The impact of regulation on agricultural innovation

Debate on 11 October 2017, European Parliament - Brussels

Choices in the regulatory cycle and innovation

Piet van der Meer

1986 – 1999: In charge of biosafety regulation in the Netherlands
2000 – 2004: Supporting EU accession countries with biosafety regulation and leading the UNEP-GEF Biosafety Implementation projects
2004 – 2017 : Supporting international organisations and governments
2006 – 2017: Teaching biosafety at the faculties of Law and Sciences, Ghent and Brussels.

Topics

- Global agricultural context and innovation
- Regulation and innovation

Global agricultural context and innovation

- Context: finding solutions for the challenges of farmers to produce ‘more with less’ under the effects of climate change.
- These multi-facetted challenges require multi-facetted solutions, including improved crops and farming practices.
- Farmers need on the short term crops that produce more per hectare and per litre of water, that are less dependent on pesticides and fertilisers, that have improved product characteristics and that can tolerate drought and flooding.
- Agenda 21 (1992): modern biotechnology is not a silver bullet, but can contribute significantly to solutions for these challenges

Global agricultural context and innovation

- Since 1992 the policy of most governments on innovative technologies can be summarised as: *“maximising benefits and minimising risks”.*
  - Maximising benefits: e.g.: setting the research agenda
  - Minimising risks: e.g.: biosafety systems and regulations.

Regulation and innovation

Regulation - the ‘Regulatory cycle’:

a) Designing regulations

b) Implementation

c) Review and assessment

Designing regulatory frameworks for biosafety

Key considerations:

- Objective
- Scope
- Regulatory tool(s)
- Structure of the regulatory framework

Designing biosafety regulations – objectives

Objectives of biosafety regulations are based on:

- Countries' national policies on biotechnology and biosafety
- Countries' international obligations

Typical elements in objectives of biosafety regulations:

- Safety for human health and the environment, e.g. "contribute to an adequate level of protection" (CPB)
- Other elements
  - Harmonisation, internal market (e.g. EU)
  - Providing a level playing field for innovation and R&D

Biosafety regulations – Scope

1. What is covered

- Which activities?, e.g.: contained use, environmental releases
- With what? e.g.: GEOs, GMOs, LMOs, PNTs.

Scope – categories

1. Organisms developed through exchanging genes between sexually compatible organisms, e.g.: cross breeding, embryo-rescue, hybrids, marker assisted selection, genome editing.

2. Organisms developed through generating additional genetic variation in existing genomes, e.g.: radiation/chemically induced mutagenesis (since 1920s), genome editing.

3. Organisms developed through introducing novel traits from unrelated organisms, e.g.: recombinant DNA, cell fusion, genome editing.

Most biosafety regulations are based on a certain level of **novelty** of the resulting organisms (e.g. CPB, EU, CDN).

Biosafety regulations – Scope

2. What is exempted

- Exempted from the start, e.g. pharmaceuticals
- Enabling mechanism for later exemptions, e.g. GMOs not likely to have adverse effects (e.g. Biosafety Protocol art. 7.4)

➢ *The choice of scope and exemptions of regulations can impact innovation.*

Regulations - choice of regulatory tools

1. Activities subject to technical standards
    - E.g. containment levels

2. Activities subject to prior notification
    - With / without waiting period

3. Activities subject to authorisation
    - Permits / Approval

➢ *The choice of regulatory tools can impact innovation*

Choice of regulatory structure

Different regulatory levels:

- Legislation (Act, Bill, Law) - Parliamentary involvement
- Implementing regulations (Regulation, Order, Decree, Rule) - Issued by the Government, based on existing legislation
- Guidelines - ‘non binding’

➢ *The choice of the regulatory structure can impact innovation*

Regulatory frameworks – Implementation

Implementation, e.g.:

- Procedures for notifications
- Risk assessment
- Public information/participation
- Monitoring and enforcement

➢ *The way in which regulations are implemented can impact innovation*

Regulatory frameworks – review and assessment

Standard practice in many countries and the EU:

- Review of the text of the regulatory framework
- Assessment of the implementation

Review of the text of regulatory frameworks

Review for conformity with key regulatory parameters:

- Clarity – e.g. vis a vis new developments, e.g. genome editing
- Transparency – e.g. decision criteria
- Consistency – e.g. internally, internationally
- Proportionality – e.g. regulatory requirements
- Workability and enforceability

Assessment of the implementation of regulations

- Efficacy – does the framework achieve its objectives?
- Efficiency – does it do so at the least possible costs?
- Unintended impacts – e.g. what are the impacts on the regulated community, such as impacts on public R&D and innovation?

Summary

- The choice of the objective, scope, regulatory tool and structure of biosafety regulations can impact innovation.
- The way in which biosafety regulations are implemented can impact on innovation.
- In reviewing and assessing regulations, the impact on innovation can be an important parameter.