Access to information regarding the use of LMOs/GMOs

including access to scientific information and

risk assessment and

potential conflicts with intellectual property rights

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Overview

- use: release (trial and commercial), open and contained, in transit, unintended (incl. transboundary).
- access = ?
- scientific information = ?
- risk assessment – whose? for what aspect? review & repeat
- conflicts with CBIs, IPRs
- what do we need?

Access = (1)

- Public = all (incl. farmer, consumer/citizen, politicians, journalists, scientists)
- Trigger points: e.g. knowing there is [should be] information to access (EU; India; Canada; US)
- Understanding what is:
  - being presented
  - Missing
  - assumption – e.g. CaMV 35S
  - …. “translator”

Access = (2)

- Affordable access (NZ 235 US$ per file; Canada xx per sheet)
- Concise vs realms
- Access to all information that is required
  - ➡ sci inf

Access = (3)

For the public to have true access to information and to effectively participate, we need:

- **Same level of scientific support as there is for legal support, because the consequences are no less from making a poor regulatory decision than a poor legal decision.**

Access = (4)

Concerning information on herbicides used with GM plants (glufosinate/Bayer)

FoE UK: Pesticide Safety Directorate (PSD) agrees to release data. Bayer sues government. Out of court settlement 2003 - FoE gets “read only” access.

FoE told Bayer it intended to use its website to tell people how to get data from regulators around the world, including Sweden (KEMI), Denmark, Ireland and the USA.

Bayer went to High Court for injunction (Oct 2003), but eventually dropped court action and signed settlement.

http://www.foe.co.uk/resource/press_releases/gm_pesticide_secrets_to_go_28062004.html

Access: other cases (5)

- AquaBounty: Salmon Canada/US/Panama – current.
  - PEI facilities: R&D – no regs, no RA
  - US: publishes AB's submission incl. summary of health effects – no Env RA
  - Down to Panama to ask C to place conditions/ biosafety measures for shipment from C.
- RIDL GE-Mosquitoes – Malaysia (sci paper)
- GURTs (terminator technology): Delta & PineLand – (patent)

Scientific Information (1)

Sound science is based on transparency, verifiability, and reproducibility (e.g. reporting of methods and data in sufficient detail, so that the resulting data and information could be confirmed independently), **and on the accessibility of data** (e.g. the availability of relevant, required data or information or, if requested and as appropriate, of sample material), taking into account the provisions of Article 21 of the Protocol on the confidentiality of information. **The provisions of sound science serve to ensure and verify that the risk assessment is carried out in a scientifically sound and transparent manner.**

Roadmap for RISK ASSESSMENT of Living Modified Organisms (UNEP/CBD/BS/COP-MOP/5/12)

Scientific Information (2)

- **to review methodology**
- **reproduce the experiments**
- **varify the findings**
- **freedom to elaborate opinions (**must be able to use and analyse data and findings and information to form a picture**).**
- **need raw data, feeding studies, methodology**
- **Need molecular data (incl. DNA sequence around insertion site & situation re genome-wide mutations**

Freedom of information

- **RTI – right to information act (India)**
  - **All but not raw data or location**
  - Only time raw data: Bt brinjal through court order Jan 2007 – given Aug 2008)
- **Europe: claiming under Aarhus**
- **US: Freedom of Information act**
- **Canada: Access to Information law (not all data – CBI withheld after Abigel case)**

Beyond the freedom of information

- **Timely** access to information
- **Effective** participation
- **Affordable** access to justice

CBI & IPRs (1)

Confidential Business Information & Intellectual Property Rights

- Australia/NZ: (f) all data public unless requested otherwise by applicant and granted by regulator after review according to certain criteria
- EU: CBI not down to EFSA but to commission (also according to criteria).
- Usually CBI granted at least for
  - animal feeding studies and
  - DNA sequences
  - Methodology
- US: field trials: almost all CBI, even name of notifier

CBI & IPRs (2)

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Conclusions

- Access to information is a right – yet it still needs to be asserted through the legal courts. This needs urgently to be addressed.
- CBI has to be limited to the absolute minimum as not to hinder or block scientific review and verification.
- Need access to scientific support
- Need agreement to post details of trials and applications for release/marketing on website to allow timely access & effective participation.