Better Risk Monitoring of GMP

Genetically modified plants (GMP) may now be commercially cultivated in the EU. According to the EU Directive 2001/18/EC, post-market monitoring (PMM) for commercial GMP cultivation has to be implemented in order to assess adverse effects of such cultivations on human health and the environment. Currently, there is no EU wide consensus on how such PMM programmes have to be designed. Consequently there is an urgent need for guidance on this subject.

Swiss researchers have recently developed a detailed conceptual framework that proposes procedures that could be used for designing PMM programs for GMP cultivation in Europe. It is based on current EU legislation and common risk analysis procedures.

The EU directive distinguishes case-specific monitoring (CSM) and general surveillance as parts of PMMs, but the specific tasks of such programmes are not clearly defined. The proposed framework is based on the authors’ identification of different objectives and tasks of CSM and general surveillance within the PMM.

Case-specific monitoring should focus on detecting the changes that are related to specific causes of GMP cultivation. Four separate phases for CSM are proposed:

1) Defining CSM strategy based on the identification of possible risks caused by the cultivation of the specific GMP;
2) Determining the scale of CSM by defining the effects magnitudes that have to be considered;
3) Planning the operational programme by selecting specific indicators to test specific hypothesis, determining the specific trigger values for each indicator and performing a feasibility study for each indicator;
4) Assure data collection, analysis and evaluation.

The general surveillance should be oriented to detection of ecological changes that should not be affected by GMP. A four step approach is proposed:

1) Definition of safeguard subjects
2) Collection and valuation of reports on adverse incidents
3) Establishing cause-effect relationships with GMP cultivation
4) Making final decisions based on the above

The uncertainties related to environmental and health risks of GMP cultivation should be managed by PMM programmes. It is important to provide the best possible expert guidance to assure the implementation of efficient PMM programmes throughout EU member counties. In this regard, the guidelines proposed in this conceptual framework could be used as bases for the EU consensus on this subject.

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Theme(s): Agriculture, Biotechnology