

The regulatory framework for biosafety of Croatia

Report of a review.

Introduction

A national biosafety framework is a combination of policy, legal, administrative and technical instruments that are set in place to address safety for the environment and human health in relation to modern biotechnology. These frameworks often focus on living modified organisms or, as they are usually referred to, genetically modified organisms (GMOs).

One of the main components of a national biosafety framework is a regulatory regime for biosafety, which often is a combination of enabling framework legislation, complemented with implementing technical regulations and guidelines.

In Croatia, activities with GMOs are currently explicitly addressed in the Nature Protection Act (Official Gazette No. 162/03), and the Food Act (Official Gazette No.117/03), which both came into force in 2003.

A draft for a Genetically Modified Organisms Act is currently being discussed by the Croatian Parliament. That draft Act contains largely the same content as the related chapter in the Nature Protection Act, with some changes such as the nomination of competent bodies.

This is the summary report of a review of the Nature Protection Act. The detailed review is presented as footnotes to the actual articles of the reviewed legislation and regulations.

This review is carried out by Piet van der Meer¹.

The review was sent to a number of experts from Governments, Academia, International Organisations, NGOs and the private sector with a request for their feedback.

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Introduction

Establishing an adequate level of biosafety is typically an ongoing, iterative process of developing a draft national biosafety framework, implementing the framework, and continuous evaluation and feedback.

Experience shows that in addition to continuous evaluation by the Government, a review by a broadly composed panel of 'outsiders', can be very useful. In order to properly appreciate the results of a panel review, two general considerations are important.

First, a review of a translated text of regulations sometimes reacts to the translation rather than to the actual legal text. It is advised that the comments of the panel members are checked against the original text.

Second, one should not forget that there are examples of seemingly 'perfect' regulatory regimes that do not function in practice, and that there are seemingly 'poor' regulatory regimes that function quite well in practice. With "biosafety systems that function well" in practice, I mean systems that come to informed decisions, based on sound science, within the legal time frames and in a transparent manner.

The overall framework

In Croatia, activities with GMOs are currently explicitly addressed in the Nature Protection Act², and the Food Act³, which both came into force in 2003.

The Nature Protection Act addresses GMOs in part II (Nature Protection) in section 6.3.

In addition to the provisions of this chapter, there are two implementing regulations: The Regulation on the minimum threshold for GMO's in products below which the products placed on the market shall not have to be labelled as products containing GMO's⁴, and

The Ordinance on the conditions to be fulfilled by a laboratory for testing, control and monitoring of GMO's and products containing GMO's.⁵

As in every country, certain other legislation may also be relevant for activities with GMOs.

The Croatian Government has listed some of that legislation on its website⁶, with a brief summary of each piece of legislation, which includes: The Water Management Act, The Regulation on Dangerous Substances in Water, The Ecological Production of Agricultural and Food Products Act, The Minor Offences Act, Consumer protection act, The Medicinal Products and Medical

² Official Gazette No. 162/03

³ Official Gazette No.117/03

⁴ Official Gazette No. 34/04

⁵ Official Gazette No. 98/04

⁶ http://en.gmo.hr/index.php/zakonska_regulativa/hrvatski_zakoni.

Devices Act, The Decision Promulgating the Science and Higher Education Act, The Amendments Act to the Transport of Dangerous Substances Act , The Waste Act , The Regulation on Conditions how to Handle Hazardous Waste , and The Seeds, Plant Material and Registration of Varieties of Agricultural Plants Act.

It is very commendable that the Croatian Government has listed this legislation on its website, as it provides transparency as well as service to applicants, who are often not aware of the types of legislation that may apply to their activities.

The overview of the legislation that may also apply to certain activities of GMOs also makes clear that there may be cases of duplication of regulation or perhaps even contradicting regulations. It is strongly advised that the Croatian Government reviews all these pieces of legislation and regulations, with a view to ensuring consistency and avoiding overlap or contradiction. Safety is not served with contradicting rules.

The Nature Protection Act,

The Nature Protection Act contains specific provisions on GMOs in the following parts:

- Part I – General Provisions, which includes definitions of genetic modification; GMOs; user of genetically modified organisms; modified living organism, contained use of modified living organisms, applicant for use, release and placing of genetically modified organisms on the market, transboundary movement of genetically modified organisms, genetically modified organism risk assessment, product of genetically modified organisms, transit of modified living organisms, placing genetically modified organisms and products on the market, modern biotechnology,
- Part II – on Nature Protection, which includes a chapter 6.3 on GMOs. (articles 92 to 141)
- Part XII on supervision, which contains in articles 250, 261 and 264 (items for inspection) provisions on GMOs,
- Part XIII on penalties, which contains in articles 272 and 273 provisions on GMOs,
- Part XIV on transitional and concluding provisions, which contains in articles 287, 288, 289 and 290 provisions on GMOs.

Detailed comments are presented as footnotes to the individual articles.

In addition, the following general points are made:

In case like this where GMOs are addressed in a broader act and 'spread out' over different chapters, it is advisable to include in a guidance document a list of the provisions that are relevant for GMOs, to avoid misunderstandings. In this particular case, possible misunderstandings will be taken away with the coming into force of the GMO Act, of which all articles will by definition be relevant to GMOs.

The regulatory system as laid down in section 6.3 (which forms the 'heart' of the regulatory regime on GMOs), is to a large extent in line with similar legislation and

regulations in many other countries, and offers a good basis for a transparent and workable system that is consistent with Croatia's (future) international obligations.

However, a number of aspects deserve closer attention to ensure that the resulting regulatory regime will indeed be transparent and workable.

1) The GMO related definitions in Part I divert in wording from related definitions in the Biosafety Protocol and the EU Directives on GMOs, and it is advisable to take a close look at those definitions and stick as close to those as possible.

2) In many articles reference is made that further (technical) details will be laid down in by-laws and rule books. Only two of those regulations are published on the Croatian web site to date. Since many of the others regulations and rule books are crucial for a proper functioning of the system, it is important that the other regulations be worked out in an integrated package.

3) A number of articles raise questions as to how this Act (and in particular the committee on Food and Feed) relates to the Food Act. Further clarification on the coordination is needed. The same applies to the bodies charged with enforcement.

4) A few articles are phrased in such a way that the resulting system would be very different from the 'standard' permit system as we find in most countries in the world with functioning biosafety systems.

Two examples:

Article 114, para 3: 'It is not permitted to release the reproductive plant material containing GMOs deliberately into the environment, except for areas of land that shall be determined by a by-law of the Government, on the proposal of the ministry responsible for agriculture and forestry and the minister responsible for environmental protection'. In its current formulation, article 114 would result in an unqualified 'ban' on GMOs. 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 Act and goes against the EU Directives. It is advised to revisit this article and to follow the approach of article 23 of the EU Directive on releases.

Article 140: 'The applicant or a legal or physical entity using GMOs shall dispose of and permanently and harmlessly destroy the wastes containing GMOs in the manner that ensures that the GMO is no longer capable of transmission or reproduction of genetic material and that its genetic material cannot be transferred to other organisms'. This probably refers to certain laboratory activities; in the case of placing crop plants on the markets this would never work in practice, nor is there – given that a risk assessment is carried out – reason to require this. This would in practice require every farmer to incinerate the rest material of the GM crops he has grown.