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Evaluating environmental risks of genetically modified crops: ecological harm criteria for regulatory decision-making

Olivier Sanvido^a, Jörg Romeis^{a,*}, Achim Gathmann^b, Marco Gielkens^c,
Alan Raybould^d, Franz Bigler^a

^a Agroscope Reckenholz Tänikon Research Station ART, Reckenholzstrasse 191, 8046 Zürich, Switzerland

^b Federal Office of Consumer Protection and Food Safety (BVL), Mauerstrasse 39-42, 10117 Berlin, Germany

^c National Institute for Public Health and the Environment (RIVM), 3720 BA Bilthoven, The Netherlands

^d Syngenta, Jealott's Hill International Research Centre, Bracknell RG42 6EY, United Kingdom

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ABSTRACT

European risk managers currently face substantial difficulty in evaluating the risks of genetically modified (GM) crops for biodiversity. This difficulty is not primarily due to a lack of scientific data (the data are abundant) but rather to a lack of clear criteria for determining what represents environmental harm. Establishing criteria that define harm is not a scientific process but a process of analysing and implementing policy requirements, and policy-makers and regulatory authorities need to define what is to be regarded harmful based on existing legislation. This process is a necessary pre-condition for the environmental risk assessment of GM crops. The present paper proposes a systematic approach on how harm can be explicitly and operationally defined for decision-making. Most legal frameworks require the protection of the environment or more specifically of biodiversity from harm. It follows that the first step in defining harm should be the characterisation of protection goals; protection goals are those valued environmental resources that should not be harmed by GM crop cultivation or by any other agricultural practice. In a second step, one must derive scientifically measurable entities (so-called assessment endpoints) on the basis of the protection goals. Such endpoints are required for regulatory decision-making because they specify what deserves protection. They furthermore allow quantifiable predictions of adverse changes during environmental risk assessment. Definitions of harm also require decisions on which environmental changes should be regarded as relevant and thus represent unacceptable harm. Using a case study comparing different effects of various pest management practices, the current paper proposes an approach that differentiates between intended effects that are acceptable and harmful unintended effects. By making explicit the assumptions underlying policy choices, the ecological criteria proposed here may result in a better and more transparent evaluation of the probability of harm to biodiversity due to the cultivation of GM crops. The paper can help risk managers improve decision-making by providing methods for deriving operational decision-making criteria from policy objectives.

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* Corresponding author. Tel.: +41 44 377 7299; fax: +41 44 377 72 01.

E-mail addresses: Olivier.sanvido@gmail.com (O. Sanvido), Joerg.romeis@art.admin.ch (J. Romeis).
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1. Introduction

Genetically modified (GM) crops are subject to regulatory approval before entering the market. In the European Union (EU), for example, approval of a GM crop for commercial cultivation requires an environmental risk assessment (ERA) of potential adverse effects on human health and on the environment (and on biodiversity in particular).¹ Approval is only granted if the ERA indicates that the risks of the GM crop are negligible. In this regulatory evaluation, risk managers² must decide which kinds and levels of environmental changes are relevant and represent environmental harm. As indicated by the current debate on the risks of GM crops for biodiversity, consensus on criteria that define environmental harm (i.e., a standard on which a judgment or a decision may be based) is presently lacking (Waltz, 2009). Especially in Europe, the environmental safety of GM crops has been constantly debated, and the interpretation of scientific data differs among stakeholders (Sanvido et al., 2007). Considering the vast amount of scientific data available, one can argue that lack of scientific data does not explain why European risk managers are having difficulty assessing the risks of GM crops. Instead, the difficulty reflects a lack of definitions and agreement on how to value biodiversity (Sarewitz, 2004).

In the context of environmental decision-making, harm is primarily a legal concept because decisions by risk managers on what is unacceptable are based on the relevant legal frameworks. Yet such decisions are not made on a purely legal basis because the decisions have a political and societal context (Devos et al., 2008). For the purposes of the present paper, however, a legal understanding of environmental harm is taken as the main point of reference, that is, what matters legally is whether harm occurs to an environmental resource that is protected by law; such an environmental resource is referred to as a protection goal and may include biodiversity and ecosystem services. Because practical and financial constraints usually make it impossible to conserve all components of the environment to the same degree, an important question is how can one define which environmental resources³ deserve particular protection. A related concern is that society often does not want to protect and to conserve all components of biodiversity; for example, society may not want to protect pests, disease vectors, or invasive species. In

the process of risk analysis, risk managers must decide as unambiguously as possible what deserves protection.

The present paper provides guidance to European risk managers on how they can clearly define what should be protected. The paper is intended to strengthen the current legislative framework on the environmental safety assessment of GM crops by supporting the translation of broad protection goals into concrete measurable indicators and parameters. The ideas presented here originate from the project VERDI (*Valuating environmental impacts of GM crops – ecological and ethical criteria for regulatory decision-making*) that offers risk managers guidance on how decision-making related to the environmental safety of GM crops could be improved, especially on how risk managers can determine whether changes in biodiversity associated with the use of GM crops represent environmental harm. Although the paper focuses on the effects of GM crops on biodiversity, the findings should be relevant to other agricultural stressors that affect biodiversity or other aspects of the environment in Europe.

2. Existing definitions of harm

A definition of harm is required to evaluate scientific data generated during ERAs. However, a concise and commonly accepted definition of “environmental harm” does not currently exist (Sanvido et al., 2011). All proposed definitions of harm (Box 1) have three features: (1) harm involves damage to an environmental resource (for example, a reduction in the conservation or sustainable use of biodiversity); (2) harm is characterised as an adverse change that is either significant or severe or that exceeds the natural range of variability; and (3) harm is measurable (or predictable). These three common features lead to three main questions that should be answered when defining environmental harm: (1) What needs to be protected? (2) What is meant by “adverse”? and (3) What is to be measured in order to predict the likelihood that harm will occur? By answering these three questions, the present paper will develop a definition of harm relevant to policy.

3. What needs to be protected?

The starting point for defining harm is the consideration of the protection goals described in existing legislation. However, legal frameworks typically are vague regarding the question of what is to be protected from the harm resulting from human activities. The formulations used in legal texts to describe protection goals are often limited to broad terms such as “environment” and “biodiversity”, which are too vague to be scientifically assessed. An approach must be identified that enables risk managers to define which environmental resources are to be protected because they are specifically valued.

Decisions about which environmental resources are to be protected⁴ should ideally be made by risk managers before problem formulation at the beginning of every ERA (Fig. 1)

¹ Although the European Commission intends to broaden the risk assessment scheme for GMOs, decisions made according to EU Directive 2001/18/EC are currently based on the question of risk. The evaluation of potential benefits is not explicitly considered during the approval process of GMOs in Europe. In other jurisdictions, however, decision making on GMOs may consider both the potential advantages of cultivating the GM crop and the risks from alternatives (Jaffe, 2004).

² In the present context, risk managers are those policy-makers and regulatory authorities who decide the acceptable level of effect for a specific protection goal during product authorisation of a particular GM crop.

³ Environmental resources to be protected can include species and habitats because of their conservation status as well as resources that provide particular ecosystem services.

⁴ When defining protection goals, risk managers need to consider that protection goals should be generic and valid for all agricultural practices.

Box 1. Proposed definitions of environmental harm.

- European Directive 2004/35/EC on Environmental Liability (European Commission, 2004): “Any damage representing a measurable adverse change in a natural resource/resource service.”
- German Advisory Council on the Environment (SRU, 2004): “Changes that go beyond natural range of variability for a particular asset of value.”
- Cartagena Protocol on Biosafety (CBD, 2009): “Measurable (or otherwise observable) loss or damage (...) that has adverse (and significant) impact upon conservation and sustainable use of biodiversity.”
- “A significant adverse effect on a biotic conservation resource (animal, plant, fungi, microorganism) or an abiotic conservation resource (soil, water, climate) that has an impact on (1) the value of the conservation resource in whole or part, (2) on the conservation resource as an ecosystem component, or (3) on the sustainable use of the conservation resource or the ecosystem with which the conservation resource is associated.” (Bartz et al., 2010)

(EFSA, 2010a; Nickson, 2008; Raybould, 2006; Wolt et al., 2010). During the problem formulation phase, definitions of harm are based on the question “What should be regarded as harmful?” These definitions precede the risk characterisation phase of the ERA in which the risk assessors scientifically evaluate whether the harm defined is likely to result from the cultivation of GM crops.⁵ It is important not to confound risk assessment with policy-making. A policy can be defined as a set of decisions that are oriented towards a long-term purpose or a particular problem (Sandford, 1985). Such decisions by governments are often embodied in legislation and usually apply to a country as a whole. Implicit in the concept of making a policy is that one has a choice or an option to have this policy or some other policy. If in practice there is no choice, then there can be no policy. It is wrong to believe that science can replace policy-making, that is, it is wrong to believe that once sufficient scientific data have been collected, policy objectives will become obvious (Raybould, 2011). Scientific analysis of risk assessment data cannot define the policy objectives (i.e., scientific analysis cannot answer the question “What should be regarded as harmful?”) because policy objectives must be defined by policy-makers before the risk assessment. Although science cannot determine what is good or bad, science can determine whether a certain activity is good or bad once “good” and “bad” have been defined. Consequently, policy-makers and risk managers must provide guidance to risk assessors during the ERA and should define which environmental resources must be protected, where they must be protected, and over what time period (EFSA, 2010c). In the following sections, a matrix for an operational definition of protection goals is proposed that will help risk assessors

⁵ At this stage of problem formulation, risk assessors need to decide whether existing data sufficiently corroborate hypotheses that harm will not occur or is unlikely to occur. New data will need to be collected only if existing data are inadequate to give sufficient confidence in an acceptable amount of risk.

evaluate the probability that protected environmental resources will be harmed. As indicated earlier, the matrix focuses on potential adverse effects of GM crops on biodiversity but can be applied to any potential harm to the environment.

3.1. A matrix for an operational definition of biodiversity in agricultural landscapes

The defining of protection goal in agricultural landscapes consists of two-steps in which protection goals are specified in the first step and assessment endpoints are specified in the second (Table 1).

3.2. Operational definition of protection goals (step 1 of the matrix)

The defining of protection goals begins by identifying the areas of protection that are documented in existing legal frameworks (Table 1). In most legal frameworks, the area of protection concerns “biodiversity conservation”, with a focus on Red List species and species of high conservation or cultural value from a range of different taxa such as mammals, birds, amphibians, insects (e.g., butterflies), and plants; biodiversity conservation in legal frameworks can also include the protection of habitats (EFSA, 2010b; European Commission, 1992, 1997; NHG, SR 451). The protection of “ecosystem services” and/or “ecosystem functions” is infrequently stated as a protection goal in the legal frameworks, or their protection is referred to only in a very broad manner. Nevertheless, given the importance attributed to ecosystem functions and services (especially the recognition that they are essential to human existence) (EASAC, 2009; Millenium Ecosystem Assessment, 2005), their protection should also be included when defining protection goals (Table 1). In an agricultural context, relevant ecosystem services include pollination, pest regulation, decomposition of organic matter, soil nutrient cycling, soil structure, and water regulation and purification (EASAC, 2009; Moonen and Barberi, 2008).

3.3. Definition of assessment endpoints (step 2 of the matrix)

In step 2, each protection goal specified in step 1 is operationally defined by one or more assessment endpoints (Table 1) (Raybould, 2006, 2007a). An assessment endpoint is defined as an “explicit expression of the environmental value to be protected as set out by existing legal frameworks” (Suter, 2000). It is important to note that an assessment endpoint is not an indicator of environmental conditions but is the ecological resource that is to be protected. An operational definition of assessment endpoints necessitates the defining of six components:

- (a) *an ecological entity that represents the selected area of protection* (e.g., Red List plant species or arthropods representing a particular ecosystem service such as pollination or pest regulation).
- (b) *an attribute to be protected*. For biodiversity conservation, the attribute is usually the abundance of the protected or valued species. For protection of ecosystem services, the

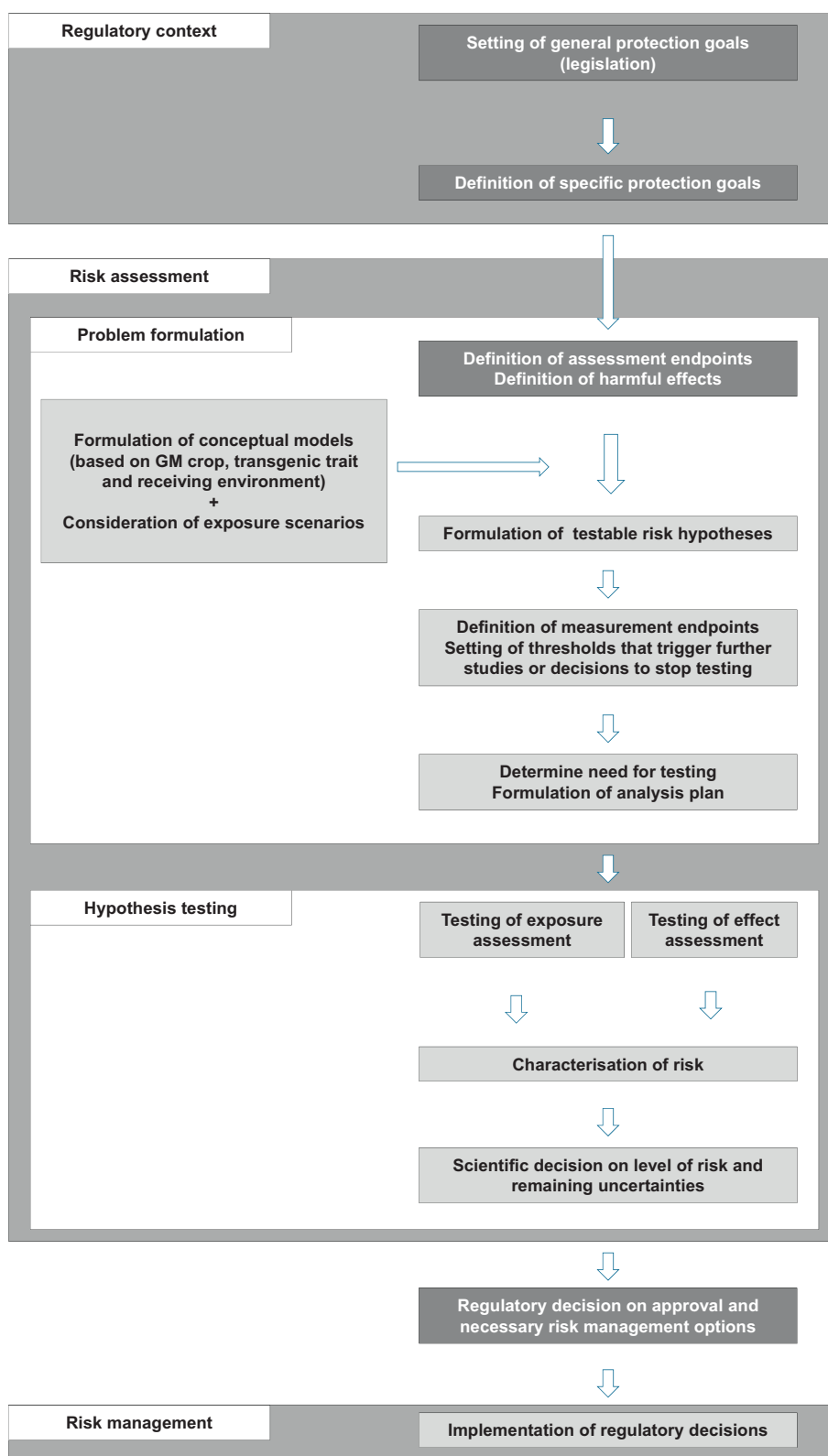


Fig. 1 – Schematic diagram representing the main components of the risk analysis of genetically modified crops. Dark shaded boxes depict policy activities that should be carried out by policy-makers or risk managers. Light grey boxes depict science-based activities that are to be conducted by risk assessors (adapted from EPA, 1998; Nickson, 2008; Wolt et al., 2010).

Table 1 – Matrix for an operational definition of environmental harm with some selected examples of how the matrix could be applied. Between the definition of assessment endpoints (step 2) and the definition of measurement endpoints (step 3), risk hypotheses need to be formulated according to conceptual models and exposure scenarios (see Fig. 1).

① Protection goals		② Assessment endpoints						③ Measurement endpoints		
Area of protection		Criteria for the operational definition of the protection goal						Criteria for the type of effect to be measured		
		Ecological entity	Attribute	Unit of protection	Spatial scale of protection	Temporal scale of protection	Definition of harmful effect	Indicator	Parameters Early tiers	Parameters Higher tiers
Biodiversity conservation	Red List species Species of high conservation / cultural value	Mammals	Abundance				Relevant decrease in abundance	Selected species		
		Birds								
		Amphibians								
		Valued insects (e.g. butterflies)	Population	Non-agricultural habitats	10 years		Mortality	Abundance		
		Valued plants								
	Protected habitats	Habitats listed in legislation					Selected habitats			
Ecosystem services	Pollination	Pollinating insects	Ecological function	Guild	Arable land and non-agricultural habitats	Following cropping season	Relevant disturbance in ecological function	Direct or indirect indicator able to demonstrate failures in ecosystem function	Mortality	Abundance
	Pest regulation	Predators & parasitoids								
	Decomposition of organic matter	Soil invertebrates, soil microorganisms		Guild	Crop fields	Following cropping season		Decomposition rate	Abundance	
	Soil nutrient cycling (N, P)	Soil microorganisms								
	Soil structure	Soil invertebrates								
	Water regulation and purification	Fish								
		Aquatic invertebrates								
		Algae								

Individual Population Guild Community	GM crop fields Other arable land Non-agricultural habitats	Present cropping season Following cropping season Time of consent (e.g. 10 years)
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Mortality Reproduction ...	Abundance Diversity ...
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attribute is some ecological function (e.g., amount of pollination).

- (c) a unit of protection. Individuals, populations, communities, and guilds are examples of units.
- (d) a quantifiable spatial unit of protection such as “GM crop fields”, “other arable land”, and “non-agricultural habitats”. Risk managers need to define whether it may be sufficient to limit protection to non-agricultural habitats (e.g., because the agricultural land is a non-suitable habitat for a certain group of species) or whether protection is necessary on arable land in general.
- (e) a quantifiable temporal scale of protection such as the present cropping season, the following cropping season, or the time approved for cultivation of the GM crop. Although most legal frameworks require that protection goals are to be protected permanently, permanence is not a quantifiable temporal scale that can be used in decision-making. For an operational definition, the temporal scale should be limited to a measurable time span in which regulatory decisions can be taken. Although the time span chosen for the temporal scale is arbitrary, an assessment over a very long time period may have low predictive value. Hence, one can argue that 10 years, which is equivalent to the time of consent foreseen by the EU and Swiss legislation for the approval of a GM plant (European Community, 2001; VGVL, SR 817.022.51), is a suitable time span.

- (f) a definition of the type of changes that are regarded harmful. Initially, the types of changes that are regarded harmful are broadly set (e.g., decreases in the abundance of a butterfly species should not exceed 50% in the field). Subsequently (i.e., during the definition of measurement endpoints), the thresholds that indicate the potential for harm and that trigger additional studies are more precisely defined (see 5).

4. What is adverse?

In defining assessment endpoints, risk managers must decide which kinds of environmental changes are relevant and especially which kinds are to be regarded as harmful (Table 1 and Fig. 1). A case study using the environmental effects of different pest management practices on non-target arthropods is used here to illustrate how risk managers can decide which kinds of environmental changes are relevant (see Supplementary Material). The approach considers that regulatory frameworks generally differentiate between “intended” effects of a pest management practice and “unintended” effects that are harmful and to be minimised. An intended effect thereby defines a change that is either the ultimate goal of a specific pest management practice or that is an inevitable and anticipated consequence of the pest management

practice (such as effects on organisms at higher trophic levels that result from the reduced abundance of the target pest that has been controlled by the pest management practice).⁶ A harmful unintended effect, in contrast, characterises all changes that do not fall into either of the latter two categories. By using this differentiation, one can outline a generic scheme for evaluating whether the effects of different pest management practices are to be regarded as intended (which are judged acceptable) or unintended and harmful (see [Supplementary Material](#)).

According to the detailed rationale presented in the [Supplementary Material](#), changes in arthropod biodiversity are considered ecologically harmful if they involve loss of protected or charismatic species. It is important to determine whether certain factors might increase the tolerance of the risk for biodiversity losses (e.g., if the losses in biodiversity do not result from losses in endemic species that are characteristic of a country). Similarly, effects on arthropod species are relevant only if these species provide an ecosystem service (such as biological control of arthropod pests) or if these effects do not allow sufficient resilience in the ecosystem service.

5. What is to be measured? Definition of measurement endpoints (step 3 of the matrix)

Once the harmful effect has been defined, conceptual models should be constructed that describe scenarios or pathways on how the cultivation of the GM crop may cause harm ([Raybould, 2011](#)) ([Fig. 1](#)). Conceptual models guide the formulation of testable risk hypotheses of no harm. When constructing a conceptual model, one should consider the nature of the crop, the introduced trait, the receiving environment, and possible ways in which assessment endpoints could be exposed to the GM crop ([Romeis et al., 2008](#); [Wolt et al., 2010](#)). Next, measurement endpoints are defined that determine the data to be collected to test the formulated risk hypotheses. Thus, measurement endpoints are used to predict harm but they are not part of a definition of harm. Measurement endpoints are rather a measurable biological characteristic that can be related to a particular assessment endpoint ([Raybould, 2006](#); [Storkey et al., 2008](#)).

Risk hypotheses are evaluated by tiered testing in which researchers start with conservative hypothesis testing (in which the likelihood of detecting potential harm is high) and only move to more realistic tests if trigger values are exceeded ([Raybould, 2011](#); [Romeis et al., 2008](#)). Risk hypotheses are evaluated in a tiered test system because the likelihood of detecting potential harm is higher in well-controlled lower tier studies than in more complex field studies. The sequence of testing continues only if potential effects are detected (that is, if the ‘no-effect’ hypothesis is rejected) or if unacceptable uncertainties about possible effects remain. A comprehensive and consistent progression from one tier to another requires

the definition of thresholds (so-called “limits of concern”) that either trigger additional studies (if the initial assessment indicates a potential for harm) or a decision to stop further testing ([Raybould, 2011](#)). Limits of concern may be set conservatively and categorically (more, few, no more than, no less than, etc.) early in the risk assessment; they are only set precisely (quantitatively) if a conservative assessment indicates the potential for harm. Limits of concern are directly related to whether the studies are performed in the laboratory or in the field. For laboratory studies, limits of concern are conservative trigger values (i.e., low values) which if exceeded indicate potential harm and the need for exposure assessments and determination of field-scale effects ([Raybould, 2011](#)). For field studies, the lower limit will usually be defined by a threshold effect, i.e., the lowest effect to cause environmental harm ([Perry et al., 2009](#)). Knowing in advance the size of the effect to be determined is crucial because this information will enable an assessment of the ability of the study to detect harm. Limits of concern are estimated from literature data, modelling, and existing knowledge ([Perry et al., 2009](#)). Moreover, given that it is impossible to assess or to measure the state of a specific protection goal as a whole, specific representative surrogates or indicators of assessment endpoints are selected for laboratory testing ([Raybould, 2007b](#); [Romeis et al., 2008, 2011](#)), field testing, or environmental monitoring ([Duelli and Obrist, 2003](#); [Reid et al., 1993](#); [Sanvido et al., 2005](#)). Selection of surrogates and indicators depends on the specific case, i.e., on the risk hypothesis derived at the beginning of the ERA for the specific GM crop ([Fig. 1](#)) ([Raybould, 2006](#); [Romeis et al., 2008](#)).

The definition of measurement endpoints requires the determination of parameters (e.g., mortality, reproduction, growth) that indicate changes in the particular surrogate or indicator species. Priority should be given to measurement endpoints that are easily interpreted and for which an adverse effect is clear ([Romeis et al., 2011](#)). Interpretation can be facilitated if standard toxicity tests and monitoring methods are available. Parameters for laboratory or glasshouse tests usually cover lethal effects (mortality) or sublethal effects (e.g., reproduction) while tests in the field often assess abundance and diversity ([Table 1](#)). Especially when impairment of ecosystem services is assessed, it may be difficult to directly measure specific indicator groups or species of organisms either in laboratory or field studies. Because all of the species or groups responsible for a particular ecosystem service are often unknown, the selection of indirect indicators may be used to demonstrate failures in ecosystem services. Failures in biological control functions, for example, could be surveyed indirectly by recording unusual pest outbreaks ([Sanvido et al., 2009](#)). Similarly, soil invertebrates and soil microorganisms could be surveyed by assessing decomposition of organic matter ([Knacker et al., 2003](#); [Zurbrugg et al., 2010](#)), soil respiration, or microbial biomass ([Ferreira et al., 2010](#); [Römbke, 2006](#)).

6. Discussion

In the risk analysis of GM crops, the responsibility to decide what deserves protection and what level of change is

⁶ We recognise that controlling the target pest is likely to harm higher trophic levels that feed on that pest. Although such effects are not intended, they have reduced relevance for the ERA of a GM crop because they are an inevitable consequence of any decision to apply a pest management practice ([Romeis et al., 2008](#)).

acceptable lies with the risk managers. Operational protection goals should be defined transparently through a dialogue between all relevant stakeholders. The matrix presented here (Table 1) can be used as a tool to structure such a dialogue. The process could include stakeholder meetings in which different conservation goals and ecosystem services are compiled and ranked. An operational definition of the category “biodiversity conservation” will ultimately necessitate the compiling of detailed lists for each group of species and habitats to be explicitly protected. For ecosystem services, function is clearly an alternative to detailed species lists because it is often unclear which and how many species are responsible for a particular ecosystem service.

The difficulty for risk managers when deciding on protection goals is that the conservation of biodiversity and the maintenance of ecosystem services, including the production of crops, may require different conservation measures. As Duelli and Obrist (2003) emphasize, each requires its own indicators, which do not normally correlate with each other. While species conservation focuses on rare and threatened species, ecosystem services concentrate on ubiquitous and abundant species because rare species are likely to have less ecological influence than abundant species. From a nature conservation point of view, those rare and threatened species that are characteristic of a specific habitat are valued more than common and widespread species; hence, reductions in prevalence or abundance are more likely to be tolerated for common species than for rare or threatened species.

The defining of protection goals will inevitably include a number of problems, and one problem concerns the conservation of biodiversity in agricultural fields, which is being vigorously debated in Europe. In many European countries, agriculture and natural habitats are intimately mixed, with around 70% of the land area being classified as agricultural (Hails, 2002). Consequently, the conservation of “common” species and communities within the farmed landscape is increasingly considered important by at least some researchers. These researchers suggest that certain common species may support biodiversity within crop fields (Marshall et al., 2003). There is controversy about whether certain common species (although not explicitly listed in the legislation) should be regarded as a protection goal because changes in the their abundance might translate to higher trophic levels (Sanvido et al., 2007) that may include Red List species or species of high conservation or cultural value. A prominent example for the conflict surrounding the protection of “common” species involves arable weeds, which on the one hand reduce agricultural yield and on the other hand represent an essential part of agricultural food webs and contribute to farmland biodiversity (Heard et al., 2005; Watkinson et al., 2000).

Even if risk managers succeed in defining operational protection goals, they will also have to decide what kind of environmental changes are relevant and represent environmental harm. Determining which changes are harmful requires reference or baseline data that can be used to compare the expected degree of change caused by different actions. However, the present legal framework for the evaluation of GM crop market approvals does not give risk managers in Europe a formal obligation to compare the effects of GM cropping to the effects caused by conventional

Box 2. Reasons for the regulation of agricultural practices.

One reason why authorities regulate technologies is to protect human health or the environment from harm (Jaffe, 2004). The question of environmental harm can only be answered provided that a particular agronomic practice is regulated by a legal framework (such as the use of pesticides). Interestingly, certain agricultural practices, such as the use of tillage or mowing machinery, are not regulated although they are known to be potentially hazardous to the environment. Tillage, for example, can cause considerable harm to earthworm populations (Ernst and Emmerling, 2009), while mowing can substantially harm field invertebrates such as grasshoppers and bees (Humbert et al., 2010, 2009). Such “classical” agricultural practices may not be regulated because they have been used for centuries and because their harmful effects have been recognized only recently.

agricultural management practices; existing agricultural technologies are evaluated according to different regulatory frameworks. The regulatory framework for pesticides, for example, uses evaluation criteria that differ from those used for GM crops. Hence, risk managers often refuse to compare the effects of GM crops to the effects caused by pesticides. Interestingly, the failure to compare the predicted outcomes of these different actions counters the intention of the EU legal framework regulating the approval and use of GM crops, which explicitly states that the “interpretation of the data collected should take account of existing environmental conditions and activities in order to determine an appropriate baseline.” (European Council, 2002).

That regulators are forced to restrict their judgements to the GM legislation leads to the irrational situation in which the same environmental effects may be judged differently depending on which agricultural management practice caused them (see Box 2 for an interesting problem for regulatory decision-making). Yet the risk managers responsible for the approval of GM crops in Europe should be aware that legislation generally aims at limiting unintended harmful effects of a technology, while intended effects are explicitly accepted to be an inevitable consequence of a particular technology. The flow chart presented in Figure A.1 will help risk managers differentiate between intended and unintended direct effects of different pest management practices on the arthropod fauna in agricultural landscapes. They can thereby decide what characterises unintended effects and which of these may represent environmental harm. This approach ensures that all technologies that could potentially harm the environment are evaluated according to the same legal criteria.

Ideally, new technologies should be assessed not only on their risks to the environment but also on their potential benefits (i.e., opportunities). Because the main objective of the EU GMO regulatory framework is to ensure a high level of environmental protection, however, it focuses on the assessment of risks and does not explicitly consider whether GM crops fulfil wider socio-economic and ecological aspirations (Devos et al., 2008). In addition to considering the potential benefits of

new technologies, those who analyse risks should also recognize that the real choice is not between GM crop management that is inherently risky and traditional pest and weed management that is completely safe. Both conventionally bred crops and GM crops have positive and negative environmental effects (Sanvido et al., 2007). Two scientific bodies have recently suggested that adoption of a specific method of crop management (whether GM or conventional) should be based on consideration of the overall environmental consequences and that such consideration will require a broader and more balanced legislative oversight in the EU (ACRE, 2007; EFSA, 2008). At the European Food Safety Authority (EFSA) colloquium concerning challenges and approaches for the environmental risk assessment of GM crops, for example, the discussion group concerned with broadening the scope of the environmental risk assessment recommended that a paradigm shift would be required to change from risk assessment as it is currently practiced to a more sophisticated assessment that balances risks and benefits (EFSA, 2008). The EFSA document further stated that the *status quo*, in which risk assessment is interpreted very narrowly in terms of adverse effects, is not sustainable, suggesting that decision support tools should be built that enable risk assessors to better consider effects of whole farming systems. However, fundamental policy concepts such as sustainability could only be considered in the ERAs for particular products if risk managers define clear policy objectives for sustainable agriculture. Apart from the fact that it is difficult to integrate a risk/benefit or a sustainability assessment in the regulatory ERA of a product, such an assessment should not be restricted to the approval of GM crops. Risks from GMOs should be evaluated according to the same criteria as risks from any other agricultural management practice. Future political and legislative processes in Europe should attempt to harmonise the different legal frameworks regulating agricultural technologies, such as the ones regulating the ERAs of pesticides and GM crops.

7. Conclusions

There is a need for generic protection goals that are independent of the agricultural technology used; what constitutes environmental harm should not be defined by the technology causing the harm. Operational harm criteria for GM crops are a prerequisite for regulatory decision-making, but such criteria are presently not clearly defined in most European regulatory frameworks. The analysis presented here shows that both protection goals and baselines are two consistently emerging issues when definitions of harm are discussed. Protection goals should be operationally defined by risk managers in a transparent process that involves a dialogue between relevant stakeholders. The ultimate decision about what deserves particular protection because it is specifically valued, however, lies with the risk managers who are responsible for the regulation of GM crops. The matrix proposed here can be used as a tool to determine in a systematic manner what deserves particular protection. It is important to recognize that this process is not scientific because science can offer little to resolve disputes over values (Pielke Jr, 2007). The definition of ecological relevance and the determination of what constitutes environ-

mental harm are highly subjective and can greatly differ depending on perspective. Science can provide the knowledge needed to understand the likely consequences of different policy options, but science cannot determine which values or perspectives are superior (Lubchenco, 1998). That responsibility lies with the policy-makers and the risk managers who regulate the use of GM crops.

Disclosure statement

In addition to scientists from the public sector, the group that developed the present manuscript included scientists from regulatory agencies and the commercial biotech industry. Although these organizations have an interest in the final outcome of the group, members of the group participated as individuals and not as representatives of these organizations. The publications of the group reflect a consensus developed as a result of its open meetings and discussions, and the opinions expressed by individuals or in group publications may not necessarily represent the policies of their organizations. Any mention of a proprietary product in meetings or publications does not constitute an endorsement or a recommendation by the group. There is no commercial sponsorship or endorsement for the group or its members, beyond the support provided to individual participants by their organizations to attend meetings.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at [doi:10.1016/j.envsci.2011.08.006](https://doi.org/10.1016/j.envsci.2011.08.006).

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Olivier Sanvido is a Research Scientist at the Agroscope Reckenholz Tänikon Research Station ART where he is a specialist on environmental risk assessment and monitoring of genetically modified (GM) plants. He has an MSc in Biology and a PhD in Plant Science. Olivier Sanvido has over 14 years of professional

experience including 4 years in regulatory affairs and quality assurance in the medical device and pharmaceutical industry. Dr. Sanvido subsequently worked in applied research at ART elaborating conceptual frameworks supporting the implementation of legal requirements for GM plants.

Jörg Romeis is a Senior Scientist and the Deputy Head of the Biosafety Unit at ART. Jörg Romeis has an MSc and a PhD in Biology and has been trained as an applied entomologist with a focus on biological control and multi-trophic interactions. For more than 11 years he has been studying the impact of insect-resistant, GM plants on non-target arthropods including herbivores, biological control organisms, and bees. Besides researching the non-target impacts of selected GM plants, Dr. Romeis has also been actively involved in developing testing protocols and guidelines for non-target risk assessment.

Achim Gathmann is a Senior Scientist at the Federal Office of Consumer Protection and Food Safety. He has an MSc and a PhD in Biology. His expertise is in agroecology, plant protection, biological control, and risk assessment of GM plants. Dr. Gathmann has been actively involved in biosafety research, environmental risk assessment, and the development of guidelines for the risk assessment of GMOs for more than 10 years.

Marco Gielkens is a Senior Risk Assessor on GMOs at the National Institute for Public Health and the Environment. He has more than 10 years of experience evaluating applications for deliberate releases of GM plants. Marco Gielkens has a MSc in biotechnology and a PhD in the molecular genetics of fungi. He has been actively involved in developing guidelines for general surveillance of GM plants and non-target risk assessment.

Alan Raybould is a Science and Technology Fellow at Syngenta and a visiting professor at the University of Southampton. He has extensive experience in conducting regulatory risk assessments of transgenic maize and cotton that produce insecticidal proteins. In his work for Syngenta, and for industry organizations such as CropLife International, he has helped develop effective environmental risk assessment methods for transgenic crops through seminars and workshops in many countries. Before joining Syngenta, Alan Raybould was a research scientist at the UK's Centre for Ecology and Hydrology where he worked on predicting the effects of pest-resistance transgenes in wild relatives of crops.

Franz Bigler has been a Senior Scientist and the Head of the Biosafety Unit at ART since 2000. He has an MSc in agronomy and a PhD in entomology and over 30 years of experience in agronomy and plant protection. His expertise is in insect ecology, plant protection, IPM-systems, biological pest control, risk assessment, and environmental effects of plant protection methods including the effects of GM plants. Dr. Bigler is author and co-author of over 120 articles in peer-reviewed journals and of many book chapters.