## 1.1. Environmental post-market monitoring of *Bt*-maize

Approaches to detect potential effects on butterflies and natural enemies

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Can post-market monitoring detect adverse environmental effects caused by the cultivation of genetically modified (GM) crops? This question was addressed by Olivier Sanvido, Stéphanie Aviron, Jörg Romeis and Franz Bigler from Agroscope Reckenholz Tänikon Research Station ART. In their report, they discuss the approach of post-market monitoring (PMM) and propose how potential adverse effects on the environment occurring from the commercial cultivation of GM crops could be detected. PMM was thereby distinguished in case-specific monitoring and general surveillance. Case-specific monitoring focuses on anticipated effects of a specific GM crop and aims to assess whether these effects on the environment do occur. General surveillance, in contrast, has the aim to detect adverse effects on the environment that were not anticipated.

### Monitoring potential effects of *Bt*-maize expressing Cry1Ab on butterflies in Switzerland during commercial cultivation

*Starting Position*
Adverse effects of GM crops should be detected to prevent the environment from damage. In the case of *Bt*-Maize, a genetically modified maize expressing the insecticidal protein Cry1Ab from *Bacillus thuringiensis,* a potential effect on butterflies can not be excluded, given the specificity of the toxin on Lepidoptera (butterflies and moths). Butterfly larvae might be harmed following ingestion of pollen from this maize. The question is whether PMM might detect adverse effects on butterfly populations, how this monitoring should be organized and what the alternatives to PMM are.

*Analysis*
The authors took a hierarchical approach considering field, landscape and regional scales to account for existing variability in butterfly biodiversity. Using an existing dataset on butterflies in 3 maize-growing regions in Switzerland, they identified that 15 out of 24 tested descriptors of environmental and farming context induced significant variability in the richness (diversity) and abundance of butterfly populations.

*The challenge*
Based on the analyses, the authors concluded, that detecting potential effects of *Bt*-maize using a case-specific monitoring-approach would need a considerable sampling effort. Sampling 100 pairs of fields or field margins would only detect large effects, e.g. a decrease of species abundance by more than 30%. Rare and – from en ecological point of view – valuable species could, therefore, hardly be monitored with a reasonable sampling effort.

*Test risk hypotheses under conditions that are most appropriate*
Hypotheses should be tested under those conditions that will most likely reveal the occurrence of the presumed effect. In contrast to monitoring potential impacts of *Bt*-maize on butterfly species in the field, potential effects might be assessed more rigorously by assessing hazard

and exposure of sensitive butterfly stages to *Bt*-maize prior to commercial approval. Unexpected effects of *Bt*-maize during commercial cultivation might moreover be detected by general surveillance as long as existing monitoring networks provide baseline data to describe existing variability. If background variability is known, species-richness of butterflies could be a suitable indicator for general surveillance.

**Approach to monitor potential effects of *Bt*-maize expressing Cry1Ab on natural enemies during post-market monitoring of GM crops**

Pre-market risk assessment (PMRA) and PMM represent two separate phases during the commercialization of a GM plant. Particularly case-specific monitoring is a risk management option to assess a risk identified during PMRA and to cover remaining uncertainties. Which uncertainties exist and whether they are acceptable must, therefore, be determined before any case-specific monitoring activity can sensibly be implemented.

*Scientifically sound strategies*
Insect-resistant GM crops (such as *Bt*-maize) raise particular questions regarding disturbances of biological control functions of beneficial insects such as predators and parasitoids (so-called natural enemies). As the Cry1Ab protein lacks toxicity to natural enemies, there is however no logical hypothesis that this group of species could be affected by *Bt*-maize. CSM is thus not evidenced. Consequently, a faunistic monitoring of specific groups of natural enemies does not constitute an appropriate approach to detect failures in biological control functions. Alternatively, an approach is proposed that consists in indirectly analysing these functions via a general-surveillance approach by surveying outbreaks of maize herbivores. Unusual pest outbreaks could e.g. be collected by questionnaires addressed at farmers growing *Bt*-maize. If a correlation between cultivation of the genetically modified crop and an unusual occurrence of specific maize herbivores were detected, more specific studies would then have to determine possible causalities to *Bt*-maize cultivation. The proposed approach takes into account the theoretical basis of functional ecology since it concentrates on biological functions instead of concentrating on species richness and abundance. This allows avoiding the collection of insignificant data that do not serve the ultimate purpose of PMM to yield a scientifically sound basis for regulatory decision-making.

**Challenges and perspectives in decision-making during environmental post-market monitoring of genetically modified crops**

An applicable criterion to valuate ‘environmental damage’ is not at hand. This poses a major problem when trying to decide on the acceptability of a particular identified risk and, consecutively, on the need for case-specific monitoring. Moreover, data collection and analysis have limits. Two main facts challenge decision makers in determining what constitutes environmental damage:

1. There are methodological limitations in unambiguously establishing what exceeds the natural variability of a particular indicator.
2. Different stakeholders may interpret scientific data differently, which results in a controversy about how the effects of GM crops should be valued.

As a remedy for these two ambiguities in the decision making process, alternative strategies are proposed..

*PMM is demanding while often not removing ambiguity*
First, the right indicators must be selected, which enable to indicate environmental changes. This is inherently difficult given that most biological indicators show a great variability. In addition, some effects can be observed only over a long time span and a multitude of existing factors may simply make it impossible to ascertain an observed effect to the cultivation of a specific GM crop. Consequently, PMM could become extremely demanding time and cost-wise while still not leading to sound data for decision makers.

*PMRA may often be more accurate than PMM*
Environmental effects may be detected more easily and more rigorously during PMRA than during PMM. PMM has the inherent limitation that ecosystems are complex and it is impossible to elucidate all interactions taking place in them. There will always be the uncertainty of whether all possible effects are known and if those can at all be detected. In addition to the uncertainties, it is often even unclear, if a measured effect in a given ecosystem is directly linked to the specific GM present.

*Conclusions for decision makers*
Regulatory decisions must, nevertheless, be taken to ensure a safe environment. Since damage - due to the methodological and practical constraints - cannot be valued by absolute values, we propose to use a comparative approach. Environmental effects of GM crops should be compared to a baseline determined by known effects of current agricultural management practices. This could enable decision making within a reasonable timeframe. It would further allow to harmonize protection goals for cultivating GM crops with the existing agricultural practices they intend to replace.

Regulatory bodies should understand the limitations of environmental monitoring programmes and, concomitantly, their usability as decision making tools. The objective to detect adverse environmental effects by GM crop cultivation through PMM may be very difficult to achieve and should therefore be discussed critically.

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