THE ASPECTS OF THE LEGISLATION IN EUROPEAN UNION AND HUNGARY WITH REGARDS TO GENETICALLY MODIFIED ORGANISMS IN LIGHT OF THE ENVIRONMENTAL PRINCIPLES AND SUSTAINABLE DEVELOPMENT

PHD THESIS – EXECUTIVE SUMMARY

AUTHOR: TAHYNÉ DR KOVÁCS ÁGNES

SUPERVISOR: BÁNDI GYULA CSC

HEAD OF DEPARTMENT AND PROFESSZOR

PÁZMÁNY PÉTER CATHOLIC UNIVERSITY

FACULTY OF LAW AND POLITICAL SCIENCES

DOCTORAL SCHOOL

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I. The aim of the research, its theme and methodology

The underlying thesis, as depicted in its title, aims to review the European and Hungarian legislation pertaining to genetically modified organisms, specifically in light of environmental and sustainable growth considerations.

Many authors have written about sustainability and sustainable growth, there are several/numerous international treaties, which define these terms. Nevertheless, it is nearly impossible to define these terms in a way that is globally accepted and in addition covers all aspects thereof. The importance of unified principles has been underlined several times in the past – especially in the course of monitoring the implementation of treaties -, nevertheless the question remains how far the states or the international community will go in the implementation of these principles bearing in mind their economic-political interests. Every principle is only as useful as the practical use it represents to society and future generations, hence contributing to the creation of necessary directives.

The implementation of general environmental principles into creation of legislation is not an easy task. In an initial step, the principles in question must appear within the legal framework, and thereafter within the specific articles, as a final step these must be present in the applied law and the judicial practice.

This means that principles must be converted into directives, that can be used within the societal-economic system in which they need to be implemented in, so as to serves the system of society and the protection of the environment. Nevertheless, we must underline that the principles do not necessarily need to be reflected in the law as mentioned in the relevant literature. Environmental awareness and sustainability can exist without being explicitly regulated.

As a second step, the principles need to be monitored and supervised as part of the applied legislation. This process needs to be seen as continuous as feedback should be implemented into the drafting process. Monitoring is not so much to be used as to control the application of the principles, but to find an equilibrium.

The legal regulation of genetically modified organisms is analyzed in light of the first step of the process. Specifically, the goal of the underlying thesis is to review whether the premise of sustainable development can be found in the legal regulation of genetic technology and in which depth, primarily with regards to deliberate release of GMOs into the environment,

coexistence, and in connection with seedcorn, food and animal feed. The analysis beyond this frame would burst the volume of the underlying thesis, albeit further research will follow in this direction.

The primary source of the analysis was the relevant legislation. We have not reviewed the implications in connection with the use of GMOs in a closed system, which is beyond the agriculture and food industries, e.g. pharma, warfare, biomass and other applications. We have also excluded the analysis of liabilities, as the scope and scale of such analysis would represent a separate thesis. Furthermore, in light of the limited scale of this thesis we have not reviewed the areas of legal enforcement, monitoring/control or feedback, although the findings herein should serve as input thereto. It is also important to underline, that the economic aspects of the topic have also been excluded, so as to focus on the legal implications.

The choice of topic was made in light of the fact that biotechnology and the quickly evolving genetic technology specifically represent one of the large challenges of the 21st century.

Within the legal environment, the regulation of this area falls within environmental law, which is a fairly young interdisciplinary science. The thesis limits the analysis on the review of areas around GMOs. Its aim is to analyze whether sustainable development is present in the regulation of GMOs and to what extent, primarily in the case of deliberate release, coexistence, use of seeds and in food as well as protection of human health.

The analysis was done along the premises of ethical, legal and economic considerations.

It is important to state, that the analyzed area is characterized by a high level of dynamic and continuous development and change, but only certain aspects thereof are analyzed. Other areas are not the subject of the underlying thesis.

The separation of the analyzed areas and those that were left out is made clearly in the first part of the thesis.

The section on fundamentals reviews the global nature of GMOs. Accordingly, we are not able to leave the ethical aspects aside, which support the analysis later on. Thereafter, we review the current legislation, which sees continuous change. The implications of sustainable development and their relationship to GMOs is discussed in the IVth section. Then, we discuss the principles of precaution and related ones. The regulation regarding the protection of human health follows, which is a primary goal of European legislation. Coexistence, as a special area of interest, is a specific form of agricultural planning.

The regulatory areas beyond the aforementioned, such as public participation, regulation of R&D, agricultural-, economic, competition law regulation are beyond the scope of the

underlying thesis. Nonetheless, this thesis may serves as a starting point for such analysis. Other areas of interest may be the application of GMOs in a closed environment, - in healthcare, - in fisheries, - in armed forces and – in biomass. Additionally the area of responsibilities/liability and the applicable regulation may be the subject of future analysis, which may provide guideline and solutions for the codificators of the future.
The areas of analysis, have been summarized in a table. It is the goal the underlying thesis to prove the aforementioned close relationship as well as to analyze how the general environmental regulations and principles (aimed at ensuring sustainable development) pervade the legal regulations of GMOs.

Dating back to the second half of the 20th century, environmental law combines areas of public, criminal, civil and commercial law. The regulation of genetic technology, which is also rather new, is closely related to environmental law although in a rather peripheral manner. Its complexity stems from the fact that the regulation of this area is pervaded by respective areas of civil-, labour-, commercial-, agricultural-, consumer protection - and patent laws and regulations.
Its place within environmental law derives from the ultimate goal of regulation – the protection of mankind and the environment

In view of the applied methodology used in the underlying thesis, it is important to state that the analyzed area of law is a relatively new one. As a result my primary source of information was relevant sections of the international, EU and Hungarian legislation as well as the available foreign literature about the topic, which remains limited due to its unresearched nature.
We have also drawn from the quasi-precedence practice of the European Court for Justice with regards to GMO regulation.

I relied largely on the legal sources of the European Union available on the internet, in addition to studies, academic research and scientific analysis of the area.
The main binding premise of this thesis is sustainability, which connected all of the regulatory areas as well as the various sections.

The thesis is structured into 3 main sections and 9 chapters along with 9 appendices.

The first section, comprising 2 chapters provides the introduction and basic terminology for the research.
The second section, being the backbone of the thesis comprises 8 chapters. It reviews the various legal instruments in general and then in light of the international-, EU, Hungarian frameworks and their implication to genetic technology.
The third section is a summary of the discussion.

Possible usage of the findings

The underlying thesis offers a number of opportunities for further research. The most imminent would be the analysis of practical usage of the legislation, whether the principles find application and the feedback into the legal framework. In addition, the findings of the underlying thesis could offer a sound basis for the analysis the legal liabilities. Another interesting area is the review of the degree of compliance of Paragraph XX., article (2) of the Fundamental Law of Hungary with the EU legistlation or even the WTO regulations. The review of the consumer protection aspects in light of genetic technology regulation would also be food for thought.

I see the benefit of the underlying thesis in filling a gap that is present within the Hungarian legal literature concerning the environmental aspects of genetic technology. The relevant Hungarian literature focuses mostly on the patenting aspects of biotechnological inventions.
This gap can be explained by the relative young nature of this area within the legislation and the deemed unimportance, not to mention the uncertainties. I strongly hope that the underlying analysis and results will positively contribute to the development of the respective literature.
An additional reason for the research and this thesis is the fast-paced development of genetic technology as a science and as such the implications affect society and mankind and the environment.
Therefore, one cannot disregard the drafting of a legal framework, better yet it needs to be improved as it should benefit human health, the environment and last but not least ensure sustainable development.

II. Summary of the scientific findings

1. The main debates surrounding GMO regulation

The use of GMOs within the field of agriculture, with all its advantages and debated effects, is commonplace globally. Academics (science, law and economics) have diverging opinions as the number of unanswered questions relating to the cultivation and utilization of GMOs remains substantial.

During the years of research, I have come to the conclusion that key questions arise from the collision of economic interests with those of environmental or healthcare; the application of the principle of precaution in connection with the deliberate release of GMOs into the environment, the environmental risk assessment, the drafting of the rules of coexistence, the application of the principle of precaution in connection with the establishment of a security zone, the adequate protection of biological resources, the efficient application of the principle of social participation and the regulation of ethical issues.

I share the views of those scientists and scholars who believe that the principle of precaution should be kept in mind at all times during the drafting of any legislation, even if the dangers and detrimental effects cannot be fully excluded.

2. The factors necessitating legal regulation

My research has confirmed that the regulation of genetic modification technology using the tools of law is crucial. The factors that make such regulation necessary can be grouped into four distinct groups.

The initial group comprises the partially undetected long-term risks of genetic technology and its implications on the flora, fauna and human beings. This serves as a basis for the principle of precaution during the drafting of any regulatory framework.

The need for regulation also derives from the fact that this area is affected by other areas regulated by the commercial (and competition) law.

The fact that genetic technology interests have entered the political arena also makes the need for regulation indispensible. Last but not least, the global take up of agricultural application of GMOs also underline the need for regulation.

3. The place of regulation of genetic technology within the EU law and the EU's GMO policies

3.1. The legislation regulating GMOs is within the area of biotechnology. During my research, I have concluded that the EU's policy for the drafting of the legal framework

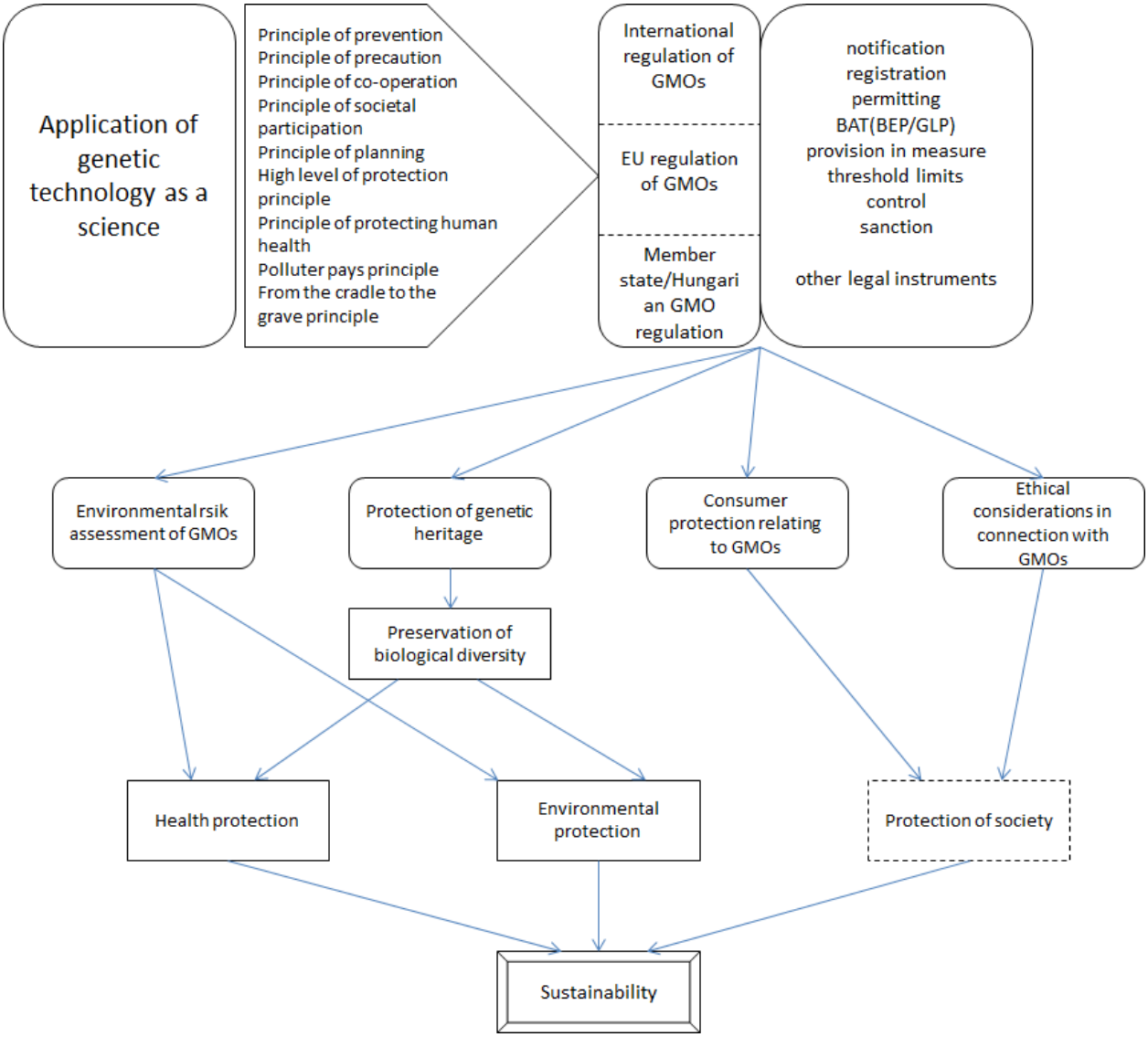
relating to genetic technology is influenced by the environmental-, the agricultural and the food safety policies. Policies relating to consumer protection and healthcare also have an influence, albeit to a much lesser extent.

3.2. I have come to the conclusion that the policies of the the EU relating to the areas of genetic technology are partially underdeveloped. In 2002, the document „Life Sciences and Biotechnology - a Strategy for Europe" formulated the EU's policy relating to GMOs. Accordingly, the results were summarized in the Committees report in 2004, nevertheless the following years brought uncertainty as to the policies relating genetic technology. It can be said that regulating the area of GMOs requires careful planning and drafting of actions and directives to address issues effectively. As a result, the EU supports continuous co-operation and consultations.

4. Environmental principles in the field of GMOs ruling

During the course of my research, having reviewed the relevant international documentation, I have come to the conclusion that the following principles influence the regulation of genetic technology: the principle of sustainable development, the principle of action at environmental damages, the principle of precaution and prevention, the principle of co-operation, the principle of scientific and technological development in the interest of the environment, the rational use of natural resources, the principle that one state should not cause damage to the other, the attention to the interests of developing countries as well as the societal participation and the principle of access to information. The overall degree of environmental action needs to be harmonized among the member states.

It was my aim to describe the scope and scale of the regulatory framework in the field of genetic technology and how this complies with the goal of sustainable development. The regulation concerning protection can be grouped into environmental-, health and societal protection. Please refer to the graph for a visual summary of the overall framework.



5. The relationship between legislation of genetic technology activities and sustainability

There is a need for co-operation on a global scale, in order to achieve sustainable development, because the effects are global and their implementation is also more efficient this way. Sustainability is directly linked to the long-term and balanced economic growth, with a view to maintain non-renewable resources. The genetic heritage (within today's biosphere) is also an integral part of our natural resources. The successful implementation of sustainability within genetic technology can only be achieved, if today's mankind uses the technological accomplishments, bearing in mind the principles of precaution and prevention, thereby being attentive to health protection. In this way coexistence is ensured for the long-term as well as the maintenance of biological diversity, in parallel allowing for societal participation and the protection of consumers, thus preservation of the societal-ethical aspects.

6. The presence of the principles of precaution and prevention with the legislation of genetic technology

During my research, I have come to the conclusion that the principles of precaution, prevention and co-operation are present within the applicable international, EU and Hungarian laws. The instruments of prevention range from reporting, registration, permitting, BAT to threshold limits.

6.1. A precondition for the efficient implementation of measures in the interest of sustainable development is the availability of an adequate IT system. The setting up of registries overlaps with the principle of co-operation. These can be done on an international, EU, member state or local level.

The international rules of registration are regulated by the Biosafety Clearing House. On an EU level, registration is the task of the Committee, while in Hungary, this is performed jointly by the Agricultural Biotechnology Center in Gödöllő (designated by the Ministry of Rural Development), the Agrobotanic Institute in Tápiószele and the Agricultural Administration Center. Regsitration is done on multiple levels, which assuming it is done efficiently, will serve the principle of prevention and precaution.

6.2. Reporting is also an instrument of prevention, which is not always separated from the regulations of permitting, since the law combines the two instruments in many cases. Within the Hungarian legislation, reporting is applicable in the process of registry of plants (within the jurisdiction of the MSzH). Within EU law, reporting is required in case of deliberate release of GMOs into the environment. The release is then not permitted until the authorities have conducted review of all documentation and completed their report (and granted approval thereto).

6.3. Permitting GMOs is a public act, which takes form in EU law. The process is initiated by a formal approach of the EFSA by the member states' relevant authority. Bearing in mind the principles of co-operation and prevention, EFSA informs all other member states and the Committee as well as the public is also granted access. The submission covers detailed documentation including a risk assessment in order to minimize risks. The final opinion of EFSA is then made public to all stakeholders.

As a result of my research, I classify permits in the field of genetic technology in the following groups: permits for activities in genetic technology, - for establishment of laboratories, - for cultivation; - for reproduction; and preliminary permits.
The main goal of all permits within the process is to minimize potential environmental- and health risks, and therefore it is pervaded by the principle of precaution. All application requirements aim to have a details assessment of all related risks. The final report of the authorities summarizes the terms and conditions as well as the limitations to any activity. The principle of precaution is further strengthened here by the public nature of the process (access of all stakeholders to information).

During my research, I have come to the conclusion that permits for cultivation (under the principle of coexistence) have certain characteristics that cannot be found among other environmental permits. The granting process is two-staged: in an initial step, the authority specifies the pre-conditions, thereafter the permit is issued once the neighboring farmers (within the security zone) have granted their respective consent (please see the corresponding figure in the main section). In summary, the implementation of the principle of coexistence is difficult, nevertheless the regulatory framework is deemed to be very detailed and satisfactory. The framework is focused on ensuring the co-operation between authorities and all other stakeholders. The principle of precaution is clearly reflected in the stringent Hungarian legal framework, which implemented a two-staged process.

6.4. Within the regulation of GMOs, BAT, BEP and GLP clearly support the principle of prevention and precaution. Within the regulation the term “technically inevitable” provides direction in the case of labeling. This is also supported by BAT, as it provides guidelines as to what is technically inevitable.
As an instrument of prevention and precaution, BEP has an important role in the regulation of GMOs, whether in the case of safe handling, storage, transport or consumption. Best practices are utilized in the field of R&D both in the areas of food and crop seeds. BEP is also present with regards to coexistence: the European Co-existence Bureau develops guidelines for co-cultivation in co-operation with the member states.
Best practice can also be found in the areas of reporting and product identification, although these regulations are not specified as best practice, their content, goal and meaning is intended to be such. Best practices can be found in the obligation to create a supervisory plan, as the integrated approach takes the risk assessment and time factor into consideration.

In the area of best practices in a laboratory environment, regulation can be split into: 1. conditions regarding personnel, 2. laboratory activities, 3. documentation of laboratory activities, 4. co-operation among laboratories and 5. mediation procedures in case of disputes. Within the EU, the legal framework regulates best practices with a high degree of thoroughness, within the sense of precaution.
As we saw during the analysis of the subsectors of the law, the principle of precaution was always in combination with an additional environmental principle (e.g. integration, participation, co-operation etc.). Within the best practices of laboratories the regulation combines the principle of precaution with that of responsibility.

6.5. It can be established that regulation is divided into three large groups when assessing an acceptable degree of usage of GMOs: regulations specifying threshold limits (food and crop seeds containing GMOs), role of threshold limits in the case of substantial equivalence; and regulations defining the security zones.
The regulations relating to threshold limits in the case of food and crop seeds provides a certain degree of flexibility as specific limits can be adjusted. The other aspect worth mentioning is that the burden of proof lies with the user of GMOs.

6.6. Another preventive characteristic of the regulatory framework is that the authority overseeing genetic technology can order the establishment of a security zone in order to ensure the protection of the environment (physical mixing, pollution via pollen and other sources of pollution make it necessary to separate the areas with GMO cultivation from those without). In addition, the term of a security zone has been implemented.

6.7. In the case of sampling by the authorities, it is important to pre-define the scale of the analysis that the monitoring authority should conduct as well as which actions can be taken based on the results. It would be practical if this was implemented in the domestic regulations as well.

6.8. The EU has implemented a forward looking and flexible regulatory framework by introducing traceability and labeling for all GMOs (food, crop seed etc.); sanction for the breach of regulations must be implemented by the member states though. The EU hereby established a framework, the details of which can be developed by the member states taking

its specific political-economic environment into consideration. This increases the efficiency and enforceability of the norm ultimately supporting prevention.

6.9. The rules of control also serve prevention, as the authority empowered to conduct controls has numerous instruments to enforce the law. It can be said that the regulation includes the rules of control and the respective sanctions in a comprehensive and cohesive manner. Sanctions must be fulfill the criteria of being efficient, proportionate and preventive.

6.10. The international co-operation in the establishment of the framework that regulates genetic technology is crucial, as it affects mankind on a global scale; certain institutions (FAO, WHO, WTO, EFTA) have a superior role therein. The rules of co-operation as set out in the Cartagena protocol can be divided into the following groups: the direct and indirect rules of co-operation; respecting the interests of developing countries in the drafting and implementation of GMO regulation, information exchange and –obligation; development of co-operation and co-operation of gene pools.
The international co-operation spreads across many areas, of which we have selected plant variety as it is highly developed.
The regulations surrounding the obligations of reporting clearly support the principles of precaution and co-operation. I have summarized my findings relating to the reporting obligations in a table for ease of use.

6.11. Co-operation within the EU is impossible without appropriate registries and integrated workflow coordination. The common characteristic of the regulatory frameworks as defined by the various policy areas, the regulations pertaining to the cross border transport of GMOs where consultation is crucial. The same applies to the co-operation in the area of genetic resource protection. The EU's role is threefold: it broadens the databases of the member states; it co-ordinates activities and finally adds the EU's directive thereto. The co-operation of laboratories can be characterized by the strive for stability and efficiency. The regulations of co-operation within the premise of coexistence can be divided into two areas: co-operation by way of accepting academic training certifications and co-operation during the establishment of a legal framework.
The Cartagena Protocol has strict rules for the event of publication of scientific data. Two kinds of solutions exist: in the case of products, member states implement the necessary security measures and then inform the Committee and all other member states. In the case of

foods, the same method applies, with the addition that they have the possibility to limit (or even prohibit) commercialization.
In the case of questions relating to ethical areas, a consultation can be called in case it is initiated by the European Commission, the Parliament, the Council, the Committee or a member state.
Co-operation (under the principle of precaution) is a strong instrument in the protection against potential risk to the environment or human health, but only if it is based on continuous, efficient consultation.

7. Environmental risk assessment in light of the principle of precaution for sustainability

7.1. The preservation of human health is the utmost priority of any EU policy and/or activity. The right for human health also includes the right for food safety. Accordingly, we can see that the regulations pertaining to environmental risk assessment and –management overlap with the principles formulated by the European Court. The European Court also states that the environmental risk assessment of each case needs to be reviewed separately with the highest degree of scientific approach, in line with the principles of precaution and protection (of human health).
This risk assessment has three goals: the definition and assessment of potential risks; to decide whether risk management is necessary and lastly to provide the possibility to define the means of risk management.

7.2. During traditional toxicological inspections, the potential effect is measured using 50-100 times stronger amount than the standard dosage. A similar test would (in the case of GMOs) fully disrupt the nutritional balance of these products, as a result of which lower limits were introduced. These lower limits in turn make the precise risk assessment more difficult. This is the reason that new legal framework is needed, along with new directives as to the control of such products.

7.3. Besides biochemical inspections environmental impact studies and constant control and monitoring are an important part of environmental risk assessment processes. Within the international regulations obligations arising from risk assessments are exchange of information and the scientific approach to the inspections.

7.4. It is crucial that a unified scientific methodology is implemented for environmental risk assessments. Whilst substantial equivalence is key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself. As there are still a number of unanswered questions around GMO activities, and whilst there is a Pan-European network of reference laboratories, risk assessment procedures are not regulated uniformly.

During my research, I believe to have uncovered a contradiction here, specifically the principle of precaution, which is a preamble of the GMO directives. The current regulation foresees a risk assessment conducted by the reporting party, which is then repeated by the authorities and EFSA, yet there is not a transparent and uniform directive as to these procedures. EFSA's activities have been questioned for their transparency and trustworthiness.

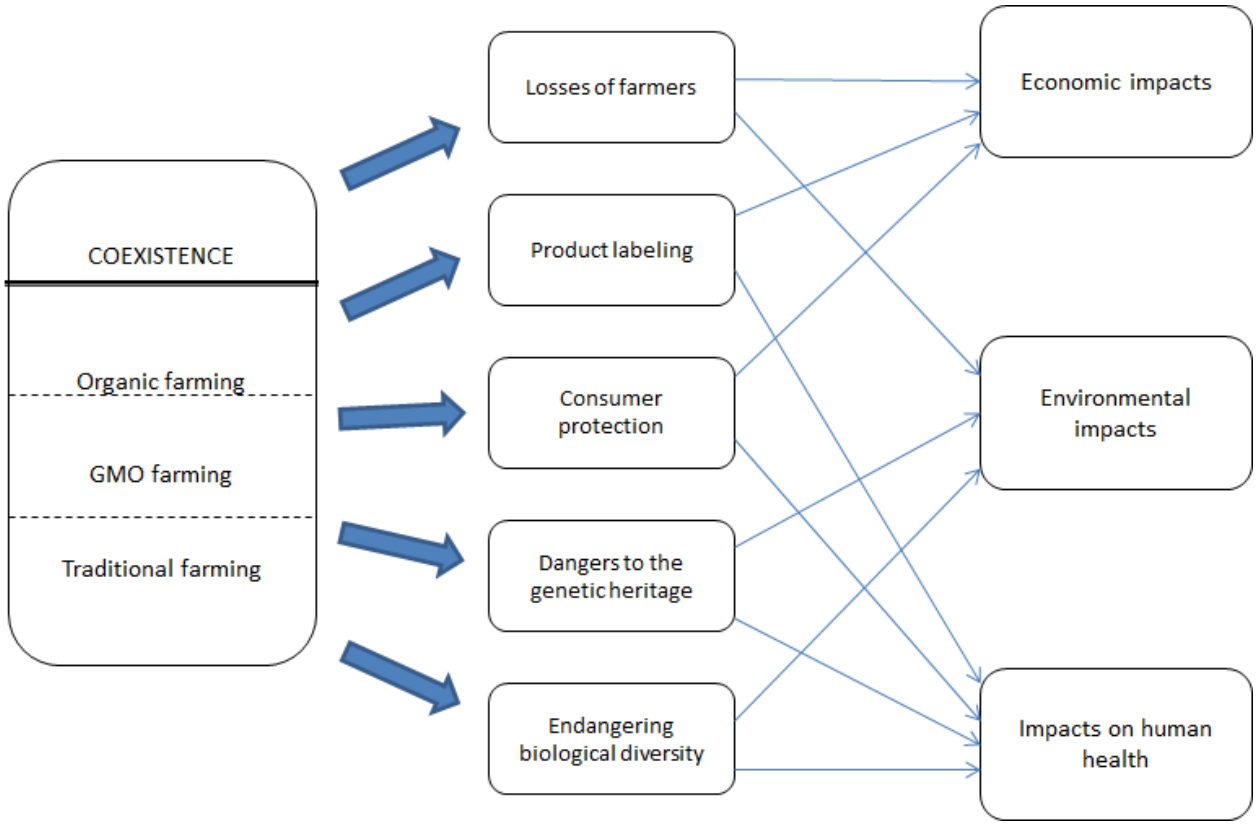
7.5. Risk assessment is comprised of appraisal, management and communication. There are a number of international institutions that participate in the establishment of the relevant guidelines. The ultimate responsibility lies with the members of industry, cultivators and the authorities.

7.6. As a result of my research, I can state that the Cartagena Protocol, being the basis for the regulation of GMOs, complies with the principles of precaution and protection of human health. There are three areas though which are not sufficiently compliant and hence represent a shortcoming. In one case, where the Protocol refers to GMO "being probably not dangerous", nonetheless the term probably is not discussed further. Here there is a breach of the principles of precaution, - the highest level of protection and - protection of human health are not sustained. Another shortcoming is that if there is a lack of scientific certainty, the importing state has the authority of deliberation, in contrast of the principles of precaution and – the highest level of protection. The third shortcoming is the opportunity for the importing state to act in line with its domestic regulations, without the pre-condition that those need to be in compliance (at least as stringent) with international regulation. Although the environmental risk assessment is the responsibility of the importing state, this would neither coincide fully with the principle of precaution nor with the protection of human health.

8. Coexistence

8.1. As part of sustainable development it is a preamble that cultivators (whether traditional, bio or using GMOs) should maintain their independency and reason for existence. This serves the interest of today's and future generations, contributing to the maintenance of biological diversity. Coexistence refers to the side-by-side use of various technologies for cultivation and the preservation thereof.

The following chart depicts the interrelated influence of various factors in a system methodology in the sense of coexistence.



8.2. The Hungarian coexistence regulation is one of the most stringent among the member states. In order to avoid mixing, GMOS cultivation is only allowed once the necessary legally binding permits have been obtained, which is a result of a two-staged process. The efficacy of such system remains questionable.

8.3. After pressure from the member states in 2009, the European Commision issued a directive (2010/C 200/01) for the establishment of rules for coexistence. According to the directive, member states can take the necessary actions to avoid the unwanted occurrence of GMOs in products; consumers and cultivators can choose among available technologies

(traditional, bio or GMO); and the EU's permitting processes should be based on scientific approach. It also formulates the principle of proportion, whereby actions to avoid the undeliberate appearance of GMOs among other plants should be proportionate with the goal that is to be achieved.

8.4. It can be said that the framework of coexistence does not regulate at which level, in which legal form and what will happen to GM-free areas.
In my opinion, the area of coexistence should be regulated in brief succinct regulation decree-type regulation, which would enable the member states to limit or prohibit the application of GMOs in their agriculture. The regulation must also include a very efficient communication system (especially along their natural borders). Beyond the aforementioned, member states should establish their own frameworks pertaining to coexistence; where the Hungarian two-staged system (which implements the principles of precaution) could serve as an example to follow. Such an EU-wide regulation would make certain changes necessary to the international frameworks, specifically the WTO-regulations.

8.5. The Committee's recommendation in connection with this subject is important, as the said document originally would not modify the process of permitting, but would allow for member states to decide whether they wish to allow the cultivation of genetically modified plants on their territory and without a emergency measures. Actions of member states are difficult to defend in front of the European Court and WTO if they are supported by ethical or moral criteria.

9. The application of the principles of precaution within the practice of the European Court of Justice

9.1. A "quasi-precedent case" of the European Court of Justice
Although the pollen at thise preliminary decision-making process derived from a variety of genetically modified maize, is not a GMO as such, as it has lost its ability to reproduce and is totally incapable of transferring the genetic material, the food supplements and honey containing itmust be regarded as 'food for human consumption containing ingredients produced from GMOs'within the meaning of the Regulation. On this point, the Court primarily takes as a basis a teleological interpretation of the concept of 'ingredient', in the light of the objective of protecting human health pursued bythe Regulation and the need to avoid products containing significant quantities of genetically modified material escaping any

safety checks. The honey and pollen-based food supplements must therefore be subject to assessment and authorisation. The circumstance that the introduction of the pollen was adventitious and not intentional has no influence on the classification of the products at issue or on the applicability of the authorisation scheme. Likewise, the obligation of authorisation exists irrespective of the proportion of genetically modified material contained in the product in question. On the other hand, labelling is compulsory only beyond a tolerance threshold of 0.9% per ingredient.

9.2. Additional court rulings

The lesson from the court ruling C-6/99 is that the Member State authority loses it competency to rule in case the Commission is involved. At the same time, the principle of precaution is not breached, because the risk assessment is completed by the authority of the Member State. The respective national authority has the possibility to decide not to forward the case to the Commission. The process guarantees are in compliance with the principles, in other words the Court has maintained the legitimacy of the GMO regulation and the authority of the Commission.

In the preliminary decision-making process C236/01, the Commission insisted on the applicable regulation at the time of the state of affairs. The Commission accepted the argumentation whereby it is the task of national courts to prove the respective dangers.

In the cases T-366/01 and T235/04, respectively, the Commission abstained from allowing to officially qualifying certain areas as GMO-free. The most important argument was that farmers should be granted the freedom of choice regarding seed crops.

In the case C-165/08, the Polish argument’s main element was of moral-ethical nature. Taking the argumentation into consideration, the Court has decided that the ethical aspects were not sufficient to decide in favour, as they are too general in their nature and combine the principle of protecting human health and the environment, which have already been considered in the directives 2001/18/EC and 2002/53/EC, respectively.

III. List of Publications

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