Comments on the European Food Safety Authority 'Guidance on the Post-Market Environmental Monitoring of genetically modified plants'

COGEM advice CGM/120419-02

Introduction

On request of the European Commission, the European Food Safety Authority (EFSA) has revised the guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified (GM) plants.[1] COGEM previously commented on the draft version of this guidance.[2] The European Commission gives Member States the opportunity to react on the final version of this guidance. On request of the Ministry of Infrastructure and the Environment, COGEM discusses in the present document how the final version of the document relates to EFSA's previously issued draft version on the guidance, and to earlier comments of COGEM on this draft version.[2,3]

Background of PMEM

For each GM plant an environmental risk assessment (ERA) is carried out to identify and evaluate potential adverse effects arising from its placing on the market. The outcome of this environmental risk assessment determines the requirements for Post-Market Environmental Monitoring (PMEM).

The purpose of PMEM is to detect any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs after they have been placed on the market. Two types of monitoring are recognized: Case-Specific Monitoring (CSM) and General Surveillance (GS). The purpose of CSM is to confirm the correctness of any assumption in the ERA on the occurrence and impact of potential adverse effects of the GMO or its use. The outcome of the ERA determines whether CSM is required. The purpose of GS is to detect unanticipated adverse effects of the GM plant or its use. GS is required for all GM plants.

A PMEM plan is legally required for each application for placing on the market of a GMO or of food/feed consisting of or containing that GMO (Directive 2001/18/EC and Regulation (EC) No 1829/2003).

Comments on the final version of the PMEM guidance

COGEM welcomes the final version of the revised Scientific Opinion on guidance on the PMEM. COGEM is pleased with the document, which brings PMEM to a more elaborate level. It clearly describes the monitoring approach and possible subjects for monitoring, and is in line with previous COGEM advices on this topic.[4,5] COGEM appreciates that most of its comments, submitted during the public consultation on the draft version of the guidance, have been taken into account.[2] In the final version of the guidance, it is emphasized that the applicant should provide raw data from CSM and GS, which enables performing of analyses by independent authorities,

like Member States or the European Commission. In addition, it is made clear that CSM is only required when risks or critical uncertainties are identified in the ERA that could lead to adverse effects on human health or the environment. Furthermore, in the guidance it is stated that the duration of GS should take into account the duration of the environmental exposure, which is a result of the life cycle and production cycle of the GM plant.

However, a few of COGEM's previous comments are not sufficiently addressed in the final version of the guidance document. These remaining points are discussed below.

General remarks

Definitions of 'damage', 'harm' and 'adverse' should be clear and unambiguous

In the draft guidance, COGEM noted that definitions of 'damage', 'harm' and 'adverse' were not unambiguous.[3] At the beginning of the draft document (Chapter II, 'Legislative background'), the definition for environmental damage as mentioned in Directive 2004/35/EC was used. This definition does not take the reversibility of damage into account. EFSA's definition on damage was not introduced until Chapter IVB on 'General Surveillance'. EFSA stated that the subject of protection is considered to be damaged if it is significantly adversely affected. According to EFSA, the identification of a significant adverse effect should consider both its intensity (e.g. extent of loss) and the value of the impaired subject of protection (e.g. high value of the populations of a species protected by law), and the reversibility of, or recovery from, the damage.

In its advice commenting on the draft version of the guidance document, COGEM noted that EFSA's definition should be introduced early in the guidance document and that the differences with the definition in Directive 2004/35/EC should be explained. In addition, it should be made clear why EFSA prefers the definition which takes reversibility into account.

COGEM observes that in the final version of the guidance document the differences in definition of damage are maintained, and that EFSA's definition on damage is still explained later in the document. COGEM stresses that the definition of damage has to be unambiguous, that EFSA's definition of damage should be introduced early in the guidance document, and that it should be made clear why EFSA prefers the definition, which considers reversibility.

Potential effects that do not reach statistical significance should not be neglected

COGEM noted that in the draft guidance, apparently contrasting statements concerning difficulties in the design of PMEM were present. On one hand, difficulties associated with the detection of effects were pointed out, but on the other hand, EFSA adhered to rather rigid criteria for statistical design and analysis. In the final version of the guidance document, EFSA reiterates that a proper statistical design is required for CSM and GS of GM plants (Chapter 4.1.2.1, 4.2.1.5 respectively).

COGEM agrees that careful attention should be given to a proper set up of an experiment, but points out that it will be difficult, and might even be impossible, to obtain statistical significant data from monitoring because of the high variability present within the environment. This is true for both CSM and GS. In case of GS, the lack of a clear hypothesis on the type of adverse effects

that might be caused by a GM plant, further hampers the possibility to perform a proper statistical analysis and to detect effects, which are statistically significant.

In view of the above-described considerations, COGEM is of the opinion that statistical significance should not be the only trigger for further research. Non-significant deviating observations could serve as an early warning signal and should be given consideration. If too much emphasis is put on the statistical significance of an observed effect, a putative effect could be neglected because it does not reach statistical significance. Past situations in conventional agriculture have shown that too much emphasis on statistical significance could lead to unjust discarding of relevant effects. Therefore, the guidance document should stress the possible importance of effects that do not fulfil the criteria of statistical significance. COGEM considers GS as an early warning signal, which in case of deviating observations triggers the need for further research.

Specific comments

Chapter 3, Interplay between ERA, Risk management and PMEM

Presence of multiple GM plants important when investigating the cause of an observed effect
In the guidance document, EFSA points out that future GS monitoring systems should not only consider individual events, but also should be concerned with the impacts on receiving environments of multiple GM plants, the interactions between GM plants and their cultivation and management.

The purpose of GS is to detect unanticipated adverse effects of the GMO or its use. The set up of a system to detect unanticipated adverse effects is not significantly different for single or multiple GM events. Therefore, in COGEM's view the presence of multiple GM events would not affect the set up and realization of the part of GS that concerns the detection of possible unanticipated effects. The presence of multiple GM events is of importance in a later phase, when investigating the cause of an observed effect.

Chapter 4, Guidance on PMEM

4.1.1 Strategy for Case-Specific Monitoring

Development of resistant insects is not an environmental risk and should not be part of PMEM
In the draft guidance document, some examples of 'Options' and 'Approaches' for CSM referred to the development of insect-resistant pests. If target pests become resistant this renders the GM plant useless and it could lead to crop losses and damage for farmers. In the final version of the document, it is still recommended that the efficacy of risk management strategies concerning the survey of the change of susceptibility of target pests is assessed by means of the 'high dose/ refuge strategy' (Box 1, Chapter 4.1.1).

COGEM is of the opinion that in general, resistance of target pests is an agricultural economic risk; it does not result in an environmental risk. Therefore, monitoring of the development of insect-resistant pests should not be part of PMEM.

4.2 General surveillance (GS)

4.2.1.3 Selection of protection goals, assessment endpoints and indicators

Sustainability should be specified and should only be part of GS when possible environmental risks are concerned

EFSA states in its guidance document that sustainable agriculture is one of the aspects that could be monitored in GS (Table 1; Chapter 4.2.1.3 'Monitoring the GM plant and its cultivation sites'). As COGEM mentioned in its previous reaction on the draft version of the guidance document, COGEM is of the opinion that in the guidance on PMEM an explicit delimitation of the sustainability aspects that have to be considered in GS should be given. In COGEM's view, these aspects should particularly concern effects of the GM plant itself, or of specific cultivation or management techniques directly linked to the GM plant.

4.2.2.1 Monitoring the GM plant and its cultivation sites

Farmer questionnaires do not contain a proper comparator

In its guidance, EFSA states that a farmer questionnaire should be designed to ensure appropriate statistical validity (Chapter 4.2.2.1, 'Design of the Farmer Questionnaire'). However, as a proper comparator is missing in the farmer questionnaires, a proper statistical analysis is hampered.

In practice, in questionnaires the 'usual situation' is used as a comparator. However, 'usual situations' are not well defined. Data on the 'usual situation' can be obtained when farmers grow GM plants and conventional crops simultaneously. In most cases, this ideal situation is unlikely to occur. The problem arises how the farmer has to obtain the data. Data from previous years are most likely not available or not representative for the circumstances in the year concerned. Management practices obtained from adjacent farms may differ. It should be realised that the approach in practice may not generate sufficient data to draw scientific conclusions.

GS for cultivation should also pay attention to monitoring of effects arising from import and processing

In the draft guidance, COGEM noted that the majority of the section on GS referred to cases where GM plants are cultivated. The set up of such a GS plan focuses on detecting unanticipated effects arising from growth of the GM plant. A separate section dedicated to the GS of GM plants intended for import and processing was present in the draft and final guidance. In its previous advice, COGEM pointed out that usually simultaneously with a license for cultivation, a license for import and processing of the GM plant is granted. The effects that may arise from import and processing might differ from the effect that could arise from cultivation. Therefore, COGEM is of

the opinion that that in those cases where import and processing as well as cultivation are granted, GS plans for both applications should be required.

Conclusion

In conclusion, the revised guidance on PMEM of GM plants is an important step forward. However, in the opinion of COGEM, the revised document can be strengthened when the following aspects are taken into account:

- COGEM stresses that the definition of damage used in the guidance document has to be unambiguous. EFSA's definition of damage should be introduced in the beginning of the guidance document. Moreover, the importance of the aspect of reversibility of damage should be elucidated.
- COGEM considers GS as an early warning signal, which in case of deviating observations triggers the need for further research. The guidance document should take into account that the criterion of statistical significance may hamper the detection and identification of the occurring of adverse events and should therefore not be a strict prerequisite for further research.
- The presence of multiple GM events should not affect the set up and realisation of the part of GS that concerns the detection of possible unanticipated effects. The set up of a system to detect unanticipated adverse effects is not significantly different for single or multiple GM events.
- COGEM is of the opinion that in general, resistance of target pests is not an environmental risk but an agricultural economic risk, since resistance results in crop losses and reduces the agronomic value of the GM crop involved. Therefore, the monitoring of the development of insect-resistance should not be a standard element of PMEM of GM plants.
- COGEM is of the opinion that PMEM should focus on effects of the GM plant itself or of specific cultivation or management techniques directly linked to the GM plant. Therefore, in COGEM's view, the guidance on PMEM should give an explicit delimitation of the sustainability aspects that should be considered in GS.
- COGEM states that in practice, in farmer questionnaires the 'usual situation' is used as a comparator. An 'usual situation' is not well defined, which hampers a proper statistical analysis. COGEM is of the opinion that farmers ideally should be asked to provide data on the 'usual situation', when they simultaneously grow conventional crops themselves.
- COGEM points out that in those specific cases, where import and processing as well as cultivation are granted, GS plans for both applications are required. This aspect should be explicitly mentioned in the guidance, to avoid possible uncertainty.

References

1. EFSA Panel on Genetically Modified Organisms (2011). Scientific Opinion ‘Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants’. EFSA Journal 9(8): 2316
2. COGEM (2011). Comments on the European Food Safety Authority draft version of the revised ‘Guidance on Post- Market Environmental Monitoring (PMEM)’. CGM/110520-01
3. EFSA Panel on Genetically Modified Organisms (2011). Draft Scientific Opinion providing ’Guidance on the Post- Market Environmental Monitoring (PMEM) of genetically modified plants’.
4. COGEM (2010). General Surveillance. CGM/100226-01
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