

Biotechnology Regulation

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Biotechnology Regulation

- Safety: environmental safety (biosafety), food safety, worker protection
- Product Regulation: seed registration, pharmaceuticals, pesticides, etc.
- Generic issues: IPR, ethics, liability, etc.

Biosafety Regulation

Topics:

- Historical and international context
- Biosafety Protocol
- National Biosafety Frameworks

Historical and international context

1972: First rDNA organism: great expectations and deep concerns.

1974/5: Asilomar conferences

1986: OECD rDNA safety recommendations

1992:
- (Rio de Janeiro) UNCED – Agenda 21
- Convention on Biological Diversity.

Historical and international context

The Convention on Biological Diversity (1992):

- ❖ Art. 8.g: “*In situ conservation of biodiversity*”
Obligation to develop national biosafety systems
- ❖ Art. 19.3: “*Handling biotechnology and distribution of its benefits*”
Consider a protocol on biosafety

The Cartagena Protocol on Biosafety

1995: COP Decision to develop a biosafety protocol

1996 – 2000: Negotiations

2000, January: Adoption of the Biosafety Protocol

2000, November: GEF strategy for capacity building

2002, September: WSSD, Johannesburg plan

2003, May: Report of the UN Secretary-General on biotech

2003, September: Biosafety Protocol comes into force

2004, February: First Meeting of the Parties to the BSP

Article 8g of the CBD and
Article 2 of the Biosafety Protocol:

“...Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations ...”

>>> National Biosafety Frameworks

National Biosafety Frameworks (NBFs)

NBFs vary from country to country, but usually have a number of common components:

1. Policy on biotechnology and biosafety
2. Regulatory regime for biosafety
3. System to handle notifications/requests for permits
4. Enforcement and monitoring
5. Public information and public participation

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Biosafety policies

Commonalities in existing biosafety policies:

- Biosafety policy is almost always part of broader policies (biotechnology, agriculture, science, etc.)
- The process builds consensus and integrates different goals into single national vision.
- The written policy serves as guidance for future choices

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Regulatory regimes for biosafety

Key considerations:

- Objective(s)
- Scope
- Structure

Regulatory regimes for biosafety

Objective(s):

Take into account:

WHY?

- The national policy on biosafety and biotechnology
- International obligations (e.g: CBD, CPB, WTO treaties, Codex Alimentarius, etc.)

Regulatory regimes for biosafety

Scope

WHAT?

2 Elements:

- *Which activities?, e.g.:*
 - Contained use,
 - Introduction into the environment,
 - Placing on the market,
 - transboundary movement.
- *With what? e.g.:*
 - LMOs/GMOs
 - Organisms with novel traits

Regulatory regimes for biosafety

Structure - different regulatory levels:

- Enabling legislation
(Act, Bill, Law)
Parliamentary involvement
- Implementing regulations
(Regulation, Order, Ordinance, Decree, Rule)
Issued by the Government
- Guidelines
“non binding”

Regulatory regimes for biosafety

Structure

Key questions:

- Use existing regulatory (sectoral) regime or develop a new, comprehensive regime?
- One national competent authority, local competent authorities?
- What is addressed on which level?
 - Act – Implementing regulations – Guidelines

The Regulatory regime for biosafety of Croatia

Topics:

- The overall framework
- The Nature Protection Act
- The draft GMO Act

The Regulatory regime for biosafety of Croatia

The overall framework: Two Acts specifically addressing GMOs (The Nature Protection Act and the Food Act), and a variety of laws that can also apply to GMOs (e.g. Water Protection Act).

-Comments from reviewers:

- 1) very good to present an overview of the overall framework on the Croatian biosafety web site
- 2) Overview shows need for coordination

The Regulatory regime for biosafety of Croatia

The current Nature Protection Act: a framework Act of which details will be worked out in by laws

Comments from reviewers:

NPA is in general similar to systems in many countries and is good basis for a workable, transparent system that is in line with Croatia's obligations, provided attention is given to:

- coordination
- by laws
- 'Ban'

The Regulatory regime for biosafety of Croatia

- Coordination: need to avoid duplication with Food Act and other legislation
- Implementing by-laws: balance placing technical details in by-laws and other guidelines
- 'Ban': article 114 effectively contains a unqualified 'ban'. Such as 'ban' is not in place in any other country inside or outside the EU, goes against the 'case by case' approach of the rest of the NPA and goes against the EU Directives

Regulatory regimes for biosafety

Important aspects:

- ❖ Clarity and transparency
- ❖ Predictability
- ❖ Consistency
- ❖ Workability
- ❖ Enforceability
- ❖ Adaptability

