Scientific Papers Series Management, Economic Engineering in Agriculture and Rural Development
Vol. 19, Issue 1, 2019
PRINT ISSN 2284-7995, E-ISSN 2285-3952

TECHNICAL, ECONOMIC AND LEGAL ASPECTS REGARDING GENETICALLY MODIFIED ORGANISMS

Romeo Cătălin CREȚU[1], Petrică ȘTEFAN[1], Ioan Iulian ALECU[1], Cătălin Constantin VOINEA-MIC[2]

[1]University of Agronomic Sciences and Veterinary Medicine of Bucharest, 59 Marasti Blvd, District 1, Bucharest, Romania, Emails: creturomeocatalin@yahoo.com, stefanmarian2004@yahoo.com, iulia_alecu_2000@yahoo.com
[2]Lawyer House Bucharest

Corresponding author: stefanmarian2004@yahoo.com

Abstract

Genetically modified organisms have represented and represent, besides an obvious gain in scientific research, a great challenge for human communities to make the wisest decisions in achieving a fair balance between "gains" and "diversity" generated by GMOs, related to direct, indirect, immediate and delayed impacts developed on the short, medium and long term on human health and the environment. This article aims to analyse the procedure for the placing on the market of genetically modified food (feed and food) and to what extent a Member State can, in relation to European legislation, refuse / postpone the cultivation of certain genetically modified varieties on the basis of analysis impact on the environment, crops, or even has the possibility to prohibit the cultivation of these varieties.

Key words**:** *evaluation registry, feed, food, genetically modified organism, label*

INTRODUCTION

Since the beginning of the European Community, Member States have placed a particular emphasis on people's health, an aspect indissolubly linked to their nutrition. In the European legislator's view, nutrition is intrinsically linked to the choice of food, which, coupled with effective state-of-the-art protection, can be made aware in the sense that the citizen has to be able to get enough information about food which he consumes so that the "choice" is made aware of the cause. Starting from the labelling of the final product in the opposite direction, it is easy to see that the citizen must be properly informed about the legal certifications obtained by the product, the production method, the production area, the methods used, and last but not least "The Origins" of the product chosen for consumption [7].

Globally, about 30% of the crops were seeded with genetically modified maize, equivalent to 55.2 million hectares. Among the major transgenic maize producing countries are the United States, Brazil and Argentina.

Starting from the basic principles underpinning the creation of the European Community, principles which have as their foundation the guarantee of a high level of protection of human health, Member States have created a legal and administrative mechanism for managing the way in which products are placed on the market genetically modified "to guarantee on the one hand the rights and interests of European citizens by making censored administrative and jurisdictional decisions at European level and on the other hand to leave to the discretionary appreciation of the Member States the opportunity to introduce these types of products in relation to the obvious needs of the communities to maintain local biodiversity and specific ecosystems created over time" [5].

Thus, in order to protect as far as possible the natural products specific to the national ecosystems, the desire for the permanent care to protect the traditional producers and, last but not least, the consumers, the Member States have developed (especially in the circumstances of recent scientific results that do not give always gaining the cause of

GMOs) assessment systems, research and procedures designed to outline the "precautionary principle" regarding the approval of the placing on the market of these types of genetically modified products.
In addition to the endorsement procedure, Member States also monitor the impact of the cultivation of these modified varieties, monitoring which targets both crops exclusively set up with genetically modified varieties and the incidence of cases of their "accidental" coexistence with varieties originating in the same category, coexistence can lead to slippages both in terms of the protection of natural varieties and in environmental protection areas [7].
On the other hand, it should be mentioned that the precautionary principle cannot be applied abusively. In this respect, it is a good "protectionist" policy of the Member States to protect the rights of citizens operating in the area of "controlled products, which is often doubled by administrative/legislative measures to "block" the market introduction of genetically modified varieties, under different pretexts, beyond the spirit and the letter of European legislation which prevails in view of the accession treaties assumed by each state".

MATERIALS AND METHODS

According to "Article 2 of the Treaty on the Functioning of the European Union (TFEU), the national States of the European Community" have the possibility to adopt normative acts aimed at prohibiting or restricting the cultivation of genetically modified organisms on national territory, even if they have been authorized be placed on the European market. Obviously, acts of "ban" are subject to European jurisdiction (CJEU). In any case, any judicial evaluation of the "refusal should be based on the findings of the European Food Safety Authority, specifically from the conclusions of the assessment report drawn up on the occasion of the GMO marketing authorization, as set out below". Practice has shown that almost always the refusal refers to the need for Community states to maintain and develop national "historical" agricultural practices based on a type of production developed in habitats and ecosystems specific to a particular geographical area certain specificities [8].
On the other hand, it must be pointed out that producers, operators of genetically modified products have rights conferred by European legislation, rights that have to be protected under the same European treaties and that is why the subject of placing these types of products on the market is a certain type of the "compromise" between the new need, the idea of progress, the idea of economy and the primordial need "to guarantee the health of the environment and ecosystems created in time so necessary for the protection and welfare of the citizens and, last but not least, of their social and economic interests".

RESULTS AND DISCUSSIONS

In a legal definition inserted in the provisions of "Law no. 247/2009 for the approval of Government Emergency Ordinance no. 43/2007 on the deliberate introduction into the environment and the placing on the market of *genetically modified organism"* that means any living organism, "with the exception of human beings, whose genetic material has been changed in a way different from the natural one, other than by crossing and/or natural recombination".
It is equally true that effective protection should primarily target the common addressees of these products, beneficiaries who should firstly, in the name of transparency, to ensure their right to accurate information about the products to be purchased. Thus, informing citizens should primarily target their food education. Education is in close and indissoluble connection with the establishment of mandatory rules for labeling GM products. "In this respect, European legislation stipulates that GMOs must be accompanied by complex labels, labels that, besides nutritional values, must necessarily include the provenance of the purchased variety being widely known that genetically modified varieties are more or less by a certain category of consumers and always origin" is reflected

in the final price of the product, it is lower than the original, unmodified genetic product. That is why the "clear" labels are meant to determine an "informed" so be it or eliminated the possibility of misleading the final recipients of the products, consumers who have the right to know exactly the methods of production and production.

It is worth mentioning in this respect the provisions of Regulation (EC) no. 1830/2003 of the European Parliament and of the Council of 22 September 2003 on the traceability and labeling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms, which sets out the terms and conditions intended to ensure that all stages the placing on the market of genetically modified organisms and foodstuffs obtained from them have been fully respected. This label must contain all the essential information and should correct the genetic modification procedures, issues mandatory under European legislative act [10].

This article aims to analyze the procedure for the placing on the market of genetically modified products (foods and feeds) and to what extent a Member State may, according to European legislation, refuse/postpone the cultivation of certain genetically modified varieties on the basis of analysis impact on the environment, crops or even have the possibility to ban the cultivation of these varieties. Approximately 14 million farmers in North America, South America, Asia, Europe, Africa and Australia cultivate transgenic plants. The world leader in the field is the USA. Over two-thirds of the food produced today in the US contains at least one ingredient derived from a genetically modified plant. The list of transgenic plant growers today includes 25 countries.

Table 1. Top 5 GMO cultivation countries

	Country	**Surface (Million ha)**
1	USA	701
2	Brazil	403
3	Argentine	24.4
4	India	11
5	Canada	10.8

Source: MADR 2016.

Globally, there are two attitudes about the use of new culture systems based on transgenic plants: increase in the number of species of transgenic plants and extending their assigned areas and limit or ban their cultivation.

USA, Brazil, Argentina, India, China, Canada, South Africa, Paraguay cultivate transgenic plants on millions or even tens of millions of hectares, the three countries (USA, Brazil, Argentina) are major world exporters of soy and corn.

The most popular GMO is soybean, with 79% of the total global area being biotech crops, while 70% of all cotton surfaces are sown with GMOs every year. The ranking is followed by maize and rape.

In the European Union: Spain planting transgenic corn since 1998.

France and Germany have temporarily suspended the cultivation of transgenic corn hybrids due to political reasons. Austria, Hungary, Greece and Luxembourg reject from the beginning the application system culture transgenic plants, also for political reasons, the European Commission and promotes the coexistence of three culture systems: conventional, organic and transgenic plants. In our country, the situation presented by the Ministry of Agriculture is analyzed in Table 2. EU Member States that adopt a reluctant attitude towards modern biotechnology products or reject them altogether avoid the fact that there is already a history of cultivation and consumption without any unexpected events. These events can not occur because the commercial introduction of transgenic plants is authorized only after rigorous risk assessment for the environment and the health of humans and animals that may be associated with this action. It is for the first time in the history of agriculture when the grower of a brewed plant has to provide scientific evidence that his product is safe for the environment and for consumption. Decisions on the use or prohibition of transgenic plants are, ultimately, political. Generally, the use of new technologies has increased crop yields by 5 to 50%. Farm incomes using new technologies increased between 1996 and 1818, with nearly $ 34 billion. The use of transgenic plants in

agriculture has also had a positive impact on the environment. Globally, between 1996 and 2016, the use of transgenic plants led to a reduction in pesticide consumption of 286 million kg, equivalent to the total amount of pesticide active ingredients used over a year on arable land in the European Union [1].

Table 2. Areas cultivated with genetically modified maize MON 810 in 2012 in Romania

Genetically modified organism				Information about the authorization holder at Community level		Information on cultivator economic operator	The geographical location of the cultivation area		Size of the area authorized for cultivation (ha)	Distance from conventional/ ecological crops (m)	Information from the commercial cultivation authorization issued by MADR through DAJ
Species	The transf event	URC, (acc. to CR(EC) 65/2004	Characteristic	Name of the legal entity	No of EC Decision	Name of the legal entity	Village	County			
Corn	MON 810 Bt	MON-00810-6	resist. to lepidinsects	Monsanto Europe SA	Dec. 98294/ CE	IICotea Ioan	Turnu	Arad	5933	min.200	authorization no. 2100/06042012
Corn	MON 810 Bt	MON-00810-6	resist. to lepidinsects	Monsanto Europe SA	Dec. 98294/ CE	SA Infratirea Turnu	Turnu	Arad	52	min.200	according to the authorization no.210 I06.042012
Corn	MON 810 Bt	MON-00810-6	resist. to lepidinsects	Monsanto Europe SA	Dec. 98294/ CE	sc AGROMILC SRL	Insuratei	Braila	10	min.200	according to the authorization no. 125 0420 12
Corn	MON 810 Bt	MON-00810-6	resist. to lepidinsects	Monsanto Europe SA	Dec. 98294/ CE	sc HOLSTMILK SRL	Insuratei	Baila	10	min.200	according to the authorization no.2/26.0420 12
Corn	MON 810 Bt	MON-00810-6	resist. to lepidinsects	Monsanto Europe SA	Dec. 98294/ CE	S.C. Lanul Aurit SRL	Vadeni	Braila	40	min.200	according to the authorization no.3/2604 20 12
Corn	MON 810 Bt	MON-00810-6	resist. to lepidinsects	Monsanto Europe SA	Dec. 98294/ CE	II Mosescu V. Dobre	Viziru	Braila	13	min.200	according to the authorization no. A/26.0420 12
Corn	MON 810 Bt	MON-00810-6	resist. to lepidinsects	Monsanto Europe SA	Dec. 98294/ CE	SC LIXAND COM SRL	Insuratei	Baila	15	min.200	according to the authorization no.710 0520 12
Corn	MON 810 Bt	MON-00810-6	resist. to lepidinsects	Monsanto Europe SA	Dec. 98294/ CE	BYBLANAGR OSRL	Viziru	Braila	15	min.200	according to the authorization no. 915 05.2012
Corn	MON 810 Bt	MON-00810-6	resist. to lepidinsects	Monsanto Europe SA	Dec. 98294/ CE	SC Petrosu SRL	T. Vladimiescu	Braila	00672	min.200	according to the authorization no. 502.05.2012
Corn	MON 810 Bt	MON-00810-6	resist. to lepidinsects	Monsanto Europe SA	Dec. 98294/ CE	SCDA Simnic	Simnic	Dolj	15	min.200	according to the authorization no. 164/23 04 2012
Corn	MON 810 Bt	MON-00810-6	resist. to lepidinsects	Monsanto Europe SA	Dec. 98294/ CE	Agro-king SRL	Carpinis	Timis	00336	min.200	according to the authorization no. 1243/17 05 2012
Corn	MON 810 Bt	MON-00810-6	resist. to lepidinsects	Monsanto Europe SA	Dec. 98294/ CE	The Belciugatele pedagogical resort	Moara Domneasca	Ilfov	1	min.200	according to the authorization no. 1/1804.2012

Source: MADR, 2013.

The impact of the cultivation of these plants on the environment, assessed by means of an indicator that integrates the different effects of using a particular pesticide in a single "field value per hectare", which allows comparison of the different products between them, decreased by 15.4%.

As a result of the cultivation of glyphosate-tolerant varieties, in the period 1996-2016, the consumption of herbicides in soybean culture was reduced globally by 4.4% (the equivalent of 62 million kg) and the environmental impact assessed by the indicator mentioned above, decreased by 20.4%. In countries where farmers cultivated resistant maize of pests' attacks (Bt technology), there was a decline in total insecticide consumption by 5% (equivalent to 8.3 million kg) and a reduction in the impact of applied insecticides on the environment by 5.3%. In BT cotton crops, total insecticide consumption decreased by 22.9% (equivalent to 128.4 million kg) and the impact of applied insecticides decreased by 24.6%.

Standard procedure for the authorization of a genetically modified variety.

To be placed on the market, the operator variety GMO or product containing a combination of genetically modified varieties must submit a notification to the competent authority of the Member State after verification is required to provide "the European Commission and the competent authorities in this field in Member States (through the Commission, in within 30 days of receipt)" the summary of the file based on the notification. Among the essential requirements that the notification dossier has to contain are the following: environmental risk assessment, market conditions,

environmental and human health information, a monitoring plan, a proposal for labeling *expressis verbis the* fact that the product is genetically modified.

Following the notification procedure, within 90 days, the competent authority of the national state shall draw up an assessment report to draw conclusions about the genetically modified products to be placed on the market and the conditions under which such introduction will be made. In the event of a negative response, the report will contain the conclusions that make the notification unacceptable, bearing in mind that, given the importance of the findings, it will be sent to the European Commission within maximum 105 days of receipt of the notification, which in turn will notify the Member States for 15 days. The report, once communicated, may be the subject of additional information requests, of the reasoned "objections concerning the placing on the market of genetically modified varieties [2]. Within 105 days of the release of the report, the national competent authority and the Commission may negotiate". If the competent national authority establishes that the genetically modified product may be authorized to enter the market and in the absence of reasoned objections from the European Commission or the Member States, the competent authority shall issue the written marketing authorization. It is valid for 10 years.

As shown above, there are situations where national states may refuse to market GMOs for various reasons.

A first refusal hypothesis has been outlined above and does not involve discussions other than those aimed at censoring the report of the competent authority of the Member State where the introduction of the genetically modified variety is requested. "The second hypothesis concerns the exceptional rule provided by the provisions of art. 20 of Regulation no. 1829/2003 on genetically modified food and feed, normative act published in the Official Journal of the European Union no. 268 of 18 October 2003"[4].

The legal text indicated is to regulate the legal "status of genetically modified organisms authorized prior to the entry into force of European Regulation no. No 1829/2003 provided that the holder of the products containing, consisting of, or produced from genetically modified organisms has been notified to the European Commission within six months after the entry into force of the new Regulation on the date of introduction of those products into the market from the European Community Framework "[4].

Products legally introduced into the European Community, other than those authorized under "the Directive no. 90/220 / EEC, Directive no. 2001/18 / EC, Directive no. 82/471 / EEC, Directive no. 70/524 / EEC, the operators of the products were obliged within 6 months from the date of application of the Regulation to notify the European Commission of the situation in which the products in question were placed on the market before the application of the act which is the common law in the matter of authorization of these products" [6].

Case Study

The legal report deduced from the case was the outcome of a request made by the Consiglio di Stato (Italy), respectively application of the reference for a preliminary ruling under Article 267 TFEU in litigation worn Pioneer Hi Bred contradictory society by Ministero delle Italia SRL Agricultural and Forestry Policy's Food Forest (Italy).

The dispute has started following the preparation of the note by the Ministry of Agricultural Policies, Food and Forestry (Italy) through which the operator of GMOs on the Agricola market in Italy, Pioneer Hi Bred Italia SRL, was informed that "the adoption by the regions of the appropriate rules to ensure the coexistence of genetically modified crops with conventional and organic agriculture, the ministry could not analyze the company's request to authorize the cultivation of genetically modified maize hybrids already registered in the Common Catalog of Varieties of Agricultural Plants" [9] .

According to art. 16 par. (1) lit. a) and lit. c) of Directive 2002/53/EC a Member State may be authorized upon application to prohibit on its territory or part of its territory using a variety or provide appropriate conditions for

cultivation based on certain specific of that State if it is shown that the cultivation of this variety could cause plant pest damage to the cultivation of other varieties or species or where there are good reasons other than those already mentioned or which could be evoked during the admission procedure in the national catalog of varieties in order to consider that the variety presents a risk to human health or the environment.

It is noted that although European legislation, by virtue of the precautionary principle, has established a complex authorization regime that allows all member states to make objections, consultations, proposals, even negotiations, during the pre-authorization period of the genetically modified variety, there may be situations in which, although no substantiated objections have been made during the assessment period, the placing on the market of the GMO would generate major risks incompatible with the fundamental principles that protect the life and health of citizens, environmental protection.

By virtue of their powers, in well-defined cases, in situations "where it is evident that food or feed originating in the Community or imported from another country could be a major risk to human health, animal health or the environment the European Commission may decide to suspend the placing on the market or use of food or feed or to lay down special conditions regarding the movement of such products" [7].

The same right is also granted to national States which, where the European Commission does not take urgent action to address the issue of the incidence of major-risk cases with regard to products already on the market, has the right to adopt intermediate protection measures.

Making use of this right, the Italian competent authority informed the company concerned that, in relation to its request to cultivate the MON 810 maize varieties already included in the European common catalog, it could not proceed with its application for authorization of the cultivation of genetically modified maize hybrids "until the adoption by the regions of the appropriate rules to ensure the coexistence of genetically modified crops with conventional and organic farming, according to the MAFFP Circular [Ministry of Agricultural, Food and Forestry Policies] of 31 March 2006" [5].

Under Italian national legislation, "the cultivation of seed products is subject to authorization by act of the Minister for Agricultural and Forestry Policies, in agreement with the Minister of the Environment and the Minister of Health, adopted following the opinion of the Genetically Modified Commodities Commission, laying down measures ensure that crops resulting from seed products of genetically modified varieties do not come into contact with crops resulting from traditional seed products and do not cause biological damage to the environment, taking into account agro-ecological, environmental and pedo-climatic features.

In essence, the Italian competent authority stated that it could not proceed with the examination of the application for authorization of the cultivation of genetically modified maize hybrids already included in the Common Catalogue "pending the adoption by the regions of the appropriate rules to ensure the coexistence of genetically modified crops with conventional agriculture and according to the MAFFP Circular [Ministry of Agricultural, Food and Forestry Policies] of 31 March 2006".

It should be noted that the company has requested the renewal of the marketing authorization for MON 810 maize varieties pursuant to Article 20 (4) of Regulation 1829/2003, the exception rule from the authorization regime provided for in the normative act.

"Solutions of the Court of Justice of the European Communities":

"Article 26a of Directive 2001/18 does not permit a Member State to generally oppose the cultivation of such GMOs within its territory until coexistence measures are taken to avoid the accidental presence of GMOs in other crops".

"Cultivation of GMOs such as MON 810 maize varieties may not be subject to a national authorization procedure where the

use and marketing of these varieties are authorized under Article 20 of The Law"[9].

CONCLUSIONS

Genetically modified organisms can only be placed on the market through specific procedures, procedures governed by the precautionary principle, duplicated by effective consultation mechanisms with the competent authorities of the "Member States and the European Commission". Given the importance and the major impact on the implementation of the economic and social realities, monitoring of GMOs must be done on a permanent basis, with Member States and the European Commission having at their disposal effective mechanisms to counteract any adverse effects that may develop over time, interim measures and reaching measures to prohibit the placing on the market of genetically modified products.

REFERENCES

[1]Ecogen, 2016, Soil ecological and economic evaluation of genetically modified crops, www.ecogen.dk, Accessed on Jan 5, 2019.
[2]Entransfood, 2017, European Network for the Safety of Genetically Modified Food Plants. www.entransfood.com, Accessed on Jan 5, 2019.
[3]Marcuta, A., Simionescu, A., Tindeche, C., Marcuta, L., 2018, Relationship between sustainable development and public health. Case study Romania, Scientific Papers. Series "Management, Economic Engineering in Agriculture and Rural Development", Vol. 18(3): 251-260.
[4]Pharma-Planta, 2017, Recombinant Pharmaceuticals from Plants for H: "alth www.pharma-planta.org, Accessed on Jan 5, 2019.
[5]Popescu, A., Dinu, T.A., Stoian, E., 2018, Sorghum - An important cereal in the world, in the European Union and Romania, Scientific Papers. Series "Management, Economic Engineering in Agriculture and Rural Development", Vol. 18(4):271-284.
[6] Research into the impact of Bt maize (Cry 3Bb1) on non-target organisms living in the soil (2005-2008), 2018, Biological Research Centre for Agriculture and Forestry (BBA) (since 2008 Julius Kuhn Institute (JKI)), Institute for Plant Protection in Field Crops and Grassland; Braunschweig SIGMEA Sustainable introduction of GMOs into European Agriculture: sigmea.dyndns.org, Accessed on Jan 5, 2019.
[7]Soare, E, Chiurciu, I, 2018, Considerations concerning the worldwide production and marketing of sunflower seeds, Scientific Papers. Series "Management, Economic Engineering in Agriculture and Rural Development", Vol. 18(3): 421-428.
[8]The Breakdown of Bt toxins and effects on micro-organisms in soil (2005-2008) - Federal Agricultural Research Center (FAL) (since 2008 Johann Heinrich von Thunen Institute (vTI)), Institute of Agroecology; Braunschweig.
[9]The Court of Justice, Pioneer Hi Bred Italy, Case (Chamber) in Case C-36/11 of 14 January 2011, published at eur-lex.europa.eu as of 06 September 2012.
[10]The Romanian Academy, 2018, Position of the academic environment regarding genetically modified plants.