

Law Analysis by [Green Action - Zelena Akcija](#)

The Croatian Parliament has adopted several laws regulating GMOs. These new laws, which are in some aspects stricter than EU law, are highly important since they can set a precedent for making GMO laws in the Balkans and in other (non-EU) parts of Central and Eastern Europe, where the regulation of GMOs is currently very weak or completely lacking. The Croatian laws entered into force in spite of pressure by the US, which in 2001 threatened Croatia with WTO action if it went ahead with its restrictive policies on GMOs.

A new law on GMOs came into force during 2005, which has many positive points, such as banning the release of GMOs in protected areas and their buffer zones, in areas of organic farming and in areas that are of importance to ecotourism. This provides a legal tool for counties to effectively declare themselves GMO-free. The law provides no labelling threshold but this has been set at 0.9% for food and 0% for seeds by means of a separate government regulation. The weak points of the law are the poorly-defined public participation provisions and the fact that the labelling threshold is not included in the law but could be changed at the whim of the health Minister with no public or parliamentary discussion. To date, in Croatia no permits have been granted for the deliberate release of GMOs - either for field trials or commercial cultivation, and no food or feed products containing GMOs have been approved.

Competent National Authorities, Source: <http://bch.cbd.int/database/record.shtml?id=10528>

Under the GMO Act (Official Gazette No. 70/2005), the Ministry of Health and Social Welfare is responsible for placing GMO food on the market and GMO food and feed for animals. In addition, this Ministry is responsible for using GMOs and/or products containing and/or consisting of, or originating from GMOs in cosmetics, pharmacy and health services for people. The Ministry of Health and Social Welfare is a central and coordinating body for performing expert activities related to GMOs.

Other competent authorities that are responsible for contained use in the closed system, deliberate release into the environment, reproductive material in agriculture, forestry and veterinary medicine, medicine in veterinary medicine and substances for protection of plants have to obtain prior approval for any decision in regards to GMOs under their responsibility from the Ministry of Health and Social Welfare.

In the Food Act (Official Gazette No.46/2007) it is clearly stated that the Ministry for Health and Social Welfare and the State Inspector's Office are the ones responsible to enforce food law, monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

Pursuant to the Act on GMOs (Official Gazette No. 70/2005), competent national authority for contained use in closed system is the Ministry of Science, Education and Sports.

Pursuant to the Act on GMOs (Official Gazette No. 70/2005), the Ministry of Agriculture, Fisheries and Rural Development is responsible for reproductive material in agriculture, forestry and veterinary medicine, medicine in veterinary medicine and substances for protection of plants.

Article 86, para 7 of the Food Act (Official Gazette No. 46/2007), covers in details the organization of

official controls on food and feed. At the level of primary production and associated operations responsible is the Department of Agricultural Inspection at the Ministry of Agriculture, Fisheries and Rural Development. Within the Ministry, some official control activities are conducted by the Veterinary Inspection and some by the border Veterinary Inspection (e.g. at the levels of production and processing: on GM food of animal origin and GM feed; at the level of retail: on GM feed; at the import: on GM food of animal origin, on GM food containing ingredients of animal origin and on GM feed, regardless of its origin).

STATUS OF BIOSAFETY IN CROATIA

Up to now Croatia has not regulated, neither by law nor other regulation, the issues related to the import/export, marketing, use and production of genetically modified organisms and products (GMOs). Croatia has signed the Cartagena protocol on September 8, 2001 and Croatian National Parliament has ratified the Cartagena Protocol on May 24, 2002. The instrument of ratification was set down on 29 August 2002.

Although at present no regulation on GMO is effective, there has been a very intensive legislative activity in this field, under the cooperation of four Ministries (Ministry of Environmental Protection and Physical Planning-MEPPP, Ministry of Health-MH, Ministry of Agriculture and Forestry-MAF, and Ministry of Science and Technology-MST), and under active participation of non-governmental organizations and the wider public.

By agreement between the above indicated Ministries it was determined that Croatia would not govern this matter by a separate law, but that it would be integrated into other two laws instead: the Law on Nature Protection (MEPPP), which will cover the area of biological safety (provisions of the Cartagena Protocol - release of LMOs into the environment, impact on biological diversity, contained use), and the Food Law (MH and MAF), which will govern the field of food made of GMOs, the obligation to label such food, monitoring, etc

Republic of Croatia sees its future as a member of EU and is undergoing the process of accession. As a part of that process, Croatia has the obligation to adjust its legislative framework according to European standards and that applies also to all regulations regarding GMOs. Integration of provisions of relevant EU Council Directives and Council Regulations into national legislation is already under way.

Provisions of the Cartagena Protocol on biosafety together with provisions of relevant EU Directives have already been adequately integrated into the Draft Law on Nature Protection, which is undergoing legislative procedure and is soon expected to enter parliamentary discussion. It should be pointed out that the Protocol is not contrary to the right of its parties to adopt stricter measures for the conservation and sustainable use of biological diversity, provided that such activity is compatible with the Protocol's aim and provisions, and that it complies with other commitments of the respective party under international law.

Through public participation in passing the Law on Nature Protection, numerous comments and suggestions were collected and integrated into the new Draft, and they refer to a significant extent

also to the field of GMOs. In this way this law should govern issues related to the import, marketing, use and production of genetically modified organisms, biological safety measures, ways of innocuous clearance of waste from LMOs, as well as monitoring and inspection. Deliberate release of LMOs into the environment or marketing thereof is permitted only under conditions prescribed by Law, in a way by which hazard with regard to biological diversity is prevented or minimized, and taking into consideration human health hazards. Detailed procedures for obtaining import permits based on previous notification, the hazard assessment procedure, conditions of limited use for laboratories, etc. will be regulated by decrees.

Matters related to the enactment of above Law will be performed by the Ministry of Environmental Protection and Physical Planning within its regular activity, in cooperation with the three previously indicated competent Ministries.

One of the basic elements for the implementation of future regulations is also the establishment of a laboratory for GMO detection, which would be used in monitoring and inspection. The establishment of an adequate laboratory has already been initiated within the Public Health Institute of the Republic of Croatia, while the necessary funds were allocated in the central budget for 2001, within the relative positions of the Ministry of Health, the Public Health Institute, the Ministry of Environmental Protection and Physical Planning, and the Ministry of Agriculture and Forestry.

Republic of Croatia has started also with the UNEP GEF Project on Development of National Biosafety Framework. The Project has started in February 2003 and is still in the first phase. For that reason the information given in a capacity building submission form is just an estimate and does not necessarily reflect the real situation in the country. The exact information on the status of biosafety will be known after the process of national survey under the Project is finished. The results of the national surveys on the status of biosafety will be known at the end of this year.

National Actions regarding "Legislative and regulatory framework":

- Development of legal frameworks

National Actions regarding "Administrative framework":

- Institutional entities for handling biosafety issues

National Actions regarding "Technical, scientific and telecommunications infrastructures":

- LMO testing laboratories and equipment

National Actions regarding "Funding and resource management":

- Financial assistance (grants or loans)

National Actions regarding "Mechanisms for follow-up, monitoring and assessment":

- none

National Actions regarding "Scientific and technical expertise":

- Detection, testing and quantitative analysis of LMOs

National Actions regarding "Legal, social and economic expertise":

- Legal drafting and analysis

National Actions regarding "Risk assessment and other scientific and technical expertise":

- none

National Actions regarding "Risk management":

- none

National Actions regarding "Public awareness, education and participation":

- Biosafety awareness activities (seminars, radio talks, etc)
- Biosafety awareness materials and equipment

National Actions regarding "Information exchange and data management (including the Biosafety Clearing-House)":

- Data collection, management and storage

National Actions regarding "Scientific, technical and institutional collaboration":

- none

National Actions regarding "Technology transfer":

- none

National Actions regarding "Identification of LMOs":

- none