

Genetically modified organisms – European and Romanian legislation

Lecturer **Ovidiu – Horia MAICAN**¹

Abstract

The paper outlines the current European Union legislation regarding biotechnology and specifically the use of genetically modified micro-organisms. The first regulation was issued in 1990 and was updated during the last 20 years. The relevance of the regulation for the industrial and environmental activities is discussed, linking in the context of the other regulations applicable to the biotechnology research and business.

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JEL Classification: K32

1. Introduction

Genetic modification of micro-organisms, plants and animals existed since the 1970s.

Genetically modified crops grow on a 25 % of the land under cultivation worldwide and some genetically modified products are already on the market in the European Union.

Genetic modification raises public concern in terms of health and environmental protection.

United Nations conventions address these concerns. The World Trade Organisation (WTO) deals with trade in genetically modified products. The European Union (EU) is both party to the UN conventions (e.g. on biosafety) and a key actor in the WTO.

2. European Union

European Union has the most severe regulations in the world for the presence of GMOs in food².

That means the labeling of food and feed where the level of approved GMO exceeds 0.9% of unintentional adventitious presence. In the situation of non-

¹ Ovidiu – Horia Maican - Law Department, Bucharest University of Economic Studies, ovidiuszm@yahoo.com.

² John Davison, GM plants: Science, politics and EC regulations, Plant Science, Volume 178, Issue 2, 2010, p. 94.

approved GMOs the threshold is 'zero'. The cargoes containing GMOs non-approved GMOs are returned to the port of origin or are destroyed.

In the EU, GM-crops are subject of Regulation 258/97). This regulation is not specific for GMOs. It was modified by Regulation (EC) 1829/2003. GMO crops are evaluated by the independent European Food Safety Authority (EFSA) established under Regulation (EC) 178/2002.³

EFSA is enforcing the Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and Regulation (EC) 1829/2003 on genetically modified food and feed.

Based on the EFSA opinion, the EC drafts a proposal for granting or refusing the authorization, which it submits to the Section on GM Food and Feed of the Standing Committee on the Food Chain and Animal Health. If this Standing Committee accepts the proposal, it is finally adopted by the EC. Another option is to send on to the Council of Agricultural Ministers, which has a time limit of 3 months to reach a qualified majority for, or against, the proposal. Without such a decision, the proposal is passed back to the EC which then adopts the proposal.⁴

European Union has GM-food and feed labeling regulations that set-up a threshold of 0.9% for the presence of EU-authorized-GMO in a cargo, or food and feed samples (Regulations 1829/2003 and 1830/2003).

Above this threshold, all foods must be labeled.

Many EU retailers (with the exception of a few products in the Czech Republic, Estonia, the Netherlands, Spain), refuse to stock or sell GMO products. Because Europe does not cultivate significant quantities of GM-crops, the labeling threshold is significant for imported food and feed from the GMO producing countries (USA, Canada, Brazil and Argentina).⁵

Field coexistence regulations are formulated by national governments, according to the principle of subsidiarity, the European Commission issuing guidelines.

The USA has no regulations on coexistence for deregulated GMOs. Like other exporting countries such as Canada, Brazil and Argentina, it does have a system of "identity preservation" which is a system of private contracts to provide importing countries with guaranteed non-GM products

The EU-US dispute over regulatory framework concerning genetically modified organisms (GMOs) is a part of global international trade talks. The US is the most important producer of GM seeds worldwide.

The European Union regulated, since 1990, four main areas of biotechnology (contained use, environmental release, intellectual property protection and transboundary movements).

Having as source the Directive 2001/18, the Regulation no 1946/2003 of 15 July 2003 on transboundary movements of genetically modified organisms" is a transposition of the Cartagena Protocol on Biosafety, entered into force in 2003.

³ John Davison, *op. cit.* p. 95.

⁴ John Davison, *op. cit.* p. 95.

⁵ John Davison, *op. cit.* p. 95.

The Protocol is setting-up a framework, based on the precautionary principle, for the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, or pose risks to human health. The Protocol concentrates specifically on transboundary movements. the Regulation applies on any movement of GMOs from the Union to third countries and viceversa. ⁶

The scope of the Directive, written in the Article 1, is to lay down “common measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment“.

The Directive is inviting member states to ensure that all the appropriate measures are taken to avoid adverse effects on human health and the environment, by assessing the risks that those contained uses may pose. The assessment shall result in the final classification of uses in four classes, from no or negligible risk to activities of high risk.

The user shall apply the general principles and the appropriate containment and other protective measures, corresponding to the class of the contained use.

It is necessary a notification to the competent authorities before to begin to use for the first time. The notification should include detailed technical description of the site, with specific emphasis on measures of containment. ⁷

In Europe, before 1998, crops such the GM corn and soybean were considered as equivalent to conventional varieties. They did not need a separate GM label. (Fontana, 2009, p 4)

Invoking the Precautionary Principle, which allows measures to be adopted in case of uncertainty or insufficient information, the European Commission decided in 1998 to place a moratorium on the approval of any new GM crop that lasted until April of 2004.

In 2004, about 45% of the corn, 85% of soybean and 76% of cotton planted in US were GM varieties. In 2003, the US was producing 2/3 of the GM crops produced in the world.⁸

The US farmers have a strong interest in a permissive GMO regulation of production, in order to exploit the new technology and in a low degree of GMO consumer regulation either at home either in their export markets, given that they supply more than half of global exports. US producers will be less competitive if they have to comply with EU labelling and traceability rules.

EU farmers have strong interest in a high degree of GMOs regulation of production and distribution. The GMO technology is less profitable for them, since non-GM crops and nature areas are much closer than in US. ⁹

⁶ George Fontana, (2010) Genetically Modified Micro-Organisms: the EU regulatory framework and the new Directive 2009/41/EC on the contained use, AIDIC Biotech Working Group Program Paper, 2010, p. 3.

⁷ George Fontana, *op. cit.*, p. 4.

⁸ George Fontana, *op. cit.*, p. 4.

⁹ Santos, A., Caetano J., EU regulation concerning genetically modified products: an issue of food security or a measure of disguised protectionism? CEFAGE-UE Working Paper, CEFAGE-UE, Centro de Estudos e Formação Avançada em Gestão e Economia Universidade de Évora, 2008 p. 10.

The regulation 258/97/EC in May 1997 has as effect the harmonization of the national new foods laws in all the Member States and a uniform pre-market approval process. The procedure requires submission of an application for pre-market approval to a Member State and to the Commission. The data package is reviewed by the Member State and the Commission's Scientific Committee on Plants. This technical body provides expert opinion for the review process. After the submission is accepted, the competent authority of the Member State has 90 days to complete a safety assessment and make a recommendation to the Commission. The recommendation and submission is distributed to the other Member States for a 60 day comment period. If the recommendation is favorable and no objections are raised by the Member States, the product is approved for the commercial market. If additional assessment is requested or objections are made, however, the European Standing Committee for Foodstuffs takes up the review with technical advice from the Scientific Committee on Plants.¹⁰

Regulation (EC) No 1829/2003 and 1830/2003 (entered into force in April 2004) provides exceeded labelling and traceability requirements for GMOs with following key elements:¹¹

- traceability (mandates product traceability through documentation and implementation for the entire supply chain).
- labelling (products containing GMOs must be labelled as such, even when undetectable by tests. Products containing traces of GMOs below the appropriate regulatory tolerances thresholds are exempt from labelling, provided that compliant traceability systems are in place and traces of GMOs are technically unavoidable).
- thresholds (0.9% tolerance thresholds for EU authorized GMOs and 0.5% for unauthorized GMOs if they have already received a favourable EU risk assessment. Compliant traceability systems must be in place and must demonstrate that any traces of GMO are adventitious and are technically unavoidable).

The commercial use of GM plants is concentrated mainly on soybean, corn, cotton, and rapeseed. The genetic modification mainly refers to herbicide tolerance and insect tolerance. In 2005 the cropped area of GM soybeans amounted to 54.4 million hectares, 60% of the worldwide soy production. Main production countries of GM soybeans are the USA, Argentina, Brazil, Canada, Paraguay, Uruguay, Romania, South Africa and Mexico. GM corn was cultivated on 21.2 million hectares in 2005 (14% of the global corn production).

GM corn was cultivated in 12 countries included the five EU member countries Spain, Germany, France, Portugal and Czech Republic with a total area of 50,000 ha in 2005. In 2005 GM cotton was grown in the USA, China, Argentina,

¹⁰ Mitten, D., MacDonald, R., Klonus D., Regulation of foods derived from genetically engineered crops, *Current Opinion in Biotechnology* 1999, 10: p. 300.

¹¹ Hirzinger, T, Menrad K, Implementation of the EU legislation concerning genetically modified organisms in the german food and feed industry 10th ICABR International Conference on Agricultural Biotechnology: Facts, Analysis and Policies, Ravello (Italy), 2006, p. 4.

India, Australia, Mexico, South Africa and Columbia on 9.8 million hectares (28% of the worldwide cotton production).

3. New evolutions

In this context labelling regulations for GMFP (Genetically Modified Food Products) stresses out this consumer's rights in the Regulation 1829/2003, regarding labelling of genetically modified food. In my opinion, the final scope of this text is respecting these two types of consumer rights:¹²

The right to information has as aim is to guide consumers' decisions on which food to consume, i.e. whether they accept or reject food containing GMO.

Legislation has its own logic for precontractual stage regulations when one of the parties is legally defined as a consumer. The differential treatment is justified by evidence of the imbalance between the two parties, which leads to the need for specific solutions favouring the "weak" party only. EU legislation uses this process to redress the imbalance in transactions between company and consumer.¹³

The first Community legal provision in the field of GMOs was Directive 90/220/EC on the deliberate release into the environment of GMOs. Until 1997, all kind of GMOs and GM foods had to seek authorisation under this Directive. In 1997 the Community adopted a new legislation, Regulation 258/97/EC concerning novel foods and novel food ingredients. The regulatory system established by Directive 90/220 and Regulation 258/97 is recognizing scientific experts as the sole authorities in the safety assessments of GM foods. The regulatory mechanism, isolated from any public influence and dominated by scientific expertise, failed to address food safety or societal concerns raised by some of the Member States and the general public.

In 2001, Directive 2001/18/EC on the deliberate release into the environment of GMOs (hereinafter Directive 2001/18) was adopted, replacing Directive 90/220. It introduced the 'precautionary principle' as the guiding principle of the safety assessment of GMOs and created for the first time opportunities for public participation into decision-making process. Another change was in 2002 the establishment of the European Food Safety Authority (EFSA) as a responsible agency in risk assessment and communication on food safety issues.

In 2003 were adopted the Regulation 1829/2003 on genetically modified food and feed and Regulation 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs.

The reform process of the European GM foods regulation was initiated by the adoption of Directive 2001/18 on the deliberate release into the environment of GMOs. Directive 2001/18 has established a process-based approach to the safety assessment of GMOs. It replaced the contested 'principle of substantial

¹² Barral, I., Labelling of Genetically Modified Food Products in EU and protection of consumers' rights 13th International Conference on Consumer Law, London, UK, 2011, p. 5.

¹³ Barral, I., op. cit, p. 5.

equivalence' with the 'precautionary principle'. The precautionary principle defines a process of decision-making under conditions of uncertainty. It means that if a proposed activity carries with the possibility of harm to human health or environment, but that harm is not scientifically proven, then the activity may not be allowed. It is a 'better to be safe than sorry' policy approach to risk regulation, since it does not accept that an activity is safe just because science cannot prove conclusively that it is dangerous. ¹⁴(Kesim, Ayirtman, p 17)

Directive 2001/18 is introducing for the first time a *mechanism for public consultation* in the authorization procedure.

According to the Directive, '[comments made] by the public should be taken into consideration in the drafts of measures submitted to the Regulatory Committee'. Directive 2001/18 introduces provisions for public participation at both national and supranational levels. In the field of the national level, the Directive states that 'Member States shall... consult the public and, where appropriate, groups on the proposed deliberate release. In doing so, Member States shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion.'. ¹⁵(Kesim, Ayirtman, p 17)

The last important step the EU has taken in order to address the legitimacy crisis is the adoption of two new regulations, Regulation 1829/2003 on GM Food and Feed and Regulation 1831/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs ¹⁶ (Rigby, 2004, p 8).

Any company developing a GM food has the obligation to submit an application for authorisation to the competent national authority of a Member State. The application must include the results of studies showing that the product poses no threats to human and animal health, and is environmentally safe. Upon receipt of application, the national authority informs the EFSA and forwards all relevant documentation. The national authority are carrying out environmental risk assessment. This procedure requires a public consultation process. Within a six-month period, the EFSA submits a report to the Commission, based on the expert advice of the GMO Panel, which is an expert committee for evaluating the safety of all GM foods. The panel is made up of independent scientists from various disciplines and they do not receive any directives from the EFSA or the EU. The EFSA is sending the report to Member States and makes it accessible to the public. The public may make comments 30 days of the publication of the EFSA's opinion, comments submitted to the Commission.

¹⁴ Kesim, K., Ayirtman, S Merits and Limits of Deliberative Public Participation in Multi-Level Governance: The Case of Genetically Modified Foods Regulations in the European Union, IPSA Paper, 5103, 2008, p. 17.

¹⁵ Kesim, K., Ayirtman, S, op. cit, p. 17.

¹⁶ Rigby, D., GM Food, Risk, Regulation and the EU-US Trade Dispute, The University of Manchester, Discussion Paper Series, Number 0410, 2004, p. 8.

Within three months of receiving the EFSA's report, the Commission forwards its official recommendation for approval to the relevant comitology committee -*Standing Committee on the Food Chain and Animal Health* (the Committee)-, which is composed of the representatives of Member States. If the Committee is approving the Commission's recommendation by qualified majority, the GM product can then enter onto the EU market. If the Committee is rejecting, the Commission then prepares a new recommendation for approval. If the Committee does not reach qualified majority, the Commission passes its recommendation to the Council of Ministers which approves or rejects the authorisation of the GM food product.

In the current regulatory regime, there are three major problems (the problem of inadequate representation in the EFSA, the problem of limited democratic control towards EFSA's activities and the problem of effective public participation in the given institutional setting).

4. Romania

Romania has a relatively long history in the cultivation of genetically modified organisms (GMOs).

GM soybean

The first commercial crop of genetically modified (GM) were introduced in Romania in 1998. It is about 14 varieties of genetically modified soybean.

Official figures show that:

- In 2004 there were 5523 ha planted with soybean,
- In 2005, 87 600 ha were cultivated with GM soybean
- In 2006 137 275.5 ha were cultivated.

When Romania became EU member in 2007, it was officially banned GM soybean cultivation in Romania, according to European regulations (GM soybean was not authorized for cultivation in the EU, is considered the economically unfeasible).

However, the same year in April, was tacitly approved for cultivation in Romania a GM maize MON810 titled (belonging to Monsanto). It was the only GMO authorized in the EU, which Romania automatically authorized. In Romania there have been performed evaluating GM maize to see what are the effects on the environment.

Regarding genetically modified maize MON810, official figures show that:

- In 2007 it reported 332.5 ha planted with MON810 maize,
- In 2008 and last year, the surfaces have increased significantly up to 6 130.44 hectares,
- Whereas this year, 2009, it was reported seeding of land total area of 3093.5177 ha.

The implications it may have been placed in the environment were not addressed by the authorities nor the international agenda nor in the accession

process. Romania is a country where maize has become a tradition, holding a valuable genetic heritage of traditional corn varieties.

The approximately 3 million hectares planted with GM maize are exposed to contamination.

Romania asked the European Commission not prohibit the cultivation of GMOs on its territory, while 19 Member States have notified Brussels that wish.

The deadline by which Member States could choose to prohibit the cultivation of GMOs in their territory expired on October 3.

GMO cultivation is permitted in the EU, but Member States may choose to prohibit or restrict the cultivation of their full territory.

The European Commission has announced that by October 3, 19 Member States have announced that they want ban GMO cultivation.

The 19 member states are Austria, Belgium (Wallonia), Bulgaria, Croatia, Cyprus, Denmark, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Slovenia and the UK (in Scotland, Wales and Northern Ireland).

There are some advantages of introducing GMOs on the market:¹⁷

- Substituting chemical treatments or other measures to combat pests is affecting the cost price of the product ;
 - To obtain products free of residues and pesticides by: restricting the use of residual herbicides (such as atrazine), herbicides eliminate eco-toxic effects, the preservation of biological quality of soil and groundwater;
 - Reduce pollution and its amendment by the nature of the work required of pest control;
 - Improving the quality of agricultural products and production capacity of species of economic interest even in difficult conditions and high accuracy and saving time for breeding;
 - Diversification of products offered to consumers, and others.
- Among the disadvantages and potential risks that have reported we have found the following:¹⁸
- The lack, so far, of transgenic plants are not attacked by all pests;
 - High cost price of the seed of transgenic plants given that it can not be amortized by perpetuating their generations, because the producing company does not guarantee qualitative parameters more than the first generation;
 - Necessity imposed by the firms producing seed, to apply a special technology, which refers to the preservation of areas under untransformed plants and susceptible to pests;
 - The danger of drug resistant toxins produced by transgenic plants by transferring certain genes from pathogens;

¹⁷ Monica Merca *Poluarea genetică : Implicații juridice, economice și sociale*, rezumat teză de doctorat (2012) p. 3.

¹⁸ Monica Merca, op. cit. (2012) p. 4.

- The risk that in some cases modified plants for resistance to a pathogen /pest fail to meet production and qualitative parameters similar to plants grown, unprocessed;
- Legislative barriers that allow or do not use genetically modified plants in farming practices;
- Antibiotic resistance.

GEO no. 195/2005 on environmental protection has transposed the definition of GMO given by Directive. 18/2001 / EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, as "any organism, except humans, the genetic material has been altered in a way that does not occur naturally by mating and / or recombination "and the concept of" modern biotechnology ", which consists of applying in vitro techniques of recombinant nucleic acid and techniques of cell fusion, other than the specific selection and improvement of traditional application that remove natural physiological barriers of reproduction or genetic recombination.

In Romania we have GEO no. 44/2007 on the contained use of genetically modified organisms, approved by Law no. 3/2008; GEO no. 43/2007 on the deliberate release into the environment of genetically modified organisms; GD. 256/2006 on feed and genetically modified food; Law no. 59/2003 ratifying the Cartagena Protocol on Biosafety to the Convention on Biological Diversity adopted in Montreal on 29 January 2000 and a series of related regulations, such as those on plants and seeds and on the coexistence of transgenic traditional cultures.

At the level of national legislation, it would be useful to include the Emergency Ordinance no. 43/2007 of specific obligations detailed in both local growers and local authorities, central respectively. It rules on the obligation to draw up plans 'coexistence', which should be finalized before the cultivation of GMOs. The local authorities or central, should establish detailed technical rules on drawing up plans for coexistence, they will be drawn to those who intend to cultivate genetically modified organisms

5. Conclusion

The legal framework for the regulation of genetically modified organisms on international level is now clear in general, including a general consensus on the main aspects of food safety assessment for human and animal health. Implementation of labeling regulations will be key to the resolution of the product regulation differences between Romania and the EU.

Worldwide harmonization of GMO approval procedures is necessary.

The challenges of the current regulatory framework of the EU are divided in two distinct categories (those resulting from the controversial nature of the GM food issue and those associated with the multi-level decision-making structure of the EU).

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