

NATIONAL BIOSAFETY FRAMEWORK – SLOVENIAN 'CHOICE'

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What factors influenced the choice of National Biosafety Framework in the Slovenia?

Until 2002 when GMO Act was adopted Slovenia did not have any specific GMO (biosafety) regulation in place.

Slovenia was to join the EU in May 2004. The EU negotiating phase didn't leave much room for a choice. Slovenia and other pre-accession countries had to implement EU biosafety regulations. So there was not really a choice for Slovenia, since biosafety is one of the safety issues which is enforced by common principles across whole region. So for Slovenia was more a question of how to tailor the EU biosafety regulations so they would function well within the existing administrative system in Slovenia. Ideally one would think that country driven approach instead of EU driven process would be absolutely better, but there are two sides of the coin.

Good things about fitting the existing EU legislation to Slovenia are:

- minimum biosafety standard is defined for a whole region (EU), which makes the safety umbrella over whole region;
- core elements are already there (scope, methodologies,...);
- one can benefit directly from experiences of other countries, which already have their systems up and running (training, consultations; networks (EU GMO inspectors, EU GMO laboratories,...));
- development and implementation is quicker and higher prioritized, because of the EU pressure.

The drawbacks of just implementing the existing biosafety model to whichever country are:

- since each existing administrative system is different, fitting brings suboptimal administrative solutions;
- putting in place (copy/paste) regulation does not mean, that one has capacities to implement it (infrastructure, knowledge, resources);
- because of the pressure and because the 'rules of the game' are known from experiences of others, there is a great danger, that stakeholders are not consulted enough and no real consensus reached within country.

Current status of biosafety regulatory system in Slovenia

Slovenian legislation related to GMOs transposes and/or enforces EC legislation and the Cartagena Protocol on Biosafety.

The Management of Genetically Modified Organisms Act (GMO Act) adopted in July 2002 (OJ 67/2002) provides a horizontal type of legislation on the use of GMOs and their products, and intermediate other existing legislation in the areas of agriculture and health care. The Act regulates contained use of GMOs, the deliberate release of GMOs into the environment, and placing on the market, importing and exporting GMOs or products containing GMOs or consisting of them or their combinations. The Act includes provisions of the Directive 90/219/EEC and 98/81/EC, Directive 2002/18/EC and some provisions from Cartagena Protocol on Biosafety, which was ratified in Slovenia in 2002 (OJ 89/02). The GMO Act is not yet fully operational, since all secondary legislation is not in place yet.

Following secondary legislation is already in force:

- Ordinance on method of operation of the two scientific committees for the field of genetically modified organisms;
- Ordinance on criteria to classify each contained use of GMO into a specific class, containment and other safety measures;
- Regulation on the elements and the extent of the risk assessment for contained use and the methodology for its production

Following secondary regulation is in preparation, most of it already past public comments phase:

- Regulation specifying detailed contents of the notification of premise for contained use and notification of contained use.
- Regulation specifying detailed contents and the extent of the emergency plan in relation to the class of the work, the methodology of its preparation, examining and supplementing and the manner and extent of informing and warning competent bodies, services and the general population in the event of an accident.
- Regulation specifying the methodology, the elements, and extent of the assessment of risk of the deliberate release of the GMO into the environment.
- Regulation specifying detailed contents of the notification for deliberate release of GMOs into the environment.
- Regulation specifying the extent and content of the report on the results of the deliberate release of the GMO into the environment.
- Regulation specifying elements and the extent of the assessment of the risk of placing a product on the market and the methodology of its production.
- Regulation specifying contents of the notification for placing a product on the market and data which shall not be part of the notification shall be specified in a separate regulation in agreement with the minister responsible for agriculture, forestry and food.
- Regulation specifying the extent and elements of the assessment report shall be specified in a separate regulation.
- Regulation specifying contents and extent of the programme of monitoring and the manner and extent of reporting shall be specified in a separate regulation in agreement with the minister responsible for health and the minister responsible for agriculture, forestry and food.
- Regulation specifying the extent of data on the packaging or in the declaration of the product and requirements for packaging the product shall be specified in a separate regulation in agreement with the minister responsible for health and the minister responsible for agriculture, forestry and food.

Even thus all the secondary legislation is not in force yet, the country is already doing the risk assessment on notifications for market release of GMO for food or/and feed or/and cultivation that receives from EFSA since 1st of May.

It is also expected that Ministry for the Environment, Spatial Planning and Energy will process the notification for premises and work on contained use by the end of 2004.

All three competent ministries have carried out monitoring of presence of GMO on Slovenian market in 2003. The results were quite comparable to situation in EU and are available on the site of Ministry for the Environment, Spatial Planning and Energy.

The provisions of the Management of Genetically Modified Organisms Act that refer to placing products on the market and to the import and export of GMOs and products, are not applying to:

- Pharmaceuticals containing GMOs or consisting of them or their combinations for use in human and veterinary medicine, which are regulated with the Medicinal Products and Medical Devices Act (OJ 101/1999). The authority competent for medicinal products and medical devices for use in human medicine is the Agency for Medicinal Products and Medical Devices under the Ministry of Health.
- Foodstuffs for use in human food containing GMOs or consisting of them or their combinations, the placing on the market and import and export of which are regulated by the Health and Hygiene Safety of Foods, and of Materials and Articles Intended to Come into Contact with Foods Act which was amended in 2002 (OJ 42/2002), with articles about novel foods covering also GMOs. The authority competent for foodstuffs for use in human food is the Ministry of Health. But since food is crosscutting issue over several ministries, The Regulation on coordination of the Ministries and their bodies in the field of food safety and risk assessment was adopted in 2003. With new EU regulation and entering of Slovenia in EU the food safety is centralized under competence of EFSA.

The Ministry of Agriculture, Forestry and Food is enforcing laws ('Forest reproductive material Act', 'Agricultural seeds and propagating material Act', 'Protection of new varieties of plants Act' and the 'Act on feeding stuffs') with provisions on GMOs which demand compliance with the Management of Genetically Modified Organisms Act. The Ministry for Agriculture has also ratified International Plant Protection Convention (IPPC) and adopted all phytosanitary standards (ISPM) that are derived for the convention.

The Ministry of Economy is enforcing Regulation on legal protection of biotechnological invention (OJ 81/003) in order to harmonies protection of invention with EU directive 98/44/EC and to maintain and encourage investment in the field of biotechnology (genetic engineering, biological material, biological processes for the production of plants and animals, methods of cultivation, etc) in Slovenia.

For more detail information and full text of laws and regulations please visit Slovenian Biosafety Clearing House (www.bch.bf.uni-lj.si.) sub-pages: Laws and regulations and National legislation. Information is also available on Ministry for the Environment, Spatial Planning and Energy site (http://www.gov.si/mop/podrocja/uradzaokolje_biotehnologija.htm)