Problems of Transboundary Movements of Genetically Modified Organisms

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PROBLEMS OF TRANSBOUNDARY MOVEMENTS OF GENETICALLY MODIFIED ORGANISMS

ABSTRACT

Genetically modified organisms make an important part of today's world. The ecosystem and its self-regulation have been damaged, i.e. the relationship between input and output elements does not occur on a spontaneous, natural level. In addition, people have realized the importance of eating habits and the quality and safety of the same is being discussed in various areas (legal, economic, political). After regulating national provisions in the area of food safety, it is necessary to define a supra-national framework in order for people to be protected to the fullest extent possible. Therefore, the subject matter of this paper is to study transboundary movement of genetically modified organisms and the analysis of relations between the Member States in the European Union. In the entire process of transboundary movement of genetically modified organisms, it is necessary to harmonize the needs of the exporting country and the importing country. It is imperative to coordinate surveillance of genetically modified organisms with an aim of preserving biodiversity and human health. Regarding legal documents, it is necessary to outline the following documents that regulate this matter: Regulation (EC) No.1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms, the Cartagena Protocol, 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 the repeal of Council Directive 90/220/ EEC. The methods used in this paper are the following: method of analysis and synthesis, historical and comparative method.

Key words: *genetically modified organisms, European Union, transboundary movements*

1. Introduction

The purpose of this paper is to critically examine the process of transboundary movement of genetically modified organisms. Prior to that, the basic thesis describes the procedure for approving genetically modified organisms. The bodies appearing in the procedure and the deadlines significant for the approval procedure have been clarified. All possible types of transboundary movements are processed in the master documents. Thematic links were made between international and European documents that regulate the subject matter in almost identical terms. The final chapter outlined the recommendations and conclusions. In the introduction it is necessary to emphasize that the paper was derived from the doctoral thesis: The Regulatory System of Genetically Modified Organisms in the European Union.

2. Approval procedure for genetically modified organisms

The twentieth century in the development of genetics represents a significant shift. The approach to life completely changed because humans began to exploit their knowledge and technology and have created new phenomena that did not exist in the natural environment. The consequence of rapid development is genetic engineering, which is one of the basic characteristics of the speed of development. The speed of development of phenomena that does not exist in a natural environment. For the purpose of protecting human life and the natural environment, a series of legal acts regulating the procedure for approving genetically modified organisms (hereinafter referred to as GMOs) were adopted. The legal documents governing the procedure for approving genetically modified organisms in the European Union are: Regulation (EC) No. (EC) No. 1829/2003 of the European Parliament and of the Council of September 22nd 2003 on genetically modified food and feed (hereinafter referred to as "Regulation 1829/2003") and Regulation (EC) 1830/2003 of the European Parliament and of the Council of September 22nd 2003 concerning traceability and labelling of genetically modified organisms and traceability of food and feed produced from genetically modified organisms and amending the Guideline 2001/18 (hereinafter referred to as "Regulation 1830/2003"). The first Regulation prescribes the procedure for the approval of GM food and feed by the European Commission, and after the completion of a risk assessment by the European Food Safety Authority (hereinafter referred to as EFSA). In addition, GM food and feed labelling rules and the presence of GM food in situations where it is technically impossible to avoid such presence have been elaborated. The second mentioned Regulation, 1830/2003, prescribes traceability and labelling. The subject of Regulation 1829/2003 is: GMOs used as food and feed material; products used as food and / feed that contain, consist of or are produced from GMOs; food and feed produced from GMOs. Prior to the release of GM food and feed into the market, it is necessary to carry out a good risk assessment to counteract any negative impact on human and animal health and the environment. The procedure is initiated by filing with the competent authority in the Member State, with the competent authority having to acknowledge receipt of the application within 14 days and notify the EFSA without delay. Thereafter, the EFSA informs the European Commission and other Member States and makes a summary of the documentation available to the public. Within 6 months of receipt of a valid request, the EFSA shall deliver its opinion. Upon receipt of the opinion of the EFSA within 3 months, the Commission shall submit to the Standing Committee on Food Chain and Animal Health (SCFCAH) a decision. The approval obtained for the above-mentioned procedure is valid for 10 years.

3. Common provisions

The purpose of acts at the international, i.e. European, level in the field of genetically modified organisms (hereinafter referred to as GMO) is to protect the environment and consumers. Depending on the particular area, the national interest, the social environment one or other option may outweigh. At the international level, the Convention on Biological Diversity[1] was adopted advocating the use of the precautionary principle in situations of significant reduction or loss of biodiversity, i.e. the lack of scientific security will not be the cause of non-

[1] Decision on the promulgation of the Confirmation of the Convention on Biological Diversity Act, International Agreements 6/96. The Convention is an international document published by the United Nations. It has three goals: to preserve biodiversity and its sustainable use and to ensure a fair distribution of benefits derived from genetic resources. It was open for signing on June 5, 1992 in Rio de Janeiro on Earth Summit, and came into force on December 29 1993.

implementation of measures to avoid or reduce the risk. In addition, the Cartagena Protocol in Article 1 refers to the precautionary principle, i.e. the purpose is to ensure an adequate level of protection in the area of safe movement, transfer and use of modified organisms, which may have a negative effect on the conservation and sustainable use of biodiversity and which may have serious risks to human health (Cartagena Protocol, Article 1). Particular emphasis has been put on the transboundary movement of GMOs.[2] The same principle is pervaded by further articles, and it is stipulated that in the case of lack of scientific safety due to the lack of relevant scientific information on the impact of living modified organisms on the conservation and sustainable use of biodiversity and the potential impact on human health, it is necessary to take the necessary measures to prevent possible negative effects (Cartagena Protocol, Article 11, paragraph 8). The actions that are implied by the Cartagena Protocol are development, handling, transportation, use, transfer and release of living modified organisms.

Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 is the parent document in the case of transboundary movement of genetically modified organisms (hereinafter referred to as: Regulation (EC) No.1946/2003). When it comes to the transboundary movement of GMOs, it is necessary to harmonize the needs of exporting countries and importing countries. In the European Union (hereinafter referred to as the EU) in the case of imports, it is necessary to meet the requirements in force in the EU and the exported food must meet the standards of the importing country. To this end, it is necessary to make communication at European level and to include both Member States and potential candidates in order to create a uniform framework for action.

The common elements in the transboundary movement of GMOs, irrespective of the type of genetic modification used, require the exporter to include the following information along with a document accompanying the GMO:

1. that the product contains or consists of GMOs,
2. unique identifying marks, if any[3]

In the case of **GMOs intended for direct use as food, feed or for processing**, in addition to the information provided so far, they must also be accompanied by an exporter's statement:

1. indicating that GMOs are intended for direct use as food, feed or for processing and clear indication they are not intended for deliberate release into the environment,
2. lists of contact for further information

When the subject is a **GMO intended for restricted use**, in addition to the information provided so far, an exporter's statement with the following content shall also be supplied:

1. all requirements relating to safe handling, storage, transport and use
2. contact for further information and, in doing so, the name and address of the individual or institution to whom the GMO is dispatched or who dispatch of the GMO

[2] Transboundary movement is defined as the movement of a living modified organism from one party to another party and extends to the movement of a living modified organism from a party to a non-party.
[3] Not applicable to products consisting of or containing GMO which will only be used directly as food, feed or for processing. The same are subject to Directive 2001/1 /EC or future legislation that would regulate traceability, marking or identification.

GMOs intended for deliberate release into the environment and all others to which Regulation 1946/2003 applies shall, in addition to the information specified at the beginning of this chapter, be accompanied by an exporter's declaration with the following content:

1. identity and the relevant characteristics and characteristics of GMOs,
2. all requirements regarding the safe handling, storage, transport and use of the same,
3. contact for further information and the name and address of the importer and the exporter,
4. statement that the transfer is in accordance with the requirements of the Cartagena Protocol applicable to the exporter[4]

In the case of transit, the exporter must provide a notification of transit of GMOs to the parties that have made a decision to regulate the same through their territory and must also notify the Biosafety Clearing House (hereinafter referred to as the BCH) regarding the decision.

4. Exports of genetically modified organisms to third countries

In the case of **deliberate introduction of GMOs into the environment**, prior to the first intentional transboundary movement of GMOs, the exporter must send a written notice to the competent authority of an import party or a non-party[5] regarding deliberate release to the environment. The notice must also contain the minimum information from Annex I to Regulation 1946/2003 and the exporter is responsible for the accuracy of the information in the notice.[6] However, if the importing party fails to confirm the receipt of the notice or does not make its decision known, this does not mean its consent to a deliberate transboundary movement. If the importing party fails to reply within 270 days of receipt of the notice, the exporter will again send a written reminder with a response time of 60 days after receipt of the reminder. The copy shall be sent to the Cartagena Protocol Secretariat, the exporting Member State and the Commission.[7] The procedure for the transboundary movement of GMOs for the purpose of deliberate introduction into the environment may continue without a reaction to the notification only if it is the procedures referred to in Articles 9 and 10 of the Cartagena Protocol or other appropriate procedures specified by the importing Party, which is not a signatory to the

[4] Not all of these have any impact on other requirements of the Community and international level and have been developed in accordance with the foreseen handling, transport, packaging and marking procedures (Article 18. of the Carthage Protocol).
[5] A non-party is thought to be a state that did not sign the Cartagena Protocol.
[6] Name, address and contact details of the exporter; name, address and contact details of the importer; identification of the GMO and if there is a domestic classification in the country of exportation; if the dates of transboundary movement are known; characteristics of parent organisms or recipient organism, taxonomic status, common name and place where it is taken or obtained; if the centres of origin and genetic diversity of the recipient organism or parent organisms are known and the characteristics of the habitat where organisms can sustain or reproduce; characteristics of the organism or organisms of the provider related to biological safety, taxonomic status, usual name, place where it was obtained or taken; description of nucleic acid or modifications, techniques and resulting GMO characteristics; the planned use of GMOs or their products, and also of processed materials which are also of modified origin and contain new combinations obtained by the techniques listed in Annex IA to Directive 2001/18; quantity or volume of GMOs for movement; previous or existing hazard assessment report; proposed methods of safe handling, storage, transport and use and packaging, marking, documentation, disposal and contingency procedures; legal status in the country of export (for example certain prohibitions, restrictions, etc.) in the situation of movement of GMOs must lit the results and the purpose of each announcement, a statement of the accuracy of the information provided.
[7] Time required to get the relevant data does not apply into deadline calculations.

Cartagena Protocol. According to the Carthaginian Protocol, in Article 9, the exporting party independently or through the importing Party informs the national body of the importing Party of the transboundary movement of live modified organism. The importing Party shall, within ninety days of receipt of the notification, confirm the same, and shall contain the following facts: date of receipt of the notification; whether it contain all necessary information and whether it will be in accordance with national regulations or according to the procedure laid down in the Cartagena Protocol. If a party does not acknowledge receipt of the notification, it does not mean that it agrees to transboundary movement. Article 10 stipulates a further procedure. Therefore, the importing party is obliged to notify the applicant in the stated period regarding the further continuation of the transboundary movement of GMOs. Within 270 days of the date of receipt of the notification, the importer party shall notify the applicant and the MBC of its decision in writing. The decision may be of the following content: unconditional approval of import or with some of the conditions; ban on imports; seeking additional information; or, inform the applicant that the time of the transboundary movement of GMOs is prolonged for a certain period of time. Also in this case, the silence of the importing party does not imply consent to the transboundary movement of GMOs. Likewise, the deadlines provided for by Regulation 1946/2003 do not apply to Articles 13 and 14 of the Carthaginian Protocol. Article 13 provides for a simplified procedure in which an importing Party may prescribe precautionary measures to the BCH for the purpose of the safe movement of live GMOs. In addition, signing of bilateral, regional and multilateral treaties is planed that can negotiate procedures for the deliberate transboundary movement of living modified organisms, provided that they do not prescribe a lower level of protection than that provided for in the Cartagena Protocol. The parties are obliged to inform the BCH about all contracts and agreements concluded. Except in the case of exceptions, where the procedure is more complicated, Member States and the Commission, after consultations with the Cartagena Protocol Secretariat, are obliged to take certain measures to facilitate the importing Party's decision on transboundary importation, and again in accordance with the Cartagena Protocol provisions.

In particular, the exporter is obliged to keep the notification, receipt of acknowledgment and the party's decision and, if possible, a non-party decision for at least five years and send a copy of the said documents to the competent body of the Member State from which the GMO is exported and to the Commission.[8] In the case of changes of circumstances that may affect the outcome of the risk assessment on the basis of which a decision has been made or have become available to the relevant scientific or technical information, a review of the decision may be requested from a party or a non-party. In the event that a Party or a non-Party fails to reply within 90 days, the exporter shall send a written reminder to the competent body of the Party or non-Party, a copy of the same to the Secretariat, and request a response within the period indicated in the reminder.

Exceptions to these rules are as follows:

1. the GMOs listed in the Decision adopted at the Conference of the Parties to the Convention will be excluded from the action and should not have negative effects on the conservation and sustainable use of biodiversity and potential risks to human health;
2. the exception applies to GMOs intended for direct use as food and feed for animals or for processing,

[8] In keeping with the confidentiality rules, the Commission will publish the said documents in accordance with EU regulations.

3. pursuant to Article 13(1) (b) and Article 14 (3)[9] of the Cartagena Protocol , it does not apply to importing Parties listed in advance by the BCH

In the case of **direct use** and placing of GMOs on the market for **direct use as food, feed or for processing**, the Commission shall, on behalf of the EU or the Member State making the decision, notify the BCH or the other party through the BCH on the decision. The information is sent to the BCH within 15 days from the day of acceptance of the decision.[10] The minimum information to be submitted is set out in Annex II.[11] The Commission or the Member State shall send a copy of the said particulars to the designated body of each Party in order to notify the Secretariat in the event that it does not have access to the BCH. The exporting Party shall comply with any decision on import intended for direct use as food, feed or for processing carried out by the Party or any other party in the case of non-Parties in accordance with its domestic legal framework and in accordance with the purpose of the Cartagena Protocol. If the party or non-party of import is a developing country and a party or non-party is a county in transition, the same shall notify the BCH through a decision to import GMOs intended for direct use as food, feed or for use, all in accordance with Article 11 (6) of the Carthaginian Protocol and the exporter will not continue with the process until the same requirement is satisfied. If a party or non-party of import fails to confirm the receipt of a notice or to publish its decision, it does not mean imply acceptance nor refusal to import GMOs for direct use as food, feed or for processing. No GMO intended for direct use as food, feed or for processing shall not be the subject of transboundary movement unless the Commission or third country's competent authority issues an approval in accordance with Article 12 of the Regulation (EC) No 178/2002, i.e. the procedure for exporting or re-exporting of food or feed for the purpose of placing on the market of a third country, taking into account the rules, codes, standards or practices of the importing country. If there is any agreement, its provisions will be applied.

GMOs intended for restricted use are also subject to the autonomous regulation of either a Party or non-Parties to the Protocol, i.e. they may, in accordance with their regulations, carry out a risk assessment and set standards for GMOs intended for restricted use.

5. Unintentional transboundary movement of genetically modified organisms

In the case of **unintentional transboundary movement of GMOs**, Member States will take the necessary measures to prevent them, and if they become aware of the potential for release of GMOs that lead or could lead to transboundary movement and could have adverse effects on conservation, sustainable use of biodiversity and human health:

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[9] Namely, the articles refer to the importation of live modified organisms to which the consent procedure is not applied because they have obtained prior notification or have concluded bilateral, regional and multilateral agreements and arrangements and the process of intentional cross-border transmission is conducted in accordance with the aforementioned.

[10] This section does not apply to deliberate release in accordance with Part B of Directive 2001/18 / EC where GMOs are not intended for direct use as food, feed or for processing

[11] Applicant's name and contact details for domestic use; name and contact details of the decision-making body; name and identity of GMOs; description of gene modification, techniques used and resulting characteristics; any GMO identification; taxonomic status, common name, place where the characteristics of the recipient organism or parental organisms are obtained or taken; centres of origin and genetic diversity of recipient organisms or parental organisms, and a description of the habitat where they can be maintained or replicated; approved use of GMOs; risk assessment report in accordance with Annex II to Guideline 2001/18; proposed methods of safe handling, storage, transportation, use and packaging, marking, documentation, disposal and contingency procedures.

1. inform the public and the Commission, all other Member States, threatened or potentially threatened States, BCH and international organizations,
2. consult threatened or potentially threatened states and assist them in defining measures that would reduce significant negative impacts[12].

6. International information procedures

Notwithstanding the emphasis on the protection of classified information by the Cartagena Protocol, Member States are obliged to notify the BCH and the Commission of:

1. national legislation and the guidelines necessary to carry out the Cartagena Protocol pursuant to Articles 11 (5) and 20 (3) (a) thereof, respectively, each Party shall submit to the BCH copies of national regulations,
2. national contact points for notification of unintentional transboundary movement,
3. all bilateral, regional and multilateral agreements concluded between Member States, relating to intentional transboundary movement,
4. all data relating to unintentional or illegal transboundary movement,
5. final decisions made by a Member State on the use of GMOs in the same and following decisions:
    - restricted use of GMOs divided into risk groups 3 or 4 which are likely to become the object of transboundary movement,
    - on deliberate release of GMOs in accordance with Part B of the Directive 2001/18 / EC,
    - on the import of GMOs into the Community[13]
6. a summary of the risk assessment and ecological review of GMOs and, where possible, information on their products, processed materials of their origin, and contains new combinations of genetic material obtained using modern biotechnology,
7. any review of decisions relating to intentional transboundary movement,
8. any decisions taken by a Member State concerning protection clauses in the Directive 2001/18 / EC or emergency measures within the legislation on GM food and feed (Regulation 1946/2003, Article 15).

Regarding the confidential data, the Commission and Member States will not disclose them. The following information shall not be considered confidential: the name and address of the exporter or importer, the general description of the GMO or the GMOs, a summary of the risk assessment of the impact on the sustainable use of biodiversity, and the impact on human health, as well as the necessary methods and plans in emergency situations. In order for the system to be networked, Member States are obliged to appoint competent bodies that will be contacting

[12] Such information shall also include data from Annex III (appropriate information on estimated quantities and relevant characteristics and / or properties of GMOs, information on the circumstances and the date of release and the use of GMOs in the country of origin, all other available information on possible negative impacts on the conservation and sustainable use of biodiversity, on human health and information on management measures, any other relevant information, contact for further information).

[13] Delivery of a decision is determined within 15 days from the day of its adoption.

at European level. Member States are obliged to make their appointments known to the Cartagena Protocol Secretariat.

The purpose of the Regulation 1946/2003 is to establish a harmonized notification and information system for transboundary movement of GMOS and to ensure the coherent implementation of the Cartagena Protocol provisions in the area of safe movement, handling and use of GMOs which may have a negative impact on biodiversity conservation and human health. Therefore, the application refers to all GMOs over which transboundary movement is applied and may have a negative impact on the protection and sustainable use of biodiversity and potential risks to human health must be taken into account.[14]

7. Conclusions and recommendations

Nowadays, human health and the environment combined with biotechnology must be in balance. Biotechnology is the science that started developing in the 20th century, but also, is a science which, at this point, has no end in sight. Any social community had to react and legally regulate the scope of biotechnology. In these situations, it is expressively stated what is at the forefront in regards to science: law or biotechnology. Thus, the legal system of any country will try to follow the biotechnological system in rational terms. Therefore, at the international, European and national level, approval procedures, deadlines and remedies have been defined. The Carthaginian Protocol and master documents at the European level in the field of genetic engineering are regulated by a one-way approach to matter. However, it is necessary to take into account differences that are characteristic of individual Member States. The recommendation is more focused on the needs of a Member States and defines control bodies at a supranational level. It is evident that this is a very sensitive matter, but also national differences must be taken into account: geographic location, historical circumstances, biodiversity and religious affiliation of the population. Consumers need protection, and legitimate protection cannot be obtained if consumers do not shape politics independently. The population is in fear and disbelief, and so far there is a wealth of evidence of situations when multinational companies' interests prevailed over the interest of the population. The foundations of each policy should be the citizens, which implies their participation in policy-making, specifically genetic engineering. Educated citizens would represent a balance to the system, a balance between power of the state and multinational companies. In this way, the theory of self-organization, i.e. homeostasis, gets its meaning.

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THE FUNCTION OF ADJUDICATION IN PROTECTION OF ECONOMIC VALUES

ABSTRACT

For decades, the contemporary theorists of law have been debating about how judges reach their decisions with the particular focus on the supreme court of a country. The different conceptions have been developed to provide answer to this question although the demarcation line between descriptive and prescriptive theories on adjudication was not always clear. A particular theoretical question is whether judges make decisions, or should make decisions, based exclusively on principles or policies are equally good reasons for decisions. Another question refers to the functions which adjudication performs in the community. This paper examines the functions and methods of adjudication with special focus on protection of the economic values prevailing in a community. After presenting various theories on adjudication, we will examine several decisions of the Constitutional Court of the Republic of Croatia with economic effects in order to compare them with the theoretical model developed on the ground of different theories analysed in the previous chapters.

Key words: *adjudication, values, theory of law, principles, policies, constitutional court*

1. Introduction

In contemporary theory of law, the discussion about what the judges do goes on for decades. The idea that the judges only apply the statutory law belongs to the 18th century doctrines while the contemporary theory of law places adjudication in the central place in the functioning of legal order. In the type of legal order which today prevails, the courts have a wide discretionary power in decision-making and also participate in a special way in 'constructing' the law itself. Courts decisions are often important both for the protection of the individual right and for the general and groups' interests. Strategic litigations appear as a new tool for changing structural relations in the community and decisions often have a strong impact on the state economy. In this article we will present and compare theories of adjudication in which the aforementioned features of the courts are outlined and based on that presentation, we will propose the model for explanation of the courts' activities. We will then apply the said model to analyse certain decisions of the Constitutional Court of the Republic of Croatia (RC) which have economic effects.