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GENETICALLY MODIFIED ORGANISMS AND PRODUCTS IN EUROPEAN LEGAL CONTEXT

GENETSKI MODIFICIRANI ORGANIZMI I PROIZVODI U EUROPSKOM ZAKONSKOM KONTEKSTU

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SUMMARY

The article is focused on basic issues of the EU legislation in the area of GMOs and GM products. The treatment of genetically modified organisms and products has been regulated in the European Union since beginning of 90's. The so called *precautionary principle* is the basic principle of EU legislation in this field. Therefore, the primary goal of legislation is to protect the environment and health. Contemporary EU legislation consists of three main groups dealing with harmonisation of authorisation procedure, labelling and traceability of GMOs and GM products and implementation of Cartagena Protocol in relation to transboundary movements of GMOs. The strict EU legal framework for GMOs has caused problems within international trade, particularly with USA, Canada and Argentina.

Key words: Genetically modified organisms; genetically modified food and feed; legal regulation; precautionary principle; international trade.

Genetically modified organisms and products represent, since the time of their origination, or more precisely since their application in political, social, scientific economic and legal area unflagging dilemma. On the one hand, there is public interest in protection of environment and human health, on the other hand there are science, corporations and their interest in profit, the necessity to solve the food shortage in third world countries and somewhere in the middle there are people who decide whose interest will preponderate and how this area will be or will not be legally regulated Genetic modification, in other words "genetic engineering" or "recombinant-DNA technology" was first applied in the seventieth of the last century. Until then, the development of this area went in two different directions also reflecting into both legal regulations and social relationships, mainly those at international trade level, where there is a conflict of interests between the European Union on the one side and the USA together with Canada and Argentina on the other side.

The purpose of this contribution is the presentation of contemporary EU legal regulation of the treatment of genetically modified organisms and products within the background of its historical development and its impacts on international relationships.

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Historical background

The first attempts in the European Union to legally regulate this area go back to 1990s. Since that time there have been great changes in this area within the EU which have been among others reflected in the legal regulations. It is necessary to say that legal development in this area is very important for understanding contemporary EU legislation. In harly 90s there came into force two basic horizontal directives which should have ensured environment and human protection within expansion of biotechnologies. Directive 90/219/EEC covered the contained use of genetically modified micro-organisms and Directive 90/220/EEC covered the deliberate release into the environment of GMOs. There were problems with the first above mentioned directive. Within the report of review of Directive 90/220/EEC[2] the Commission announced the problem points in implementation of this Directive:

- Insufficient clarification concerning the objectives for risk assessment which has hindered full harmonisation between Member States at the research and development stages and which has led to disagreements between Member States at the stage of products placing on the market;

- Absence of a risk classification as well as of a link between administrative procedures and identified risk, which may result in cumbersome procedures for low risk releases

cumbersome administrative procedures and approval system for placing products on the market, of which have led to delays in approving products;

- Absence of a possibility to resolve controversy through consultation of independent Scientific Committee(s);

- Current labelling requirements.

Nevertheless, the mentioned defects, doubts of the Member States as well as Commission itself about the efficiency of existing legal system and assertion of precautionary principle in these situations led to factual moratorium[3] on new authorizations of GMOs which has remained to the enactment of contemporary legal regulation.

Precautionary principle

The so called precautionary principle is the basic principle of acquis communitaire in field of GMOs. The basic message of the Precautionary Principle is that on some occasions, measures against a possible hazard should be taken even if the available evidence is not enough to conclude the existence of the hazard as a scientific fact. The lack of full scientific evidence is a prerequisite for applying the principle, if scientific evidence is certain then the measure would be of prevention rather than precaution[4]. In other words it is necessary to prevent the damage before it happened and in case that it cannot be scientifically proven that the substance or activity is not safe enough it is forbidden to release it into the environment. Therefore, the primary goal of legislation is to protect the environment and health. The goal is being supported by another one - to ensure the free movement of safe and healthy GMO products in the European Union. The principle is being very strictly and unmercifully enforced by the European Union and there are no exceptions even for the Member States. Contrary to this principle, there is another principle called sound science which is advocated by the USA, WTO, Japan, etc. Pursuant to this principle the decisions are made on the basis of what can be quantified, without considering what is unknown or cannot be measured[5].

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[2] Report on the Review of Directive 90/220/EEC in the context of the Commissions Communication on Biotechnology and the White Paper COM (96) 630 Final

[3] The moratorium was officially notified by six EU Member States (Austria Denmark, Greece, France, Italy and Luxembourg) in 1999 and 2000. See Draft minutes of the 2194th Council meeting (Environment) available on http://register.consilium.europa.eu/ /pdf/en/99/st09/st09433.en99.pdf

[4] Connelly, J and Smith, G, 2003, 2nd Edition. *Politics and the Environment - from theory to practice.* Routledge, London and New York p.288.

[5] Tickner J, Raffensperger C.: The Precautionary Principle in Action –Handbook, Science and Environmental Health Network

Contemporary legislation

It can be said that the EC legislation practically regulates all aspects of GMO and GM products whether used for scientific purposes, in food chain or agriculture. Contemporary European legislation consists of three main groups dealing with harmonisation of authorisation procedure, labelling and traceability of GMOs and GM products and implementation of Cartage Protocol in relation to transboundary movements of GMOs.

GMO and the environment

The first law is presented by 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 Council Directive 90/220/EEC, as amended, establishing Community authorisation procedure for the placing on the market of GMOs, as or in products, within the EU based on risk assessment and consent of competent authority. There are three main objects expressed in this Directive:

- to protect human health and the environment from the deliberate release of GMOs,
- to approximate the legislation of the Member States on the deliberate release of GMOs,
- to ensure the safe development of industrial products utilizing GMOs.

Next to precautionary principle the step by step principle[6] is being applied and also ethical aspects may be taken into consideration for the introduction of GMOs into the environment. GMOs which have been released or placed on the market are the object of monitoring because of potential adverse effects on human health or the environment. Among other things, this Directive also stipulates mandatory post-marketing monitoring system of GMOs and relating traceability as well as the obligation to inform properly the consumer. There were also introduced unified procedures requiring a case-by-case evaluation of the risks to human health and the environment. One of the most important articles of this Directive is Article 23 setting up so called *safeguard clause* which means that Member States may, for justifiable reasons, provisionally restrict or even ban the usage or sale of GMO food and feed within its territory.

GM food and feed

The second Community legislation group includes the GM food and feed issues. Regulation (EC) No 1829/2003 on genetically modified food and feed, as amended, lays down specific authorisation procedure for all food and feed containing GMOs[7]. This Regulation sets up three basic objectives:

- Protection of human as well as animal health by establishing the system of safety assessment before GM food and feedstuff are placed on the market.
- Establishing harmonised, efficient, transparent and time limited procedures on risk assessment as well as authorisation of GM food and feedstuff.
- Insurance of clear labelling[8] of GM food and feedstuff both for farmers as well as consumers.

Moreover, the principle "*one door - one key*" is applied so that the obtained authorisation for GMO under this Regulation can be used both for food and feed and also for cultivation. Risk assessment carried out in accordance with the requirements referred to in Directive 2001/18/EC and risk management are divided

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[6] See recital 24 of Directive 2001/18/EC

[7] There is also a special implementing Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

[8] This shall not be applied to foods and feedstuff containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

between European Food Safety Authority and European Commission in the order given. As such, it is possible to submit a single application for acquiring both the authorisation for the deliberate release of a GMO into the environment, under the criteria laid down in Directive 2001/18/EC and the authorisation for use of this GMO in food and/or feed under the criteria laid down in Regulation 1829/2003. According to this Regulation it is possible to gain permission[9] for placing the specified GM food and feed on market within the European Union, so it is not necessary to ask for approval in each Member State. The applications are submitted to the competent authority of the Member State where the product is first to be marketed. The application must clearly define the scope of the application, indicate which parts are confidential and must include few items, among others monitoring plan, a labelling proposal or detection method for the new GM food or feed. This authorisation, valid within the European Community, is granted subject to a single risk assessment process covering both the environmental risk and human and animal health safety assessment under the responsibility of the European Food Safety Authority[10] and a single risk management process involving the Commission and the Member States through a regulatory committee procedure.

This Regulation also establishes a dual system for the placing of novel foods and novel food ingredients on the EC market, either using the application to acquire an authorization or using the notification by the interested party. The Regulation sets up the obligation to establish and maintain a Community Register of genetically modified food and feed by the Commission

This regulation also governs special procedures for those GMO products which had been lawfully placed on the market in the Community before the date of application of this Regulation[11].

The Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and the amending Directive 2001/18/EC, afford the homogeneous legal frame both for labelling as well as for traceability at all stages of their placing on the market and thereby facilitate monitoring and also the implementation of control measures. Unlike the general character of two previously mentioned EU rules this Regulation has more character of *implementing instrument*[12] by which the objectives of above mentioned rules can be fulfilled.

Transboundary movements of GMOs

The last important Community legal act in this field, Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms, reacts to international law requirements related to movements of GMOs among countries and insurance of restraint of potential adverse effect of these movements. The main purpose of this Regulation is to implement the provisions of the Cartagena Protocol13 on preventing biotechnological risks which was signed by Member States and European Community in 2000. According to this Regulation, all Member States are obliged to take the necessary and appropriate legal, administrative and other measures to implement its obligations under the Cartagena Protocol. There are procedures requisite for the transboundary movement of GMO food and feed covering among others notification on import and export of GMO intended for deliberate release into the environment, providing information to the Information System for Biological Safety and identification and accompanying standards.

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[9] In case of probability that the final product will be used both as foodstuff and feedstuff, it shall be approved to both purposes, Regulation 1829/2003.

[10] According the Article European Food Safety Authority publishes an opinion, which is available to the public and the public has the possibility to make comments.

[11] See Article 8 and subsequent.

[12] See more Christoforou T.: The regulation of genetically modified organism in the European Union: the interplay of science, law and politics *GoMmmOons Market Law Review* 41: 637–709, *Kluwer Law International.*, 2004.

[13] See http://www.cbd.int/

International Trade Relationships

The dispute between the EU and the USA, Argentina and Canada (hereinafter complainants) within World Trade Organisation (WTO) has been the result of five years moratorium on the marketing of new GMOs. According to complainant a suspension of approvals of GMOs and GM food in the EU was contrary to WTO Agreements, which was finally confirmed in WTO Panel Report[14]. This Report stated that:

- The general moratorium led to undue delay in the completion of the EC approval procedure conducted in respect of at least one biotech product at issue and thereby to the European Communities acting inconsistently with Annex C(1)(a) and, by implication, Art. 8 of the SPS Agreement[15];

- In 24 of the 27 product-specific approval procedures it examined, the procedure had not been completed without undue delay. In respect of these procedures, the European Community had, therefore, acted inconsistently with Annex C(1)(a) and, by implication, Art. 8 of the SPS Agreement;

- Ninth EU Member State[16] safeguard measure was not based on a risk assessment as required by Article 5.1 of the SPS Agreement, and it was not consistent with the requirements of Article 5.7 of the SPS Agreement. Therefore, the European Community has acted inconsistently with its obligations under Article 5.1. and the second and third requirements in Article 2.2 of the SPS Agreement.

The Panel report was not appealed and was adopted by the WTO Dispute Settlement Body in November 2006. The European Community accepted recommendations, arising from the Report, to bring the relevant EC and Member State measures to conform with its obligations under the SPS Agreement within 12-month "reasonable period of time" for implementation which was agreed with complainants. Both Canada and Argentina gradually prolonged the period 31 March 2010 and 31 July 2009, and after many mutual discussions with both states there was reached mutually agreed solution based on the establishment of a regular dialogue (exchange of information) on issues of mutual interest on biotechnology applied to agriculture and related trade issues of mutual interest that would contribute to avoiding unnecessary obstacles to trade.[17]

The dispute with the USA is still running, the questions about (dis) proportion of EU legal regulation in the area of authorization and labelling of GMOs and GM products are still present[18], even though, according to European Commission[19], the EU's regulatory system for authorizing GMOs is in line with WTO rules and functional : it is clear, transparent and non-discriminatory.

CONCLUSION

Despite the above mentioned comprehensive legal regulation based on *precautionary principle* and aiming to ensure a high level of protection of the environment, human and animal health, the attitude of individual EU Member States as well as European public towards GMO is rather reserved to negative. Since

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[14] See One-page summary of key findings of disputes DS291, DS292 and DS293 available on http://www.wto.org/english/tratop_e/ /dispu_e/cases_e/1pagesum_e/ds291sum_e.pdf or Report Panel - Part 8 available on http://trade.ec.europa.eu/doclib/docs/2006/ /october/tradoc_130757.pdf

[15] The WTO Agreement on the Application of Sanitary and Phytosanitary Measures. For full text see http://www.wto.org/ /english/tratop_E/sps_e/spsagr_e.htm

[16] Namely Austria, Greece, France, Germany, Italy and Luxemburg.

[17] See http://trade.ec.europa.eu/doclib/press/index.cfm?id=536

[18] WTO Panel Report does not say e.g. whether biotech products in general are safe or not, whether the European Community has a right to require the pre-marketing approval of biotech products or whether the European Communities' approval procedures which provide for a product-by-product assessment requiring scientific consideration of various potential risks, are consistent with the European Communities' obligations under the WTO agreements.

[19] See http://ec.europa.eu/environment/biotechnology/pdf/memo_28_02_06.pdf.

2004. about 30 GMOs have been authorized. However, the recent events prove (e.g. cultivation ban on GM maize in Austria and Hungary[20]) that the suspicion of GMOs still remains.

The issues, which will be solved in early future and which will influence the further development of EU legislation in this controversial area, have arisen from the conclusions of bloc's environment ministers (Environment Council) stated at the end of 1998[21]. Among others, they are long-term environmental risk assessment and monitoring of GMOs, socio-economic implications of placing GMOs on the market and the problems of delimiting of GMO-free zones and asserting of national safeguard measures.

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SAŽETAK

Članak je usmjeren na osnovna pitanja zakonodavstva EU u području genetski modificiranih organizama (GMO) i genetski modificiranih (GM) proizvoda. Tretiranje GMO i GM proizvoda regulirano je u Europskoj uniji od početka 90-ih godina. Tzv. "princip opreza" je osnovni princip zakonodavstva na tom području. Stoga je prvenstveni cilj zakonodavstva zaštita okoliša i zdravlja. Suvremeno zakonodavstvo EU sastoji se od tri glavne skupine koje se bave usklađivanjem postupaka odobrenja, označavanjem i porijeklom GMO i GM proizvoda te provođenjem Protokola iz Kartage u vezi s prekograničnim kretanjima GMO-a. Strogi zakonski okviri Europske unije za GMO-e stvorili su probleme u međunarodnoj trgovini osobito s SAD-om, Kanadom i Argentinom.

Ključne riječi: genetski modificirani organizmi, genetski modificirana hrana i krmiva, zakonski propisi, princip opreza, međunarodna trgovina

[20] There still exists so-called 'safeguard clause' in Directive 2001/18/EC which provisionally allows restrict or prohibit the use and/or sale of the GM product on territory of the Member State if there is a justifiable reason s with respect to risk to human health or the environment.

[21] See http://register.consilium.europa.eu/pdf/en/08/st16/st16882.en08.pdf