

Implementation Issues of Genetically Modified Organism's, the EU Policy and Development of Biosafety System in Latvia

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Abstract

The paper presents results of the studies dedicated to the issues related to: 1) implementation of the European Union (EU) policy in the sphere of genetically modified organisms (GMOs) in Latvia, and 2) development of national biosafety system in accordance with the EU, and international legislation and recommendations, where the aim of system is to ensure the safe circulation of GMOs based on scientific risk assessment. An effective biosafety system covers divergent areas such as agriculture, food, feed, environment as well as health and education, and comprises extremely demanding administrative procedures including risk assessment. Environmental biosafety presumes that we have the ability to identify risks associated with GMOs, and thereby design the appropriate measures to minimise or negate these risks. The paper describes the research results of acting Latvia's biosafety system with the analysis of the key elements: national policy, regulatory system or legislation and institutional system, inter alia research and scientific capacity. The main conclusion is that on the whole the system has been developed in accordance with the EU and international requirements, but still a lot of effort is required for the system improvement and increasing its capacity. Therefore the paper suggests possible ways to improve this system and to make it more efficient.

Key words: biosafety system, genetically modified organisms

Introduction

At present the information about genetically modified organisms (GMOs) more often appears in the public space of the European Union (EU), where in the regulatory enactments GMOs are defined as:

- organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination¹⁷;
- any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology¹⁸.

GMOs may be plants, animals or most commonly micro-organisms (including bacteria, viruses parasites and fungi).

The products arising from modern biotechnology provide new opportunities to achieve sustainable productivity gains in agriculture (McLean M.A. et al., 2002). Concerns over their possible environmental and health implications stimulated regulatory mechanisms for food safety and environmental risk assessment.

The concept of biosafety was developed and the establishment of a regulatory framework to ensure human and environmental safety has become essential to biotechnology development¹⁹. Environmental biosafety is environmental protection attained by the adoption and implementation of policies and procedures that assess, evaluate and mitigate the potential of GMOs to cause unacceptable ecological change. Environmental biosafety presumes that we have the ability to identify risks associated with GMOs, and thereby design the appropriate measures to minimise or negate these risks. World Conservation Unit³ (IUCN) stressed that there are two opposing views to this - one says, we have very limited experience, we never know the risks, and therefore let us reject GMOs, but the other says there are too many opportunities that it might work, let us proceed, put in the necessary precaution and learn/change as we go along.

Over the past two decades, national biosafety frameworks, guidelines, and regulatory systems have often been implemented on a "piece-by-piece" basis in response to the demands or urgent needs of the

¹⁷ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

¹⁸ Cartagena Protocol on Biosafety to the Convention on Biological Diversity

¹⁹ http://www.genecampaign.org/new_bio-policy-re/SaturninaHalos.pdf

moment. Ideally, a biosafety system would be developed from a comprehensive plan. However, building such a system and making it operational is complicated by the fact that there is neither single best approach nor standard that reflects national environmental, cultural, political, financial, and scientific heterogeneity.

The review of literature shows that two positions exist – 1) positive and advantages point of view for GMOs use, particularly of GM crops, and 2) negative standpoint, which stressed the threats of GMOs and GM crops through uncontrolled and unlimited introduction of them in the environment or market (Bakshi A., 2003; Brookes G., Barfoot P., 2006).

IUCN²⁰ recognized that therefore in society we can find different opinions about GMOs, because part of the society consider that GMOs is an instrument, how to increase the scale of food production without the need to convert more land to cultivation, but others think that GMOs may have a variety of impacts on people and animals, and especially on ecosystems and lands not under cultivation.

The European Commission²¹ (EC) notes that new technologies of genetic modifications open wide opportunities for improving traits of crops and animals and their nutritional value in the interests of consumers. The EC also emphasizes that the development of modern technologies is an important tool to encourage the economic growth and competitiveness as well as create new work places.

The modern biotechnology offers large opportunities to improve human's welfare. However, these opportunities may be provided only when biotechnology is developed and used considering appropriate safety measures in relation to the environment and human's health, as using of GMO is associated with certain risk²².

Therefore, the establishment of an effective national biosafety system is critical to ensure a high level of environment and human health protection, to increase public confidence in the control of biotechnology, and to set a clear legal framework for research organizations and industry. Moreover, in establishing national biosafety system, international agreements and standards should be considered.

The **aim** of this paper is to estimate the implementation issues of the EU GMO policy and development of national biosafety system in Latvia.

The following **objectives** for achieving the set aim were defined:

– to analyse acting legislation, institutional, administrative and financial capacity and compliance with the EU and international statements in Latvia;

– to work out the proposals for the improvement (normative, institutional, administrative, scientific and financial funding, surveillance, risk assessment and management etc.) of national biosafety system.

For studies various **materials** were used such as: normative basis of the EU and Latvia; scientific publications and reports, guidelines, methodologies and reports of international organizations and institutions; information from the MoA and MoE information obtained from consultations with governmental and non-governmental organizations.

For solving the defined tasks the adequate research **methods**: analysis, data grouping, reference, logical and abstract constructive, and expert methods etc., were used.

Results and discussion

1. Latvia's National biosafety system

The development and implementation of an effective national biosafety system is important for several key reasons: to ensure safe access to products of modern biotechnology; to build public confidence; to encourage the growth of domestic modern biotechnology, and to comply with international standards and agreements (McLean M.A. et al., 2002). There is no single best approach in the development and implementation of a national biosafety system and each country is faced with unique challenges.

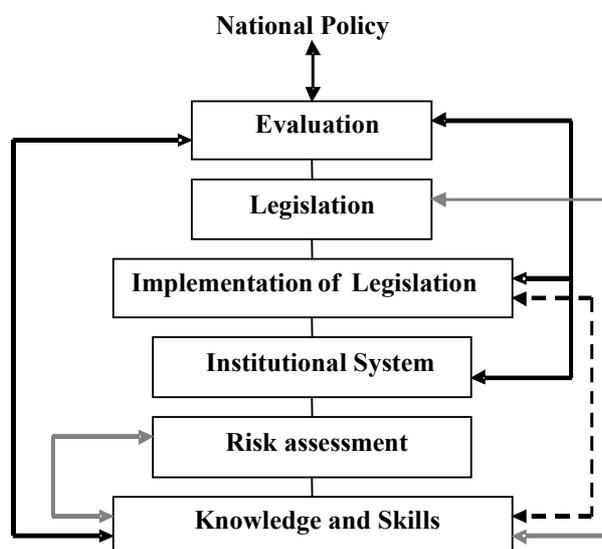
²⁰ Genetically Modified Organisms and Biosafety: http://www.iucn.org/bookstore/HTML-books/PGC1-genetically_modified_organisms/cover.html#fn1

²¹ The mid term review of the Strategy on Life Sciences and Biotechnology COM/2007/0175 final, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0175:FIN:EN:HTML>

²²) Genetically Modified Organisms and Biosafety: A background paper for decision-makers and others to assist in consideration of GMO issues. - http://www.iucn.org/bookstore/HTML-books/PGC1-genetically_modified_organisms/cover.html#fn1

Notwithstanding that Latvia is a small country and a new EU member state, the national biosafety system has been developed and implemented in accordance with the international and EC statement, where the key elements of system are: biosafety policy, legislation and institutional system.

The process of development, establishment and implementation of a national biosafety system is shown in a schematic way (Figure 1), where the system needs continuous improvements.



Source: author's modification from McLean M.A. et al., 2002

Figure 1. Scheme of biosafety system development and implementation

A national biosafety framework is a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the field of the safe transfer, handling and use of GMOs resulting from modern biotechnology (McLean M.A. et al., 2002; Milavec M. and Racman D.S., 2007; Nap J.P. et al., 2003) that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health²³.

Scientific risk assessment is the cornerstone of biosafety regulatory systems (McLean M.A. et al., 2002) and public-policy decisions related to the safety and acceptability of GMOs²⁴, int al. GM crops.

Human resource development is a very important aspect too for doing research and development work in the field of biotechnology as well as to launch public awareness programme for increasing knowledge in risk assessment and benefit of biotechnology.

1.1. Biosafety policy

McLean M.A. et al. (2002) thought that, ideally, the evolution of a national biosafety system begins with the elaboration of a national policy consistent with other policy objectives related to food, agriculture, the environment, and sustainable development and biosafety policy articulates a national approach to biosafety regulation, and the goals and objectives of the regulatory framework.

The development of a national biosafety policy in Latvia was initiated in 2000 by the Latvian Food centre. Latvia has not defined the issues, where the national biosafety policy would differ from the general EU biosafety policy, and in line with this EU policy Latvia is a party to the Convention on Biological Diversity, Cartagena Protocol on Biosafety and Aarhus Convention.

Presently the biosafety policy in Latvia is a part of wider policies in the field of the environmental protection, biodiversity conservation and food safety. State environmental policy is formed on the basis of the following internationally recognized principles of the environmental protection: the principle of

²³ National Biosafety Framework. http://www.doe-bd.org/bangladesh_nbf.pdf

²⁴ <http://www.biosafety-cee.org>

sustainable development, the “polluter pays” principle, the precautionary principle, and the assessment principle.

However analysing the current Latvia’s state position and decisions in the sphere of GMOs we came to the conclusion that not always basing on the scientific risk assessment, which, due to the lack of financing regulatory according to the European Food Safety Authority (EFSA) and other international organizations, was one of the main elements in developing effective national biosafety policy and was highly recommend to perform. McLean M.A. et al. (2002) indicate that in the process of development of national biosafety policy, it is necessary to clearly define national priorities that are based on scientific substantiations – risk analysis. Therefore the EU member states national biosafety policy, for instance Germany, Denmark, the United Kingdom, Spain, is based on detailed risk analysis, which consists of several main elements – risk management decision, risk assessment, and risk communication.

In general the analysis of situation showed that Latvia as a state with an open market economy and being a member of the EU favoured the development and safe use of modern biotechnology. However the existing national biosafety policy is incomplete, and therefore there is a need to improve its effectiveness by defining national priorities regarding the use of modern biotechnology products in agriculture and food/feed industry and establishing mechanism for scientifically based risk assessment and management.

1.2. Legislation

Latvia ratified the Convention on Biological Diversity (CBD) on 8 September 1995 in order to ensure conservation and sustainable use of the country’s rich biological diversity and accordingly, the Cartagena Protocol on Biosafety (CPB) on 22 January 2004 had been ratified. Smal M. et.al. (2006) considered that biosafety laws and regulations had been developed in response to the implementation of the CPB and stressed that biosafety regulatory processes were precautionary by definition.

After Latvia’s accession to the EU it adopted all the EU legislation, inter alia in the field of biosafety and GMOs. In the EU the GMs regulatory system is composed of several regulations, directives and amendments thereof, that are assembled in a time-consuming and highly complex interplay between the European Commission (EC), the European Parliament (EP), the relevant Council of Ministers and individual Member States.

Latvia’s legislation in the sphere of GMOs and biosafety consists of binding international treaties and relevant EU and national normative acts, like the experience of other EU member states (Milavec M., Racman D.S., 2007; Sanvido O. et al., 2006). The provisions of international treaties, EU directives and other EU legislative acts, which are not directly applicable, are implemented into the national legislation. The EU regulations are directly applicable in Latvia, and relevant national legislation may not regulate the same aspects of GMOs and biosafety issues.

The main legal acts in Latvia on biosafety; environmental protection and food safety are the following:

- Environmental Protection Law (adopted on November 29, 2006 with amendments of July 19, 2007);
- Plant Protection Law (adopted on December 17, 1996. with amendments of January 1, 2007);
- Law on the Supervision of the Handling of Food (adopted on February 19, 1998 with amendments of January 1, 2007);
- Cabinet Regulations No. 189 Labour Protection Requirements when Coming into Contact with Biological Substances” of May 21, 2002 “.

Currently the main legal acts, which directly regulate GMOs sphere in Latvia is:

- Law “On Circulation of Genetically Modified Organisms” (passed on December 5, 2007). The necessity of adoption a new version of Regulations which could replace the existing “Regulations Regarding the Contained Use and Deliberate Release into the Environment and Placing on the Market of Genetically Modified Organisms, as well as “Procedures for the Monitoring Thereof” by December 1, 2008 have been fixed by the above mentioned law;
- Cabinet Regulations No. 333 “Regulations Regarding the Contained Use and Deliberate Release into the Environment and Placing on the Market of Genetically Modified Organisms”, as well as “Procedures for the Monitoring Thereof” of April 20, 2004 (with amendments of January 10, 2006).

However, considering that the Regulations No. 333 were elaborated in relatively short term, there exist several shortages, for instance, there are no requirements ensuring co-existence of genetically modified crops, as well as there is lack of requirements for public information and its participation in the decision making process, which arises from Directive 2001/18/EC and Directive 90/219/EEC.

1.3. Institutional system

Many researchers (Matzk A., Bartasch D., 2006; Gathmann A., Bartsch D., 2006) recognized that an effective national biosafety system could be very complex, with the involvement of several competent authorities. Either in Latvia the institutional system that is responsible for biosafety, the implementation of GMOs policy and for handling notifications and requests for GMOs use and/or authorisation, which is based on the relevant EU regulations and the national legislation drafted on the basis of the EU directives, is quite complex.

The main institution responsible for legislation elaboration in the area of GMO is the **Ministry of Agriculture** (MoA). Considering that presently in Latvia there is no advisory institution that could coordinate the elaboration of national biosafety policy, the MoA in the process of elaboration legislative acts cooperates with the MoE, the Ministry of Welfare and Ministry of Health, as well as with different scientific and non-governmental organizations.

In accordance with the Regulations No. 333 competent institutions that are responsible for handling notifications and requests for authorisations are the following:

- **Food and Veterinary Service - FVS** (an institution subordinated to the MoA) is responsible for handling notifications and requests for authorisations with respect to the contained use of GMO, placing on the market GMO and derived products;
- **Nature Protection Board** (an institution subordinated to the MoE) is responsible for handling notifications and requests for authorisations with respect to deliberate release of GMO into the environment.

The Regulations No. 333 establish the following institutions that perform the functions of the state supervision and control of GMO use and distribution:

- Food and Veterinary Service;
- State Plant Protection Service;
- State Environmental Service;
- State Labour Inspectorate.

Main non-governmental organizations that are involved in the elaboration of legislation and decision-making are: Latvian Society of Geneticists and Selectionists; Environmental Advisory Committee; Cooperation Council of Agricultural Organizations.

The following research institutions in Latvia implement fundamental and applied researches in the field of GMOs and their risk assessment, in al. post-market monitoring issues, for instance, the evaluation of baseline indicators:

- University of Latvia, Institute of Microbiology and Biotechnology;
- University of Latvia, Faculty of Biology;
- University of Latvia, Institute of Biology;
- Latvia University of Agriculture, Institute of Soil and Plant Sciences;
- Latvian Biomedical Research and Study Centre;
- Latvian State Centre of Plant Protection.

In general the existing institutional system in Latvia is completely developed, but to ensure its effectiveness there is a need to build capacity of institutions responsible for handling notifications, as well as controlling and research institutions.

2. Recommended improvements of biosafety system

2.1. National biosafety policy and legislation

For ensuring effective biosafety policy several proposals have been made with the main proposals as follows:

- 1) allocation of funding from the state budget for GMO risk assessment and research, particularly for cost-benefit analysis of GM crop cultivation (until now there is lack of finances for these purposes);
- 2) establishment of GMO Monitoring Council;
- 3) development of risk assessment and management system.

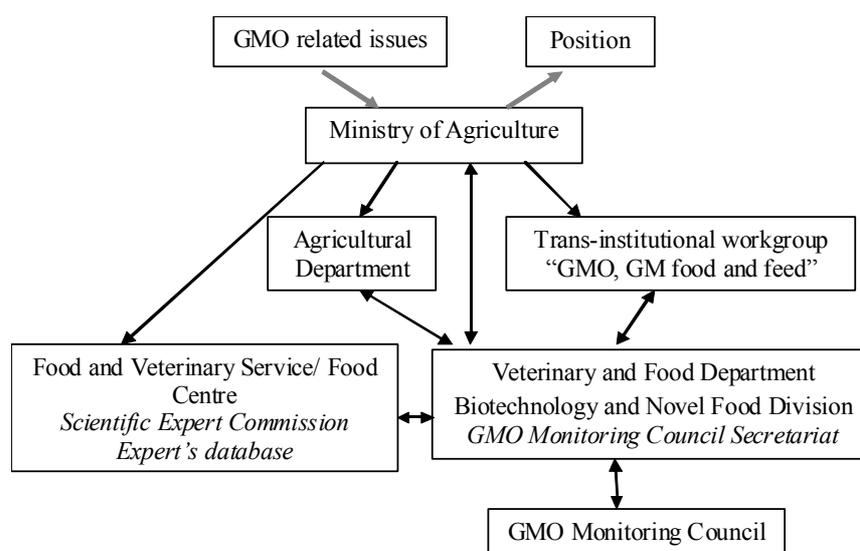
Within this system we suggest that the functions of coordinating institution shall be implemented by the FVS (Food Centre) performing the following tasks:

- to be the Secretariat of Scientific Expert Commission;
- to develop and keep experts and research database;

- to collect and analyse data with the purpose to monitor and assess GMO related risks that have direct or indirect impact on human, animal health and environment;
- to collaborate with scientific institutions and experts, give scientifically based opinion on products containing GMO;
- to promote and coordinate scientific research on indicators necessary for GMO risk assessment;
- to collaborate with other EU competent authorities in joint network.

For improving legal basis in GMO area and providing better collaboration between competent institutions, we suggest that the elaboration of normative acts should be concentrated in one central institution, like, Veterinary and Food Department (VFD) of the MoA.

Several governmental and non-governmental institutions are involved in GMOs strategy and policy development, but only the VFD is responsible for many GMOs related issues, we propose the following mechanism (Figure 2) for the preparation of Latvia's GMOs policy and position, where the VFD could play the central role.



Source: made by the authors

Figure 2. Mechanism for the preparation of Latvia's GMOs policy and position

In the process of elaboration laws and regulations, and preparation of the position VFD should consult with Food Centre, Scientific Expert Commission, GMO Monitoring Council, trans-institutional workgroup, Agricultural Department of the MoA and non-governmental institutions.

2.2. Recommended improvements for capacity building

The authors have worked out some suggestions, proposals and recommendations for building Latvia's institutional, scientific and technological capacity.

For capacity building of institutions which are responsible for handling notifications and requests for the authorization we propose the following future needs:

- to improve the knowledge of experts in the field of biosafety and risk assessment;
- to elaborate effective methodical skills, and to improve the knowledge quality at different levels of the authorization process;
- to review the financial resources allocated for expertise in the process of risk assessment;
- to work out technical guidance for applicants explaining the application procedure and authorisation process.
- While for the capacity building of supervision or control institutions, which perform control of GMOs in practice it could be advisable to perform the following measures:

- to work out guidance notes and manuals for inspectors, and implement informative and educational activities on GMO issues;
- to elaborate effective methodical skills, and to promote the knowledge quality at different levels of monitoring and controlling processes;
- to improve material resources for expertise in the process of control on GMO use;
- to develop infrastructure for GMO detection and also facilities for assessment/ evaluation.

The scientific and research potential or capacity of Latvia's research institutions is sufficient but for several reasons it is not used completely due to:

- the lack of public procurement, and therefore the financing;
- incomplete coordination between different research institutions.

For different kind of research, for example, research connected with co-existence of GM crops with conventional and organic agriculture, and post-market monitoring after introduction of GM crops, the comprehensive analysis of different factors is required, and for this the consortium of several research institutions could be developed, where the participation of experts that represent different scientific fields, e.g., biotechnology, molecular biology, agronomy, plant protection, plant physiology and pathology, entomology and microbiology etc. is needful.

Conclusions

The result of studies showed that the present Latvia's biosafety system with the following key elements: national policy, regulatory system or legislation and institutional system, inter alia research and scientific capacity, has been developed in accordance with the EU and international requirements, guidelines and recommendations, but still a lot of effort is required to improve its capacity and management.

To ensure effective implementation of national biosafety policy, it is necessary to strengthen institutional mechanisms for oversight and control use of GMOs, and to allocate the funding for development of scientific based risk assessment.

Latvia's legislation in the sphere of GMOs and biosafety consists of international treaties and relevant EU and national regulatory enactments, but it is necessary to make improvements in several regulations, particularly in the field of co-existence of GM crops with convention and organic agricultural practice.

Latvia's institutional system, which is responsible for biosafety system, the implementation of GMOs policy and for handling notifications and requests for GMOs use and/or authorisation is more or less developed, but for ensuring its effective operation and effectiveness it is necessary to build the capacity of institutions connected with risk assessment, and institutions that are responsible for handling notifications.

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