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Publiziert mit Unterstützung des Schweizerischen Nationalfonds zur Förderung
der wissenschaftlichen Forschung.

Bibliografische Informationen der Deutschen Nationalbibliothek
Die Deutsche Nationalbibliothek verzeichnet diese Publikation in der Deutschen Nationalbibliografie;
detaillierte bibliografische Daten sind im Internet abrufbar über http://dnb.d-nb.de.

ISBN 978-3-7281-3443-1 (Printausgabe)

Download open access:
ISBN 978-3-7281-3464-6/DOI 10.3218/3464-6

www.vdf.ethz.ch

TABLE OF CONTENTS

CHAPTER 1

EXECUTIVE SUMMARY

1 EXECUTIVE SUMMARY

The legal framework regulating the approval and use of genetically modified (GM) plants demands that regulatory decisions determine what kind of environmental changes are relevant and represent environmental damage[1]. The current debate on the impacts of GM crops on biodiversity illustrates that consensus on criteria[2] that would allow a commonly accepted evaluation of environmental damage is presently lacking. Especially in Europe, GM crops have been a constantly debated issue, and the interpretation of scientific data is controversially discussed by the different stakeholders involved. Considering the vast amount of scientific data available, one can argue that the current debate is not primarily due to a lack of scientific data, but more to a lack of clear criteria that allow one to put a value on the impacts of GM crops on biodiversity.

Ultimately, any decision by regulatory authorities on what they judge being unacceptable is based on the relevant legal frameworks. Usually, such decisions are taken in a political context that weighs scientific, ethical and economical criteria with cultural, religious, aesthetic and other relevant social beliefs and practices. Terms such as risk and safety are linked to a conception of damage. Damage, however, cannot be defined on a purely scientific basis. The normative character of the term "damage" implies that both choice and definition of what constitutes a risk are impossible without a value judgment. Damage has thus to be defined together with an ethical evaluation as ecological analyses alone cannot discover "correct" or "objective" criteria for damage.

The project VERDI (Valuating environmental impacts of GM crops – ecological and ethical criteria for regulatory decision-making) is an interdisciplinary collaboration between environmental biosafety and ethics that intends to offer European policy-makers and regulatory authorities guidance on how decision-making related to GM crops could be improved. Concentrating on environmental impacts of GM crops on biodiversity, the project addresses both the ecological and the ethical questions involved in finding an operational approach to the evaluation of environmental damage.

Two case studies with the currently most prevalent GM traits (insect-resistance based on Bt and herbicide tolerance) are used to discuss the open questions involved. Considerable scientific data on the environmental impacts of these two traits have been gathered in the past 15 years, allowing one to determine how such an evaluation could be performed to be generically applicable to different types of GM crop traits, including new applications of biotechnology.

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1 In the following, the two terms "damage" and "harm" are used interchangeably

2 The term criteria is used hereafter in the sense of a standard on which a judgment or decision ma e based.

Stakeholders from different European countries including regulatory authorities, agricultural biotech companies and academia were invited to two expert workshops. In the first workshop, current approaches and challenges in the regulatory decision-making process related to GM crops were analyzed. The second expert workshop aimed at determining what particular effects of GM crops on biodiversity are to be judged as unacceptable harm based on an ecological and an ethical valuation comparing effects of GM crops on biodiversity to environmental effects of current agricultural management practices. Results and feedback obtained during the work-shops were used to elaborate a synthesis of the relevant ethical and ecological aspects when evaluating impacts of GM crops on biodiversity.

The results obtained reveal that both protection goals and baselines are two consistently emerging issues when discussing a definition of damage. Protection goals as specified by existing legislation are the exclusive starting point for a definition of damage for regulatory authorities. Yet, the legislative terms to describe the protection goal "biodiversity" are too vague to be scientifically assessed. Two matrices are proposed to address this problem. The first matrix introduces the Ethical Reference System (ERS), being the first step in a systematic process aiming at the specification and justification of plausible ethical criteria to evaluate the risks of GM crops on biodiversity. The second matrix allows for an operational definition of biodiversity by specifying the areas of protection as well as assessment and measurement endpoints based on a number of defined criteria. While the initial proposal regarding what to protect has to be framed by the regulatory authorities, the operational definition of protection goals should be defined in a transparent process involving a dialogue between all relevant stakeholders. The presented matrix can thereby be used as a tool to structure the dialogue, especially when defining both assessment and measurement endpoints. The process could include stakeholder meetings where stakeholders would compile and rank different conservation goals and ecosystem services.

Baselines are recognized to be the second crucial point in decision-making processes as they determine what makes a change to be damage. Due to their vague definition, the use of baselines as a decision support tool nevertheless remains ambiguous, necessitating a more precise characterization. Common to all baseline definitions is the term "comparison." Theoretically, decisions are always taken relative to a comparator that determines the current practice that is judged being acceptable. According to this baseline conception, the impact of a specific technology can only be compared if the impacts of current practices are known. However, as GM and non-GM-based management practices are regulated according to different regulatory frameworks in Europe, a direct comparison of the effects of a GM cropping system to its conventional non-GM counterpart is impossible under the current Swiss and EU regulatory frame-work. The baseline approach is thus principally not always applicable as, for example, the EU regulations demands that one assess potential indirect or cumulative long-term effects of GM crops while this is not a requirement for conventional pest management practices. Nevertheless, an important point to consider in such a comparison refers to the fact that all regulatory frameworks differentiate between "intended" effects of a specific management practice and "unintended" effects that are to be minimized. This differentiation allows for the outlining of a generic scheme that permits one to evaluate whether the effects of different agricultural management practices are to be regarded as intended effects (which are judged acceptable) or as unintended effects that could represent environmental damage. This differentiation may help to overcome the principal difficulties of the initial baseline conception. In a first case study with Bt-maize, a flow chart is presented that can help risk assessors to differentiate the effects of various pest management practices used for European Corn Borer management in maize on the arthropod fauna in agricultural landscapes.

In a second case study with GM herbicide-tolerant maize, criteria for regulatory decisions for noninsecticidal GM crops were determined. In contrast to Bt-maize, the assessment of the direct effects of the genetic modification is not the primary concern for noninsecticidal GM crops. Rather, changes in agricultural management may be the primary cause of possible indirect effects on farmland biodiversity. The evaluation of indirect impacts prior to approval of the GM crop is challenging. It might be difficult to perform such an evaluation within the time frame normally available for pre-market risk assessment as long time periods are usually needed for indirect environmental changes to become apparent. These types of effects might, moreover, only become apparent during the large scale cultivation of GM crop events under real agricultural management. The establishment of risk mitigation measures thus appears to be a valid option to increase the level of safety. The goal of these risk mitigation measures should be to avoid the risk of reduced crop yields and the long-term build-up of problematic weed communities while supporting a sustainable degree of farmland biodiversity. Four risk management options are proposed that can help to achieve a balance between agricultural production and the support of desired noncrop plants in arable fields.

All technologies that could potentially harm the environment should be evaluated according to the same legal criteria, for example, according to their novelty and not to the process of their development. Hence, what constitutes environmental damage should not be defined by the technology causing it, but by the type of damage that should to be avoided. The elaborated ethical and ecological criteria herein may allow a generally acceptable evaluation of damage that can be applied to a wide range of different GM crops. The criteria could help regulatory authorities to improve decision-making and to take more accurate and coherent decisions. This may ultimately avoid decisions on environmental risks of GM crops being arbitrary in comparison to other technologies.

CHAPTER 2

INTRODUCTION

2 INTRODUCTION

2.1 Existing definitions of environmental damage

The legal frameworks regulating the approval and use of GM crops require regulatory authorities to decide what kind of environmental changes are relevant and represent environmental damage.[3] The current debate on the impacts of GM crops on biodiversity illustrates that consensus on criteria that would allow a commonly accepted evaluation of environmental damage is presently lacking. Especially in Europe, GM crops have been a constantly debated issue and the interpretation of scientific data is debated controversially by the different stakeholders involved. Considering the vast amount of scientific data available, one can argue that the current debate is not primarily due to a lack of scientific data, but more due to a lack of clear definitions regarding how to put a value on the impacts of GM crops on biodiversity.

Given the complexity of the questions involved, a concise and commonly accepted definition of "environmental damage" is currently missing. A number of definitions have been proposed (Box 1) that all entail some challenges regarding their practical application (see section 2.2).

Common to all proposed definitions are the following three features:

- Damage is occurring to a natural resource or resource service such as the conservation and sustainable use of biodiversity,
- Damage is measurable by some means,
- Damage is characterized by an adverse change that is either significant, severe or exceeding the natural range of variability

The common features lead to three main questions that need to be answered when approaching a definition of environmental damage. These questions are not addressed in sufficient detail in the existing definitions mentioned above:

- What needs to be protected?
- What is to be measured?
- What is adverse?

To answer the first question, one needs to define the protection goals that should not be harmed and more particularly one must to find an applicable definition of the concept of biodiversity. It can be noted that the concept of biodiversity is well defined in theory, though there are a number of difficulties that

[3] In the following, the two terms "damage" and "harm" are used interchangeably.

Box 1: Proposed definitions of environmental damage

- 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)

might hinder decision-making in practice (see section 4). How can scientists and policy-makers determine what requires protection? To answer the second question (What is to be measured?), one can remark that we generally focus on those biological entities that are regarded worth of being evaluated. The question thus remains as to how to decide which biological entities are to be selected for this evaluation and how measurable entities can be defined that can be used in regulatory decision-making (see section 5). Finally, to answer the third question (What is adverse?), one has to recognize that a purely scientific definition of what has to be considered adverse is impossible. Decision-making processes are always influenced by ethical values, political, social and economical factors. The question then arises regarding how strong the different fields are weighed (see section 9).

Pertinent to the last two questions is the question "How to value?" This is key when discussing definitions of environmental damage. The difficulty linked to the question as to how to perform a value judgment lies in the inherent complexity of combining the subjectivity of the matter, which is due to different viewpoints and situations, with the apparent need for objectivity when it comes to regulatory decision-making. Criteria that would allow a generally acceptable evaluation of damage and which are applicable in practice could help regulatory authorities to improve decision-making and thus avoid decisions on environmental risks of GM crops being arbitrary.

2.2 Difficulties to apply existing criteria for environmental damage

The difficulty to find an unambiguous definition of environmental damage is primarily due to the challenge of applying the criteria that have thus far been proposed to assist regulatory authorities when evaluating environmental damage in actual situations of decision-making. A number of authors have proposed to evaluate damage according to criteria such as "spatial and temporal extent," "severity" and "reversibility" of effects (Ammann *et al.*, 2000; ACRE, 2002; Nöh, 2002) Decisions determining whether observed effects fulfill the proposed criteria for environmental damage are difficult to take due to methodological limits in data collection and analysis. Scientific methods are only partially capable of adequately evaluating the magnitude of change of a particular environmental resource. Environmental sciences can help to assess the abundance of a particular species group, but it is usually difficult to determine whether an observed change in a species group is exceeding the natural variation of the species group. This is because appropriate baseline data is often lacking and because agro-ecosystems are dynamic and subject to constant change. Long time periods are usually needed for environmental changes to become apparent and it may be impossible to determine whether observed changes will be reversible at some later point in the future.

A practicable definition of environmental damage necessitates criteria that are less prone to the methodological challenges posed by scientific methods. Decision criteria to evaluate effects of GM crops on biodiversity could be defined using an approach where GM crop effects are compared to known effects of current agricultural management practices. By putting a relative value on the effects of GM crops in comparison to known environmental effects of current crop management practices, decision criteria would be placed in a context where practical experiences exist. Provided that this approach is scientifically valid and ethically justifiable, the approach would allow one to decide whether experienced GM crop effects are ecologically significant and why they are judged to be unacceptable.

2.3 Research questions and goals of the project

Ultimately, any decision by regulators on what they judge being unacceptable is based on the existing legal frameworks. In addition to considering the actual legal basis, such decisions are usually taken in a political context that weighs scientific, ethical and economical criteria with cultural, religious, aesthetic and other relevant social beliefs and values. Concentrating on environmental impacts of GM crops on biodiversity, the project addresses both the ecological and the ethical questions involved in finding an operational approach for the evaluation of environmental damage. The project aims at offering guidance about how decision-making related to GM crops could be improved to all stakeholders involved in the process of risk assessment of GM crops (policy-makers, regulatory authorities, agricultural biotech companies and scientific expert panels). The main goals of the project are:

- To identify the main challenges for regulators when assessing and judging environmental impacts of GM crops including the most important ethical and ecological knowledge gaps for the interpretation of scientific data
- To analyze types and magnitudes of biodiversity impacts of current crop management practices and (known) impacts of GM crops on biodiversity
- To perform a comparative ethical and ecological valuation of impacts of current crop management practices and impacts of GM crops on biodiversity
- To develop decision-criteria and guidance for an ethical and ecological evaluation of impacts of GM crops on biodiversity considering the experienced impacts of current crop management practices

2.4 Relation between ethics and ecology in the context of the given research question

Terms such as risk and safety are linked to a conception of damage. The notion of damage or benefit depends on our negative or positive valuation of impacts. The normative character of the term "damage" implies that both choice and definition of what constitutes a risk are impossible without a value judgment. What we choose and define to be a risk is based on a certain normative background. Damage must therefore be defined together with an ethical evaluation as ecological analyses alone cannot discover "correct" or "objective" criteria for damage. Natural sciences can thereby only determine the probability that a certain impact will occur or the likely consequence if a certain impact has occurred. Ethics is necessary to clarify the concept of damage in general and the concept of environmental damage in particular. Both are evaluative concepts referring to changes or states of affairs that must be assessed negatively. On the basis of this conceptual analysis, it becomes possible:

- to critically analyze the appropriateness of legal risk concepts (given that a risk is a function of probability and extent of damage); and
- to develop scientifically sound and intersubjectively acceptable criteria[4] for the valuation of environmental damage that can be shared and accurately communicated between different individuals.

Ecology as a science needs to rely on ethics if it strives to evaluate possible and real impacts of GM crops on biodiversity because concepts such as damage or risk, which play a pivotal role in this evaluation, are inherently value-laden. The evaluation of impacts of GM crops on biodiversity in the context of current agricultural systems includes both ethical and ecological questions that need to be clarified. From an ecological perspective, for example, not every environmental impact is of ecological significance and leading to relevant impacts on biodiversity. From an ethical point of view, not every ecologically relevant impact on biodiversity is necessarily considered to be morally wrong. Whether it is wrong or not primarily depends on the importance that one ascribes to biodiversity. While there is agreement among ethicists that biodiversity is valuable, there is no agreement on the importance of this value (compared to other relevant values) and whether it is an inherent or just an instrumental value.

The outlined research questions necessitate a true interdisciplinary approach, which, however, includes some challenges. One difficulty is that ecology and ethics use different approaches. A challenge in finding an adequate approach to environmental damage lies in the inherent difficulty to combine the descriptive scientific approach with the normative approach used in ethics. Natural sciences try to establish the empirical facts of a matter (what is the case), whereas ethics determine what ought to be the case. Probably even more challenging is the fact that central concepts such as damage or risk are understood in different ways by ethicists and ecologists. In the present project, it took a considerable amount of time to realize that there are diverging interpretations of these concepts and to agree on common definitions of these concepts. The common understanding now makes it possible to proceed to the final phase of this project, concretizing the ethical and ecological criteria for the evaluation of impacts of GM crops on biodiversity in a way that will make them applicable for regulators in actual situations of decision-making.

[4] Intersubjectively acceptable criteria are normative criteria that a rational person, that is, a well-informed person being committed to the best rationale available, would accept after a critical assessment. Such criteria are thus inherently universal and independent from a particular, subjective context.

2.5 Methods and approaches of the project

A particular strength of the project was its focus on two expert workshops inviting regulators, members of biosafety committees and scientists with a background in ethics, ecology and agriculture from different European countries to combine their efforts in order to create an elaboration of solutions to the open questions addressed. The project followed a stepwise approach consisting of five project phases that were centered on the two expert workshops:

Phase 1: Review and analysis of current knowledge
The first project phase consisted of an analysis of the relevant scientific literature to prepare the first expert workshop that took place in phase 2 of the project and to select an appropriate method to be used for the group discussions during the workshop. In order to benefit the most from the discussions planned for the first workshop, the project team decided to make use of professional workshop moderation. The moderator team from Genius GmbH (Darmstadt, Germany) recommended the use of the Crea-Space method for the workshop, a method supporting the development of creative potentials in teams and larger groups (El Hachimi and von Schlippe, 2003). The tool is methodologically derived from Organizational Development and serves to provide a framework for the achievement of self-organization processes. In the context of the present project, it was deemed to be the ideal tool to effectively introduce issues derived from first results to a constructive discussion level. In order to avoid a bias towards a predetermined position supported by the project team workshop, participants were thus not provided with any background documentation prior to the workshop.

Phase 2: First expert workshop: problem identification for decision-making
In order to analyze current regulatory decision-making processes, regulators, members of biosafety committees and representatives of the agricultural biotechnology industry from different European countries were invited to a first expert workshop in June 2008. Workshop participants were supplemented by scientists with a background in ethics, ecology and agronomy (see Annex 1: List of workshop participants). The aim of the first workshop was to determine current approaches and challenges when evaluating scientific data on impacts

of GM crops on biodiversity. The discussion during the group works and in the plenum illustrated that both protection goals and baselines were two consistently emerging issues. Protection goals as specified by existing legislation were regarded as the exclusive starting point for regulatory authorities for a definition of damage. Any negative impact on these protection goals would consequently constitute damage. Baselines were recognized as being the crucial point of any decision-making process of determining what makes a change to be judged as damage.

Phase 3: Comparative ethical and ecological evaluation

Phase 3 aimed at developing solutions for the challenges that had been identified by invited experts during the first expert workshop when evaluating impacts of GM crops on biodiversity. Four approaches were developed to help regulatory authorities addressing the challenges of vague definitions for both protection goals and baselines. Prior to the second expert workshop, experts were provided with four background documents proposing solutions as to how the question of unclear definitions of both protection goals and baselines could be addressed. The first two approaches aimed at enabling a more generic definition of protection goals in the context of agricultural management. The two latter approaches proposed a methodology for a comparative environmental risk assessment that can be used to approach the question of an appropriate baseline. For the comparative risk assessment, two currently commercialized GM crops (Bt-maize and GM herbicide tolerant maize) were used as case studies to specifically discuss the environmental impacts of these GM crops in comparison to current pest and weed management practices.

Phase 4: Second expert workshop: criteria for evaluation of impacts of GM crops on biodiversity

The proposed approaches of both the environmental biosafety and the ethics project parts were presented and discussed during the second expert workshop taking place in June 2009 in Engelberg, Switzerland, involving many of the experts that had attended the first expert workshop (see Annex 1: List of workshop participants). The background documents elaborated during phase 3 of the project were critically discussed with all participating experts during the group works taking place in the second workshop. All documents were not meant to be conclusive as experts were invited to provide feedback and criticism to the approaches proposed. The background documents were discussed in four group works to determine both strengths and weaknesses of the four proposed approaches:

- Group work 1: Ethical reference system to assess biodiversity
- Group work 2: Operational definition of protection goals
- Group work 3: Comparative environmental risk assessment Bt-maize
- Group work 4: Comparative environmental risk assessment GMHT maize

For each group work, participants were randomly grouped into three working groups. In each group, a rapporteur took notes on the main results of the discussion and presented the results in a short presentation to the plenum in a plenary session following the group work.

Phase 5: Synthesis of workshop results – preparation of guidance document
During the last step of the project, results and feedback obtained during the second workshop were used to elaborate a synthesis of the relevant ethical and ecological aspects when evaluating impacts of GM crops on biodiversity. The results of the four group works and the feedback collected by experts were used to improve the approaches proposed (see sections 8–9). The project results were revised and compiled into a guidance document that can be used for an informed decision-making process for the evaluation of impacts of GM crops on biodiversity. The guidance document summarizes criteria to assist decision-making on the relevance of impacts of GM crops on biodiversity.

2.6 Outline of the report

The first part of the report contains an executive summary (chapter 1), a general introduction (chapter 2) and a general definition of the term damage (chapter 3) that is mainly influenced by ethical considerations.

The second part of the report (chapters 4–8), which was written by Agroscope ART, is primarily dealing with the ecological conception of environmental damage:

Chapter 4 presents the general definition of the term "biodiversity," introduces the different components of biodiversity and discusses the diverse motivations to preserve biodiversity. Moreover, environmental protection goals as specified by Swiss legislation are described with regard to agriculture in general and more specifically in view of the use of genetic engineering. Finally, the ecological relevance of biodiversity is discussed for species and habitat diversity and for ecosystem functions.

Chapter 5 presents an approach as to how operational protection goals for the evaluation of impacts of GM crops on biodiversity could be defined. A matrix is introduced that lists all entities of biodiversity that require protection. The matrix lists factors that need to be considered when defining corresponding assessment and measurement endpoints. It is stressed that clearly defined endpoints are necessary for regulatory decision-making as they specify what deserves protection. It is recommended that one define indicators and parameters that can be measured to determine whether harm to the protection goals specified occurred.

Chapter 6 discusses the issue of using thresholds in environmental decision-making. It is recognized that the legal frameworks regulating the use of GMOs operate according to the thresholds-concept (i.e., risks are acceptable as long as they do not exceed a certain specified threshold). It is nevertheless also emphasized that regulatory authorities do not provide clear threshold values, which challenges decision-making processes.

Chapter 7 discusses how a baseline for the comparison of different agricultural management practices could be defined to determine whether the cultivation of GM crops is better, equal or worse than current practices. Pest management in maize is used as a case study to compare different GM and non-GM based cropping systems. It is concluded that it is impossible to perform a generic comparison of different pest management practices, mainly because these are regulated based on different legal frameworks. Instead, an approach is proposed that allows differentiating between intended and unintended effects of the pest management practice applied. The proposed flow chart can further be used to determine which type of unintended effects may represent environmental damage.

Chapter 8 uses the effects of different weed management practices in maize to discuss how one can cope with rather vaguely definable damages on farmland biodiversity that might occur from changes in agricultural management practices. Since long time periods may elapse before these damages become apparent, appropriate risk management options might be a valuable option to Reduce the risks of these damages occurring.

The third part of the report (chapter 9), which was presented by *Ethik im Diskurs*, discusses the topic from the ethical point of view.

Chapter 9 introduces the ethical reference system (ERS) as a useful tool for regulatory decision-making that allows specifying and justifying plausible ethical criteria for the evaluation of environmental impacts of GM crops on biodiversity. It is emphasized that the ERS provides regulators with a general orientation grid by describing the different ethical theories that may underlie the protection of biodiversity. The ERS helps to determine which ethical position one intuitively favors and facilitates a more reflected understanding of the ethical views enshrined in the law.

The report ends with a chapter summarizing general recommendations to decision-makers (chapter 10)

Finally, Annex 2, which was presented by *Ethik im Diskurs*, characterizes the term "risk" and discusses it from a general point of view, and more specifically in the context of the given research questions. Although the report mainly focuses on the question as to how one can find criteria to determine what constitutes environmental damage, the term "risk" is a recurring topic when discussing definitions of damage. Under certain circumstances (e.g., if it is difficult to clearly characterize which impacts constitutes damage), relying on risk mitigation measures may be an adequate measure to approach this question.

CHAPTER 3

A GENERAL DEFINITION OF DAMAGE

3 A GENERAL DEFINITION OF DAMAGE

In everyday language, something is called damage or harm if state S2 represents a change that is valued negatively compared to an initial state S1. If, for instance, a house burns to the ground and its inhabitants lose their belongings, or if a healthy person falls ill and suffers from the illness, this is called damage or harm. It is important to realize that damage is an evaluative notion, even though the evaluation is based on the establishment of facts. For this reason, there can be no value-free scientific risk assessment. Science can ascertain the actual state of something and it can describe and explain changes and its related ecological implications. However, science can only answer the question from a scientific perspective as to how this state or these changes should be evaluated.

To be more exact, damage as an evaluative notion does not denote a change that is evaluated negatively, but a change that ought to be evaluated negatively. In order to determine whether a state or an event is damage, we need a reference system. The purpose of this system is to name the values or goods that allow justified negative evaluations of changes. These may be "zero values" such as freedom from pain and suffering (whereby the negative change essential for damage would be the occurrence of pain and suffering) or positive values such as pleasure, beauty, bodily integrity or life (in the sense of being alive).

The evaluative dimension of the notion of damage consists of two aspects. On the one hand, suffering damage is always bad for the individuals (entities) affected. That is the prudential dimension which refers to what is good or bad for an individual living organism. On the other hand, damage is usually something that should not to be inflicted on others or something the others should be protected from. This is the ethical dimension. It is also the normative basis of the legal understanding of damage.

From an ethical point of view, damage is not necessarily bad or reprehensible. Rather, damage is either neutral or relevant. "Neutral" means that nobody can be held responsible for it. A congenital disease, for instance, may damage the affected child, even though it is the unpredictable result of a natural genetic process. "Relevant" means that the damage is to be evaluated negatively or positively in a moral sense. If the evaluation is negative, the infliction of damage is morally inadmissible; if it is positive, the infliction is morally admissible or even required. The latter is the case, for example, when a teacher gives a student a bad grade. This may damage the student: she may feel bad or have to repeat a course. However, if the grade is adequate to her performance, the infliction of damage is morally justified. On the other hand, torturing someone just for the fun of it implies inflicting a kind of damage that is morally prohibited.

What kind of entities can be damaged? In everyday language, there are different kinds of damage: economic damage, political damage, environmental damage, damage to persons, animals, plants or engines, construction damage, fire damage – to name just a few. These damages can be roughly classified into three main groups: systemic damage, functional damage and damage of individual beings. Environmental damages, for instance, are systemic damages, engine damage is a functional damage and damage to persons is a damage of an individual being (a person).

If we were to undertake a thorough and comprehensive conceptual analysis of the notion of damage, the following questions would have to be answered:

- Can there be systemic damages? Is it plausible to assume, for instance, that an ecosystem as such is damaged if its homeostatic equilibrium is disrupted?
- Can a loss of biodiversity as such be damage?
- Can plants or any other nonsentient living beings be damaged as such?
- Can nonliving entities (a car) or parts thereof (a car engine) be damaged as such?

In order to answer these questions, one would have to clarify what conditions must be met for the correct application of the notion of damage. This would be tantamount to an ontological analysis of the conditions of damage. The main questions to be tackled would be:

- Can nonexisting entities (for instance, dead persons) be damaged as such?
- If only existing entities can be damaged as such, what is an existing entity?
- If something exists only nominally, that is, as an abstract entity (such as, for example, an ecosystem), can it be damaged as such?
- Does damage presuppose the ability of experiencing it?

This analysis of the general notion of damage would be necessary before proceeding to the analysis of the specific notion of environmental damage. Unfortunately, most analyses performed by ecologists and ethicists do not follow this two step procedure. This is why their discussion of this topic is rather unsatisfactory.[5]

[5] One would be able to show that none of the conceptions or criteria of ecological damage that play a role in this discussion, especially with regard to GMOs – such as, evolutionary integrity, selective advantage, natural variation, similarity, impairment of biodiversity – are convincing.

However, for the purposes of this project, an indepth ethical analysis of the concept of harm in general and environmental harm in particular is not necessary. The main reason is that we will take as our main point of reference not an ethical, but rather a legal understanding of these concepts since we are mainly interested in helping regulators to decide whether environmental changes, especially changes in biodiversity associated with the use of GM crops, represent environmental damage; and if so, how severe the damage is.

As pointed out before with regard to the general definition of damage, there is no difference between ethics and the law. Both agree that the conception of damage refers to goods and values that deserve protection. Additionally, both agree that it is the aim of the respective ethical or legal norms to prevent damage from occurring. The difference is that legal regulations have a different perspective – they primarily aim at legal certainty – and are often the result of political or social compromises. This is why these regulations frequently reflect conflicting or incompatible evaluative beliefs that are based on incompatible value theories. Furthermore, the status of ethical values that are reformulated in legal terms often remains vague. With regard to environmental protection and the regulation of GM crops, however, this is no problem as long as there is a list of (more or less) well-defined protection goals which can serve as references for the determination of what has to be considered when evaluating damage. To give an example: whether biodiversity is intrinsically or only instrumentally valuable is ethically very important, but legally irrelevant. What matters legally is only whether it is a protection goal or not. If it is a protection goal, the question to be answered is how one can ascertain in specific cases whether the legal norms referring to this goal have been violated, for instance, by a reduction in biodiversity, and if so, how the damage is to be valuated. This problem of finding an operational definition of the protection goal biodiversity with regard to the possible effects of GM crops will be dealt with in section 5.

It is important to bear in mind that regulators have to take ex ante decisions. They have to decide, for example, whether a certain GM crop may be approved for commercial use. This decision should be based, among other things, on a risk assessment in which the potential ecological damage on valued species or on ecosystem service is linked to the probability of this damage occurring. This assessment is legally (and ethically) required as long as there is no certain causal knowledge concerning the real effects of the GM crop in question on biodiversity. In chapter 7 and 8, we will mainly concentrate on effects and the damage associated with it. This will allow, for instance, for identifying potential ecological damage of different pest and weed management practices on biodiversity. The question remains, however, how far it is possible on the basis of our current knowledge to determine the probability of this damage occurring (see Annex 2: What is risk?).

CHAPTER 4

CHARACTERIZING THE PROTECTION GOAL "BIODIVERSITY"

4 CHARACTERIZING THE PROTECTION GOAL "BIODIVERSITY"

4.1 Background

Protection goals as specified by existing legislation are the exclusive starting point for regulators for a definition of damage related to the evaluation of GM crops. Typically, legal frameworks make relatively vague specifications on the question regarding what it is to be protected from harm resulting from human activities. Both from an ethical and ecological point of view, the legislative terms used to describe the protection goals "environment" and "biodiversity" are however too vague to be scientifically assessed. The use of criteria to evaluate damage necessitates finding an operational way of how to characterize the protection goal "biodiversity." In a first step, the term "biodiversity" is thus examined more closely, followed by a discussion of the environmental protection goals as specified by Swiss legislation both from a general point of view and more specifically in relation to the use of genetic engineering. Finally, a proposal is made as to how the protection goal "biodiversity" in agricultural landscapes could be operationally defined.

4.2 What is biodiversity?

4.2.1 General definition

Although the term biological diversity – or biodiversity – has been extensively used in the past decades, the underlying concepts and definitions are anything but uniform. Probably one of the most prevalent definitions is given by the Convention on Biological Diversity (CBD) stating *"Biological diversity means the variability among living organisms from all sources including (…) terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems"* (CBD, 1992). As such, biodiversity is essentially an abstract concept, albeit one of which most would say that they have some intuitive understanding. Biodiversity is often termed as the variety of life on earth and the natural pattern it forms (CBD, 2000). The range of possible interpretations of such a conception of biodiversity is not simply wide, but it is so wide that it becomes exceedingly difficult to comprehend (Gaston, 1996). As a consequence, the concept of biodiversity is imprecise and it risks being defined so broadly that it equates to the whole of biology. Unfortunately, a definition treating biodiversity as more or less all living things on earth is of little use to policy-making where alternatives have to be selected in light of given conditions to guide and determine present and future decisions.

4.2.2 Distinguishing between different components of biodiversity

A number of schemes have been proposed to distinguish the major features of biodiversity and to better characterize what constitutes the "variety of life." A more specific definition is given by Redford and Richter (Redford and Richter, 1999), defining biodiversity as *"the variety of living organisms, the ecological complexes in which they occur, and the ways in which they interact with each other and the physical environment."* The authors propose to define biodiversity in terms of different components – genetic, population / species and ecosystems – each of which has compositional (the identity and variety of elements), structural (the physical organization or pattern of elements) and functional attributes (ecological and evolutionary processes). The three latter attributes refer to an approach initially suggested by Noss (Noss, 1990) to characterize biodiversity in terms of ecological processes recognizing that biodiversity is not simply the number of genes, species, ecosystems or any other groups of things in a defined area (as defined by the (CBD, 1992). Although such a scheme may be helpful in facilitating a practicable approach to refining the concept of biodiversity, one has to recognize that even the refined concept (Table 1) has its operational limits. Many of the terms used to describe the different attributes of biodiversity are still too broad to be effectively used in a decision-making process that aims at quantifying biodiversity changes.

4.2.3 Motivations to preserve biodiversity

The primary motivation to preserve biodiversity is often purely in the self-interest of mankind (CBD, 2000). The global loss of biodiversity is said to threaten food supply, the source of wood, medicine, energy and essential ecological functions as well as opportunities for recreation and tourism.

The Secretariat of the CBD lists a vast number of "goods and services" provided by ecosystems:

- Provision of food, fuel and fiber
- Providing of shelter and building material
- Purification of air and water
- Detoxification and decomposition of wastes
- Stabilization and moderation of Earth's climate
- Moderation of floods, droughts, temperature extremes and the forces of wind
- Generation and renewal of soil fertility including nutrient cycling
- Pollination of plants including many crops
- Control of pests and diseases

Table 1: Concept of the term "biodiversity" according to its three main components and the corresponding attributes (based on Noss, 1990; Kaennel, 1998; Redford and Richter, 1999).

	Genetic diversity	**Species diversity**	**Ecosystems diversity**
Composition (Identity and variety of elements)	Phenotypic diversity Variety, cultivar Subspecies	Species richness Species abundance Species evenness Species density Endangered species Threatened species	α, β, γ-diversity Landscape types Communities Ecosystems
Structure (Physical organization, pattern of elements)	Genetic structure	Population structure	Landscape patterns Habitat structure
Function (Ecological and evolutionary processes)	Gene flow Genetic processes	Surrogate species Indicator species Keystone species Flagship species Umbrella species	Landscape processes Land-use trends Ecosystem processes / services Parasitism, predation Pollination Soil processes Nutrient cycles (C, N, P, S) Biomass production

- Maintenance of genetic resources as key inputs to crop varieties and livestock breeds, medicines and other products
- Cultural and aesthetic benefits
- Ability to adapt to change

Today, ecosystem services are usually described according to the definition given by the Millennium Ecosystem Assessment (Millennium Ecosystem Assessment, 2005; EASAC, 2009). Ecosystem services are thereby defined as the benefits people obtain from ecosystems and they are categorized into four broad categories:

- Supporting services, which provide the basic infrastructure of life, including the capture of energy from the sun, the formation and maintenance of soils for plant growth and the cycling of water and nutrients (these services underlie all other categories).
- Regulating services, which maintain an environment assisting human society, managing the climate, pollution and natural hazards such as disease, flood and fire.
- Provisioning services providing the products on which life depends (food, water, energy) and the materials that human society uses for fashioning its own products.
- Cultural services providing landscapes and organisms that have significance for humankind because of religious or spiritual meanings they contain or simply because people find them attractive.

The need to preserve biodiversity is moreover often linked to different obligations (Kunin and Lawton, 1996; SCNAT, 2006):

- Moral and ethical obligations: biodiversity represents a heritage that has to be preserved for future generations.
- Human well-being: many organisms (flowers, birds, butterflies) bring pleasure to many people and enrich their lives. Biodiversity is furthermore important for personal recreation and regeneration as people enjoy and relax in a natural, diverse environment.
- Insurance: biodiversity can be useful as a potential resource for survival in a changing environment by providing new drugs, food stuffs or genetic resources for crops and farm animals.
- Ecosystem services: organisms provide essential services maintaining the life-support systems of the planet (see above).
- Economy: biological resources are the pillars upon which human civilizations are built as they support such diverse industrial sectors as agriculture, pharmaceuticals, construction, waste treatment and tourism.
- Preservation of the homeland ("Heimat"): Species and habitats in a particular country constitute an important part of the homeland and create identity.

Most people would certainly agree that a number of the mentioned obligations are justified, but there are inevitably also debates on the question whether all of these obligations are valid and which are to be preferred over others. However, such a discussion opens up a vast number of topics that are not relevant for the ultimate purpose of the present report. Discussing the different value positions relevant to the different motivations and determining which are ethically relevant and defendable is therefore beyond the scope of this report. The presented Lists are therefore to be seen as an unranked list of values that shape the discourse about policy goals when trying to find an operational definition of biodiversity (see section 5).

4.3 Environmental protection goals as specified by Swiss legislation

4.3.1 General environmental protection goals related to biodiversity

In Switzerland, the protection of biodiversity is laid down in a number of national legislations based on international environmental treaties[6] and on the Swiss Federal Constitution. The overall environmental policy goal is thereby to preserve and to promote native species and their habitats. The legislation is complemented by a number of enactments of the Swiss Federal Council that have a binding status for the federal authorities such as the "Landschaftskonzept Schweiz" (landscape concept Switzerland) (Buwal, 1999). Therein, a number of more detailed environmental policy goals are specified. In general, anthropogenic influences on the environment should not lead to additional Red List species and to a reduction of widespread species. Moreover, threatened species and their habitats should be preserved, their conservation status should not decrease and the number of Red List species should diminish yearly by 1%. Detailed lists of protected species and habitats are listed in respective legal texts (NHG, SR 451; NHV, SR 451.1).[7]

4.3.2 Environmental protection goals related to agriculture

According to the Swiss Federal Constitution, agriculture has four main goals: (1) to assure the provisioning of the population, (2) to preserve the natural resources on which life depends, (3) to maintain cultural landscapes and (4) to support a decentralized settlement of the country. In order to achieve these policy goals, the Federal Office for the Environment (FOEN) and the Federal Office for Agriculture (FOAG) specified a number of environmental policy goals for the agricultural sector. The policy goals are defined based on current legal requirements as

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[6] Such as the Convention on Biological Diversity, the Convention on the Conservation of European Wildlife and Natural Habitats and the International Treaty on Plant Genetic Resources for Food and Agriculture

[7] Similar legal texts exist in the European Union, e.g., the Council Directive 92/42/EEC of 21May 1992 on the conservation of natural habitats and of wild fauna and flora (European Commission 1992)

laid down in various acts, ordinances, international treaties and decisions of the Swiss Federal Council (Bafu/BLW, 2008). Based on these premises, agriculture has to contribute substantially to the conservation and promotion of biodiversity. Biodiversity is thereby classified into three main aspects: (1) species and habitat diversity, (2) genetic diversity within species and (3) functional biodiversity.

4.3.2.1 Species and habitat diversity

An important policy goal of Swiss agriculture is to preserve and promote native species that are typical for agricultural landscapes (i.e., species that mainly occur on agricultural land or depend on agricultural use). The environmental policy goals for agriculture give very precise indications on which species and habitat deserve protection within agricultural landscapes as two types of species groups are specified deserving special considerations: (1) target species are locally or regionally occurring species that should be preserved and promoted as they are threatened on a national level. In addition, Switzerland carries particular responsibility within Europe for the conservation of these species, while (2) character species are characteristic for a particular region and they are representative for a specific habitat (i.e., they serve as an indicator for quality of the habitat they occur in). The environmental policy goals for agriculture moreover provide detailed species lists for both target and character species that were elaborated by a working group involving multiple stakeholders from agriculture and nature conservation (Bafu/BLW, 2008). The lists cover a large number of taxa that deserve special consideration. The faunal taxa include mammals, birds, reptiles, amphibian, beetles, bees, butterflies, lacewings, dragonflies, grasshoppers and mollusca, while the floral taxa consist of flowering plants, ferns, mosses, lichens and fungi. The report further specifies a number of habitats that should be preserved and promoted as they are typical for agricultural land uses (e.g., ecological compensation areas, meadows and pastures, hedgerows, ruderal areas etc). Given that the character species listed are representative for a wide range of these habitats, the approach combines the conservation of species and habitat diversity.

4.3.2.2 Genetic diversity within species

Genetic diversity is a prerequisite for the long-term survival of wild species. The Swiss environmental policy goals for agriculture demand the preservation of genetic diversity of the species and habitats that are to be protected as set out above. In addition, the national action plan on the conservation and sustainable use of plant genetic resources for food and agriculture aims at preserving a broad genetic diversity of the crop plants present in Switzerland and their wild relatives in view of food production and security. Plant genetic resources are the starting point for any plant breeding program that aims at developing tailor-made varieties for future needs. Apart from economic benefits, plant genetic resources also have ecological value (e.g., by being adapted to local conditions such as being resistant to plant diseases) and cultural value (e.g., by representing traditional regional production).

4.3.2.3 Functional biodiversity

According to the Swiss environmental policy goals for agriculture, agricultural production has to preserve the ecosystem services provided by biodiversity. The part of the biosphere providing the desired ecosystem services is termed "functional biodiversity." Human society obtains a wide array of important benefits from biodiversity and associated ecosystems. These ecosystem services are essential to human well-being and to sustaining life on earth since these services operate on such a large scale, and in such complex ways, that most services could not be replaced by technology (Daily, 1999; CBD, 2000; Daily *et al.*, 2000). Functional biodiversity covers ecosystem services such as soil fertility, natural pest regulation and pollination by insects (see section 4.2.3). The economic value of 17 ecosystem services for the entire biosphere has been estimated to $33 trillion per year (Costanza *et al.*, 1997). The production of 84% of crop species cultivated in Europe, for example, directly depends on insect pollinators, especially bees (Gallai *et al.*, 2009), while predators and parasitoids fulfill relevant ecological functions by contributing to the natural regulation of arthropod pest populations within crop fields in agricultural landscapes. The total economic value of pollination worldwide is estimated to amount to €153 billion, which represented 9.5% of the value of the world agricultural production used for human food in 2005 (Gallai *et al.*, 2009). The value of natural pest control attributable to insects in the United States is estimated to be US $4.5 billion annually (Losey and Vaughan, 2006).

4.3.2.4 Programs to assess Swiss environmental policy goals for agriculture

To determine whether the current Swiss environmental policy goals for agriculture are met, there is a need for programs assessing the status of the different components of biodiversity. The status of implementation of these programs varies considerably among the different components of biodiversity. Several programs are running that assess the state of species and habitat diversity in Switzerland. Instruments assessing species and habitat diversity include among others the Red List species, the Biodiversity Monitoring Switzerland (BDM, 2009), and the Swiss Bird Index (Keller *et al.*, 2008). These instruments assess a number of different indicators and allow one to obtain a relatively good estimation of the state of species diversity and to a lesser extent of habitat diversity. Only a few activities have been started for genetic diversity. Genetic diversity is primarily collected and inventoried for arable crops, vegetables, fruit trees and for forage grasses as part of the national action plan on the conservation and sustainable use of plant genetic resources for food and agriculture. Although not yet collected, there are plans to inventory the genetic diversity of wild plants that are relatives of crop plants and for wild plants used for medicinal purposes or as ornamental plants (Häner and Schierscher, 2009). No information is currently available on the state of functional biodiversity as no programs for its assessment are implemented.

4.3.3 Specific protection goals related to genetic engineering

In Switzerland, the use of genetic engineering is regulated on the constitutional level (BV, SR 101). According to Article 120 BV, humans and their environment shall be protected against the misuse of genetic engineering. The rationale for this specific regulation is founded on the novelty of the technology and the uncertainties related to the consequences of the transformation process of genetically modified organisms (GMOs). The Swiss Federal Law relating to Nonhuman Gene Technology specifically prescribes the protection of humans, animals and the environment from abuses of genetic engineering (GTG, SR 814.91). In particular, the law mandates that GMOs intended for use in the environment may only be marketed if experiments in contained systems or field trials have shown that they: (a) do not impair the population of protected organisms or organisms that are important for the ecosystem in question; (b) do not lead to the unintended extinction of a species of organism; (c) do not cause severe or permanent impairment of nutrient flows; (d) do not cause severe or permanent impairment of any important functions of the ecosystem in question, in particular the fertility of the soil; and (e) do not disperse, or rather, their traits do not spread in an undesired way.

4.4 The ecological relevance of biodiversity

4.4.1 Species and habitat diversity

Species richness is often used as a surrogate for overall biodiversity even though the nature and identification of species continues to be controversial, though no one thinks that species richness is all there is to biodiversity (Maclaurin and Sterelny, 2008). Habitats with a high species richness are frequently regarded as being more valuable than habitats with a lower species richness. However, species richness is not always an appropriate indicator for the ecological value of habitats as the habitat type plays an important role in the evaluation. Generally spoken, species-poor habitats often contain common, widespread species, whereas species-rich habitats are more likely to contain rare and threatened species. Yet, some habitats such as moorland are characterized by being inherently species poor and by containing particularly adapted, rare species. Certain disturbances, such as increased nutrient inputs, might lead to a local increase in biodiversity in these habitats due to the invasion of less specialized and more widespread species that would not be able to survive in the originally nutrient-poor environment. As the invading species are generally more competitive, they usually replace the initial, rare species that can typically be found in this particular habitat type. From a nature conservation point of view, the increased biodiversity found in these typical habitats is not desired as the specialized, rare species represent a particularly valuable component of biodiversity (Duelli, 1994; Kägi *et al.*, 2002). Similarly, recent results of the Swiss Biodiversity Monitoring showed a slight increase in species richness in meadows when compared to the first assessment in 2001 (BDM, 2009). However, the analyses also showed that the increase was mainly due to the occurrence of widespread and generalist species already present in intensively managed, nutrient rich meadows. The net increase in species richness was thus not particularly valued as rare and specialist species characteristic for agricultural landscapes were missing.

Further examples show that increases in species richness are not always regarded as a positive development from a nature conservation point of view. Despite a global perception of declining biodiversity, managers are frequently presented with situations where biodiversity is increasing due to the arrival of invasive species (Thompson and Starzomski, 2007). Invasions by alien species are however regarded as being one of the major direct causes of biodiversity loss (among other factors such as land use change, pollution, unsustainable natural resources use and climate change) (Slingenberg *et al.*, 2009). Losses of native species may not result in net changes in biodiversity if exotic species move into an area and replace them. To the public and conservation managers, however, the loss of particular, valued native species is of concern, more so than the net change in biodiversity (Thompson and Starzomski, 2007).

4.4.2 Ecosystem functions and species diversity

Rationales for the protection of biodiversity are often based on the argument that species provide ecological goods and services that are essential for human welfare. Some consensus appears to be crystallizing on the overall significance of maintaining ecosystem integrity and function (Gaston, 1996). This puts more emphasis to ecological processes than is immediately evident from many definitions of biodiversity, for example, the one put forward by the CBD (CBD, 1992) that does not encompass functional diversity enabling most ecosystem services. The preservation of functional diversity also necessitates other conservation strategies than would be the case if primarily individual species would have to be preserved. One of the central questions in ecology is therefore how biodiversity relates to ecological functions. Several hypotheses have been formulated to describe the relationship between ecosystem functions and species diversity:

- Diversity-stability hypothesis (Macarthur, 1955; Elton, 1958): Early theories established the axiom that diverse ecological communities are the most stable. The rate of ecosystem processes is highest with the greatest number of species. As the number of species in the system increases, the ability to recover from disturbances is higher.
- Rivet hypothesis (Ehrlich and Ehrlich, 1981): The rivet hypothesis assumes that the loss of species has an increasingly critical effect on the function of an ecosystem. All species are equally important in maintaining the system's stability and every species has an equal and additive effect on function. While the effect of the loss of one species may be relatively small, the loss of several species can lead to the complete collapse of the functioning ecosystem.
- Redundancy hypothesis (Walker, 1992): This hypothesis predicts that not all species are of concern as some are redundant. A loss of species richness may be of little consequence to ecosystem functioning because functional groups comprise many different species. Losing most species may have little effect, but the loss of some species may result in a dramatic destabilization of the system.

- Idiosyncratic hypothesis (Lawton, 1994): This hypothesis suggests that there is no clear relationship between species number and ecosystem functions since the contribution of species to function is unpredictable as both the identity and order of species loss will affect function differentially. Ecosystem function changes when diversity changes, but the magnitude and direction of change are unpredictable as the roles of individual species are complex and varied.
- Insurance hypothesis (McNaughton, 1977; Naeem and Li, 1997): According to this hypothesis, biodiversity insures ecosystems against declines in their functioning. More diverse ecosystems are more likely to contain some species that can withstand perturbations and thus compensate for functional loss of other species being reduced or eliminated by the perturbation.

There is rather little scientific evidence from experimental studies supporting both the diversity-stability hypothesis and the rivet hypothesis. Evidence in support of a linear dependence of ecosystem function on diversity (i.e., that even rare species contribute to function) is practically nonexistent (Schwartz *et al.*, 2000). There is nevertheless convincing evidence that species-rich systems deliver ecosystem services more reliably than species-poor ones. Empirical data suggests that the ecological stability is generated more by a diversity of functional groups than by species richness, which supports the insurance hypothesis (Peterson *et al.*, 1998). Ecosystem services typically do not depend on the presence of specific species, especially not rare, narrowly distributed species (Maclaurin and Sterelny, 2008). At least among species within the same trophic level, rarer species are likely to have small effects. Species are thus not of equal importance to ecosystem services and species richness per se is not necessarily a key element of ecosystem functioning. Moreover, landscape complexity may compensate for biodiversity loss because of local management intensity. The diversity of arable weeds, for example, is higher in organic than in conventional fields, but only in simple landscapes, as landscape diversity enhances species diversity in conventional fields to a similar diversity level (Roschewitz *et al*., 2005). In contrast to what may be expected, introducing diverse habitats (and less intensive practices such as organic farming) has only a great effect in simple landscapes and will positively influence resilience (i.e., the capacity to maintain ecosystem services after disturbance), whereas complex landscapes are already characterized by a high biodiversity sustaining ecosystem services (Tscharntke *et al.*, 2005). Negative impacts of intensive farming such as herbicide applications only occur in simple landscapes where colonization of arable weeds from the surrounding is limited, whereas complex landscapes appear to mitigate local anthropogenic weed elimination.

Hence, ecosystem properties may be insensitive to species loss as (i) ecosystems may have multiple species carrying out similar functional roles, (ii) some species may contribute relatively little to ecosystem properties, or (iii) properties may be primarily controlled by abiotic environmental conditions (e.g., weather events) (Hooper *et al.*, 2005). The most dramatic changes in ecosystem services are likely to come from altered functional compositions of communities and from the loss (within the same trophic level) of locally abundant species rather than from the loss of already rare species (Diaz *et al.*, 2006). Interestingly, most conservation efforts concentrate on rare species. Rare species, however, may not interact strongly with other species in the ecosystem, nor be able to replace the effect of a dominant species. In conservation terms, it is more crucial to identify which species are likely to have disproportionate effect if they are lost. Especially in agroecosystems, species richness is often less important for ecosystem functions than the presence of a small subset of species (Shennan, 2008). High diversity of functional groups may allow reorganizations after disturbances due to a higher number of insurance species. Agricultural landscapes must be a mosaic of well connected early and late successional habitats to support a high biodiversity and thereby the capacity to recover from minor and major small- and large-scale disturbances (Tscharntke *et al.*, 2005). From an ecosystem service conservation perspective, it is thus more important to protect species which have no functional equivalent and to maintain diversity within functional groups than to focus on conserving particular individual species (Thompson and Starzomski, 2007).

4.4.3 Summary of the ecological relevance of biodiversity

In the following, we will argue that there are two main motivations for the conservation of biodiversity: (1) the protection of rare and threatened species and (2) the functioning of ecosystem services based on genetic and species diversity (ecological resilience). Genetic diversity (i.e., biodiversity within species) is thereby crucial to a species' ability to adapt to its environment. An important evaluation criterion for the conservation of rare and threatened species is the specific value given to a particular taxon or species. Although habitats having more biodiversity are generally valued higher,[8] the conclusion that more biodiversity is normally better is not always valid. Species richness is not always an appropriate indicator for the ecological value of habitats as the habitat type plays an important role in the evaluation. Some habitats such as moorland are characterized by being inherently species poor but by containing particularly adapted, rare species. Similarly, species richness is often less important for agroecosystem functions than the presence of a small subset of species (Shennan, 2008). High diversity of functional groups may nevertheless allow reorganizations after disturbances due to higher number of insurance species.

Rare and threatened species being characteristic for a specific habitat are still clearly valued higher than common and widespread species. Hence, the reduction of rare or characteristic species is usually evaluated negatively, whereas reductions of common species are normally tolerated. Yet, the loss of common species having no functional equivalent is the major concern for ecosystem service conservation. Rather than from the loss of already rare species, the most dramatic changes in ecosystem services are likely to come from altered functional compositions of communities and from the loss of locally abundant species (Diaz *et al.*, 2006). The difficulty for decision makers when deciding on the accurate conservation strategy is that biodiversity conservation and ecosystem services may necessitate different conservation measures. As Duelli and Obrist (2003) emphasize, each of the two aspects requires its own indicators which do normally not correlate with each other. While species conservation focuses on rare and threatened species, ecosystem services concentrate on ubiquitous species as a species on the verge of extinction is likely to have less significant ecological influence. Conservation efforts still tend to support the management of single, endangered species (or increasingly the preservation of specific habitats), while the preservation of ecosystem services is rarely an explicit management goal. To preserve the services that ecosystems provide to humans, management efforts should focus on preserving or restoring the biotic integrity of natural systems in terms of species composition, relative abundance, functional organization, and species numbers rather than on maximizing the number of species present or conserving particular individual species (see section 9.4).

[8] Generally, species poor habitats often contain common, widespread species whereas species-rich habitats are more likely to contain rare and threatened species.

CHAPTER 5

OPERATIONAL DEFINITION OF PROTECTION GOALS

5 OPERATIONAL DEFINITION OF PROTECTION GOALS

5.1 Difficulty to find an unambiguous definition of the term biodiversity

One of the goals of the present study is to obtain a practicable conception of biodiversity that can be used to describe the agricultural context prevalent in Switzerland. Scientifically, the term "biodiversity" can be differentiated into different components (genetic, species and habitat diversity) and into different attributes such as composition, structure and function (see section 4.2). Although the scientific classification provides a more precise definition of biodiversity, the refinement also substantially broadens the conception of biodiversity without facilitating its operational use in decision-making. Despite its multiple dimensions, biodiversity is usually equated with species richness only (Feld *et al.*, 2009). Not surprisingly, the functional, structural and genetic components of biodiversity are still poorly addressed. This may, to a certain extent, be due to scientific limitations of finding appropriate indicators for these components, but also reflects the fact that biodiversity assessment and monitoring until recently has been mainly driven by conservation biologist. This becomes apparent when looking at the programs implemented in Switzerland to assess biodiversity (see section 4.3.2). The biodiversity components most often measured today are species richness and habitat diversity, while genetic diversity is primarily covered by assessing the number of livestock breeds and crop varieties (BDM, 2009). Moreover, there are literally no routine monitoring programs that assess ecosystem services or ecosystem functions.

If even a refined concept of biodiversity (see Table 1) remains difficult to apply in practice, how can the concept then be made operational to support policy decisions? The variety of different definitions shows that biodiversity cannot be defined as a clearly measurable quantity, that is, it is impossible to provide an index allowing to rate ecosystems or collections of entities according to their degree of diversity (Norton, 2008). One has to recognize that it is probably similarly impossible to find an unambiguous scientific definition of the term biodiversity. The goal should thus be to find an approach that enables stakeholders agreeing upon the way forward. The definition must allow one to find a common language that allows communication about what deserves protection because it is specifically valued. As with other metaconcepts, such as, sustainability or ecosystem health, biodiversity achieves operative sense only when it is clearly defined and used as a means to inform specific management decisions in specific ecosystems using specific indicators (Failing and Gregory, 2003).

Focusing on the management context necessitates going beyond general definitions to set scale and context-specific management objectives. At this stage, managers (i.e., regulatory authorities) need to deal with the difficult question of what is desired. Ultimately, policy decisions on what is to be protected are based on the legal frameworks regulating the conservation of biodiversity (see section 4.3). Nevertheless, policy decisions are inevitably linked to practical and financial constraints, making it impossible to conserve all components of biodiversity in the same manner or in the way it would be desired. The protection of biodiversity, as laid down in the legislation, is a man-made concept reflecting social values. When thinking about an apparently scientific concept such as biodiversity, one is forced to conclude that the concept remains ambiguous until it is clear what society is caring about (Norton, 2008). One could thus argue that a policy-relevant definition has to be guided by both social and scientific criteria as what deserves protection is also defined by what people care about. Determining what truly deserves protection will thus inevitably be based on the motivations for biodiversity conservation, on the relevance that is given to biodiversity to serve these motivations (see section 4.2.3) and on the implicit values underlying the protection of biodiversity (see Box 2). Science and empirical evidence can thereby guide the discourse about policy goals and indicate what ecological theories tell us about the relevance of biodiversity (see section 4.4).

5.2 A matrix for an operational definition of biodiversity in agricultural landscapes

Protection goals, as laid down in the existing legal frameworks, are usually described too vaguely to be scientifically assessed and to support regulatory decisionmaking. In the following, a matrix for an operational definition of protection goals is proposed that consists of a three-step process specifying protection goals, assessment endpoints and measurement endpoints (Table 2). The first two steps allow a more explicit characterization of the protection goal "biodiversity in agricultural landscapes" by specifying a number of assessment endpoints that describe the entities deserving protection in more detail. In the third step, measurement endpoints are defined that represent a measurable ecological characteristic, which can be related to the assessment endpoint chosen. The matrix presented herein will not be able to deliver a definite answer to the challenge of defining fully operational protection goals. The matrix should rather be seen as a tool that supports an operational definition of biodiversity. A true operational definition of protection goals will need to be elaborated in a transparent process involving all relevant stakeholders (regulators, applicants and scientists) (see section 5.3). The matrix is furthermore not restricted to GM plants and may thus form the basis for any evaluation of environmental impacts on biodiversity in agricultural landscapes.

5.2.1 Definition of protection goals

The first step for the definition of protection goals aims at identifying the different areas of protection to be considered as laid down in existing legal frameworks. The area of protection has been divided into the two principal categories, that is, *"biodiversity conservation"* and *"ecosystem services"* (Table 2). *Biodiversity conservation* covers red list species and species of high conservation or cultural value from a range of different taxa including mammals, birds, amphibians, insects (such as butterflies) and plants. In addition to species diversity, biodiversity conservation also involves protected habitats and landscapes.

Protection in this category primarily focuses on habitats as the term "landscape" is often less clearly defined and habitats are the units usually listed in the legislation (European Commission, 1992; NHV, SR 451.1). The operational definition of these two categories will ultimately necessitate compiling detailed lists for each group of species and habitats to be explicitly protected.

The second area of protection relates to *ecosystem services* that are essential to human existence. Ecosystem services relevant in an agricultural context include pollination, pest regulation, decomposition of organic matter, soil nutrient cycling, soil structure and water regulation and purification.

5.2.2 Definition of assessment endpoints

The second step aims at performing an operational definition for the protection goals specified in step 1 (Table 2). Each protection goal is defined by one or more *assessment endpoints* (Raybould, 2006, 2007). An assessment endpoint is thereby defined as an *"explicit expression of the environmental value that is to be protected as set out by existing legal frameworks"* (Suter, 2000). Assessment endpoints are thus the valued attribute of an environmental entity deemed worth of protection. Broad assessment endpoints tend to be less valuable than more specific ones, but endpoints should not be too restrictive, either. It is important to note that an assessment endpoint is not an indicator (i.e., it is not an environmental measure generated by a monitoring program that intends to be indicative of some environmental conditions), but the thing itself to be protected. An operational definition of assessment endpoints necessitates defining the following criteria:

- An ecological entity being representative of the area of protection selected (e.g., predators and parasitoids representing pest regulation)
- An attribute to be protected, for example, "abundance" or "ecological function"
- A unit of protection (individuals, populations, communities, guilds[9])
- A quantifiable spatial scale of protection[10] (GM crop field, other arable land, nonagricultural habitats)
- A quantifiable temporal scale of protection (present cropping season, following cropping season, time of consent of the GM event[11])
- A definition of the type of effects that are regarded to be harmful (i.e., a relevant decrease in abundance or a relevant disturbance in ecological function)

Ideally, assessment endpoints should also satisfy the following criteria (adapted from (Suter, 2007):

- As assessment endpoints are the basis for decision-making, they should reflect *policy goals and societal values*
- Ecological entities selected should be *ecologically relevant*
- Ecological entities selected should be potentially highly *exposed and responsive* to exposure
- Assessment endpoints should be *operationally definable* (i.e., it should be clearly specified what must be measured or modeled)
- Assessment endpoints should have the *appropriate scale* to the site or action assessed
- *Good techniques* must be available to risk assessors (e.g., standard toxicity tests, monitoring methods) to assess assessment endpoints

[9] A guild defines a group of species that exploit the same class of environmental resources in a similar way.

[10] The proposed spatial scales allow a more unambiguous classification than a classification using field, field borders, landscapes as the two latter terms are often not clearly defined. Using biodiversity conservation of plants as an example, the proposed scales allow one to determine whether weeds are regarded a protection goal. Weeds are only regarded to be worth of protection in case the spatial scale of protection is extended to GM crop fields and other arable land. In case the spatial scale for valued plants is restricted to nonagricultural habitats, weeds are explicitly not regarded as a protection goal.

[11] According to Swiss and EU legislation, the approval of a GM variety is granted for 10 years.

Table 2: Matrix for an operational definition of the protection goal biodiversity for an environmental risk assessment of GM plants

❶ PROTECTION GOALS		❷ ASSESSMENT ENDPOINTS		
		CRITERIA FOR THE OPERATIONAL DEFINITION OF THE PROTECTION GOAL		
Area of protection		Ecological entity	Attribute	Unit of protection
Biodiversity conservation	Red List species Species of high conservation / cultural value	Mammals	Abundance	
		Birds		
		Amphibians		
		Valued insects (e.g., butterflies)		
		Valued plants		
	Protected habitats	Habitats listed in legislation		
Ecosystem services / functions	Pollination	Pollinating insects	Ecological function	
	Pest regulation	Predators and parasitoids		
	Decomposition of organic matter	Soil invertebrates, soil microorganisms		
	Soil nutrient cycling (N, P)	Soil microorganisms		
	Soil structure	Soil invertebrates		
	Water regulation and purification	Fish		
		Aquatic invertebrates		
		Algae		

Individuals
Populations
Communities
Guilds

				3 MEASUREMENT ENDPOINTS		
				CRITERIA FOR THE TYPE OF EFFECT TO BE MEASURED		
	Spatial scale of protection	Temporal scale of protection	Definition of harmful effect	Indicator	Parameters Early tiers	Parameters Higher tiers
			Relevant decrease in abundance	Selected species		
				Selected habitats		
			Relevant disturbance in ecological function	Direct or indirect indicator able to demonstrate failures in eco-system function		

GM crop fields
Other arable land
Nonagricultural habitats

Present cropping season
Following cropping season
Time of consent (e.g., 10 years)

Mortality
Reproduction
...

Abundance
Diversity
...

The process of precisely describing the different attributes of biodiversity is not completed with the definition of assessment endpoints as these are not able to provide the evidence base for policy decisions. The final task is the production of a plan to test the risk hypotheses. Testing involves the definition of measurement endpoints that define the indicator of change that will actually be recorded as part of the environmental risk assessment.

5.2.3 Definition of measurement endpoints

The last step aims at defining criteria for the types of effects to be measured. These measurement endpoints are a measurable ecological characteristic that can be related to the assessment endpoint chosen (Raybould, 2006; Storkey *et al.*, 2008). A measurement endpoint can thus be regarded as an indicator allowing for conclusions about changes in the assessment endpoint. Given that it is impossible to assess or to measure the state of a specific protection goal as a whole, specific surrogates or indicators being considered representative for the area of protection are to be selected (Reid *et al.*, 1993; Duelli and Obrist, 2003; Sanvido *et al.*, 2005). Selection of indicators can often only be performed on a case-by-case basis that considers both the risk hypothesis derived from the initial problem formulation pertinent to a specific GM crop and the tier best suited to test the risk hypothesis (Raybould, 2006; Romeis *et al.*, 2008a). The definition of measurement endpoints further requires defining parameters (i.e., measure of biological effects such as death, reproduction, and growth) that are able to show changes in the particular indicator species. These parameters can include measures of exposure as well as measures of effects and differ depending on the tier (i.e., laboratory, glasshouse or field) that is best suited to test the risk hypothesis. Parameters for lower tiers usually cover lethal (e.g., mortality) or sublethal effects (e.g., reduced reproduction) while higher tiers are rather characterized by parameters such as abundance and diversity.

The choice of measurement endpoints is also a factor of practical constraints related to the design of appropriate sampling protocols and the selection of available sampling methodologies. As this topic is exceeding the scope of this report, it will not be explored in full detail. It is nevertheless important to recognize that even the most plausible risk hypothesis that a GM crop might harm the environment may lead to uncertain conclusions if it is not tested rigorously (Raybould, 2007). To allow decision-making, tests must be conducted as such that the defined risk hypothesis is confirmed with the maximum possible accuracy and probability. This requires that the hypothesis is focusing on detecting ecologically relevant effects. Apart from proper experimental design and statistical planning (Fairweather, 1991; Perry *et al.*, 2003; EFSA, 2009a), the rigorous testing of a hypothesis needs to answer the question regarding under what conditions the existence of a supposed risk is most likely revealed. For example, only if a particular stressor (e.g., the Bt-toxin) causes a relatively strong effect under field conditions, it will not be blurred by a number of influencing factors which will cause different, overlapping smaller effects. Given that the influence of the various factors is hardly distinguishable, it could become very difficult to unambiguously determine the causality between a particular effect and the factor causing it. The likelihood to detect a relevant effect in an environmental multifactorial setting (as typical for environmental monitoring programs) might thus be much lower than detecting one in a more controlled setting with only a few factors involved. Hence, testing a risk hypothesis in a more controlled setting such as a laboratory or greenhouse might generally be more rigorous than testing the hypothesis under more ecological conditions (Raybould, 2007; Romeis *et al.*, 2008a).

5.3 Application of the matrix for an operational definition of protection goals

5.3.1 Approaching an operational definition of the protection goal biodiversity

Operational protection goals are a prerequisite for regulatory decision-making as they specify what deserves protection. Assessment endpoints thereby specify the ecological entities and their related attributes to be specifically protected while measurement endpoints enable to select those indicators that are to be used to determine with the maximum possible rigor the likelihood that harm might occur (or has occurred) to the protection goals chosen. While the definition of protection goals is essentially a generic process applicable to agriculture management at large, the more precise definition of both assessment and measurement endpoints has to be carried out on a case-by-case basis for each specific GM crop. A thorough problem formulation is thereby an essential prerequisite for the operational definition of these endpoints where the nature of the crop introduced, the genetically modified trait and the receiving environment are considered (Romeis *et al.*, 2008a; Wolt *et al.*, 2010).

Given that protection goals are set by existing legal frameworks, the initial proposal what to protect has to be framed by the regulatory authorities involved in the risk analysis of GM crops. There is general consensus that biodiversity protection goals, as specified by existing legislation (such as Red List species, protected habitats, etc.) (see section 4.3), are to be protected. There is, however, controversy surrounding the necessity of the protection of "common" species that are not explicitly listed in the legislation, but that fulfill important ecosystem services and may be reduced by common agricultural practices. The operational definition of protection goals should therefore ideally be defined in a transparent process involving a dialogue between all relevant stakeholders (regulators, applicants and scientists). The matrix presented herein (Table 2) can thereby be used as a tool to structure the dialogue, especially when defining both assessment and measurement endpoints. The process could include stakeholder meetings where stakeholders would compile and rank different conservation goals and ecosystem services.

Agreeing on endpoints (and thus policy targets) for biodiversity conservation and ecosystem services is likely to be a difficult task for at least two reasons. First, the complexity of the underlying system means that endpoints are difficult to define in a way that is both operational for public policy and possible to communicate to policy-makers and the public. Reducing these difficulties by using vague terms such as "ecological integrity" will not solve the problem. Second, the problems are exacerbated by the fact that endpoints for biodiversity conservation and ecosystem functioning will sometimes contradict each other. Setting ecologically-based endpoints may require balancing competing goals (e.g., the protection of rare species vs. the preservation of common species) that are guaranteed to be a source of controversy both for scientists and the public. The content of the matrix will to a great extent depend on the motivations (see section 4.2.3) and on the value systems underlying the preservation of biodiversity (see Box 2) of the various stakeholders involved in the operational definition of protection goals. Stakeholders will inevitably have competing motivations and values. Failures to disclose differing motivations and value systems will have important policy implications as the operational definition of protection goal necessitates to agree on common policy goals. The operational definition of protection goals will therefore inevitably also include a number of challenges. Some of these challenges for a number of ecological entities are discussed in the next section. To address these challenges, the motivations and the values underlying the protection of biodiversity need to be explicitly stated and assessment and measurement endpoints need to be adapted to these motivations and values. The Ethical Reference System presented in section 9.2 can thereby be a tool supporting such an exercise.

Nevertheless, it is important to consider that stakeholder approaches have limitations when it comes to decision making. Setting priorities and making informed decisions requires both scientific and value judgments (Failing and Gregory, 2003). These are distinct judgments to be made by different individuals. Nonscientific stakeholders should be asked to make only value judgments in consultative processes, but not scientific judgments for which they are not qualified and informed. Evaluating the relevance of the data is a task that necessitates expert knowledge (see section 9.1). This is thus the task of scientists and not of the public as the latter lacks the necessary knowledge. It is crucial to recognize that decision-making requires that one considers sound science and not democratic consideration of different viewpoints and interests of stakeholders. This is because decision-making is an executive force and not a legislative force. Democratic considerations have been considered during the drafting of the legislation, but once in place, the legislation has to be carried out by the regulatory authorities considering sound scientific principles.

Box 2: Different value systems underlying the preservation of biodiversity

The necessity to preserve biodiversity may, to a certain extent, be based on a scientific rationale (Chapin *et al.*, 2000; McCann, 2000; Tilman, 2000; Diaz *et al.*, 2006), but the question “why?” remains ultimately a normative one that has to be answered based on the prevalent societal and ethical value systems. The process of finding an operational definition of biodiversity will inevitably necessitate decision-makers to make a trade-off as the different value systems often contradict each other. These contradictions become apparent if one compares three possible value systems that may have an influence on the motivation to preserve biodiversity: (1) intrinsic value, (2) demand value and (3) option value.

Intrinsic value

The idea that biodiversity is intrinsically valuable enjoys wide support as it reflects that we care for nature not as a resource, but rather as a good in itself (Maclaurin and Sterelny, 2008). The preamble to the CBD, for example, gives an intrinsic value to biological diversity and the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components (CBD, 1992).

Demand value
One of the simplest motivations to preserve biodiversity derives from broadly utilitarian theories of environmental ethics (see section 9.3.1), that is, from the idea that the moral worth of an action is determined solely by its contribution to overall utility (e.g., to the maximization of happiness or pleasure as summed among all persons). The value of an ecosystem and its components thereby equates with the resources and services they provide to humans – they have a demand value that warrants the investment required for their conservation (Maclaurin and Sterelny, 2008). Such an approach would lead the society to place a high value on protecting the basic ecological mechanisms on which humans depend. A demand value approach does furthermore not tie value to diversity per se as importance is more tied to specific uses. This may include the importance as a resource, a crucial ecological function or a rather obscure attribute as being loved by the general public. Following a rather strict utilitarian theory, the demand value approach faces some challenges as the theory can hardly aggregate individual cost benefit trade-offs into a collective assessment – benefits to some always impose costs on others.

Option value
Option value, being the third utilitarian theory, links utility much more closely to diversity. Option value is an insurance concept borrowed from economics that is based on two basic ideas. First, species (or ecosystems) that are not of value to us at present may become valuable at some point in the future. Second, as our knowledge improves (and as circumstances change) we might discover new ways in which they can be valuable (Maclaurin and Sterelny, 2008). The crucial point about option value is making diversity valuable. The approach suggests preserving a biodiversity as rich and representative as possible as it is not known in advance which species will prove to be important. This is probably also one of its most obvious limitations as the approach, understood in its most broad interpretation, would demand that everything has to be preserved just in virtue of being useful in some conceivable future event. This would result in the ineffective goal of preserving biodiversity in all possible respects. One solution would be to focus not on mere possibilities, but on probabilities that a certain feature could prove to be valuable under some circumstances (Maclaurin and Sterelny, 2008). Species loss may not be important in terms of the role of the species now, but rather in terms of that species being available to fulfill a functional role in a future environment (Thompson and Starzomski, 2007). Clearly, the option value approach also suggests that many species do not have high enough option value to justify major expenditures on their conservation. The approach recognizes that many species are of great value, but it does not imply that all species or all biological systems, are of important value and should to be saved.

5.3.2 Examples for some selected protection goals

In the following, the proposed matrix for an operational definition of biodiversity (see section 5.2) is completed for some selected protection goals to illustrate how such a definition could be performed. The operational definition thereby consists of specifying the area of protection and of defining assessment and measurement endpoints (Table 3). Here, the protection goals are differentiated into the two main areas of protection, that is, biodiversity conservation and ecosystem services.

5.3.2.1 Definition of assessment endpoints for biodiversity conservation

The first step in the definition of assessment endpoints aims at identifying the different areas of protection as laid down in existing legal frameworks. For biodiversity conservation, the area of protection includes Red List species and species of high conservation and cultural value. In the present example, the ecological entities to be protected are restricted to valued plants and valued insects (in particular, butterflies being a species group with a high conservation value where more than 50% of the species occurring in Switzerland are Red List species).

Red List species are defined for both plants and insects (Duelli, 1994; Gonseth, 1994; Moser *et al.*, 2002). Similarly, species of high conservation value and cultural value are specified in the environmental policy goals for agriculture specifying target species[12] and character species[13] (Bafu/BLW, 2008) (see section 4.3.2). The unit of protection for biodiversity conservation of all of these species is usually specified on the basis of populations or communities and the attribute to be protected is the abundance of the respective populations and communities.

The first difficulty when defining assessment endpoint for biodiversity conservation is the definition of the spatial scale of protection. Logically, the spatial scale of protection for valued plants and valued insects (such as butterflies) should be set to nonagricultural habitats as agricultural fields cannot be regarded as typical habitats for Red List species and species of high conservation and cultural value. Typically, the primary aim of agricultural fields is the production of food and feed and not the production of biodiversity. Yet, the promotion or conservation of biodiversity in agricultural fields is a complex topic that is hotly debated in Europe. It is argued that in many European countries, agriculture and natural habitats are intimately mixed with around 70% of the land area being classified as agricultural land (Hails, 2002). Consequently, the conservation of "common" species

[12] Target species are locally or regionally occurring species that should be preserved and promoted as they are threatened on a national level.

[13] Character species are characteristic for a particular region and they are representative for a specific habitat.

and communities within the farmed landscape is seen as an emerging paradigm (Marshall *et al.*, 2003). Hence, there is controversy about the question whether certain common species (although not being explicitly listed in the legislation) should be regarded as a protection goal since effects on these species might translate to higher trophic levels. These higher trophic levels 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 are agricultural weeds that on the one hand have the potential to reduce agricultural yield, but that do also form an essential part of food webs in agricultural landscapes contributing to farmland biodiversity (Watkinson *et al.*, 2000; Heard *et al.*, 2005). The question is thus what characterizes a "valued" plant species. Though there is a need to promote biodiversity not only in nonagricultural habitats, we believe that classifying certain common species (such as weeds) as a generic protection goal might lead to a number of conflicts. Rather, a balance between adequate weed control and the opportunity to retain some plants to support biological diversity should be searched (see section 8.2.2).

A second difficulty is linked to the definition of the temporal scale of protection. On the one hand, many legal frameworks such as the Swiss Gene Technology Act require that the protection of biodiversity and its sustainable use is permanent (GTG, SR 814.91). It is moreover known that long time periods may be needed before ecological effects become apparent. In the UK, it took several decades before marked reductions in farmland biodiversity were noticed (Fuller *et al.*, 1995; Robinson and Sutherland, 2002). On the other hand, regulatory decisions have often to be taken within shorter timeframes than decades, which makes it necessary to find a compromise for a measurable temporal scale. We propose to define the temporal scale according to the time of consent that is granted for GM events, which is currently 10 years (European Community, 2001; GTG, SR 814.91). After the 10-year period, regulatory authorities can decide whether impairment in a particular protection goal has occurred and they can use this information when deciding on the renewal of consent.

5.3.2.2 Definition of measurement endpoints for biodiversity conservation

The first step when defining measurement endpoints for biodiversity conservation consist in selecting appropriate indicator species. The term indicator is used here according to Duelli and Obrist (2003), who defined that "an indicator should be a measurable portion of an entity that correlates with this larger entity." On the one hand, biodiversity indicators can be defined on a more general basis to be indicative for a larger entity such as "biodiversity in agricultural landscapes." For such biodiversity assessments, several indicators such as flowering plants, birds, and butterflies are usually combined to assure the quality of the data obtained (Jeanneret *et al.*, 2003; BDM, 2009). On the other hand, indicator species can also be specifically selected to test a particular risk hypothesis. If, for example, a GM crop expresses a toxin with a specific toxicity against a particular group of organisms (such as Cry1Ab against Lepidoptera), the risk hypothesis should focus on testing nontarget lepidopteran species as an effect is most probably occurring in this species group (Romeis *et al.*, 2008a).

A critical aspect when defining operational protection goals for biodiversity conservation is linked to the difficulty to define measurable endpoints for Red List species. Red List species can often not be chosen as the primary indicator as they can either not be tested under laboratory conditions due to their conservation status or they occur too rarely in agricultural landscapes to be easily monitored and to allow for proper statistical analyses (Aviron *et al.*, 2009). Laboratory toxicity studies and monitoring programs therefore need to rely on surrogate species that are intended to be representative for a specific group of Red List species. Although the utility of the concept of surrogate species is a constantly debated issue[14] both in conservation biology (Caro and O'Doherty, 1999) and ecotoxicological testing (Cairns, 1983), the surrogate approach is still the standard practice mandated for environmental risk assessment of pesticides and GMOs in most countries. Hence, the choice of surrogate species is most likely inevitable as it is impractical to assess biodiversity as a whole.

The last step in the definition of measurement endpoints for biodiversity conservation consists of the choice of appropriate parameters for early and higher tier studies. The term parameter is hereby used as being subsidiary to the term indicator since effects on a given indicator are often assessed by the measurement of several parameters that are able to show changes in the indicator chosen (Sanvido *et al.*, 2005) (see section 5.2.3). "Mortality," "development time" or "reproduction" could, for example, be possible parameters for early tier studies, while parameters for higher tier studies could be "abundance" or "diversity."

[14] The critiques of this approach center on the question as to which species is best suited to represent a specific group of species.

Table 3: Examples how to use the matrix for an operational definition of protection goals (biodiversity) for some selected protection goals

1 PROTECTION GOALS		2 ASSESSMENT ENDPOINTS		
		CRITERIA FOR THE OPERATIONAL DEFINITION OF THE PROTECTION GOAL		
Area of protection		Ecological entity	Attribute	Unit of protection
Biodiversity conservation	Red List species Species of high conservation / cultural value	Valued insects (e.g., butterflies)	Abundance	Population
		Valued plants		Population
Ecosystem services / functions	Pollination	Pollinating insects	Ecological function	Guild
	Pest regulation	Predators and parasitoids		Guild
	Decomposition of organic matter	Soil invertebrates, soil microorganisms		Guild

			❸ **MEASUREMENT ENDPOINTS**		
			CRITERIA FOR THE TYPE OF EFFECT TO BE MEASURED		
Spatial scale of protection	Temporal scale of protection	Definition of harmful effect	Indicator	Parameters Early tiers	Parameters Higher tiers
Nonagricultural habitats	10 years	Relevant decrease in abundance	Selected species	Mortality, Development time (larvae)	Abundance, Diversity
Nonagricultural habitats	10 years		Selected species	not applicable	Abundance, Diversity
Arable land, Nonagricultural habitats	10 years	Relevant disturbance in pollination of crops	Honey bee	Mortality, Development time (larvae)	Abundance, population growth
Arable land	10 years	Relevant disturbance in pest regulation of crops	Selected species, unusual pest outbreaks	Mortality, Reproduction	Abundance
Arable land	10 years	Relevant disturbance in decomposition of organic matter	Selected species, decomposition rate of organic matter	Mortality, Reproduction	Abundance

GM crop fields
Other arable land
Nonagricultural habitats

Present cropping season
Following cropping season
Time of consent (e.g., 10 years)

Mortality
Reproduction
...

Abundance
Diversity
...

5.3.2.3 Definition of assessment endpoints for ecosystem services

In the following, the example for the definition of assessment endpoints for ecosystem services will focus on pollination, pest regulation and the decomposition of organic matter. The relevant ecological entities are pollinating insects, predators and parasitoids as well as soil invertebrates and microorganisms. The attribute to be protected is the respective ecological function. The appropriate unit of protection for all three ecosystem services is the guild, that is, a group of species that exploit the same class of environmental resources in a similar way.

Differences exist regarding the appropriate spatial scale of protection. The ecosystem service "pollination" should in principle be protected across the whole landscape, that is, in GM crop fields, on other arable land and in nonagricultural habitats. Natural pest regulation and the decomposition of organic matter, in contrast, are two ecosystem services that are more relevant on agricultural land than in nonagricultural habitats (i.e., on GM crop fields and on other arable land). Like for biodiversity conservation, the temporal scale of protection is set to 10 years, that is, the time of consent for GM events. Harmful effects are defined as relevant disturbances in the respective ecological function.

5.3.2.4 Definition of measurement endpoints for ecosystem services

The first step when defining measurement endpoints consists of the selection of appropriate indicators that are indicative for the respective ecosystem service. Key species or guilds that are representative of different functional groups are known in most systems and appropriate indicator species can be selected (Romeis *et al.*, 2008a). These indicator species should be representatives of ecologically and economically important arthropod taxa in the crop. A common indicator for pollinating insects, for example, is the honey bee, which has been a key test species in ecotoxicological testing for a long time (Malone and Pham-Delegue, 2001; Romeis *et al.*, 2008a). Species selection for pest regulation and decomposition of organic matter, in contrast, is a relatively new topic that has only recentl y received major attention. Species that could be selected as appropriate indicator for the discussed ecosystem services are to be determined.

In addition to performing direct measurement of specific indicator organism groups or species, it may be appropriate to additionally select an indirect indicator able to demonstrate failures in the respective ecosystem service. Failures in biological control functions, for example, could be surveyed indirectly by recording unusual pest outbreaks (Sanvido *et al.*, 2009). Soil invertebrates and soil microorganisms could be surveyed by assessing decomposition of organic matter (Knacker *et al.*, 2003; Zurbrügg *et al.*, 2010) or parameters such as soil respiration and microbial biomass (Römbke, 2006; Ferreira *et al.*, 2010).

Parameter selection for early tier studies should consider the known mode of action of an insecticidal protein against the sensitive targets. In the case of Cry1Ab proteins, for example, sensitive Lepidoptera larvae are killed relatively quickly after ingestion of the protein. Consequently, one would select "mortality" as the appropriate parameter. In the case of an insecticidal protein that is known to reduce the fecundity, but that is also known to have no lethal effect, the parameter "reproduction" would be a more appropriate endpoint than "mortality."

CHAPTER 6

THE USE OF “THRESHOLDS” TO EVALUATE RISKS AND CHANCES

6 THE USE OF "THRESHOLDS" TO EVALUATE RISKS AND CHANCES

The idea that risks are acceptable as long as they do not exceed a certain predefined threshold is a concept that is often emerging in discussions related to decision-making in risk assessments. The use of thresholds is thereby often linked to the issue of balancing risks and benefits or more precisely risks and chances.[15] When discussing the application of thresholds and the issue of balancing risks with chances, it is important to consider that both concepts have their foundation in specific ethical theories (i.e., either deontology or utilitarianism). Depending on the ethical theory that is underlying the relevant legal frameworks, there may be differences how these concepts may be applied in a decision-making process. The term "threshold" is furthermore often used in different connotations in ethics and ecology. In the following, the implications of these differences for regulatory decision-making are shortly described.

6.1 Thresholds in ethics

What are the ethical criteria for acceptable risks? One option that underlies many legal frameworks is that the risks individuals or populations are exposed to (without their consent) are acceptable as long as they do not exceed a certain predefined threshold. Another option is that risks are acceptable (or even obligatory) if they are necessary for realizing the greatest expected net benefit. The first criterion is advocated by deontological theories, the second by utilitarian theories. It is important to note that, contrary to a widespread belief, the deontological and the utilitarian criterion of risk acceptability cannot be combined since they are mutually exclusive.

6.1.1 Deontological approach

According to deontological approaches (see section 9.3.2), decisions are based on an absolute normative threshold defining a limit that no risk may exceed (Figure 1). The main idea underlying the deontological criterion is that there is a duty of care according to which risks should be reduced to a point where the occurrence of harm is not to be expected. Requiring zero risk, however, cannot be justified since this would make social life impossible. That is why a normative threshold is introduced. Risks exceeding this threshold are prohibited, irrespective of the chances associated with them, while risks below the threshold are acceptable. All options where the risk remains below the specified threshold (B & C)

[15] Despite the frequent use of the term "benefit" as the opposite of the term "risk," the term "chance" would be the correct antonym to risk. The correct antonym to "benefit" is "damage" as both terms describe a factual statement whereas both the terms "risk" and "chance" incorporate a probability component, namely, the probability that a damage (from a risk) or that a benefit (from a chance) might occur, respectively.

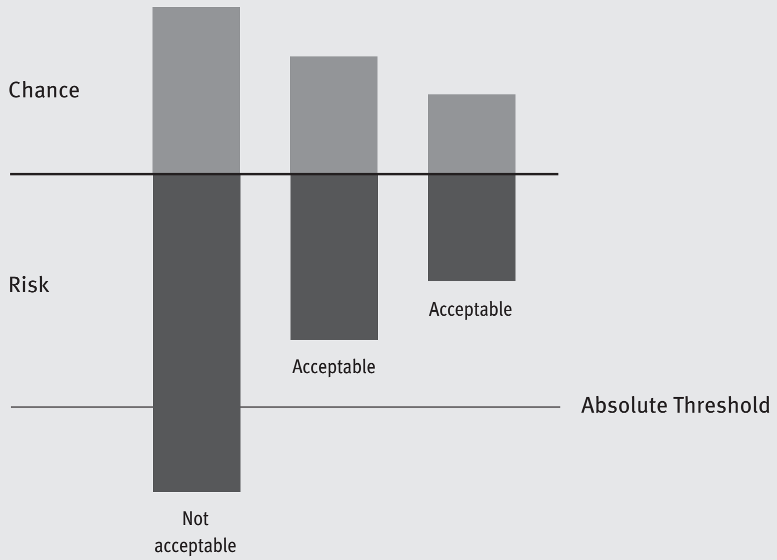


Figure 1: Graphical scheme illustrating the deontological approach to the threshold conception. Balancing the risks and chances of the two acceptable options, B and C, is permitted. Although the chance of option A exceeds the ones of options B and C, option A is not acceptable as the risk exceeds the absolute threshold.

are acceptable. If the risk of an option exceeds the defined threshold, it has to be reduced by appropriate risk management options to possibly remain below the threshold. Within the acceptable options (i.e., those options where the risk remains below the given threshold), the one bearing the lowest risk or impact may be preferred. There is, however, no obligation to choose the option bearing the lowest risk. Among the acceptable options, balancing risks and chances is thus permitted (i.e., balancing the chances of options B and C with their respective risks).

6.1.2 Utilitarian approach

According to the utilitarian approach (see section 9.3.1), decisions ought to be based on the highest expected benefit (Figure 2). The main idea underlying the utilitarian criterion is that there is only one moral duty: the duty to maximize expected net benefit. If this goal can only be reached by exposing other individuals or populations to certain risks, this must be done, even if these risks are very high. For each option, the total chance is compared to the total risk. There is an obligation to choose the option with the highest expected benefit (total chance minus total risk). When following a utilitarian approach, there is no normative threshold.

Utilitarianism needs a theory of intrinsic values to be able to determine risks and chances and to weigh them up against each other. Chances refer to the probability of intrinsic value (benefit) occurring, risks to the probability of intrinsic disvalue (damage) occurring. Weighing risks and chances and summing them up, however, presupposes a common scale, a common currency, as it were, that allows adding and subtracting them. However, what does this currency consist of? There have been several attempts of solving this problem (for instance, by using a monetary currency as in willingness to pay or willingness to compensate), but all of them have shown to be problematic.

A further problem affecting the determination of risks or damage is how conflicting protection goals should be weighed. Of course, the law can settle this problem by fiat. However, if policy makers want to preserve legal coherence, they should try to determine the relative value of different protection goals by deriving this value from higher-order protection goals. Take, for instance, the protection goals biodiversity and water. If there is a conflict between these two protection goals, we need to know which of them has greater relative value with regard to a higher-order protection goal such as the maintenance of ecosystem stability. In many cases, the law does not sufficiently specify the relation between higher-order protection goals and subordinate protection goals. This problem does not seem unsolvable, however. What would be needed in our example is a determination of the instrumental, that is, functional value of water and biodiversity with regard to ecosystem stability in a way that makes it clear which of the two protection goals should be assigned priority. This determination should be specific enough to be applicable in concrete situations where regulators must choose between these conflicting protection goals.

6.2 Thresholds in ecology

An ecological threshold can be described as a point or a zone where there is a relatively rapid change from one ecological condition to another (Huggett, 2005; Luck, 2005). According to this theory, at a threshold, even small changes in environmental conditions will lead to large responses in ecosystem state variables

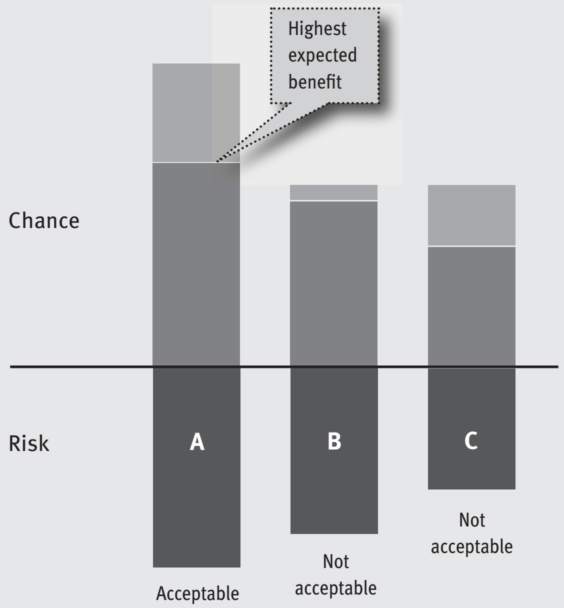


Figure 2: Graphical scheme illustrating the utilitarian approach to balancing risks and chances

(Groffman *et al.*, 2006; Suding and Hobbs, 2009). One idea underlying the threshold concept is its practical use for management decisions as exceeding specific ecological thresholds would indicate that an ecosystem is moving away from a desired state.[16]

The term threshold is closely linked to the concept of resilience, which is often defined as the capacity of ecological systems to recover from disturbances (Walker, 1995). Resilience is thereby equated to the time needed for a system to return to a global equilibrium state following a perturbation. In the ecological literature, it is thus associated with the concept of ecological stability. [17] Accordingly, some authors postulate a threshold of biodiversity below which ecosystems lose the self-organization that enables them to provide ecological services (Perrings and Opschoor, 1994). Ecosystems would thereby become increasingly

[16] The question as to what defines a desired state includes a subjective value judgement, a question which can not be answered from a purely scientific and objective perspective.

[17] The term “ecological stability” is one of the most nebulous terms in ecology as up to 163 different definitions of the term have been counted (Grimm and Wissel 1997, Muradian 2001).

unstable as diversity decreases. As threshold patterns follow a discontinuous, nonlinear behavior, ecosystems would not be robust enough to resist species deletion and lose their capacity to absorb perturbations once species diversity falls below the stability threshold. This would require that ecosystems have a "saturation point," that is, ecosystem services would not increase above a certain diversity level even when biodiversity is increased. Such a pattern is quite similar to the rivet hypothesis (Ehrlich and Ehrlich, 1981), which suggests that ecosystems can initially afford continual removal of its component without experiencing a loss of function, while at a certain point only one additional species extinction leads to a loss of the function (see section 4.4).

In a second definition of resilience, the existence of multiple "stable" states in ecosystems is emphasized.[18] Resilience is thereby defined as the ability of a system to withstand changes and to maintain its structure and patterns before flipping to another stable state (Holling, 1973; Peterson *et al.*, 1998; Gunderson, 2000). One key distinction between the two definitions of resilience lies in the assumptions regarding the existence of multiple stable states. The first definition, where resilience is essentially defined as the return time to equilibrium, assumes that there exists only one stable state. The second one, in contrast, presumes the existence of multiple stable states and the tolerance of the system to perturbations that facilitate transitions among them (Gunderson, 2000). The existence of multiple stable states and transitions between these states have been described in a range of ecological systems, such as for example the transition from grassland or abandoned arable land to shrubland and subsequently to woodland (Harmer *et al.*, 2001; Kuiters and Slim, 2003). Both ecological theories and empirical evidence clearly show that alternative stable states can coexist side-by-side (Scheffer and Carpenter, 2003). Landscapes often comprise a mosaic of patches with different alternative stable vegetation types that remain unaltered for decades until an extreme event triggers a shift in the pattern

In theory, ecological thresholds must not be restricted to species extinction leading to the collapse of ecosystem functions, but thresholds can also be related to habitat loss. This other theoretical pattern predicting ecological thresholds is linked to habitat fragmentation and metapopulation models (Hanski, 1998). Species loss may also occur due to habitat loss and fragmentation, in particular due to the loss of habitat connectivity. Connectivity loss thereby disables the dispersal and exchange of individuals between metapopulations occurring in

[18] Ecosystems are obviously never stable in the sense that they do not change. There are always constant fluctuations of natural populations due to seasonality and environmental conditions (Scheffer and Carpenter 2003).

different habitat patches. As the loss of habitat connectivity is a highly nonlinear process, theory predicts that species loss occurs after the degree of connectivity has fallen below a certain critical threshold. The same may be true for ecosystem services such as biological control functions of natural enemies where habitat fragments support a less diverse community of natural enemies resulting in lower predation or parasitation rates on pest populations (Kruess and Tscharntke, 1994; With *et al.*, 2002).

6.3 Using thresholds in regulatory decision-making

What are the conclusions for regulatory decision-making when considering the above mentioned ethical and ecological considerations for the use of thresholds and in particular regarding the question under what circumstances one is allowed to balance risks and chances? The ethical considerations are insofar relevant as many legal frameworks such as the Swiss Gene Technology Law are mostly based on deontological considerations. Different options are thereby acceptable as long as their associated risks do not exceed a certain predefined threshold. The ethical considerations are also important when answering the question when to balance risks and chances. Again, the deontological approach underlying many legal frameworks determines that balancing risks and chances between different options is permitted for those options where the risks of each option remains below the given threshold. Balancing risks and chances is thus not per se prohibited.

Using a threshold to define damage would be an elegant approach as it would allow more or less unambiguous decisions what represents unacceptable harm. In principle, every indicator value that would exceed the threshold would be damage. Unfortunately, thresholds are difficult to apply in practice as the legal frameworks regulating the use of genetic engineering in Switzerland do not define such thresholds. Without such thresholds, a coherent application of the law is, in principle, impossible as regulatory authorities have no clearly quantified indications that allow them to ensure the protection of human health and the environment. Similarly, applicants (i.e., usually the companies that intend to market a GMO) face regulatory uncertainty as they are not able to predict the overall costs and the time necessary for product approval. This is in contrast to, for example, the regulation of plant protection products which provides standard criteria for the evaluation and approval of these products in Annex 6 of the respective ordinance (PSMV, SR 916.161). If such thresholds are missing, it is clearly the responsibility of the regulatory authorities to provide applicants with such thresholds as the authorities are responsible for the execution of the law.

Based on these theoretical considerations, the difficult question to answer from an ecological point of view is how to define such thresholds. We argue that ecological thresholds for regulatory decision-making of GM crops are difficult to apply in practice. One of the major factors inhibiting the use of ecological thresholds in environmental management is the lack of general principles for applying these concepts to different kinds of response variables and ecosystems (Groffman *et al.*, 2006). In nature, populations usually fluctuate around some trend or stable average and ecosystems are assumed to respond smoothly to gradual change in external conditions. Occasionally, however, such a scenario is interrupted by an abrupt shift to a dramatically different regime. Dramatic regime shifts are known for a range of ecosystems including lakes, coral reefs, oceans, forests and arid land (Scheffer *et al.*, 2001; Scheffer and Carpenter, 2003). While both theoretical hypotheses and practical examples support the existence of discontinuities in ecological processes, it is very difficult to support such patterns with empirical data as most experimental studies are not able to show a clearly discontinuous relationship between stability and diversity (Muradian, 2001). Most studies face the difficulty to clearly define the characteristics of different alternative stable states, mainly as these are highly dependent on the chosen temporal and spatial scales. Hence, each stressor and ecosystem response must be evaluated independently, a process that is usually not appropriate for regulatory decision-making as it requires years of site-specific research. Ecological sciences are currently more able to predict the magnitude of change (i.e., the possible alternative state) than the precise threshold value (Muradian, 2001). With growing ecological experiences, thresholds for certain ecological groups may become available. Nevertheless, one has to recognize that for most ecological indicators, fully operational thresholds will probably rarely be available. This inevitably challenges policy-makers as they cannot precisely rely on defined ecological thresholds that would facilitate decision-making processes. If thresholds are missing, damage should be defined by using a baseline approach (see sections 7 and 8). In principle, the baseline approach should allow one to determine when a change has to be regarded a damage as the definition of damage is not depending on a precise threshold, but on the comparison of two different states. The first state (i.e., the status quo) is thereby indicating how things usually are. Damage occurs if the difference between the status quo and the second state is judged to be too sufficiently large to be adverse.

CHAPTER 7

A FIRST BASELINE APPROACH – DIFFERENTIATING EFFECTS OF DIFFERENT PEST MANAGEMENT PRACTICES IN MAIZE

7 A FIRST BASELINE APPROACH – DIFFERENTIATING EFFECTS OF DIFFERENT PEST MANAGEMENT PRACTICES IN MAIZE

7.1 The challenge of selecting an appropriate baseline

The discussions during the first expert workshop showed that baselines were recognized as being a crucial point of any decision-making process as they serve as a reference to determine what makes a change a damage. Moreover, the baseline approach seems to be the only practicable way of evaluating damage as the threshold approach appears to have serious limitations that impede its practical use in regulatory decision-making (see section 6.3).

Most people consider having an intuitive notion of the term "baseline." However, looking at existing definitions in different texts, it becomes apparent that these definitions are anything but uniform. As a basic definition, a baseline can be defined as *"an initial set of critical observations or data used for comparison or a control"* (Merriam-Webster Online, 2011). The EU Directive 2004/35/EC on environmental liability defines the term as *"a reference to assess the significance of any damage that has adverse effects on reaching or maintaining the favorable conservation status of protected habitats or species. The significance has to be assessed by reference to the conservation status at the time of the damage, the services provided by the amenities they produce and their capacity for natural regeneration. Significant adverse changes to the baseline condition should be determined by means of measurable data"* (European Commission, 2004). More specifically, referring to the assessment of GMOs, the European Food Safety Authority defines the term baseline as *"the current status quo, e.g., current conventional cropping or historical agricultural or environmental data. The baseline serves as a point of reference against which any effects arising from the placing on the market of a GMO can be compared"* (EFSA, 2006).

Due to the vague definitions of the term "baseline," the use of the baseline concept as a decision support tool remains ambiguous necessitating a more precise characterization. A common point pertinent to all definitions is the term "comparison" – semantically decisions should therefore theoretically always be taken relative to a comparator. Ultimately, the question as to what represents environmental damage is nevertheless a legal problem. Legally, the baseline for any evaluation of damage from GMOs should be set by what is already regarded representing damage today. This implies that potential damage resulting from GMOs should be evaluated according to the same criteria as any damage that might occur from other technologies, for example, chemical pesticides.[19]

[19] Provided that there is a legal framework regulating the technology (e.g., pesticides). The approach is not valid for techniques that are not regulated such as the use of mowing or tillage machinery.

The implicit baseline for the evaluation of impacts of GM crops on biodiversity corresponds thus to current agricultural management practices where the impact of the GM cropping system are evaluated against the impacts caused by the cropping practices that are replaced. This leads to the question how impacts of different agricultural management practice could be compared to determine whether the impacts of the GM cropping system are lower, equal or higher than those of current practices. A direct comparison is difficult as these impacts vary depending on a number of different factors. A simple, easily applicable generic comparison of the GM cropping practice with the most common current pest management practice is almost impossible and beyond the scope of this report. Comparative impact assessments can thus only be performed on a case-by-case basis where the nature of the crop, specific aspects of the pest management practices applied and the receiving environment are considered. Different regulatory frameworks are moreover used as a basis to evaluate the effects of different pest management practices, which makes it almost impossible to directly compare the effects of a GM cropping system to its conventional non-GM counterpart. Nevertheless, an important point to consider in each comparison refers to the fact that all regulatory frameworks differentiate between "intended" effects of the cropping practice applied and "unintended" effects that are to be minimized. Such a differentiation should allow outlining a generic scheme that permits to evaluate whether the effects of different pest management practices are to be regarded as intended effects (which are regarded acceptable) and unintended effects that could represent environmental damage. This differentiation will in the following be used to establish an approach that can help to differentiate between these two types of effects (see section 7.3).

7.2 Case study 1: Effects of Bt-maize on nontarget arthropods

The impacts of genetically modified Bt-maize on arthropod biodiversity in comparison to current pest management practices used for European Corn Borer management in maize in central and western Europe are taken as an example to show how it is necessary to differentiate between different types of effects when evaluating environmental damage. Current crop protection practices considered include two current (non-GM) practices (insecticides and biological control using *Trichogramma*). Given that both Bt-maize and current pest control practices display insec ticidal properties, this case study will concentrate on the question as to whether arthropods other than the pest(s) targeted by the toxin are harmed. Other concerns that are brought up regarding environmental risks of GM crop cultivation such as impacts on farmland biodiversity due to changes in the agricultural practice associated with the adoption of GM crops (e.g., soil tillage, cropping intervals, or cultivation area) will not be covered by the present case study as these concerns are not pertinent in the case of Bt-maize.[20] Similarly, concerns such as gene flow and invasiveness are negligible as there are no cross-compatible wild relatives of maize in Europe and shed maize kernels and seedlings do not survive winter cold in Central and Western Europe.

7.2.1 Background information on European Corn Borer management in maize

7.2.1.1 Damage in maize by the European Corn Borer

An important group of insect pests in maize are lepidopteran stem borers such as the European Corn Borer (ECB, *Ostrinia nubilalis*). The ECB is considered a widespread maize pest in most maize growing regions in Central and Western Europe. In the main cultivation areas in Europe affected by ECB, the pest is the most important maize pest, causing yield losses of 5–30% if no pest control is applied. Damage caused by ECB usually varies highly among regions and years.

7.2.1.2 Current European Corn Borer control practices in Europe

Most maize growers in Europe rely on conventional crop protection practices to manage the ECB, including cultural, biological or chemical (insecticidal) methods. However, apart from sweet maize, where insecticides are commonly used against the ECB, only a small percentage of the maize crop area (approx. 5–20%) is sprayed with insecticides. This is mainly due to technical difficulties of spraying and problems in assessing the correct time of spraying. Insecticide use in maize is therefore largely restricted to the control of soil pests such as wireworms (and cutworms) via seed coating and granules. In areas where the ECB is controlled by insecticides, most often Pyrethroids are used (active ingredients: (Alpha)-Cypermethrin, Deltamethrin or Lambda-Cyhalothrin), although the use of more selective insecticides such as Indoxacarb or Diflubenzuron is increasing. Although decreasing in recent years, some European regions still use older broad-spectrum insecticides such as Organophosphates (active ingredient, e.g., Chlorpyrifos), which were already on the market in the 1960s. The maize area where the ECB is controlled using biological control by the parasitic wasp *Trichogramma brassicae* amounts in Western Europe to 140,000 hectares,

[20] Points to consider for changes in agricultural management practice will be discussed in the second case study on noninsecticidal GM crops (see section 8).

which is still relatively small (approx. 4–5%) compared to the total area (3.3 million hectares) where ECB damage is regularly above the economic injury level in the European Union (EU-27). In addition, farming practices are used to help manage insect pests by physically destroying pests essentially through stalk destruction in the Fall and ploughing of maize stubbles prior to planting.

7.2.1.3 European Corn Borer control using Bt-maize

Bt-maize is genetically modified maize that carries a gene from the soil bacterium *Bacillus thuringiensis* (Bt). The different strains of *B. thuringiensis* contain varying combinations of Cryproteins (so called Bt-toxins) and each of these insecticidal proteins is known to have a very selective toxicity against different groups of arthropods (Höfte and Whiteley, 1989; Schnepf *et al.*, 1998; de Maagd *et al.*, 2001). Bt Cry proteins are currently the only insecticidal proteins that are commercially used in GM crops. The gene inserted into Bt-maize expresses the insecticidal protein Cry1Ab that confers resistance to Lepidoptera (moths and butterflies). It was initially developed to control the ECB, but has shown to be also effective against various other lepidopteran pests, such as the Mediterranean Corn Borer *(Sesamia nonagrioides)*, which is restricted to the southern parts of Europe.

7.2.1.4 Environmental hazards associated with insecticides

Broad-spectrum insecticides usually have moderate to highly toxic effects on a wide range of organisms (European Union, 2009a). Environmental impacts of insecticides strongly vary depending on the product applied, its active substance, the application rate, the formulation and the application technique. For the present case study, two active substances were selected that are used for ECB management in maize in Europe. The first active substance (Lambda-Cyhalothrin; a pyrethroid) is an older broad-spectrum insecticide that is still widely used, while the second is a more selective insecticide (Indoxacarb; an oxadioazine). Acute toxicity data for the two active substances Lambda-Cyhalothrin and Indoxacarb are taken from review reports from the EU Pesticides database (European Union, 2009a) and from Pesticide factsheets of the U.S. Environmental Protection Agency (EPA, 2009),

Pollinator, beneficial arthropods, and butterflies*:* Broad-spectrum insecticides such as Lambda-Cyhalothrin are highly toxic to a wide range of invertebrates including honey bees. A repeatedly observed effect of many broad-spectrum insecticides is the promotion of secondary pest outbreaks. These generally occur when insecticide applications kill natural enemies that were controlling a herbivore species that was not a pest before. These species can then increase to densities that cause damage. The new classes of more selective insecticides such as Indoxacarb have several advantages over the older broad-spectrum insecticides. Most are less likely to harm natural enemies and other nontarget species. Indoxacarb, for example, is very effective against lepidopteran larvae, but allows most predators and immature parasitic wasp attacking these larvae to survive. Indoxacarb is also practically nontoxic to bees. Insecticides generally tend to have immediate, but predominantly short-term (2–3 months) effects on nontarget arthropods, as affected population may be able to recover due to the recruitment of new individuals from unaffected populations.

7.2.1.5 Environmental hazards associated with biological control using *Trichogramma*

The egg parasitoid *Trichogramma brassicae* is the only invertebrate used in augmentative biological control in maize (Bigler *et al.*, 2010). Two ecological concerns are discussed related to the use of this exotic species in biological control programs in Europe. The first concern relates to the establishment of *T. brassicae* under fields conditions following its dispersal into nontarget habitats. Because of their broad host range, the second concern relates to the question is whether mass releases of *T. brassicae* may have ecologically significant direct and / or indirect effects on nontarget arthropods. Given that *T. brassicae* can successfully overwinter in diapause under Swiss climatic conditions, one can assume that the species would establish in most regions of Europe if nontarget hosts are available. *T. brassicae* density increases during mass releases, but drops to prerelease densities 2–3 weeks after the last release, indicating that only a small fraction (less than 10%) of the released population disperses out of maize fields to nontarget habitats. Permanent establishment occurs only in limited areas of seminatural and natural habitats making effects on native *Trichogramma* populations unlikely. As *T. brassicae* has a clear host plant and habitat preference, the parasitoid does not successfully attack arthropod host eggs on other plants than maize. The effect on lepidoptera and aphid predators under semifield and field conditions is thus very low. Short-term mortality caused by *T. brassicae* in off-crop habitats is likely, but has a negligible to low population and community effect, as the magnitude is likely to remain below a 40% reduction in the size of nontarget lepdoptera populations. Quantitative effects will moreover be temporary and of transient nature.

7.2.1.6 Environmental hazards associated with Bt-maize

Given the insecticidal properties of the Cry1Ab toxin, most concerns relate to the question as to whether Bt-maize harms organisms other than the pest(s) targeted by the toxin. As of May 2009, 89 original research articles have been published addressing effects of Bt-maize (or the purified toxin) on different groups of organisms both in the laboratory and in the field (Naranjo, 2009). Most published studies have been performed by public research after the approval of the respective Bt-maize events in 1996. In addition, studies performed by the applicants (i.e., the company marketing the crop) have been conducted prior to the market approval of Bt-maize (EPA, 2001; Mendelsohn *et al.*, 2003; OECD, 2007). Data for the Bt-toxin Cry1Ab are taken from the U.S. EPA Biopesticides registration action document on *Bacillus thuringiensis* plant-incorporated protectants (EPA, 2001).

Pollinators: Honey bees are the most important pollinators of many agricultural crops worldwide. Because of their importance to agriculture, they have been a key test species used in environmental safety assessments of Bt-maize. These assessments have involved comparisons of honey bee larval and adult survival on purified Cry proteins or pollen collected from Bt-maize versus survival on non-Bt-maize material. A recent meta-analysis combining the results of 39 studies assessing different Cry proteins found no statistically significant effect of Bt Cry protein treatments on survival of honey bees.

Beneficial arthropods: Another important group of nontarget organisms providing ecological and economic services within agricultural systems are parasitoids and predators (so-called natural enemies). One hypothesis is that Bt-maize could alter the biological control functions of beneficial arthropods, which are important for controlling herbivorous insect populations in maize. Nontarget organisms have to ingest the insecticidal protein expressed in Bt-maize in order to be directly affected. Ingestion can occur via several ways of exposures. Exposure can either occur by feeding on plant material (e.g., leaves, pollen), by feeding on insects that have previously fed on GM crops (and therefore contain the toxin) or via exposure through the environment, e.g., when toxins from plant residues persist in the soil. In order to be affected by the toxin, natural enemies would moreover need to be sensitive to Cry1Ab. Overall, several meta-analyses have shown that the majority of studies conducted in the laboratory and in the field show no adverse effects on nontarget organisms resulting from direct toxicity of the expressed Bt-toxins (Wolfenbarger *et al.*, 2008; Naranjo, 2009). Some laboratory studies revealed indirect prey-quality mediated effects due to Bt-maize. Under field conditions, these secondary trophic effects may be caused by changes in the availability and / or the quality of target herbivores with specialist natural enemies (often parasitoids) depending entirely on the target pest (i.e., the ECB). Such effects are common for any pest control method; they are of minor concern within an environmental risk assessment context and they should be differentiated from direct effects of a toxin. The weight of considerable data available from field studies gives evidence that Bt-maize has no ecologically relevant effects on a number of taxa, especially in comparison with alternative pest control measures such as broad-spectrum insecticides. The results confirm the high specificity of Cry1Ab having a very narrow range of activity restricted to the target pest and closely related species. Biodiversity is thus higher in Bt-maize fields in comparison to maize fields treated with traditional insecticides having a broader range of activity.

Butterflies: A particular focus was laid on butterflies as Cry1Ab confers resistance to Lepidoptera and as butterflies are considered to be a species group with a high aesthetic value serving as symbols for conservation awareness. Butterfly larvae can be exposed to Cry1Ab in the vicinity of Bt-maize fields (up to approximately 2 meters from the border) when feeding on host plant leaves naturally dusted with maize pollen during anthesis (flowering). Especially the case of the Monarch butterfly (*Danaus plexippus*) caused much public interest and led to a debate over the risks of Bt-maize as one study had found that when pollen from a commercial variety of Bt-maize (event Bt11) was spread on milkweed leaves in the laboratory and fed to monarch butterfly larvae, after four days almost half of the tested larvae died (Losey *et al.*, 1999). Extensive follow-up studies showed that initial reports of toxicity of high doses of Cry1Ab toxin to butterflies in the laboratory did not necessarily mean that there would be exposure to toxic levels in the field (Sears *et al.*, 2001; Dively *et al.*, 2004). The proportion of Monarch butterfly population exposed to Bt-pollen in the field was estimated to be less than 0.8%. Although similarly detailed data is not available for Europe, the data available provide confidence that commercial cultivation of currently available Bt-maize varieties constitutes a low risk for European butterfly species. This conclusion is based on the assumption that larval exposure to Cry1Ab is relatively low for European butterfly species considering the low expression level of the toxin in pollen of the only approved Bt-maize event MON810, the fact that most pollen is deposited within a few meters from the field border, and that maize is not considered a host plant for nontarget butterflies.

7.3 Approach to differentiate effects of various pest management practices on nontarget arthropods

The flow chart presented in Figure 3 proposes an approach as to how the effects of different pest management practices on the arthropod fauna can be differentiated and compared. Effects are thereby considered within the whole system "agricultural landscape"[21] and cover both biodiversity conservation (species and habitat diversity) and functional biodiversity (i.e., ecosystem services) issues. The first part of the flow chart relates to crop protection and has to be answered based on the spectrum of activity of the respective crop protection method applied. Therein, the first two questions help to differentiate between intended effects on target pests and other (potential) pests and unintended effects on nontarget arthropods that may represent environmental damage. The second part of the flow chart (Questions 3 to 11) has to be answered based on the species groups potentially affected. Biodiversity entities potentially affected are determined based on the Swiss environmental protection goals related to agriculture where biodiversity is classified into three main aspects: species and habitat diversity, genetic diversity within species and functional biodiversity (see section 4.2.3). Genetic diversity is thereby regarded as an important part of functional diversity as it is crucial to a species' ability to adapt to its environment.

7.3.1 Crop protection

Existing regulatory frameworks acknowledge the fact that agricultural management involves crop protection and that these practices inevitably comprise certain environmental impacts. The regulation aims at ensuring that occurring impacts are restricted to target pests, while possibly excluding unintended effects on nontarget organisms. Three types of effects can be differentiated when comparing the effects of different crop protection practices: (1) intended effects on pests, (2) inevitable trophic effects due to the absence of these pests and (3) unintended effects on the arthropod fauna in agricultural crops and the wider landscape.

[21] Realistically, adverse effects on arthropods occur with a higher probability in crop fields rather than outside the crop or on a landscape scale. This is basically because the exposure of nontarget arthropods to the stressor (e.g., the insecticidal protein) is highest in crop fields. Whether effects occurring in the crop translate to the landscape scale is depending on a number of factors such as the magnitude of effects and the type of species affected.

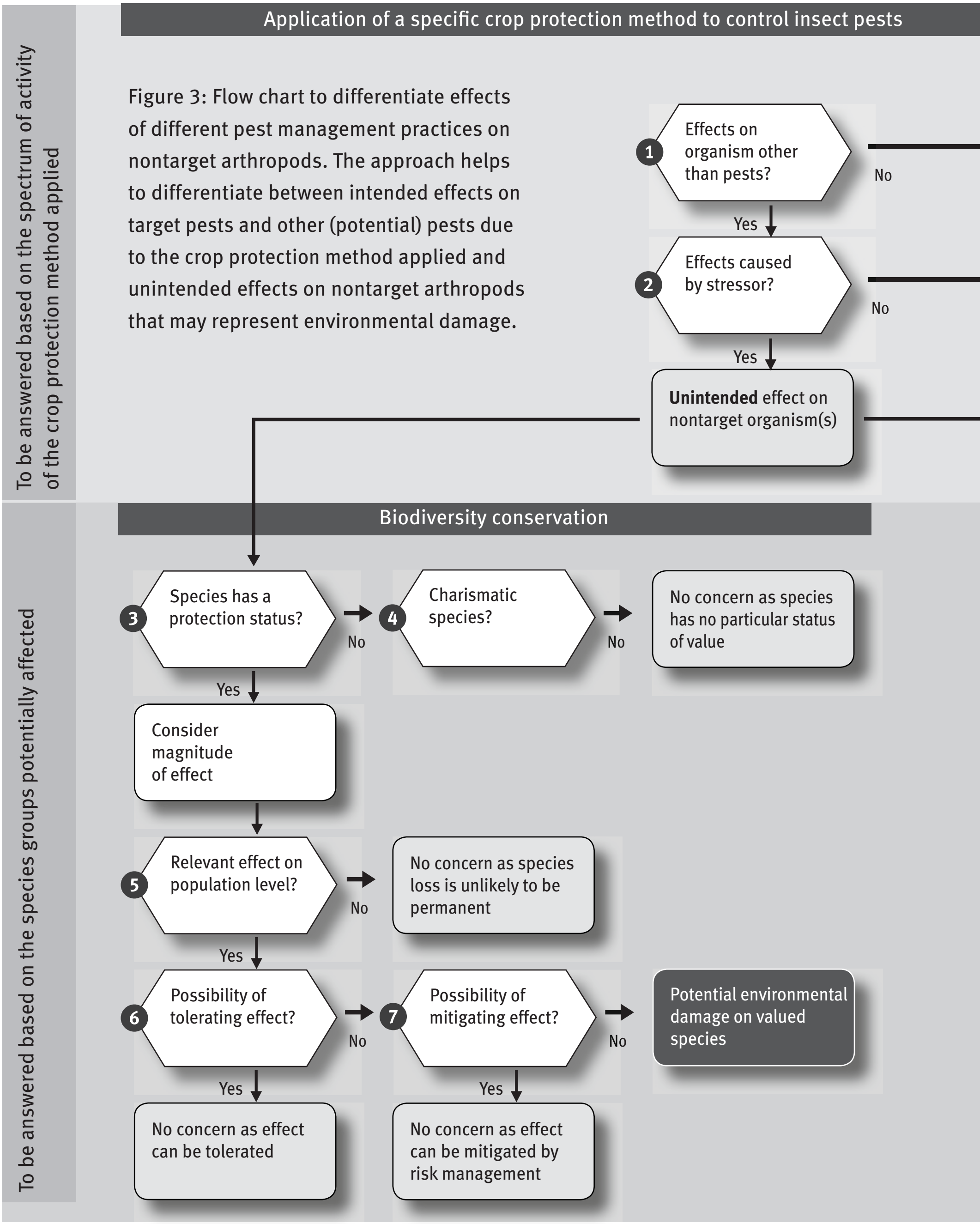
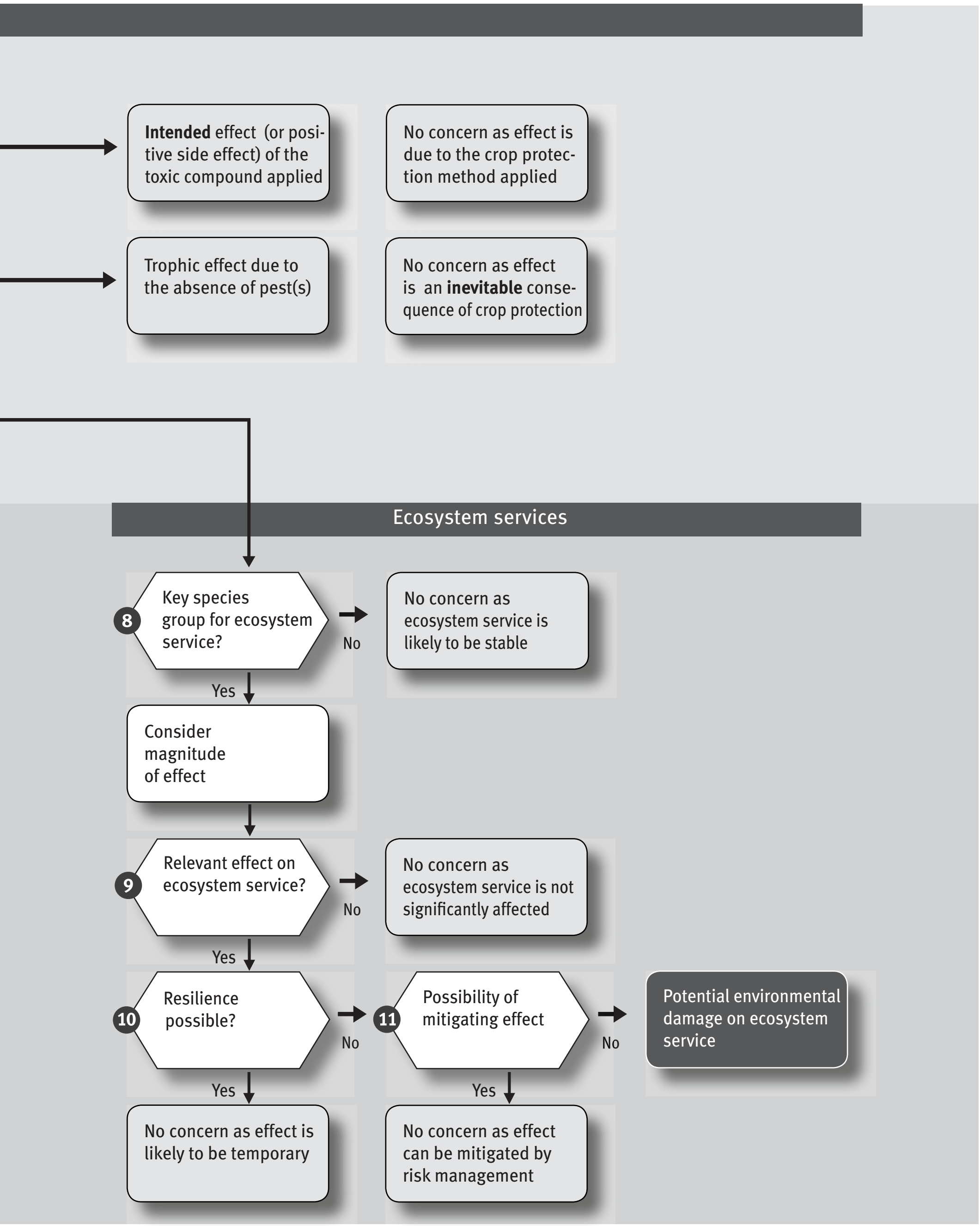


Figure 3: Flow chart to differentiate effects of different pest management practices on nontarget arthropods. The approach helps to differentiate between intended effects on target pests and other (potential) pests due to the crop protection method applied and unintended effects on nontarget arthropods that may represent environmental damage.


Intended effect (or positive side effect) of the toxic compound applied
No concern as effect is due to the crop protection method applied
Trophic effect due to the absence of pest(s)
No concern as effect is an inevitable consequence of crop protection
Ecosystem services
8 Key species group for ecosystem service?
No
No concern as ecosystem service is likely to be stable
Yes
Consider magnitude of effect
9 Relevant effect on ecosystem service?
No
No concern as ecosystem service is not significantly affected
Yes
10 Resilience possible?
No
11 Possibility of mitigating effect
No
Potential environmental damage on ecosystem service
Yes
No concern as effect is likely to be temporary
Yes
No concern as effect can be mitigated by risk management

Question 1: Effect on other organisms than target pests?
The first question aims at determining whether there are effects on other organisms than the target pest. This acknowledges that all effects that are directly associated to target pests are clearly of no concern as they are the primary aim of any crop protection method applied[22] (Question 1 in Figure 3). Some pest management practices may also be effective against (potential) pest organisms other than the pests specifically targeted by the toxin. One can argue that these effects are also of no concern as they relate to organism groups that are regarded being secondary or minor pests. Their partial control is often regarded as a positive side effect of the pest management applied as these species are generally not regarded as representing a particular value.

Question 2: Effect caused by the environmental stressor?
The second question evaluates whether the effect is directly caused by the environmental stressor (i.e., the insecticidal compound / protein or parasitation by *T. brassicae*) or whether it is a trophic effect due to the absence of pests. Trophic effects that are related to the absence or to a reduced (nutritional) quality of target pests or hosts are an inevitable consequence of all crop protection methods applied (OECD, 1993; EFSA, 2006; Romeis *et al.*, 2008a). Such effects are of no particular concern as organisms that are primarily depending on target pests as a food source (predators) or as a host (parasitoids) are inevitably reduced in their abundance if target pests are absent or of reduced (nutritional) quality (Question 2 in Figure 3). In the case of Bt-maize, for example, certain parasitoids such as *Macrocentrus* grandii may be totally absent in the crop as they are entirely relying on the target pest (i.e., the ECB larvae) for their development[23] (Romeis *et al.*, 2006; Wolfenbarger *et al.*, 2008).

All effects that are not directly linked to target and potential pests can be viewed to represent unintended effects. To decide whether these unintended effects represent environmental damage, it has to be determined which environmental entities are of value to the society (Raybould, 2007). The matrix enabling an operational definition of protection goals thereby defines what entities are to be regarded as nontarget organisms by assigning value to those entities that deserve protection based on the legal framework (see section 5). As a next step, one has to evaluate whether the unintended effects relate to a biodiversity conservation issue (Questions 3 – 7 in Figure 3) (see section 7.3.2) or to an ecosystem service (Questions 8 – 11 in Figure 3) (see section 10.1.1).

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[22] Reductions in target pest populations are to a certain extent mitigated as plant protection methods usually never kill 100% of the individuals.

[23] Insect-resistant GM crops have to be cultivated with a certain percentage of nontransgenic refugia to prevent resistance development in target insects. These refugia allow specific natural enemies to survive and propagate.

7.3.2 Biodiversity conservation

Question 3: Does the species have a protection status?

The first question to be answered when determining whether effects on arthropods are affecting biodiversity conservation is whether these effects are related to species having a particular protection status (Question 4 in Figure 3). Three categories of species have a particular legal protection status in Switzerland: (a) the IUCN[24] Red List of threatened species being the most comprehensive resource detailing the global conservation status of plants and animals (Rodrigues *et al.*, 2006), (b) species threatened on a national level and (c) species characteristic for a specific habitat and / or region. Red Lists are a legally binding instrument of biodiversity conservation assigning these species an absolute protection status (NHV, SR 451.1). The two latter categories of species are related to the overall environmental policy goal in Switzerland to preserve and promote domestic species and their respective habitats (Duelli, 1994; Bafu/BLW, 2008).

Groups of Red List species that are assigned with a specific protection status are characterized by the availability of sufficient expert knowledge to perform a judgment on their conservation status. For many groups of invertebrates, however, detailed data and expert knowledge is often missing and their conservation status is not known. Although being of conservation interest, some arthropod groups are, for example, not listed in the Red Lists. Regulatory decision-making based on Red Lists therefore has limitations for invertebrates as decisions can only be made for those taxa that are listed and explicitly protected. Ultimately, one has thus to accept that we can only evaluate what is perceived to be important by having been listed.

Question 4: Is the species a charismatic species?

In case an effect is not related to a species having a particular protection status, the next question to be answered is whether the effect is associated with a charismatic species (Question 5 in Figure 3). Although not having a particular legal protection status, a number of specie groups are regarded as being of conservation value primarily because of their aesthetic, cultural or other relevant value. For the arthropod fauna, these include, for example, a number of butterfly and ladybird beetle species that are not explicitly listed as either Red List species or species threatened on a national level.

[24] International Union for Conservation of Nature and Natural Resources

In case a particular effect is neither related to a species with a protection status nor to charismatic species, one can reasonably assume that the species affected are judged to be of no particular value. Any effect is thus of minor concern for biodiversity conservation and is therefore not regarded as representing environmental damage.

7.3.2.1 Consider magnitude of effect

In case a particular effect relates to either species with a protection status or to charismatic species, one has to determine the magnitude of the environmental impact of the specific pest management practice. The impact of a specific pest management practice depends on a number of different influencing factors that vary depending on the nature of the environmental stressor (Table 4). These factors can only be assessed on a case-by-case basis, taking into account the conditions prevalent in a particular receiving environment. Ideally, such an assessment would need to estimate all influencing factors. In many cases, however, it may not be necessary to assess all factors as the occurrence of an effect may become highly unlikely in the absence of certain decisive factors (e.g., because the spectrum of activity and the mode of action of the stressor exclude a toxic effect on a particular group of valued species). Similarly, it may sometimes not be necessary to assess all factors experimentally as meaningful estimations can be deduced from existing data or by theoretical considerations. This might be particularly relevant for those cases where it is impossible to obtain sufficient individuals for a meaningful experimental assessment, for example, in the case of a specific Red List species. Assessments in the case of Red List species might nevertheless also be carried out experimentally by using appropriate surrogates.

Even for a specific crop such as maize and a pest such as the European Corn Borer, an application-based assessment can often only be performed on a regional basis as pest management decisions greatly vary among regions in Europe (Meissle *et al.*, 2010). Different approaches are possible to define what characterizes a region. According to the new regulation on plant protection products (European Union, 2009b), for example, the EU is divided into three different geographical zones.[25] Other approaches define more detailed biogeographical regions, such as the Natura 2000 network specifying nine regions or the SEAMzones approach proposing 12 environmental zones across the EU (Hazeu *et al.*, in press). Regulatory authorities demanding for regional

[25] Zone A – North: Denmark, Estonia, Latvia, Lithuania, Finland, and Sweden
Zone B – Center: Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, and United Kingdom
Zone C – South: Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, and Portugal

assessments nevertheless need to consider that these need to remain practicable as assessments become increasingly impracticable the more regions have to be considered.

Question 5: Is there a relevant effect on population level?
A relevant impact on biodiversity conservation is characterized by an explicit reduction in population size of a particular species or by a clear reduction of its area of distribution (Duelli, 1994). Such an evaluation can of course only be performed if the prior abundance and distribution of the species is known. Unfortunately, such data is often not available, in particular, for most invertebrate groups that count for approximately 98% of all animal species (Duelli, 1994). The conservation status of most species having a particular protection status is therefore usually deduced from current knowledge on their specific habitat requirements. According to the Swiss legal frameworks, the value of a specific habitat is judged based on the rareness of the species (potentially) being present in this habitat (NHV, SR 451.1). In general, the rarer the species present, the more value is given to the habitat from a biodiversity conservation point of view. This is based on the rationale that in case of a widespread impairment of a specific habitat, one can reasonably assume that the species specifically depending on this habitat will be impaired too.

According to the Red List species concept, every loss is principally to be regarded as damage as the legal frameworks assign these species a priority status. With regard to biodiversity conservation, this would imply a zero tolerance towards clear and widespread reductions in population size of Red List species (i.e., a reduction of the total number of individuals of that taxon). In practice, however, reductions in population size are most often not abrupt, but continuous, meaning that a particular species will not go extinct immediately. The IUCN works with different Red List categories that describe the conservation status of a particular species ranging from extinct (EX) to least concern (LC). Species in the categories critically endangered (CR), endangered (EN) and vulnerable (VU) are denoted as threatened (Table 5) (Gärdenfors, 2001; IUCN, 2001; Rodrigues *et al.*, 2006). Instead of immediate extinctions, biodiversity losses are therefore evaluated based on transfers between different threatened categories. Moving a taxon from a higher to a lower risk category is usually regarded as being positive while transfers from categories of lower risk to higher risk indicate biodiversity losses.

Table 4: Factors influencing the magnitude of environmental impacts of Bt-maize, insecticide applications and biological control organisms that have to be considered when determining whether ecologically relevant effects on population level of valued species occur (ecological relevance is determined based on questions 5 – 7 and 9 – 11 in Figure 3, respectively) (adapted and expanded based on Sears *et al.*, 2001).

8	**Bt-maize**
	STRESSOR-RELATED
1	Spectrum of activity and mode of action of the stressor produced by the transgenic trait
2	Susceptibility of organism to the insecticidal protein
3	Amount of stressor present in the environment based on the following factors a–d
a	Spatial distribution of Bt-maize in the landscape (depending on the percentage of maize cultivation in a given region and the adoption rate of Bt-maize)
b	Amount of insecticidal protein expressed in a specific plant tissue based on temporal expression levels and patterns
c	Dispersal of the stressor in the environment based on pollen distribution patterns, root exudates, crop residues (if stressor is expressed in these tissues)
d	Degradation of the stressor in the environment based on environmental fate
4	Temporal duration of exposure based on timing, duration and intensity of the stressor being present in the environment
	PROTECTION GOAL-RELATED
5	Number of individuals / proportion of the population exposed to the stressor based on the following factors a–c
a	Occurrence and spatial distribution (regional, landscape, habitat) of a valued species or its sensitive life stages
b	Occurrence and spatial distribution of the species' host plants (if applicable)
c	Amount of plant tissue consumed by organisms in the sensitive life stage

Insecticides	Biological control agents *(Trichogramma)*
Spectrum of activity and mode of action of active ingredient of the insecticide	Host range of *T. brassicae*
Susceptibility of organism to the active ingredient	Parasitation rate of *T. brassicae*
Amount of stressor present in the environment based on	Number of adult parasitoids present in the environment based on
Percentage and spatial distribution of maize fields in the landscape where the insecticide is applied	Percentage and spatial distribution of maize fields in the landscape where *T. brassicae* is released
Amount of insecticide active ingredient present on crops and / or host plants (depending on deposition rate)	Amount of females of *T. brassicae* deployed in maize fields
Dispersal of the insecticide in the environment based on formulation, application technique, drift factor and vegetation distribution factor	Dispersal rate of parasitoids outside of maize fields
Degradation of the active ingredient in the environment based on environmental fate of the active substance and formulation	Survival of adult parasitoids in the environment
Temporal duration of exposure based on timing, duration and application rate of the insecticide	Temporal duration of exposure based on timing, duration and number of applications of *T. brassicae*
Number of individuals / percentage of the population exposed to the stressor based on	Number of individuals / percentage of the population exposed to the stressor based on
Occurrence and spatial distribution (regional, landscape, habitat) of a valued species or its sensitive life stages	Occurrence and spatial distribution (regional, landscape, habitat) of a valued species or its sensitive life stages
Occurrence and spatial distribution of the species' host plants (if applicable)	Occurrence and spatial distribution of the species' host plants (if applicable)
Amount of stressor ingested or contacted by organisms in the sensitive life stages	Number of hosts encountered by adult parasitoids

Table 5: Summary of the five criteria (A – E) used to evaluate if a taxon belongs to a threatened Red List species category (modified based on IUCN, 2008).

9	10
A	**POPULATION REDUCTION** (past, present and / or projected)
A1	Observed reduction that is clearly reversible AND understood AND ceased
A2	Observed reduction that may not have ceased OR may not be clearly understood OR may not be clearly reversible
A3	Projected or suspected population reduction up to a maximum of 100 years
A4	Observed reduction where the time period includes both the past and the future
B	**GEOGRAPHIC RANGE** (either B1 or B2)
B1	Extent of Occurrence (EOO) (see footnote 23)
B2	Area of Occupancy (AOO) (see footnote 24)
	and 2 of the following 3
	Severely fragmented locations
	Continuing decline
	Extreme fluctuations
C	**SMALL POPULATION SIZE AND DECLINE**
	Number of mature individuals (and either C1 or C2)
	Estimated continuing decline up to a maximum of 100 years
C1	Continuing decline
C2	(a i) of mature individuals in largest subpopulation
	(a ii) or % mature individuals
	(b) extreme fluctuations in the number of mature individuals
D	**VERY SMALL OR RESTRICTED POPULATIONS**
	Either Number of individuals
	or Restricted AOO
E	**QUANTITATIVE ANALYSIS**
	Probability of extinction in the wild is at least

Critically endangered	Endangered	Vulnerable
> 90%	> 70%	> 50%
> 80%	> 50%	> 30%
> 80%	> 50%	> 30%
> 80%	> 50%	> 30%
< 100 km2	< 5000 km2	< 20,000 km2
< 10 km2	< 500 km2	< 2000 km2
= 1	≤ 5	≤ 10
n.a.	n.a.	n.a.
n.a.	n.a.	n.a.
< 250	< 2500	< 10,000
25% in 3 years or 1 generation	20% in 5 years or 2 generations	10% in 10 years or 3 generations
< 50	< 250	< 1000
90–100%	95–100%	100%
n.a.	n.a.	n.a.
< 50	< 250	< 1'000
n.a.	n.a.	AOO > 20 km2 or # locations ≤ 5
50% in 10 years or 3 generations (max. 100 years)	20% in 20 years or 5 generations (max. 100 years)	10% in 100 years

The IUCN Red List criteria are based on biological indicators showing whether populations are threatened with extinction (e.g., rapid population decline or very small population size). Five criteria have been defined to determine whether a taxon belongs to any of the three threatened categories. To list a particular taxon in a threatened category, only one of the criteria needs to be met. The five criteria are (IUCN, 2001, 2008):

- The extent of past, present and / or projected population reduction measured over the last 10 years or three generations (whichever is longer).
- The geographic range measured as either the extent of occurrence (EOO)[26] or the area of occupancy (AOO).[27]
- Small population size measured as the number of mature individuals.
- Very small population or very restricted distribution (either measured as the number of mature individuals or the restricted AOO).
- Quantitative analysis of extinction risk (e.g., Population Viability Analysis)

The list of criteria is insofar interesting as for each criterion precise quantitative thresholds have been defined to support decision-making (Table 5). For criterion A, for example, the extent of population reduction that has to be observed to categorize a taxon as being threatened ranges from "exceeding 30%" to "exceeding 90% reduction" depending on the respective category. For criterion B, the geographic range of a taxon has to be limited to occurrence on less than 100 km^2 up to less than 20,000 km^2 (for the EOO), or to less than 10 km^2, or less than 2000 km^2, respectively for the AOO. Most criteria also include subcriteria that are used to justify more specifically the listing of a taxon under a particular category. Subcriteria for criteria B and C include, among others, either the degree of fragmentation of a taxon, or continuing declines in various parameters (such as, the area, extent and quality of habitats, or a continuing decline in the number of mature individuals over a certain time period).

In case a particular effect is neither widespread nor of a high magnitude, one can reasonably assume that the effect is of no concern for biodiversity conservation and that it is therefore not regarded as representing environmental damage. In case there is a relevant effect on biodiversity, the next question to ask is whether there is a possibility of mitigating the risk for biodiversity loss by certain risk management measures (Question 7 in Figure 3).

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[26] The Extent of Occurrence (EOO) is a parameter that measures the spatial spread of the areas currently occupied by the taxon.

[27] The Area of Occupancy (AOO) is a parameter that represents the area of suitable habitat currently occupied by the taxon.

Question 6: Is it possible to tolerate biodiversity losses of species with a protection status or of charismatic species?
Rare species in agricultural landscapes are often remains of ancient agricultural practices. Historically, low intensity land management has resulted in a rich assemblage of species in agricultural landscapes (Stoate *et al.*, 2009). Over centuries, anthropogenic influences shaped the initial woodland prevalent in Central and Western Europe into a cultural landscape dominated by rural activities. Different agricultural management practices divided the landscape into a multitude of diverse habitats that allowed a wide variety of species to colonize the newly created habitats. This resulted in an increase of biodiversity prior to the industrialization of agriculture in the middle of the last century. It has been estimated that 50% of all species in Europe depend on agricultural habitats, including a number of threatened and endemic species (Stoate *et al.*, 2009). Yet, agricultural intensification over the past 60 years has led to significant impacts on the environment. The mechanization of agriculture has facilitated degradation in habitat quality and increasing habitat homogeneity. This led to the elimination of many landscape elements and habitats that were typical for a number of specialized taxa. The species richness and habitat diversity of nearly all farmland has furthermore declined due to more intensive field management, that is, among others higher pesticide and fertilizer use and the simplification of crop rotations (Stoate *et al.*, 2001; Robinson and Sutherland, 2002; Tilman *et al.*, 2002). Species present in agricultural landscapes today tend to be habitat generalists. One may thus argue that the few rare species occurring in agricultural landscapes are particularly valuable as their habitats are predominantly threatened from disturbances and habitat loss.

When evaluating widespread biodiversity losses in agricultural landscapes, one may ask whether certain reductions in the population size of protected or of charismatic species are tolerable. In the following, we will argue that local biodiversity losses of protected species may, to a certain extent, be tolerable if populations of that taxon still occur or may develop in other, undisturbed habitats. The argument is related to the dilemma that Red Lists are often used (or even laid down in existing legal frameworks) on a national or on a regional level, but were initially developed to assess extinction risk of entire populations of species at the global level. The use of Red Lists at the national level may thus be misleading as a population can be distributed over more than one country, which makes it difficult to estimate the extinction risk of the part of the population resident within the target country (Gärdenfors, 2001). Evaluations of species losses thus require considering the scale of reference: according to the Red Lists concept, endemic species that are threatened on a global or on a European level, but that typically only occur in Switzerland, deserve particular priority as their disappearance would represent an irreversible loss of biodiversity.[28] The same is true for regional populations that are isolated from conspecific populations outside the region (IUCN, 2003). However, when the extinction criteria are applied to populations separated by a geopolitical border, or to regional populations where individuals move to or from other populations beyond the border, the extinction criteria may be inappropriate because the unit being assessed is not the same as the whole population or subpopulation. As a result, the estimate of extinction risk may be inaccurate. A more accurate approach to evaluate species losses would be to assess in a first step whether a population is endemic to a country, or completely isolated from other populations of the same species. In a second step, it should be considered whether the target population is part of a more widely distributed population. If this is the case, the Red Lists category should be adjusted, that is, usually downgraded, to one that more appropriately reflects the long-term extinction risk of the subpopulation (Gärdenfors, 2001).

Local population reductions may moreover partly be buffered by population movements from other habitat patches as according to metapopulation ecology, landscapes can be viewed as networks of habitat patches in which species occur as discrete local populations connected by migration (Hanski, 1998). Especially charismatic species are often not particularly rare species and local reductions in population size may be buffered by migration between different metapopulations. For rare species, however, recolonization of disturbed habitats may be difficult as a particular species may only occur in a few distinct habitats and the habitats may be too distant to allow migration of the species between the habitat patches.

In case the effect cannot be tolerated, the next question to be asked is whether there is a possibility of mitigating the biodiversity loss (Question 8 in Figure 3).

Question 7: Is it possible to mitigate the risk for biodiversity losses of species with a protection status or of charismatic species?

In case there is a risk for a relevant biodiversity loss, it has to be determined whether the risk can be mitigated by specific risk management measures. If the risk can be mitigated, it is of no particular concern and can thus not be regarded as representing environmental damage.

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[28] Most habitats of endemic species in Switzerland are typically located in areas with almost no human impact such as alpine or forest areas.

In conclusion, effects on arthropod biodiversity are only to be regarded as potential ecological damage in case biodiversity losses are related to either species with a protection status or to charismatic species. It is moreover important to determine whether the population losses are widespread and of a high magnitude and whether certain factors apply that might allow tolerating the risk for biodiversity losses (e.g., in case they do not relate to endemic species that are particularly characteristic for Switzerland). Finally, damage only occurs if it is impossible to mitigate the biodiversity losses.

7.3.3 Ecosystem services

If an effect on arthropod biodiversity is not related to a biodiversity conservation issue, it may be related to an ecosystem service. Ecosystem services are those properties of ecosystems (e.g., climate regulation, nutrient cycling, pollination, and provision of food and fiber) that either directly or indirectly benefit human activities (Hooper *et al.*, 2005; EASAC, 2009). Rationales for the protection of biodiversity are often based on the argument that species provide these ecological goods and services that are essential for human welfare (see section 4.2.3).

Question 8: May certain species be lost without impairing the ecosystem function?

In contrast to biodiversity conservation issues, where the focus of conservation is clearly laid on specific species to be protected, it is less clearly defined how many and which species provide a specific ecosystem service (see section 4.4.2). One of the most important ecosystem services provided by arthropods in agricultural landscapes is the biological control of arthropod pests within crops fields (Kruess and Tscharntke, 1994; Wilby and Thomas, 2002; Kremen, 2005; Tscharntke *et al.*, 2005). A crucial question when determining what represents environmental damage in this context is thus whether certain species may be lost without impairing the ecosystem function as the species are redundant (Question 9 in Figure 3). This leads to the question as to whether there is a functional relationship between species diversity and ecosystem function, that is, whether more species generally lead to more stable ecosystem services. Available data show that species richness often seems to be not so important for agroecosystem function, as even only one or a few species might ensure a particular function (Hooper *et al.*, 2005; Moonen and Barberi, 2008; Shennan, 2008) (see section 4.4).

There is nevertheless convincing evidence that species-rich systems deliver ecosystem services more reliably than species-poor ones. This is because in diverse communities, redundancy among species can buffer processes in response to changing environmental conditions and species losses. Ecosystem services typically do, however, often not depend on the presence of specific species, especially not rare, narrowly distributed species. They more likely depend on common and widespread species than on rare species (Diaz *et al.*, 2006; Maclaurin and Sterelny, 2008). From a functional point of view, reductions in population size of a redundant species may thus be tolerable and be of no concern if the function is fulfilled by other species. In case a species is not redundant, one has to determine the magnitude and the spatial extent of the impact to evaluate whether its loss constitutes environmental damage (Question 10 in Figure 3).

7.3.3.1 Consider magnitude of effects

The factors to be considered when taking into account the magnitude of effects on ecosystem services are principally comparable to those relevant for biodiversity conservation issues (see Table 4) as functions are ultimately also carried our by specific species groups.

Question 9: Is there a relevant effect on an ecosystem service?

Potential ecological damage on ecosystem functions occurs if there is a relevant impact on population level of a nonredundant species responsible for a particular ecosystem service. This is essentially the case if local reductions in population size are not buffered in due time by migration from other populations occurring in nearby habitat patches. Changes in ecosystem functions are usually difficult to assess as the precise nature of a particular function is often unknown. It is, for example, often not known how much a particular species contributes to a specific function such as biological control of pest species. In contrast to biodiversity conservation issues, where population reductions of valued species can normally be assessed directly, ecosystem functions usually have to be assessed indirectly. By analyzing the general state of ecosystem functions, one obtains a more accurate indication whether functional biodiversity is affected. An indirect survey can be performed by recording an indicator able to demonstrate a failure in the function. Failures in biological control functions, for example, can be assessed more accurately by observing unusual pest outbreaks rather than by monitoring specific groups of natural enemies (Sanvido *et al.*, 2009).

If there is no relevant effect on population level of a nonredundant species responsible for a particular ecosystem service, there is no environmental damage. In case there is a relevant effect, it has to be determined whether resilience is possible to avoid environmental damage.

Question 10: Is resilience possible?
In case a relevant impairment of an ecosystem function occurs, one has to determine whether the reduction may be able to recover within a certain period of time (Question 11 in Figure 3). Local resilience thereby depends strongly on the ability of organisms to recolonize from neighboring habitat patches (i.e., on the distance to the nearest suitable habitat and the dispersal capability of the organisms in questions) (Swift *et al.*, 2004). The time period allowed for resilience has still to be defined. Definitions could, for example, be based on the standards that are applied for plant protection products. For pesticide applications, the potential for recovery after a toxic effect was observed should possibly occur within one year after application (Candolfi *et al.*, 2000; European Commission, 2002).

Question 11: Is it possible to mitigate the risk for a particular ecosystem service?
In case resilience is unlikely to occur within the defined time period, the last step when evaluating environmental damage is to determine whether a relevant risk for a particular ecosystem function can be mitigated by appropriate risk management measures (Question 12 in Figure 3). In case mitigation is possible, the risk is of no concern whereas otherwise it has to be regarded as environmental damage.

7.3.4 Open questions resulting from the discussed case study of Bt-maize

The initial question of this section was how impacts of different agricultural management practice could be compared to determine a baseline that can serve as a comparator. The baseline would ultimately allow regulatory decisions whether the impacts of the GM cropping system are lower, equal or higher than those of current practices. The analysis showed that it is almost impossible to perform a generic, easily applicable comparative impact assessment of different pest management practices. Impacts of cropping systems depend on a variety of different factors that can only be assessed on a case-by-case basis. A generic comparison is moreover complicated by the fact that the impacts of different pest management practices are either not regulated or regulated based on different regulatory frameworks. This leads to the somehow irrational situation that the same impacts may be judged differently depending on what pest management practice caused them. This contradicts the initial assumption that the baseline for any evaluation of damage from GM crops is legally set by what is already regarded representing damage today. In our opinion, this dilemma is one of the most important open question that has to be resolved when discussing what baseline has to be considered when evaluating environmental impacts of GM crops. As long as pest management practices having similar impacts on the environment are regulated differently, it will not be possible to find a reasonable solution to determine a baseline suitable for regulatory decision-making of GM crops. This dilemma is particularly incoherent when considering that the use of broad-spectrum insecticides is generally known to have wider environmental impacts than the use of Bt-maize (Romeis *et al.*, 2008b; Wolfenbarger *et al.*, 2008; Naranjo, 2009).

The first question that arises from the present case study is whether the risks of the different pest management practices for biodiversity should be evaluated based on their specific impacts on single groups of species or based on an overall sum of impacts. A comparison based on the overall sum of impacts on biodiversity might actually be useful in practice to allow decision-makers comparing the ecological footprint of different agricultural management practices, but current legislation does often not allow decisions based on averaged risk. Regulatory decisions are usually based on absolute risks, meaning that if a technology is harmful it will not get approval because another technology is more harmful. Similarly, risks are not averaged – a technology does not obtain approval just because there is no risk for certain groups of organism if there is a high risk for other groups of organisms. The case study is thus probably more relevant for a comparison of the ecological impacts of different crop protection methods on a particular group of organisms than for a comparison of the overall risks.

Second, the question arises as to what agricultural management practice is to be considered as a comparator when performing such an evaluation for Bt-maize. One could argue that a "no treatment" scenario would be an appropriate baseline considering that only a small percentage (approx. 5–20%) of the maize area in Europe is sprayed with insecticides against the ECB and 5% is treated with *Trichogramma* (see section 7.2.1). However, this argument is in our opinion not a logical rationale supporting a "no treatment" scenario as a realistic baseline since the fact that approximately 75% of the maize area is not treated against the ECB is primarily an economic decision taken by farmers. This decision is often due to ECB damage remaining below the economic injury level and technical difficulties to apply insecticides in tall maize. This results in a lack of profitability of the control methods available. Since farmers would have the option to use approved insecticides or *Trichogramma*, these should also be used as a comparator for a current management practice.

CHAPTER 8

A SECOND BASELINE APPROACH – DIFFERENTIATING EFFECTS OF DIFFERENT WEED MANAGEMENT PRACTICES IN MAIZE

8 A SECOND BASELINE APPROACH – DIFFERENTIATING EFFECTS OF DIFFERENT WEED MANAGEMENT PRACTICES IN MAIZE

8.1 Differences to the case study with Bt-maize

The aim of the second case study is to determine the bases and criteria for regulatory decisions in the case of noninsecticidal GM crops. The main question is: what differentiates regulatory decisions for noninsecticidal plants from those for insecticidal plants such as Bt-maize? In contrast to Bt-maize, where direct effects as a result of the toxicity of the insecticidal compound are a main point to consider, the assessment of the toxicology of the genetic modification is not the primary concern for noninsecticidal GM crops. Rather than expressing a specific toxin in the crop, the genetic modification allows cultivating the crop under a different agricultural management, which may lead to indirect impacts on farmland biodiversity. In the following, genetically modified herbicide tolerant (GMHT) maize is taken as an example for a GM crop where the main focus is to determine the consequences of changes in agricultural management practice. As in case study 1, the environmental impacts of current agricultural management are the basis for regulatory decisions on GHMT maize. Here, this includes comparing the environmental impacts of current weed management practices in maize with those caused by weed management practices associated with GMHT maize.

8.2 Case study 2: Effects of GMHT maize on farmland biodiversity

8.2.1. Environmental impacts of different weed management practices in maize

Damage in maize by weeds

Weeds are the most important pest group in maize in temperate climates where the potential loss without crop protection due to weeds is estimated to be higher than the sum of potential losses due to animal pests, pathogens and viruses (Oerke, 2006). Mainly due to low competitiveness of young maize seedlings, actual losses to weeds (despite weed control) average 5% in Western Europe. Without weed control, estimated losses might average up to 40%.

8.2.1.1 Current weed management practices in maize in Europe

All weed management practices in every cropping system aim at obtaining, as far as possible, a weed-free field during the critical growth stage. As this is often difficult to achieve, farmers aim at keeping weeds below a certain economically acceptable threshold level. Weed control in maize is always necessary in temperate climates during the critical growth stage. Since maize develops slowly after seeding in comparison to native weeds, the crop has to be protected from weed competition between the 2- and 8-leaf stages to prevent yield losses (Ammon, 1993; Häni *et al.*, 2006; Dewar, 2009). Weeds may be controlled by mechanical weeding and / or by the use of synthetic herbicides. Weed control in conventional maize cultivation typically includes tillage prior to sowing and usually up to two pre- and post-emergence herbicide treatments. In Switzerland, for example, approximately 85% of the conventional maize area is ploughed prior to sowing, while only 15% are cultivated using conservation tillage practices (Häni *et al.*, 2006).

8.2.1.2 Hazards of current weed management practices in maize

Conventional weed management practices in maize are usually based on using an herbicide mix containing a combination of three to four active ingredients (Devos *et al.*, 2008; Dewar, 2009). This allows farmers to establish locally adapted herbicide regimes that consider the weed species present, as well as soil type and conditions.

Direct toxic effects of herbicides

Although there have been herbicides that were toxic to humans and dangerous to handle for farmers, most of these products are no longer used in European agriculture and they have been replaced by newer products. Many newer herbicides used in conventional maize possess little or no direct toxicity to mammals, birds, earthworms, bees and beneficial arthropods as herbicides target highly specific biological or biochemical processes within plants. Some of the herbicides used in conventional cropping systems may show direct toxic effects on aquatic organism.

Indirect effects of herbicides

The intensive use of herbicides may promote a number of indirect environmental effects such as the development of resistances in weeds, the enhancement of soil erosion and the contamination of surface water. These concerns are however independent from the use of either conventionally bred or GMHT varieties, but a result of the herbicide regime applied.

Impacts of tillage on soil

Most farmers use tillage (ploughing) to prepare the soil for planting. Excessive tillage, however, is known to cause soil structure changes, increase the susceptibility to soil erosion and reduce soil moisture. Loss of top soil due to tillage may cause environmental degradation that can last for centuries. Ploughing is also known to be the most destructive cultivation method affecting invertebrate populations through physical destruction, desiccation, depletion of food and increased exposure to predators (Stoate *et al.*, 2001).

8.2.1.3 Weed management using GM herbicide-tolerant maize

Genetically modified herbicide-tolerant (GMHT) crops permit the use of broad spectrum herbicides such as glyphosate (Roundup Ready®) or glufosinate-ammonium (Liberty®) at the postemergence phase. Growing GMHT crops allows growers to use one broad-spectrum herbicide controlling a wide range of both broadleaf and grass weeds instead of several herbicides. GMHT maize is presently primarily cultivated in the United States. Up to a few years ago, GMHT maize varieties only accounted for about 10–20% of the U.S. maize acreage mainly because GMHT varieties were not available in many of the most popular hybrid varieties and as these varieties were not approved for import into Europe (Gianessi, 2005). Slower adoption of GMHT maize may also have been due to the fact that many farmers are able to control weeds in maize by conventional weed management at moderate costs. Farmers using GMHT maize varieties generally have difficult-to-control weed problems that require more costly programs, especially as conventional herbicide regimes may not always provide consistent season-long control. With the increasing adoption of stacked GM maize varieties in the U.S., the use of GMHT in combination with insect-resistance is growing. In the European Union, GMHT maize is currently not approved for commercial cultivation, but several applications are pending. Several GMHT maize events are approved for importation into the EU as food and feed.

A similar herbicide regime as with GMHT maize can be applied when using Clearfield® maize varieties that are tolerant to the broad-spectrum herbicide imidazolinone. Given that these varieties have been developed by traditional breeding, the use of these varieties is however not specifically regulated as for GM crops.

8.2.1.4 Concerns associated with GMHT maize

The use of broad-spectrum herbicides along with the cultivation of GMHT crops raises three main concerns:

Potential shifts of weed populations resulting in impacts on farmland biodiversity

Broad-spectrum herbicides allow a more efficient control of a very wide spectrum of weeds. This could lead to a decline in the long-term persistence of arable weed seeds in the soil. Invertebrates, small mammals and seed-eating birds might thus be threatened by reduced food resources. Whether any such trend becomes apparent depends upon the management of all crops in a given crop rotation. Although herbicide management may have an impact on arable biodiversity, crop type and sowing season have a far greater impact on the functional composition of plant and invertebrate communities in arable systems (Hawes *et al.*, 2003).

Selection of resistant weeds by intensive herbicide applications

Rotating GMHT crops resistant to herbicides having the same mode of action and/or applying glyphosate or glufosinate-ammonium at multiple occasions during the growing season highly intensifies the selection pressure on weeds and favors resistance development. However, numerous weed species have evolved resistance to a number of herbicides long before the introduction of GMHT crops. The experiences available from regions growing GMHT crops on a large-scale confirm that the development of herbicide resistances in weeds is not a question of genetic modification, but of the crop- and herbicide management applied by farmers.

Increased herbicide use

There are many criticisms arguing that the adoption of GMHT crops would generally lead to an increased use of herbicides. Studies can be found to support this view (Benbrook, 2001, 2003), but there appear to be more studies supporting a small, but statistically significant reduction in herbicide use as a result of the adoption of GMHT crops (Carpenter *et al.*, 2002; Fernandez-Cornejo and McBride, 2002; Brimner *et al.*, 2005; NRC, 2010). Because the reduction varies between crops and regions, it is however difficult to draw a general conclusion.

8.2.1.5 Uncertainties related to the environmental impacts of GMHT maize

As no GMHT maize has been approved for commercial cultivation in the EU, there are currently theoretical experiences on how weed management in Europe would change under real agricultural conditions (Devos *et al.*, 2008; Dewar, 2009). Environmental impacts due to crop management changes are usually difficult to assess because they are often caused by many interacting factors and do only show up after an extended period of time. Considering the widespread effects modern agricultural systems had in the last decades, changes in management practices are probably among the most influential factors that could lead to biodiversity changes. It is, however, crucial to bear in mind that management changes are not limited to the adoption of GMHT crops. They do occur in any (non-GM) crop management strategy, and could also be caused by the adoption of new pesticides, cultivation techniques or crop varieties.

8.2.1.6 Potential environmental chances of growing herbicide-tolerant crops

Mitigation of negative environmental impacts of soil tillage

The negative environmental impacts caused by tillage operations can be mitigated by the application of conservation tillage. GMHT varieties facilitate farmers to adopt conservation tillage practices (Dewar, 2009; NRC, 2010). Since weed control can be done during the postemergence phase, there is no need for pre-seeding tillage and direct-seeding techniques can be applied. These conservation tillage practices leave a layer of plant residues on the soil surface, preventing soil erosion, reducing evaporation and increasing the ability of the soil to absorb moisture. A richer soil biota develops that can improve nutrient recycling. Earthworm populations are generally higher in no-till fields than in ploughed fields. There is also evidence that conservation tillage can provide a wide range of chances to farmland biodiversity by improving agricultural land as habitat for wildlife (Holland, 2004). The greater availability of crop residues and weed seeds can improve food supplies for insects, birds, and small mammals. In addition to a reduction in soil erosion and degradation, less frequent soil cultivation also results in a decrease in the emission of greenhouse gases, partly arising from a reduction in fuel use (Brookes and Barfoot, 2005; Burney and Lobell, 2010).

Lower toxicity of the herbicides used with herbicide-tolerant crops
Although new herbicides show a relatively low toxicity, glyphosate and glufosinate ammonium are less toxic to human health and the environment compared to the replaced herbicides. In addition, they do not move readily to ground water, resulting in fewer losses of chemicals by leaching and run-off from the field (Duke, 2005; Fernandez-Cornejo and Caswell, 2006; Devos *et al.*, 2008; Dewar, 2009).

8.2.2 A risk assessment approach for GMHT maize

Discussions among participants of the second expert workshop showed consensus that there were no fundamental differences in how to approach a risk assessment for GMHT maize and Bt-maize apart from the problem formulation that has to consider indirect effects for GMHT maize as well. An environmental risk assessment of GMHT crops thus raises two major concerns: (1) direct toxic effects and (2) indirect food web effects.

8.2.2.1 Direct toxic effects of GMHT maize

Two types of direct toxicity have to be considered related to GMHT crops: (a) effects resulting from the genetic modification due to the expression of a novel protein enabling the herbicide tolerance and (b) toxic effects caused by the herbicide applied.

Effects caused by the novel protein: Tolerance to glyphosate is enabled by the introduction of a gene coding for 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from *Agrobacterium* sp. As EPSPS enzymes occur in a wide range of plants and fungi, and in some microorganisms, humans and the environment have a long history of dietary exposure to these proteins. No adverse effects have been reported with their intake (EFSA, 2009b). The same applies for the gene coding for PPT-acetyltransferase (PAT) that is responsible for tolerance to glufosinate-ammonium. The PAT gene was originally isolated from *Streptomyces viridochromogenes*, an aerobic soil actinomycete. The PAT enzyme is therefore naturally occurring in the soil and there are extensive studies showing the safety and specificity of this enzyme.

Toxic effects caused by the herbicide applied: There is currently a debate among different regulatory bodies in the EU under what regulation direct effects of the herbicides used with GMHT crops have to be assessed. In principle, both

Directives 2001/18/EC (European Community, 2001) and 91/414/EEC[29] (European Commission, 1991) are relevant for the risk assessment of GMHT crops. The registration and use of herbicide active ingredients in the EU is an issue for Directive 91/414/EEC. The environmental risk assessment of pesticides includes an assessment of impacts on certain nontarget organisms (such as fish, Daphnia, algae, birds, mammals, earthworms, bees and beneficial arthropods and nontarget plants) and studies of residual activities in soil and water (EFSA, 2009b). Where herbicides are used as integral parts of biotechnology-based weed management strategies, the ERA must also consider their impact on biodiversity under Directive 2001/18/EC. These impacts, however, primarily relate to changes in agricultural practice resulting in impacts on farmland biodiversity that may be classified as indirect impacts (see section 8.2.1).

With regards to direct toxic effects of the herbicides used with GMHT crops, participants of the second expert workshop agreed that there was no need to retest an active ingredient that had been approved under Directive 91/414/EEC. This finding is in agreement with the recommendations made by the European Food Safety Authority (EFSA, 2009b).

8.2.2.2 Indirect impacts of GMHT maize on farmland biodiversity and food webs

Probable changes in weed management practices due to the adoption of GMHT crops inevitably raise concerns on indirect impacts on farmland biodiversity, especially as modern agricultural systems had considerable negative impacts on global biodiversity in the past. The widespread use of herbicides in agriculture, for example, has resulted in a landscape in which many fields have very few weeds and very few invertebrates providing little food for birds. This shift in the type and density of weeds in the fields was partly responsible for the remarkable decline in both plant and animal biodiversity in many farming areas (Krebs *et al.*, 1999; Chamberlain *et al.*, 2000; Robinson and Sutherland, 2002). Additional influencing factors include the crop cultivated as well as the crop rotation applied. In the UK Farm Scale Evaluations (FSE), for example, differences in biodiversity between crops exceeded differences between GMHT crops and conventional crops (Hawes *et al.*, 2003). Weeds and some invertebrate groups were, for example, more abundant in oilseed rape (both GMHT and conventional) than in sugar beets or maize.

In view of an environmental risk assessment that aims to address changes in management practice, one must recognize that farming systems are highly dynamic and that environmental impacts are caused by a wide range of agronomic

[29] A new legislative framework on pesticides was adopted in October 2009 by the European Parliament. The Council. Regulation (EC) No. 1107/2009 repealing Directives 79/117/EEC and 91/414/EEC came into force in June of 2011.

and environmental factors. These may vary from region to region and be subject to changes over time. Discussions during the second expert workshop showed that participants judged the assessment of weed shifts and the estimation of subsequent consequences for farmland biodiversity to be very difficult. In particular, field studies restricted too few sites and sampling years may not provide sufficient data to draw conclusions on the ecological relevance of changes occurring at the field scale over several years. The obtained data may thus not automatically be extrapolated to the landscape level. Most participants agreed that performing a meaningful risk assessment enabling a proper characterization of the impacts of herbicide regimes associated with GMHT crops on biodiversity is not practicable within the time limits given by a regulatory approval process. The apparent limits of the environmental risk assessment necessitate thus considering additional options how potential declines in farmland biodiversity due to the adoption of GMHT crops could be mitigated (such as, setting up appropriate risk management measures).

8.2.2.3 Risk management options to mitigate declines in farmland biodiversity
When discussing appropriate risk management options to mitigate declines in farmland biodiversity, it is important to recognize that the loss of more specialized taxa has been a major factor responsible for the decline in farmland biodiversity over the last decades (Robinson and Sutherland, 2002). Many bird and butterfly species that declined markedly in the period prior to 1970 were dependant on areas of extensive low-input cultivation or on the presence of non-cropped habitats. Butterflies as well as bird species now typical of farmland in Western Europe are those that tend to be habitat generalist. More intensive field management, degradation in habitat quality (such as the disappearance of large stretches of hedgerows), and increasing habitat homogeneity (across all-scales) are currently the most important drivers of biodiversity loss.

Regulatory authorities may consider the retention of arable weed populations in crop fields to be a protection goal since weeds are considered to play a role within agroecosystems in supporting biodiversity (Marshall *et al.*, 2003). The promotion of weeds to support farmland biodiversity nevertheless represents a certain conflict since farmers are naturally predisposed to see weeds as pests. They thus tend to keep weeds below certain densities in every agricultural management practice to avoid reduced yields or harm to the harvested product. On the other hand, in many European countries, large areas are dominated by human activities and the conservation of species and communities within the farmed landscape is an emerging paradigm (Marshall *et al.*, 2003). As the management of weeds to support biodiversity inevitably involves the risk of reducing crop yield and the build-up of problematic weeds, there is a need to find a balance between adequate weed control and the opportunity to retain some plants to support biological diversity. One proposal is to manage low populations of "beneficial" weed species, which could provide a low level of competition with the crop and have value as a resource for higher trophic groups (Marshall *et al.*, 2003; Storkey and Westbury, 2007).

The choice of appropriate assessment and measurement endpoints (see section 5.2) is crucial for an environmental risk assessment addressing consequences of changes in weed management practice. Ultimately, it has to be agreed on how many weeds we want to have in arable fields, recognizing that farmers do not aim at having as less weeds as possible in the field, but at obtaining as much yield as possible. Indirect effects on farmland biodiversity to a great extent depend on the agricultural management applied and impacts can be mitigated by good stewardship programs. The goal of risk mitigation measures aiming at promoting an ideal weed management should be to avoid the risk of reduced crop yields and the long-term build-up of problematic weed communities. Two risk management options could be envisaged that would help to achieve a balance between agricultural production and support of "desired" weeds in arable fields:

1. A relatively unspecific option tolerating a certain level of weeds in arable fields. This could be achieved by three approaches:
   a. A spatial approach separating arable fields into a zone of intensive agricultural production and zones of conservation headland[30] where no (or reduced) herbicide use would be allowed. Zones of conservation headland would represent zones of "cultivated wildlife" while zones of intensive production would allow to use herbicides without restriction (provided they are used according to the legal specifications). Conservation headlands could be located on field margins and corners considering that these areas tend to be less productive in terms of crop yield, but have higher weed abundance and diversity (Storkey and Westbury, 2007).
   b. A management approach based on band-spraying that allows choosing an optimal application time of the herbicide depending on the weed pressure. This reduces the number of herbicide sprays, which results

[30] Conservation headlands denote a zone located within the arable land. They thus differ from uncropped areas outside the arable land such as field margins and set-aside land. Annual weeds growing on conservation headlands usually depend on regular disturbances; they may, for instance, support a different fauna than vegetation covers on uncropped land dominated by perennial species (Pidgeon *et al.* 2007) .

in environmental chances compared with the conventional practice. Depending on the herbicide management chosen, it can either enhance weed seed banks and Autumn bird food availability, or provide early season chances to invertebrates and nesting birds (Ammon, 1993; Dewar *et al.*, 2003; May *et al.*, 2005).

c. A technical approach of leaving a proportion of rows of arable fields unsprayed to promote the growth of flowering and seedling arable weeds (Pidgeon *et al.*, 2007). Model calculations for GMHT sugar beets, for example, have shown that leaving one row in every 50 unsprayed would achieve a weed seed production equivalent to current conventional practice.

2. A more specific option aiming at managing low populations of "beneficial weeds" in the field. Beneficial weed species are characterized by a low level of competition with the crop and by having a potential value as a resource for higher trophic groups (Storkey and Westbury, 2007). Under standard weed management practices, such less competitive annual broadleaf plants tend to have a selective disadvantage compared to competitive perennial species including many grass weed species.[31] Grass weed species tend to be relatively poor resources for higher trophic groups. Lists of beneficial weed species showing a positive number of associated insect species, being part of the diets of farmland birds and showing a low to moderate competitive ability with crops have been published (Marshall *et al.*, 2003). Weed management practices can be adapted to promote beneficial weeds by relying on selective herbicides that control grass weed infestations while leaving most broadleaf species (Storkey and Westbury, 2007).

8.2.3 Application of the proposed approach

The above mentioned considerations show that one of the main challenges for an ERA of GMHT crops is developing a meaningful problem formulation. In contrast to an ERA for an insecticidal crop such as Bt-maize, where the risk consists in more or less probable adverse effects on other organism than the target pest, the range of indirect impacts on farmland biodiversity that could occur due to the adoption of GMHT crops is very large. This makes it difficult to formulate clear risk hypotheses that could be tested, especially as the conceivable impacts are often more or less vague concerns than risks in the pure sense of the term. At least from an ecological point of view, performing a

[31] The shift from broad-leaf weed species to grass weeds has furthermore been favored by the shift from Spring to Autumn sowing dates due to the planting of Winter cereals (Storkey and Westbury 2007).

meaningful characterization of the impacts on farmland biodiversity resulting from the adoption of GMHT crops is thus very challenging within an environmental risk assessment. As the risk cannot be adequately assessed prior to approval of the GM crop, the establishment of the proposed risk mitigation measures appears to be a valid option. Considering that all weed management practices have widespread impacts on farmland biodiversity, it would however be irrational from a scientific point of view to make such measures only mandatory for the cultivation of GMHT crops. The question remains thus whether agricultural policies should attempt to make such measures binding for all cropping systems or whether the conditions imposed for GMHT crops should be similar to those imposed on conventional herbicide regimes. Ideally, similar risk mitigation measures should be mandatory for all herbicide regimes used in any agricultural cropping system independent of the use of GMHT crops. If the final aim is to protect the environment from harm, there are no convincing arguments in favor of applying a more stringent regulation for one particular technology if a similar technology might result in similar environmental impacts.

The classical toxicological testing approach derived from pesticide testing shows limitations as soon as potential effects are not linked to specific toxic compounds present in the crop, but to changes in the agricultural management practice that result from the adoption of the novel crop. These limitations clearly become apparent for noninsecticidal crops such as GMHT maize where changes in management practice may have much more substantial impacts on farmland biodiversity than the pure toxicity of the protein enabling the herbicide tolerance. One possibility to assess changes in management practice can be to perform a broader comparative risk assessment that considers and balances the impacts of existing and new agricultural management practices. Performing such a comparative risk assessment necessitates new multicriteria approaches such as the Comparative Sustainability Assessment proposed by the UK Advisory Committee on Releases to the Environment (ACRE, 2007), the qualitative multiattribute model DEXi (Bohanec *et al.*, 2008) or methods used for Life Cycle Assessments (Bockstaller *et al.*, 2009). Multicriteria approaches are particularly relevant considering that the adoption of GMHT crops might have environmental chances when compared to current non-GM weed management regimes (see section 8.2.1). In addition to chances for farmland biodiversity (due to the adoption of conservation tillage practices), chances may also be relevant for other environmental compartments such as soil and water (e.g., lower toxicities of the herbicides used with GMHT crops) or air (e.g., decreased emissions of greenhouse gases as a result of less frequent soil cultivation with machinery and less fuel use).

Multicriteria approaches might be a meaningful way of allowing assessing changes in management practices that may not only bear risks, but also offer environmental chances. The circumstances describing when risks may be balanced with chances will be elaborated in more detail in the following section as this question depends on the ethical conception underlying the relevant legal frameworks. The question is also closely linked to the conception of using thresholds in decision-making. Thresholds are needed from a legal perspective in case the law follows a deontological approach, which is, for example, the case for the legal frameworks regulating the use of genetic engineering in Switzerland.

Multicriteria approaches may also prove to be relevant if decisions require trade offs between different protection goals belonging to other environmental compartments than biodiversity. How to deal with conflicting protection goals will also be elaborated in the following section.

CHAPTER 9

ETHICAL REFERENCE SYSTEM TO ASSESS BIODIVERSITY

9 ETHICAL REFERENCE SYSTEM TO ASSESS BIODIVERSITY

9.1 The deficiencies of the Ethical Matrix

In the first workshop, the Ethical Matrix was proposed as a tool to find applicable criteria for environmental damage (Figure 4). The discussions during the workshop showed that this approach was not convincing as it had operational limits. However, the reason for these operational limits became not quite clear during the first workshop. In order to find an alternative, more promising approach, it is important to figure out the weaknesses of the Ethical Matrix, especially with regard to the main aim of the project, which is to find practicable criteria to evaluate environmental impacts of GM crops on biodiversity.

The aim of the Ethical Matrix (EM) as developed by Mepham and colleagues is *"to help decision-makers (…) reach sound judgments or decisions about the ethical acceptability and/or optimal regulatory controls for existing or prospective technologies in the field of food and agriculture"* (Mepham *et al.*, 2006). The main reasons why the Ethical Matrix proves unsatisfactory according to our opinion are the following:

- The EM has no plausible answer to the question why the ethical principles listed in the matrix should be selected. Proponents of the EM would reject this objection arguing that the answer is given by moral common sense or common morality. From the point of view of common morality, they claim, it is uncontroversial that principles such as benefit, harm, fairness, dignity and naturalness belong to the matrix. The notions "moral common sense" and "common morality" refer to the pretheoretical ethical beliefs shared by a majority of people. These beliefs are also called intuitions. Intuitions, however, do not have any normative force – contrary to what the proponents of the EM assume – as they are just the product of history, culture and upbringing. That is why these beliefs cannot take on a justificatory function.[32] Thus, even if it may seem obvious to most people, for instance, that dignity is a fundamental ethical principle, this does not justify putting dignity on the list of ethical principles. Whether it really is such a principle can only be determined by theoretical reflection. On a theoretical level, however, there is disagreement as to whether dignity is a valid ethical principle or not. This applies even more to a value such as naturalness. The principles chosen therefore should be the principles vindicated by the most plausible systematic normative ethical theory. That means that the EM is not even a good starting point for ethical deliberation.[33]

[32] This is a systematically important point at which the approach chosen in this project differs from the influential theory of Beauchamp and Childress (2001) on which the proponents of the Ethical Matrix base their approach.

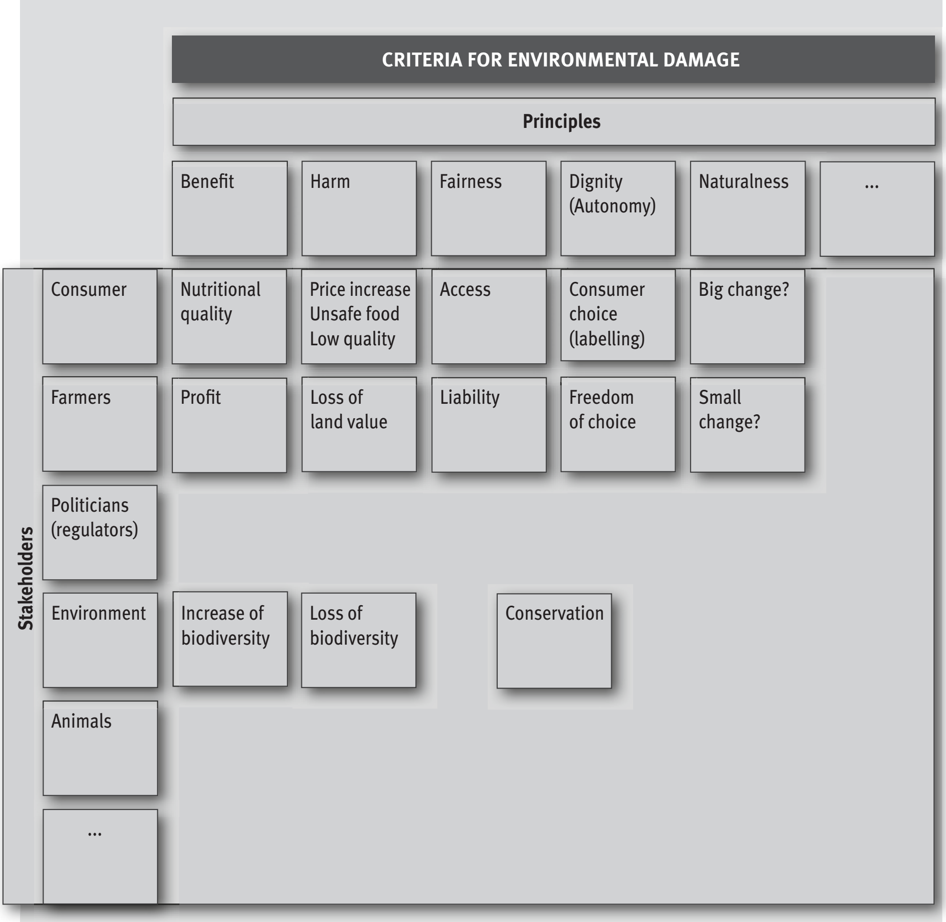

Figure 4: Ethical Matrix proposed during the first expert workshop describing how criteria for ecological damage could be approached.

- Even if all the ethical values or principles on the list were accepted as sound ethical values, the EM would be of no practical assistance in reaching ethically justified decisions. In this case, decision-makers would have a list of moral principles and some indication how these principles could be specified regarding the ethical issue at hand. However, the EM does not give them any assistance in determining their relative normative weight. This becomes especially clear

[33] In other words, the EM as a tool or framework does not dispose of the means required to reach its declared goal: "(…) to facilitate ethical assessments and decision-making" (Beekman *et al.* 2006). This objection persists even if it is granted that the EM is "not designed to replace ethical judgement" or to calculate "a best ethical option" (Beekman *et al.* 2006)

in cases of conflict. If, for example, benefit and autonomy collide, what should the decision-makers decide? The EM remains silent about this. The correct answer is: it depends on the normative background theory. A deontologist (see section 9.3.2), for instance, would argue that autonomy must be respected even if by disrespecting it, the net benefit could be increased. A consequentialist (see section 9.3.1), on the other hand, would argue that autonomy should not be respected if this leads to an increase of the net benefit. Again, this means that we must resort to established systematic normative ethical theories such as consequentialism or deontology in order to determine the significance or weight of a moral principle – something that the EM seeks to avoid at all costs.[34] The proponents of the EM try to solve the problem of weighing by claiming that the moral principles on the list are *prima facie* principles, that is, principles that although they are generally valid may be overridden in specific cases (Mepham *et al.*, 2006). However, this is no solution as it leaves open which principle may be overridden in which case. For this reason, the EM as a tool does not have the resources necessary to enable well-considered moral judgments.

- There is a further reason why the EM is not a useful tool within the context of this project. The aim of the project is to develop ethical and ecological criteria for regulatory decision-making regarding the risks of GM crops for biodiversity. Regulators do not have a legislative, but an executive function. Their task is to apply the democratically adopted law. The application or implementation of the law, however, is not itself a democratic process in the sense that decisions must be based on the different (scientific or ethical) viewpoints one finds in a pluralist society. If a law such as the Swiss Federal Law relating to nonhuman Gene Technology demands a scientific risk assessment in order to determine the risks of a release of GM plants, the competent authorities must ensure that such an assessment is carried out. What is required in this respect is sound science and not democratic consideration of different viewpoints and interests. Science is truthoriented. It requires special skills and knowledge. This is why specially trained people are needed to perform scientific risk assessments. These people are experts in their field. Decisions concerning risks should therefore be based on their expertise. The same applies to ethics, which is a science like any other science. Thus, if ethics plays any role in the implementation of a law, what is required is ethical expertise.[35] This implies giving concrete answers to concrete questions and not just proposing an ethical framework for

[34] The reason being that these theories supposedly cover only one aspect of common morality – which the proponents of the EM regard as the normative foundation of all morality – and are thus inadequate if they claim to be allencompassing theories.

decision-making such as the EM. As far as risk assessment is concerned, ethics could either clarify on which ethical theory or theories the legal criteria for acceptable risks are based or it could contribute to developing clearer and more concrete criteria for acceptable risks. The former would help regulators to better understand the normative basis of their decisions. The latter would help them to better justify and improve the quality of their decisions.

This critique of the EM, based on a scientific – and therefore fallibilistic – conception of ethics, was the starting-point for preparing the second workshop. The conclusions to be drawn from the failure of the EM to deliver what was originally hoped for are clear. In order to develop ethical criteria for regulatory decision-making regarding the question of acceptable risks of GM crops for biodiversity, one must proceed as follows:

- Systematically develop possible ethical criteria for assessing changes in biodiversity and evaluating the risks of biodiversity loss in agriculture.
- As these criteria are theory-based, the next step is to choose the most plausible systematic normative ethical theory and spell out what this entails for the acceptability of risks of biodiversity changes in agriculture.
- Apply these criteria to the issue of evaluating environmental impacts of GM crops on biodiversity (in the context of a comparative risk assessment).

The time-consuming first step was taken before and during the second workshop. Special care was taken to formulate all systematically relevant ethical options of assessing changes in biodiversity and the risks associated with it. The result is a new "ethical matrix" which, as the discussions during the second workshop clearly showed, does not only have the advantage of systematic completeness. It also allows regulators to find out for themselves which normative ethical theory they favor. Moreover, it helps them understand which ethical theory or ethical considerations underlie the legal regulations on which they base their decisions.

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[35] One could raise the objection that ethical considerations taking place within the law, as it were, must take into account the "fact of pluralism," that is, the need to recognise a multiplicity of perspectives in the ethical debate, in the sense that none of the pertinent theories can simply be dismissed as irrational. This objection could be justified by arguing that a modern constitutional state cannot be guided by the fundamental ethical principles of one specific ethical theory. Instead it is required to listen to the different standpoints in order to base its own activity on a minimum ethical consensus. This is the only way that the state can avoid being in thrall to particular groups and preserve its ideological neutrality. This argument, however, is not plausible. If ethical reflections are a part of the executive process, there is no point in demanding that the regulatory authorities should strive for a minimal consensus. Rather, the aim should be to ensure that the best possible arguments prevail. For this reason, the authorities involved should base their decisions on expert opinion, that is, on the expertise of professional ethicists.

This ethical reference system is science-based. It is therefore rather demanding and can only be useful to nonexperts if they are carefully instructed and accompanied by professional ethicists at least during the first stage of the process. Ethicists must explain the basic theoretical approaches and they must point out the implications of these approaches. The latter is especially important in order to enable regulators to take a well-considered decision as to which theory they favor. Here is one example: at the beginning of the discussion, many participants of the second workshop declared themselves to be ecocentrists. Most of them changed their minds when they realized that in order to be ecocentrist, one must accept, for instance, that biodiversity is a real entity that is not just instrumentally, but intrinsically valuable, that is, valuable for its own sake. Furthermore, many participants were not aware that for ecocentrism, ecosystems are real, intrinsically valuable entities as well. Favoring such a point of view has far reaching consequences as it implies that biodiversity and ecosystems must be taken into account morally independently of their instrumental value for human – or other living – beings. That does not refute ecocentrism, but it shows that someone calling himself an ecocentrist must be willing to accept these consequences.

9.2 Introduction to the ethical reference system

In order to better understand the ethical reference system (ERS) to assess biodiversity[36] changes (see Table 6), some introductory remarks are given. From an ethical point of view, the concept of biodiversity (as an important protection goal) can only be operationalized if its normative status has been determined. This is not a scientific, but an ethical or axiological issue. The question to be answered is what kind of value should be assigned to biodiversity. The ethical theories listed in the ERS answer this question differently. To give some examples:

- According to deontological anthropocentrism, biodiversity has a purely instrumental value: it is only valuable for farmers insofar as being part of their capital, but does not have any other value. From this perspective, it does not make sense to claim, for example, that certain species should be protected for their own sake. The approach thus rejects the view that Red List species are an entity to be protected as such. This implies that the extinction of Red List species is not per se a harm.

[36] A definition of the concept of biodiversity is given in section 4.2.

- As there is no moral right to enjoy the *beauty* of a species, aesthetic reasons play no role in deontological anthropocentrism. The value of rare species for human beings is part of consequentialist anthropocentrism.
- At the other end of the theoretical spectrum, one finds ecocentrism. According to this position, biodiversity is a real entity that can be damaged as such because it is intrinsically valuable, that is, valuable for its own sake. This means that any loss in biodiversity is characterized as harm, irrespective of the instrumental value biodiversity may have for farmers or other people.

In the following, biodiversity is understood as a given value. The question thus is not whether biodiversity is valuable or not. Rather, the question is why or when (i.e., under what conditions or circumstances) the loss of biodiversity is a harm, given that biodiversity is a vaguely defined legal concept. How this question is answered depends on the ethical theory one favors. Regarding agriculture, there are eight possible ways for an ethical evaluation of biodiversity losses and the risks associated with it (Table 6).[37] The ERS is specifically meant to give a systematic overview of the possible ethical criteria for evaluating the risks of an (unspecified) biodiversity loss in agriculture.

9.3 Explanations on the ethical reference system

In the following, we would like to explain the main ideas underlying the ERS to assess biodiversity changes and the risks associated with it (Table 6).

There are four basic theoretical approaches to answer the question regarding which objects deserve moral consideration: anthropocentrism, pathocentrism, biocentrism and ecocentrism (first column from the left). Moral consideration means that these objects can rightfully make moral claims on us. That does, however, in itself not indicate how these claims are to be assessed. Rather, the answer to the latter question depends on a further fundamental distinction in ethics, namely, the distinction between deontology and consequentialism (or utilitarianism) (second column from the left). Each of the four approaches in environmental ethics can be understood in a deontological or in a utilitarian manner. Taking into account that the deontological view distinguishes between a direct and an indirect assessment (third column from the left), there are twelve ways of morally evaluating the risk of a biodiversity loss in agriculture.

[37] Note that even though deontological approaches distinguish between direct and indirect aspects, these are in each case just internal aspects of the same theory.

Table 6: Ethical reference system
to assess biodiversity changes

Anthropocentric	Deontological	Direct
		Indirect
	Utilitarian	
Pathocentric	Deontological	Direct
		Indirect
	Utilitarian	

	Only a farmer's own arable land	Including other farmer's arable land	Environment (outside arable land)
	Morally neutral (Maximal extent of harm: destruction of the farmer's own property, i.e., the capital of biodiversity)	Threshold value Possible impairment of other farmer's property rights	Irrelevant
	Threshold value Possible impairment of other people's rights (strangers)	Threshold value Possible impairment of other people's rights	Threshold value Possible impairment of other people's rights
	Probable harm to human beings on a farmer's own arable land minus probable benefit due to loss of biodiversity on this land (probably irrelevant)	Probable harm to the human beings on the arable land affected minus probable benefit due to loss of biodiversity on the arable land affected	Probable harm to human beings minus probable benefit
	Morally neutral (Maximal extent of harm: destruction of the farmer's own property, i.e., the capital of biodiversity)	Threshold value Possible impairment of other farmer's property rights	Irrelevant
	Threshold value Possible impairment of the (moral) rights of sentient beings due to loss of biodiversity on a farmer's own arable land	Threshold value Possible impairment of the (moral) rights of sentient beings due to loss of biodiversity on all the arable land affected	Threshold value Possible impairment of the (moral) rights of sentient beings
	Probable harm to sentient beings minus probable benefit to sentient beings due to loss of biodiversity on a farmer's own arable land	Probable harm to sentient beings minus probable benefit to sentient beings due to loss of biodiversity on all the arable land affected	Probable harm to sentient beings minus probable benefit to sentient beings

Biocentric	Deontological	Direct
		Indirect
	Utilitarian	
Ecocentric	Deontological	Direct
		Indirect
	Utilitarian	

Only a farmer's own arable land	**Including other farmer's arable land**	**Environment (outside arable land)**
Morally neutral (Maximal extent of harm: destruction of the farmer's own property, i.e. the capital of biodiversity)	Threshold value Possible impairment of other being's property rights	Irrelevant
Threshold value regarding possible harm to the inherent worth of living beings due to loss of biodiversity on a farmer's own arable land	Threshold value regarding possible harm to the inherent worth of living beings due to loss of biodiversity on all the arable land affected	Threshold value regarding possible harm to the inherent worth of living beings due to loss of biodiversity
Probable harm to living beings minus probable benefit due to loss of biodiversity on a farmer's own arable land	Probable harm to living beings minus probable benefit due to loss of biodiversity on all the arable land affected	Probable harm to living beings minus probable benefit
Threshold value Possible harm to biodiversity	Threshold value Possible harm to biodiversity Possible impairment of other beings property rights	Threshold value Possible harm to biodiversity
Threshold value Possible harm to the inherent worth of living beings, ecosystems and biodiversity due to loss of biodiver-sity on a farmer's own arable land	Threshold value Possible harm to the inherent worth of living beings, ecosystems and biodiversity due to loss of biodiver-sity on all the arable land affected	Threshold value Possible harm to the inherent worth of living beings, ecosystems and biodiversity due to loss of biodiversity
Probable harm to living beings and ecosystems minus probable benefit due to loss of biodiversity on a farmer's own arable land. Plus direct change of the value of biodiversity	Probable harm to living beings and ecosystems minus probable benefit due to loss of biodiversity on all the arable land affected Plus direct change of the value of biodiversity	Probable harm to living beings and ecosystems minus probable benefit due to loss of biodiversity on all the arable land affected Plus direct change of the value of biodiversity

As far as agriculture is concerned, it seems appropriate to distinguish between

- whether only a farmer's own arable land is affected by a possible loss of biodiversity due to his own cultivation practices (fourth column);
- whether the biodiversity of other farmer's arable land is also possibly affected by these cultivation practices (fifth column) and
- whether the biodiversity of the environment outside arable farm land is possibly affected as well (sixth column).

It is important to bear in mind that this is a general normative reference frame that does not distinguish between different cultivation practices. This means that the same normative criteria apply to GM crops as well as to conventional crops.

First, the four theoretical approaches in environmental ethics have to be defined:

1. Anthropocentrism: All and only human beings are moral objects.

The only beings morally counting for their own sake and therefore to be respected are human beings.[38] All other beings are just means to their ends. Biodiversity has the same normative status: it is valuable only insofar as it is necessary or useful for human well-being. This position is called ethical anthropocentrism. Ethical anthropocentrism must not be confused with epistemic anthropocentrism, being the view that humans can only disclose the outside world as well as moral values and moral norms by using human concepts and human judgments.

2. Pathocentrism: All and only sentient beings, that is, beings able to experience pleasure and pain – or, more generally, beings able to experience the bad as bad and the good as good – count morally for their own sake.

Which beings are sentient? Philosophical and scientific knowledge shows that most humans and vertebrates are (and maybe, for example, also other animals

[38] The main problem of anthropocentrism is to give a plausible normative interpretation of the concept "human being." If it means "being a member of the species *homo sapiens*," it is not plausible as to why this biological definition should be morally relevant, that is, why all and only the members of this species should have a moral status (provided there are species in an ontologically robust sense). If it refers to certain properties, for instance, the property of "being able to reason," it is not plausible why we should call this interpretation anthropocentrism – and not, for example, ratiocentrism. The reason is, first, that not all human beings have this ability, and, second, that nonhuman individuals such as angels, extraterrestrials or primates might have it too. If the morally relevant property is "having an immaterial soul" or "being made in the image of god," the problem is that this presupposes a metaphysical or religious doctrine that cannot be intersubjectively justified.

such as octopuses and squids). Whether invertebrates and plants are sentient is contentious. In the following, we will assume that invertebrates and plants are not sentient, that is, they are not able to feel pleasure and pain. From a pathocentric perspective, the value of biodiversity is purely instrumental deriving from its function for the survival or well-being of sentient beings.

3. Biocentrism: All and only living beings count morally for their own sake.
According to biocentrism, it ought to be respected that living beings have a "good of their own." This kind of good is defined as the one being essential for the flourishing of living beings. It is usually based on the *telos* (purpose) of a respective species (that can only realize itself in individual beings). It is what constitutes their *inherent worth* (Eigenwert). That is, for example, why we do not respect an indoor plant if we let it wither.

Harm is thus not bound to pain and suffering as in pathocentrism, but to flourishing. A living being is harmed to the extent that it is hindered from leading a species-appropriate life – a life that is typical or ideal of beings of its kind – or from unfolding its individual capacities and talents. From a biocentric viewpoint, biodiversity does not have a value of its own. It is valuable only insofar as it is indispensable or useful for the survival or well-being of individual living beings of any kind.

4. Ecocentrism: Not only individual living beings, but also nonliving individual entities such as stones and collective entities such as populations, habitats, ecosystems, rivers or species count morally for their own sake, irrespective of their importance for individual living beings.
Ecocentrism implies that not only individual living beings, but also entities such as ecosystems or populations or nature as a whole can be in a good or a bad condition or state, and that they can be harmed as such. This is because they also have a good of their own and can therefore flourish or be prevented from flourishing. In ecocentrism, biodiversity is regarded as a real – as opposed to a nominal – entity.[39] This entity ought to be protected as such because of its inherent worth. This protection may be morally required even if it is against the interests of living beings, human beings included.

[39] *Real* means that the concept "biodiversity" is equivalent to an actual entity "out there" in the world. "Nominal" means that the concept "biodiversity" is just an abstract concept of classification (i.e., certain features or groups of features in the world are subsumed under one term without claiming that there is something out there that is common to all of these features thereby constituting biodiversity).

9.3.1 Consequentialism / Utilitarianism

In a next step, we have to define what is meant by "deontological" and "utilitarian" (or "consequentialist").

Utilitarianism is the paradigm case of a moral theory named *consequentialism*. Consequentialism is the ethical view according to which the rightness of an act or a measure solely depends on its consequences (as opposed to the intrinsic nature of the act). Consequentialism requires that one choose among those acts (or measures) available, the act having the best consequences. In order to do that, three questions must be answered:

- Which alternative actions are there (in a situation where one must take a decision)?
- What impacts are to be expected with regard to each possible action?
- How are the expected impacts to be assessed?

According to utilitarianism, impacts on all beings affected by an action must be taken into account. These impacts are to be assessed with regard to their consequences for the happiness of all those being affected. Happiness is a generic term referring to intrinsic values of any kind, be it pleasure (and pain) as in classical utilitarianism or – in addition to pleasure – values such as friendship, love, beauty or knowledge as in some contemporary forms of utilitarianism. The decisive point is that all variants of utilitarianism agree that there is just one moral duty: the duty to maximize utility. In each case, the action must be chosen which results in most happiness for all those being affected.

Due to their general structure, consequentialist theories such as utilitarianism always have a risk ethical element. They have to take into account that in many cases we do not know for sure whether the intended consequences of actions will actually occur, but we only know that their occurrence may be expected with a certain probability. Hence, what they assess are not the consequences themselves, but the expectation value of alternative actions. Accordingly, one ought to choose those actions that maximize the expectation value for all those being affected.

To further emphasize, according to utilitarianism, an act is right and thus morally obligatory if its expected utility, that is, the total amount of value[40] resulting, is greater than the total amount of value for any other alternative action that the agent could perform instead. In other words, one must always choose the best option available. It is not permissible to choose the second best option. To do so would be morally wrong.

[40] Total amount of value means, that is, the total amount of (expected) good / benefit for all minus the total amount of (expected) bad / harm for all.

9.3.2 Deontology

Deontological theories claim that the ethical assessment of actions must not be based on their consequences alone. From a deontological point of view, certain acts are morally wrong in themselves, that is, irrespective of their consequences (such as the intentional killing of an innocent person). Such acts are prohibited even if they would increase or maximize net benefit. Moral prohibitions of this deontological kind serve as constraints with regard to utilitarian considerations of total utility.

One way to conceptualize this idea of constraints is to refer to moral rights. To say, for example, that an individual being has a moral right to life means that this right must be respected even if disrespecting it would lead to an increase of the total amount of value. In other words, this being should not to be killed even if killing it would increase or maximize total utility.

Concerning the ethical assessment of risks, deontological theories imply defining threshold values. Risks that are above a threshold value are morally prohibited, whereas risks below such a value are permissible or acceptable. The general risk ethical criterion is the criterion of due diligence or duty of care. According to this criterion, other beings may only be exposed to a risk if the risk-exposing person (or institution) has taken all necessary precautionary measures to avoid – with the highest probability feasible – the occurrence of a potential harm.

The general idea underlying the criterion of duty of care is as follows: the concept of harm is defined by reference to moral rights – infringing on these rights means causing harm to the right-holder. Such harm is morally unjustified even if by inflicting it, one increases total utility.[41] Which rights exist depends on the normative background theory. Most theories would agree on moral rights, such as, among others, the right to dispose of one's own body and one's own life, a right to bodily integrity, a right to freely choose one's own way of life, a right to property and a right to life.

To extend the harm principle – the prohibition to infringe on other being's rights without their consent – to all situations where others are exposed to a risk, that is, to demand zero risk and thus to require that others ought not to be exposed to any risk, cannot work in real life for a fundamental reason: it would

[41] This is a provisional conception. It may be more plausible to decouple the concept of harm completely from the concept of the infringement or violation of moral rights. Consequently, there would be no moral harm. Harm would always be prudential harm. As far as moral rights are concerned, their violation would, of course, remain morally wrong, but it would not be a harm inflicted on the being(s) whose right(s) is (are) violated. This conception, however, would not change the risk criterion as sketched above. The core idea would still be using threshold values regarding the violation of moral rights in order to separate acceptable from inacceptable risks.

cause a blockade that would make social life impossible. However, since every harmful event is something negative that should be avoided, exposing others to risk (without their consent) is only admissible if all precautionary measures have been taken to reduce the risk to a point where the occurrence of harm can be deemed unlikely. Risk thresholds then serve to determine how far a risk must be reduced in order to be acceptable.

According to deontology, there is no "best option" that one must choose. Rather, deontology distinguishes between acceptable and inacceptable options. Inacceptable options ought not to be chosen, irrespective of their potential or expected consequences.[42] Deontology does not prescribe which options to choose, in case several acceptable options exist.

Consequentialism and deontology are mutually exclusive. They cannot be combined to form a kind of ethical "super theory."

At this point, we would like to illustrate these general deliberations in the context of agriculture using anthropocentrism as an example.

9.3.3 Anthropocentrism

Deontological anthropocentrism

As far as the farmer's own property is concerned, the risk of a reduction in biodiversity is morally neutral. The reason is that the farmer may expose his own property to any risk. This applies as long as only his property is affected. The maximal extent of harm that may occur due to a reduction of biodiversity is a diminishment or destruction of his property (presupposing that biodiversity is a part of his capital).

The situation changes if the farmer, by using certain cultivation practices, exposes biodiversity on other farmer's arable land to a risk. Suppose these practices would lead to a complete extinction of bees on his land, and, as a consequence, the loss of bees imposes the risk of a reduction in biodiversity on neighboring farmers. As far as their property rights are concerned, these farmers can legitimately demand that the biodiversity on their land remains intact. The disappearance of just one species due to the cultivation practices of another farmer must be considered a violation of a property right (assuming that biodiversity is part of the farmer's capital) and thus a severe harm. Hence, the probability that this happens must be very low. On this basis, deontological anthropocentrism would try to determine a threshold value that allows deciding whether the risk is acceptable or not.

[42] That is why deontological approaches reject harm / risk-benefit/chance - analyses in case of inacceptable options.

The risk of a reduction in biodiversity outside agricultural land due to cultivation practices is irrelevant in this context, insofar as no individual property right is affected. There is no probability that this right may be violated. From an anthropocentric-deontological perspective, there is no other moral right that could play a role in this context as there is no individual moral right to biodiversity.

With regard to the indirect assessment, the question is whether the farmer exposes other human beings on his land or on other farmer's land or outside arable land to a risk. In order to be a risk, there must be a probability that biodiversity losses would violate certain moral rights of these humans. Of the rights mentioned above, the only relevant right is the right to life and limb (bodily integrity). It is questionable, however, whether there is any probability (higher than zero) that this right could be negatively affected by a reduction in biodiversity. In the case that this would be possible, the deontological approach would again determine a threshold value. Again, the decisive point would be that the probability of a harm occurring must be very low.

Utilitarian anthropocentrism

According to utilitarianism, one ought to choose the action that maximizes the expectation value for all those being affected – in this case, for all human beings who are affected.[43] As far as the farmer's own land is concerned, there are two scenarios. In the first scenario, he is the only human being affected by a loss of biodiversity. Supposing that utilitarianism advocates duties to oneself, that is, a moral duty to maximize one's own happiness, one could argue that he must calculate the possible (economic) gains and the possible costs and then choose the option with the greatest expectable utility (total amount of chances minus total amount of risk). It is then perfectly conceivable that a reduction in biodiversity could be preferable to the status quo; for instance, if reduction means the elimination of pests which in turn increases the probability of higher yields. In the second scenario, we try to calculate the expectation value for human beings who are on this farmer's land. This case seems to be morally irrelevant because it is hard to see what the possible benefit or possible harm engendered by the loss of biodiversity could consist of.

If other farmer's arable land is affected, the situation becomes more complicated. What must be taken into account are the possible positive and negative impacts of a reduction in biodiversity caused by all farmers. The same reduction in biodiversity that could be preferable to the status quo in the case of farmer A

[43] This kind of utilitarianism would have to argue that only the pleasure and pain of human beings (or only the fulfilment of human desires) counts morally.

(because it has a higher expectation value) might have to be assessed as undesirable in the case of farmer B because it has a lower expectation value than the status quo. What utilitarianism requires in such a situation is figuring out which of the following two options is the best (better than the other option if there are only two). Option 1: the total sum of the expectation value of farmer A and the expectation value of farmer B resulting from the reduction in biodiversity. Option 2: the total sum of the expectation value of farmer A and the expectation value of farmer B based on the status quo ante. If the expectation value of option 1 is lower than the expectation value of option 2, the loss of biodiversity must be judged negatively. In that case, there is a duty to reverse the loss of biodiversity, even if this means that farmer A is worse off as a result (in utilitarianism distributive considerations are irrelevant).

The same procedure has to be applied if we take the environment outside agriculture into consideration.

9.4 Application of the proposed approach

As mentioned before, the ERS is the first step in a systematic process aiming at the specification and justification of plausible ethical criteria to valuate environmental impacts of GM crops on biodiversity. This step is important in two respects.

1. It lays the systematic foundation for the determination and justification of the targeted ethical criteria. As pointed out above, the full development of these criteria would require choosing the most plausible systematic normative ethical theory and then applying the respective criteria to the question of risk and harm regarding biodiversity. This, however, would be beyond the scope of this project since this is the most basic systematic question of normative ethics in general. What can be said, nonetheless, is the following: Irrespective of which theory turns out to be the most plausible one, all theories share some common ground with regard to the assessment of the risks associated with GM crops. They all agree – albeit for different reasons – that the commercial use of GM crops can only be allowed if there is sufficient knowledge regarding the risks involved. Deontologists would argue that this is required because without this knowledge it is not possible to determine whether the risks exceed the threshold value separating permissible from impermissible risks. Utilitarians would argue that without this knowledge, it is not possible to determine whether the expected net benefit of an

agriculture with GM crops (or the net benefit of specific GM crops) would exceed the expected net benefit of an agriculture without GM crops. Furthermore, they all agree that the current scientific risk knowledge does not yet suffice to justify the commercial release of GM crops. Given this knowledge it is still not possible to determine in a sufficiently reliable way whether the risks of these crops (especially regarding worst cases) are above or below the threshold. Nor is it possible to determine whether the commercial use of (specific) GM crops would lead to an (long term) increase of the net benefit in agriculture (as compared with conventional agriculture). Thus, they would all plea for more risk research based on the step-by-step procedure.

2. The ERS may be useful for certain practical purposes. Three are worth mentioning:
   a. By providing regulators with a general orientation grid, the ERS enables them to see which ethical position they intuitively favor.
   b. The ERS helps regulators to question their point of view and to modify it accordingly. It also facilitates a better and more reflected understanding of the ethical view(s) enshrined in the law. As a consequence, regulators are better able to communicate their position to the "outside world" (industry, scientific community, media, and public at large).
   c. The ERS improves comprehension of certain tensions, for instance the tension between the two aspects of protection that are essential for biodiversity: the protection of rare and threatened species on the one hand, and the functioning of ecosystem services on the other hand. These two aspects may lead to dilemmas for decision makers because the relevant legal regulations are based on two different ethical theories that exclude each other. Biodiversity conservation is usually based on an ecocentric approach according to which biodiversity is intrinsically valuable (and rarity is valuable in itself). This implies that especially rare species are entities that deserve protection irrespective of their value for ecosystem stability and for human beings. The protection of ecosystem services is mainly based on an anthropocentric approach according to which biodiversity is only instrumentally valuable, namely, insofar as it is necessary for human well being. If only the anthropocentric approach were relevant for the legal interpretation of biodiversity, there would be no tension between the two main aspects

since the protection of rare species would not be intrinsically, but just instrumentally valuable, i.e., valuable insofar as the existence of these species contributes to human well being – just like the functioning of ecosystem services. Suppose decision makers have to decide between the preservation of a functionally irrelevant rare species and the preservation of a functionally indispensable common species. The question then would be: which species is more important for ecosystem stability and thus ultimately for human well being (given that ecosystem stability is instrumentally valuable for human well being)? So there would be a clear normative criterion that would permit, at least in principle, one to answer this question without facing any dilemmas.

CHAPTER 10

RECOMMENDATIONS FOR DECISION-MAKERS

10 RECOMMENDATIONS FOR DECISION-MAKERS

10.1 Ethical considerations when evaluating effects of GM plants

The perception of risk and damage is governed by societal and individual value judgments. Risk assessors and regulators need to bear in mind that the term "environmental damage" can be characterized based on different ethical theories. The ethical theories mentioned in the present project can be a useful tool for regulatory decision making. Most importantly, they provide regulators with a general orientation on possible ethical viewpoints related to value judgments necessary when defining environmental protection goals and facilitate a more reflected understanding of the ethical views enshrined in the law. Moreover, it may help regulators to take more accurate and coherent decisions and to better communicate their position to other stakeholders.

The coherence requirement implies that what should be valuated is not so much the technology to produce GM crops, but, rather, the products of this technology. So when we try to determine the damage GM crops may cause to biodiversity, we should use the same criteria that we use when we try to determine the damage to biodiversity that may be brought about by conventionally produced crops. Ethical reflection can help to define these criteria.

1ST RECOMMENDATION

Regulators (and other stakeholders involved in the discussion on the environmental impacts of GM plants) should be aware that different ethical theories underlie the definition of environmental damage. However, as law is not based on a consistent ethical theory, regulators are faced with the difficulty that these theories may sometimes be incompatible. Regulatory authorities should use the ethical theories presented herein to explore the subject of environmental damage. By understanding how the existing theories influence decision-making, they should make sure that the law is coherently applied.

From an ethical coherence view, cultivars with new traits that have been produced through genetic engineering should be valuated according to the same normative criteria of environmental damage as products produced by conventional breeding.

10.2 Protection goals

Protection goals as specified by existing legislation are the exclusive starting point for regulators for a definition of damage. Policy decisions on what ultimately has to be protected are based on the existing legal frameworks. Nearly all legal frameworks demand the conservation and sustainable use of biodiversity. However, due to practical and financial constraints, it is impossible to conserve all components of biodiversity in the same manner. Hence, one needs to be able to decide which components of biodiversity deserve particular protection. Both from an ethical and from an ecological point of view, the legislative terms used to describe the protection goal "biodiversity" are too vague to be scientifically assessed. To define scientifically measurable characteristics for each ecological entity deserving protection, we propose to first define assessment endpoints that are an explicit expression of the environmental value that is to be protected. In a second step, measurement endpoints that represent a measurable ecological characteristic that can be related to the particular assessment endpoint are to be defined. We have specified a matrix listing entities of biodiversity that need protection as well as criteria that need to be considered when defining corresponding assessment and measurement endpoints. The presented matrix can be used as a tool to structure the dialogue between the different stakeholders, especially between regulators and applicants.

Regulatory authorities need to be aware that setting endpoints will require balancing competing goals that will be a source of controversy. Biodiversity conservation, for example, usually focuses on rare and threatened species, while restoring ecosystem services necessitates concentrating on ubiquitous species as a species on the verge of extinction is likely to have less significant ecological relevance. Similarly, although there is general consensus that the ecological entities specified by legislation to deserve protection have to be respected (such as Red List species and protected habitats), there is controversy over the necessity to protect "common" species that are not explicitly listed in the legislation, but that are reduced by common agricultural practices (such as agricultural weeds that may be an essential part of food webs in agricultural landscapes contributing to farmland biodiversity, but that also reduce agricultural yield).

2ND RECOMMENDATION

Regulators should actively promote approaches that enable stakeholders to agree on what deserves protection because it is specifically valued. Regulatory authorities can use our matrix specifying protection goals as well as assessment and measurement endpoints as a starting point for discussing generic and operational biodiversity protection goals among all stakeholders of GM plants. The matrix can thereby be adapted to regional or country specific needs. We recommend that science and empirical evidence support the discourse about policy goals and indicate what ecological theories tell us about the relevance of biodiversity.

10.3 Thresholds

Using a threshold to define damage would be an elegant approach as it would allow more or less unambiguous decisions which represent unacceptable harm. In principle, every indicator value that would exceed the threshold would indicate damage. Unfortunately, the threshold principle is currently not applicable in practice as the legal frameworks regulating the use of genetic engineering in Switzerland and in the European Union (EU) do not define specific threshold values. This is mainly due to the difficulty to define thresholds for ecological indicators. Ecological thresholds must be evaluated independently for every single species or species group – a procedure that is usually not appropriate for regulatory decision-making. With growing ecological experiences on the cultivation of GMOs, thresholds for certain ecological groups may become available. Nevertheless, one has to recognize that for most ecological indicators fully operational thresholds will probably rarely be available in the near future. These complexities inevitably challenge decision-makers as they generally have no clearly quantified thresholds that allow them to decide what represents damage.

3RD RECOMMENDATION

In theory, thresholds would be an elegant approach to define damage as every indicator value that would exceed the threshold would indicate damage. Hence, where available, ecological thresholds should be used for decision-making. However, regulators should keep in mind that ecological thresholds are seldom available in practice as ecological sciences are most often not able to provide precise threshold values that would indicate when damage occurs. If thresholds are missing, damage should be defined by using a baseline approach. The baseline allows one to determine when a change has to be regarded as a damage without relying on a precise, fixed threshold as the definition of damage is performed by comparing two different states. The first state (e.g., the impacts caused by current agricultural management practices) is thereby indicating what is accepted. Damage occurs if the difference between the accepted state and the state to be evaluated is judged to be sufficiently large to be adverse.

Note, however, that from an ethical point of view, this understanding of baseline is problematic insofar as normatively speaking the baseline should include criteria of acceptability. What is acceptable and what is actually accepted may, but must not coincide.

10.4 Comparative assessments and baselines

The project showed that generic comparative assessments of different agricultural management practices are very complex and difficult to perform because the impacts of cropping systems depend on a variety of different factors that can often only be assessed on a case-by-case basis. It is therefore not possible to reduce these impacts to one common "currency" that would allow a generic comparison. This challenges the initial assumption of the project that comparative assessments are the only way to allow a coherent evaluation of environmental risks of GM crops. Every generic comparison inevitably results in omitting important details that influence the character and the magnitude of a specific environmental impact of a particular technology.

It is important to recognize that regulatory authorities do often not have a legal basis or formal obligation to perform a comparative assessment as existing agricultural technologies are evaluated according to different regulatory frameworks. More precisely, the regulatory framework for pesticides uses other evaluation criteria than the one for GMOs. Hence, regulatory authorities often refuse to compare the effects of GM crops to the effects caused by, for example, pesticides. As regulators are forced to restrict their judgments to the GM legislation, this leads to the irrational situation that the same environmental impacts may be judged differently depending on what agricultural management practice caused them. In our opinion, this incoherence is one of the main reasons for the current paralysis of the regulatory framework for GM crops in Switzerland and in the EU.

As long as technologies having similar environmental impacts face different regulatory regimes, a comparative assessment cannot be performed and it is impossible to draw a baseline for regulatory decisions. Baselines (i.e., the comparator which serves as a basis for comparison) are nevertheless essential for decision-making as they define what makes a change to be regarded damage. Legally, the baseline for the evaluation of damage from GMOs should be set by what is already regarded representing damage today. If GMOs would be regulated on the same legal basis as other agricultural management practices such as pesticides, a comparison would be possible as the baseline would be characterized by those environmental impacts that are already approved and thus implicitly accepted.

4TH RECOMMENDATION

Future political and legislative processes in Switzerland and in the EU should attempt to harmonize the legal frameworks regulating GMOs and other agricultural management practices that serve similar purposes (such as the use of pesticides). Agricultural technologies should be assessed based on their individual properties and on their risk for the environment and not just because they have been created by a specific methodology or technology. Regulators from different authorities should initiate discussions to create a legal framework or a formal process that allows for a comparative approach in situations where the comparison of technologies is appropriate and where there is a risk that the same protection goals may be adversely affected.

10.5 Weaknesses of the regulatory system for GM crops

The legal requirements in Switzerland and in the EU require that risks for the environment are assessed prior to the approval of GM crops. In order to assess the safety of GM crops, applicants of new GM crops need clear indications from regulatory authorities regarding protection goals (i.e., regarding the environmental entities to be protected from damage). Unfortunately, regulatory authorities in Switzerland and in the EU do currently not provide applicants with sufficient information on operational protection goals when evaluating environmental risks of GM crops.

The GMO regulation in the EU is marked by a poor communication between applicants and the responsible regulatory authorities. Regulatory authorities are usually not allowed to communicate with applicants to discuss scientific questions and other issues relevant for preparing dossiers for the application of GM crops. The process of communication between regulatory authorities and applicants is practiced very differently in other countries such as Australia, New Zealand, Canada and the U.S., where applicants seek advice from regulators at an early stage and during the process of dossier preparation. These practices clearly allow a more coherent application of the legal framework and it would be helpful if such practices would also become accepted in Switzerland and in the EU.

5TH RECOMMENDATION

We firmly believe that it is the responsibility of regulatory authorities to ensure that the approval process of new technologies is coherent and performed according to transparent criteria. Regulatory authorities need to provide applicants with precise operational protection goals and they need to clearly indicate what other relevant information they may need for the evaluation of environmental impacts of GM crops. Protection goals have to be defined by regulatory authorities in a consensus process involving all stakeholders as applicants alone cannot address the public and seek for consensus.

10.6 Regulatory burden for GM crops

One can argue that evaluating the consequences of crop management changes related solely to the introduction of GM crops is an inappropriate burden as there are numerous agricultural crop management practices that evolve constantly. New plant species and plant varieties are introduced and new cropping systems are developed with much lower request for regulatory review and approval. These novelties may have a far larger environmental impact than the choice to grow GM crops. Although this obvious deficit of the current legislation is recognized, this concern is seldom addressed in current regulatory discussions on GM crops.

6TH RECOMMENDATION

It is our firm belief that all technologies that could potentially harm the environment in a similar way should be evaluated according to the same legal standards. GM crops should not principally be regarded as a potential harmful technology, but as an agricultural management tool that is comparable to other existing management practices that can have adverse environmental impacts depending on their use. Hence, GM crops should rather be regulated by a legislation that is regulating technologies with similar purposes (e.g., the plant protection legislation or va riety approval) than under a separate regulation. This could imply that the responsibilities for regulating GM crops would be assigned to other regulatory authorities than it is today.

10.7 Acknowledgements

The present study was funded by the Swiss National Science Foundation within the National Research Program 59 "Benefits and risks of the deliberate release of genetically modified plants." The authors would like to thank all experts that participated in two expert workshops that were held during the project and that helped to develop the presented results herein.

The results presented in the present book have been published in two peer-reviewed publications:

Sanvido, O., Romeis, J., Bigler, F., (2011).
Environmental change challenges decision-making during post-market environmental monitoring of transgenic crops. Transgenic Research 20, 1191-1201.

Sanvido, O., Romeis, J., Gathmann, A., Gielkens, M., Raybould, A., Bigler, F., (2011).
Evaluating environmental risks of genetically modified crops: ecological harm criteria for regulatory decision-making. Environmental Science & Policy, DOI 10.1016/j.envsci.2011.1008.1006.

CHAPTER 11

REFERENCES

11 REFERENCES

ACRE (2002). The criteria used by ACRE to gauge harm when giving advice on the risks of releasing genetically modified organisms to the environment, Department for Environment, Food and Rural Affairs – Advisory Committee on Releases to the Environment, London. pp. 19

ACRE (2007). Managing the footprint of agriculture: towards a comparative assessment of risks and benefits for novel agricultural systems, Department for Environment, Food and Rural Affairs – Advisory Committee on Releases to the Environment, London. pp. 97. www.defra.gov.uk/ENVIRONMENT/acre/fsewiderissues/acre-fse-060317draft.pdf

Ammann K, Rufener Al Mazyad P, and Jacot Y (2000). Konzept und praktische Lösungsansätze zur ökologischen Begleitforschung. *in* "Nachhaltige Landwirtschaft und grüne Gentechnik" (Schulte E and Käppeli O, eds.), BATS – Fachstelle für Biosicherheitsforschung und Abschätzung von Technikfolgen, Basel. pp. 96–112.

Ammon HU (1993). Von der Unkrautbekämpfung zur Regulation der Grünbedeckung im Mais. *Landwirtschaft Schweiz*, 6: (11–12) 649–660.

Aviron S, Sanvido O, Romeis J, Herzog F, and Bigler F (2009). Case-specific monitoring of butterflies to determine potential effects of transgenic Bt-maize in Switzerland. *Agriculture, Ecosystems and Environment*, 131:137–144.

Bafu/BLW (2008). Umweltziele Landwirtschaft – hergeleitet aus bestehenden rechtlichen Grundlagen, Umwelt-Wissen Nr. 0820. Bundesamt für Umwelt, Bern. pp. 221

Bartz R, Heink U, and Kowarik I (2010). Proposed definition of environmental damage illustrated by the cases of genetically modified crops and invasive species. *Conservation Biology*, 24: (3) 675–681.

BDM (2009). Zustand der Biodiversität in der Schweiz: Ergebnisse des Biodiversitäts-Monitorings Schweiz (BDM), Umwelt-Zustand 0911. Bundesamt für Umwelt, Bern. pp. 112

Beauchamp TL, and Childress JF (2001). Principles of biomedical ethics, Oxford University Press, Oxford UK. pp. 472.

Beekman V, de Bakker E, Baranzke H, Baune O, Deblonde M, Forsberg EM, de Graaff R, Ingensiep HW, Lassen J, Mepham B, Porsborg Nielsen A, Tomkins S, Thorstensen E, Millar K, Skorupinski B, Brom FWA, Kaiser M, and Sandøe P (2006). Ethical biotechnology assessment tools for agriculture and food production, Agricultural Economics Research Institute (LEI), The Hague NL. pp. 59. www.ethicaltools.info/content/ET1%20Final%20Report%20(Binnenwerk%2059p).pdf

Benbrook C (2001). Do GM crops mean less pesticide use. *Pesticide Outlook*, 12: (October) 204–207.

Benbrook C (2003). Impacts of genetically engineered crops on pesticide use in the United States: the first eight years, BioTech InfoNet. pp. 42

Bigler F, Babendreier D, and Van Lenteren JC (2010). Risk assessment and non-target effects of egg parasitoids in biological control. *in* "Egg parasitoids in agroecosystems with emphasis on *Trichogramma*" (Consoli FL, Parra JRP and Zucchi RA, eds.), Vol. 9, Springer, Dordrecht NL.

Birkhofer A (1980). The German risk study for Nuclear Power Plants. pp. 11. http://www.iaea.org/Publications/Magazines/Bulletin/Bull225_6/225_604792333.pdf

Bockstaller C, Guichard L, Keichinger O, Girardin P, Galan MB, and Gaillard G (2009). Comparison of methods to assess the sustainability of agricultural systems. A review. *Agronomy for Sustainable Development*, 29: (1) 223–235.

Bohanec M, Messean A, Scatasta S, Angevin F, Griffiths B, Krogh PH, Znidarsic M, and Dzeroski S (2008). A qualitative multi-attribute model for economic and ecological assessment of genetically modified crops. *Ecological Modelling*, 215: (1–3) 247–261.

Brimner TA, Gallivan GJ, and Stephenson GR (2005). Influence of herbicide-resistant canola on the environmental impact of weed management. *Pest Management Science*, 61: (1) 47–52.

Brookes G, and Barfoot P (2005). GM crops: the global economic and environmental impact – the first nine years 1996–2004. *AgBioForum*, 8: (2&3) 187–196.

Burney JAD, S J, and Lobell DB (2010). Greenhouse gas mitigation by agricultural intensification. *Proceedings of the National Academy of Sciences of the United States of America*, 107:12052–12057.

Buwal (1999). Landschaftskonzept Schweiz, Bundesamt für Umwelt, Wald und Landschaft, Bern. pp. 56

BV (SR 101). Bundesverfassung der Schweizerischen Eidgenossenschaft, Systematische Sammlung des Bundesrechts, Bern. pp. 90

Cairns J (1983). Are single species toxicity tests alone adequate for estimating environmental hazard. *Hydrobiologia*, 100:47–57.

Candolfi M, Bigler F, Campbell P, Heimbach U, Schmuck R, Angeli G, Bakker F, Brown K, Carli G, Dinter A, Forti D, Forster R, Gathmann A, Hassan S, Mead-Briggs M, Melandri M, Neumann P, Pasqualini E, Powell W, Reboulet JN, Romijn K, Sechser B, Thieme T, Ufer A, Vergnet C, and Vogt H (2000). Principles for regulatory testing and interpretation of semi-field and field studies with non-target arthropods. *Anzeiger für Schädlingskunde – Journal of Pest Science*, 73: (6) 141–147.

Caro TM, and O'Doherty G (1999). On the use of surrogate species in conservation biology. *Conservation Biology*, 13: (4) 805–814.

Carpenter J, Felsot A, Goode T, Hammig M, Onstad D, and Sankula S (2002). Comparative environmental impacts of biotechnology-derived and traditional soybean, corn, and cotton crops, Council for Agricultural Science and technology, Ames, Iowa. pp. 200

CBD (1992). Convention on Biological Diversity, United Nations Environment Programme, Rio de Janeiro. pp. 31

CBD (2000). Sustaining life on earth – how the Convention on Biological Diversity promotes nature and human well-being, United Nations Environment Programme, Montreal. pp. 20

CBD (2009). MOP 4 Decision BS-IV/12 Liability and Redress under the Cartagena Protocol on Biosafety, Convention on Biological Diversity, Montreal. pp. 24

Chamberlain DE, Fuller RJ, Bunce RGH, Duckworth JC, and Shrubb M (2000). Changes in the abundance of farmland birds in relation to the timing of agricultural intensification in England and Wales. *Journal of Applied Ecology*, 37: (5) 771–788.

Chapin FS, Zavaleta ES, Eviner VT, Naylor RL, Vitousek PM, Reynolds HL, Hooper DU, Lavorel S, Sala OE, Hobbie SE, Mack MC, and Diaz S (2000). Consequences of changing biodiversity. *Nature*, 405: (6783) 234–242.

Costanza R, dArge R, deGroot R, Farber S, Grasso M, Hannon B, Limburg K, Naeem S, Oneill RV, Paruelo J, Raskin RG, Sutton P, and vandenBelt M (1997). The value of the world's ecosystem services and natural capital. *Nature*, 387: (6630) 253–260.

Daily G (1999). Developing a scientific basis for managing earth's life support systems *Conservation Ecology*, 3: (2) 14.

Daily GC, Soderqvist T, Aniyar S, Arrow K, Dasgupta P, Ehrlich PR, Folke C, Jansson A, Jansson BO, Kautsky N, Levin S, Lubchenco J, Maler KG, Simpson D, Starrett D, Tilman D, and Walker B (2000). Ecology – The value of nature and the nature of value. *Science*, 289: (5478) 395–396.

de Maagd RA, Bravo A, and Crickmore N (2001). How *Bacillus thuringiensis* has evolved specific toxins to colonize the insect world. *Trends in Genetics*, 17: (4) 193–199.

Devos Y, Cougnon M, Vergucht S, Bulcke R, Haesaert G, Steurbaut W, and Reheul D (2008). Environmental impact of herbicide regimes used with genetically modified herbicide-resistant maize *Transgenic Research*, 17:1059–1077.

Dewar AM (2009). Weed control in glyphosate-tolerant maize in Europe. *Pest Management Science*, 65: (10) 1047–1058.

Dewar AM, May MJ, Woiwod IP, Haylock LA, Champion GT, Garner BH, Sands RJN, Qi AM, and Pidgeon JD (2003). A novel approach to the use of genetically modified herbicide tolerant crops for environmental benefit. *Proceedings of the Royal Society of London Series B-Biological Sciences*, 270: (1513) 335–340.

Diaz S, Fargione J, Chapin FS, and Tilman D (2006). Biodiversity loss threatens human well-being. *Plos Biology*, 4: (8) 1300–1305.

Dively GP, Rose R, Sears MK, Hellmich RL, Stanley-Horn DE, Calvin DD, Russo JM, and Anderson PL (2004). Effects on monarch butterfly larvae (Lepidoptera : Danaidae) after continuous exposure to Cry1Ab-expressing corn during anthesis. *Environmental Entomology*, 33: (4) 1116–1125.

Duelli P (1994). Rote Liste der gefährdeten Tierarten in der Schweiz, Bundesamt für Umwelt, Wald und Landschaft, Bern. pp. 97

Duelli P, and Obrist MK (2003). Biodiversity indicators: the choice of values and measures. *Agriculture, Ecosystems and Environment*, 98:87–98.

Duke SO (2005). Taking stock of herbicide-resistant crops ten years after introduction. *Pest Management Science*, 61: (3) 211–218.

EASAC (2009). Ecosystem services and biodiversity in Europe, European Academies Science Advisory Council, London UK. pp. 70. www.easac.eu/document.asp?id=90&pageno=&detail=5&parent=

EFSA (2006). Guidance document of the scientific panel on genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed. *The EFSA Journal*, 99:1–100.

EFSA (2009a). Scientific opinion on statistical considerations for the safety evaluation of GMOs, European Food Safety Authority, Parma. pp. 62

EFSA (2009b). Scientific opinion: Applications (references EFSA-GMO-NL-2005-22, EFSA-GMO-RX-NK603) for the placing on the market of the genetically modified glyphosate tolerant maize NK603 for cultivation, food and feed uses, import and processing and for renewal of the authorisation of maize NK603 as existing products, both under Regulation (EC) No 1829/2003 from Monsanto. *The EFSA Journal*, 1137: (1–50).

Ehrlich PR, and Ehrlich AH (1981). Extinction. The causes and consequences of the disappearence of species, Random House, New York. pp. 305.

El Hachimi M, and von Schlippe A (2003). Crea-Space – eine Methode zur Entwicklung des kreativen Potenzials in Teams und grösseren Gruppen. *Organisationsberatung – Supervision – Coaching*, 2:137–144.

Elton CS (1958). The ecology of invasions by animals and plants, Methuen and Co. Ltd., London. pp. 181.

EPA (2001). Biopesticides registration action document – *Bacillus thuringiensis* plant-incorporated protectants, U.S. Environmental Protection Agency, Washington DC. pp. 481. www.epa.gov/pesticides/biopesticides/pips/bt_brad.htm

EPA (2009). Pesticides: Topical & Chemical Fact Sheets. U.S. Environmental Protection Agency http://www.epa.gov/pesticides/factsheets/

European Commission (1991). Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EC), Commission of the European Communitites, Brussels. pp.

European Commission (1992). Council Directive 92/42/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, Commission of the European Communities, Brussels. pp. 66

European Commission (2002). Guidance document on terrestrial ecotoxicology under Council Directive 917414/EEC, Directorate E – Food Safety: plant health, animal health and welfare, international questions, Brussels. pp. 39

European Commission (2004). Directive 2004/35/CE of the European parliament and of the council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage, European Parliament and the Council of the European Union, Strassburg. pp. 19

European Community (2001). Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, European Parliament and the Council of the European Union, Brussels. pp. 38

European Union (2009a). EU Pesticides database. http://ec.europa.eu/sanco_pesticides/public/index.cfm

European Union (2009b). Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the marketand repealing Council Directives 79/117/EEC and 91/414/EEC, European Parliament and the Council of the European Union, Brussels. pp. 50

Failing L, and Gregory R (2003). Ten common mistakes in designing biodiversity indicators for forest policy. *Journal of Environmental Management*, 68: (2) 121–132.

Fairweather PG (1991). Statistical power and design requirements for environmental monitoring. *Australian Journal of Marine Freshwater Research*, 42:555–567.

Feld CK, da Silva PM, Sousa JP, de Bello F, Bugter R, Grandin U, Hering D, Lavorel S, Mountford O, Pardo I, Partel M, Rombke J, Sandin L, Jones KB, and Harrison P (2009). Indicators of biodiversity and ecosystem services: a synthesis across ecosystems and spatial scales. *Oikos*, 118: (12) 1862–1871.

Fernandez-Cornejo J, and Caswell M (2006). The first decade of genetically engineered crops in the United States, United States Department of Agriculture – Economic Research Service, Washington DC. pp. 30

Fernandez-Cornejo J, and Mc Bride WD (2002). Adoption of bioengineered crops, Economic Research Service, United States Department of Agriculture, Washington, DC. pp. 61

Ferreira EPD, dos Santos HP, Costa JR, De-Polli H, and Rumjanek NG (2010). Microbial soil quality indicators under different crop rotations and tillage management. *Revista Ciencia Agronomica*, 41: (2) 177–183.

Fuller RJ, Gregory RD, Gibbons DW, Marchant JH, Wilson JD, Baillie SR, and Carter N (1995). Population declines and range contractions among lowland farmland birds in Britain. *Conservation Biology*, 9: (6) 1425–1441.

Gallai N, Salles JM, Settele J, and Vaissiere BE (2009). Economic valuation of the vulnerability of world agriculture confronted with pollinator decline. *Ecological Economics*, 68: (3) 810–821.

Gärdenfors U (2001). Classifying threatened species at national versus global levels. *Trends in Ecology & Evolution*, 16: (9) 511–516.

Gaston KJ (1996). What is biodiversity. *in* "Biodiversity – a biology of numbers and difference" (Gaston KJ, ed.), Blackwell Science, Oxford UK. pp. 1–9.

Gianessi LP (2005). Economic and herbicide use impacts of glyphosate-resistant crops. *Pest Management Science*, 61: (3) 241–245.

Gillies D (2000). Philosophical theories of probability, Routledge, London, New York. pp. 240.

Gonseth Y (1994). Rote Liste der gefährdeten Tagfalter der Schweiz. *in* "Rote Liste der gefährdeten Tierarten der Schweiz" (Duelli P, ed.), Bundesamt für Umwelt, Wlad und Landschaft, Bern. pp. 48–51.

Grimm V, and Wissel C (1997). Babel, or the ecological stability discussions: An inventory and analysis of terminology and a guide for avoiding confusion. *Oecologia*, 109: (3) 323–334.

Groffman P, Baron J, Blett T, Gold A, Goodman I, Gunderson L, Levinson B, Palmer M, Paerl H, Peterson G, Poff N, Rejeski D, Reynolds J, Turner M, Weathers K, and Wiens J (2006). Ecological thresholds: The key to successful environmental management or an important concept with no practical application? *Ecosystems*, 9: (1) 1–13.

GTG (SR 814.91). Bundesgesetz über die Gentechnik im Ausserhumanbereich (Gentechnikgesetz), Systematische Sammlung des Bundesrechts, Bern. pp. 14

Gunderson LH (2000). Ecological resilience – in theory and application. *Annual Review of Ecology and Systematics*, 31:425–439.

Hacking I (2001). An introduction to probability and inductive logic, Cambridge University Press Cambridge. pp. 320.

Hails RS (2002). Assessing the risks associated with new agricultural practices. *Nature*, 418: (6898) 685–688.

Hajek A (2009). Interpretations of probability, Stanford Encyclopedia of Philosophy. pp. http://plato.stanford.edu/entries/probability-interpret

Häner R, and Schierscher B (2009). First step towards CWR conservation in Switerland. *Crop wild relative* (7) 14–17.

Häni F, Popow G, Reinhard H, Schwarz A, and Tanner K (2006). Pflanzenschutz im integrierten Ackerbau, 6th/Ed., Landwirtschaftliche Lehrmittelzentrale, Zollikofen.

Hanski I (1998). Metapopulation dynamics. *Nature*, 396: (6706) 41–49.

Harmer R, Peterken G, Kerr G, and Poulton P (2001). Vegetation changes during 100 years of development of two secondary woodlands on abandoned arable land. *Biological Conservation*, 101: (3) 291–304.

Hawes C, Haughton AJ, Osborne JL, Roy DB, Clark SJ, Perry JN, Rothery P, Bohan DA, Brooks DR, Champion GT, Dewar AM, Heard MS, Woiwod IP, Daniels RE, Young MW, Parish AM, Scott RJ, Firbank LG, and Squire GR (2003). Responses of plants and invertebrate trophic groups to contrasting herbicide regimes in the Farm Scale Evaluations of genetically modified herbicide-tolerant crops. *Philosophical Transactions of the Royal Society of London Series B-Biological Sciences*, 358: (1439) 1899–1913.

Hazeu GW, Metzger MJ, Mücher CA, Perez-Soba M, Renetzeder C, and Andersen E (in press). European environmental stratifications and typologies: An overview. *Agriculture, Ecosystems and Environment*doi:10.1016/j.agee.2010.01.009.

Heard MS, Rothery P, Perry JN, and Firbank LG (2005). Pedicting longer-term changes in weed populations under GMHT crop management. *Weed Research*, 45: (5) 331–338.

Höfte H, and Whiteley HR (1989). Insecticidal crystal proteins of *Bacillus thuringiensis. Microbiological Reviews*, 53: (2) 242–255.

Holland JM (2004). The environmental consequences of adopting conservation tillage in Europe: reviewing the evidence. *Agriculture Ecosystems & Environment*, 103: (1) 1–25.

Holling CS (1973). Resilience and stability of ecological systems. *Annual Review of Ecology and Systematics*, 4:1–23.

Hooper DU, Chapin FS, Ewel JJ, Hector A, Inchausti P, Lavorel S, Lawton JH, Lodge DM, Loreau M, Naeem S, Schmid B, Setala H, Symstad AJ, Vandermeer J, and Wardle DA (2005). Effects of biodiversity on ecosystem functioning: A consensus of current knowledge. *Ecological Monographs*, 75: (1) 3–35.

Huggett AJ (2005). The concept and utility of 'ecological thresholds' in biodiversity conservation. *Biological Conservation*, 124:301–310.

IUCN (2001). IUCN Red List Categories and Criteria: Version 3.1., IUCN Species Survival Commission, Gland Switzerland and Cambridge UK. pp. 30

IUCN (2003). Guidelines for the application of IUCN Red List criteria at regional level Version 3.0, IUCN Species Survival Commission. IUCN, Gland, Switzerland and Cambridge, UK. pp. 26

IUCN (2008). Guidelines for using the IUCN Red List categories and criteria Version 7.0, Prepared by the Standards and Petitions Working Group of the IUCN SSC Biodiversity Assessments Sub-Committee in August 2008. Gland, Switzerland and Cambridge UK. pp. 70. http://intranet.iucn.org/webfiles/doc/SSC/RedList/RedListGuidelines.pdf.

Jeanneret P, Schüpbach B, and Luka H (2003). Quantifying the impact of landscape and habitat features on biodiversity in cultivated landscapes. *Agriculture, Ecosystems and Environment*, 98:311–320.

Kaennel M (1998). Biodiversity: a diversity *in* definitions. in "Assessment of biodiversity for improved forest planning" (Bachmann P, Köhl M and Päivinen R, eds.), Kluwer Academic Publishers, Dordrecht NL. pp. 71–81.

Kägi B, Stalder A, and Thommen M (2002). Wiederherstellung und Ersatz im Natur- und Landschaftsschutz, Leitfaden Umwelt Nr. 11. Bundesamt für Umwelt, Wald und Landschaft (BUWAL), Bern. pp. 123

Keller V, Kéry M, Schmid H, and Zbinden N (2008). Swiss Bird Index SBI: Update 2008. Faktenblatt, Schweizerische Vogelwarte, Sempach CH. pp. 4. http://infonet.vogelwarte.ch/upload/25729251.pdf

Knacker T, Forster B, Römbke J, and Frampton GK (2003). Assessing the effects of plant protection products on organic matter breakdown in arable fields-litter decomposition test systems. *Soil Biology & Biochemistry*, 35: (10) 1269–1287.

Krebs JR, Wilson JD, Bradbury RB, and Siriwardena GM (1999). The second silent spring? *Nature*, 400: (6745) 611–612.

Kremen C (2005). Managing ecosystem services: what do we need to know about their ecology? *Ecology Letters*, 8: (5) 468–479.

Kruess A, and Tscharntke T (1994). Habitat fragmentation, species loss, and biological control. *Science*, 264: (5165) 1581–1584.

Kuiters AT, and Slim PA (2003). Tree colonisation of abandoned arable land after 27 years of horse-grazing: the role of bramble as a facilitator of oak wood regeneration. *Forest Ecology and Management*, 181: (1–2) 239–251.

Kunin WE, and Lawton JH (1996). Does biodiversity matter? Evaluating the case for conserving species. *in* "Biodiversity – a biology of numbers and difference" (Gaston KJ, ed.), Blackwell Science, Oxford UK. pp. 283–308.

Lawton JH (1994). What do species do in ecosystems. *Oikos*, 71: (3) 367–374.

Losey JE, Rayor LS, and Carter ME (1999). Transgenic pollen harms monarch larvae. *Nature*, 399: (6733) 214.

Losey JE, and Vaughan M (2006). The economic value of ecological services provided by insects. *Bioscience*, 56: (4) 311–323.

Luck G (2005). An introduction to ecological thresholds. *Biological Conservation*, 124:299–300.

Macarthur R (1955). Fluctuations of animal populations, and a measure of community stability. *Ecology*, 36: (3) 533–536.

Maclaurin J, and Sterelny K (2008). What is biodiversity?, The University of Chicago Press, Chicago. pp. 217.

Malone LA, and Pham-Delegue MH (2001). Effects of transgene products on honey bees (*Apis mellifera*) and bumblebees (*Bombus* sp.). *Apidologie*, 32: (4) 287–304.

Marshall EJP, Brown VK, Boatman ND, Lutman PJW, Squire GR, and Ward LK (2003). The role of weeds in supporting biological diversity within crop fields. *Weed Research*, 43: (2) 77–89.

May MJ, Champion GT, Dewar AM, Qi A, and Pidgeon JD (2005). Management of genetically modified herbicide-tolerant sugar beet for spring and autumn environmental benefit *Proceedings of the Royal Society B-Biological Sciences*, 272: (1559) 111–119.

McCann KS (2000). The diversity-stability debate. *Nature*, 405: (6783) 228–233.

McNaughton SJ (1977). Diversity and stability of ecological communities – comment on role of empiricism in ecology. *American Naturalist*, 111: (979) 515–525.

Meissle M, Mouron P, Musa T, Bigler F, Pons X, Vasileiadis P, Otto S, Antichi D, Kiss J, Palinkas Z, Dorner Z, van der Weide R, Groten J, Czembor E, Adamczyk J, Thibord JB, Melander B, Cordsen Nielsen G, Poulsen RT, Zimmermann O, Verschwele A, and Oldenburg E (2010). Pests, pesticide use and alternative options in European maize production: current status and future prospects. *Journal of Applied Entomology*, 134:357–375.

Mendelsohn M, Kough J, Vaituzis Z, and Matthews K (2003). Are Bt crops safe? *Nature Biotechnology*, 21: (9) 1003–1009.

Mepham B, Kaiser M, Thorstensen E, Tomkins S, and Millar K (2006). Ethical Matrix: manual, Agricultural Economics Research Institute (LEI), The Hague NL. pp. 45. http://www.ethicaltools.info/content/ET2%20Manual%20EM%20(Binnenwerk%2045p).pdf

Merriam-Webster Online (2011). Merriam-Webster Online Dictionary copyright © 2005 by Merriam-Webster, Incorporated Merriam-Webster Inc., P.O. Box 281, Springfield, MA www.m-w.com

Millenium Ecosystem Assessment (2005). Ecosystems and human well-being: Synthesis, Island Press, Washington DC. pp. 137

Moonen AC, and Barberi P (2008). Functional biodiversity: an agroecosystem approach. *Agriculture Ecosystems & Environment*, 127: (1–2) 7–21.

Moser D, Gygax A, Bäumler B, Wyler N, and Palese R (2002). Rote Liste der gefährdeten Farn- und Blütenpflanzen der Schweiz, Bundesamt für Umwelt, Wald und Landschaft, Bern; Zentrum des Datenverbundnetzes der Schweizer Flora, Chambésy; Conservatoire et Jardin botanique de la Ville de Genève, Chambésy. pp. 118

Muradian R (2001). Ecological thresholds: a survey. *Ecological Economics*, 38: (1) 7–24.

Naeem S, and Li SB (1997). Biodiversity enhances ecosystem reliability. *Nature*, 390: (6659) 507–509.

Naranjo SE (2009). Impacts of Bt crops on non-target invertebrates and insecticide use patterns. *CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition and Natural Resources*, 4: (11) 1–11.

NHG (SR 451). Bundesgesetz über den Natur- und Heimatschutz, Systematische Sammlung des Bundesrechts, Bern. pp. 24

NHV (SR 451.1). Verordnung über den Natur- und Heimatschutz, Systematische Sammlung des Bundesrechts, Bern. pp. 30

Niehaus R (1984). The future role of risk assessment in nuclear safety. pp. 7. www.iaea.org/Publications/Magazines/Bulletin/Bull254/25402043036.pdf

Nöh I (2002). Bewertung von Umweltwirkungen gentechnisch veränderter Organismen (GVO). *UWSF – Zeitschrift für Umweltchemie und Ökotoxikologie*, 14: (3) 155–163.

Norton BG (2008). Towards a policy-relevant definition of biodiversity. *in* “Saving biological diversity” (Askins RA, Dreyer GD, Visqilio GR and Whitelaw DM, eds.), Springer. pp. 11–20.

Noss RF (1990). Indicators for monitoring biodiversity – a hierarchical approach. *Conservation Biology*, 4: (4) 355–364.

NRC (2010). The impact of genetically engineered crops on farm sustainability in the United States, Committee on the Impact of Biotechnology on Farm-Level Economics and Sustainability. National Research Council, Washington DC. pp. 240

OECD (1993). Safety considerations for biotechnology: scale-up of crop plants, Organisation for Economic Co-Operation and Development, Paris. pp. 43

OECD (2007). Consensus document on safety information on transgenic plants expressing *Bacillus thuringiensis*-derived insect control proteins, Organisation for Economic Co-Operation and Development, Paris. pp. 109

Oerke EC (2006). Crop losses to pests. *Journal of Agricultural Science*, 144:31–43.

Perrings C, and Opschoor H (1994). The loss of biological diversity: some policy implications. *Environmental and Resource Economics*, 4: (1) 1–11.

Perry JN, Rothery P, Clark SJ, Heard MS, and Hawes C (2003). Design, analysis and statistical power of the Farm-Scale Evaluations of genetically modified herbicide-tolerant crops. *Journal of Applied Ecology*, 40:17–31.

Peterson G, Allen CR, and Holling CS (1998). Ecological resilience, biodiversity, and scale. *Ecosystems*, 1: (1) 6–18.

Pidgeon JD, May MJ, Perry JN, and Poppy G (2007). Mitigation of indirect effects of GM crops. *Proceedings of the Royal Society B-Biological Sciences*, 274:1475–1479.

PSMV (SR 916.161). Verordnung über das Inverkehrbringen von Pflanzenschutzmitteln, Systematische Sammlung des Bundesrechts, Bern. pp. 290

Raybould A (2006). Problem formulation and hypothesis testing for environmental risk assessment
of genetically modified crops. *Environmental Biosafety Research*, 5: (3) 119–125.

Raybould A (2007). Ecological versus ecotoxicological methods for assessing the environmental risks of transgenic crops. *Plant Science*, 173:589–602.

Redford KH, and Richter BD (1999). Conservation of biodiversity in a world of use. *Conservation Biology*, 13: (6) 1246–1256.

Reid WV, Mc Neely JA, Tunstall DB, Bryant DA, and Winograd M (1993). Biodiversity indicators for policy-makers, World Resources Institute, New York. pp. 42

Robinson RA, and Sutherland WJ (2002). Post-war changes in arable farming and biodiversity in Great Britain. *Journal of Applied Ecology*, 39: (1) 157–176.

Rodrigues ASL, Pilgrim JD, Lamoreux JF, Hoffmann M, and Brooks TM (2006). The value of the IUCN Red List for conservation. *Trends in Ecology & Evolution*, 21: (2) 71–76.

Römbke J (2006). Tools and techniques for the assessment of ecotoxicological impacts of contaminants in the terrestrial environment. *Human and Ecological Risk Assessment*, 12: (1) 84–101.

Romeis J, Bartsch D, Bigler F, Candolfi MP, Gielkens M, Hartley SE, Hellmich RL, Huesing JE, Jepson PC, Layton R, Quemada H, Raybould A, Rose RI, Schiemann J, Sears MK, Shelton AM, Sweet J, Vaituzis Z, and Wolt JD (2008a). Nontarget arthropod risk assessment of insect-resistant GM crops. *Nature Biotechnology*, 26:203–208.

Romeis J, Meissle M, and Bigler F (2006). Transgenic crops expressing *Bacillus thuringiensis* toxins and biological control. *Nature Biotechnology*, 24: (1) 63–71.

Romeis J, Meissle M, Raybould A, and Hellmich RL (2008b). Impact of insect-resistant genetically modified crops on non-target arthropods. *in* “Environmental impact of genetically modified/novel crops” (Ferry N and Gatehouse AMR, eds.), CABI, Wallingford, UK. pp. 163–196.

Roschewitz I, Gabriel D, Tscharntke T, and Thies C (2005). The effects of landscape complexity on arable weed species diversity in organic and conventional farming. *Journal of Applied Ecology*, 42: (5) 873–882.

Sanvido O, Romeis J, and Bigler F (2009). An approach for post-market monitoring of potential environmental effects of Bt-maize expressing Cry1ab on natural enemies. *Journal of Applied Entomology*, 133:236–248.

Sanvido O, Widmer F, Winzeler M, and Bigler F (2005). A conceptual framework for the design of environmental post-market monitoring of genetically modified plants. *Environmental Biosafety Research*, 4:13–27.

Scheffer M, Carpenter S, Foley JA, Folke C, and Walker B (2001). Catastrophic shifts in ecosystems. *Nature*, 413: (6856) 591–596.

Scheffer M, and Carpenter SR (2003). Catastrophic regime shifts in ecosystems: linking theory to observation. *Trends in Ecology & Evolution*, 18: (12) 648–656.

Schnepf E, Crickmore N, Van Rie J, Lereclus D, Baum J, Feitelson J, Zeigler DR, and Dean DH (1998). *Bacillus thuringiensis* and its pesticidal crystal proteins. *Microbiology and Molecular Biology Reviews*, 62: (3) 775–806.

Schwartz MW, Brigham CA, Hoeksema JD, Lyons KG, Mills MH, and van Mantgem PJ (2000). Linking biodiversity to ecosystem function: implications for conservation ecology. *Oecologia*, 122: (3) 297–305.

SCNAT (2006). Die Schweiz braucht eine Biodiversitätsstrategie!, Swiss Biodiversity Forum, Berne. pp. 4. www.biodiversity.ch/downloads/Argumente_D.pdf

Sears MK, Hellmich RL, Stanley-Horn DE, Oberhauser KS, Pleasants JM, Mattila HR, Siegfried BD, and Dively GP (2001). Impact of Bt corn pollen on monarch butterfly populations: A risk assessment. *Proceedings of the National Academy of Sciences of the United States of America*, 98: (21) 11937–11942.

Shennan C (2008). Biotic interactions, ecological knowledge and agriculture. *Philosophical Transactions of the Royal Society B-Biological Sciences*, 363: (1492) 717–739.

Slingenberg A, Braat H, cvan der Windt H, Rademaekers K, Eichler L, and Turner K (2009). Study on understanding the causes of biodiversity loss and the policy assessment framework, ECORYS Nederlands BV, Rotterdam NL. pp. 206. http://ec.europa.eu/environment/enveco/biodiversity/pdf/causes_biodiv_loss.pdf

SRU (2004). Environmental report 2004: ensuring environmental protection capacity, German Advisory Council on the Environment. pp. 115

Stoate C, Baldi A, Beja P, Boatman ND, Herzon I, van Doorn A, de Snoo GR, Rakosy L, and Ramwell C (2009). Ecological impacts of early 21st century agricultural change in Europe – A review. *Journal of Environmental Management*, 91: (1) 22–46.

Stoate C, Boatman ND, Borralho RJ, Carvalho CR, de Snoo GR, and Eden P (2001). Ecological impacts of arable intensification in Europe. *Journal of Environmental Management*, 63: (4) 337–365.

Storkey J, Bohan DA, Haughton AJ, Champion GT, Perry JN, Poppy GM, and Woiwod IP (2008). Providing the evidence base for environmental risk assessments of novel farm management practices. *Environmental Science & Policy*, 11: (7) 579–587.

Storkey J, and Westbury DB (2007). Managing arable weeds for biodiversity. *Pest Management Science*, 63: (6) 517–523.

Suding KN, and Hobbs RJ (2009). Threshold models in restoration and conservation: a developing framework. *Trends in Ecology & Evolution*, 24: (5) 271–279.

Suter GW (2000). Generic assessment endpoints are needed for ecological risk assessment. *Risk Analysis*, 20: (2) 173–178.

Suter GW (2007). Ecological risk assessment, Second/Ed., CRC Press, Boca Raton FL, USA. pp. 643.

Swift MJ, Izac AMN, and van Noordwijk M (2004). Biodiversity and ecosystem services in agricultural landscapes – are we asking the right questions? *Agriculture, Ecosystems and Environment*, 104:113–134.

Thompson R, and Starzomski BM (2007). What does biodiversity actually do? A review for managers and policy makers. *Biodiversity and Conservation*, 16: (5) 1359–1378.

Tilman D (2000). Causes, consequences and ethics of biodiversity. *Nature*, 405: (6783) 208–211.

Tilman D, Cassman KG, Matson PA, Naylor R, and Polasky S (2002). Agricultural sustainability and intensive production practices. *Nature*, 418: (6898) 671–677.

Tscharntke T, Klein AM, Kruess A, Steffan-Dewenter I, and Thies C (2005). Landscape perspectives on agricultural intensification and biodiversity– ecosystem service management. *Ecology Letters*, 8: (8) 857–874.

VGVL (SR 817.022.51). Verordnung des EDI über gentechnisch veränderte Lebensmittel, Systematische Sammlung des Bundesrechts, Bern. pp. 12

Walker B (1995). Conserving biological diversity through ecosystem resilience. *Conservation Biology*, 9: (4) 747–752.

Walker BH (1992). Biodiversity and ecological redundancy. *Conservation Biology*, 6: (1) 18–23.

Watkinson AR, Freckleton RP, Robinson RA, and Sutherland WJ (2000). Predictions of biodiversity response to genetically modified herbicide-tolerant crops. *Science*, 289: (5484) 1554–1557.

Weil L (2002). Charakterisierung der Risiken der Kernenergienutzung. pp. 147. www.uni-saarland.de/fak7/fze/AKE_Archiv/AKE2004H/AKE2004H_Vortraege/AKE2004H_05Weil_Charakterisierung_derKernenergieRisiken/AKE2004H_05aWeil_habil2002_Risiken-derKernenergienutzung.pdf

Wilby A, and Thomas MB (2002). Natural enemy diversity and pest control: patterns of pest emergence with agricultural intensification. *Ecology Letters*, 5: (3) 353–360.

With KA, Pavuk DM, Worchuck JL, Oates RK, and Fisher JL (2002). Threshold effects of landscape structure on biological control in agroecosystems. *Ecological Applications*, 12: (1) 52–65.

Wolfenbarger LL, Naranjo SE, Lundgren JG, Bitzer RJ, and Watrud LS (2008). Bt crop effects on functional guilds of non-target arthropods: a meta-analysis. *PLoS One*, 3: (5) e2118. doi:10.1371/journal.pone.0002118.

Wolt JD, Keese P, Raybould A, Fitzpatrick JW, Burachik M, Gray A, Olin SS, Schiemann J, Sears M, and Wu F (2010). Problem formulation in the environmental risk assessment for genetically modified plants. *Transgenic Research*, 19:425–436.

Zurbrügg C, Hönemann L, Meissle M, Romeis J, and Nentwig W (2010). Decomposition dynamics and structural plant components of genetically modified Bt maize leaves do not differ from leaves of conventional hybrids. *Transgenic Research*, 19: (2) 257–267.

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ANNEX 2: WHAT IS RISK?

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Andreas Bachmann and Klaus Peter Rippe, Ethik im Diskurs

Intensive discussions within the project team regarding the conception of risk have shown that this concept needs to be clarified more thoroughly. The main reason is that the standard approach used in environmental risk assessment to assess risk as a function of exposure and hazard must be questioned from a scientific theoretical point of view as it does not indicate where the aspect of probability, which is essential for an adequate definition of risk, comes into play. The debate within the project team on this issue resulted in the formulation of some preliminary theses by the two ethicists, Andreas Bachmann and Klaus Peter Rippe, that must be provocative to any risk researcher. In the following, we want to present these theses being fully aware of their provocative and controversial character.

What is risk?

Risk as a technical term is characterized as a function of the extent (or the magnitude) and the likelihood (or probability) of harm.[44] Both variables – probability and magnitude of harm – are equally essential. Harm denotes something that should be evaluated negatively. Therefore, the concept of risk is inherently value laden. For this reason, determining risks is not a purely scientific issue. At best, empirical science can determine the probability of a future event occurring. It cannot determine, however, how this fact – the fact that something will occur with a certain probability – should be evaluated, i.e., whether it is a risk, that is acceptable or not.

This technical definition of risk must be distinguished from two nontechnical usages. First, in everyday language, the term risk often only refers to the probability that harm will occur. The term risk is used in this way, for example, when we say that there is only a small risk of being killed in a plane crash. Second, the term risk at times only refers to the possible magnitude of harm. This is the case, for example, when we say that lung cancer is one of the major risks that affect smokers.

It is important to keep in mind that the *technical concept* of risk always refers to both, the magnitude and the probability of harm. To give an example: since the risk of being killed implies a great harm, it can only be considered to be small if the probability of occurrence of this harm is extremely low.

[44] If function is understood as a product then risk is a product of the probability and the extent of harm. In other words: risk is an expectation value. The following example may illustrate what this means: If in situation a) there is a 1% probability of 10'000 people dying and in situation b) a 50% probability of 200 people dying the risk, i.e. the expectation value in both cases is 100 dead people. Identical expectation values should be evaluated identically. This means that if the risk of situation b) is deemed inacceptable this also applies to the risk of situation a).

What is the relation between risk and hazard? Hazard is usually defined as the intrinsic ability or the potential of something (an individual being, a substance, an action, an event etc.) to cause harm. Without hazard, there can be no harm and thus no risk. In this sense, hazard is a necessary condition of risk; but it is not an aspect or a component of risk. A toxin, for instance, may have the intrinsic ability to kill people. However, it becomes a risk only if someone is exposed to it. If this happens, its potential to cause harm may turn into a real harm; i.e., there is a certain probability that harm will actually occur.

Every hazardous entity is a source of risks. The hazard, i.e., the harm potential related to this source exists irrespective of whether anybody is exposed to the risk source.[45] A risk, however, emerges only when someone is actually exposed to the risk source. Therefore, exposure is another necessary condition of risk: without exposure, there is no risk. Exposure in this sense is a digital concept: either one is exposed to a risk source or one is not exposed. As long as nobody is exposed to a potentially lethal toxin, for example, there is no risk since there is no probability of a harm (death in our example) occurring. In this respect, the likelihood of being exposed is therefore irrelevant. Those who use the term "likelihood of exposure" usually refer to a certain percentage of a population that will presumably be exposed to a hazard. This kind of likelihood, however,

[45] Hazard designates the harm potential, i.e., the intrinsic ability to cause harm. It is therefore completely independent of the probability of harm occurring. For example, if the harm potential of a big avalanche is greater than the harm potential of a small avalanche, this means that the big avalanche can – has the intrinsic ability to – cause more harm than the small one. The former could, let us say, lead to the complete destruction of a protection forest whereas the latter could only lead to a destruction of a small part of this forest. This hazard exists irrespective of any probability of the respective harm occurring. Another example may help to further clarify this point: Toxic substance A and toxic substance B both have the ability to kill. This is their hazard. The probability that death occurs if a person ingests either of these substances may vary because substance A is more toxic than substance B. Hence, it may be true that substance A is more likely to kill this person than substance B. However, this does not affect the hazard, i.e., the intrinsic ability to cause harm. Rather, it presupposes the determination of the hazard: Even though both substances can be deadly (hazard), substance A is more likely to kill a person than – the same quantity of – substance B. If this is plausible, however, are there not two different hazards relating to these substances? The answer is no because, as far as the intrinsic ability to kill individual persons is concerned, substance A and substance B are identical. In colloquial language, the answer may be different. It is completely normal to say that substance A is more hazardous than substance B, that is, when a person is exposed to these substances, substance A is more likely to kill this person than the same quantity of substance B. Thus understood, however, hazard is just another word for risk (not in a technical sense though, but rather in the everyday sense mentioned above referring to the probability that a harm will occur). For this reason, it seems advisable to forego the concept of hazard altogether and to use the notions of harm potential and risk instead, the latter being defined as a function (the product) of probability and magnitude of harm.

is not part of the risk itself. In order to determine a risk, the only relevant factor is the number of individuals (or the percentage of a population) actually being exposed.[46] Of course, certain features or parameters of exposure may have an effect on probability. For instance, temporal duration or frequency of exposure (or magnitude of dose) may play a role: the more frequent and the longer an individual or a population is exposed to a risk source, the higher the probability is of harm occurring. However, this kind of exposure is not equal to the actual probability. Rather, the connection is inferential insofar as information regarding temporal duration, frequency or magnitude of dose can be used to estimate the likelihood of the occurrence of harm.

As shown, neither hazard nor exposure – understood as the bare fact of being exposed to a risk source – is a component of a risk. Yet, in order to determine a risk, we have to know the hazard (i.e., the intrinsic ability of a risk source to cause harm) as well as the (approximate) number of individuals or the percentage of a population actually exposed to this source.[47] This knowledge is necessary because without it, the probability and the magnitude of harm associated with a risk source cannot be determined. However, further knowledge is required to determine probability and magnitude of harm. Some examples – nuclear power plants, avalanches, ecotoxicology – may be useful to clarify this point.

Nuclear power plants

The hazard of nuclear power plants, that is, their intrinsic ability to cause harm, is extremely great. Worst case scenarios assume that a core melt accident could lead to the death of thousands of people. This hazard exists independently of whether anybody would be harmed by such an accident; that is, it would also exist if a remotely controlled nuclear power plant was situated in the middle of a deserted area so that nobody would be killed by a core melt. If this were the case, nobody would be exposed to this risk source. Consequently, the possible harm could not turn into a probable harm and there would thus be no risk. In reality, however, the situation is quite different since many atomic power plants are situated in densely populated areas, which means that countless people are actually exposed to this risk source. In order to determine the risk for these

[46] In many cases, an exact number cannot be ascertained. Thus, the number of individuals (or the percentage of a population) actually being exposed to a risk source must be estimated. The term "likelihood of exposure" refers to this estimate. If the exact number (or the exact percentage) cannot be provided, this entails an uncertainty with regard to the determination of a risk.

[47] As mentioned, exposure also comprises aspects such as how much of a substance someone encounters. This may have an influence on the probability of a specified harm occurring.

people, we have to know the probability and the magnitude of harm. Suppose the probability of a reactor meltdown accident is 1:33,000 years. Suppose, furthermore, that the number of dead people (including late fatalities) in case of such an accident amounts to 50,000. Given that quantifiable risks can be expressed in terms of expectation values (i.e., the product of the two variables probability and magnitude of harm), the risk (the expectation value) amounts to 1.5 dead persons per year.

A major problem is whether, and if so how, the probability and the magnitude of harm can be calculated. A purely mathematical calculation is almost never possible. Usually, the two variables of a risk must be estimated whereby the estimates are based on experience and/or model calculations. How these variables are determined depends on the case at hand.

Regarding the risk of a meltdown accident in a nuclear power plant, the analysis of the probability component is a complex procedure (Birkhofer, 1980; Weil, 2002).[48] It basically consists of recording the possible accident sequences induced by an initiating event by means of event trees and then calculating the probabilities of failure of the different safety systems ultimately leading to a core melt by means of fault tree analyses using Boolean logic. One problematic aspect of this approach is that its results are afflicted with uncertainties resulting from unverifiable assumptions and models. Another problematic aspect is that experts do not agree on the concept of probability. Some of them favor a subjectivistic probability theory according to which probability is a measure of degree of belief. Others favor an objectivistic probability theory according to which probability refers to the relative frequency of an event (Birkhofer, 1980; Weil, 2002).

Depending on the direction in which the radioactive radiation released by a core melt moves, the magnitude of harm (expressed in lives lost) is great(er) or small(er). What is thus required for the risk assessment of a Maximum Credible Accident (MCA) – beyond calculating the probability of a core melt accident – is to determine the probability of the direction in which the radiation would move in case of an MCA. MCA refers to the worst possible magnitude of harm ("hazard"): the greatest number of people possibly harmed (i.e., killed) in the short and long run by a core melt accident and its associated discharge of radioactivity. Given the state of scientific knowledge, it is clear that this harm, as well as the probability of its occurrence, can only be roughly estimated, but not precisely determined (Niehaus, 1984; Weil, 2002).

[48] In the following, only the risks of purely technical failures are taken into consideration. We are well aware, however, that other aspects such as human failure or external factors (for instance, earthquakes or tsunamis, or a combination of both) are also relevant for the determination of the risk.

This example highlights that when we are about to perform a risk assessment, we do not only want to know what may or could happen, we want to know the probability with which it will happen. In our example, we want to know the probability of a core melt accident occurring and we want to know the probability of the radioactive radiation released by this accident to harm (kill) the greatest possible number of people.

This example also shows that risk assessments can be replete with uncertainties regarding the probabilities and the magnitude of harm. These uncertainties limit the accuracy and reliability of risk statements. Hence, they should be reduced as far as possible. In many cases, however, it will not be possible to completely eliminate them.

Avalanches

While risks of nuclear power plants are mainly induced by a certain technology, the risks associated with avalanches may be regarded as primarily induced by natural processes.[49] The official scientific terminology (see www.slf.ch) in this area is muddled as it equates hazard with the probability of an avalanche occurring and risk with potential harm. Both terms are used in a wrong way. Hazard means the *potential* of an avalanche to cause harm. The aspect of probability is not included. And risk is not potential harm, but *probable* harm. Furthermore, since risk always contains a harm component, it must not be confounded with the probability of some event occurring. The use of the risk concept is only adequate if the event in question must be considered harmful. Avalanches are only risks therefore, if they threaten individuals (or material assets) that would be harmed with a certain probability in case they would be triggered.

As far as the probability of triggering avalanches is concerned, European avalanche bulletins content themselves with qualitative statements, distinguishing between five levels: low, limited, medium, high and very high. These levels are rather vaguely defined. "Low," for instance, means that due to generally very stable snow, avalanches triggered by persons are unlikely and confined to very few extremely steep slopes. "Very high" means that due to generally unstable snow, even on gentle slopes, many large spontaneous avalanches are likely to occur. To reach this degree of precision, a great amount of data and experience is required. Since avalanches are complex phenomena, even this does not seem to suffice, however, to determine probabilities quantitatively – much less to predict avalanches with certainty.

[49] Even though they can be considerably increased or decreased by human behavior.

As far as the hazard of avalanches is concerned, the decisive criterion is avalanche size. There are four sizes: sluff, small, medium, large. “Small,” for example, means that the avalanche can bury, injure or kill a person. “Large” means that also large trucks and trains as well as large buildings and forest areas can be buried and destroyed.

Knowing the level of probability and hazard, however, is not sufficient to determine the risks associated with avalanches. The aspect of probability mentioned above solely refers to the likelihood that avalanches are triggered by spontaneous events or human activity. The probability of harm remains unknown. The aspect of hazard solely refers to possible harm, not to probable harm. What is lacking is the determination of the probabilities related to the different levels of hazard. For that purpose, the component of exposure needs to be analyzed. Exposure has two aspects. On the one hand, the aspect of being exposed to a risk source: if someone is not exposed to an avalanche in the sense that he cannot possibly be harmed for reasons of spatial distance, there is no corresponding risk. On the other hand, exposure has characteristics such as temporal duration or geographical location that affect the probability of being harmed: depending on the route skiers or climbers choose, for instance, the probability of being harmed (i.e., injured or killed) by an avalanche is greater or lower. Again, given the state of knowledge, these risks can only be determined qualitatively. They cannot be quantified because neither the probability of being injured or killed by an avalanche nor the number of persons being exposed can be precisely (numerically) ascertained.

Ecotoxicology

In ecotoxicology, risk is commonly interpreted as a function of exposure and hazard. This interpretation is not equivalent to the standard definition of risk being a function of probability and magnitude of harm since probability is not the same as exposure and magnitude of harm is not the same as hazard.

As explicated before, hazard is the intrinsic ability or the potential of something – a toxic substance in our case – to cause harm. In other words, hazard refers to the possible harm such a substance may bring about. Risk assessments, however, do not aim at determining possible harm. Rather, they are targeted at determining (more or less) *probable harm*. To reach this goal, exposure analysis is the next necessary step. Again, the two aspects of exposure must be carefully distinguished. First, there is only a risk if someone is exposed to the hazardous risk source. Second, every exposure is characterized by certain properties (exposure factors), such as, temporal duration, frequency, dose, number of individuals exposed etc. These properties must be known in order to determine the probability of harm. They are, however, neither equal to the actual probability nor do they suffice as such to calculate this probability. What is also required is a stochastic deliberation reflecting the fact that there is not enough causal knowledge for making deterministic predictions.

An example may serve to illustrate how this might work. A population of 100 fish is exposed to a certain dose of a toxic substance. Within a certain period of time, 50% of the fish die. This is the harmful effect caused by the toxic substance. From this, a stochastic conclusion regarding risks can be drawn (provided the sample is large enough), namely, the conclusion that the probability of dying amounts to 50% (under laboratory conditions) for every fish of a population exposed to this dose of a toxic substance.[50]

There is an important difference between the statement "dose x of a toxin will lead to the death of 50% of the members of the exposed population" and, "there is, *ceteris paribus*, a 50% probability for each member of the exposed population to die of dose x of a toxin." The first is a prediction based on a cause-effect-relationship. It states a certainty as opposed to the second statement which expresses a probability implying an uncertainty whether the future event actually will take place. The former is a deterministic prediction, and the latter is a probabilistic prediction. The aim of risk assessments are accurate probabilistic predictions. Deterministic predictions by contrast are not part of such an assessment. If deterministic predictions are possible, we should not speak of "risk analysis" or "risk assessment."

This caveat is important for the following reason. Given that we live in a causally determined world,[51] it would be possible to predict any event with certainty if we knew all relevant causal factors.[52] Under such conditions, there would be no risks. The world, however, is so complex that, given the current state of science, it is impossible in many cases to make reliable predictions based on our knowledge of cause-effect-relationships. In this situation, we have to content ourselves with probabilistic predictions, especially with regards to complex systems. In justifying such predictions, three limiting factors play a crucial role:

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[50] "Every fish" does not refer to the single fish as an individual, but as a member of a certain fish species.

[51] If quantum mechanics is true, physical processes at subatomar scales cannot be explained deterministically. At this level, therefore, only probabilistic predictions would be possible.

[52] Thus, uncertainty is always due to lack of information or knowledge. There is no uncertainty that a possible increase in knowledge could not eventually eliminate, provided determinism is true.

- *Time axis:* Observation periods are usually rather limited. It is thus difficult to predict (in a probabilistic sense) what may happen in the long-term.
- *Amount of data:* Sufficient data for making reliable probability statements is often not available. Yet, without sufficient data, the risk level cannot be determined. Given a sample of 100 persons of whom 50 are smokers and 50 are nonsmokers it is not possible to derive any scientifically sound statement regarding the (absolute) risk of lung cancer for smokers in general.
- *Causal factors:* Laboratory experiments often do not – or, given the current state of knowledge, cannot – detect all relevant causal factors. And even if all relevant causal factors are known, their interaction may be too complex to allow deterministic predictions.

It may be argued that the toxic effects of a substance can be determined more reliably in the laboratory than in the reality of a complex system because the causal factors can be controlled more accurately within the laboratory. However, what we want to know in the end are the effects of the toxin under *real* environmental conditions, that is, under conditions in which a whole array of other factors may influence the effects of the toxin. These effects are too complex to be deterministically predicted, for instance, by extrapolating them out of the available limited knowledge. At this point, we have to resort to risk analysis, ultimately aiming at scientifically sound probabilistic predictions. However, here we face yet another problem. In the laboratory, the hazardousness of a toxin can be ascertained under specific and controlled conditions. In field trials, the results achieved in the laboratory can be tested, although only under restricted conditions and for a limited amount of time. At most, field trials thus enable a more complex causal analysis. However, this is not enough to make sufficiently reliable risk statements as field trials cannot generate the amount of data necessary to make sound probabilistic predictions about effects in complex environmental systems. Presumably, the only way to achieve this is to monitor *real* systems, whereby "monitoring" means collecting the data required to make well-founded probabilistic predictions.

What does this mean with regards to the risk assessment of GMO? It is important to note that the approach sketched thus far is only tenable in this respect if certain assumptions concerning GMO in general, GM crops in particular prove to be plausible.[53] The basic question is: If a crop such as maize is changed by inserting a foreign gene into its genome, is the GM maize just the old maize plus

[53] The following remarks are owed to critical comments of Alan Raybould on the first draft of this chapter.

the new trait or should it be regarded as a new kind of maize? How one answers this question has considerable repercussions on environmental risk assessment. The approach outlined in this chapter builds on the assumption that the transgenic maize is a new kind of maize. It cannot be maintained if this maize is just the old kind with a new trait. What is meant by this difference and what are the implications for risk assessment?

Suppose a foreign gene expressing a toxic protein is inserted into a plant. If this GM plant B is the conventional plant A plus this new trait, that would entail the following:

- As far as risks are concerned there is no difference between plant A and plant B regarding the already known risks of plant A. Hence, if the risks of plant A are sufficiently known and deemed to be acceptable, there is no need for risk tests on plant B.
- Risk tests are only required with regards to the new gene expressing a toxic protein. This can be done in the laboratory, for instance, in order to examine the effects of the toxin on non-target organisms. Given that it is clear what is meant by harm in this context and what needs protecting from harm (targets for protection), this allows testing whether the GM crop in question is environmentally safe. It can then be argued that it is safe if the likelihood of unacceptable harm occurring is minimal. This can be ascertained by exposing the non-target organisms to a dose of this toxin that is (much) higher than these organisms will encounter under real conditions. If the toxin even in this case does not cause any harm that is regarded as inacceptable the GM plant as a whole can be considered safe (enough). Field trials are therefore not necessary as regulatory authorities may permit commercial-scale cultivation of the crop without requiring more data.

There are two main objections to this view of the relation between the nature of a GM crop and risk assessment:

- This approach is not a risk model aimed at the determination of risks as the product of probability and harm. It is a causal model aiming at the detection of cause-effect-relations. Depending on the dose a toxin has certain impacts on target and non-target organisms deemed to be positive or negative (or neutral). These relations between cause and effect can be ascertained in the laboratory. To ensure that the GM plant is safe (enough), the targets for protection are exposed to a dose considerably higher than they will be exposed to in the field. If no negative effect is observed, the conclusion is drawn that the risk – the probability of unacceptable harm – is minimal. Only at this point, risk seems to play a role. However, what risk means is no more than the general epistemic proviso that we are not infallible and that it cannot be absolutely ruled out, therefore, we may have overlooked something.[54] This, however, is not what is meant by risk assessment, at least not if risk is defined in terms of probability and (magnitude of) harm. To be sure, this does not show that the concept of GM crops underlying this approach is inadequate. It only shows that this concept is not satisfactorily connected to risk assessment, understood as a genuinely probabilistic approach, but to a causal model which seeks to predict the effects of cultivating (certain) GM crops (for instance, on non-target organisms). Those in favor of this approach should therefore forego the concept of risk and use a deterministic, not a probabilistic language.

- A second objection is that conceiving of a GM plant as the conventionally bred template plus trait X resulting from genetic modification is inadequate. A GM plant is not the sum of the original plant's traits and trait X. It cannot be ruled out that this trait substantially changes the character of the GM crop in question due to effects on the genetic level (multiple insertions, deletion, filler DNA) and/or to epigenetic mechanisms (gene silencing, positional effects, and pleiotropic effects). The question is what this means for risk assessment. The main point is that the GM crop may not just show unintended but unexpected traits. For this reason, lab tests trying to determine the risks associated with this crop are of limited significance. They must be supplemented by field trials and by post-market monitoring. At this point, it is important to emphasize that environmental risk assessment should not be conceived of as a pragmatic tool for decision-making under conditions of limited time and money. Rather, its purpose is to generate the scientific risk knowledge necessary to decide whether the risks associated with GM plants are acceptable or not. Whatever is necessary to fulfill this task must be done – regardless of how long it takes and how much it costs. Of course, field trials as well as post-market monitoring should be based as far as possible on clear risk hypotheses. It does not make sense to collect large amounts of data if these data do not help improve risk knowledge. Yet, as long as we do not understand all the environmental factors that could influence the GM plant and the interplay between these factors and the structure of the plant field trials are necessary. This is so even if it were true that in many or even most

[54] In German, this is expressed by the phrase: "mit an Sicherheit grenzender Wahrscheinlichkeit."

cases, the environment mitigates rather than exacerbates potentially harmful effects. One central aim of risk assessment consists precisely of determining the probability of those – maybe not very common – cases in which harmful effects are exacerbated and not mitigated by the environment.

Above, an argument was mentioned according to which a GM crop is safe (enough) if the probability of unacceptable harm occurring is minimal. However, whether this argument is valid cannot be decided by empirical science since it concerns a normative question that lies beyond the reach of science: the question of acceptability. Thus, even if it were true that the risks of GM crops – including the risks concerning worst cases – can be ascertained in the laboratory, this would not entail that the commercial release of a GM crop is admissible if the likelihood of unacceptable harm is minimal.

As far as the normative criterion for risk acceptability is concerned, there are two prominent approaches that reject the idea that activities or technologies that have the ability to cause inacceptable harm are acceptable, all the same provided the probability of this harm occurring is minimal.

- The first approach is based on the maximin or minimax criterion. According to this criterion, unacceptable harm means harm that must be prevented at all costs. This implies that the likelihood must be zero, whenever possible. And this, in turn, entails that the respective activity – in our case, the commercial release of a GM crop – must be prohibited given that this is the only way to lower the likelihood of the harm occurring to zero. However, *almost zero* is not enough.
- The second approach is based on a threshold criterion according to which risk as the product of probability and magnitude of harm must not exceed a predefined threshold value. This implies that even if the probability of a harm occurring is extremely low, this per se does not justify the risk – or rather the activity associated with this risk – because the harm may be so severe that the risk is still above the threshold.

Regarding some quite well-known GM plants, for example, Bt-maize, one could argue that by now we do have enough data and knowledge to conclude that the risks associated with them are so low as to be negligible and therefore acceptable. This conclusion can only be valid, however, if the probability regarding the worst case, i.e., the greatest possible harm, can be determined with sufficient precision. "Sufficient precision" does not require quantitative specification. Qualitative determination may also be acceptable. For this to be the case, however, one condition must be met: it must be possible to categorize the probability in a way that allows comparing it to the probabilities of other risks, for instance, the probability of a strong earthquake – deemed to be low or very low. Otherwise, it remains too vague, making it impossible to decide whether the corresponding risk is acceptable or not.[55]

The same problem arises with regard to unintended effects of GM plants. In this case, the analysis of worst case scenarios should aim at estimating the probability with which, for example, pleiotropic and epigenetic effects trigger a dynamic that would result in an irrevocable destabilization or even complete collapse of ecosystem equilibrium. The main problem here is that on the one hand, it is inadmissible to extrapolate from the laboratory to the reality of complex ecological or agricultural systems whose causal factors are scarcely known.[56] On the other hand, it is not possible in this case to derive probabilities of specific events that have never occurred from known effects. It is an open question, then, as to how the probability of a maximum possible harm occurring can be determined, if it can be determined at all.[57] Since this is an important point, it is necessary to take a closer look at the conventional deterministic approach of assessing toxic risks of GM plants. In our context, the main point to discuss is whether this approach is able to give due consideration to the aspect of probability.

[55] It is often argued that the risks of a GM crop are acceptable if they are not (significantly) greater than the risks of its conventional counterpart. This normative argument is untenable for the following reason. Logically, the fact that B (a GM crop) is not worse than A (the respective non-GM crop) does not make A good or acceptable. It does not imply anything about the value of A. Even if A were very bad (harmful) and utterly inacceptable, it would still be true that B is not worse than A. Obviously, this does not make B acceptable. So this kind of comparison is empty with regard to the question of the acceptability of B. In other words, it only works if A is acceptable. However, how do we know that? The point is: Acceptability is a normative concept that cannot be determined just by looking at legal regulations. There are many legal regulations of risks that are accepted; and yet the risks regulated are inacceptable. Acceptability must be logically distinguished from acceptance. In this sense, it is a normative or ethical concept. Ultimately, the different ethical risk theories provide the standards for acceptable risks. Therefore, the *baseline* for acceptability cannot be an existing legal standard regulating conventional agricultural products. Acceptability must refer to normative standards that are independent of legal regulations even though they may happen to be enshrined in the law.

[56] This refers to the worst case scenario outlined above: the collapse of eco systems resulting from a dynamic due to pleiotropic or epigenetic effects. The point is simply this: whatever we may be able to test in a lab, it will not suffice to allow deriving the probability of this worst-case occurring. In other words, it will not suffice to justify the conclusion that the likelihood of the worst-case happening is so low as to be negligible and thus acceptable.

[57] We will come back to this point at the end of this section.

A common test of acute toxicity is the LD50 test. In this test, an animal population is exposed to a certain dose of a toxin leading to the death of 50% of the individuals of this population. The toxic substance is the source of hazard. Hazard refers to the ability or potential of this substance to bring about a certain harm – death in the case of LD50. Exposure denotes the fact that a population has been exposed to a hazard over a certain period of time.

LD50 tests are of a deterministic kind. Once the test has established the dose leading to the death of 50% of the exposed population, it is possible to make predictions based on this result. These predictions are deterministic – as opposed to the probabilistic predictions typical of risk assessments: they allow predicting a future event, namely, that *ceteris paribus* 50% of a population exposed to a certain dose of a toxin will die thereof, with certainty because they are based on the knowledge of cause-effect-relations.

This deterministic approach underlies ecotoxicological tests. Regarding biodiversity, for example, the hazard of a stressor on the environment is characterized in the laboratory or under field conditions using a number of surrogate species that are thought to be indicative for biodiversity. The intention of the tests is to determine the (detrimental) effects of the stressor on the species chosen at given levels of exposure. To this point, this is a purely deterministic procedure determining causalities; even though it is commonly called "risk assessment." The main question then is how the results of these tests can be transferred to agricultural systems. Basically, there are two options: either it is justified to directly transfer them or a direct transfer is not justified and some intermediate steps are required.

To justify a direct transfer, the following ontological statement would have to be true: the same causal factors determine the effects of the stressor – irrespective of whether we are in the laboratory or in the open system. This implies that there are no additional – maybe as yet unknown – environmental factors that could influence the (harmful) effects of the stressor under real conditions. If that were true, we could, given that we are able to exactly determine the exposure factors, predict the harm a GM plant would cause once it would be commercially cultivated. There would be no need to draw upon probabilities below one and above zero as the probability factor would be one or zero. Probability one means it is 100% certain that x will occur. Probability zero means it is 100% certain that x will not occur. The aspect of uncertainty regarding the occurrence of harm would not exist, and therefore there would be no risks since uncertainty is essential for any risk.

In this context, the proponents of the deterministic approach argue that environmental risk assessment is basically an extrapolation of the results of the hazard characterization and the exposure assessment performed. Extrapolation, however, is an ambiguous notion. For instance, if a vehicle covers a distance of 200 meters in 12 seconds and 1000 meters in 60 seconds, one can extrapolate that in 90 seconds it would cover 1500 meters. Understood as a prediction, this is true if the speed of this vehicle is not influenced (i.e., changed) by any additional internal or external causal factors. In that case, extrapolation enables a kind of deterministic prediction. This, however, presupposes that we know all the relevant causal factors. Otherwise, the extrapolation is afflicted with uncertainty and we have to resort to a probabilistic analysis. In that case, extrapolation only allows probabilistic predictions.

Applied to the assessment of GM crops, this means that an extrapolation in the deterministic sense is only possible if 1) all causal factors relevant in view of the possible harm caused by these crops and active under laboratory as well as real conditions are known; and if 2) these causal factors are identical. If conditions 1 and 2 are met, we should avoid speaking of risks and risk assessment since risks essentially imply uncertainty. If conditions 1 and 2 are not met, we should avoid speaking of a "deterministic approach" in the context of risk assessment and use the term "probabilistic approach" instead.

Given the current state of scientific knowledge, it is more plausible to understand extrapolation in a probabilistic sense. The main reason is that, as mentioned before, we do not know all causal factors possibly relevant under the environmental conditions of open agricultural systems and therefore cannot transfer laboratory results or results of field trials directly to these systems. In other words: it cannot be ruled out that the effects of GM crops within these systems are shaped by influencing factors we do not know. That is why for the time being, safe deterministic predictions regarding these effects are out of reach.[58]

The deterministic approach does not seem to be able to take the aspect of probability adequately into account. This is no surprise as the approach is geared to causal analysis, allowing reliable deterministic predictions based on cause-effect relationships. In this approach, there is no room for uncertainties

[58] Accurate probabilistic predictions concerning the risks of GM crops also require causal knowledge, without, however, being reducible to this knowledge. It is important to note that causal knowledge is not always necessary. The lung cancer risk of smokers, for instance, can be probabilistically predicted on the basis of statistical knowledge alone. Statistical knowledge does not presuppose causal knowledge: even if one has no clue regarding the causal connection between smoking and lung cancer one can make an accurate probabilistic prediction.

and thus for probabilities except probability = 1 (100%) or 0 (0%). The probabilistic approach seems better suited to handle the uncertainties we are faced with due to a lack of causal knowledge.[59]

The main difficulties concerning the calculation or estimation of probabilities have already been mentioned. In conclusion, it may be helpful to list them once again:

- In order to reach sound stochastic conclusions about possible harmful effects in complex environmental systems, a large amount of data is required. A good example to illustrate this point is meteorology. Weather forecasts are probabilistic predictions. They are probabilistic because the weather system is too complex and too dynamic to allow deterministic predictions, at least given the current state of meteorological knowledge. In order to make probabilistically accurate forecasts, two things are needed: first large amounts of (relevant) weather data; and second, probability calculations. Good weather forecasts are thus based on enough data-based information on one hand, and on the other hand, on meteorological and mathematical knowledge backed by sufficient computing capacity.[60]

  What would adhering to a probabilistic risk approach mean with regard to environmental risk assessment in the area of GM crops? Given that agricultural systems are as complex and dynamic as weather systems, and given that a GM plant is a new kind of plant and not just the old plant plus the new trait, the following conclusion can be drawn: a full-fledged scientific risk analysis necessitates a) a large amount of (relevant) data that cannot be accumulated by a laboratory experiment or even a field trial restricted to a few sampling sites, but only by monitoring real large-scale agricultural systems where GM crops are cultivated; and b) ecological and mathematical knowledge backed up by sufficient computing capacity.

[59] It is important to distinguish between two different risk-related uncertainties. 1) The uncertainty regarding a future event happening; 2) Uncertainties regarding the determination of a risk. To give an example, when a person plays Russian Roulette, there is a probability of 1 in 6 that this person will be killed by a pistol bullet. Thus, regarding the determination of the risk, there is no uncertainty since the probability can be mathematically calculated and the possible extent of harm is unequivocally clear (provided that death is harm). This does not detract from the fact, however, that it remains uncertain whether this person will die. In this respect, only a probabilistic prediction is possible since we do not have the causal knowledge required for a (justified true) deterministic prediction.

[60] This does not mean that scientific weather forecasts are necessarily more precise than forecasts made by "weather prophets" who base their predictions on subjective experience and historical knowledge. Yet, it is beyond reasonable doubt that scientific forecasts are incomparably more reliable and trustworthy than forecasts made by lay people. The reason is that they are grounded in a much better understanding of the weather system, understood as "deterministic chaos."

- In view of unintended (and unexpected[61]) effects of GM plants, the probabilistic approach is faced with a different problem when it comes to estimating the probability of the worst case scenario occurring. The problem is, we cannot directly infer the probability of this worst case on the basis of known effects.

Thus far, we have outlined the problems to be overcome when trying to calculate probabilities with regard to the risks associated with GM crops. It has not been made sufficiently clear, however, which methods may help to solve these problems. The remainder of this chapter will be devoted to this topic.

The question to be answered is: how can statements such as, "The probability of harming non-target organisms by commercially cultivating Bt-maize is (very) high/ (very) low (or alternatively, is x%)" or "The probability of a complete collapse of ecosystem equilibrium (harm) caused by pleiotropic and epigenetic effects is (very) high/ (very) low (or, alternatively, is x%)" be justified? What methods can be used in order to calculate or at least reasonably estimate these probabilities?

Methods

The standard formula of the classical conception of probability is

$$p(E) = \frac{N(E)}{N} \quad .$$

That is, probability p regarding event E is equal to the ratio of the number of favorable cases N(E) to that of all the cases possible N.

This formula allows calculating probabilities quantitatively in two kinds of cases:

- In cases where physical conditions are irrelevant and p can be calculated purely mathematically (lottery[62])

[61] Insofar as unexpected (and maybe even unexpectable) effects result from the dynamic and complex interplay between the GM plant and the open agricultural system, they can only be detected by monitoring this system. Of course, they must first manifest themselves before one can start thinking about the risks associated with them.

[62] The probability of getting the correct six numbers in lottery 6/49 is 1/14 million. This probability is calculated by means of mathematics alone. This probability means that getting six right is extremely unlikely – irrespective of the number of players taking part in the lottery. However, the more players there are, the greater is the probability that one of them will win. The same event whose occurrence is extremely unlikely for each player becomes very likely (weak law of large numbers).

- In cases where the calculation of p can be based on physical symmetries (fair coin, fair die, roulette etc.[63]).

If there is no physical symmetry, as in the case of GM crops, the method of the classical conception cannot be applied. At this point, the method of the frequency account comes into play. This method is also based on the formula of the classical conception since the frequency conception is, structurally speaking, the a *posteriori* version of the classical conception: "it gives equal weight to each member of a set of events, simply counting how many of them are 'favorable' as a proportion of the total. The crucial difference, however, is that where the classical interpretation counted all *possible* outcomes of a given experiment, finite frequentism counts *actual* outcomes" (Hajek, 2009).

If, for instance, an asymmetrical die is biased in favor of number four, the appropriate way to find out the probability of this number occurring is to conduct a sufficiently long series of throws in order to ascertain p via relative frequency. In other words: in empirical cases like these, what is needed to ascertain p are the data required to determine relative frequency in a reliable manner since this frequency is (approximately) equal to p.[64] Suppose, for instance, a parachutist worries about the safety of his two parachutes. He wants to know the probability that neither of them will open. In order to calculate this probability, we have to know the probability of each parachute not to open. This is something we can know only a *posteriori*, that is, based on experiences made with this product. Suppose it is known that the parachute opens in 999 of 1000 cases. Thus, p(E not open) would be 1/1000. If this applies to both parachutes, the probability we are looking for would be 1/1000 x 1/1000 = 1/1,000,000 (using the rule of multiplication). Statistically speaking, this means that in one in a million cases, both parachutes remain closed.

How do we find out that the parachutes in question open in 999 of 1000 cases? The answer given is *by experience*. In this context "experience" has different aspects. 1) Parachutes are a fully developed technology. Thus, if someone constructs a new parachute, it is possible to derive some conclusions regarding the probability of it not functioning based on the accumulated

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63 Physical symmetry is never completely perfect and hence always a kind of idealization. Yet it makes sense to suppose its existence in these cases since it allows calculating p accurately enough for practical purposes. This also applies in the case of the fair coin even though the result p=1/2 does not take into account the possibility of the coin landing "edge."

64 In case p is known, it is very likely according to the law of large numbers that the proportion of favourable events, (i.e., the relative frequency), will be approximately equal to p.

knowledge of parachute technology. 2) Tests performed before market launch 3). Monitoring of the product after market launch. Since the technology is already fully developed, 1) and 2) are presumably sufficient to come to a plausible estimate of p (provided the new parachute is not revolutionary). However, the exact probability can only be ascertained by collecting enough data after market launch to produce reliable statistics based on relative frequency.

Basically, this approach is applicable in a wide range of cases, especially cases belonging to the realm of the natural sciences. Take meteorology once again as an example. What is meant by a forecast statement such as, "There is a 30% probability of rain tomorrow?" It means, there is rain on 30% of all the days characterized by the same (or similar) weather conditions as tomorrow. "Tomorrow" here does not refer to a single event, but to an instance of a type. In order to be correct, the forecast presupposes a quantity of data large enough to facilitate reliable statistical statements concerning the probability of rain under conditions defined by variables such as air pressure, cloud types, and temperature.

Regarding natural events, the problem of determining the probability of single cases is often not as urgent as it may seem. Of course, we want to know how the weather will be like tomorrow. Thus, we refer to a single case: a unique future event (there is only one tomorrow). It is true that the method of relative frequency is unable to assign probabilities to single cases. However, this does not imply that there is always a relevant difference between statistical probabilities and single case probabilities. Regarding the weather forecast, the difference between tomorrow as a single case, a token, and tomorrow as an instance of a type may be negligible since the relevant variables may enable quite specific probabilistic predictions so that single case and instance of a type practically coincide.

This may be different when we consider, for instance, probabilities pertaining to the life of a particular individual. Consider, for example, customer profiles used by insurances to calculate the life risk of their clients. According to the frequency conception, insurances should take into account all variables that may have an impact on life expectancy such as age, sex, and health. The more variables being used, the more individualized the corresponding probability statement. Nonetheless, the probability is only an approximation to an individual case since its calculation is based on the principle that the narrowest (most specified) reference class for which reliable statistics is available should be chosen.

Again, this does not necessarily mean that there are practically relevant differences between this probability and the probability of the single case. Intuitively, however, there may be such differences. Therefore, the question arises of how probabilities pertaining to individual persons can be determined.

Imagine the following case (Gillies, 2000): Mr. Miller, 60 years old, has been smoking three packets of cigarettes per day for thirty years. What is the probability that he will live until the age of 70? Suppose there is a reliable statistics for these kinds of cases. The probability of Mr. Miller living until the age of 70 is the frequency of those in this class who have lived until the age of 70. It seems reasonable, however, to adjust this probability if we learn that Mr. Miller comes from a very large family who all smoke three packets of cigarettes per day, but none of whom died before the age of 70. The question is, how much would the probability change if there were no statistical data available concerning individuals who belong to such unusual families? In this case, we seem to be forced to resort to a rather subjective and vague estimate.[65]

However, the probability regarding adverse effects of (specific) GM crops on biodiversity is primarily a statistical, not a single case probability. From a methodological viewpoint, this means that this probability should be determined by means of the frequentist approach. This approach is based on experience. In the case of GM crops, experience comprises the same aspects as in the parachute example: 1) Conclusions regarding p that are based on the knowledge we already have. 2) Tests before commercialization of GM crops (in the laboratory; field trials); 3) Monitoring after market launch. The main questions to be answered are: what kind of and how much information do we need to derive statistically valid probabilistic conclusions? And, how do we get this information? Some of the difficulties in answering these questions have already been mentioned. In light of the methodological deliberations just made, one difficulty regarding the quality of the data required can be formulated more clearly. The frequentist method is a quantitative method. It is based on the idea that probability can and must be determined quantitatively. This does not necessarily imply that every probability must be expressed by an exact number. It may also be the case that we can only specify a particular range. Maybe the probability of an event is above 1% and below 10%. And within that band,

[65] In some cases, the best method to use in order to estimate singular probabilities may be Bayes' rule. This rule allows adjusting subjective probabilities in a controlled way in the light of new experience. However, in most cases, the data resulting from the new experience can also be interpreted objectively (i.e., in a frequentist manner) by forming appropriate reference classes. Bayes' rule is to be favored only in cases where we have good reasons to assume that there is a practically relevant difference between type- and token-probability.

it is impossible to assign probabilities. However, what about qualitative probability statements? One might think that according to frequentism, such statements cannot be scientifically sound and are therefore inadmissible. However, we could also argue that qualitative characterizations of probabilities such as "low" or "high" can be acceptable, provided that they are not completely arbitrary. However, this only makes sense if they are implicitly connected in some way to numbers. On the one hand, we have here a conventional element: to call a probability of 40% low is not plausible given the way we use the word "low" in this context. On the other hand, qualitative characterizations may refer to an approximate range within which they cannot be exactly localized. If not even such a range can be determined, possible qualitative probability statements remain vague. They are then expressions of subjective beliefs that are not intersubjectively justifiable.

Given a liberal understanding of the frequentist method, it may, in the sense just indicated, be admissible to estimate probabilities even if this only allows qualitative characterizations. One should be aware, however, that this becomes problematic if one wants to know the probability of the greatest possible harm occurring (worst case). Take nuclear power plants as an example. In this case, the probability of the worst case cannot be derived from experience in the sense discussed above. There has hardly been any Maximum Credible Accidents (MCA). So it is not possible to produce a reliable statistics in the sense of relative frequency. There is, however, another option, namely, probabilities can be determined sequentially. As pointed out before, this is done by a complex component analysis. The probabilities of a malfunction of the different safety systems are calculated and then multiplied (Weil, 2002). This presupposes that these probabilities can be determined at least approximately. And this, in turn, presupposes enough experience with the specific technologies being used. If such an analytical procedure is not applicable due to lack of experience regarding these specific technologies, then a worst case probability cannot be derived from probabilities associated with known effects. In this case, the only remaining option is to base probabilities on model assumptions or scenarios. This may still allow an approximate preliminary calculation of the overall probability. The more assumptions that have to be made, however, the greater is the uncertainty concerning this probability, until a point is reached where probability statements become so vague as to be virtually empty and useless.

The question regarding GM crops is whether there is any way in which plausible probabilities of worst-case scenarios can be determined. Since in scenarios of this kind, GM crops as complex biological organisms are situated in complex ecosystems whose behavior in many respects is scarcely known, a component analysis is not possible. This means that these probabilities cannot be derived (extrapolated) from known effects and their probabilities. The only option seems to be to operate with scenarios that are based on knowledge and on assumptions that have not been scientifically verified. Whether this allows determining the probabilities of worst cases with the precision minimally required is a question that needs further consideration.

The debate on the possible impact of genetically modified (GM) crops on biodiversity shows that so far there is no consensus on generally accepted assessment criteria for environmental harm. This debate stems primarily not from a shortage of data, but rather from the absence of criteria for assessing the effects of GM plants on biodiversity. Since there are no exact assessment criteria, regulatory decision-making processes are often not transparent and can be difficult to understand. This increases the danger that decisions on environmental risks from GM plants may appear arbitrary.

The VERDI Project (Valuating environmental impacts of genetically modified crops – ecological and ethical criteria for regulatory decision-making) is a interdisciplinary collaboration between biosafety experts and risk ethicists. Its aim is to develop recommendations for decision makers and regulatory authorities, thus helping to improve the regulation of GM plants. The results show that both the unambiguous description of protection goals and the establishment of a basis of comparison are two essential criteria when defining harm.

The book presents a proposal how criteria for the evaluation of GM crops could be developed. The book is directed to all those involved in the debate on benefits and risks of genetic engineering, in particular to decision-makers and regulatory authorities, but also to scientists from academia and the agricultural biotechnology industry.

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Diese Publikation ist auch als
E-Book erhältlich (open access).
DOI 10.3218/3464-6

ISBN: 978-3-7281-3464-6 (E-Book)

ISBN: 978-3-7281-3443-1 (Print)

Benefits and Risks of the Deliberate Release of Genetically Modified Plants
National Research Programme NRP 59