



# Liability in Biotechnology

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Workshop on liability and redress in biotechnology, World Trade  
Institute, Berne, 16 May 2007

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# Liability in environmental law

- Environmental laws/treaties establish substantive standards of protection
- Liability regimes (secondary rules) complement primary rules to foster effective implementation and prevention of environmental harm
- Liability does not lead to rejecting specific technologies but contributes to their effective regulation



# Environmental aspects of biotechnology: biosafety

- Rationale: regulation of environmental, health and socio-economic side-effects of the introduction of GMOs into the environment
- Basis: precautionary principle recognising need for regulatory intervention even where negative impacts not fully ascertained
- Integral part of biotechnology regulation alongside other rules/regulations, such as incentives offered by patents



# Liability and biosafety

- Aims
  - Compensation of environmental harm, risk to health, socio-economic impacts
  - Prevention of harm
  - Incentives/disincentives for economic activity clarified
- Basis: precautionary principle



## Principles (adapted from Swiss Biosafety Law – international treaties)

- Strict liability
- Liability channeled exclusively to the person commercialising/exporting
- Limitations may be placed on amount and duration (with subsidiary state responsibility)
- Different types of damages covered such as:
  - Environment
  - Health
  - Socio-economic (e.g., loss of organic certification)



## Principles (ctd)

- Burden of proof simplified in favour of affected party
- Prescription of 30 years from time GMO marketed or occurrence of event causing damage



# Harmonisation of liability rules

- International level regime required for transboundary aspects
  - Liability for activities of private entities
  - State responsibility where states are the primary actors (for instance, food aid)
- National level regimes required to:
  - Complement international regime being negotiated
  - Address issues arising with non-state parties to the Biosafety Protocol
  - Address strictly domestic issues



# Competing liabilities

- Two types of liability:
  - Environmental liability based on recognition that GMOs can be harmful
  - Patent liability based on economic right
- Patent liability must be balanced with environmental liability and both harmonised



# Alternatives to liability

- Criminal sanctions
  - For instance: Council of Europe Convention on the Protection of the Environment through Criminal Law, 1998
- Dis/Incentives for introduction of GMOs through use of biosafety clauses in intellectual property law



# Conclusions

- Harmonisation at the international level required to complement the rules adopted under the Biosafety Protocol
- National level rules required to complement international rules
- Swiss biosafety act provides an appropriate model in substance and as a political compromise
- Alternatives to liability such as criminal sanctions do not offer the same flexibility
- Potential clash of liabilities necessitates adoption of environmental liability rules