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THE IMPORTANCE OF AUTONOMY OF EUROPEAN UNION MEMBER STATES WITH REGARD TO THE USE OF GENETICALLY MODIFIED ORGANISMS ON THE RIGHT TO HEALTHCARE – AN ANALYSIS OF JUDGEMENTS OF THE COURT OF JUSTICE OF THE EUROPEAN UNION

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Abstract The European Union Member States (hereinafter: EU MS) have the possibility of restricting or banning the cultivation of GMOs under the Directive 2015/412 but under certain conditions. EU MS must also pay attention to the provisions of the Treaty on the Functioning of the Euro-pean Union or Treaty Establishing the European Community (hereinafter: TFEU), the provi-sions relating to the free movement of goods, which is one of the key objectives of the func-tioning of the European Union. This contribution is based on the data obtained from an analy-sis of Court of Justice of the European Union (hereinafter: CJEU) cases concerning the use of genetically modified organisms (hereinafter: GMO(s)). The analysis highlights the link between environmental risk assessment and the right to healthcare. The purpose of this paper is to make the individual aware of the possibilities they have regarding the use of GMOs.

Keywords
Directive 2001/18, Directive 2015/4120, Directive 2018/350, high level of protection of human life and health, possibility of restricting or prohibiting the production of GMOs, free movement of goods, environmental risk assessment

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1 Introduction

The use of GMOs in the daily lives of the people of the European Union (hereinafter: the EU) has recently become quite a topical issue. Some oppose the use of GMOs (*e.g.* direct use of GMOs, indirect use of GMOs), while others agree or support the use of GMOs.

The purpose of this article is to present a simple area of GMO use, in particular, to present key concepts that help explain this phenomenon. Thus, the beginning of this article first defines the legal framework for the use of GMOs, which applies to all Member States. This explains the autonomy of each EU MS in the use of GMOs. In order to make the interpretation of the use of GMOs in each EU MS accessible and understandable to the reader, the article analyses the judgements of the Court of Justice of the EU (hereinafter: CJEU) dealing with the use of GMOs.

The analysis is based on the correlation between the first variable, *i.e.* risk assessment for the use of GMOs and another variable: *i.e.* the right to healthcare of the individual. The analysis also showed that the correlation between the two variables shows that individual EU MS are aware of possible violations of EU law as defendants. However, due to the interpretation of the precautionary principle, they act differently than required by the legal framework for GMO use. Defendants, in most cases, receive warnings, reminders or fines from the CJEU. In order to maximise the health of humans, animals and plants in this area, it is necessary to respect every judgement and implement it as such (*e.g.*, adoption of legislation on the use of GMOs; repayment of fines; transparent labelling of products with GMO label, *etc.*).

The analysis also showed that the variable, *i.e.* the risk assessment for the use of GMOs in EU judgements, needs to be further specified. Moreover, the above-mentioned judgements of the CJEU have been analysed mainly in terms of interference with the individual's right to health care. This analysis of judgements was prepared in the context of writing the author's doctoral dissertation (Meško Kuralt, 2021b: 188-187).

2 On the autonomy of EU MS regarding the use of GMOs in general

In general, products labelled as GMO-free are those products that did not contain GMOs in their production (*i.e.*, from the production of raw materials for the product to the processing and production of raw materials into a product). On the other hand, there are products that do not have this label, which can result in two options. The first option is a product that does not have a GMO-free label but contains GMOs, and the second option is a product that does not have a GMO-free label and does not contain GMOs. Regardless of labelling, products on the market can have certain effects, which can be positive or negative (Meško Kuralt, 2021a: 44).

A GMO is an organism whose genetic material is altered by processes that alter the genetic material differently than it does under natural conditions through crossbreeding or natural recombination. All GMOs authorised for import into the European market are pre-screened by the European Food Safety Authority – EFSA, which follows professional guidelines. Moreover, the legislation of EU MS stipulates that products produced with or from GMOs must be clearly labelled (Neuwirth and Svetlicinii, 2015: 330-334).

It is generally accepted that the 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 repealing Council Directive 90/220/EEC[1] (hereinafter: Directive 2001/18) and Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[2] (hereinafter: Regulation 1829/2003) established a comprehensive legal framework for the authorisation of GMOs, which is fully applicable to GMOs, for cultivation in all EU MS. Under this legal framework, the risk for each GMO is thus assessed separately before it is placed on the market. This shall take into account direct and indirect[3] effects, immediate and delayed effects, and cumulative long-term effects on human health and the environment (Meško Kuralt, 2021b:207-209).

[1] OJ L 106, 17/04/2001.
[2] OJ L 268, 18/10/2003.
[3] These are the effects that relate to primary effects on human health or the environment. They arise from the existence of GMOs as such and not from a causal chain of events (Annex II to Directive 2001/18).

The main purpose of the GMO approval process is thus to ensure a high level of protection of human, plant and animal life and health and to establish a safe environment, thus establishing the interests of consumers and, at the same time, the efficient functioning of the internal market (Weatherill, 2011: 833-834; De Ruijter, 2019:3-8).

In 2015, the Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18 as regards the possibility for the EU MS to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory[4] (hereinafter: Directive 2015/4127) entered into force, introducing in EU MS the possibility of restricting or banning the cultivation of GMOs as an exception to the rule defined by the Directive 2001/18 (*i.e.* the opt-out concept). This exemption only applies if an EU MS also requires a restriction or prohibition under certain conditions laid down in advance. As this is a complex procedure, the author will first present the procedure for enforcing such restrictions or prohibitions followed by individual court cases that are already dealing with this procedure. In reviewing court cases, the author mainly focused on the conditions for accepting a restriction or prohibition, the reasons for accepting or rejecting a restriction or prohibition, and possible sanctions for non-compliance with an individual restriction or prohibition at the national level.

Two amendments should be highlighted as important innovations of the Directive 2015/412. The first concerns the adoption of appropriate measures to prevent possible cross-border infections in neighbouring EU MS, where the cultivation of GMOs is prohibited. The second change concerns the cultivation of GMOs. In other words, an individual EU MS may ask the European Commission during the approval process or during the renewal of an approval to adjust the geographical scope of the GMO so that all or part of the territory in each EU MS is excluded from cultivation. This means that an individual EU MS applies for an exemption, to which it receives a reply from the European Commission. In doing so, it must pay attention to stating the valid reasons why an individual EU MS wishes to apply this exemption in all or part of its territory. EU MS may, during the authorisation procedure for a particular GMO or during the renewal process, require that the

[4] OJ L 68, 13/03/2015.

geographical scope of the written authorisation be adjusted so that all or part of the territory of each EU MS is excluded from cultivation. The European Commission also decides on this request by issuing a written approval and an approval decision adopted in accordance with Articles 7 and 19 of Regulation 1829/2003. If the EU MS does not request amendments, it may take measures to restrict or prohibit the cultivation of GMOs or groups of GMOs if such measures comply with EU law, which is justified, proportionate and non-discriminatory. These conditions are thus based on compelling reasons, which are:

- environmental policy objectives;
- spatial planning;
- purpose of the land;
- socio-economic effects;
- avoiding the presence of GMOs in other products, without prejudice to Article 26a of the Directive 2015/412;
- objectives of agricultural policy;
- public order (Article 26b of Directive 2015/412).

Despite the fact that the opt-out concept gives EU MS greater freedom to take measures under Article 26b of the Directive 2015/412, they are limited by legal rules, especially the principle of the primacy of EU law over the law of individual EU MS (Klemenčič, 2010:71-73; Knez, 2008: 9-11).

If an individual EU MS decides again to grow GMOs on its territory, it shall address the application to the competent authority that issued the written authorisation or to the European Commission to amend the geographical scope of the authorisation or authorisation decision accordingly. It is important to emphasise that restrictive or prohibitive measures do not affect the free movement of authorised GMOs as or within products (Article 26b of Directive 2015/412).

The Directive 2015/412 also provides for transitional measures. From 2 April 2015 to 3 October 2015, it was therefore considered that an individual EU MS could request an adjustment of the geographical scope, but only if the application or permit was issued before 2 April 2015. The European Commission submitted a request

from an EU MS. Immediately to another EU MS. If the application is still ongoing and the applicant does not confirm the geographical scope, the geographical scope shall be adjusted accordingly. Written approval is then issued because of the adjusted geographical scope of the application. However, where a permit has already been issued, and the holder of the permit does not confirm the geographical scope, the permit may be amended accordingly. In the absence of any requirement to restrict or prohibit the cultivation of GMOs or if the notified or authorised holder confirms the geographical scope, the procedure laid down for cultivation shall apply mutatis mutandis. However, the provisions on transitional measures do not affect the free movement of goods produced from GMOs or GMO goods (Article 26c of Directive 2015/412).

As Devos *et al.* (2017), in the field of GMO authorisations, evaluations are also carried out, which are included in the annual reports on environmental monitoring of GMOs after placing on the market (Post-Market Environmental Monitoring - PMEM). These reports thus provide a stricter and standardised approach, regardless of whether it is an approval of a new GMO or an extension of a new GMO. In particular, the recommendations aim to assist in obtaining evidence and to ensure that as many relevant resources accompany the notified application for GMO approval/renewal for GMOs as possible, thus reducing bias. Such recommendations thus primarily promote the transparency of data on GMO use monitoring.

In Slovenia, The Restriction or Prohibition of the Cultivation of Genetically Modified Plants Act[5] (hereinafter: Restriction Act of the Cultivation of GMP) entered into force in 2015, which determines measures for the possibility of restricting or prohibiting the production of genetically modified plants (hereinafter: GMP), conditions and procedures for the adoption and abolition of these measures, competent authorities and cooperation between them. The Restriction Act of the Cultivation of GMP also determines the manner of notifying the European Commission and EU MS of the decisions taken regarding the restriction or prohibition of GMP production and the commission for assessing the reasons for restricting or prohibiting GMP production, its tasks and responsibilities (Article 1 of the Restriction Act of the Cultivation of GMP).

[5] Official Gazette of RS, No. 69/15.

For Slovenia, the production of GMPs may be restricted or banned if one of the following reasons is identified:

a) is or could be contrary to the adopted objectives and measures of the agricultural policy, environmental policy or spatial planning policy, in particular, if the production of GMPs is linked to issues of national, regional or local importance, such as:

- maintenance and development of agricultural practices that ensure the sustainable use of production potentials in agriculture, especially agricultural land,
- protection of agricultural land against a permanent change of use,
- preservation and development of existing local agricultural structures,
- protection and preservation of certain natural landscape features and areas with typical cultural landscape elements,
- protection and conservation of biodiversity, including the conservation of certain habitats or specific ecosystem functions, and
- protection and preservation of soil and water quality;

b) causes or is likely to create obstacles or additional burdens in the implementation of the policies referred to in the previous point;

c) has or could have negative economic and social effects on agriculture[6] or the economy because:
- effective measures could not be taken to prevent the unintentional presence of genetically modified crops in other crops,
- GMP production would prevent growers from choosing between conventional and organic production and GMP production,

[6] Given that the development of global agriculture is one of the key areas of sustainable development, i.e. it will be necessary to increase the quantity and quality of food production, agriculture must become more sustainable by reducing the use of fertilizers and plant protection products. This goal can only be achieved through sustainable intensification, which includes genetic improvement of plants so that they become more tolerant of biotic and non-biotic stressors, make better use of photosynthesis and nutrients in the soil, and increase the nutritional value of basic crops (Aerni, 2019).

- disproportionately high costs would be incurred in the production of non-GM plants due to the avoidance of the presence of GMOs in these plants and their products, and
- the cultivation of GMPs would be contrary to public opinion or cultural tradition;

d) is or could be in conflict with the provision of public order if the unhindered exercise of rights and fulfilment of duties under the Constitution and laws is endangered (Article 4 of the Restriction Act of the Cultivation of GMP).

The above-mentioned reasons may be used individually or in combination, except for the reason referred to in point d, which cannot be used in isolation. The following measures may be taken to restrict or prohibit the cultivation of GMPs:

- geographical exclusion of GMPs still in the process of being approved or
- a ban on the production of already approved GMPs in the entire territory or part of the territory of the Republic of Slovenia (Article 4 of the Restriction Act of the Cultivation of GMP).

Measures may be taken for a specific GMP or a group of GMPs. If it is established that the reasons for taking measures of geographical exclusion or prohibition of production in the entire territory of an individual EU MS have ceased, the government shall decide to submit a request to the European Commission to reintegrate all or part of the territory of the Republic of Slovenia. to authorise the placing of GMOs on the EU market for the purpose of GMO cultivation or to adopt a regulation governing the cessation of the ban on the cultivation of a particular GMP and inform the European Commission and other EU MS (Article 10 of the Restriction Act of the Cultivation of GMP).

3 The legal significance of the correlation between risk assessment in the GMO approval process or later in the use of GMOs and the right to healthcare in the broadest sense of the word

In the EU MS, the use of GMOs is regulated in two different procedures. Pursuant to Directive 2001/18, decisions are thus taken on the deliberate release of GMOs for any purpose other than placing them on the market (**first procedure**) and the procedure for placing GMOs as or on products on the market (**second procedure**). In accordance with Regulation 1829/2003, a procedure is underway for the approval of genetically modified food and genetically modified feed (**third procedure**). The first procedure for deciding on the deliberate release of GMOs for any purpose other than placing them on the market is governed by the standard authorisation procedure (Article 6 of Directive 2001/18). If changes occur, in particular, if sufficient experience is gained with the release of certain GMOs into certain ecosystems and the required conditions are met, the procedure may be changed (Article 7 of Directive 2001/18).

Directive 2001/18 also lays down the procedure for amendments and new information. This is the procedure to be followed when there is any change or unintentional change in the deliberate release of GMOs after authorisation or when new risk information becomes available during or after the authorisation procedure (Article 8 of Directive 2001/18).

Genetically modified products or GMOs from products placed on the market (second procedure) are also subject to the normal procedure (Article 14 of Directive 2001/18).

I believe that this is a more normatively demanding procedure than the decision-making process on the deliberate release of GMOs.

The process of placing GMOs on the market thus contains information on data and results obtained from research and studies related to the impact of the release on human health and the environment; environmental risk assessment; the conditions for placing the product on the market, the proposed approval period, which may not exceed ten years; monitoring plan; labelling proposal (Article 13 of Directive

2001/18). One of the important topics attached to the authorisation process is the environmental risk assessment of an individual GMO. The evaluation can thus be carried out based on an assessment of direct or indirect effects, immediate effects or delayed effects. The evaluation shall be performed in accordance with Annex II to Directive 2001/18 (*i.e.*, in accordance with the characteristics, methods and principles for environmental risk assessment).

The third procedure for authorising the placing on the market of GM food and GM feed also requires a scientific risk assessment demonstrating that the GMO products are as safe as those of non-GMOs. In addition, a labelling proposal and a method for determining GMOs must be submitted for authorisation. A monitoring plan is not mandatory for this process. As with the procedures in Directive 2001/18, this procedure also considers that the safety requirement is since the use of GMOs must not have or have no harmful effects on human, animal, plant, or environmental health (Article 4 and 16 of Regulation 1829/2003).

4 The link between risk assessment and the right to healthcare - an analysis of the case law of the CJEU

The connection between the environmental risk assessment posed by a particular introduction of GMOs into the environment, either by deliberate release or by the way the GMO is placed on the market, and the right to healthcare were analysed in case law between 2003 and 2018, pending before the CJEU.

It is generally accepted that the CJEU decides on cases referred to it. The most common areas of consideration are interpretations of EU law. It should be added that individual national courts of EU MS ensure the correct application of EU law, but if there is a different interpretation and application of EU law or if a national court has doubts about the interpretation or validity of EU law, it is possible to ask for clarification. In the same way, it is also possible to check if a national rule or practice is in line with EU law. The court also deals with law enforcement or infringement proceedings. These are lawsuits against individual EU MS for violating EU law. The Commission can bring an action before the CJEU, but it can also be brought by another EU MS. If the CJEU finds an infringement, the EU MS must

remedy it immediately; otherwise, a new procedure will follow in which it can (may) impose a fine on the EU MS (Greer *et al.*, 2020: 10, 101-103; European Union, 2020).

In addition to deciding on actions for failure to fulfil obligations by an EU MS (Articles 258 and 259 of the Treaty on the Functioning of the European Union or Treaty Establishing the European Community[7] (hereinafter: TFEU)) and on actions for non-enforcement of a judgement (Article 260 TFEU), the Court also deals with actions for annulment (Article 263 TFEU) and actions for failure to act (Article 265 TFEU). Preliminary decisions (Article 267 TFEU) confirm the compliance of the international agreement with EU law (Article 218 TFEU) (Avbelj, 2011: 35-54).

The CJEU also deals with actions for damages in connection with sanctions by the EU institutions. Thus, anyone whose interests are harmed by the acts or omissions of the EU institutions, or their staff can bring an action against them before the CJEU (European Union, 2020).

In other words, if an EU MS does not implement the directive within the prescribed period or does not implement it properly, the omission may lead to the liability of the state to the individual. If an EU MS does not transpose the provisions of the directives into its national law in time and the individual loses certain rights, the state is (objectively) liable for damages. The compensation that the state must pay to an individual thus compensates for the loss of rights that the individual cannot exercise (Ferčič *et al.*, 2011: 104-109).

Most of the analysed cases were referred to the CJEU for interpretation of EU law based on a reference for a preliminary ruling (10 cases out of a total of 16 cases). Among the court cases considered are two cases (*i.e.* Case C-439/05P and Case C-454/05P[8]) in which the annulment of an EU legal act was requested (Corcione, 2018: 345-356**).**

In four cou

rt cases, the CJEU ruled on default. In the first case, the court ruled on non-compliance, and the Court referred to the defendant, *i.e.* the French Republic (Case

[7] OJ C 306, 17/12/2007.

[8] *Land Oberösterreich, Republic of Austria v Commission of the European Communities*; ECLI:EU:C: 2007:510.

C-121/07[9]). In the first case, the CJEU had decided that the applicant pays a lump sum of EUR 10 million, and in another case (Case C-165/08[10]), the Republic of Poland, as the applicant, pays all its own costs and 2/3 of the flat-rate costs of the other parties. In this case, no other fines were imposed. Also, in the third and fourth cases (Case C-281/11[11], Case C-478/13[12]), the CJEU did not impose additional financial sanctions on the defendant, *i.e.* in both cases, the Republic of Poland. From this, it must be concluded that with the exception, *i.e.* in Case C-121/07, the CJEU does not assess monetary sanctions but only decides on the correctness of compliance or non-compliance with obligations under EU law. This means that a new procedure whereby the CJEU would impose a fine on a country for failing to remedy an infringement is not a normal procedure. For a proven correlation between variables, *i.e.* during the environmental risk assessment and the right to healthcare, these court cases need to be analysed in more detail in terms of content (see Table 1). Given the existence of the first variable, *i.e.* environmental risk assessment, the author notes that the second variable is also changing (*i.e.* the right to healthcare). The first variable, therefore, depends on the second variable. In the author's opinion, this correlation is expressed with emerging diseases, with potential diseases that could arise if GMOs were released, or with deliberate releases into the environment for any reason, such as placing on the market or placing on the market as a product of products or other adverse effects on humans, animals, plants, or the environment (Meško Kuralt, 2021b).

As regards the definition of environmental risk assessment,[13] which is regulated in more detail in Annex II to Directive 2001/18, it should be noted that this is an abstract concept of assessing the (harmful) effects of GMOs on human health and

[9] *Commission of the European Communities v French Republic*, ECLI: ECLI:EU:C:2008:695.

[10] *Commission of the European Communities v Republic of Poland* (Genetically modified organisms - Seed - Prohibition on placing on the market - Prohibition on inclusion in the national catalogue of varieties - Directives 2001/18/EC and 2002/53/EC - Reliance on ethical and religious grounds - Burden of proof) *ECLI:EU:C*:2009:473.

[11] *European Commission v Republic of Poland* (Failure of a Member State to fulfil obligations - Contained use of genetically modified micro-organisms - Directive 2009/41/EC - Incorrect and incomplete transpositio) ECLI:EU:C:2013:855.

[12] *European Commission v Republic of Poland* (Manualment of Nature - Directive 2001/18 / CE - Distribution of structural modalities (OGM) in the environment - Mise sur le marché - Article 31, paragraph 3, sous b) - Localization of OGM cultivates - Obligation d 'Information des autorités compétentes - Obligation d'établir un registre public - Coopération loyale) ECLI:EU:C:2014:2253.

[13] The main objective of the procedure for the authorisation of genetically modified food under Regulation 1829/200 seeks to ensure that the placing on the market of such products does not pose a risk to human or animal health or the environment. From this point of view, scientific risk assessment is at the heart of the process, so any authorisation to place a product on the market must be duly substantiated, based on a scientific assessment issued by EFSA (European Commission, 2015). Articles 7 and 19 of Regulation 1829/2003 provide that, in addition to the EFSA opinion, the EC may take into account "other legitimate factors relevant to the present case".

the environment. The environmental risk assessment thus divides the effects into potential effects, direct or indirect effects, and immediate or delayed effects that the deliberate release or placing on the market of GMOs may affect human health or the environment. In preparing the environmental risk assessment, in addition to the precautionary principle[14], general principles should be taken into account, including:

- identified characteristics of the GMO and its use that could cause adverse effects;
- the environmental risk assessment must be carried out on a scientific basis and in a transparent manner on the basis of available scientific and technical data;
- the environmental risk assessment must be carried out on a case-by-case basis, which means that the information required may vary according to the type of GMOs concerned;
- if new information is available on the GMO and its effects on human health or the environment, the environmental risk assessment needs to be re-performed;
- findings on the changed risk assessment for the environment;
- determining whether risk management needs to be modified accordingly (Annex II to Directive 2001/18).

[14] Vos and De Smedt (2000) state in the report that the effects of the precautionary principle take precedence over other economic interests. The main effect of the precautionary principle thus relates to the protection of public health, the provision of safety, and the maintenance of a healthy environment. The authors also analyse the judgments of the CJEU and the General Court and note that decisions relating to the precautionary principle fall into three categories, namely: the reasons for initiating the application of the principle, considerations that the regulator must take into account when making decisions, and requirements to be met by legal acts based on the principle. The authors add that the CJEU must first decide whether the reference to the precautionary principle was justified. Next, the CJEU defines the precautionary principle and examines the elements that justify the application of the precautionary principle. At this stage, the CJEU first examines whether the conditions for the application of the precautionary principle based on sufficient scientific (uncertainty) are met. At the same time, the conditions ensure that the regulator does not make decisions based on purely hypothetical risks. Furthermore, a decision is made on the indications of the requirement for scientific assessments and societal preferences. As the CJEU finds it difficult to decide on such topics, the test at the CJEU is limited to obvious errors. The last, third factor that the CJEU takes into account in its decisions on the precautionary principle is whether the decision-making measures are proportionate and not geared towards a 'risk-free' approach (Vos and De Smedt, 2000).

The use of the methodology for determining the environmental risk assessment is divided according to the characteristics of the GMO and the release and into the pre-prescribed steps of the environmental risk assessment. Thus, the environmental risk assessment is conducted case-by-case (European Food Safety Authority Panel on Genetically Modified Organisms, 2013).

In doing so, the relevant technical[15] and scientific details relating to the recipient or parental organism, the GMO, the intended release, the environment or the interaction must be taken into account. As required by the Directive 2001/18, information on releases of similar organisms or organisms with similar characteristics and their interaction with similar environments may be helpful in assessing the risk to the environment (Annex II to Directive 2001/18).

In order to form a final environmental risk assessment, it is necessary to follow the following steps, namely:

- first step - identification of characteristics that may cause adverse effects (*i.e.* to determine the characteristics, it is necessary to compare the characteristics of GMOs with the characteristics of the unchanged organism, even if there is a low probability of their occurrence);
- second step - evaluation of the possible consequences of each adverse effect, if any (*i.e.* an evaluation that must be assumed; the extent of the consequences is likely to be influenced by the environment and the mode of release);
- third step - evaluation of the probability of occurrence of each specific possible adverse effect (*i.e.* characteristics of the environment in which the GMO is intended to be released and the mode of release);

[15] Genetic modification techniques are: nucleic acid recombination techniques; techniques involving direct input of hereditary material; cell fusion or hybridisation techniques in which the fusion of two or more cells in non-natural ways forms living cells with new combinations of hereditary genetic material. However, techniques that are not considered to result in genetic modification are: "in vitro fertilisation" (*i.e.* artificial insemination) and natural procedures such as: conjugation, transduction, transformation, and induction of polyploidy. Genetic modification techniques also include the technique of mutagenicity and the fusion of plant cells of organisms that can exchange genetic material through traditional cultivation methods, which are not used as such by the Directive 2001/18 (Annex I A to Directive 2001/18).

- fourth step - assessment of the risk posed by each identified characteristic of the GMO (*i.e.* such an assessment must be made with the most recent state of combining the likelihood of adverse effects and the magnitude of the consequences, if any);
- fifth step - application of risk management strategies due to the deliberate release or placing on the market of GMOs;
- sixth step[16] - identification or evaluation of the overall risk of the GMO (Annex II to Directive 2001/18).

The need for a preliminary environmental risk assessment to take into account all the above steps is also agreed upon by international researchers who conducted a study in 2017 confirming that GMPs are the subject which preliminary environmental risk assessments are based on in order to identify potential environmental impacts (Arpaia *et al.*, 2017:123-132).

Another study from 2019 (Giraldo et al., 2019) should be highlighted, which points out that the aim of the environmental risk assessment is to assess the impact of products from the new crop variety on human, animal and environmental health. The authors of the study also point out that, although many studies have been published on the risk assessment of GM food, little research on GM feed has been taken into account, although between 70 % and 90 % of all GM crops and their biomass are used as animal feed. In addition, they add that GM feed is only used for animal feed, so the assessment of genetic changes may only be relevant for livestock feeding. Moreover, the Scientific Panel on Genetically Modified Organisms considers that seven other areas should be considered when preparing an environmental risk assessment:

- characteristics of relatives, including genetic transfer of plants to plants;
- transfer of plant genes into the microorganism;
- interaction of GMPs with target organisms;

[16] As follows from the Directive 2018/350, which amends the provisions of the Directive 2001/18, risk management strategies are considered to be written in terms of reducing hazards or exposures or both and are at the same time proportionate to the projected risk reduction. If possible, risk reduction shall be quantified. Where such a definition or assessment is not possible, a qualitative risk assessment (*e.g.* 'high', 'moderate', 'low' or 'negligible') shall be provided, and the extent of the impact explained for each category.

- interaction of GMPs with non-target organisms, including selection criteria, appropriate species and relevant functional groups for risk assessment;
- the impact of specific cultivation, management and harvesting techniques, including consideration of production systems and the reception environment;
- impacts on biogeochemical processes;
- effects on human and animal health (European Food Safety Authority, 2010).

Table 1: First and second variable – correlation

No.	Case law of CJEU	First variable (environmental risk assessment)	Second variable (right to healthcare)
1.	C-236/01[17] of 9. 9. 2003	Only on the basis of scientific knowledge can it be demonstrated that there is a risk of effects that may be dangerous to human health so that a simplified procedure for placing novel foods on the market cannot be carried out.	There is a risk of effects that may be dangerous to human health.
2.	C-132/03[18] of 26. 5. 2005	The exemption from mandatory labelling of GMO ingredients also applies to foods for particular nutritional uses for infants and young mothers, provided that their presence is due to accidental contamination and does not exceed a threshold of 1 %.	Accidental contamination (this cannot be prevented) and a pre-determined threshold (less than 1 %, otherwise labelling is required) are two phenomena that can have consequences for human health.
3. and 4.	C-439/05P and C-454/05P of 13. 9. 2007	In that case, the condition of scientific knowledge proving the existence of a specific problem has not been satisfied.	There is no correlation between the variables.
5.	C-121/07 of 9. 12. 2008	The Member State has not taken all the measures necessary to comply with the judgement concerning the failure to transpose the provisions on the deliberate release of GMOs into national law	Failure to comply with the judgement may cause damage to the environment and endanger human health.
6.	C-552/07[19] of 17. 2. 2009	The determination of the site of release is defined on the basis of all the information provided by the applicant, including	Potential effects of GMOs on human

[17] *Monsanto Agricoltura Italie and others*, ECLI:EU:C:2003:431.
[18] *Ministero della Salute v Coordinamento della associazioni per la difesa dellambiente e dei diritti degli utenti e dei consumatori in drugi*, ECLI:EU:C:2005:310.
[19] *Commune de Sausheim v Pierru Azelvandru*, ECLI:EU:C:2009:96.

No.	Case law of CJEU	First variable (environmental risk assessment)	Second variable (right to healthcare)
		information relating to the environmental risk assessment, which must not be kept confidential. The risk assessment is only feasible with full knowledge of the intended release; otherwise, the potential effects of the GMO on human health and the environment cannot be assessed.	health and the environment.
7.	C-165/08 of 16. 7. 2009	All necessary measures have already been taken in respect of each GMO, and the maize variety has already been entered into the common crop catalogue so that a Member State unilaterally prohibits the marketing of GMO seeds in breach of the provisions of Directive 2001/18.	Refusal to register a variety in the national catalogue is possible only if all appropriate measures have not been taken to avoid a risk to public health (this is certainly not the case when the variety has already obtained a permit issued under Directive 2001/18).
8.	C-442/09[20] of 6. 9. 2011	The term GMO does not include a substance that has lost its ability to reproduce and is therefore incapable of transferring genetic material. The limit value for the presence of GMOs in an individual component is 0.9%. If the value is higher, the product must be marked accordingly.	There is no correlation between the variables.
9.	C-58/10 to C-68/10[21] of 8. 9. 2011	An element of urgency to take emergency measures and the existence of a situation that is likely to pose a high risk.	Many risks pose an obvious danger to human health, animal health or the environment.
10.	C-36/11[22] of 6. 9. 2012	The cultivation of GMOs need not be subject to a national authorisation procedure where the use and marketing of those varieties are accepted in the common catalogue of varieties of agricultural plant species in accordance with Regulation 1829/2003; similarly, the provisions of Directive 2001/18 provide, in general, that the Member States may not oppose cultivation until coexistence measures have been adopted to prevent the unintended presence of GMOs in other crops.	Health and environmental protection requirements have already been addressed in the approval and acceptance process.

[20] *Karl Heinz Bablok and Others v Freistaat Bayern*, ECLI: EU:C:2011:541.
[21] *Monsanto SAS and others v Ministre de l'Agriculture et de la Pêche*, ECLI:EU:C:2011:553.
[22] *Pioneer Hi Bred Italia Srl v Ministero della Politiche ogricole alimentari e forestali*, ECLI:EU:C:2012:534.

No.	Case law of CJEU	First variable (environmental risk assessment)	Second variable (right to healthcare)
11.	C-542/12[23] of 8. 5. 2013	Directive 2001/18 does not allow a Member State to oppose the cultivation of GMOs on its territory on the ground that obtaining a national authorisation constitutes a coexistence measure aimed at preventing the unintentional presence of GMOs in other crops.	Health and environmental protection requirements have already been addressed in the approval and acceptance process.
12.	C-281/11 of 19. 12. 2013	In order to ensure uniform application first in the EU, a Member State should transpose the concepts relating to amendments to a directive verbatim into national law. In the event that the notifier withdraws the application for a permit for the use of GMOs in closed systems, the transmitted data must be removed from the register.	The correct transposition of provisions into national law ensures the uniform application of EU law in all Member States. Data already provided shall be withdrawn in order not to cause further confusion.
13.	C-82/12[24] of 27. 2. 2014	The retail tax on mineral oils is not in itself intended to ensure the protection of health and the environment. It is only a financial measure.	There is no correlation between the variables.
14.	C-478/13 of 2. 10. 2014	The Member State has not laid down an obligation to inform the competent authorities of GMO sites, has not established a register of sites and has not made this information available to the public, nor has it complied with its obligations under Directive 2001/18.	There is a risk of effects that may be dangerous to human health.
15.	C-402/13[25] of 5. 11. 2014	The provisions of Regulation 1791/2006 do not preclude determining when to carry out the slaughter of animals unless it is objectively necessary.	There is no correlation between the variables.
16.	C-111/16[26] of 13. 9. 2017	The European Commission need not take urgent action if it is not clear that the product may pose a serious risk to human health, animal health or the environment; The precautionary principle, as defined in Article 7 of Regulation 178/2002, must also be interpreted as meaning that it does not	Scientific evidence and studies are needed to prove a serious risk to human health. In addition to the priority principle, it is necessary to ensure

[23] *Tribunale di Pordenone proti Fidenato Giorgio*, ECLI: EU: C: 2013:298.
[24] *Transportes Jordi Besora SL v Generalitat de Catalunya*, ECLI:EU:C:2014:108.
[25] *Cypr ltd v Kypriaki Dimokratia*, ECLI:EU:C:2014:2333.
[26] *Tribunale di Udine v Giorgiu Fidenatu, Leandru Tabogi, Lucianu Tabogi*, ECLI:EU:C:2017:676.

No.	Case law of CJEU	First variable (environmental risk assessment)	Second variable (right to healthcare)
		give the EU Member States the possibility to take urgent interim measures solely on the basis of this principle without fulfilling the conditions set out in Article 34 of Regulation 1829/2003.	that food/feed is likely to pose a serious risk to human, animal or environmental health and that the risk cannot be adequately managed by measures.

Source: author's work

A detailed analysis of the relationship between the first and second variables arising from the case law of the CJEU shows the relationship defined at the level of risk or potential risk to human, animal, plant, and environmental health. The judgements do not explain in what way and with what probability an individual risk to human, animal, plant and environmental health may be or has not materialised. Also, except for some court proceedings, criminal sanctions for non-compliance with EU law in the field of GMOs or with the enforcement of EU law into national law are not imposed in judgements (Meško Kuralt, 2021b: 230-231; Aerni, 2019; Lamping, 2012: 123-129[27]; Heubuch, 2016: 20-22[28]).

In the case of GMO-containing litigation, the author believes that the relationship between the first and second variables would be even more identifiable if the risks to human, animal, plant and environmental health were described in more detail in each litigation. Monitoring judgements containing GMOs means implementing the sanctions imposed by the CJEU, *i.e.* payment of the imposed fine, exercising control over the deadlines set in connection with the transposition of x provisions from EU law into national law (Meško Kuralt, 2021b: 230-231).

[27] According to Aerni (2019), EU Member States should take appropriate measures to better coordinate their regulatory approach with GMOs through risk management principles, and risk management should get rid of the process based on a risk assessment approach. This has not happened, as the precautionary principle has ceased to be a tool for responsible risk management. This principle has become a convenient reason ("excuse") to postpone the decision to approve GMOs, with the main emphasis being that the harmful effects of GMOs cannot be ruled out.

[28] Footnote 17.

5 The impact of the protection of the right to healthcare is greater than the impact on the risk assessment in the GMO authorisation process

In the GMO authorisation process, there is the concept of the right to healthcare and the concept of environmental risk assessment, which are already interdependent. Because of this, it cannot be argued that the effect of protecting the right to healthcare outweighs the impact on risk assessment. The latter is done before the approval of an individual GMO, so the author believes that at this stage, adverse effects on human health would not or should occur (Meško Kuralt, 2021b: 231).

However, the adverse effects of the use of GMOs may arise due to subsequently changed circumstances which did not exist at the time of the application for GMO authorisation or which occurred later, unexpectedly. One of the changed circumstances that may arise after the approval of a GMO is the case of an accident[29] (*i.e.* unintentional release of the GMO). The accident thus directly or belatedly endangers human health or the environment, and the person responsible for the accident must immediately[30] inform the competent authority and provide the necessary information to assess the impact of the accident while responding appropriately.

The information to be provided includes:

- a description of the circumstances of the accident;
- a description of the identity and quantity of GMOs released;

[29] An accident means any event which results in the significant and unintentional release of genetically modified organisms during their use in a closed system, which could pose an immediate or subsequent threat to human health or the environment (European Commission, 2016).

[30] Finland has received some notifications of minor accidents (i.e. needle stings) in Class 2 activities without consequences. The Netherlands reported 13 accidents without consequences for health or the environment, namely a minor fire in a biosafety cabinet in a laboratory; a minor collision in a corridor during the transport of waste in which a Class 2 microorganism was present; on two isolator accidents involving genetically modified influenza animals; about damage to the glass wall of the laboratory, *etc.* Slovakia reported three fire accidents at various facilities, namely at the Institute of Virology (Classes 1 and 2), at the Institute of Neuroimmunology (Classes 1 and 2) and at the Slovak University of Technology (Class 1). Sweden reported one needle accident. In addition, the United Kingdom reported eight accidents involving the use of GMOs in a closed system. Of these, Class 2 GMOs were involved in six accidents, and Class 3 GMOs were involved in two accidents. Belgium reported one accident (fire) in a bio-waste storage facility that was not reported to the competent authority (European Commission, 2016).

- all the information necessary to assess the effects of the accident on human health and the environment which are known, and all the information relating to the occurrence of the accident which is also foreseen;
- urgent action is also needed.

If an accident plan is specified, the responsible person shall take it into account, namely:

- GMO control procedures are carried out in the event of an unexpected spread;
- perform a method to decontaminate or eliminate the consequences of the accident;
- perform a method of removing or rehabilitating plants, animals, soil, *etc.*, that were exposed during an accident or spread (Brandenberg *et al.*, 2011: 59-61).

The precautionary principle as such has a positive effect at the national and international level, as it ensures an adequate level of protection of the environment and human health. In addition, the precautionary principle is a fundamental principle of European environmental policy and means that, in case of doubt, the benefit of protecting the environment from other interests prevails. At the forefront is the duty of preventive action, *i.e.* adoption of measures to prevent both an imminent threat of environmental damage and damage per se (Article 10 (2) of the Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (hereinafter: Directive 2004/35) (European Commission, 2000).

As already mentioned, the CJEU applied the precautionary principle for the first time in Case C-157/96,[31] stating that where there is uncertainty about the existence and extent of risks to human health, the institution may take safeguards. These safeguards take effect immediately, without having to wait for the reality and seriousness of these risks to become fully apparent. The generally accepted position of the EU Court is that the right to healthcare is a fundamental right enjoyed by every individual in Slovenia and the territory of the EU Member States. The right to healthcare thus establishes a health condition that strives for the best possible health of the population. The basic purpose of environmental risk assessment in the process of authorisation of GMOs is the protection of human, animal, plant and environmental health, *i.e.* more broadly than the protection of human health.

The last amendment to the Directive 2001/18 is the Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18 of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms (hereinafter: Directive 2018/350). This Directive is based on the changes needed to prepare an environmental risk assessment.

The main purpose of the environmental risk assessment in the GMO approval process is to prevent negative effects on human health and the environment. The Directive 2001/18 is based on the approximation of the laws, regulations and administrative provisions of the EU MS, as well as on the protection of human health and the environment when deliberately releasing GMOs for any reason other than placing them on the market and placing GMOs on the market as products or in products. In addition to the Directive 2001/18, Regulation 1829/2003 and Regulation 172/2002 are also important.

However, the main purpose of these two regulations is to ensure a high level of protection of human health and consumer interests in food while ensuring the smooth functioning of the internal market. Thus, the main purpose of risk assessment is to protect human, animal, plant and environmental health. To protect the health of humans, animals, plants, and the environment at the highest possible

[31] *United Kingdom of Great Britain and Northern Ireland v Commission of the European Communities* (Agriculture - Animal health - Emergency measures against bovine spongiform encephalopathy - 'Mad cow disease') *ECLI*:EU:*C*:1998:191.

level, the author believes that the risk assessment always needs to be monitored. This means that risk assessment must be provided before, during and after the authorisation of the use of a particular GMO. Of particular note is the fact that the environmental risk assessment needs to be monitored after approval, mainly by the changing area of each approved GMO (*e.g.,* unannounced changes to the GMO product or GMO, changes in the environment, accidents at work with GMOs) (Meško Kuralt, 2021b: 232-233).

It follows from Article 1 of the Directive 2018/350 that the long-term effects of GMOs arise from either the delayed response of organisms or their offspring to long-term or chronic exposure to GMOs or from the widespread use of GMOs in time and space. In order to identify and assess the potential long-term adverse effects of GMOs on human health and the environment, it is necessary to know the long-term interactions between GMOs and the environment, the characteristics of GMOs becoming relevant in the long term and data obtained from repeated deliberate releases or placing over time.

According to Eriksson and others (2020: 349-351), the measurement of the long-term effects of GMOs on human health and the environment is strongly influenced by the case-by-case principle (*i.e.* risk assessment on a case-by-case basis adopted by Article 7 of the Directive 2001/18). This principle allows for a simplified risk assessment process only if sufficient practical experience is gained with a particular product or property.

As is apparent from the Directive 2018/350, the EFSA guidelines were designed primarily to communicate GMPs for placing them on the market. The EFSA guidelines are based on increasingly comprehensive and precise guidelines such as:

- the definition of general and specific aspects of environmental risk assessment;
- identifying intentional and unintentional changes;
- identification of long-term adverse effects and cumulative long-term adverse effects in the environmental risk assessment process; data quality;
- the complexity of transformation events (or gene changes) in notifications;

- characteristics of GMOs and releases;
- steps in the environmental risk assessment process, such as problem description, including hazard identification, risk identification, and conclusions on environmental risk assessments in specific risk areas.

As a result, the risk assessment process for GMOs in the EU is becoming increasingly static to the point that it has become too cumbersome to cope with technological and scientific developments (Eriksson *et al.*, 2020: 349-351).

6 Conclusion

As already pointed out, the main purpose of the GMO approval process is to ensure a high level of protection for the human, plant and animal world.

It is also important to ensure a safe environment and to establish the interests of consumers while ensuring the effective functioning of the internal market.

Last but not least, this follows from the first paragraph of Article 168 TFEU (this means that a high level of protection of human health must be ensured in all policies and activities of the EU institutions).

Regardless of the area covered by the CJEU judgements (*e.g.* whether it is the authorisation of GMOs or the exemption from the labelling of GMO ingredients, or the prohibition of the marketing of GMOs), there is one prevailing guideline in each judgement, *i.e.* observance of the precautionary principle, which is a fundamental principle of European environmental policy and means that, in case of doubt, the benefit of environmental protection overrides other interests (principles). In the field of GMO-containing litigation, the author believes that the relationship between the first and second variables would be even more identifiable if the risks to human, animal, plant and environmental health were described in more detail in each case. In order to increase the visibility and effectiveness of ECJ judgements containing GMO relationships, the author believes that close monitoring of these judgements is needed (Meško Kuralt, 2021b).

Monitoring judgements containing GMO relationships means actually implementing the sanctions imposed by the CJEU, *i.e.* payment of the fine imposed, exercising control over the deadlines set in connection with the transposition of x provisions from EU law into national law. Moreover, as the scope of GMOs is part of environmental policy, the author believes that this area is also subject to rights, such as the right of access to information, the right to public participation in decision-making, and the right of access to justice.

Because the two concepts, *i.e.* rights to healthcare and the concept of, *i.e.* the environmental risk assessment in the GMO approval process, are interdependent, it cannot be argued that the impact of the protection of the right to healthcare is greater than the impact on the risk assessment. The latter is done before the approval of an individual GMO, so the author believes that any harmful effects on human health do not or should not occur at this stage. Adverse effects of the use of GMOs may arise due to subsequently changed circumstances, which did not exist at the time of submitting the application for the approval of GMOs or occurred subsequently, and above all, unexpectedly.

The CJEU broadened the interpretation of Article 36 TFEU by clarifying that EU MS actions are permissible even where they can be justified without distinguishing between domestic and foreign products. In the Casiss de Dijon case (C-120/78)[32], the CJEU developed the method of objective justifications, *i.e.* mandatory requirements or also the rule of reason. The latter means that, exceptionally (if necessary and on the basis of mandatory requirements), EU Member States may restrict access to the national market to the goods from another EU MS with reasonable action. Article 36 TFEU thus applies only to directly or formally discriminatory measures (*i.e.* import licenses, checks, attestations, public contracts, *etc.*), while the Cassis de Dijon rule applies to indirectly or materially discriminatory measures. Indirect or materially discriminatory measures (*i.e.* presumption of free trade, production standards, packaging, composition, *etc.*) can also be applied to Article 36 TFEU if it has clear discriminatory effects on imports (Hojnik, 2010: 224-227).

[32] *Cassis de Dijon*, ECLI:EU:C:1979:42.

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