Journal für Kulturpflanzen, 63 (7). S. 211–216, 2011, ISSN 0027-7479 Verlag Eugen Ulmer KG, Stuttgart

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Post Market Environmental Monitoring of Genetically Modified Herbicide Tolerant Crops (Working group report from the 4th International Workshop on PMEM of Genetically Modified Plants, Quedlinburg, Germany 2010)

Anbaubegleitendes Monitoring von gentechnisch veränderten, herbizidtoleranten Kulturpflanzen (Bericht der Arbeitsgruppen vom 4. internationalen Workshop zum Anbaubegleitenden Monitoring von gentechnisch veränderten Pflanzen, Quedlinburg, Deutschland 2010)

Abstract

According to European Union (EU) legislation, genetically modified (GM) crops released for commercial cultivation have to be monitored. Here we summarise the discussion of a working group that convened during the 4th International Workshop on Post Market Environmental Monitoring (PMEM) of Genetically Modified Plants in Quedlinburg from 3–4 May 2010 to discuss the necessity, extent and design of PMEM plans of genetically modified herbicide tolerant (GMHT) crops. The following workshop report summarises the questions specific to the monitoring of GMHT crops and seeks to answer what should be monitored and who should perform such a monitoring. In addition, the main challenges when monitoring GMHT crops are presented and it is discussed how these challenges could be addressed.

Key words: Genetically modified herbicide tolerant crops, Genetically modified plants, Post Market Environmental Monitoring, Directive 2001/18/EC

Zusammenfassung

Der kommerzielle Anbau gentechnisch veränderter Pflanzen (GVP) muss gemäß der Gesetzgebung der Europäischen Union überwacht werden. Hier fassen wir die Diskussionen einer Arbeitsgruppe zusammen, die sich während des 4. Internationalen Workshops zum Anbaubegleitenden Monitoring von GVP vom 3. bis 4. Mai 2010 in Quedlinburg getroffen hat. Die Arbeitsgruppe hatte zum Ziel, die Notwendigkeit, das Ausmaß und den Aufbau eines Monitoring von gentechnisch veränderten herbizidtoleranten Pflanzen zu diskutieren. Der folgende Arbeitsgruppen-Bericht fasst die spezifischen Fragen, die sich bei einem solchen Monitoring stellen, zusammen und es wird versucht, die Frage zu beantworten, was überwacht werden sollte und wer eine solche Überwachung durchführen sollte. Zusätzlich werden die größten Herausforderungen bei der Überwachung von herbizidtoleranten GVP präsentiert, und es wird diskutiert, wie diesen begegnet werden könnte.

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Accepted
2 May 2011

Stichwörter: Gentechnisch veränderte Pflanzen (GVP), Herbizidtoleranz, Anbaubegleitendes Monitoring, Richtlinie 2001/18/EG

Introduction

According to European Union (EU) legislation, the commercial cultivation of genetically modified (GM) crops is subject to Post Market Environmental Monitoring (PMEM) (European Communities, 2001). PMEM should ensure the detection of potential adverse effects of GM crops on the environment at an early stage. Monitoring data should allow regulatory authorities to decide whether environmental harm occurred and whether corrective action is necessary. PMEM is divided into case-specific monitoring (CSM) and general surveillance (GS) (European Communities, 2001; European Council, 2002). CSM focuses on anticipated adverse effects of a specific GM crop and aims to assess whether these environmental effects occur during commercial cultivation. GS, in contrast, aims at detecting adverse effects on the environment that were not anticipated during pre-market risk assessment (PMRA). The EU legislation specifies different needs regarding the two types of monitoring programmes. While GS has to be performed in any case, CSM may not be required when the conclusions of PMRA identify an absence of risk or negligible risk (European Council, 2002). The decision to initiate a CSM programme is triggered by scientific uncertainties arising from PMRA that would justify further inquiry, for example, in case potential risks could not be adequately addressed during PMRA because the anticipated effects may only appear after large-scale releases or after longer time periods. Each PMRA is shaped by the scientific knowledge available at the time it is conducted and it can therefore be limited by scientific uncertainties. Monitoring data generated in the context of CSM may enable to overcome these uncertainties and re-inform the PRMA. Ultimately, the European Commission and the Member States define the PMEM activities needed when issuing consent for commercial cultivation of a specific GM crop.

Following the three workshops taking place from 2006 to 2008, the 4th International Workshop on PMEM of Genetically Modified Plants took place from 3–4 May 2010 in Quedlinburg, Germany. A number of new challenges linked to PMEM of GM crops were explored in various talks on the first day of the workshop and in three working groups that took place on the second day of the workshop. One of these challenges concerned the monitoring of genetically modified herbicide tolerant (GMHT) crops. The first generation of GMHT crops enables the use of non-selective broad-spectrum herbicides that contain the active substance glyphosate or glufosinate-ammonium to control weeds in agricultural fields. In principle, herbicide regimes used in GMHT crops allow farmers to control both broadleaf and grass weeds with one non-selective herbicide instead of using a broad range of active ingredients to control specific types of weeds. Non-selective broad-spectrum herbicides are applied post-crop emergence to established weeds while selective herbicides used in conventional weed management are applied when weeds are still in an early developmental stage.

In the EU, no GMHT crop is currently commercially cultivated, but several applications of GMHT maize, sugar beet and soybean are pending. The use of broad-spectrum herbicides along with the cultivation of GMHT crops raises several specific environmental concerns that could be the subject of PMEM (reviewed by Beckie et al., 2006; Cerdeira and Duke, 2006; Dewar, 2009). These concerns were discussed in a working group involving 16 participants from nine European countries on the second day of the workshop. The following questions were considered: (1) what are the specific questions regarding the monitoring of GMHT crops, (2) what should be monitored and who should conduct it, and (3) what are the main challenges when monitoring GMHT crops.

The discussions in the working group were initiated by two input statements that were presented by two workshop participants. Both proposed answers to the above-mentioned questions from their point of view. The first statement was presented by Esteban Alcalde from Syngenta Spain while the second statement was given by Adinda De Schrijver from the Belgian Scientific Institute of Public Health. The two input statements were meant to reflect the opinion of a member of the agricultural biotechnology industry and one of a regulatory authority involved in the risk assessment and approval process of GM crops. Both participants nevertheless emphasised that their statement was to be regarded primarily as their personal opinion that would not necessarily reflect the opinion of the industry or of a particular competent authority. The two input statements were followed by a discussion involving all participants of the working group. In this paper, the results of this discussion are summarised and structured in the context of the above-mentioned monitoring questions.

What are the specific questions regarding the monitoring of GMHT crops?

Both input statements emphasised that different legal frameworks have to be considered when discussing specific questions regarding monitoring of GMHT crops. While the herbicide use is regulated under the plant protection products (PPP) Directive 91/414/EEC[1] (European Commission, 1991), potential adverse effects on farmland biodiversity resulting from the use of the GMHT crop are regulated under the GMO Directive 2001/18/EC (European Communities, 2001). It was recognised that the interplay of these two Directives and the question which Directive applies under what circumstances is at the heart

[1] A new legislative framework on pesticides has been adopted in October 2009 by the European Parliament and the Council. Regulation (EC) No. 1107/2009 repealing Directives 79/117/EEC and 91/414/EEC will come into force in June 2011.

of discussions that aim at deciding on the monitoring requirements for GMHT crops.

The first specific question identified was if the cultivation of GMHT crops requires the establishment of a CSM programme. There was consensus among participants that the decision whether CSM is required would ultimately depend on the outcomes of the PMRA. In this respect, the question "what types of concerns representing damage have to be considered" was identified as one of the crucial questions. This question will drive the environmental risk assessment (ERA) prior to approval. The ERA conclusions will in turn influence the monitoring strategies to be selected and implemented for GMHT crops. Participants agreed that ultimately the question what to monitor will depend on what environmental entities are to be protected from harm (protection goals).

A second specific point of the discussion was what is to be regarded as the stressor, that is, whether the GMHT crop itself, the herbicide application or the change in weed management practice is the ultimate stressor. It was noted that it would be necessary to develop different monitoring plans depending on what is regarded as the stressor. If, for example, the herbicide application would be regarded as the main stressor, monitoring would rather focus on the detection of weed resistances, while if changes in agricultural management were regarded as the stressor, one would focus more on monitoring effects on farmland biodiversity.

What should be monitored?

As stated in both input statements, the use of GMHT crops gives rise to a number of concerns. Certain concerns are more or less directly associated with the agronomic practice such as the development of resistant weeds by intensive herbicide applications or the occurrence of HT volunteers in subsequent crop rotations. Other concerns are more related to farmland biodiversity in general such as potential declines in valued species (e.g. bird species depending on weed seeds) or the impairment of specific ecosystem services (e.g. biological control functions of natural enemies).

Weed resistance

The experiences with growing GMHT crops on a large-scale since more than a decade confirm that the evolution of herbicide resistance in weeds is not a question of genetic modification, but of the crop and herbicide management applied by farmers (Beckie et al., 2006; Cerdeira and Duke, 2006). There is evidence from GMHT crop cultivation in the United States that the continuous use of glyphosate-based herbicides as the only weed control strategy is causing changes in weed flora and favours the selection of resistant weeds (Heap, 2010; Waltz, 2010).

Whether weed resistance is a specific concern to be included in a monitoring plan for GMHT crops was debated by the participants. It was mentioned that monitoring weed resistance could be challenging as numerous weed species have evolved resistance to a number of herbicides long before the introduction of GMHT crops (Heap, 2010). Since its first introduction as Roundup® in 1974, glyphosate has, for example, been marketed in several formulations in a wide number of countries around the world, and is the world's most widely used herbicidal active substance in both agricultural and non-agricultural situations. It will therefore be very difficult to determine whether acquired weed resistance is due to glyphosate uses in GMHT cropping systems, or uses in conventional weed management. Nonetheless, it is recognised that the rapid adoption of GMHT crops along with minimal or conservational tillage systems has exacerbated weed resistance evolution (National Research Council, NRC, 2010; Powles, 2008, 2010).

The question was raised whether a resistant weed necessarily represents damage and if yes to whom. Weed resistance was considered mainly an agronomic concern for the companies selling the herbicide as they will not be able to sell their product in the longer run if resistance to a particular herbicide occurs too frequently. Nevertheless, the control of resistant weeds may require additional herbicides, which in turn may have less favourable environmental impacts. For example, one may have to revert to the previous herbicide control regime in which several selective herbicides with poorer ecotoxicological profiles are used (Bonny, 2008; Kleter et al., 2008). It was also noted that the potential loss of glyphosate to significant areas of world cropping may be considered a threat to global food production.

It was noted that farmers are usually not able to determine whether weeds survive herbicide applications due to weed resistance or due to an herbicide that did not work. However, the farmer could notify the supplier that the herbicide is not working and this may trigger sampling and analysis. Most participants agreed that farm questionnaires (Schmidt et al., 2008) are a good early alert system to report weed control failures, as the farmer will be the first one to observe weeds that escape control on his fields. Questionnaires for farmers form a useful tool that enables to report on observations of effects linked with the cultivation of GM plants: farm questionnaires use fist-hand observations and rely on farmers' knowledge and experience of their local agricultural environments (Schmidt et al., 2008). Monitoring weed resistance is furthermore a good agronomic practice recommended by the herbicide suppliers and applied through their stewardship programs.

Occurrence of herbicide tolerant volunteers

Volunteers are crop plants emerging within agricultural fields as a result of previous cropping. Crop rotations that include GMHT crops having the same trait (e.g., glyphosate tolerance) may result in crop volunteers tolerant to the frequently applied herbicide. Herbicide tolerant volunteers might be more difficult to control in subsequent crops and they may exacerbate weed problems. The ques-

tion whether there is a necessity to actively monitor for herbicide tolerant volunteers was discussed among participants and the question was asked whether the occurrence of these volunteers was to be regarded as a particular concern. It was agreed that their occurrence could be monitored as part of GS, for example, by recording them in farm questionnaires as the farmer will be the first one to detect these volunteers. Again, the importance of protection goals was emphasised, that is, the necessity to define what needs to be protected from damage. If the occurrence of herbicide tolerant volunteers was not defined to represent a concern, there was also no particular need to monitor for these volunteers.

Impacts on farmland biodiversity

There are concerns that broad-spectrum herbicides allow a more efficient control of a wide spectrum of weeds. This could lead to a decline in arable weed seeds in soil, which might indirectly result in declines in farmland biodiversity as invertebrates, small mammals and seed-eating birds might be threatened by reduced food resources (Heard et al., 2005; Watkinson et al., 2000). It was noted that weed management in general entails the difficulty to balance food production (and hence crop protection) with the support of farmland biodiversity. When discussing this issue among participants, there was again consensus that the definition of protection goals (food security *versus* farmland biodiversity) was crucial to determine the monitoring needs. This definition includes in particular answering the question how many weeds or what type of weeds are desired in agricultural fields.

Participants questioned whether impacts on farmland biodiversity were a monitoring topic that was to be specifically addressed only for GMHT crops considering that weed control is an essential part of every agricultural practice and weed management practices in cropping systems aim at obtaining, as far as possible, a weed-free field during the critical growth stages. The answer to this question might depend on the weed control efficacy, that is, on the question whether the herbicides used with GMHT crops allow a more efficient weed control than the ones that are replaced. It was mentioned that theoretical desk studies during PMRA that compare the environmental footprint of different GMHT and non-GMHT weed management scenarios could be helpful in answering this question and in determining the necessity for a specific monitoring of farmland biodiversity. However, it was also observed that the interpretation of monitoring results needs to consider that glyphosate and glufosinate-ammonium are also used in conventional weed management, for example to clean up stubbles prior to cultivation (Dewar, 2009). For some crops it might therefore be challenging to specifically assign observed effects to the use of GMHT crops. It was finally noted that, although herbicide management may have an impact on farmland biodiversity, crop type and sowing season have a far bigger impact on the functional composition of plant and invertebrate communities in arable systems (Hawes et al., 2003).

What are the challenges for PMEM of GMHT crops and how could they be addressed?

Clarification of the key points relevant for the discussion

The discussion in the working group clearly showed that there was a need for harmonisation of a number of key points that were recurrently appearing during the discussion. Three key points among the ones that most essentially need clarification are: (1) what are the protection goals (food security vs. farmland biodiversity)? (2) which baseline should be applied (conventional weed management vs. other)? (3) what is the stressor when applying GMHT crops (GMHT plant vs. herbicide application vs. change in weed management)? As long as these points are not clarified, it might be impossible to come to reasonable conclusions regarding the monitoring necessities for GMHT crops.

Clarification of the scope of the two relevant regulatory frameworks

When deciding on monitoring requirements for GMHT crops, it is important to define which regulation applies to the different concerns identified. Is the GMO Directive or the PPP Directive the main normative reference or do both regulations interplay with each other? Clarifying the interplay between these two regulatory frameworks is crucial when discussing the monitoring needs for GMHT crops. The discussions in the working group gave the impression that this interplay was not absolutely clear. This could be due to the fact that the PPP Directive focuses mainly on assessing direct toxic effects, while the GMO Directive also aims at assessing effects on the wider environment. It was particularly stressed that herbicide regimes used in GMHT crops are assessed today more strictly than conventional, non-GM herbicide regimes, as assessing GMHT crops regimes includes evaluating potential effects on farmland biodiversity. The latter is not a requirement for non-GM crop herbicide regimes To avoid duplications of herbicide regime assessments, it was suggested that all herbicide regimes are assessed according to the same standards, that is, to clearly separate herbicide effects from those of the GMHT crop. This led to the conclusion that which regulation applies depends primarily on what is regarded to be the main stressor when using GMHT crops. The PPP Directive should be regarded the relevant framework if the herbicide use is regarded to be the main stressor, whereas the GMO Directive should apply if the GMHT crop is regarded to be the main stressor.

Methodology and proportionality of monitoring

Given that GMHT crops allow a different weed management, it would be necessary to monitor the whole cropping system (rotation, tilling system, soil fertility etc.) instead of just one particular parameter. Given the variability of existing agricultural practices, such a monitoring programme would entail considerable methodological challenges. Con-

sidering that conventional weed management practices or conventionally-bred HT crops[1] are equally dynamic systems that permit similar cropping practices as GMHT crops, the proportionality of such a monitoring programme is questionable. Desk studies during PMRA comparing the environmental footprint of different herbicide regimes applied in GMHT and non-GMHT cropping systems could thereby be more rigorous in answering the relevant questions than the performance of an environmental monitoring after approval.

Implementation and responsibilities

One practical difficulty is deciding who is responsible for monitoring GMHT crops. Herbicides used with GMHT crops could be marketed by different companies that are decoupled from the company selling the GMHT crop seed. One could argue that PMEM should be conducted by the company marketing the GMHT crop seed, but this company is usually not in control of the sales system of all components (e.g. plant protection products) used in a particular cropping system. National competent authorities might address this gap with the assistance of the biotechnology industry and the herbicide providers.

Baseline

Especially when discussing potential effects on farmland biodiversity, there is currently no consensus among competent authorities on the baseline against which effects of GMHT cropping must be compared. During the discussion, most participants agreed that the baseline to be considered would logically be set by existing weed management practices considering that conventional weed management is the most common agronomic practice that may result in similar environmental impacts. It was also recognised that the high variability of weed management regimes would not facilitate the application of a common baseline generically applicable to most cropping scenarios. However, the weed management of GMHT and non-GMHT crops will have similar effects on wider biodiversity. This is a strong argument to use similar assessment procedures for both types of HT crops. There is a considerable amount of experience with assessments under the PPP Directive. Data requirements and assessment criteria under this Directive are well established and have proven their practicability. Requirements and assessment criteria will be developed further with the application of the new Regulation (EC) No 1107/2009.

Risk mitigation instead of monitoring

Considering the various methodological and organisational challenges mentioned above, one can argue that risk mitigation measures might be more efficient to delay resistance evolution in weeds, reduce HT volunteers or to diminish harm to farmland biodiversity than performing GMHT monitoring programmes that may not always provide clear results for decision-making. Several cultural and mechanical practices to mitigate resistant weeds and HT volunteers have been suggested, including the use of different herbicide regimes relying on several active substances with different mode of actions and on crop rotation (Beckie et al., 2006; Cerdeira and Duke, 2006; Dewar, 2009). Some of these measures are already today part of the stewardship programmes recommended by the companies marketing the herbicides that have been developed in the frame of the PPP Directive, which aim at a sound use of the technology. Impacts on farmland biodiversity may be mitigated by (1) set-aside headland; (2) better margin management; (3) in crop weed refugia; (4) less intense weed management; (5) band spraying; (6) reduced tillage operations; and (7) overwintered stubbles (Dewar, 2009). Most participants agreed that the implementation and the efficiency of these risk mitigation measures should be monitored. It was, however, left open who would be responsible for such a programme and how such a monitoring should be performed. Farm questionnaires would certainly be an appropriate measure to document risk mitigation measures.

Note: The views expressed in this publication represent the opinion of the authors in their personal capacity and do not necessarily reflect the view of the institutions where they are employed.

[1] Clearfield® varieties that are tolerant to the broad-spectrum herbicide imidazolinone allow similar herbicide regimes as with GMHT crops. As the Clearfield® varieties were not developed through genetic engineering, they are not considered to be "genetically modified" under current EU regulation.

Acknowledgements

The authors would like to thank Esteban Alcalde for his very helpful contributions to the manuscript and the participants of the working group for the fruitful discussion.

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