Post Market Environmental Monitoring:
how it works for risk managers

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1. Legal provisions in GMO legislation on ERA

1. Very specific requirements as regards Environmental risk assessment (ERA) in legislation

2. EFSA mandated by Commission to update their ERA guidelines by March 2010

3. ERA Guidelines clarify further the requirements of the legislation, which remain applicable ; contribute to clarity and transparency for all players (companies, public authorities, risk assessors, etc.)

4. These updated ERA Guidelines will be submitted by COM to Member States for vote in course of 2010

2. Who are the risk assessors in the case of cultivation files ?

- The company notifiying the request for autorisation (« notification »)
- The Member State who is designated the « lead competent
- EFSA

3. ERA informs monitoring

1. The environmental risk assessment delivered by the three «*main players*» (company; lead CA ; EFSA) has to cover inter alia risk assessment and a «***management strategy***»

2. Legislation specifies for example:

   Step 5 of ERA states "*The risk assessment may identify risks that require management and how best to manage them and a* ***risk management strategy*** *should be defined*"

   Step 6 of ERA states "*An evaluation of the overall risk of the GMOs should be made taking into account any* ***risk management strategies*** *which are proposed*".

   Annex II C.2 of Directive 2001/18/EC and Regulation (EC) No. 829/2003 describes the steps in the ERA

3. **Risk Management** includes :
   - management measures as such (refuge zones, borders rows, studies, etc)
   - monitoring measures.

4. Legal provisions for monitoring

Objective and principles of monitoring plan

- confirm adverse effects identified in the ERA: Case specific monitoring (CSM)
- anticipate adverse effects not identified in the ERA: General Surveillance (GS)
- Case-by-case basis

Annex VII of Directive 2001/18/EC,COM Decision 2002/811/EC – guidance notes supplementing Annex VII, Commission Decision (Article 4)

Notification: Inclusion of monitoring plan is mandatory

Article 13, Annex VII – Directive 2001/18/EC
Article 5, 17 - Regulation (EC) No 1829/2003

Autorisation: must specify monitoring requirements

Article 19 – Directive 2001/18/EC
Article 16, 19 – Regulation (EC) No 1829/2003

5. Purpose of monitoring

Must be useful

- to protect the environment effectively
- to confirm the ERA
- to reassure public at large on safety of product

May be adapted depending on results : is therefore instrumental

Must be made available to the public : specific provisions in the legislation requiring public access

6. Who is responsible for monitoring

- The company (consent holder): to carry out the monitoring, comply with the monitoring requirements and reporting back
- Commission and MS : to define as risk managers the most appropriate risk management
- Member States : may also carry out monitoring in context of their responsibility of ensuring implementation at national level, what happens in a number of Member States (FR, SP, DE, etc.)

7. Reporting/ transparency

- **Post-market monitoring and reporting**

  Post-market monitoring and reporting are obligatory
  Monitoring plan may be adapted

  Article 20 – Directive 2001/18/EC
  Articles 9, 21 - Regulation (EC) No 1829/2003

- **Public Access to monitoring reports**
  Article 19, 20 – Directive 2001/18/EC
  Article 9, 21 - Regulation (EC) No 1829/2003

8. Follow up to monitoring

Monitoring reports have to be useful

Discussion initiated by DG ENV with MS in 2009 to analyse the reports

DG ENV will make monitoring reports available on internet (public availability also at national level)

Role of lead CA

9. Standard reporting format

- Content and presentation of monitoring reports instrumental
- Standard format also useful to have transparency, clarity and comparability over time and between various GMOs

  "facilitate the implementation and explanation of this Annex" (Dir 2008/27) Annex VII of Dir 2001/18.

- Standard format voted by large majority of Member States in 2009 and will come into force before end of 2009
- Under new format consent holder will for example be specifically invited to :
  - interpret and analyse data (for example literature review) ;
  - explain how the monitoring results and their interpretation support the conclusions.

10. Monitoring key to ERA

Article 10

" After completion of a release and thereafter at any intervals laid down in the consent on the basis of the results of the ERA the notifier shall send to the CA the result of the release in respect of any risk to human health or the environment…."
("Reporting by notifiers on releases")

*M*onitoring must therefore be :
- clearly designed
- useful to protect the environment
-transparent and inform the public at large

Particularly important in the case of cultivation files where is no consensus as regards risk and also to build gradually confidence

Biotechnology website

http://ec.europa.eu/environment/biotechnology/index_en.htm