718**	**766.217**	**4,6 %**
Euphydryas aurinia	**Area of distribution (ha)**	**Area maize (ha) in distribution area**	**Maize in % of distribution area**
Alpine	6.018.446	176.551	2,9 %
Atlantic	10.241.976	372.629	3,6 %
Boreal	1.642.455	2.679	0,2 %
Continental	9.759.502	332.544	3,4 %
Mediterranean	7.136.901	81.217	1,1 %
Pannonian	500.629	68.337	13,7 %
total	**35.299.908**	**1.033.957**	**2,9 %**

2.6.3 Discussion

FFH species were used as an example on how to select harmonized protection goals at EU level for consideration in the ERA of GMOs. Start of the selection procedure was the evaluation of distribution of the respective species in different biogeographic regions. Next step was to evaluate whether there is a possible overlap of the occurrence of the selected Lepidoptera with maize growing regions by a GIS-based analysis. In the present analysis it was shown that certain Lepidoptera may be more relevant for consideration in the ERA of GMOs than others due to the concentration of maize in their distribution area. The methodological limits of such an analysis must, however, be taken into consideration. The maize area as based on the NUTS2 regional level and aggregated at the biogeographical level does not give any indication on where in a specific region maize is actually grown. Maize cultivation may be clustered within a biogeographical region, hence, in certain instances it may not overlap with the distribution area of a particular species. However, the presented evaluation gives an indication on the overlap which needs further validation.

No information is currently available on the distribution of FFH Lepidoptera in those regions where the highest maize share is given. The Black sea region and the Steppic region are of high significance with respect to maize cultivation in Europe; hence, distribution data of FFH species in these regions are urgently needed.

2.7 Case Study: Protected areas in the Biogeographic Regions

2.7.1 Introduction

In the European Union protection of areas is to a large extent affected by the Habitats Directive (92/43/EEC), together with the Birds Directive (79/409/EEC). Article 11 of the Habitats Directive requires Member States to monitor the habitats and species listed in the annexes and Article 17 requires a report to be sent to the European Commission every 6 years ("Article 17 reporting"). The currently available Article 17 report covers the period from 2001 to 2006. Natural habitat types of Community interest listed in Annex I and animal and plant species of Community interest for which the designation of special areas of conservation is required (forming the Natura 2000 network) constitute the most stringent protection sites at EU level.

The Article 17 reporting covers the habitat types and species in the whole territory of the Member State concerned and is not limited to those within Natura 2000 sites. The current available data do not cover Bulgaria and Romania, which joined the EU on January 1st 2007 which was after the end of the reporting period.

In addition, the European inventory of nationally designated areas (CDDA) holds information about protected areas and the national legislative instruments, which directly or indirectly create protected areas. The database, operated by the European Environment Agency, is an inventory of nationally protected areas, with data aggregated at EU level (see also Chapter 2.2). The CDDA database includes spatial information on each protected area (http://www.eea.europa.eu).

Corine Landcover is an inventory of land cover in 44 classes, and presented as a cartographic product, at a scale of 1:100 000. This database is operationally available for most areas of Europe. The Corine databases and several of its programmes are operated by the European Environment Agency (EEA).

These three databases with data aggregated at EU level were used for the evaluation of the distribution of protected areas in the Biogeographic Regions.

2.7.2 Methods

The Corine-Landcover (CLC) classes “arable land” and “heterogeneous agricultural areas” and their distribution throughout the biogeographic regions, compared with the distribution of protected areas, were evaluated by a GIS-based analysis. For this purpose, the following data were used:

a) Protected areas

For protected areas two datasets have been combined:

- Protected areas as reported in the CDDA, the European inventory of nationally designated areas, available at the EEA. CDDA: version 10 und shapefile v10 as published Dec 2012: **http://www.eea.europa.eu/data-and-maps/data/nationally-designated-areas-national-cdda-7**

- the European dataset on Natura 2000, also at EEA. http://www.eea.europa.eu/data-and-maps/data/natura-2#tab-european-data (Upload 18. Apr 2012)

From these datasets all categories have been used, not specifically considering the level of protection, or the status of the national designation of a FFH area, or the completeness of a national delivery. A common dataset has been produced through merging both datasets, resulting in a combined dataset indicating the presence of protected areas in the European Union mentioned in at least one of those two datasets, independent of their protection status. The spatial resolution has been defined in a square raster of 5.000 m, calculations were performed in precision of hectares.

b) Corine Landcover

From the Corine Landcover dataset 2006 (EEA: version 16: 04/2012; raster data on land cover for the CLC2006 inventory) the Classes 2.1 “Arable land” and 2.4 “Heterogeneous agricultural areas” have been selected as areas where GMO cultivation is possible. This data set is denominated as “arable land”. Data was used in the version of a 100 m raster.

Data of EU member states were used (including Croatia, excluding Greece). No Corine Landcover data from Greece are currently available.

Results are displayed as percentage of area. Results were grouped according to the Biogeographic Regions. The biogeographical regions dataset contains the official delineations used in the Habitats Directive (92/43/EEC) and for the EMERALD Network set up under the Convention on the Conservation of European Wildlife and Natural Habitats (Bern Convention).

c) Distribution of FFH habitat types

The Article 17 report database on habitat distribution for habitats listed in the FFH directive was used for data on FFH habitat type distribution, as available by the EEA.http://bd.eionet.europa.eu/activities/Reporting/Article_17

Distribution data in this database is gridded to 10 km in order to homogenize the differences in data resolution in the different countries. Around 60 habitat types are reported in these files.

2.7.3 Results

a) Protected areas and arable land in different Biogeographic Regions

Arable land is highest in the Steppic and the Pannonian BGR (

Figure 6). The share of arable land is ranging from 0 to 69 % of the total land area (Table 7). The share of protected areas in the BGR varies from 4 to 67 % of total land area, with the highest proportion in the Black Sea BGR (Table 7). Nevertheless, the Alpine and the Macaronesian BGRs have also a high share of protected areas (46 % and 47%, respectively). Approximately one quarter of the total land of the Continental and the Mediterranean BGR is covered by protected areas (Figure 7).

Arable land takes a lower proportion inside the protected areas (column 4) compared with its overall proportion (column 1) in all BGR. In other words,

protection status is more frequent in non-arable areas. The share of arable land in protected areas is remarkably different in the BGRs; it ranges between 0% and 34%, with an overall share of 21% arable land in protected areas. Six of ten BGRs are above the overall level with their presence of arable land in protected areas. In four BGRs (Black Sea, Continental, Pannonian and Steppic) about 30 % of the arable land lies in protected areas (column 4). This indicates a significant spatial relationship between agriculture and protected areas in these BGR.

Similarly, the proportion of protected land in arable land (column 3) is generally lower than the share of protected areas in the overall area (column 2). The Black Sea BGR has an extraordinary high proportion of protected land in arable land (52 %).

Table 7: Shares of arable land and protected areas in different Biogeographic Regions (BGR) in the European Union.

	1	2	3	4
	share of arable land	**Share of protected areas**	**Share of arable protected areas in arable land**	**Share of arable land in protected areas**
Alpine	8%	46%	23%	4%
Arctic	0%	4%	0%	0%
Black Sea	41%	67%	52%	32%
Continental	48%	26%	16%	29%
Macaronesia	16%	47%	16%	5%
Mediterranean	42%	26%	16%	25%
Pannonian	61%	20%	11%	34%
Steppic	69%	22%	11%	34%
Atlantic	41%	21%	13%	24%
Boreal	15%	10%	5%	7%
other BGRs	3%	2%	0%	0%
total	36%	24%	14%	21%

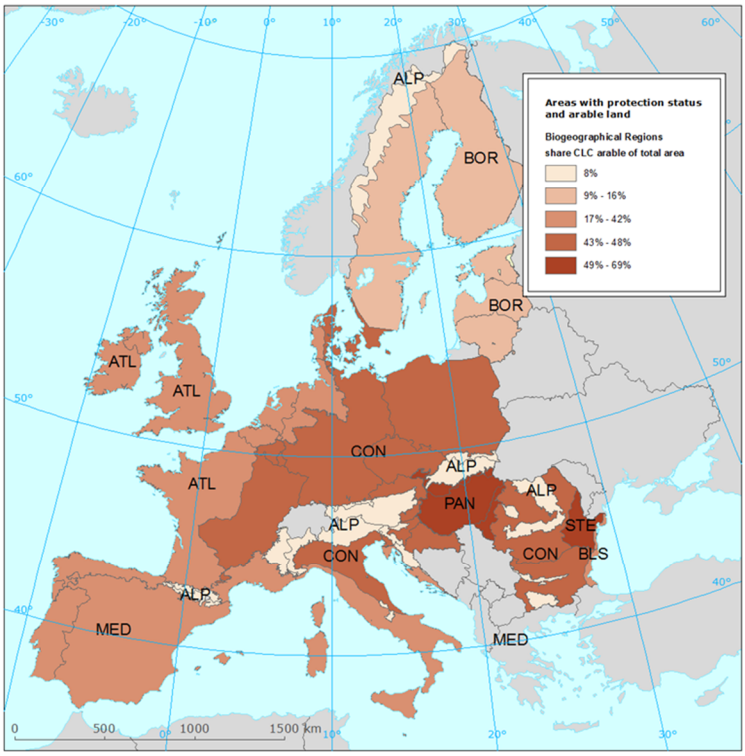

Figure 6: Share of arable land in Biogeographic Regions (EEA, calculation: Umweltbundesamt)

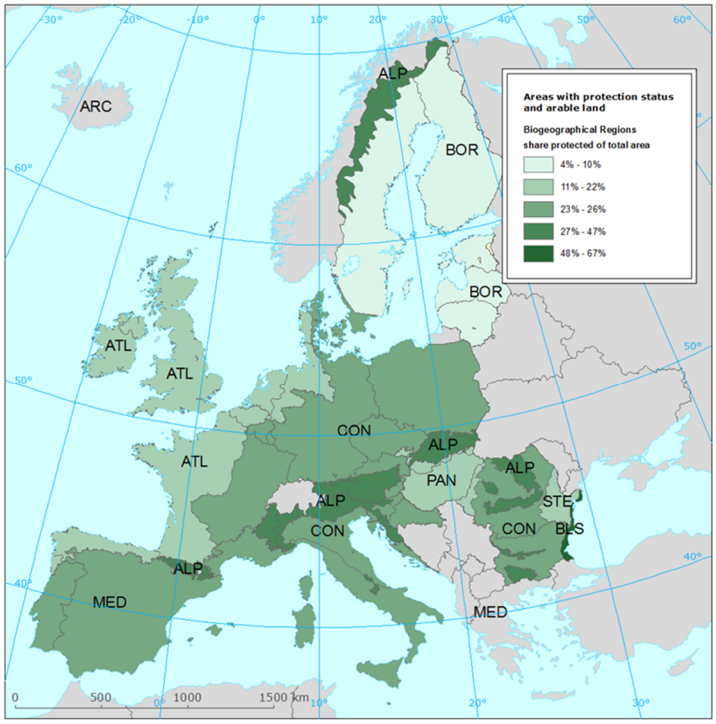

Figure 7: Share of protected areas in Biogeographic Regions (EEA, calculation: Umweltbundesamt)

b) Overlap of FFH-habitats and arable land in different Biogeographic Regions

Table 8 shows the size and the share of arable land according to Corine Landcover classes (see methods) in different Biogeographic Regions in the EU. The largest share of arable land is represented by a small BGR, the Pannonian BGR, with 60 % of the BGR corresponding to arable land while in the Alpine BGR only 7 % of the area can be attributed to arable land. Approximately half (48 %) of the total land area of the largest BGR, the Continental BGR, can be attributed to arable land.

Table 8. Size and share of arable land. in six different Biogeographic Regions (BGR) in the European Union: CLC = Corine Land Cover

BGR	CLC arable (m^2)	arable land share
ALP	21.949.310.000	7 %
ATL	319.847.620.000	41 %
BOR	126.264.730.000	15 %
CON	501.571.260.000	48 %
MED	315.617.680.000	42 %
PAN	66.182.090.000	60 %
	1.351.432.690.000	**35 %**

Two FFH habitat classes were selected and analysed regarding their spatial proximity to arable land.

First, the habitat 6210 `Semi-natural dry grasslands and scrubland facies on calcareous substrates´ was selected. Habitats of this class are largely distributed throughout Europe. In particular this habitat class is threatened by changes in agriculture, such as abandonment and overgrazing. It is reported from all 6 BGR. Second, the habitat 2340 `Pannonic inland dunes´ was selected. This habitat class is restricted to two BGR and three EU Member States (Austria, Hungary and Slovakia).

In Table 9 and Table 10 the distribution and share of the FFH habitat class 6210 and 2340 in the different BGR is shown.

The distribution of habitat 6210 has its highest share in the BGR Pannonian, Continental, Alpine and Atlantic with approximately 40 % share of the total area. Within its distribution area between 15 and 51 % of the area are classified as arable, the highest shares with around 50 % are situated in the Pannonian, the Atlantic and the Continental BGR. For this habitat the share of arable land is higher in the BGR Alpine, Atlantic and Boreal if compared to the share of arable land in the respective BGR in total (see Table 8 above). In three of the four BGR where this habitat class is largely distributed (Atlantic, Pannonian and Continental) the share of arable land is much higher than the average arable share of all BGR (37 %), indicating a close spatial relationship between this habitat class and land used for agriculture in these BGR.

In contrast to habitat class 6210 the habitat class 2340 is restricted to the Pannonian BGR with a small distribution area also in the Continental BGR.

Although only a small area of this habitat class lies in the Continental BGR about 70 % of this distribution area can be attributed to arable land. Also in the Pannonian BGR there is a high connectedness for this habitat class with arable land.

Table 9. Distribution and share of FFH habitat class 6210 (Semi-natural dry grasslands and scrubland facies on calcareous substrates) in the 6 Biogeographic Regions (BGR). CLC = Corine Landcover

BGR	CLC arable (m^2)	Share arable land	Share of habitat class in total area in BGR
ALP	17.790.460.000	15 %	39,9 %
ATL	146.547.450.000	48 %	38,8 %
BOR	35.875.630.000	37 %	11,6 %
CON	189.382.850.000	45 %	40,1 %
MED	18.709.360.000	25 %	10,1 %
PAN	24.307.310.000	51 %	43,1 %
average		**37 %**	

Table 10. Distribution and share of FFH habitat class 2340 (Pannonic Inland Dunes) in the 6 Biogeographic Regions (BGR). CLC = Corine Landcover

BGR	CLC arable (m^2)	Share arable land	Share of habitat class in total area in BGR
ALP	0	0	0
ATL	0	0	0
BOR	0	0	0
CON	493.730.000	70 %	0,07 %
MED	0	0	0
PAN	3.489.480.000	48 %	6,63 %
average		**59 %**	

2.7.4 Discussion

The Biogeographic Regions differ considerably regarding their share of arable land and land dedicated to nature protection. Generally, the Pannonian and the Steppic BGR have the highest shares of arable land but in these BGR there is also the highest share of arable land in protected areas indicating a high spatial connectivity between agriculture and nature protection. Other BGR such as the Alpine or the Macaronesian BGR support high shares of protected areas but have rather low shares of arable land, indicating a separation of agriculture and

protected areas. Remarkably, also the Continental BGR with a more than average arable land share has a relatively high share of arable land in protected areas.

Similarly, for FFH habitat types the analysis shows that there are significant differences in the distribution of specific habitat types between the different BGR. A particular habitat type may be more frequent in a particular BGR than in another. However, even if a habitat type may not be frequent in a BGR it may still contain a high share of arable land indicating a spatial relatedness between this habitat type and agricultural activities.

For the purpose of the ERA of GMOs this GIS-based analysis is a valuable tool for a first assessment of differences of protected areas and protected habitats between different Biogeographic Regions in the European Union. Depending on the GMO, its traits and potential risks, it may help selecting regions where further risk assessment studies should be performed or it may help excluding regions where due to a lack of protection goals potential risks can be excluded.

3 CONSIDERATION OF PROTECTION GOALS IN THE ERA OF GMOS

3.1 Introduction

In the EU the principles and basic elements for the ERA of GMOs have been laid down in Directive 2001/18/EC and the respective Guidance Notes (EC 2002). The most recent result of the continuous effort of risk assessment experts and scientists to develop and improve a common methodology for the ERA based on these legal requirements is the "Guidance on the environmental risk assessment of genetically modified plants" published by EFSA (EFSA 2010a). Amongst others it contains a clear requirement to consider protection goals in the ERA of GMOs as it calls for the identification of those *'aspects of the environment that need to be protected from harm'* in step 1 of the ERA, the problem formulation (EFSA 2010a, p.15). Due to the transitional period for the implementation of this Guidance Document experience with its application is currently rather limited.

The requirements for ERA of GMOs are in some cases open to interpretation and therefore the implementation may differ among risk assessors. The purpose of this study was to find out which protection goals are considered to be relevant for the ERA of GMOs in different Member States and which of those are actually taken into account when evaluating an ERA. Additionally the aim was to get an overview on the awareness for protection goals defined at the national or regional level.

3.2 Materials and Methods

The aim of this Task of WP2 was to find out about the use of protection goals in GMO risk assessment. For this purpose a survey among EU Member States (MS) was conducted. As the response rate was rather low and as the analysis showed a need for clarification on several issues, e.g. the terms used, it was decided to conduct telephone interviews with experts involved in risk assessments of GMOs from different EU MS to complement the information collected by the survey. The results gained in the online survey and in the interview which overlap to a certain extent were combined.

3.2.1 The Online Survey

As a first step a survey was conducted in order to collect basic information on the role of protection goals in the Environmental Risk Assessment (ERA) of GMOs. The survey (see Annex I) consisted of relevant questions concerning the ERA for field trials and for the placing on the market of GMOs. Additionally general aspects, e.g. the level at which environmentally relevant protection goals have been defined or potential considerations of the ecosystem service concept, were included.

The invitation to participate in the survey was distributed among all Competent Authorities (CA) in the EU Member States for Directive 2001/18/EC and Regulation (EC) No. 1829/2003. In some countries the CAs maintain a close

cooperation with national expert institutions with respect to the ERA of GMOs. These institutes were also included in the mailing list. The invitation to participate to this survey was also sent to the Secretariat of the EPA Network an informal group of the Heads and Directors of European Environmental Protection Agencies (EPA), and similar bodies across Europe, like the Secretariat of the ENCA network, a network of European Heads of Nature Conservation Agencies were informed.

An online tool (Survey Monkey) was chosen to carry out the survey. The online survey was opened on August 8th 2012 and was planned to run until the end of September. Due to a low response rate and upon request of some CAs the answering period was extended until the end of October. All answers received via the online tool were delivered by experts from national CAs or national expert institutions involved in the ERA of GMOs. The requests for participation sent to the Secretariats of the EPA and ENCA Network obviously were not forwarded to relevant experts and therefore there was no response to the survey from this group.

Twelve responses from ten EU MS were received. In nine cases answers were provided by the national CA and in three cases the questionnaire was completed by environment institutes closely involved in the ERA of GMOs.

3.2.2 Expert Interviews

Interviews were conducted to complement and to refine the picture gained with the survey with all EU MS experts (except one) who filled out the online survey. Additional EU MS experts were invited to the interviews aiming at covering at least all EU MS in which field trials take place in the course of the AMIGA project (see Table 11).

The interview was often conducted with the same person who had answered the online survey. However in five cases the CA referred to experts of an expert institution involved in the ERA of GMOs at the national level for the interviews. In four cases these expert institutions were environmental institutes. In some cases additional national experts from nature conservation institutes had to be contacted for clarification of certain aspects (e.g. Red Lists).

Table 11: Overview of AMIGA regions, EU MS involved in the AMIGA project and EU MS involved in survey and interviews

AMIGA region	AMIGA countries in the EU	AMIGA countries with field trials	EU MS involved in survey and interviews
Continental	AT, DE, SK	DE, HU, SK	AT, DE, HU, SK
Boreal	FI, SE	FI, SE	FI, SE, LT
Atlantic	BE, DK, IE, NL, UK	DK, IE, NL	BE, DK, IE, NL
Balkan	BG, RO	BG, RO	BG
Mediterranean	ES, FR, IT,	ES, FR, IT	ES, FR

It has to be noted that the information gained in the interview is based on the expert opinion of the interviewed person. It does not represent the official political position of the MS concerned. It also has to be taken into account that in some EU MS different CAs are responsible for Directive 2001/18/EC and Regulation (EC) No. 1829/2003. Therefore different views may not only exist between CAs and national expert institutions involved in the ERA of GMOs but also between various CAs. Despite these facts the information gained is presented on a MS basis, in order to draw a picture of the practice and - as far as possible - of the entirety of experts' views regarding protection goals in a particular EU MS. In some cases the analysis is not made per EU MS but per institution interviewed, which is indicted in the legend accompanying the tables.

The questions and an explanatory note regarding ecosystem service categories were sent out beforehand in order to allow for preparation or to get information from other involved experts (see Annexes). The questionnaire comprises 4 groups of questions:

1) Organization of the handling of applications in the respective MS (CAs, expert institutions and committees involved)
2) Consideration of protection goals with respect to biodiversity in the ERA
3) Consideration of ecosystem services in the ERA
4) Other protection goals considered important for ERA

As group one was mainly aimed to get some background information for a better understanding of the organizational structure in different countries the analysis (see 3.3 to 3.6) has been performed only for groups 2-4.

3.2.2.1 Assessment of the consideration of protected species & areas in the ERA of GMOs

As in the interviews the consideration of protected species and protected areas in the ERA of GMOs was discussed separately for applications for deliberate release and for placing on the market/cultivation, the results are presented reflecting these two different levels of authorization.

First the MS experts were asked to provide information on their experience in handling applications - for deliberate release and placing on the market/cultivation, respectively - and second to give their view on the importance of the consideration of protected species and areas in the ERA. Although in the questionnaire the term 'protected habitat' has been used, in the interviews it was clarified that any kind of protected area - independent of the specific protection goals the area was set up for – should also be included.

In the analysis the expert opinion received was assigned one of three categories: '*considered*', '*not considered*', and '*unclear*'. For four EU MS answers from more than one expert were received. Naturally these answers differed and reflected various expertise as well as differing tasks of the experts with regard to GMOs. As the focus was on the question whether a respective protection goal is being consider important for the ERA in an EU MS or not, it was not considered necessary to differentiate between various experts opinions. If a certain protection goal is considered relevant by one of the experts of an EU MS, the category 'considered' was assigned to the EU MS in the data presentation.

'*Considered*' in the context of this survey means that the respective protection goal is already considered (in MS which do perform environmental risk assessments for cultivation, or which do so in the context of field trials), where this has been done by the MS in comments on applications for placing on the market of GMOs, or where the expert is of the opinion that it would be considered, in case field trails take place in the MS in the future.

'*Not considered*' means that the respective protection goal is not or would not be considered.

The category '*unclear*' has been assigned to those cases, in which MS experts referred to no or little experience gained with applications and there is some uncertainty about the handling of this issue on expert level or because there is no clear policy .

3.2.2.2 Assessment of the consideration of ecosystem services

The Member States' experts were asked whether in their opinion ecosystem services (ES) could potentially be adversely impacted by GMO cultivation (Annex II, Question 3b) and whether ecosystem services were already taken into consideration during the ERA of GMOs (Annex II, Question 3a).

The ES were categorized based on the classifications of MEA (2005), EFSA (2010c) and de Groot (2010). However, some sub-categories were added, deleted or amended with respect to the context of GMO risk assessment. The following categories were used:

1. Provisioning services are services that describe the material or energy outputs from ecosystems (food, water etc.).
2. Regulating services are services that ecosystems provide by acting as regulators, e.g. regulating the number of plants that are pollinated.
3. Supporting services underpin all other services as ecosystems are the planet`s life-support systems. Ecosystems provide space for organisms and maintain a diversity of plants and animals.
4. Cultural services are the non-material services and benefits people get from ecosystems.

Explanations for each sub-category were provided to the experts (see Annex III).

Additionally they were asked to rank various ecosystem services with respect to their relevance for GMOs on a scale of 1 (very unlikely) to 6 (very likely). If a range was given, e.g. 2-3 for a particular ecosystem service, the lower figure was chosen for the analysis. It was clarified in the interviews that the totality of GMOs currently marketed and that regarding ES only the European context is to be considered in this respect. The experts ranked the ES according to the likelihood with which they might be affected by GMOs in their view. This provides information on which ecosystem services might be included in the ERA of GMOs in the future.

3.3 Consideration of protected species in the ERA for GMOs

The assessment of potential effects on non-target organisms is a very important element in the ERA of GMOs. However it has been criticized that species of conservation concern are not adequately taken into account in the ERA of GMOs (Dolezel et al. 2011). Such species often enjoy a legally defined special protection status which may be set at various levels.

Species protected by the Habitat Directive (Directive 92/43/EEC) and which are listed in the respective Annexes of this directive are also protected at national level. However for the purpose of this survey protected on the basis of the Habitat Directive are differentiated from species protected under national law. The reason is that the latter may comprise additional species, because national nature conservation laws have been established independent from and usually before the Habitat Directive entered in to force. Additionally they are subject to revisions and adaptations according to national policies and thus may differ from the species listed in the Annexes of the Habitat Directive. Moreover in some EU MS protected species may also be defined at subnational (i.e. regional) level.

One of the goals of the interviews was to get information about in how far protected species are being considered in practice when conducting ERA of GMOs in applications for deliberate release or for placing on the market/cultivation in the EU MS (Question 2 a & b, Annex II).

3.3.1 Consideration of protected species in applications for deliberate release

The competence for applications for deliberate release rests with the national CA of the respective EU MS. The evaluation of the ERA submitted by the applicant is usually carried out by the CA, often together with national expert agencies, advisory boards or scientific committees.

Potential risks identified for a specific GMO vary and thus not all protection goals might possibly be adversely affected by the use of a certain GMO. This will depend on the characteristics (crop plant, traits) of the respective GMO, the receiving environments and the extent and scale of its potential use. This fundamental principle is reflected in the case-by-case principle established in Directive 2001/18/EC and is applied in all EU MS. However, the experience in the MS with applications for field trials varies substantially. In countries where no or almost no applications have been filed no or very little experience has been gained in this respect. Consequently the question of potential risks for protected species and habitats may not yet have been clarified in the respective MS.

Table 12: Consideration of protected species in the ERA of GMOs notified for deliberate release (the number of expert opinions received per EU MS varies)

Species protected at	considered	Not considered	Unclear
EU Level	AT, BE, DE, DK, ES, FI, HU, NL[1],SE, SK	FR	BG, IE, LT
National level	DE, DK, ES, FI, HU, SE, SK	AT[2], BE[2], FR, NL[3],	BG, IE, LT
Subnational level	AT, BE, DE, ES, FI	FR, NL, SE	BG, DK, HU, IE, SK, LT

[1] In the Netherlands species are only considered as far as they occur in Natura 2000 areas

[2] species are not protected at the national but at the regional level only

[3] it is unclear, whether species beside FFH species are also protected at the national level in the Netherlands

Ten MS experts clearly stated that the already do or would consider species protected at EU level in the ERA of applications for deliberate release of GMOs. Species protected at the national level are equally being considered by experts in all but one of those EU MS. In Germany a beetle *(Osmoderma eremita)* which is listed in Annexes II and IV of the Habitat Directive has rendered a field trial impossible due to its occurrence in the proximity of the planned location of the field trial. In the Netherlands protected species are only considered in so far as they occur in Natura 2000 areas. However in Austria and Belgium species are only protected at the regional level and not at the national level due to the national assignment of competences for nature protection. These species are being or would certainly be considered in the ERA for deliberate releases. Three MS experts stated that not sufficient experience had been gained to answer this question.

According to experts in five EU MS (AT, BE, DE, ES and FI) species which are protected at a regional level are also taken into account in applications for deliberate release. However as in Austria and Belgium the protection of species is entirely the responsibility of regional authorities this leads to differences in the species protected in the different regions.

3.3.2 Consideration of protected species in applications for placing on the market/cultivation

Regarding the application for placing on the market a similar picture arose. Only the experts of France and the Netherlands pointed out that protected species are not specifically being considered in the ERA of GMOs in their MS. However potential effects on non-target species are being considered in these two MS, but in the Netherlands only in respect to the chosen baseline which is conventional agriculture. Beside these two MS and Bulgaria and Lithuania, for which experts expressed uncertainty in this respect, experts of all other MS in principle consider protected species protected at the national level in the assessment of applications for placing on the market. Experts from Finland and

Sweden stressed that they would only pay attention to protected species, if cultivation of the respective GMO would be feasible in their country. In Hungary nationally protected species have been considered in import bans enacted according to the safeguard clause in Directive 2001/18/EC. Experts of Austria, Germany and Spain highlighted that species protected at subnational/regional level are equally taken into account. Experts in Spain pointed out that even invasive species (e.g. *Nicotiana glauca*) are taken into consideration with respect to authorizations for placing on the market/cultivation.

Table 13: Consideration of protected species in the ERA of GMOs notified for placing on the market (the number of expert opinions received per EU MS varies)

Species protected at	Considered	Not considered	Unclear
EU Level	AT, BE, DE, ES, DK, FI, HU, IE, SE, SK	FR, NL[1]	BG, LT
National level	DE, DK, ES, FI[2], HU, IE, SE[2], SK	AT[3], BE[3], FR, NL[1]	BG, LT
Subnational level	AT, DE, ES	BE, DK, FI, FR, HU, NL[1], SE, SK	BG, IE, LT

[1] refers to conventional agricultural practice as the baseline for the ERA and as the reason for not taking protected species into account.

[2] only if cultivation of the respective GM crop would be feasible in the respective MS

[3] protected species are covered by laws at the regional level

3.4 Consideration of protected areas in the ERA for GMOs

The designation of protected areas is one of the most often used instruments in nature conservation. This instrument has long been used by MS to protect specific habitats and species of conservation concern. Depending on the administrative structure in EU MS the designation of protected areas may not only take place at the national level, but often is assigned to regional authorities. In each MS a range of different categories (e.g. national park, nature conservation areas, landscape protection areas) exist, ranging from categories focusing on ecological objectives to those adopted to protect areas of specific cultural value. In addition to these nationally protected areas EU MS have been obliged to establish the Natura 2000 network, a network of protected areas in Europe required for the implementation of the Habitat Directive (Directive 92/43/EEC) and the Bird Directive (Directive 79/409/EEC, updated by Directive 2009/147/EC). In particular these areas had to be designated for the protection of habitats listed in Annex 1 and species listed in Annex 2 of the Habitat Directive.

The discussion on whether the cultivation of a GMO may have potential effects on protected areas has always been a delicate matter. The reason is that in

particular as a cause-effect relationship between the cultivation of a GMO and potential effects on protected areas may not be established easily. The interviews aimed to get information on how protected areas are being included in the ERA of GMOs in applications for deliberate release as well as in applications for placing on the market/cultivation (Question 2 a & b, Annex II).

3.4.1 Consideration of protected areas in applications for deliberate release

Almost all of the MS experts stated that protected areas are considered in the ERA of applications for deliberate release of GMOs (Table 14). Only in the Netherlands a distinction is made between the consideration of Natura 2000 areas and areas protected at the national level. Experts from Austria, Germany, Spain, Finland and Sweden explicitly point out that areas protected at subnational/regional level are taken into account in the ERA for deliberate release of GMOs.

Table 14: Consideration of protected areas in the ERA of GMOs notified for deliberate release (the number of expert opinions received per EU MS varies)

Areas protected at	Considered	Not considered	Unclear
EU level	AT, BE, BG, DE, DK, ES, FI, HU, IE, NL, SE, SK	FR[1]	LT
National level	AT, BG, DE, DK, ES, FI, HU, IE, SE, SK	BE[2], FR[1], NL[3]	LT
Subnational level	AT, DE, ES, FI, SE	FR[1], NL[3]	BE, BG, DK, HU, IE, SK, LT

[1] no field trials are located in protected areas, but apart from that they are not specifically being considered in the ERA

[2] protected areas are covered by laws at the regional level

[3] only Natura 2000 areas are taken into account; field trials are not located in or near Natura 2000 areas

In most EU MS risk assessors take the position of a precautionary approach with respect to the locations where field trials are allowed to take place. This means that they pay attention that field trials are not placed in close vicinity to protected areas. Moreover risk management measures, like isolation distances, are applied in order to prevent potential damage for nearby protected areas. On the other hand some MS experts reason that due to the limited scale of field trials and their carefully selected position in agricultural areas, sustained damage for protected areas is unlikely to occur.

While in some EU MS a precautionary approach of GMO risk assessment, which includes a careful selection of field trial locations, is deemed to be satisfying, in other MS legal provisions aiming at the protection of certain areas independent from the ERA have been established. In Hungary for instance

according to the gene technology act so called 'gene bank areas', a concept that includes nature conservation aspects and agricultural aspects (e.g. seed production), could be taken into consideration in authorizations for deliberate release. In Bulgaria for example deliberate release and cultivation of GMOs is generally forbidden within the boundaries of protected areas, within a distance of 30 km from those areas and within a distance of 10 km of registered fixed beehives (BG GT-Act, Art. 80). In Germany the potential risk for Natura 2000 areas resulting from the planting of GMOs within such sites is being evaluated in nature impact assessments on a case by case basis (BNSchG, §35). Additionally following an agreement between the involved agencies also potential effects of deliberate releases are being taken into account if the chosen site lies within 1000 m of a Natura 2000 area (BMG 2009).

Protected areas established at the subnational level are or would be considered in Austria, Germany, Spain, Finland and Sweden. For experts from Belgium, Bulgaria, Denmark, Hungary, Ireland, Slovakia and Lithuania there is no clarity on this point. This may either be due to lack of experience gained with applications and thus with the approach of the experts involved at the national and regional level or due to the lack of protected areas established at the subnational level in the respective MS.

3.4.2 Consideration of protected areas in applications for placing on the market/cultivation

Due to lack of cases and relevant traits for which relevant risk scenarios for protected areas could be established most MS experts could not recall any specific cases in which protected areas were specifically considered in the ERA of applications for placing the market/cultivation. However in many EU MS (9 out of 14 for Natura 2000 areas; 7 out of 14 for nationally protected areas) experts call for the consideration of protected areas for the ERA in applications for placing on the market/cultivation and underline the importance of these protection goals. In addition experts of Austria, Germany and Spain explicitly point to the consideration of areas protected at subnational/regional level.

Table 15: Consideration of protected areas in the ERA of GMOs notified for placing on the market (the number of expert opinions received per EU MS varies)

Areas protected at	Considered	Not considered	Unclear
EU Level	AT, BE, DE, DK, ES, FI, HU, IE, SK	FR, NL, SE[1]	BG, LT
National level	AT, DE, ES, FI[2], HU, IE[2], SK	BE[3], DK, FR, NL, SE[1]	BG, LT
Subnational level	AT, DE, ES	BE, DK, FI, FR, HU, NL, SE[1], SK	BG, IE, LT

[1] not routinely, only if risk is identified

[2] only if cultivation of the respective GM crop would be feasible in the respective MS

[3] protected areas are covered by laws at the regional level

In Bulgaria distances to Natura 2000 areas are established on a general basis (BG GT-Act, Art. 80). In Austria cultivation of GMOs needs to be notified to regional authorities which may impose special conditions for protected areas (genetic technology precaution laws of the Austrian Federal Provinces/States). In Germany the cultivation of a GMO is subject to a nature impact assessment if it takes place within a Natura 2000 area or - according to an agreement between the involved agencies – within a distance of 1000 m from that area. While only in Austria, Germany and Spain experts consider protected areas set at the regional level in the ERA of GMOs for placing on the market/cultivation, in eight EU MS these are not taken into account (BE, DK, FI, FR, HU, NL, SE, SK). Among those are not only EU MS in which protected areas are not established at the subnational level, but also a MS with extensive competences at the regional level in this respect.

3.5 Consideration of ecosystem services in the ERA of GMOs

During the problem formulation in the ERA of GMOs, the protection goals which are potentially adversely affected when a certain GMO is cultivated in the EU need to be defined (EFSA 2010a). According to the approach chosen by EFSA these do not only include the protection of biodiversity, but also imply the protection of ecosystem functions and services (EFSA 2010a, 2010b). Ecosystem services (ES) are defined as "direct and indirect contributions of ecosystems to human well-being" and arise from the interaction of biotic and abiotic processes (de Groot et al. 2010). These services are in decline as pressures on the environment increase. Some of these services (e.g. water quality, soil condition, species diversity, cultural landscape) are significantly influenced by agriculture. Therefore the objective was to find out whether the concept of ecosystem services is explicitly or implicitly being considered in the ERA of GMOs (Question 3 a & b, Annex II).

Ten experts pointed out that they would already consider certain ecosystem services in the ERA, either directly or indirectly (Table 16). The ES were ranked by 10 experts of 14 EU Member States (Table 16). For Germany experts of two different authorities involved in GMO risk assessment answered the relevant questions.

Regarding the consideration of ES in the ERA of GMOs for example, potential effects of GMOs on “ecological functions” were mentioned by experts from Hungary and the Netherlands. “Biological control” was mentioned by experts from Belgium and Austria. Experts from France particularly stressed the evaluation of agronomic impacts in this respect (e.g. pest resistance) in addition to evaluation of the environmental impact. Experts from Denmark noted that ecosystem functions would be indirectly considered in the ERA by considering biodiversity protection. Experts from Sweden stated that generally all ecosystem services would indirectly be taken into consideration in the ERA by formulating risk hypotheses and conducting scenario assessments which could indicate whether a certain ecosystem service would be at risk. Other ecosystem functions which according to the experts’ opinions are already considered in the ERA of GMOs were: pollinators/pollination, soil functions, soil quality and fertility, species diversity, water quality, and nutrient cycling.

Many experts stressed explicitly the importance of the case-by-case approach for the evaluation of possible effects of a GMO on ecosystem services as the potential effects would depend on the GMO and its traits. In this context one expert also noted that the evaluation of potential effects of GMOs on ecosystem services can be answered only retrospectively, i.e. for GMOs that are ready for market introduction, but not for GMOs with traits to be developed in the future. Hence, the results may be very different for future GMOs.

One expert stated that the consideration of ecosystem services in the ERA of GMOs would hardly be feasible at EU level (i.e. during the notification procedure) but should rather be handled at the national level.

Other experts stated that effects of GMOs on the ecosystem service category 4 (cultural services) would be difficult to evaluate as there is no scientific rationale behind them or because they are socio-economic services and hence not relevant for the ERA of GMOs.

Table 16: Ecosystem services considered in the ERA of GMOs (x = yes, - = no)

EU Member State	ES already considered in the ERA	MS experts provided ranking of ES
AT	x	x
BE	x	x
BG	-	-
DE	x	x[1]
DK	x	x
ES	x	-
FI	x	x
FR	x	x
HU	x	x
IE	-	x
LT	-	x
NL	x	-
SE	x	-
SK	-	-

[1] two CAs provided an evaluation of ES

Between 53 and 67% of the experts were ranking individual ecosystem services according to their importance for ERA. In category 1 (provisioning services) the ES ‘water’ was most often ranked. In category 2 (regulating services) the ES ‘pest and disease regulation’, ‘resistance to invasion and ‘seed and propagule production and dispersal’ and in category 3 (supporting services) the ecosystem services ‘maintenance of genetic diversity’ and ‘provision of habitat’ were most frequently ranked (see Figure 8).

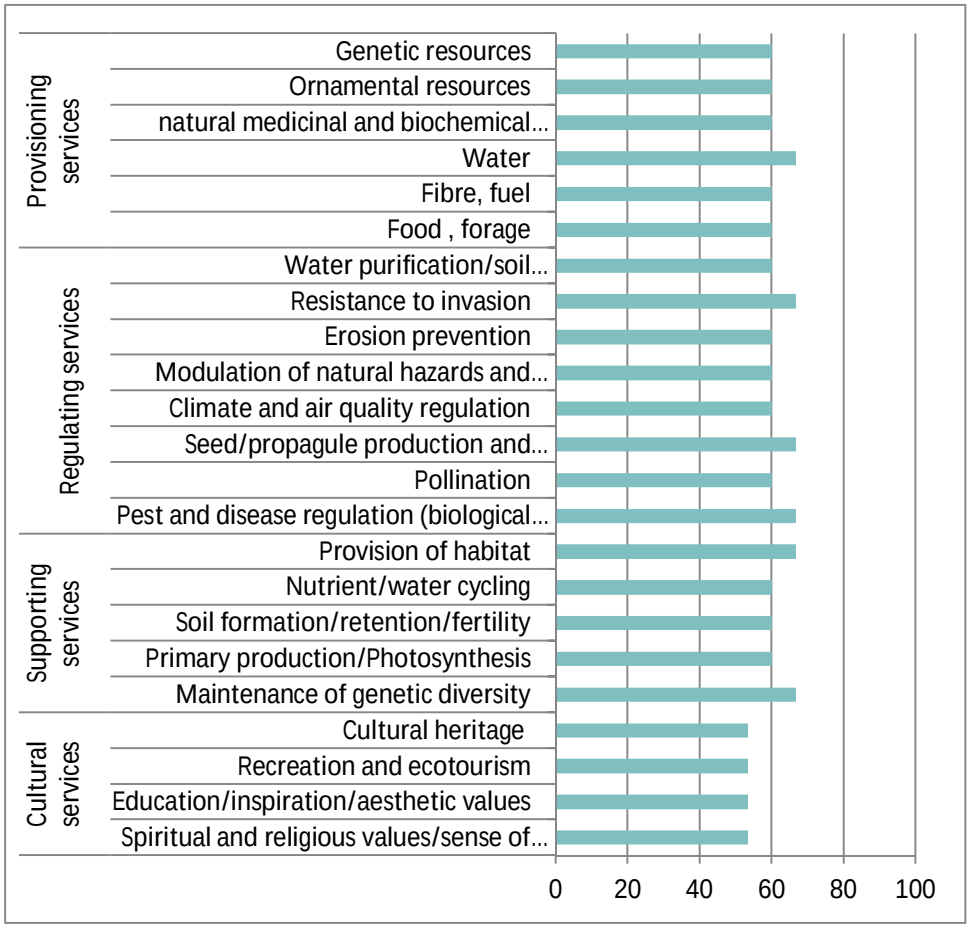

Figure 8: Percentage of EU MS experts ranking the different ecosystem services

All ecosystem services were ranked by at least one expert. The value to be assigned to the importance of any ecosystem service ranged from 1 to 6. The highest value (6) was assigned to 13 of 23 ecosystem services. In the category provisioning services 5 out of 6 ES were given at least once the highest value. In the category regulating services, the highest value was given to 3 out of 8 ES. In the supporting services, the highest rating was also given to 3 out of 5 ES. In the cultural service category the highest rating was given to 2 out of 4 ES sub-categories.

The average rating value given for a particular ecosystem service by all experts interviewed is shown in Figure 9. The highest values were assigned to the ES "genetic resources" of category 1, "pollination" of ES category 2, "maintenance of genetic diversity" and "soil formation/retention/fertility" of ES category 3 and "education/inspiration/aesthetic values" of ES category 4. The lowest values were given to the ES sub-categories "ornamental resources" (category 1), "climate and air quality regulation", resistance to invasion" and "erosion prevention" (category 2), "primary production/photosynthesis" (category 3) and "cultural heritage" (category 4).

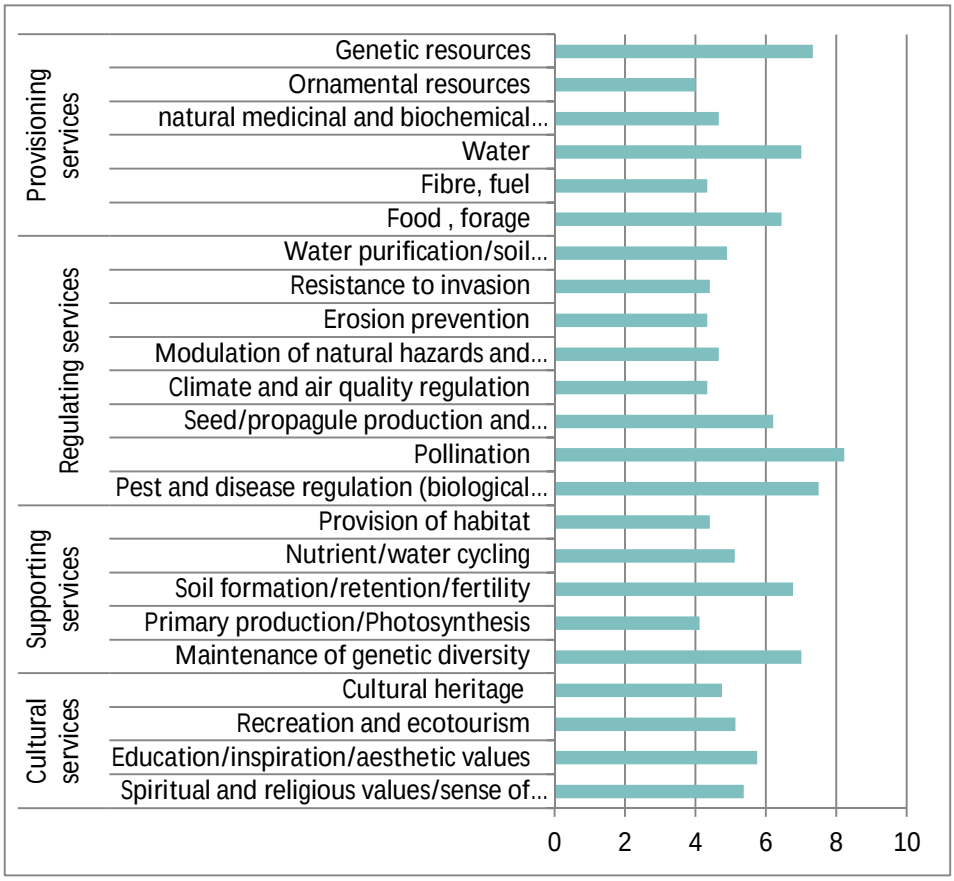

Figure 9: Average rating value given to individual Ecosystem Service categories by EU MS experts

In addition to information on the use of the ecosystem service concept in the ERA of GMOs information on references to ecosystem services in existing legislation or strategies/policy documents in the various MS was collected in the survey (Question 12, Annex I). The focus was on ecosystem services which are significantly influenced by agriculture (e.g. water quality, soil condition, species diversity, cultural landscape). Agricultural production benefits from ecosystem services (e.g. soil fertility, pollination), but also provides the basis for certain ES such as biodiversity in cultural landscapes (Umweltbundesamt 2011). The table below shows that ecosystem services are often referred to in existing legislation as well as in strategy/policy documents (

Table 17). According to the opinion of the GMO experts in particular the following ES are incorporated in existing legislation as well as in policy documents: water, fertile soil, feed and fertilizer for agricultural production, existence of natural biodiversity and genetic resources. However, this question could often not been answered by GMO experts; between three and five experts, respectively, did not provide answers.

Table 17: Status of the consideration of ecosystem services in national legislation and policy documents based on expert opinions (n=11)

	In existing legislation	In policy document	In both	no answer provided
Water supply	2	-	6	3
Fertile soil	1	2	5	3
Pollination	2	2	2	5
Pest and disease regulation	3	-	4	4
Protective function of agricultural landscapes	1	3	3	4
Renewable energy sources	2	1	4	4
Food production	2	1	4	4
Feed & fertilizer for agricultural production	2	-	5	4
Recreational services via supply with valuable natural and cultural landscapes[1]	1	3	2	5
Recreational services by hunting, collecting and observation of wild species	2	1	4	4
Existence of natural biodiversity	1	-	6	4
Genetic resources	1	2	5	3

[1] Including economic benefits for tourism

3.6 Other protection goals considered relevant for GMOs

Besides protection goals which need to be dealt with only in the risk assessment there are others which need to be handled in the risk management, e.g. outcrossing or resistance development. Regarding these aspects the aim was to find out whether MS take into account relevant specifications set at national or subnational level (Question 2 & 6, Annex I). In addition to that other protection goals (e.g. Red List species) which may be considered important for the ERA of GMOs by MS experts (Question 4, Annex II) were identified.

3.6.1 Protection goals recognized in the risk management of GMOs

Aspects that receive special attention in the ERA of GMOs are the possibility of the spread of transgenes via outcrossing or the possibility of resistance development in target pests. The reason is that both aspects generally are

recognized as undesired effects which may result from the cultivation of GMOs. With respect to the potential of outcrossing of GMOs special care needs to be taken in the case of the cultivation of oilseed rape, because of the occurrence of wild relatives in the EU. Regarding resistance development compulsory insect resistance management plans are implemented as risk management measures.

In order to find out potential differences between but also within EU MS regarding the above mentioned aspects, these specific points were included in the online survey (Questions 2 & 6, Annex I).

Table 18: Level at which protection goals relevant for risk management are laid down and which are being considered by EU MS experts in the evaluation of applications for the deliberate release of GMOs (DE1 and 2, and FI 1 and 2 indicate answers from experts from different institutions with different responsibilities regarding ERA)

	National	Subnational	Both (national & subnational)	Not taken into account
Prevention of outcrossing	AT, BG, DE 1, DK, NL, LT	BE	FI 1+2, ES, DE 2	-
Prevention of resistance development	AT, DK, NL, LT	FI 2	ES, DE 2	DE 1, BE; BG, FI 1,

Regarding the prevention of outcrossing most experts state that in their MS (or in their institution) risk management requirements which are set at the national level (ten out of eleven) are considered. Additionally four MS (institutions) take risk management measures into consideration which are set at the subnational level. With respect to the management measures aiming at the avoidance of resistance development in target pests, six MS/institutions consider requirements established at the national level and two of those additionally consider subnational requirements. For both aspects there is one MS/institution each which exclusively deals with specifications set at the subnational level.

Table 19: Level at which protection goals relevant for risk management are laid down and which are being considered by EU MS experts in the evaluation of applications for the placing on the market of GMOs (DE1 and 2, and FI 1 and 2 indicate answers from experts from different institutions with different responsibilities regarding RA)

	National	Not taken into account at the national level
Prevention of outcrossing	AT[1], BG, DE 1+2[1], ES[1]	BE, DK, FI 1+2, NL, LT
Prevention of resistance development	DE1+2[1], ES[1]	AT, BE, BG, DK, FI1+2, NL, LT

[1] the respective protection goal is also considered at the regional level

As far as the consideration of respective risk management requirements in applications for placing on the market/cultivation is concerned fewer experts (six

out of eleven and three out of eleven respectively) stated that national rules are taken into consideration in addition to those laid down at EU level. However three of them, respectively two, pointed out that in addition subnational rules are being considered.

3.6.2 Red Lists of species and Red Lists of habitats

Red Lists are scientific instruments to categorize the degree of endangerment of species. The IUCN has established endangerment categories and criteria to evaluate species according to their risk of becoming extinct (endangered, critically endangered, vulnerable etc.). This concept was developed primarily for application at the global level, but is increasingly being used for assessments at various levels (e.g. European Red Lists). A large number of Red Lists are available also at the national or subnational level using varying classification systems of threat. At the national or subnational level these lists provide the basis for the definition of species and habitats which are to be protected under national or subnational nature conservation law. The survey also sought information on what kind of Red Lists are available in the EU MS and whether they are attributed any significance with respect to the ERA of GMOs (Question 2.c - 2.g, Annex II).

All of the fourteen EU MS included in our assessment have drawn up a Red List of species and in twelve of those MS the Red Lists include Lepidoptera (

Table 20). In addition five MS have a Red List of habitats and seven have Red Lists also at subnational level. In Finland Red Lists of habitats have also been drawn up at regional level and as there species may also be protected at local level, even local Red Lists exist. For almost half of the EU MS experts interviewed (six out of fourteen) Red Lists are considered important for the ERA of GMOs. Not all of these experts explicitly consider them in the ERA of GMOs, but acknowledge the strong influence of this scientific instrument for decision making in general. However, experts from Germany, Denmark, Belgium and Austria stress that endangered species (e.g. Red Lists species) are taken into account. In Finland Red Lists would be taken into account if cultivation of the GMO was relevant for Finland.

Table 20: Existence of Red Lists in EU MS and their relevance for the ERA (Y= yes, N= no, '?'= unknown)

EU MS	Red List of species[1]	Red List of habitats	Red Lists at subnational level[2]	Red Lists of Lepi-doptera[3]	Red Lists considered important for ERA
AT	Y	Y	Y	Y	Y
BE	Y	N	Y	Y	?
BG	Y	Y	N	?	?
DE	Y	Y	Y	Y	Y
DK	Y	N	Y	Y	?
ES	Y	N	Y	Y	Y
FI	Y	Y	Y	Y	Y
FR	Y	N	N	Y	?
HU	Y	Y	N	N	Y
IE	Y	N	Y	Y	Y
LT	Y	N	N	Y	?
NL	Y	N	?	Y	N
SE	Y	N	N	Y	?
SK	Y	N	N	Y	Y

[1] Red List of species often do not comprise all species groups

[2] subnational Red Lists usually comprise species and not habitats; it was not assessed whether all or only some regions or provinces of a EU MS have drawn up Red Lists

[3] at national level; it was not assessed whether they include all groups of Lepidoptera or only diurnal butterflies

3.6.3 Other protection goals considered important for the ERA of GMOs

The questionnaire also asked if there are any other protection goals, which, in the opinion of the experts, should be taken into consideration during the ERA of GMOs (Question 4, Annex II). Member State experts considered several protection goals relevant for the ERA of GMOs (see

Table 21). Some experts stated that some of the protection goals mentioned below are already covered by the ERA of GMOs (e.g. soil function, aquatic ecosystems, plant health). Experts from the Netherlands stated that no other protection goals are relevant for GMOs than for conventional agriculture. Three member state experts stated that the protection goals should be considered differently depending on the scale of the release of a GMO (experimental release into the environment versus placing on the market). In case of commercial cultivation of a GMO a stronger impact on a particular protection goal might be expected.

Integrated pest management/plant health was considered relevant by 5 of 14 experts. One expert also considered the maintenance of weed control as relevant; although this point is dealt with in many ERAs of GMOs (in particular for cultivation purposes).

The protection of soil function and fertility was considered relevant by 6 of 14 experts, the protection of sustainable agriculture by 5 of 14 experts. Experts stated that sustainable agriculture would not play a major role in conventional agriculture in their MS; hence it would also not be an important protection goal for GMOs.

The protection of aquatic ecosystems was considered relevant in 4 of 14 expert opinions.

Genetic resources were considered important by experts of Hungary and Austria. For Hungary they were considered important with relation to the preservation of traditional varieties and local breeds and case for Austria relating to the maintenance of a GMO free seed production.

Other protection goals mentioned by experts referred to habitats, landscapes or regions that require specific protection for different reasons. Such “high value areas” might be: traditional rural biotopes, landscapes and pastures (FI), GMO free areas (LT) or ecological sensitive areas (AT).

One expert mentioned traditional cultural crops that require specific protection. Experts from Germany mentioned “responsibility species”. These are species for which a particular country has a high responsibility for its conservation from an international perspective. The reason might be because this species only occurs in this particular country or because a high percentage of the world population occurs only in this country.

Also air quality was mentioned by one expert as protection goal, referring to the application of plant protection products. Other protection goals mentioned are long-term effects, cumulative effects and ecological functions in general.

Table 21: Protection goals other than biodiversity considered important in the ERA of GMOs by EU Member States experts.

MS	IPM, plant health	Soil function, soil fertility	Sustainable Agriculture	Aquatic ecosystems	Genetic resources	other
AT					x	Ecological sensitive areas
BE						weed control
BG						Traditional crops
DE	x	x				cumulative effects, „responsibility species“
DK	x	x	x	x		
ES		x	x			
FI	x	x	x	x		Tradit. rural biotopes, landscapes, pastures
FR						Long-term effects, ecological functions
HU		x		x	x	Air quality/micro- and local climate
IE			x			
LT						Long-term effects, GMO free areas
NL	x	x				
SE	x	x	x	x		
SK						

3.7 Summary

Although the experience of CAs with applications varies among EU MS this obviously does not negatively influence the awareness of the importance of protection goals in general. A clear majority of experts confirmed the importance of the consideration of species and areas protected at the EU and national level and of ecosystem services in general. In half of the EU MS the experts interviewed consider Red Lists important for the ERA. Moreover most experts declared that in case of deliberate releases national, in some EU MS even subnational, protection goals are taken into account. Beside protected species and areas this concerns in particular protection goals widely recognized in risk management, such as the prevention of outcrossing or the development of resistance in target pests. Even those experts, for who expressed uncertainty on how to consider protected species and areas in the ERA of GMO in their country, stressed the importance of these protection goals for the ERA of GMOs.

Protected species and protected areas receive the highest attention of all protection goals and are an inherent part of the ERA in some EU MS. In practically all EU MS protected areas set up at the national level are taken into account in the ERA of GMOs for the deliberate release at national level. Only in one EU MS the consideration is restricted exclusively to Natura 2000 areas. For GMO applications for placing on the market/cultivation, however, the consideration of areas protected at the national level differs among EU MS. Some MS consider them in the ERA on a case-by-case basis, some only if cultivation of the respective crops would be feasible on their territory. Some MS do not think that the consideration of protected areas and species is relevant at this level of authorization. Some EU MS take nationally protected areas into account when authorizing field trials at national level but do not consider them for applications for placing on the market/cultivation. This seems to be rather due to procedural and administrative reasons. At the national level CAs have the possibility to influence the position of a field trial if a protected area lies in the vicinity and/or to impose risk management measures (e.g. isolation distances). In decisions on GMOs authorized for placing on the market/cultivation restrictions aiming at avoiding potential risk for protected areas have never been laid down. Therefore some EU MS have established additional national requirements aiming at the prevention of possible negative effects from GMOs on protected areas (e.g. defined isolation distances in Bulgaria, requirement for the notification of cultivation and possibility for risk management measures with respect to protected areas opposed by regional authorities in Austria or the possibility for a nature impact assessment according to the FFH Directive in Germany)

The majority of experts stated that species protected at the EU level, i.e. according to EU Directives 92/43/EEC and 2009/147/EC are equally taken into account in the ERA of GMOs in applications for deliberate release and in applications for placing on the market. Regarding species protected at the national level - beside those experts who expressed uncertainty of the handling of this issue due to lack of national experience - again a majority stated their importance for the ERA of GMOs for both levels of authorization. Only in one EU MS protected species are only considered in so far as they occur in Natura 2000 areas. In addition in half of the EU MS Red Lists of species are considered important for the ERA of GMOs. This is remarkable as in the first place Red Lists are a scientific instrument on which usually the selection of species protected at the national level is based upon. According to the expert opinions not only species enjoying a legal protection status are being taken into account, but also endangered species are considered important for the ERA. National Red Lists usually do not cover all species groups. For Lepidoptera, an order which is of high importance for many current GM crop plants, respective Red Lists do exist in most EU MS. So far Red Lists of habitats/biotope types have been elaborated in a minority of EU MS and thus have not yet received attention by GMO experts. It has to be noted, however, that despite in half of the EU MS Red Lists of species receive a high awareness with respect to the ERA, the perception of endangered species by GMO experts is quite low in other EU MS. For instance among some GMO experts uncertainties existed with respect to the existence of Red Lists at the national level.

Diverging views were also revealed with respect to species and areas protected at the subnational, i.e. regional, level. While in some EU MS it is considered important to take species and areas protected at the regional level into account

in the ERA of GMOs, in particular for deliberate releases, in other EU MS this is not the case. Four (for deliberate release), respectively two (for placing on the market/cultivation), EU MS experts underline the importance of the consideration of species protected at the regional level. However, some experts were unclear about the relevance of species and areas protected at regional level and some did not take them into account at all. As far as applications for placing on the market/cultivation are concerned most experts did not consider species and areas protected at the regional level important for the ERA. This inconsistency among EU MS seems to be due to different administrative structures, for instance with regard to nature protection, but also regarding GMOs. While in some EU MS (e.g. AT, DE, BE and FI) regional authorities have extensive or exclusive responsibilities as far as nature protection is concerned, in other EU MS (e.g. NL) this issue is exclusively dealt with at the national level. Similarly, the involvement and competences of regional authorities with respect to GMOs differs among EU MS. In Spain for instance the autonomous communities (ACs) are responsible for the authorization of field trials for other purposes than variety registration and all ACs are represented in the National Commission on Biosafety. In other EU MS regional authorities have a veto right (BE), are consulted (AT, DE) or not involved at all (F) regarding the authorization of field trials. For placing on the market/cultivation the involvement of regional authorities is the exemption and not the rule. In addition environmental institutes are not routinely involved in the ERA of GMOs in all EU MS. The various administrative structures in EU MS, however, seem not only to play a role for the awareness of regional protection goals at national level but also for their consideration in the ERA.

The concept of ecosystem services is considered useful to raise public awareness for the significance of direct and indirect contributions of ecosystems to human well-being. Recently this concept has attracted a lot of attention in approaches which aim at the measurement and evaluation of these services. Regarding the ERA of GMOs most experts were of the opinion that these ecological services and functions are already directly (e.g. consideration of effects on *Orius* sp. which are used as biological control in maize production systems in Spain) or indirectly (e.g. via scenario assessment) taken into account. Many experts highlighted the necessity of the case-by-case approach also regarding the identification of potential effects of GMOs on ecological services. In general, most experts were of the opinion that certain ecosystem services could possibly be impacted by GMOs. This shows a high awareness for the potential of GMOs to have indirect and long-term effects. Experts were asked to rank ecosystem services according to their relevance for the ERA of GMOs. ‘Pollination’ was ranked highest, followed by ‘pest and disease regulation’ and ‘genetic resources’ as well as ‘soil formation/retention/fertility’, ‘maintenance of genetic diversity’ and ‘water’. These are all ecosystem services which are clearly linked to issues of concern discussed with respect to the use of GMOs in the past years: potential effects on non-target arthropods (e.g. pollinators, predators), which are important elements of agricultural ecosystem, indirect effect of herbicides applied with herbicide tolerant GMOs, potential effects on the genetic resources in centres of origin of crop species and on the diversity of breeds in general. It has to be noted that a third of the experts felt uneasy about ranking ecosystem services because in their view this would contradict the case-by-case approach and thus did not provide any rankings. Nevertheless those ES on which, in the opinion of the experts, the focus ought

to be put in the ERA of GMOs could be depicted - at least for those GM crops currently available. So although the biggest concerns regarding potential long-term and indirect effects of GMOs could be highlighted, it is interesting that all categories of ES were ranked by experts – although sometimes very differently. For instance cultural services, such as 'education/inspiration and aesthetic value' were ranked high by some experts, although others did not consider cultural services relevant for the ERA at all. This dissimilarity is also reflected in the current discussion on socio-economic effects of GMOs, where yet no consensus has emerged on if and how these effects should be taken into account in when authorizing GMOs.

Other protection goals which were mentioned as being important in the context of the ERA of GMOs more or less emphasize the same aspects as were already highlighted for ES: soil function and fertility, aquatic systems and genetic resources. Above this, many agricultural aspects (e.g. integrated pest and weed management, plant health, sustainable agriculture, traditional crops and traditional rural biotopes) were mentioned, as well as some nature conservation aspects (e.g. ecological sensitive areas and responsibility species). So the various expert opinions identified further aspects, which deserve consideration in the ERA of GMOs.

Overall, the high awareness for the issue of protection goals is generally linked to a great uncertainty with respect to its satisfying integration in the ERA of GMOs. This may on the one hand be due to the rather limited experience with the cultivation of GMOs in some EU MS and to the hitherto existing practical handling of notifications at the national level the other hand.

The rather limited experience with ERAs in some EU MS is mostly due to the fact that in some MS only few notifications for deliberate releases have been submitted and only few MS have evaluated GMO applications for cultivation so far (e.g. NL, BE and ES). Regarding notifications for placing on the market this may also be the result of the approach in some EU MS (in particular in the Boreal region) only to comment on the ERA if cultivation of the respective GMO is agronomically feasible in their territory. Thus, as there is a lack of relevant cases, risk assessment bodies, which in all EU MS are established to support the CAs, sometimes do not get involved. So due to concrete causes discussions among experts and authorities at the national level are limited in some EU MS. Therefore the experts interviewed expressed uncertainty about the attitude of these expert institutions, Scientific Committees and Advisory Bodies vis-à-vis the consideration of protection goals in the ERA of GMOs.

Another aspect which also contributes to this fact is that field trials are never placed in or near Natura 2000 areas in practically all EU MS. In addition according to the expert opinions this equally applies for areas protected at the national level in a majority of EU MS. So there seems to be a socio-political consensus in most EU MS that field trials, in many cases including the required isolation distances, will not be placed in or near protected areas. This approach ignores the fact that in contrast to many nationally protected areas for each Natura 2000 area specific protection goals had to be defined and laid down in the national decree establishing the Natura 2000 area. These goals may have different purposes ranging from the conservation of a specific rare or endangered habitat type (e.g. marsh areas) to the provision of specific functions (e.g. breeding grounds for protected bird species). So depending on the specific protection goals of a specific area a field trial with a certain GMO in or close to

this protected area may not necessarily put this goal at risk. However, this question has never been thoroughly evaluated due to the politically delicate nature of this matter and this situation has thus not stimulated the technical examination of the issue of protection goals for the ERA of GMOs among authorities and experts at the national level in the past.

4 DISCUSSION

Differing views among EU MS authorities and between EU MS and the European Commission regarding potential risks of GMOs have dominated the discussions on the authorizations for placing on the market/cultivation of GMOs in the EU in the past. These differences are to some extent grounded in divergent views on protection goals and their consideration in the ERA. From the information provided by EU MS experts in the online survey and the interviews it became clear that there is a high awareness regarding the issue of protection goals in general. Recently the requirement to consider protection goals for the ERA of GMOs laid down in the EFSA guidance document on ERAhas triggered discussions with respect to this issue (EFSA 2010a).

The EFSA Guidance Document calls for the identification of those “aspects of the environment that need to be protected from harm according to environmental protection goals set out by EU legislation” during the problem formulation step in the ERA (EFSA 2010a). On a general level this document puts a clear focus on the protection of biodiversity and ecosystem functions, but also opens up the ERA process to the potential consideration of species of conservational importance as well as protection goals such as sustainable land use and ecosystem services. Several legal and strategic documents of the EU related to environmental protection are listed which should be considered in the ERA of GMOs (EFSA 2010a). However protection goals are not only defined at EU level but are also set by EU MS at the national and subnational level. A systematic compilation of EU-wide nationally protected habitats and species is hardly feasible, due to the high complexity and greatly varying administrative structures in different MS..

Beside the designation of a protection status to a certain species at EU level, Member States have also protected certain species on the basis of national or sometimes regional legislation. The protection status and the number of protected species differ within the Member States but also with one Member State if species are also protected on a regional level..

While distribution data of species protected at EU level are accessible via the Article 17 Report data base maintained by the EEA this is not equally the case for nationally protected species. For protected habitats the situation is better as the coordinates are accessible via a GIS database at the EEA not only for Natura 2000 areas but also for nationally designated areas. However, information about the specific protection goals of an individual protected area should have to be considered. These are laid down in the respective national decrees establishing the protected area and are therefore only available in the national language of the respective EU MS.

Less concrete protection goals which often exist as general concepts (e.g. protection of biodiversity or soil protection) are usually addressed in a range of different legislative acts or national policy and strategy documents of a specific EU MS. Again differences in administrative structures and the diversity of resulting legislation hamper their systematic compilation.

In the survey and the interviews it became clear that the appraisal of protection goals by GMO experts varies significantly among EU MS and among expert institutions. For example while endangered species (i.e. Red Lists species) are considered highly relevant for some, others do not taken them into account in

the ERA of GMOs at all. Diverging views also exist with respect to species and areas protected at regional level which are important to some GMO experts for the ERA of GMOs but not for others. This inconsistency seems to be reflected in differences between EU MS regarding the involvement of regional authorities or environmental institutes in the ERA of GMOs. In addition the various administrative structures in EU MS seem to influence the awareness of regional protection goals at national level as well as their consideration in the ERA.

There seems to be a consensus among GMO experts that protected species and habitats are important protection goals for the ERA of GMOs and the potential of indirect and long-term effects of GMOs on ecosystem services. However, significant inconsistencies could be identified with respect to those ES, on which in the experts' view focus should be put on in the ERA. While some experts ranked cultural services quite high others did not consider them relevant for the ERA at all. Similar aspects as for ES were highlighted by experts for other protection goals which in their view should be considered in the ERA of GMOs (e.g. soil function and fertility, aquatic systems, plant health, sustainable agriculture), but no structured approach with respect to the concretization of protection goals beyond policy objectives laid down in national policy strategies (e.g. biodiversity strategy) was known to the experts. This shows that while the protection of species defines a concrete protection goal most other protection goals lack concretization. In order to finally be able to translate environmental protection goals into measurable assessment endpoints in the ERA process (EFSA 2010a), it is necessary to further define those protection goals which so far only exist as general concepts.

Definitions of explicit and representative targets for protection are necessary in order to establish measurable assessment endpoints.

One possibility of EU-wide accession and consideration of protection goals is the use of EU-harmonized data on protected species and habitats of the Habitats Directive. Species and habitats protected at EU level are widely recognized protection goals for which strict protection obligations exist, not only at national but also at EU level. However, these data do only cover part of the protected area and species as they do not include areas or species protected according to national or regional laws. Data availability on the national or regional level is scarce or varies highly in quality - even within one Member State. Therefore, though these data might be extremely relevant, at the current stage of data availability they can only be used by the national authorities but hardly on a European level.

As shown exemplarily in this report, the evaluation of the occurrence of FFH lepidopteran species in different biogeographic regions in the EU by a GIS-based approach can help to select species relevant for the ERA of insect resistant GM maize. Such an approach can be extended to other GMOs, depending on the trait and the crop plant in question. This may be one way forward in the consideration of protection goals in the ERA of GMOs.

This proposal might be a valuable tool for the involved authorities in defining protection goals and species and habitats which require special attention in the risk assessment. This method can provide basic data, which need to be assessed by an expert group for their relevance for the GMO which is evaluated, especially regarding the crop/trait combination. Based on such an evaluation regulatory consequences regarding the environmental risk

assessment or even the design and distribution of field trials might be identified. However, this needs to be done on a case-by-case basis as foreseen in the respective legislation.

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ANNEX I

Protection Goals in the Environmental Risk Assessment of GMOs

Field Trials: GMO authorization according to Part B of EU Directive 2001/18/EC

1. Please indicate your name, your institution and your contact details (This information is for internal purposes only and necessary for data evaluation. The data will be anonymized for evaluation and publication).

   Name

   Institution

   Department

   Homepage

   e-mail adresse

   phone number

2. Protection goals can be defined on different political or legislative level. What kind of protection goals are being considered in your country in the environmental risk assessment of GMPs for field trials according to part B of EU Directive 2001/18/EC? Please indicate the level on which they are defined by checking the appropriate boxes (multiple responses possible). If applicable, please enter further information regarding the definition on a subnational (e.g. regional) level.

   a) **species :**

   □ EU □ national □ subnational □ not taken into account

   If possible, please specify the subnational level:

   □ province □ community □ region □ other

   b) **habitats:**

   □ EU □ national □ subnational □ not taken into account

   If possible, please specify the subnational level:

   □ province □ community □ region □ other

   c) **prevention of outcrossing:**

   □ EU □ national □ subnational □ not taken into account

   If possible, please specify the subnational level:

□ province □ community □ region □ other

d) **prevention of resistance development:**

□ EU □ national □ subnational □ not taken into account

If possible, please specify the subnational level:

□ province □ community □ region □ other

e) **avoidance of admixture:**

□ EU □ national □ subnational □ not taken into account

If possible, please specify the subnational level:

□ province □ community □ region □ other

f) **others (please specify):**

□ EU □ national □ subnational □ not taken into account

If possible, please specify the subnational level:

□ province □ community □ region □ other

3. Are there any protected species being considered in the ERA beyond those covered by Directive 92/43/EEC (FFH Directive; Annexes 2 & 4). Please indicate possible contact points in your country for further information.

□ yes □ no □ I don't know possible points of contact_____

4. If protected species are being considered in the ERA, what kind of species (i.e. animals, plants) are these? Please check the appropriate boxes.

□ butterflies, moths (Lepidoptera) □ beetles (Coleoptera)
□ bees, wasps etc. (Hymenoptera) □ caddisflies (Trichoptera)
□ cross-breeding/pollination partners □ wild relatives
□ others (please specify)_____

5. Are there any protected habitats being considerd beyond those covered by Directive 92/43/EEC (FFH Directive; Annex 1). Please indicate possible contact points in your country for further information.

□ yes □ no □ I don't know

possible points of contact_____

Placing on the market: GMO authorization according to Part C of EU Directive 2001/18/EC

6. Protection goals can be defined on different political or legislative level. What kind of protection goals (e.g. species habitats) are being considered in the environmental risk assessment of GMPs for the placing on the market accroding ot Part C of EU Directive 2001/18/EC? Please indicate the level on which they are defined by checking the appropriate boxes (multiple responses possible). If applicable, please enter further information regarding the definition on a subnational (e.g. regional) level.

   g) **species :**

   □ EU □ national □ subnational □ none

   If applicable, please specify the subnational level

   □ province □ community □ region □ other

   h) **habitats:**

   □ EU □ national □ subnational □ none

   If applicable, please specify the subnational level

   □ province □ community □ region □ other

   i) **prevention of outcrossing:**

   □ EU □ national □ subnational □ none

   If applicable, please specify the subnational level

   □ province □ community □ region □ other

   j) **prevention of resistance development:**

   □ EU □ national □ subnational □ none

   If applicable, please specify the subnational level

   □ province □ community □ region □ other

   k) **avoidance of admixture:**

   □ EU □ national □ subnational □ none

   If applicable, please specify the subnational level

   □ province □ community □ region □ other

   l) **others:**

   □ EU □ national □ subnational □ none

   If applicable, please specify the subnational level

   □ province □ community □ region □ other

7. Are there any protected species being considered in the ERA beyond those covered by Directive 92/43/EEC (FFH Directive; Annexes 2 & 4). Please indicate possible contact points in your country for further information.

   □ yes □ no □ I don't know possible points of contact_____

8. If protected species are being considered in the ERA, what kind of species (i.e. animals, plants) are these? Please check the appropriate boxes.

   □ butterflies, moths (Lepidoptera) □ beetles (Coleoptera)
   □ bees, wasps etc. (Hymenoptera) □ caddisflies (Trichoptera)
   □ cross-breeding/pollination partners □ wild relatives
   □ others (please specify)

9. Are there any protected habitats being considerd beyond those covered by Directive 92/43/EEC (FFH Directive; Annex 1). Please indicate possible contact points in your country for further information.

   □ yes □ no □ I don't know

   possible points of contact_____

General aspects regarding protection goals

10. For which of the following environmentally relevant protection goals do legal requirements exist in your country and at which level?
    Please indicate whether these goals have been set at national and/or at regional level and indicate the respective Competent Authorities for this protection goal. If possible, please specify the subnational level (e.g. province, community,).

Protection goal	**National** (national, subnational, not existent)	**Subnational** (province, community, region, other)
species/wildlife conservation		
protection of biotopes/habitats		
protection of biodiversity		
protection of genetic diversity		
protection of ecosystems		
protection of ecosystem services		

protection of landscapes		
soil protection		
water protection		
conservation and sustainable use of natural resources		
preservation of cultural and traditional characteristics		
preservation of natural and cultural specificities		
process conservation/protection (Enabling all natural processes for a given ecosystem)		
maintenance and improvement of a favourable conservation status		
others		

11. Please list the relevant Competen Authorites for the above mentioned protection goals

Protection goal	Compentent Authority
species/wildlife conservation	
protection of biotopes/habitats	
protection of biodiversity	
protection of genetic diversity	
protection of ecosystems	
protection of ecosystem services	
protection of landscapes	
soil protection	
water protection	
conservation and sustainable use of natural resources	
preservation of cultural and traditional characteristics	
preservation of natural and cultural specificities	
process conservation/protection (Enabling all natural	

processes for a given ecosystem)	
maintenance and improvement of a favourable conservation status	
others	

12. Which of the listed ecosystem goods and services of agriculture do you think are either referred to in existing legislation or in strategies/policy documents in your country? Please selcet the appropriate answer.

Selected ecosystem goods & services	**Covered by existing legislation**	**in policy/strategy documents**	**In both**	**Not at all**
Water supply				
Fertile soil				
Pollination				
Pest and disease regulation				
Protective function of agricultural landscapes (e.g. relating to erosion, avalanches, floods, carbon reservoir)				
Renewable energy sources				
Food production				
Feed and fertilizer for agricultural production				
Recreational sevices via supply of valuable natural and cultural landscapes (and economic benefits for tourism)				
Recreational sevices by hunting, collecting and the observation of wild species				
Existence of natural biodiversity				

(supply with various species, habitats and ecosystems beyond their economic value)				
Genetic resources (genetic diversity and objects of cultural value)				

13. Please specify the legislative or political document the respective ecosystem goods and services are referred to.

Selected ecosystem goods & services	**Specification of the respective legislative or political document**
Water supply	
Fertile soil	
Pollination	
Pest and disease regulation	
Protective function of agricultural landscapes (e.g. relating to erosion, avalanches, floods, carbon reservoir)	
Renewable energy sources	
Food production	
Feed and fertilizer for agricultural production	
Recreational sevices via supply of valuable natural and cultural landscapes (and economic benefits for tourism)	
Recreational sevices by hunting, collecting and the observation of wild species	
Existence of natural biodiversity (supply with various species, habitats and ecosystems beyond their economic value)	
Genetic resources (genetic diversity and objects of cultural value)	

14. Are you aware of any environmentally relevant protection goals in your country in national policy documents/strategies or defined “soft”

protection goals (e.g. Red List of species, Red List of habitats/biotop types, GMO free production), which go beyond those laid down in the legal framework. Please specify.

Textbox_____

15. Are you aware of any activities (e.g. studies, workshops, etc.) concerning the development or firm establishment of more concrete protection goals in any environmentally relevant field (e.g. nature conservation, agriculture, forestry, town and country planning) ? Please indicate.

    Textbox_____

ANNEX II

Questionnaire for CAs who already answered the online questionnaire

Introduction

GM plants may have adverse effects on biodiversity and its functions at several levels (EFSA 2010a). Since the environment is to be protected from harm according to protection goals set out by the EU and member state legislation, the protection of species, habitats, ecological functions and ecosystem services should also be considered in the environmental risk assessment of GMOs (EFSA 2010a, 2010b). Environmental protection goals need to be translated into measurable assessment endpoints in the ERA process (EFSA 2010a).

Our task in the AMIGA project is to identify protection goals, in particular those which are regionally relevant and differ among EU member states. With this interview we aim at collecting information on environmental protection goals in different EU member states which might be relevant for the ERA of GMOs.

Question 1: GENERAL QUESTIONS

a) Is your institution the Competent Authority for GMO authorization according to Directive 2001/18/EC and Regulation (EC) 1829/2003?

b) What is your institution`s task in this context?

- environmental risk assessment
- food/feed safety
- both/other

c) Do you cooperate with other authorities in your country regarding GMO authorizations?/Are any other authorities involved in GMO authorizations (e.g. regional authorities, environmental agencies)

- For part B notifications
  - o If yes, which:
- For part C notifications
  - o If yes, which:

The EFSA GMO Panel applies a broad approach for the definition of environmental protection goals that includes the wider biodiversity and ecosystem functions (EFSA 2010a, EFSA 2010b).

Question 2: BIODIVERSITY

In the EU the conservation and protection of biodiversity is of great importance and mainly comprise the protection of species and habitats (Council Directive 92/43/EEC, Council Directive 97/409/EEC).

a) Has your institution carried out an environmental risk assessment for a deliberate release of a GMO into the environment for any other purposes than placing on the market (**Part B** notifications)?

   a. If yes, did you take protected species and habitats into consideration?

      i. If yes, which?
      ii. At which level are they protected?

	at EU level	**at national level**	**at subnational level**
Protected Species			
Protected Habitats			

b) Has your institution carried out or commented on the environmental risk assessment of a GMO notified for placing on the market as or in products (commercial releases; **Part C** notifications)?

   - Carried out the ERA
   - Commented on the ERA

   a. If yes, were protected species and habitats taken into consideration?

      i. If yes, which?
      ii. At which level are they protected?

	at EU level	**at national level**	**at subnational level**
Protected Species			
Protected Habitats			

c) Have you considered any other protection goals of relevance for the conservation and protection of biodiversity (e.g. species of conservation concern, such as red list species)?

   i. for part B

ii. for part C

d) Do national red lists exist in your country? (e.g. for species, for habitats)

e) Do red lists also exist on subnational/regional level in your country? (e.g. for species, for habitats)

f) Which status do they have? (e.g. referred to in any legal document, basic scientific instrument)

g) Do they exist for Lepidoptera?

- If yes: On which administrative level? (e.g. national, subnational)
- If possible, give us the name of experts who might know about red lists.

Question 3: ECOSYSTEM SERVICES

During the problem formulation in the ERA of GMOs, the protection goals which are potentially adversely affected when a certain GMO is cultivated in the EU need to be defined (EFSA 2010a). According to the approach chosen by EFSA these do not only include the protection of biodiversity, but also imply the protection of ecosystem functions and services (EFSA 2010a, 2010b). Ecosystem services are defined as 'the direct and indirect contributions of ecosystems to human well-being' and arise from the interaction of biotic and abiotic processes (de Groot et al. 2010). These services are in decline as pressures on the environment increase. Some of these services (e.g. water quality, soil condition, species diversity, cultural landscape) are significantly influenced by agriculture.

a) Did your institution ever take ecosystem services into consideration when carrying out/commenting on an environmental risk assessment of GMOs?

b) In general, do you think ecosystem services could possibly be impacted when cultivating GMOs?

   i. If yes, which of the following ecosystem services do you think could be adversely impacted by GMOs? [Please indicate on a scale of 1 (very unlikely) to 6 (very likely)]

Ecosystem service*		**1-2-3-4-5-6**
Provisioning services	Food , forage	
	Fibre, fuel	
	Water	
	natural medicinal and biochemical resources	
	Ornamental resources	
	Genetic resources	
Regulating services	Pest and disease regulation (biological control); regulation of infectious disease in humans	
	Pollination	
	Seed/propagule production and dispersal	
	Climate and air quality regulation	
	Modulation of natural hazards and extreme events	
	Erosion prevention	
	Resistance to invasion	
	Water purification/soil remediation/waste treatment	
Supporting services	Maintenance of genetic diversity	
	Primary production/Photosynthesis	
	Soil formation/retention/fertility	
	Nutrient/water cycling	
	Provision of habitat	
Cultural services	Spiritual and religious values/sense of place	
	Education/inspiration/aesthetic values	
	Recreation and ecotourism	
	Cultural heritage	

Other *(open question)*		

* The ecosystem service classification is based on MEA (2005), EFSA (2010c) and de Groot (2010), but some categories are added, adapted or deleted. For explanation see separate document.

Question 4: OTHER PROTECTION GOALS

Are there any other protection goals which should be taken into consideration during the environmental risk assessment of GMOs?

a) If yes, which?
(*e.g. soil functions, plant health, sustainable agriculture, aquatic ecosystems)*

b) If yes, are they different for Part B/Part C notifications?

c) Are there any strategies/legislative acts/laws in your country for the protection of biodiversity/soil/water?
[e.g. national biodiversity strategy]

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ANNEX III

Ecosystem services classifications

Ecosystem services are the benefits humans receive from ecosystems (EFSA 2010). Ecosystem services have also been defined as the "direct and indirect contributions of ecosystems to human wellbeing" (de Groot 2010). The classification of ecosystem services was originally developed by the Millennium Ecosystem Assessment (MEA 2005) and comprised four categories of services. These include the production of goods (provisioning services), life support processes (regulating and supporting services), and life fulfilling conditions (cultural services).

- Provisioning services are services that describe the material or energy outputs from ecosystems (food, water etc.).
- Regulating services are services that ecosystems provide by acting as regulators, e.g. regulating the number of plants that are pollinated.
- Supporting services underpin all other services. Ecosystems are the planet`s life-support systems. Ecosystems provide space for organisms and maintain a diversity of plants and animals.
- Cultural services are the non-material services and benefits people get from ecosystems.

Ecosystem service		Explanation
Provisioning services	Food , forage	Ecosystems provide food and feed (from managed agro-ecosystems or natural ecosystems)
	Fibre, fuel	Ecosystems provide raw material materials (timber, biofuels, plant oils etc.)
	Water	Ecosystems play an important role in hydrological cycles and contribute to water provision, regulation and purification
	natural medicinal and biochemical resources	Ecosystems provide traditional medicines or biochemcial resources for pharmaceutical, cosmetic and industrial use
	Ornamental resources	Ecosystems provide resources of cultural and aesthetic value, e.g. resources for fashion, handicraft, decoration etc.
	Genetic resources	Ecosystems provide

		genetic resources for crop improvement. Genetic diversity provides the basis for locally well-adapted cultivars and a gene pool for developing crops and livestock.
Regulating services	Pest and disease regulation (biological control); regulation of infectious diseases in humans	Ecosystems and ecological relationships (predators and parasites) regulate pests and diseases affecting plants, animals and people
	Pollination	Pollinating insects (birds, bats) and wind regulate the development of fruits, vegetables and seeds
	Seed/propagule production and dispersal	The survival of plant species depends on the production of seed and propagules. Wind, water and animals regulate the amount and distance of dispersal of seeds and other plant dispersal units
	Climate and air quality regulation	Climate conditions are influenced by changes in ecosystems: e.g. vegetation regulates the air quality by removing pollutants; ecosystems store and sequester greenhouse gases
	Modulation of natural hazards and extreme events	Ecosystems create buffers against natural hazards; e.g. trees stabilizing slopes
	Erosion prevention	Vegetation cover is a key factor in the prevention of soil erosion
	Resistance to invasion	Ecosystems with autochthonous species with a similar niche as invasive species prevent the establishment of non-

		native species
	Water purification/soil remediation/waste treatment	Ecosystems can filter waste, e.g. through the activity of microorganisms in soil or water
Supporting services	Maintenance of genetic diversity	Genetic diversity enables evolution and adaptive radiation of species
	Primary production/Photosynthesis	Photosynthesis is the basis for the production of plant biomass
	Soil formation/retention/fertility	Ecosystems maintain well-functioning soils required for plant growth
	Nutrient/water cycling	Ecosystems recycle organic and inorganic matter
	Provision of habitat	Ecosystems provide habitats for feeding, nursing, developing, reproducing and thus support the life cycles of species. The availability of certain ecosystem services (e.g. sea food) may be dependent on the state of different habitats (e.g. mangroves as nursery for fish or shrimp)
Cultural services	Spiritual and religious values/sense of place	Specific natural features such as forests, caves or mountains have religious meanings or are considered sacred.
	Education/inspiration/aesthetic values	Ecosystem and natural landscapes are the source for inspiration for art, culture and science; certain spieces are assigned a certain protection status and other species are of cultural or aesthetic value independent of their protection status (e.g. Monarch butterfly).

	Recreation and ecotourism	Ecosystems provide services via the supply of natural and cultural landscapes and resources (e.g. hunting, collecting, observation of wild species)
	Cultural heritage	Certain ecosystems are valued for their structures constructed or modified by man, and their typical biota (e.g. traditional landscapes)

Sources:

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De Groot, R. (2010). Integrating the ecological and economic dimensions in biodiversity and ecosystem service valuation. The Economics of Ecosystems and Biodiversity: The Ecological and Economic Foundations. **www.teebweb.org**

MEA (2005). Ecosystems and human well-being : health synthesis. A report of the Millennium Ecosystem Assessment. **www.unep.org**