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## EUROPEAN INSTITUTIONAL FRAMEWORK FOR GENETICALLY MODIFIED ORGANISMS

### Abstract:

The aim of this paper is to present the composition and functioning of the EU institutions involved in receiving, analysing, approval or rejection of the application for the use of genetically modified organisms. The manner of participation of each institution is presented by using the comparative and historical method, as well as the method of analysis. The advantage of these methods is a detailed analysis of the rights and responsibilities of all participants in the approval process for genetically modified organisms.

The paper analyses all the EU institutions that are directly or indirectly associated with the approval procedure, and those are: European Food Safety Authority, European Parliament, European Commission and Court of Justice of the European Union. The problem of the whole institutional framework is an insufficient contribution of the constituent activity of the EU member states and their national authorities and whole process should be based more on the principle of subsidiarity.

### Keywords:

European Union, genetically modified organisms

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## Introduction

Genetically modified organisms (GMOs) are still unknown term in the world. Or they are simply unknown to some final consumers so as not to cause further panic among the population. Every now and then we have a chance to read about the genetically modified organisms and their consequences. The predecessors of genetically modified organisms, in the harsh sense of the word, are cloning and eugenics because the basic meaning of both is an artificial effect on life. So, we can say that a man is dealing with this issue for many years. With all the numerous approaches to genetically modified organisms, the focus of this paper is on EU institutions that are involved in the approval procedure. As an independent institution that participates in the approval procedure is the European Food Safety Authority (EFSA). The EFSA is crucial for risk assessment of food and feed and its safety. As an independent body, the EFSA provides scientific advices and it is a centre of information exchange. The European Parliament participates in the legislative procedure and through that legislative procedure it affects the position of GMOs. The European Commission has an important role because it is consisted from various institutes and research centres specialized in studies on food and the impact of GMOs on food. The last institution regarding the GMOs regulation is the Court of Justice of the European Union. The Court of Justice of the European Union with its concrete, life action creates the case-law, and thus forms the status of genetically modified organisms.

### European Food Safety Authority

The purposefulness of activity of agencies is in fact of creation of a special body whose function is to perform regulatory and other tasks from the relevant

areas. Regulatory agencies came from the US regulatory independent commissions and agencies. The characteristics of them are: activities are performed independently of political influence; employees of the same agencies reflect professionalism, quality, reliability; this way of functioning ensures more detailed regulation and knowledge of the individual parts of the system; provides better control and better legal protection of users and consumers. In the field of genetically modified organisms the European Agency Food Safety Authority appears.

"The European Food Safety Authority (EFSA) is key agency in the European Union (hereinafter referred to as: EU) for risk assessment of food and feed. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA offers independent scientific advice and clear communication on existing and future risks. "[1] The purpose was to form an independent body that would be a source of scientific advice and communication on risks when it comes to food for both human and for animal consumption. As for legal status, EFSA has legal personality and acts independently of the institutions of the European Union. The founders are the European Parliament and Council via Regulation 178/2002.

One reason for creation of this agency is a series of food scandals which have occurred during the 1990s. It is necessary to protect consumers, improve food safety and to retain existing and restore lost confidence in the food supply in the EU. Since the risk assessment is carried out separately from risk management, the EFSA, with its scientific opinions and advice, constitutes the basis of European policies and legislation and support to the European Commission, European Parliament and Member

States in order to make appropriate decisions in risk management. Areas of action EFSA are: food and animal feed safety, nutrition, animal health and welfare and plant protection.

The role of EFSA is to point out all the risks in the food chain. The basis for EFSA action is self-initiative, but it also acts at the request of the European Commission, European Parliament and Member States. It is not included in the decision making or management, for example in the process of adoption or revision of EU legislation on food and animal feed safety, the process of approval of certain additives, pesticides etc., "but aims to provide appropriate, consistent, correct and timely information on food safety to all interested parties and the public at large on the basis of their own risk assessment and scientific expertise". [1] The EFSA has so far issued over 450 scientific opinions on, for example, bovine spongiform encephalopathy (BSE), transmissible spongiform encephalopathy (TSE), safety of many food additives (GMO, wild and farmed fish, etc.). In addition, EFSA works and on its own initiative, so-called self-tasking, especially in the areas where the risks are still emerging, and where scientific approaches and knowledge are still at the starting levels. In order to ensure complete "scientific integrity and to stay informed", EFSA is working with other Member States in order to collect the appropriate scientific data.

Article 22 of Regulation 178/2002 states the mission of EFSA, which, in that sense, is: to provide scientific advice and scientific and technical support in all situations that have points of contact with food or feed; taking care of the system of protection of people and their health, animal health and welfare, plant health and the environment; collect the

necessary data to be able to properly monitor the risks associated with food and feed etc.

The task of the EFSA is to:

"Provide the Community institutions and Member States with the best possible scientific opinions in all areas provided for by Community legislation or any other question within the mission;

enhance and coordinate the development of uniform risk assessment methodologies in all areas within its mission;

provide scientific and technical support to the Commission in all areas of the mission and, when prompted, interpretation and consideration of risk assessment opinions;

carry out their scientific studies necessary for the achievement of the mission;

search for, collect, collate, analyse and summarize scientific and technical data in the fields within its mission;

take action to identify and characterize emerging risks in the fields within its mission;

establish a system of networks of organizations operating in all areas of the mission and be responsible for their work;..." [2]

Regulation 178/2002 lists the individual principles that mark EFSA actions and effects:

1. the first principle that is mentioned is the principle of independence, according to which the members of the Board, the Advisory Forum and the Director shall act in the public interest. They are required annually to, in writing, sign a declaration of commitment and a declaration

- of the absence of any direct or indirect interests that could affect their independence.
2. Transparency of the EFSA is ensured by the following actions: publication of agendas and minutes of the Scientific Committee and Scientific Council and opinions of the same immediately after acceptance; the publication of information that make up the opinion; publication of the annual interests statements of members of the Board of Directors, Advisory Forum, Scientific Committee and Scientific Council and the Director General; publishing the results of their scientific research; the publication of annual reports on their activities; publishing requests from the European Parliament, the Commission or Member States when scientific opinion is rejected or changed and stating the reasons for rejection or changes.
  3. regarding confidentiality, all the information needed in order to ensure public health shall be published while other information is confidential and shall not be disclosed to third parties.
  4. the principle of communication by which EFSA communicates in a way that all interested parties receive reliable, objective and accessible information.
  5. access to documents has to be greatly emphasized.
  6. EFSA maintains contacts with representatives of consumers, producers and other interested parties.

EFSA is composed of the following bodies: Board of Directors, Director with his staff, the Advisory Forum and Scientific Committee and Scientific Council. The board consists of 14 members appointed by the Council in cooperation with the European Parliament and on the basis of a list drawn up by the European Commission, with one member being a representative of the European Commission. They

serve for four years and their mandate can be reappointment once. They meet on the proposal of the President or at least a third of its members. The meetings are attended the Board and Director, but without voting rights. Board shall appoint the Director General for a term of five years with the possibility of reappointment. The list of candidates published by the European Commission after a public competition in the Official Journal of the European Union and elsewhere, depending on the needs. Before appointment, the candidate nominated by the Board will be invited to the European Parliament to give a statement and answered questions. The Director may be removed by the Board of Directors by majority of its members.

Next body, according to Regulation 178/2002, the Advisory Forum consists of representatives of Member States, or their competent authorities which perform similar tasks as the EFSA. Each Member State sends one representative. But that representative cannot be a member of the Board of Directors. Advisory Forum has the following powers:

advises the Director General regarding his/her obligations under Regulation 178/2002, and in particular on the draft of EFSA work program and the priority of the applications submitted for scientific advice;

is a mechanism of exchange of information on potential risks and ensure close cooperation between EFSA and the competent authorities of Member States.

The last bodies in the line are the Scientific Committee and scientific councils, which are responsible for providing scientific opinions according to their competences and have the ability to, when needed, organize public hearings. The

Scientific Committee is responsible for ensuring overall coordination when it comes to consistency of scientific opinions procedures. It consists of the president of the scientific council and six independent experts who may not be members of the scientific councils.

The Council for genetically modified organisms (hereinafter referred to as: the Council) studies GMOs and GM food and GM feed. Members of the Council are appointed by the EFSA and the Board of Directors for three years with the possibility of reappointment. Appointments are made on the basis of open competition and after strict assessment of candidates. Council members sign the declaration of interests to ensure their independence during operation. In terms of procedure, the Council is of great importance because the Commission shall forward the request and ask EFSA for a scientific risk assessment. The Board performs a detailed risk assessment on the safety. Detailed analysis consists of 21 independent experts in the Council for the following areas: biochemistry, microbiology of food and organic food, soil microbiology, molecular biology, genetics, toxicology, pathology animal, immunology, biotechnology, food science, ecology, biology of plants, agronomy, entomology and statistics.

There is a situation when different scientific opinions arise and where there is a disagreement between the EFSA's scientific opinions and the scientific opinions of other bodies performing similar tasks, and in such situations a cooperation between them is organized.

In order to ensure faster and easier communication, exchange of information, theoretical and practical knowledge EFSA promotes European networking of organizations participating in the areas of EFSA's

mission. List of competent authorities of the Member States which take part in EFSA's mission is drafted by the Administrative Committee on a proposal from the Director General. EFSA Networks consists of a number of organizations and experts from Member States, led by EFSA and supported by its appropriate units.

## European Parliament

The European Parliament is a representative of the citizens, and is elected every five years in a direct way. Its main functions are: adopts European laws together with the Council of Ministers; cooperates with other institutions in order to check the democratic nature of action; together with the Council of Ministers discusses the budget and adopts the same. After the Lisbon Treaty, the position of the European Parliament is greatly changed. Namely, it cooperates with the Council of Ministers in the ordinary legislative procedure, i.e. co-decision procedure in the field of consumer protection, the environment, etc., but after the Lisbon Treaty Parliament's influence spread to some other areas, such as agriculture, energy policy, immigration and EU funds. The seat of the European Parliament is in three cities: Brussels, Strasbourg and Luxembourg, with administrative offices based in Luxembourg, plenary sessions are held in Strasbourg and Brussels, meetings of the Committee are held only in Brussels.

The legislative process is also significantly amended by the Lisbon Treaty. The legislative procedure or co-decision procedure was introduced by the Maastricht Treaty in 1992 and amended by the Treaty of Amsterdam. The entry into force of the Lisbon Treaty the same is called ordinary legislative procedure, but also has become the main legislative procedure in the European legal system. The ordinary

legislative procedure in a number of policy equates legal power of the European Parliament and the Council of Ministers, i.e. a number of laws are adopted together by the European Parliament and the Council.

## European Commission

The European Commission represents the interests of the EU and constitutes one of the fundamental institutions. Its main task is to implement policies and channel the funds from the European funds. Within the Commission acts Directorate General for Health and Food Safety (hereinafter referred to as DG SANTE) whose main goal is "to make Europe a healthier, safer place where consumers can be assured that their interests are protected. „The fact is that it is impossible to establish a zero risk to consumers or society as a whole, but in any case, DG SANTE operates in terms of risk reduction and management. The objectives of DG SANTE are:

1. "to protect and improve public health
2. ensure that European food is safe and healthy,
3. protect the health and welfare of farm animals,
4. protect the health of crops and forests." [3]

In terms of methodology, DG SANTE has planned the following activities: monitoring (monitoring regulations, and their implementation at national, regional or local level that are related to food safety, consumer rights and public health); listening (this implies involvement of all stakeholders in the process); action (action depending on the particular circumstances, and taking into account a number of laws, regulations, projects, etc.).

Joint Research Centre, ( hereinafter referred to as JRC) is a Directorate General of the European Commission. It is based in Brussels, and its function is to provide a number of scientific and technical

information in areas of EU policy. It was founded by the Founding Treaty of 1957, or the Euratom Treaty. Since the role of Euratom agreements promoting nuclear safety and security in general in Europe, the JRC's own scientific and technical support is focused in this direction. However, over time the JRC has expanded its areas of activity in other domains including life sciences, energy, security and consumer protection. Institute for Health and Consumer Protection (hereinafter referred to as: IHCP) is one of the seven institutes of the JRC and is responsible for protecting the interests and health of consumers by providing scientific and technical assistance to assessing the risks and benefits and by controlling traceability. The activities are focused in the following areas: GMOs, nanotechnology, health and the environment, consumer products and nutrition, alternatives in situations involving animal testing. The JRC has for years worked on the creation and adaptation of funds and tools used for tracking GMOs that are put on the market, and also to prevent the "entry" of unapproved GMOS. IHCP plans to, on the basis of Reference Laboratory for GM Food and Feed (hereinafter referred to as: EURL-GMFF) introduce a uniform method that would be applied in all laboratories and would allow detection and determination of quantities of GMOs in food and feed. Today's role and importance of EURL-GMFF was established in 2004 by defining the status of the European GMO legislation. Its duties and responsibilities are as follows: assessment of the validity of methods of detection of GM food and feed and scientific risk assessment; preparation and distribution of the control samples to the competent laboratories; competence in solving potential disputes between the laboratories of the Member States when it comes to different results in detecting GMOs; to help the national reference

laboratories. All data on all phases of the discovery, validation, etc., are available on the Internet (description of the event, a unique identifier of GMOs, information about the applicant, check the status of the validity of the required methods). The same information is reported to the EFSA and published on its website. In addition, it acts as a coordinator when it comes to national reference laboratories and their detection methods. It is important to emphasize that, for the purpose of standardization out cooperation with the European Network of GMO Laboratories (hereinafter referred to as: ENGL) is carried out. ENGL is a collection of European experts who play a significant role in the development and harmonization of testing methods, detection, identification and quantification of GMOs. It was opened on 4th of December 2002 in Brussels and currently consists of more than 100 national reference laboratories of all Member States and also from Norway and Switzerland.

When it comes to other areas, or the area of health and the environment, IHPC examines the risks associated with: air pollution, chemicals, pesticides, noise, etc. In order to provide high quality in this area, IHPC collaborates with other departments of the European Commission, other organizations in the European Union, the World Health Organization and other parties. In the area of consumer goods and food, IHPC assess the benefits and risks of food products with respect to human health.

The practice of the Court of justice of the European Union on genetically modified organisms

After principles, legal rules and organizational forms it is necessary to mention the "last cog in a wheel", i.e. courts that participate in application of laws. Courts "give life" to a rigid legal rule and

separate judgments of the Court of Justice of the European Union are stated on the issues of GMOs.

The Court of Justice (there is a controversy regarding the translation and the use of the term "justice" in the terminology of the Court. For example, the term is used in English, French, Italian system while the Germans omitted that term of the official name) of the European Union has three judicial authorities: the European Court of Justice), the General Court and specialised courts. The Lisbon Treaty also changed the name of the Court of First Instance into the General Court. The seat of the Court is in Luxembourg. Within the European Court operates one judge from each member state and 11 independent lawyers. The General Court is also made up of one judge from each Member State, and the composition of the specialized court is defined by the founding act, i.e. a decree. The choice of judges and prosecutors is done at the national level, and they are elected by the governments of the Member States via mutual agreement. However, the novelty brought by the Lisbon Treaty is the establishment of the Committee (Article 255 of the TFEU), whose function is to give opinions on the suitability of the candidate. Change came with the Charter of Fundamental Rights of the EU. The status of the Charter is legally binding, so a question arose regarding the emergence and regulation of individual rights, for example "ban on the creation of human body or parts that would be a source of financial gain" [4] , "ban on cloning of human beings" [4]. The application of the Charter is limited and difficult because the same does not apply to regulations of Poland and Great Britain.

The Lisbon Treaty introduced significant changes in some procedures. So, the novelty refers to the system of direct judicial review or submission of a



claim for annulment of: legally binding acts of the European Council, offices and agencies (so far the ability to control depended on the legal nature of the legal act) and other bodies. Active legitimation is also expanded in terms of the individual as the applicant (Article 230 of the EU Treaty, and in terms of procedural legitimacy of individuals, stated: "Any natural or legal person may, under the same conditions, institute proceedings against a decision addressed to that person or against a decision which, although in the form of a regulation or decision addressed to another person, is of direct and individual effect on the last." However, in Article 263/4 of the Treaty on the Functioning of the European Union applicant's status is changed to read as follows: "Every natural or legal person may, under the conditions set out in the first and second paragraphs, institute proceedings against addressed to that decision or that the same person of direct and individual concern, and against a regulatory act which is of direct interest to them, and not require any implementing measures." There are differences in those interpretation (for example the deletion of certain expressions, defining the regulatory act, implementing measures etc.) and the meaning depends on the Court's interpretation of the Court of the EU, and the Committee of the Regions (based on Article 263/3 of the Treaty on the Functioning of the European Union: "The Court has jurisdiction under the same conditions in actions brought by the Court of Auditors, the European Central Bank and the Committee of the Regions for the purpose of protecting their prerogatives." In addition, Article 8 (2) of the Protocol on the application of the principles of subsidiarity and proportionality clearly emphasizes the following: "... The Committee of the Regions can take such actions against legislative acts for the adoption of

which the Treaty on the Functioning of the European Union provided for consultation", and indirectly to the national parliaments (apart from changes envisaged in the Lisbon Treaty, the Protocol no. 2 on the application of the principles of subsidiarity and proportionality in Article 8 (1), which stipulates: "The Court of Justice of the European Union shall have jurisdiction in cases of violation of the principle of subsidiarity, the legislative acts adopted in accordance with Article 263 of the Treaty on the Functioning of the European Union by Member States, or is notified in accordance with their legal order by the national parliaments or their houses."

In addition to these changes, the Court has given the power to control the validity and interpretation of acts of agencies, bodies and offices. The novelty of the system is the introduction of an emergency preliminary ruling procedure when prompted by the national court before which the action is being taken for a person who is in custody. Emergency preliminary proceedings were initiated on 1st of March 2008, relating to the third pillar of the EU and Title IV, Part Three of the EC Treaty, that is thematically focused on the areas of visa, asylum, immigration and other policies related to free movement of persons (from Article 61 to 69). Thus, the effect of the Court, in regard to the previous procedure, is focused on preliminary issues related to the area of freedom, security and justice, and situations in which a persons before the national courts of the Member States is in custody.

Several rulings by the Court that are highlighted which are, in fact, indicators of the practical application of legal rules. If you start from the newer verdicts, the first in the series refers to the judgment of the Court (Grand Chamber) of 6th of September 2011 (Case C-442/09 Karl Heinz Bablok and Others vs.

Freistaat Bayern [2011] ECR Page 00000) which refers to Regulation (EC) No. 1829/2003 (Articles 2 to 4 and Article 12), Directive 2001/18 / EC (Article 2), Directive 2000/13 / EC (Article 6) of Regulation (EC) No. 178/2002 (Article 2). The judgment refers to the presence of pollen from GM plants and side effects when put on the market, the definition of “organism” and “food for human consumption containing ingredients produced from genetically modified organisms.” According to Article 2.5 of Regulation (EC) No. 1829/2003 the definition of GMOs does not include pollen derived from a variety of GM maize, which has lost the ability to reproduce and is totally incapable of transferring the genetic material which it contains. In accordance with Articles 2.1, 2.10 and 2.13 and Article 3 (1) (c) of Regulation 1829/2003, Article 2. Regulation 178/2002, Article 6 (4) (a) of Directive 2000/13 / EC the following matter is not considered to be GMO: pollen containing genetically modified DNA or genetically modified protein; products such as honey or food supplement containing such substances that represent “food ... containing ingredients produced from [genetically modified organisms]”. Furthermore, Articles 3 (1) and 4 (2) of Regulation 1829/2003 imply an obligation of authorization and supervision of food and the tolerance on the labelling, provided for in Article 12 (2) of the same Regulation cannot be applied analogously to the previous articles.

The following case T-139/07 (Case T-139/07 Pioneer Hi-Bred International vs. Commission) refers to appear before Court of First Instance between the “Pioneer Hi-Bred International” against the Commission on 4th of September 2009 on the approximation of laws during the deliberate release of genetically modified organisms into the environment. The applicant was “Pioneer Hi-Bred International”, and respondent was the Commission of the European Communities.

The aim of this action was towards the harmonization of rules on release of genetically modified maize 1507 to the market, but the Commission has failed to fulfil its obligations provided for in Article 18 (1) of Directive 2001/18 / EC. Since there has been a failure, there is no need for court ruling and the Commission shall reimburse its costs and expenses of the applicant.

Ruling of the Court of First Instance (Fourth Chamber) of 5th of October 2005 is a dispute between Land Oberösterreich and the Republic of Austria and the Commission of the European Communities on the harmonization of legislation and national provisions on the derogation from harmonization measures, ban on use of genetically modified organisms in Upper Austria and the conditions for the application of Article 95 (5) of the EC Treaty (Joined cases T-366/03 and T-235/04 Land Oberösterreich and Republic of Austria vs. Commission of the European Communities [2005] ECR II-04005) which reads: “... after harmonization measures are adopted by the Council or the Commission, and a Member State deems it necessary to adopt new national provisions based on new scientific evidence relating to the protection of the environment or the working environment based on problems specific to a Member State, provided that the same occurred after the adoption of the measures, the duty of a Member State is to inform the Commission of the implementation thereof and the reasons for the implementation”. The verdict was in favour of the European Commission. On appeal (Joined Cases C-439/05 P and C-454/05 P) a verdict was issued on 13th of September 2007, also not in the favour of the Republic of Austria.

## Conclusion

The system of genetically modified organisms (GMOs) is contradictory to the principle of subsidiarity. That principle, in the harsh sense of the word, is the basic setting and the starting point in relation to European and national. Namely, the member states in the current situation can only ask questions and look for reasons, as well as they can hope that the mentioned system is not just a "pass" for multinational companies. The current approval system is well designed, but only for the purposes of international trade. Only in that scenario, the uniform and centralised system can be justified. But, there must be awareness that it is difficult to establish a uniform system at the global level. That is because of different interpretations and approaches to a number of terms, problems and uncertainties due to the diversity of all member states. The evidence of centralization is also the fact that the risk assessment and final decision perform EFSA and European Commission Standing Committee on Plants, Animals, Food and Feed. The self-organization of the mentioned institutions, their activity, and the way of relating to the member states should be focused on the principle of subsidiarity. The member states have already indicated their freedom of decision making and acting, on their biodiversity which is different from one to the other. They pointed difficulties that arise by adopting a centralized system of approval of GM food and feed. They also referred on national orientation of that matter and editing system in accordance with national regulations and needs, with mandatory participation of the public, while respecting the provisions of environmental and consumer protection. Therefore, the organization should focus on self-organization and autopoiesis theory, with reference to natural laws as a starting point. The

starting point of every action should be the lowest level of activity, including the participation of citizens. Whereat, each part of the system has its whole, its subjectivity, and again represents a coherent whole with other systems. The system was not created by the method of induction but by the method of deduction. The criticism of the system of genetic engineering is that, when designing regulations, the integral social development is not taken into account. The individual "development" and a contribution were bypassed because the participation of citizens in policy-making of genetic engineering did not come to the fore. The centre of mission should be the system of action "from below", the so called "bottom-up" approach.

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