EuropaBio Approach to General Surveillance for Cultivation of GM Crops

Workshop on Post Market Environmental Monitoring of Genetically Modified Plants: Challenges for PMEM – Multiple/stacked events and long-term effects

3rd May 2010, Quedlinburg, Germany
Agenda

• Introduction
• Harmonised General Surveillance for cultivation
• Farmer questionnaire
• Surveillance networks
• Complementary elements
• Conclusions
• Perspectives
Introduction
Regulatory Framework

The post-market environmental monitoring plan


- Based on the outcome of the risk assessment carried out in accordance with Annex II of Directive 2001/18/EC

- Developed according to principles and objectives outlined in
  - EFSA Guidance Document (2006) for the risk assessment of GM plants and derived food and feed

- Implemented according to the conditions specified in the authorisation

⇒ Authorisation holders are responsible for compliance with monitoring conditions. An annual report on the implementation and the results of the monitoring has to be submitted to the regulatory authorities for the duration of the authorisation
Directive 2001/18/EC requires that both case-specific monitoring and general surveillance are considered as post-market implementing measures.

- **Case-specific monitoring (CSM)** – to monitor for potential adverse effects of the GMO or its use identified in the environmental risk assessment (e.r.a.)

- **General surveillance (GS)** – to anticipate for unintended adverse effects of the GMO or its use on human and animal health or the environment
Introduction

General Surveillance

General Surveillance is not based on a specific hypothesis. In accordance with Decision 2002/811/EC and the EFSA Guidance Document, it should

- Focus on unanticipated adverse effects
- Be proportionate to the exposure to the environment
- Make use of routine practices and historical knowledge
- Be unbiased for different traits and crops
- Be cost-effective
EuropaBio is developing a holistic and harmonised approach to General Surveillance meeting the requirements of the legislation.

The approach is based on five elements:

1. Farmer questionnaire
2. Environmental surveillance networks
3. Peer reviewed publications
4. Companies’ stewardship activities
5. Issue alerts

The five elements are fully complementary tools that are fit for the purpose to identify any potential adverse effects arising from the presence of GM crops. They are science-based, multifunctional, and dynamic to account for experience/advanced methodology.
Protection goals:
- Ecological systems and biodiversity
- Soil function
- Sustainable agriculture
- Plant health
- Human and animal health

Influencing factors:
- Climatic conditions
- Landscaping, restructuring
- Other human activities
  - Urbanisation
  - Industrialization
  - Transportation
  - Energy production
  - Pollution
  - Electro-magnetism...
- Diseases and pests
- Agricultural practices
  - Cropping system
    » Choice of crop
    » Choice of variety (GM or non-GM)
    » Rotation
    » Fertilizer
    » Pesticide
Farmer Questionnaire
Rationale for Harmonisation

• Based on Wilhelm et al. (2004) and Schmidt et al. (2008) and further developed based on feedback from the EU Commission

• Uniform format: i) better farmer engagement
  ii) coherence across responses

• Improved comparability of datasets between products

• Allows to develop a broader baseline

• Allows to establish common databases and analytic tools

• Harmonise the survey methodology
Farmer Questionnaire

Focus

- **General farm information** → General information on farm and crop growing area (fixed factors)

- **Agricultural practice** → General agricultural practice for growing crop on the farm (adjustable and random factors)

- **Observation of GM crop** → Characterisation of the GM crop and its use compared to conventional (monitoring characteristics)

- **Implementation of product specific management conditions** (if applicable)
Farmer Questionnaire
Parameters

Monitoring parameters

Coding parameters
- geographic coordinates
  - country, post code, town

Monitoring object = Field and Surroundings

Monitoring characteristics = GM vs. non-GM crop

Adjustable Factors
- e.g. Cultivation data
  - dates, measures, means, amounts

Random Factors
- e.g. Environment data
  - diseases, weeds, pests

Fixed Factors
- e.g. Soil data
  - type, previous crop in rotation
Farmer Questionnaire
Monitoring Characteristics

Example for Monitoring Characteristics

### 3.2. Characteristics of event xxx in the field (compared to conventional maize)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>As usual</th>
<th>More vigorous</th>
<th>Less vigorous</th>
<th>Accelerated</th>
<th>Delayed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germination vigour</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to emergence</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to male flowering</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plant growth and development</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incidence of stalk/root lodging</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to maturity</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yield</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occurrence of Volunteers from previous year planting (if relevant)</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If any of the answers above is different from « As usual », please specify:
Example for fixed factors

1.5. Soil characteristics of the maize grown area:
Mark the predominant soil type of the maize grown area (soil texture):

- O Very fine (clay)
- O Fine (clay, sandy clay, silty clay)
- O Medium (sandy clay loam, clay loam, sandy silt)
- O Medium-fine (silty clay loam, silt loam, loam)
- O Coarse (sand, loamy sand, sandy loam)
- O No predominant soil type (too variable across the maize grown area on the farm)
- O I do not know

Characterise soil quality of the maize grown area (fertility):

- O Below average – poor
- O Average – normal
- O Above average – good

Organic carbon content (%)........... ________________
Example for random factors

1.6. Local pest and disease pressure in maize:

Characterise this season’s general pest pressure on the maize cultivated area:

- Diseases (fungal, viral)……………….  O Low  O As usual  O High
- Pests (insects, mites, nematodes)….  O Low  O As usual  O High
- Weeds…………………………………. O Low  O As usual  O High
Farmer Questionnaire
Adjustable Factors

Example for adjustable factors

2.5. Mark all typical weed and pest control practices in maize at your farm:

- Insecticide(s)
  - If box checked, do you treat against maize borers? [ ] Yes  [ ] No
- Use of biocontrol treatments (e.g. Trichogramma)
- Herbicide(s)
- Mechanical weed control
- Fungicide(s)
- Other, please specify:

2.6. Application of manure to maize grown area: [ ] Yes  [ ] No

2.7. Typical time of maize sowing range (DD:MM – DD:MM):

____ / ____  ____ / ____
Farmer Questionnaire
Specific Measures

Example of product specific management measures

• Assess applicability to other crop/trait combinations and either replace or delete

3.4. Characterise the INSECT pest control in event xxx fields (compared to conventional maize)

On the two insects controlled by event xxx, overall efficacy of the GM varieties on:

1. European corn borer (Ostrinia nubilalis):
   - O Very good
   - O Good
   - O Weak
   - O Don’t know

2. Pink borer (Sesamia spp):
   - O Very good
   - O Good
   - O Weak
   - O Don’t know

Additional comments:

________________________________________________________________________

________________________________________________________________________
Example of product specific management measures

- Assess applicability to other crop/trait combinations and either replace or delete

4.3. Prevention of insect resistance

Did you plant a refuge in accordance with the technical guidelines?

   O Yes
   O No, because the surface of event xxx planted on the farm was < 5 ha
   O No, because ______________________________

   ______________________________
   ______________________________

   ______________________________

   ______________________________
Adapting farmer questionnaire for other traits and crops

Establishing a network of independent third parties collecting and analysing farmer questionnaire data

Building up a sustainable database for surveillance of GM crops that can also be used for future risk assessments

- Data can be categorised (influencing factors, monitoring characters, …) and compared with each other within the database and/or with other surveillance databases
- Correlations can be established in time and space
Environmental surveillance networks do not distinguish between agricultural practices; they are equally relevant for all GM crops and traits.

Harmonisation allows to:

- Improve the quality of the data collected and of the reporting
- Bring consistency across
  - Criteria for the selection of networks
  - Methodology in the assessment of data
  - Translations of surveillance reports to improve comparability of data and the reporting process
- Have a unique platform negotiating the use of their data with networks
Methodology

• Identify existing environmental surveillance networks
• Determine suitability of networks based on set criteria (e.g. protection goals, geographical coverage, reporting frequency, etc.)
• Contact networks and establish agreements to use their surveillance data
• Collect and analyse network data on yearly basis for inclusion in annual monitoring report

The selection of networks will be regularly reviewed to ensure the quality of the collected data, as well as its representativeness of GM crop market penetration.
Complementary Elements

Elements that are currently not harmonized, but are complementary to the farmer questionnaire and the existing networks

- Peer reviewed publication
  - For specific trait/crop combinations a common approach can be envisioned; collection and database entry complementing the individual event specific publications

- Company stewardship
  - Specific to individual authorisation/consent holder and respective event or trait/crop combination

- Issue alerts
  - Will be channelled and addressed on an individual authorisation/consent holder basis
Conclusions

• The power of the overall harmonised approach to General Surveillance resides in its multifaceted nature

• The approach ensures a reliable collection, analysis and reporting of existing data through clear methodologies such as the farmer questionnaire and existing environmental surveillance networks

• It helps authorisation holders to comply with monitoring requirements based on Directive 2001/18, Regulation 1829/2003 and the authorisation decision
Conclusions

• The approach will remain flexible enough to be able to account for:
  – Feedbacks from the different stakeholders (risk managers, farmers, networks)
  – Adaptation to the new knowledge that it will create
  – New technological developments (methodology)

• It allows further development towards
  – Sustainable database
  – Harmonised overall monitoring plan
  – Harmonised monitoring format
Perspectives

• Exchange with Commission and Member States on Harmonised General Surveillance for Cultivation

• Apply the modules of the harmonised farmer questionnaire to other crop/trait combinations

• Conclude harmonised approach on existing surveillance networks

• Schedule workshop to provide for more in depth presentation of the five elements of General Surveillance for cultivation and their implementation as part of the overall post-market environmental monitoring plan for GM crops
Thank you

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