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PERSPECTIVE

Environmental change challenges decision-making during post-market environmental monitoring of transgenic crops

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Abstract The ability to decide what kind of environmental changes observed during post-market environmental monitoring of genetically modified (GM) crops represent environmental harm is an essential part of most legal frameworks regulating the commercial release of GM crops into the environment. Among others, such decisions are necessary to initiate remedial measures or to sustain claims of redress linked to environmental liability. Given that consensus on criteria to evaluate 'environmental harm' has not yet been found, there are a number of challenges for risk managers when interpreting GM crop monitoring data for environmental decision-making. In the present paper, we argue that the challenges in decision-making have four main causes. The first three causes relate to scientific data collection and analysis, which have methodological limits. The forth cause concerns scientific data evaluation, which is controversial among the different stakeholders involved in the debate on potential impacts of GM crops on the environment. This results in controversy how the effects of GM crops should be valued and what constitutes environmental harm. This controversy may influence decision-making about triggering corrective actions by regulators. We analyse all four challenges and propose potential strategies for addressing them. We conclude that environmental monitoring has its limits in reducing uncertainties remaining from the environmental risk assessment prior to market approval. We argue that remaining uncertainties related to adverse environmental effects of GM crops would probably be assessed in a more efficient and rigorous way during pre-market risk assessment. Risk managers should acknowledge the limits of environmental monitoring programmes as a tool for decision-making.

Keywords Environmental monitoring · EU Directive 2001/18/EC · Environmental harm · Evaluation criteria

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Introduction

The approval of GM crop varieties is generally more rigorously regulated than that of conventionally bred crops, particularly since the novelty of genetic engineering and the scientific uncertainties related to the transformation process of GM crops raised regulatory concerns. Generally, legal frameworks require that a novel transformation event obtains approval for commercial cultivation (Jaffe 2004). Approval is based on a pre-market risk assessment (PMRA) aiming at excluding potential adverse effects of the GM plant on human health and on the

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environment. In some legislations, such as the one of the European Union (EU), the introduction of GM crops into the environment is furthermore performed according to the step-by-step principle, that is, the scale of GM crop releases can only be increased if a risk assessment based on information of the preceding step results in an estimation of an acceptable risk for the next step (OECD 1986; European Community 2001). Potential adverse effects of a GM crop are there investigated in a first step in a controlled setting under confined conditions (e.g., in the laboratory or in the greenhouse). Where necessary, and if a risk assessment based on the information gained under confined conditions results in an acceptable risk estimation, the release can be gradually increased to include more complex and realistic conditions (e.g., in the field). Approval for commercial cultivation is only granted if the risk assessment indicates that the risk of the GM crop on the environment is sufficiently low to be acceptable. In addition, some countries such as South Africa, Brazil and the EU mandate post-market environmental monitoring (PMEM) programmes to detect and prevent adverse effects on the environment possibly deriving from the commercial cultivation of GM crops (European Community 2001; Jaffe 2004; Sanvido et al. 2009; Melo et al. 2010).

PMEM can have different aims (ACRE 2004; EFSA 2006): it may be a compliance monitoring that aims at examining whether mandatory risk mitigation measures, such as the planting of refuges in the case of insect resistance management, are implemented by farmers. Monitoring may also aim at assessing the efficiency of implemented risk mitigation measures, for example, by monitoring the potential build-up of resistance in target organisms in an insect resistance management programme. In the following, we will concentrate on a third type of monitoring, the direct monitoring of potentially adverse impacts of GM crops on specified protection goals such as protected butterfly species. Other types of monitoring such as the two types mentioned above are outside the scope of this perspective paper.

Based on the PMEM data collected, risk managers need to be able to make unambiguous decisions whether environmental harm to a specific protection goal has occurred or will occur from the release of GM crops to initiate remedial measures or to sustain claims of redress linked to environmental liability. An agreement on a strictly scientific and objective definition of harm is however difficult. The notion of harm or benefit depends on our negative or positive evaluation of a change. What we choose and define to represent harm is based on a certain normative background. In practice, any decision-making process is thus never simply based on scientific data, but it is always influenced by ethical values, as well as political, social, and economical factors. Yet, most currently proposed definitions of environmental harm have concentrated on defining the term on a scientific basis. A common feature of these definitions is the aim to detect relevant ecological changes that lie outside the naturally occurring range of variability (ACRE 2002; European Commission 2004; SRU 2004; CBD 2006; Bartz et al. 2010). The European Directive on environmental liability (2004/35/CE), for example, defines the term 'environmental harm' as any measurable adverse change in a natural resource or a measurable impairment of a natural resource service (European Commission 2004), without specifying the magnitude of change that would represent harm. The current debate on potential risks of GM crops on the environment exemplifies that consensus on a comprehensible definition of harm is presently lacking. To some extent this is certainly due to the fact that applicable criteria to evaluate environmental impacts of GM crops are missing. Consequently, there is a risk that regulatory decisions regarding the environmental risks of GM crops could be made on an arbitrary basis. Not surprisingly, there is considerable debate on the risks of GM crops for the environment (Hails 2000; Sanvido et al. 2007; Devos et al. 2008; Waltz 2009). In this paper, we analyse the difficulties in coherently defining environmental harm and propose solutions how these difficulties could be addressed. In our analysis, we concentrate on ecological questions related to environmental decision-making based on the results of PMEM of GM crops. We believe that the difficulties related to an unambiguous definition of environmental harm have four main causes that will be discussed below. Our analysis might help to initiate a discussion on the limits of environmental decision-making during PMEM of GM crops under current legislation and might further indicate a way forward in defining applicable criteria to evaluate environmental harm.

Challenge no. 1: Difficulty to evaluate the range of variability of environmental changes

A fundamental challenge for decision-making during PMEM of GM crops relates to the question how to distinguish "unusual" changes from "usual" variability. Scientific methods are only partially capable of adequately evaluating the range of variability of change in an environmental resource. While environmental sciences can help to assess the abundance of a particular biodiversity indicator (e.g., butterfly species) in an agro-ecosystem, it is usually difficult to determine whether an observed change exceeds the existing variability within such a species, especially since appropriate baseline data is often lacking.

The European Commission (EC) recommends in its PMEM legislation that the interpretation of scientific data collected during PMEM of GM crops should consider existing environmental conditions and activities in order to determine an appropriate baseline (European Council 2002). In their guidelines, the EC suggests two approaches as to how this baseline could be determined: (1) by monitoring the environmental conditions prior to the introduction of GM crops, or (2) by a parallel monitoring of "GMO-areas" and "non-GMO areas" (European Council 2002). We argue that both approaches are difficult to implement in practice. First, it may be difficult to use the environmental state prior to the introduction of GM crops as a baseline, given that agricultural systems display considerable dynamics in time and space (Tilman et al. 2002; Green et al. 2005; Tscharntke et al. 2005; Wilhelm and Schiemann 2006). Similarly, parallel monitoring may be difficult because of the variability between agricultural production systems, landscapes and regions. It may be almost impossible to find two agricultural regions differentiated only by the factor GM crop cultivation.

Solution no. 1: The choice of baselines for the comparison of scientific data

The question of the baseline that indicates which changes represent harm will have to be addressed by means other than the ones originally proposed by the guidance notes supplementing Annex VII to Directive 2001/18/EC (European Council 2002). An approach that could be feasible within the time periods available for decision-making could be to compare the environmental effects of GM crops to a baseline that is constituted by known effects of current agricultural management practices (such as pesticide use, tillage, mowing, crop rotation, cultivar choice) (ACRE 2007; Sanvido et al. 2007). The GM crop would be put within the context of its respective cropping system since environmental impacts are mostly caused by the agricultural production system (where the GM crop is one factor among others) rather than by the GM crop alone. The impacts of the new GM cropping system could then be compared to the impacts caused by the agricultural management practices that have been replaced by the adoption of the GM crop. Performing such a comparative impact assessment necessitates new multi-criteria approaches such as the Comparative Sustainability Assessment proposed by the UK Advisory Committee on Releases to the Environment (ACRE 2007), the qualitative multi-attribute model DEXi (Bohanec et al. 2008) or methods used for Life Cycle Assessments (Bockstaller et al. 2009). Multi-criteria approaches are particularly relevant considering that the adoption of certain GM crops might have environmental benefits when compared to current non-GM management regimes. Furthermore, such a comparative ecological evaluation of effects of current and of GM crop management practices on biodiversity could enable to decide within the timeframe generally available for decision-making which GM crop effects are judged to be ecologically harmful when compared to common impacts caused by agricultural practices that have been replaced or alternative practices that are still in place.

Challenge no. 2: Difficulty to ascribe environmental changes to a particular cause

Decision making does not only require reliable information on changes in the state of the environment but also on the causes of these changes (Vos et al. 2000). However, a high degree of complexity in environmental conditions and a high number of influencing factors (e.g., bio-geographical region, landscape heterogeneity, site and weather conditions, agricultural practices) make it difficult to ascribe an observed change to a particular cause (e.g., the cultivation of a particular GM crop). Even though

these difficulties are common in ecology and not restricted to PMEM of GM crops, they are particularly relevant if there is a need to determine the cause of an observed change as a basis for decision-making. The difficulties are caused by the interaction of two aspects: (1) the lack of baseline data to separate GM crop effects from existing variability and (2) the unknown causes of observed changes. The difficulties in determining causality between observed environmental changes and a particular cause, may be illustrated by an example related to butterfly communities in Switzerland (Aviron et al. 2006, 2009b). The example relates to a frequently expressed concern that GM maize expressing the insecticidal protein Cry1Ab from *Bacillus thuringiensis* (so-called *Bt*-maize) could have adverse effects on butterfly populations following ingestion of *Bt*-maize pollen by butterfly larvae. Larvae are most likely exposed to the Cry1Ab protein in the vicinity of maize fields where pollen is deposited on plants on which they are feeding. As maize is a recently introduced species in Europe, it is not a significant food source for endemic butterfly species (EFSA 2005). Impacts due to pollen dispersal are thus likely to be transient and minor, as the exposure of European butterfly species to Bt-maize pollen has been judged to be negligible (Perry et al. 2010). Nevertheless, potential effects could not be completely excluded considering the specific toxicity of Cry1Ab on butterflies and a low probability that adverse effects may only appear after large-scale releases. Risk managers could therefore ask notifiers to perform PMEM to detect such effects and possibly relate them to the cultivation of *Bt*-maize. In the mentioned studies by Aviron and colleagues (Aviron et al. 2006, 2009b), the influence of a multitude of interacting factors (e.g., biogeographical region, landscape characteristics, habitat type and agricultural management) on the variability of butterfly communities had been determined. The analysis was based on an extensive dataset that included both the presence and abundance of butterfly species in three agricultural regions in the Swiss lowlands as well as 31 descriptive factors characterizing the environmental context at the field, landscape and regional scale (Aviron et al. 2009a). The analysis showed that butterfly communities displayed a strong variability in space and time. Despite the extensive data set used, almost half of the total variability (47%) remained unexplained. By single factor, the highest share of variability (26%) was explained by regional location (i.e., arable, grassland or mixed farming region), followed by habitat type (5%), landscape context (1.5%), field management (1.4%) and site conditions (0.5%) while 19% of the variability was explained by interactions between the recorded factors (Aviron et al. 2006, 2009b). Apart from the regional location, most factors had only a small influence on the variability in butterfly communities. Transferring this example to the GM crop context suggests that a single factor (such as *Bt*-maize) would need to have a strong effect on butterflies to be clearly distinguishable within the existing variability of butterfly communities. One might thus argue that it may be unlikely that such a marked effect would not have been detected during PMRA where potential adverse effects have been assessed prior to approval for commercial cultivation.

Solution no. 2: Determine the causes for the variability of biodiversity indicators to address the complexity of ecological systems

To determine whether an observed change lies within the existing variability of a species group, the magnitude (and if possible the sources) of the variability should be quantified as precisely as possible. Variability is caused by several factors in space and time, but also by the methodology used in data collection. Statistical data analysis may help to determine the overall variability within a data set and help to identify trends and seasonality in long-term ecological data sets (Ferguson et al. 2008). To understand and manage the interactions between farming and ecological systems and, in particular, to determine the drivers of biodiversity in agricultural landscapes, a hierarchical approach should be adopted (Baudry et al. 2000; Aviron et al. 2006). Most ecological processes and interactions depend on scales much larger than a single habitat and it is therefore important to link spatial patterns and ecological processes on a landscape scale (Steffan-Dewenter et al. 2002). Two spatial scales are especially relevant for the analysis of PMEM data: the field scale describing land use and cultivation practices, and the landscape scale describing regional land use and crop patterns (Aviron et al. 2006, 2009b). Approaches such as landscape classification and typology (Bailey and Herzog 2004; Bürgi et al. 2004;

Groom et al. 2006) may help to classify landscapes along varying gradients of GM crop cultivation and other parameters describing land use and land cover. Knowledge of the distribution of different land use and land cover types may facilitate the sampling of monitoring data for many indicators (Bailey and Herzog 2004). Stratified sampling, that is grouping landscapes and habitats into relatively homogeneous, non-overlapping subgroups before sampling, may facilitate the comparison of monitoring data. Since it is important to determine the cause of detected changes for later decision-making, it is not sufficient to monitor only one particular indicator (e.g., butterfly abundance), but there is a need to combine monitoring with the recording of a number of explaining variables as shown in the mentioned example on the variability of butterfly communities (Aviron et al. 2006, 2009b).

Challenge no. 3: Long time periods are needed for changes to become apparent

Environmental changes usually become apparent only after a long period of time since it is often difficult to decide whether observed data represent a trend, a cycle or a noise (Usher 1991) (Fig. 1). A good example for the interaction of these three factors is the significant decline in British farmland biodiversity, which only became apparent many decades after agricultural intensification had started (Chamberlain et al. 2000; Donald et al. 2001; Robinson and Sutherland 2002). The cause of this decline was difficult to establish, given that it could not be ascribed to only one factor. In fact, the decline had been caused by the interaction of a number of factors, such as the intensification of agricultural management and an associated degradation in habitat quality, the reduction and fragmentation of habitats, and the homogenisation of agricultural landscapes (Chamberlain et al. 2000; Robinson and Sutherland 2002; Royal Society 2003).

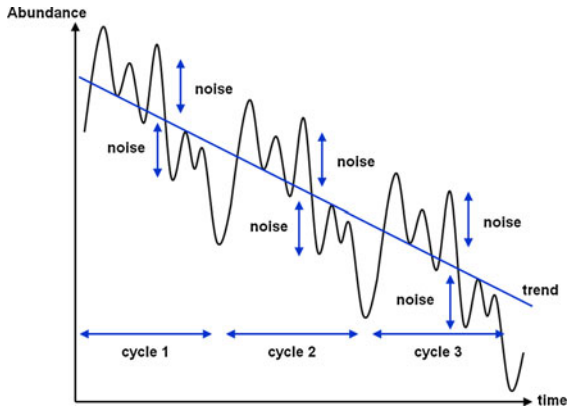

Fig. 1 Environmental monitoring data may be divided into three different types (trend, cycles and noises) (Usher 1991). It may be difficult to detect trends in a particular biodiversity indicator due to background noise and cycles

Solution no. 3: Determine the need for post-market monitoring activities

The fact that long time periods are needed for ecological trends to become apparent limits the value of monitoring programmes as a tool for decision-making. One of the obvious solution for risk managers to cope with this challenge is to determine the need for PMEM activities considering that it may well be that decisions may be taken by other means than by environmental monitoring. According to the EU legislation, PMEM is composed of two conceptually different programmes (European Community 2001; Sanvido et al. 2005; EFSA 2006). The first, case-specific monitoring (CSM) is focussing on anticipated effects of a specific GM crop and aims to assess whether these effects on the environment do occur during commercial cultivation (European Community 2001; European Council 2002). The second programme, general surveillance (GS), in contrast, has the aim to detect adverse effects on the environment that were not anticipated during PMRA. In particular, GS aims at detecting unanticipated effects that cannot be foreseen during PMRA on specific protection goals. Since there is an inherent challenge in trying to detect the unexpected, GS must concentrate on the environmental resources that need to be protected, rather than focusing on a specific hypothesis, as is done for CSM (Sanvido et al. 2005; Bartsch et al. 2006). Given its aim to detect all different kinds of environmental effects that could not be expected based on the information that was available prior to the approval of the GM crop, a characteristic feature of GS is the unspecific nature of this type of monitoring (ACRE 2004). GS can therefore be described as a type of survey that has to rely largely on existing monitoring networks

(Sanvido et al. 2005; Bartsch et al. 2006; EFSA 2006) and on farmer questionnaires that are specifically addressed at those farmers cultivating GM crops (Schmidt et al. 2008). Of course, the unpredictable nature of the types of effects to be detected limits the informative value of all types of monitoring programmes used for GS, especially as detected adverse environmental effects cannot be automatically related to the cultivation of GM crops and causalities have be investigated separately in additional risk assessment studies (Sanvido et al. 2005). Regulatory authorities need to take these limitations into consideration when requesting and interpreting GS monitoring data.

Different necessities regarding the two types of monitoring programmes are specified in the legislation. While GS has to be performed in any case, CSM may not be required where the conclusions of PMRA identify an absence of risk or negligible risk (European Council 2002). In the remaining of this paragraph we will concentrate on analysing the difficulties related to performing a meaningful CSM that is able to reduce uncertainties that may persist from PMRA.

According to the current legal framework of the EU, the decision to initiate CSM activities requires open issues arising from PMRA that are subject to a degree of scientific uncertainty (European Community 2001). To determine whether scientific uncertainties remain requires thus a consistent problem formulation where the need for CSM activities is established. CSM requires a plausible risk hypothesis to assess whether a specific GM crop might harm a particular environmental resource. However, even the best risk hypothesis may lead to uncertain conclusions if it is not tested rigorously (Raybould 2007; Romeis et al. 2011). To allow decision-making, the 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 environmental harm to a defined protection goal. For a practical assessment of the protection goal "biodiversity" there is a need to refine the general concept of biodiversity and to define a scientifically measurable attribute (a so-called assessment endpoint) that is more accurately representing the particular protection goal set by public policy (EPA 1998; Suter 2000; Raybould 2006; Romeis et al. 2008). For CSM of *Bt*-maize, for example, the population sizes of non-target butterflies could be an assessment endpoint representing the protection goal "butterfly abundance". A hypothesis supporting decision-making for CSM would be to determine whether the cultivation of *Bt*-maize leads to unusual population declines in non-target butterfly populations in the field. Such a hypothesis is more meaningful than simply testing whether there are differences in butterfly abundance between *Bt*-maize and non-*Bt*-maize fields. The aim to rigorously test a hypothesis leads to the question under what conditions the existence of these effects is most likely revealed. Under field conditions, as shown in the example on the variability of butterfly communities in agricultural landscapes (Aviron et al. 2006, 2009b), environmental effects are influenced by a multitude of interacting factors. Unless a particular stressor (e.g., the *Bt*-toxin) causes a relatively strong effect, it is likely that a number of influencing factors will cause different, overlapping effects. Given that the influence of the various factors could be 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 multi-factorial setting (as typical for a monitoring programme) might thus be much lower than detecting one in a more controlled setting with only a few factors involved. Depending on the risk hypothesis, testing in a more controlled setting such as a laboratory or semi-field might thus be more rigorous than testing the hypothesis under more realistic conditions during commercial cultivation (Raybould 2006, 2007; Romeis et al. 2008). Well replicated studies performed under controlled environmental conditions considering realistic effect sizes derived from statistical power analysis (Perry et al. 2009) might resolve remaining scientific uncertainties more thoroughly than environmental monitoring studies that are difficult to interpret due to various confounding environmental factors. Laboratory studies will usually select simple parameters such as mortality that ensure interpretability of the results obtained (Romeis et al. 2011). To obtain additional certainty, studies are often conducted at the highest possible concentration of the test substance that can be delivered with the test system, typically at concentrations that exceed the concentration present in the plant by a factor 10–100. In case no effect can be observed at such worst-case exposure conditions, there is a relatively high

certainty that there will be no effect at the concentration that the species are exposed to in the field. In case uncertainties on the safety of the test substance remain, one may conduct additional studies by varying endpoints or by conducting studies under more realistic, but still controlled, environmental conditions. Uncertainties on the specificity of the test substance may, for example, be addressed by testing a broader spectrum of test species. Uncertainties on cumulative long-term effects may be addressed by assessing sub-lethal parameters (e.g., fecundity, development time or adult weight) or by conducting multi-generation studies. Finally, ecological modelling could be used to help design and interpret laboratory effect tests (Perry et al. 2010, 2011; Raybould et al. in press). Depending on how conservative one wished to make the assessment, different simulations could be used to determine the parameters that should be assessed in laboratory studies and the size of the adverse effect in those studies that should trigger further evaluation.

It is important to remember that CSM is a risk management option that may be selected to reduce remaining uncertainties, but it is not a programme to repeat studies that have been performed during PMRA on a larger, commercial scale to confirm the previously obtained results and especially the non-occurrence of effects. CSM should thus only be initiated if there are reasoned grounds supporting the assumption that a monitoring programme will deliver substantial data for later decision-making that cannot be obtained during PMRA.

Challenge no. 4: Controversial evaluation of environmental protection goals

Decision-making by risk managers is influenced by the fact that scientific data on potential impacts of GM crops on the environment is valued differently by the stakeholders involved in the debate and that environmental protection goals are described relatively broadly in the legislation. 'Protection of biodiversity', for example, is a broad statement of a desired environmental condition, which leaves room for interpretation. Differing interpretations by stakeholders on which environmental resources are covered by the term "biodiversity" lead to differing value judgements on what should not be affected by the cultivation of GM crops and on how effects of GM crops on these resources should be valued. A good example for this controversy are the interpretations of the results of the UK Farm Scale Evaluations (FSE). In the FSE, as a result of a lower abundance of flowering weeds, lower numbers of invertebrates (such as butterflies and bees) were found in both genetically modified herbicide tolerant (GMHT) sugar beet and oilseed rape, whereas generally higher numbers of invertebrates were found in GMHT maize when compared to their conventional non-herbicide tolerant counterpart (Brooks et al. 2003; Haughton et al. 2003; Bohan et al. 2005). The British authorities concluded that growing conventional beet and spring rape was better for many groups of wildlife than growing GMHT beet and spring rape (DEFRA 2005). In their evaluation of the FSE results, the authorities considered the retention of arable weed populations in British fields to be a protection goal, since weeds in the UK are considered to play a role within agro-ecosystems by supporting biodiversity (Marshall et al. 2003). However, other interpretations of the FSE results are possible. In an interpretation by Australian scientists it was claimed that the maintenance of weeds on farms was not considered to be a focus of national biodiversity efforts (CSIRO 2003). They judged that, given that most weeds represent exotic species, it was unlikely that more effective weed control would harm the ecology of Australian conservation areas. The example shows that, depending on the value criteria applied in a specific country, risk managers can have differing opinions on the question of whether weeds in arable fields should be promoted to sustain invertebrates and birds that are depending on them as food sources.

Solution no. 4: Define generic environmental protection goals valid for all agricultural management practices

In the debate surrounding the FSE results, the effects caused by the particular herbicide management strategy applied in the FSE have often been considered to be generally valid for GMHT crops. This analogy has partly arisen because the results from the farm scale were inadvertently extrapolated to the landscape level and because it was not taken into account that weed management strategies other than

the one used in the FSE are possible (Chassy et al. 2003; Freckleton et al. 2003; Sanvido et al. 2007). Conversely, it has been suggested that GMHT crops might promote farmland biodiversity by delaying and reducing herbicide use, and by allowing weeds and associated wildlife to remain in fields longer (Firbank and Forcella 2000; Dewar et al. 2003; May et al. 2005). The use of GMHT technology in the United States and in Canada, for example, was accompanied by a series of management changes, including the adoption of conservation tillage practices, which are considered to have several environmental benefits (Carpenter et al. 2002; Phipps and Park 2002; NRC 2010). These include beneficial impacts on farmland biodiversity since conservation tillage results in a greater availability of crop residues and weed seeds, which in turn improve food supplies for insects, birds, and small mammals (Holland 2004).

From a scientific point of view, it would have been more reasonable to evaluate the environmental effects observed in the FSE based on the weed management applied rather than on the technology used to create the crops. Glyphosate, for example, is the herbicide used most frequently on GMHT crops, but it is also one of the most widely used herbicides in conventional agricultural management systems (Woodburn 2000; Cerdeira and Duke 2006; Powles 2008). There is, in principle, no logical justification to evaluate indirect environmental effects that are caused by glyphosate applications in GMHT crops differently than similar effects resulting from conventional glyphosate applications. In general, it would be more objective to follow the same regulatory approach when managing risks associated with technologies or applications that are likely to result in similar environmental effects. Crops that are tolerant to broad-spectrum herbicides, for example, can be developed not only by genetic engineering but also by traditional breeding (Tan et al. 2005). The adoption of these so-called Clearfield^{TM} varieties could result in similar environmental impacts as the adoption of GMHT crops, given that both crops allow the application of herbicides that control a broad spectrum of grass and broadleaf weeds. Interestingly, as the Clearfield^{TM} varieties were not developed through genetic engineering, they are not considered to be "genetically modified" under current EU regulation (European Community 2001). Consequently, they are not subject to particular safety assessments prior to their commercial approval or to PMEM programmes. Considering the special attention paid in the EU regulation to the protection of the environment from potential adverse effects of GM crops, the regulative approach followed by the EU is lacking consistency (Morris 2007; Morris and Spillane 2008). If the final aim should be to protect the environment from harm, there are no convincing arguments in favour of applying a more stringent regulation for one particular technology if a similar technology might result in similar environmental impacts.

Conclusions

There remain a number of challenges in the analysis of PMEM data and in using them for regulatory decision-making processes. Considering these challenges, PMEM could become an extremely demanding endeavour in time and costs and often lead to results that cannot be used for regulatory decision-making. Keeping this in mind, it should be questioned if such high costs would be proportional and comply with the cost-effectiveness laid down in the EU directive 2001/18/EC. One has to consider that there are no monitoring requirements for other environmental stressors such as pesticides that are known to have broader environmental impacts than GM crops. Current PMEM data requirements may therefore be particularly disproportionate to the identified level of risk of GM crops considering the results of a number of recent studies which have shown that GM crops often have smaller environmental impacts than the conventional agricultural management practices they have replaced (Romeis et al. 2006; Sanvido et al. 2007; Wolfenbarger et al. 2008; NRC 2010). We argue that remaining uncertainties related to the adverse environmental effects of GM crops would probably be assessed in a more efficient and rigorous way during pre-market risk assessment. Risk managers should acknowledge the limits of environmental monitoring programmes as a tool for decision-making. The objective of PMEM as intended by European legislation to detect adverse environmental effects caused by the cultivation of GM crops within a reasonable time period for decision-making may therefore be difficult to attain and should be critically discussed.

For data evaluation, one might argue that we still do not know enough about ecological systems to be

able to identify what we want to protect and hence what we should be measuring (Calow 1994). Although this statement was initially made in relation to the ecotoxicology of pesticides, it is similarly valid for the GM crop debate. Yet decisions have to be taken, recognizing that uncertainties may not be resolved (CBD 2000) and that decision-making necessitates the definition of operational protection goals (EFSA 2010). Given the complexity of ecological systems, we will never be able to elucidate all interactions taking place in such systems and uncertainties will always remain. Our analysis shows that an unambiguous definition of what is considered to represent environmental harm caused by GM crops is difficult. It is probably impossible to assess environmental harm in terms of absolute values, mainly because there are methodological constraints associated with collecting and analysing the data required to decide whether an observed change fulfils criteria of environmental harm. The proposed comparative approach, where environmental effects of GM crops are compared to a baseline constituted by known effects of current agricultural management practices, could be a way to enable decision-making within the time periods available. This approach could allow to harmonize protection goals for GM crop cultivation with those of similarly regulated sectors, such as the plant protection sector or eventually even to define generic assessment endpoints (Suter et al. 2004) that would represent environmental resources that are considered to be worthy of protection not only in the context of GM crops.

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