

Networks and environmental observation programs as a tool for general surveillance – first experience and future requirements

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Abstract

Consent holders make use of the opportunity to involve existing observation programs or networks in the general surveillance of GMOs. Three core strategies are currently established: the participation of European trade organisations, contributions of designated experts and the assessment of data gathered by environmental observation programs operated by third parties. In this contribution, needs for improvement are identified based on the analysis of monitoring plans and reports. Reported results and conclusions drawn by the consent holder are often neither traceable nor assessable because of the lack of explanations of monitoring objectives, methods and data analysis. To assure a reliable general surveillance of GMOs, science-based criteria for the selection of appropriate programs and networks as well as a data quality management are essential and must be developed. Agreements concerning the availability of data have to be settled before consent for placing GMOs on the market can be given.

Introduction

It is recommended by European legal provisions to use existing monitoring schemes for the general surveillance of GMOs. The guidance notes to Annex VII of Directive 2001/18/EC state that

“GS could, where compatible, make use of established routine surveillance practices such as monitoring of agricultural crops, plant protection, veterinary and medical products as well as ecological monitoring, environmental observation and nature conservation programs” (EC 2002). The guidance notes continue that

”If established routine surveillance practice is used in the general surveillance, this practice should be described as well as the changes in the practice needed to fulfill a relevant general surveillance” (EC 2002).

All currently established general surveillance plans make use of this opportunity (EFSA 2009). Although the approaches applied are quite different from each other, they all reveal strong deficiencies and require fundamental improvement.

Strategies

At present, three core strategies are implemented: participation of European trade associations, contribution of designated experts and the assessment of data gathered by environmental observation programs operated by third parties.

European trade organisations

European trade associations like COCERAL (importers/traders), UNISTOCK (silo operators) or FEDIOL (processors) are involved in the monitoring of crops approved for import and processing, feed or food uses (EFSA 2009). The idea is that the associations inform and remind their member organisations and companies annually

- to monitor for adverse effects,
- to inform their own member companies of this requirement and
- to report any findings to the European trade association.

The European trade association will report directly or via EuropaBio to the party who is holder of the consent to release the GMO (consent holder).

It is remarkable that neither the monitoring plans nor the reports give any information concerning the monitoring procedure. It remains unclear who participated in the monitoring and what kind of response is generated. No details on monitoring objectives, methods, locations, frequencies or expertise of participants are given (EFSA 2009). Hence, the monitoring conducted by European trade associations and the reported results are neither traceable nor assessable.

Designated experts

In the case of imported genetically modified carnation stems the general surveillance of potential environmental effects is carried out by experts (EFSA 2009). Three breeders and six botanists who are concerned with *Dianthus* biology were asked to alert the consent holder to any unusual hybrids that are found during their routine surveys. In addition, the consent holder asked herbaria, national botanical survey networks, plant protection services and botanical gardens in Europe to be alerted in case of dispersal of GM carnation or the occurrence of hybrids. To benefit from the knowledge of designated experts is a step forward. However, the participation of the above mentioned experts and institutions is voluntary and there are no binding agreements. Therefore, no systematic observations are conducted and any findings and reports will occur by chance.

Environmental observation programs

A “German network monitoring” was implemented in Germany in 2008 during the cultivation of MON810. Its main strategy is to review the reports published annually by selected environmental observation programs (BVL 2008) in order to find out if any adverse effects of MON810 cultivation can be identified. Whenever adverse effects are recognized, the consent holder will contact the corresponding observation programs and ask for the relevant primary data to analyse them.

The monitoring report (Monsanto 2009) delivered in March 2009 showed that this strategy has failed and needs fundamental improvement. Only some of the selected environmental observation programs publish their data in publicly available reports. Even if results are available, they do not necessarily provide relevant information. The observation programs were established for other purposes than monitoring environmental effects of GMOs. Thus, scope and parameters, time, frequency and scale of data collection as well as the methods for sampling and analysis do not fit into the task of GMO monitoring.

Another problem of this strategy is that program coordinators or responsible persons are not contacted beforehand about an agreement on the delivery of data. Collectors of data, who are often volunteers, may show reluctance to provide their data to consent holders, as some did in 2008 (Agrarheute 2009a,b).

Conclusions

In principle, existing networks, services and environmental observation programs could make a valuable contribution to general surveillance (Züghart et al. 2008). However, precise and science-based criteria are needed to select appropriate networks and observation programs. Options for adaptation or enlargement of programs are to be considered. If existing networks and programs are not suitable, additional monitoring tools or surveys have to be implemented.

In order to ensure a suitable and sound data base, quality management is crucial. Thus, clearness concerning observation objects, monitoring design, experts involved, information flow and data analysis is essential. Agreements concerning access to data or results should be settled before the authorisation for placing a GMO on the market is granted.

If significant effects on human health or on the environment are reported, in-depth studies should be carried out to determine the causes (EFSA 2006). However, it is still not defined in which case further studies are indicated, how such studies should be designed and who will be responsible for their conduct. Therefore, a process that allows clear and fast responses to findings from environmental observation programs or networks must be developed.

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