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New plant breeding techniques and genetic engineering: legal approach**

1. Introduction

'New plant breeding techniques' – i.e. genome editing[1] – have recently become a hot topic on the agenda and have triggered several debates. Human-modified genetic stock of living organisms is not a new-fangled invention. However, as a lot of other technologies, this is also developing day by day, with which progression shall the law inevitably keep pace with even in this exceptionally antinomic field. The fore-mentioned procedures are regarded by some remarkably safe and precise, thus according to their viewpoint the organisms obtained this way do not count as genetically modified organisms. On the other hand there are people who argue for regulations as strict as possible. Nevertheless, law cannot participate in endless debates. Pending legal situations have to be resolved for the safety and welfare of society and citizens. From the perspective of Hungary this question is even more stressed, since paragraph 2 of Article XX of the Fundamental Law of Hungary expressly states that Hungary shall promote the effective application of the right to physical and mental health by – among others – an agriculture free of genetically modified organisms.

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[1] The essence of genome editing (to put it more simply the modification of genes) is to improve and modify specific attributes of living organisms without having to implant genes from different species. With genome editing the DNA can be modified in a way similar to processes in the nature. It is more precise then previous processes, thus lowering the risk of unintended effects. The process has several potential agricultural utilizations, such as the development of disease- or virus-resistant breeding stocks. With adequate legal framework genetic diseases which are caused by only one mutation could be cured (circa 8000 of these are known). Mutagenesis is a kind of genome editing. In the course of mutagenesis a give gene is modified. Notedly the process is the modification of particular sequences of areas of genes by molecular intervention, which changes the order of synthesizing protein amino acid. With directed techniques of mutagenesis random or even directed changes can rapidly and efficiently be made in recombinant proteins. In effect we can sort out proteins and enzymes which in some aspects have better, more preferred or even new attributes, all this within sampling circumstances defined by ourselves. Rákhely Gábor: *Biokatalízis, biokonverziók, biotranszformációk*, Szegedi Tudományegyetem, 2012, source (2018.03.05.): http://www.tankonyvtar.hu/hu/tartalom/tamop412A/2011_0025_bio_4/index.html

Recently several scientific professional documents and opinions have been published in this topic. The present study highlights the most important ones among these.

2. Commitments of scientific bodies

In 2017 the European Academies Science Advisory Council (EASAC) has made a report about genome editing, the newest technique of genetic engineering. The process itself is the deliberate modification of a DNA sequence which can revolutionize science in a lot of fields, including human and animal health, food industry and agriculture. The most important message of the report may be that the process of creating legal regulations should not be based on the actual technology, but instead on its future appliance and the achievements (of the product). The regulations relating to the applications should be based on actual evidences which are attentive to both the potential advantages and possible risk factors. These regulations should be commensurable and flexible enough to be able to adapt to the future advancements of technology. Concerning the abovementioned process, genome editing was not the first procedure it was mentioned in connection with, we could've also heard about it relating to GMOs. The US has created its legal regulations in accordance with this very legislative conception. This solution is the opposite of the EU, which has a legislative conception that focuses on the (gene)-technology instead of the (genetically modified) organism.

The report of the EASAC does not only draw up recommendations relating to genome editing, but also to the creation of the rules concerning gene technology. It emphasizes the importance of publicity, since there should be trust between scientists and society. It also states that the affected people have to be involved in the dispute about potential advantages and possible risk factors. We also have to aim for global rightfulness and the scientific community has to work together in order to decrease social differences. The possible ways of achieving this are the active transfer of knowledge, the international partnership of scientists and the provision of free access to tools and education. In the process of creating regulations we should not forget that the decisions of the EU have and can have unintended effects outside the EU. According to the report of the EASAC the former decisions of the EU on genetically modified products effected the scientists, farmers and politicians of the developing countries adversely.[2]

One of the event's most important background materials was a commitment which the presidency of the Hungarian Academy of Sciences (HAS) adopted on 28th November 2017 without counter-votes. The commitment was created by *Dénes Dudits*,[3] *György Kosztolányi* and *Pál Venetianer*.

[2] European Academies' Science Advisory Council: *Genome editing: scientific opportunities, public interests and policy options in the European Union*, EASAC Policy Report 31, 2017.03.

[3] Dudits Dénes is the author of many articles in connection with the topic, including: Dudits Dénes – Balázs Ervin: Meghaladott jogi környezet, *Magyar Mezőgazdaság*, 2017/32, 18; Dudits: Nem alkotmányba való – A GMO-k hazai elutasításáról, *Figyelő*, 2014/23, 48-49; Dudits: Az agrárium jelenét, jövőjét formáló molekuláris növénybiológia és zöld biotechnológia, *Magyar*

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In essence it originates from the commitment of the EASAC.[4] Concerning the commitment of the presidency of the HAS it should also be noted that the HAS took the side of the European Academies by stating that genome editing as a form of precision breeding technique can fundamentally differ from the creation of genetically modified organisms. According to the scientific forum there is need for discussion and the citizens should be appropriately informed about the possibilities and potential risks of new genome editing techniques – putting special emphasis on the most commonly used CRISPRS/Cas9 technology.[5] One important element of the commitment is that it refers to the potential connection between genome editing and the Fundamental Law of Hungary. It states that "it is backed by scientific evidence not to view genome editing as genetic modification (as stated in the commitment of the EASAC), in which case the utilisation of such organisms is not in conflict with the Fundamental Law of Hungary".[6]

Another group of representatives of scientific life – including *András Székács*[7] and *Béla Darvas*[8] – sees genome editing in a different way.

Tudomány, 2014/10, 1176-1188; Dudits: Honnan hová tart a zöld agrár-biotechnológia Magyarországon?, in: Fehér Attila (edit.): *A növények molekuláris biológiájától a zöld biotechnológiáig: Dudits Dénes akadémikus 70. születésnapjára*, Budapest, Akadémiai Kiadó, 2014, 240-276; Dudits: Géntechnológiával az egészséges növényekért: rezisztencianemesítés a genomika eszközeivel, *Georgikon for agriculture: A multidisciplinary journal in agricultural sciences*, 2013/1, 8-28; Balázs Ervin – Dudits Dénes – Sági László (edit.): *Genetikailag módosított élőlények (GMO-k) a tények tükrében*, Szeged, Barabás Zoltán Biotechnológiai Egyesület – Pannon Növény-biotechnológiai Egyesület, 2011; Dudits: Géntechnológia a növénybiológiai kutatásban és a bioiparban, *Magyar Tudomány*, 2007/4, 404; Dudits: A génkutatás-genomika szerepvállalása a növények nemesítésében, *Magyar Tudomány*, 2003/10, 1263-1272; Dudits: A géntechnológia módszerének felhasználása a növényi produkció optimalizálásában, *Acta biologica Debrecina*, 2002. Vol 22, 170; Balázs Ervin – Dudits Dénes (edit.): *Precíziós nemesítés: kulcs az agrárinnovációhoz*, Budapest, Agroinform Kiadó és Nyomda Kft, 2017, 194.

[4] Hungarian Academy of Sciences: *Precision genome editing for a liveable world*, Budapest, 6 December 2017.

[5] Hungarian Academy of Sciences 2017.

[6] Hungarian Academy of Sciences 2017, Introduction.

[7] Székács András has many publications on the subject, including: Darvas Béla – Füleki Lilla – Bánáti Hajnalka – Deli Szabina – Székács András: A GM növények engedélyezési stratégiái a világ országaiban, *Növényvédelem,* 2014/3, 121-127; Darvas Béla – Székács András: Növénytermesztési módok eltérő környezetanalitikai és ökotoxikológiai következményei, *Biokultúra*, 2013/1, 13-15; Darvas Béla – Deli Szabina – Németh Gyöngyi – Bánáti Hajnalka – Füleki Lilla – Székács András: Géntechnológiai úton módosított növényekkel 1999 és 2012 között végzett szabadföldi kísérletek Európában és Magyarországon, *Növényvédelem*, 2013/11, 491-500; Darvas Béla – Székács András: GM-növények ellenálló és tűrőképessége. Tolerancia, rezisztencia és biodiverzitás, *Élet és tudomány*, 2012/7, 198-200; Darvas Béla – Székács András (edit.): Az elsőgenerációs géntechnológiai úton módosított növények megítélésnek magyarországi háttere, Budapest, a Magyar Országgyűlés Mezőgazdasági Bizottsága, 2011; Székács: Ökotermékeink tisztasága, *Biokontroll: kutatás, fejlesztés és innováció az agrár-környezetvédelemben*, 2011/3, 3; Darvas Béla – Székács András: Növényvédelem és fenntarthatóság I.: Kémiai növényvédelem, *Biokultúra*, 2010/2, 9-11; Darvas Béla – Székács András:

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Among the opposition of new technologies there is a very stressed argument according to which the emerging processes and unintended mutations caused by genome editing techniques are still unknown up to this very day. These all call for the use of the precautionary principle. The standpoint of the ENSSER in this matter[9] is that new genetically engineered products have to be regulated as strictly as genetically modified organisms and we have to move from the use of the precautionary principle to the verification of damages. New techniques of gene technology demand precaution and their risks have to be assessed case by case, in an *ad hoc* way. We should not underestimate the risks of biological terror either. These arguments all support the viewpoint that there is need for a regulation that is based on both the process and the product. This has to be conducted in a way that in the future evades the negative social judgement of genetically modified foods. The general public also has to be informed in the most versatile way possible.

Among the creators of the commitment adopted by the HAS there was no legal scholar, hence it did not approach the jurisprudential and legislative aspects that appear in the works of *Gyula Bándi*,[10] *László Fodor*[11] and *Ágnes Tahyné dr. Kovács*[12] about

Növényvédelem és fenntarthatóság II.: Géntechnológia a növényvédelemben, *Biokultúra*, 2010/3, 12-14; Darvas Béla – Székács András: A géntechnológiai úton módosított növények megítélése az Európai Unió keleti határán: Approaches toward genetically modified plants at the eastern border of European Union, *Biokontroll: kutatás, fejlesztés és innováció az agrár-környezetvédelemben*, 2010/1, 13-23; Darvas Béla – Lauber Éva – Takács Eszter – Székács András: GM-növények mérlege a növény- és környezetvédelemben I, *Környezetvédelem*, 2009/1, 24-25; Darvas Béla – Lauber Éva – Takács Eszter – Székács András: GM-növények mérlege a növény- és környezetvédelemben II, *Környezetvédelem*, 2009/2, 26-27.

[8] Darvas Béla has published several writings on the topic, including: Darvas Béla – Füleki Lilla – Bánáti Hajnalka – Deli Szabina – Székács András: A GM növények engedélyezési stratégiái a világ országaiban, *Növényvédelem*, 2014/3, 121-127; Darvas Béla – Székács András: Növénytermesztési módok eltérő környezetanalitikai és ökotoxikológiai következményei, *Biokultúra*, 2013/1, 13-15; Darvas Béla – Deli Szabina – Németh Gyöngyi – Bánáti Hajnalka – Füleki Lilla – Székács András: Géntechnológiai úton módosított növényekkel 1999 és 2012 között végzett szabadföldi kísérletek Európában és Magyarországon, *Növényvédelem,* 2013/11, 491-500; Darvas: A GM-növények mellékhatásai, *Magyar mezőgazdaság*, 2011/40, 28-30; Darvas: Biotechnológia pro ökológia. Árnyjáték alapfokon, *Környezetvédelem*, 2007/4, 30.

[9] *European Network of Scientists for Social and Environmental Responsibility Statement on New Genetic Modification Techniques*, 27 September 2017, in (2018.04.15.): https://ensser.org/publications/ngmt-statement/

[10] Bándi Gyula has published several high-impact studies on the connection between environmental protection and the constitution, including: Bándi: A visszalépés tilalma és a környezetvédelem, in: Gellén Klára (edit.): *Honori et virtuti*, Szeged, Pólay Elemér Alapítvány, 2017, 9-23; Bándi: A környezeti értékek valamint a visszalépés tilalmának értelmezése, *Iustum Aequum Salutare*, 2017/2, 159-181; Bándi: Fenntarthatóság, reziliencia, önkormányzatok, in: Fodor László – Bányai Orsolya (edit.): *A települési önkormányzatok szerepe a környezeti politika és jog alakításában*, Debrecen, Debreceni Egyetemi Kiadó, 7-28; Bándi: A környezethez való jog – újratöltve, *Acta Humana*, 2016/2, 7-25; Bándi: Right to Environment – Procedural Guarantees, in: Bándi Gyula (edit.): *Environmental Democracy and Law*, Groningen – Amsterdam, Europa Law Publishing, 2014, 77-94; Bándi: Gondolatok az elővigyázatosság elvéről, *Jogtudományi Közlöny*,

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environmental law and the connection between environmental law, constitutional law and genetically modified organisms.

In the legal judgement of genome editing the upcoming decision of the Court of Justice of the European Union about new breeding techniques and genetic modification will play a significant role. The assigned advocate general, Michael Bobek has published his opinion in January in relation with a similar case. In the aforementioned case the French Council of State (*Conseil d'État)* asked for preliminary ruling from the Court of Justice of the European Union. One of the questions said: "Do organisms obtained by mutagenesis constitute genetically modified organisms within the meaning of Article 2 of Directive [2001/18]"? Though the advocate general gave a positive answer – he said that organisms obtained by mutagenesis constitute genetically modified organisms, although they are exempt under the annexes of the mentioned directive[13] – the opinion does not bind the Court of Justice of the European Union, whose commitment is still pending.

We will get back to the detailed review of the opinion of the advocate general later. Before that we should point out that regarding the Fundamental Law's conception of 'an agriculture free of genetically modified organisms' there have already been difficulties of interpretation in several aspects. Formerly the Parliamentary Commissioner for Future Generations (PCFG) – essentially with harsh respect to the

2013/10, 471-480; Bándi: A környezethez való jog értelmezése a fenntartható fejlődési stratégia és az Alaptörvény fényében, *Acta Humana*, 2013/1, 67-92; Bándi: Gondolatok a környezethez való jogról, in: Raisz Anikó (edit.): *A nemzetközi környezetjog aktuális kihívásai*, Miskolc, Miskolci Egyetem, 2012, 6-15; Bándi: Environmental aspects of the new Hungarian Constitution, *Environmental Liability*, 2011/5, 75-78; etc.

[11] See in particular: Fodor László: Verfassungsrechtlicher Rahmen für Umweltschutz im neuen ungarischen Grundgesetz, in: Lothar Knopp – Heinrich Amadeus Wolff (edit.): *Umwelt – Hochschule – Staat*, Berlin, Duncker und Humblot, 2016, 69-83; Fodor: A természeti tárgyak helye és szerepe az új alkotmányban, in: Drinóczi Tímea – Jakab András (edit.), *Alkotmányozás Magyarországon 2010–2011*, Budapest – Pécs, Pázmány Press, 2013, 89-103; Fodor: A víz az alaptörvény környezeti értékrendjében, *Publicationes Universitatis Miskolcinensis Sectio Juridica et Politica*, 2013/31, 336, 341; Fodor: A környezethez való jog dogmatikája napjaink kihívásai tükrében, *Miskolci Jogi Szemle*, 2007/1, 5-19; Fodor: *Környezetvédelem az Alkotmányban*, Budapest – Debrecen, Gondolat Kiadó, 2006; Fodor – Orth: Umweltschutz in der ungarischen Verfassung, *Osteuropa Recht*, 2005/1, 1-16; Fodor: A környezetvédelem megjelenése Európa alkotmányaiban, *Publicationes Universitatis Miskolcinensis Sectio Juridica et Politica*, 2002/22/2, 373-400; etc.

[12] Tahyné Kovács Ágnes: *A genetikailag módosított szervezetekre vonatkozó szabályozásról egyes környezetjogi alapelvek, különösen a fenntartható fejlődés tükrében*, Budapest, PhD Thesis, Pázmány Péter Katolikus Egyetem, Tahyné Kovács: *Jelölti válasz `A genetikailag módosított szervezetekre vonatkozó szabályozásról egyes környezetjogi alapelvek, különösen a fenntartható fejlődés tükrében´ című PhD disszertáció opponensi véleményeire.* PPKE JÁK, Budapest, 2013b. október 10, 3-6; Tahyné Kovács: Gedanken zur verfassugsrechtlichen Interpretierung der gesetzlichen Regelung der GVOs in angesichts der Verhandlungen der neuen GVO Verordnung der EU und des TTIP (Transatlantic Trade and Investment Partnership), *JAEL*, 2015/18, 72-79.

[13] Case C-528/16, request for a preliminary ruling from the Conseil d'État (Council of State, France), 18 January 2018, ECLI:EU:C:2018:20.

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precautionary principle – has adopted a very strict interpretation[14] of the Fundamental Law's related regulations. There have been several other Hungarian legal scholars as well who have explained their point of view of this matter.[15] *Szilágyi János Ede, Raisz Anikó* and *Kocsis Bianka* have summarized the legal interpretation issues of the related regulations of the Fundamental Law as follows. "*The main questions among these – inter alia – are as follows: (a) what kind of activities and products are covered by the Fundamental Law, (b) what the binding force of these regulations looks like, and (c) in what relation are they with EU Law. Without debating the statements of the certain studies, our standing-point is the following in connection with the interpretation of the regulation of the Fundamental Law on GMO-free agriculture. According to us, the exact meaning of this order of the Fundamental Law has not been cleared yet. However, it could be ascertained that this rule is not a directly predominant ban (more likely an instruction to orient the legislators of the state). At first, this rule was referred to mostly in connection with restrictions on cultivation of GM-plants by the Hungarian legislator (this is a narrow interpretation). Thus, this narrow interpretation does not exclude that imported GM-products*

[14] „The Hungarian Constitution declares with the clear prohibition of agricultural use of genetically modified organisms that – according to the precautionary principle – it does not aim at turning the country and its inhabitants into a test-site, especially with regard to the fact that the results of these experiments may only become visible after decades." PCFG Statement No. 258/2011 of April 25, 2011 on state responsibility resulting from the new Constitutions' provisions on environmental protection and sustainability, point 7. Translated by: Raisz Anikó – Szilágyi János Ede: Development of agricultural law and related fields (environmental law, water law, social law, tax law) in the EU, in countries and in the WTO, *JAEL*, 2012/12, 111, 137.

[15] Fodor László: A GMO szabályozással kapcsolatos európai bírósági gyakorlat tanulságai, in: Csák Csilla (edit.): *Jogtudományi tanulmányok a fenntartható természeti erőforrások körében*, Miskolc, Miskolci Egyetem, 2012, 74; Fodor: *Környezetjog*, Debrecen, Debreceni Egyetemi Kiadó, 2014, 113-114; Raisz Anikó: GMO as a Weapon – a.k.a. a New Form of Aggression?, *Hungarian Yearbook of International Law and European Law 2014*, The Hague, Eleven, 2015, 275-276, 279-281; Julesz Máté: GMO-mentes alkotmány, *Orvosi Hetilap*, 2011/31, 1255-1257; Raisz Anikó – Szilágyi János Ede: Development of agricultural law and related fields (environmental law, water law, social law, tax law) in the EU, in countries and in the WTO, *JAEL*, 2012/12, 110-112; Szilágyi János Ede: A zöld géntechnológiai szabályozás fejlődésének egyes aktuális kérdéseiről, *Miskolci Jogi Szemle*, 2011/2, 36-54; Szilágyi: *Tudományos munkásság áttekintő összefoglalása*, Miskolci Egyetem Habilitációs Füzetei, Miskolci Egyetem, Miskolc, 2015, 36-38; Szilágyi: Változások az agrárjog elméletében?, *Miskolci Jogi Szemle*, 2016/1, 48-49; Szilágyi János Ede – Tóth Enikő: A GMO-mentes mezőgazdaság megteremtésének újabb jogi eszköze, *Publicationes Universitatis Miskolcinensis Sectio Juridica et Politica*, 2017/35, 482-483; T. Kovács Júlia: *Az élelemhez való jog társadalmi igénye és alkotmányjogi dogmatikája*, PhD Thesis, Budapest, Pázmány Péter Katolikus Egyetem, 2017; T. Kovács: Az Alaptörvény GMO-mentes mezőgazdaságra vonatkozó rendelkezése, in: Cservák Csaba – Horváth Attila (edit.): *Az adekvát alapjogvédelem*, Budapest, Porta Historica, 2017, 147-150; T. Kovács: A GMO-mentes Alaptörvény hatása a mezőgazdaságra – különös tekintettel a visszaszerzett EU-tagállami szuverenitásra és a TTIP-re, in: Szalma József (szerk.): A magyar tudomány napja a Délvidéken 2014, Újvidék, VMTT, 2015, 308-309. About other aspects of GMO legislation beside constitutional law, see Kovács Judit Nóra: Észrevételek az USA GMO politikájához, in: Csák Csilla (edit.): *Jogtudományi tanulmányok a fenntartható természeti erőforrások körében*, Miskolc, Miskolci Egyetem, 2012, 104-115; Olajos István: A géntechnológiai tevékenység szabályozása Magyarországon, in: Szilágyi János Ede (edit.): *Környezetjog*, Vol II, Miskolc, Novotni Kiadó, 2008, 73-88.

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(e.g. food) could be purchased by Hungarian consumers. However, for about two years, the decision-makers interpret other questions as well as falling under the category of GMO-free agriculture (beside the cultivation of GM-plants), e.g. the intention to establish the conditions of a GMO-free food production in Hungary. In our opinion, the category of GMO-free agriculture gives such a wide framework of interpretation that even this latter, wide interpretation could fall under this category."[16]

3. New plant breeding techniques and genetic engineering in the light of the precautionary principle

During the course of the scholarlike interpretation of the issue at hand we cannot forget the review of case C-528/16 which is currently before the Court of Justice of the European Union. The assigned advocate general, *Michael Bobek* has published his opinion on the case in January. The French Council of State (*Conseil d'État)* asked for preliminary ruling from the Court of Justice of the European Union. The most relevant question for our article could be the fourth in which the French Council of State asked from the Court of Justice of the European Union the following question: "May the validity of Articles 2 and 3 of and Annexes I A and I B to Directive [2001/18] with regard to the precautionary principle guaranteed by Article 191 (2) of the Treaty on the Functioning of the European Union, in that those provisions do not subject genetically modified organisms obtained by mutagenesis to precautionary, impact assessment and traceability measures, be called into question, taking account of the development of genetic engineering processes, the appearance of new plant varieties obtained by means of those techniques and the current scientific uncertainty as to their impacts and the potential risks they represent for the environment and human and animal health?"[17]

Besides the precautionary principle we should also mention the principles that preventive action should be taken, which is one of the most important principles of environmental protection. The principle implies taking action against the known and hereby expected effects and also against the damaging processes. The precautionary principle became part of the EU's legislation with the Maastricht Treaty as a 'complementation' to the principles that preventive action should be taken. The two principles together warn us that with adequate attention even the unintended consequences can be evaded.[18]

The precautionary principle thinks one step ahead of the principles that preventive action should be taken and it presumes a priori that human actions can lead to environmental harm.[19] The principle is based on the recognition that our scientific knowledge is limited. Due to scientific advancement there can be products that today are seen harmless, but later we can realize that they can lead to serious damages in the

[16] Szilágyi János Ede – Raisz Anikó – Kocsis Bianka: New dimensions of the Hungarian agricultural law in respect of food sovereignty, *JAEL*, 2017/22, 170, 191, doi: 10.21029/JAEL.2017.22.160.
[17] Case C-528/16, request for a preliminary ruling.
[18] Bándi: *Környezetjog*, Budapest, Szent István Társulat, 2014b, 35-36.
[19] Bándi 2014b, 35-36.

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environment. In the name of precaution the effects of environment using actions have to be decreased to the minimum, even if it is still unknown whether they have harmful effects or not. The Netherlands even have a unique principle for the lowest possible usage of the environment which is called the *ALARA*[20] *principle.*[21]

The aim of the provision in section 2 of Article 191 of the Treaty on the Functioning of the European Union is to provide a high level of protection of the environment with preventive decision-making in case of a possible risk. Its practical appliance covers a lot wider area, it includes the food regulations of the EU and also human, animal and floral health. Its practical advantage is that if the available data are not enough for a full risk assessment, then with its appliance the release of potentially harmful products can be evaded or these products can even be called back from the market.[22] This requirement can also be enforced by several procedural guarantees, i.e. the EU-wide authorisation of genetically modified organisms and foods or the opportunity of member states to contradict, which allows the state-wide restriction of production and distribution despite the authorisation.[23]

In the case law of the Court of Justice of the European Union the precautionary principle is mostly interpreted as a principle which allows different parties – i.e. member states or the Commission – to adopt temporary risk management measures without having to wait for the realization of the possible risks. In the absence of harmonization we can even refer to the principle in itself as a justification of restrictive measures. However this can only happen if several conditions are met. The essence of these conditions is that we need at least some scientifically backed and perceivable risk to exist. The fear of a risk of a new thing or the fear of a risk in a broad and general sense is not enough, because in this case we cannot convincingly state whether a new invention is safe or not. The referring court also stated that given the absence of assessment and surveillance in case of organisms obtained by mutagenesis there is a risk that calls for the use of the precautionary principle. Practically this means that with the absence of conclusive scientific data proving that organisms obtained by mutagenesis are safe, that is said to amount to a breach of the precautionary principle, thus potentially justifying the annulment of Articles 2 and 3 of the GMO Directive and its Annexes I A and I B.[24]

Michael Bobek, on the other hand stated that there is no such circumstance that would justify the use of the precautionary principle and the annulment of the afore-mentioned Annexes. He emphasized that given the case law of the Court of Justice of the European Union a mere 'risk uncertainty' does not support the use of the principle. There is need for the identification and the independent scientific support of the actual risks. A fear of a risk, or risk of a risk, is not enough.

[20] *As low as reasonably achievable.*
[21] Fodor László – Baranyi Tamás – Tóth Katalin: *Környezetjog,* Debrecen, Lícium-Art, 2006, 59-65.
[22] European Commission: *Communication on the Precautionary Principle.* COM (2000) 1, 2.II.2000.
[23] Fodor – Baranyi – Tóth 2006, 64.
[24] Case C-528/16, request for a preliminary ruling.

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Before taking sides concerning the use of the precautionary principle regarding new gene editing techniques we cannot forget to mention the Hungarian regulations. We can say without a doubt that the current Hungarian politics expressly rejects genetically modified foods and it commits itself to a food market totally free of genetically modified organisms. However we cannot overlook the fact that Hungary accessed to the EU in 2004 and as a member state Hungary is obliged to enforce EU law in its territory, including the provision of the free movement of goods. The primary source of law in Hungary is the Fundamental Law. Several of its regulations are in connection with the topic of this article. Section 1 of Article P of the Foundation may be mentioned here, which states that: "Natural resources, in particular arable land, forests and the reserves of water, biodiversity, in particular native plant and animal species, as well as cultural assets shall form the common heritage of the nation; it shall be the obligation of the State and everyone to protect and maintain them, and to preserve them for future generations." Article XX expressly states the requirement of an agriculture free of genetically modified organisms in connection with physical and mental health. An agriculture free of genetically modified organisms is a new element compared to the Constitution. However, the requirement does not mean that every genetically modified food will disappear from our country.[25]

Regarding the afore-mentioned regulation there have been interpretation problems before. Several legal scholars have tried to interpret – so far, without success – the mentioned article and tried to answer what types of conducts and products does its scope extend to, what sort of binding power do the regulations have and in what kind of relation are they with EU law. In the beginning the regulation has been referred to only in connection with the restriction of the cultivation of genetically modified organisms. Based on this narrowed interpretation the decision makers should not aim to stop imported genetically modified products from getting to Hungarian consumers. At the same time it seems that the decision makers include other issues in the category of an agriculture free of genetically modified organisms more and more besides cultivation, such as the production of GM-free foods.[26]

Due to the fact that the Hungarian Constitutional Court has not yet interpreted the idea of an agriculture free of genetically modified organisms we can only proceed from section 2 of Article XX of the Fundamental Law and from the interpretation of the Constitutional Court about the other elements of the listing. On the grounds of these the afore-mentioned turn of the Fundamental Law means the obligation of the state to create such an economic and legal environment that provides the best conditions for an agriculture free of genetically modified organisms. This all originates from the objective institutional-protection obligation of the state which can be derived from the right to health. We can still state that Hungary has not taken sides in this issue. However, as long as the issue at hand is not decided scientifically and there is risk that the use of GM techniques will have a harmful effect on human health the state is obliged by the precautionary principle to defend its citizens by all available means.[27]

[25] Árva Zsuzsanna: *Kommentár Magyarország Alaptörvényéhez*. Budapest, Wolters Kluwer, 2013.
[26] Szilágyi – Tóth 2017, 479-499.
[27] T. Kovács 2015, 300-319.

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The PCFG has also made a statement about article XX of the Fundamental Law: "With the clear, exact prohibition of the agricultural application of genetically modified organisms – in accordance with the precautionary principle – the Hungarian legislator expresses the demand not to turn the country and the population into an experimental plant, with special regard to the fact that the results of such experiments might be revealed only decades after."[28]

In the course of evaluating this issue from a Hungarian perspective we cannot forget to look at the regulations of the Hungarian Act on Environmental Protection.[29] The Act tries to clarify issues of theoretical significance and also systematizes the applied legal institutions mainly in the field of public administration. The preamble of the Act which states the principle of harmonious development, sustainability and the protection of future generations is of utmost importance.[30] Paragraph 6 is the most important for our article, which states that: "The environment has to be used in a way that pays respect to the precautionary principle, spares and uses environmental elements economically, reduces waste management and also re-winds and re-uses produced materials. In favour of prevention the most efficient solution and in case of conducts defined by particular acts the best available technique has to be applied regarding environmental usage."[31]

In Hungary prevention and the precautionary principle are all part of the Act on Environmental Protection. In the spirit of these principles the Act demands the use of the most efficient solutions and the best available techniques (BATs). From 2001 the Act even defines the concept of these ideas. The technique is the best if it is the most efficient in favour of the high level of protection of the environment. The technique is available in case it can be used with acceptable conditions on the given level of development and also the holder of the plant can access it in a reasonable manner.[32]

Paragraph 4 of the Act even defines precaution among the definitions: "Precaution is a decision and a measure required for the prevention or reduction of the future damage of the environment."[33] The definition of the principle in an Act has theoretical significance, since Hungary complied with its duty as an EU member state and implemented this fundamental environmental principle in its jurisdiction. This way, in the name of precaution Hungary has pledged itself to decrease the effects of environmental using actions to the minimum, even if it is still unknown whether these actions have harmful effects or not.

[28] Statement nr. JNO-2582011. (25. April 2011.) of the Hungarian Parliamentary Commissioner for Future Generations on the responsibility of the state arising from the environmental and sustainability provisions of the new Fundamental Law.
[29] 1995. évi LIII. törvény a környezet védelmének általános szabályairól.
[30] Bándi: *Környezetjog,* Budapest, Szent István Társulat, 2011, 23-26.
[31] 1995. évi LIII. törvény a környezet védelmének általános szabályairól.
[32] Fodor: *Környezetvédelmi jog és igazgatás,* Debreceni Egyetemi Kiadó, 2012, 51-52.
[33] 1995. évi LIII. törvény a környezet védelmének általános szabályairól.

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4. Assessing new plant breeding techniques from the perspective of present and future generations

As usual in this case we can also differentiate between two opposing opinions. One party favours new plant breeding techniques and urges moderate regulation, while the other side opposes these techniques and urges the acceptance of strict rules.

Despite having fewer representatives, we cannot overlook the arguments of those who favour new gene-modifying techniques, since they also have several convincing arguments. According to a study conducted in 2014 the so called GMO 1.0. products have fed more than 100 billion food-producing animals up until that day and no study has revealed any adverse effects. Globally, food-producing animals consume 70 to 90% of genetically engineered (GE) crop biomass, even so no study could find any difference between food derived from animals fed with conventional crops and food derived from animals fed with GE crop biomass.[34] *Mark Lynas* writer, journalist and environmental activist is also among those who favour new gene-modifying techniques. In his 2018 speech on the Oxford Farming Conference he said that it is surely wrong to constrain scientific innovation in the absence of any demonstrated risk after twenty years of safe use. In the name of advancement, the world has to move from the age of chemistry to the age of biology. Ha made a warning that the EU can seclude itself from innovation and reformation, however if the world is headed in a different direction sooner or later even the EU has to face these issues.[35]

We can also not forget to separate the freedom of research and the free movement of goods from each other. Scientific progress cannot and should not be stopped, thereby member states have to be provided the freedom of research as an immanent element of innovation. This can also help legislators by finding out how much and what kind of risks do they have to face in connection with GM products. Nevertheless this does not mean that the products derived from these researches have to get to the shelves of shops.

In the end we still cannot forget the use of the precautionary principle. There is need for a strict regulation of new technologies from the beginning, until it is not too late. There is always the possibility of deregulation if we later find out that a product is harmless, however damages that have already occurred can lead to irreversible consequences.

[34] A. L. Van Eenennaam – A. E. Young: Prevalence and impacts of genetically engineered feedstuffs on livestock populations, *Journal of Animal Science,* 2014/92, 4255-4278, doi: 10.2527/jas2014-8124.

[35] Mark Lynas: *Speech to the Oxford Farming Conference*, in (02.05.2018): http://www.marklynas.org/2018/01/mark-lynas-speech-to-the-oxford-farming-conference-2018/

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In view of the effect of the decision on genome editing on future generations Bándi Gyula as the PCFG has made an official statement.[36] He said that "until there is professional consensus on plants derived from genome editing – with the use of the precautionary principle – in the perspective of legislation the scope of the GM-regulation covers these techniques too…"

As a support of his summary statement the PCFG has made the following proclamation regarding the new technology itself: "The use of genetic and biotechnological techniques … can set a problem primarily in the fields of agriculture and food industry. In case of first generation GM plants which have foreign species' genes inserted into them … the use of substantial equivalence is obviously wrong… In theory the case is different in case of new types of genome editing techniques where foreign genes are injected into the gene pool of the plant only temporarily and the result is the mere specific modification of the gene. As a result of this new wave of research and development process the question of legal regulation arose. However, this can under no circumstances mean the allowance of the cultivation of these plants without further research."

Following this the PCFG has also mentioned the Fundamental Law's conception of an "agriculture free of genetically modified organisms". He stated that: "This is a mandatory provision derived from the Fundamental Law. Its content can only be defined by science and the technical agreement of professionals working with genetically modified organisms… The question, judgement and content of genetic modification is fundamentally not a legal question, however the consequences do need legal interpretation."

In the end the PCFG has even mentioned the precautionary principle. "When …. a lot of open questions remain for science and scientists which means there is no uniform, crystallized point of view, then again law comes into the view, and within law the precautionary principle which is of particular interest in cases of public health and environmental protection. The core of the principle is that when the scientific judgement is unsure in case of deciding a professional question, then in order to properly enforce protected rights a thorough risk assessment has to be conducted. In the end we have to decide along the narrowest interpretation without giving space to consequences which cannot be reversed or only at extraordinary difficulties. Thus, the right interpretation of the Fundamental Law is that genome editing and similar techniques have to be viewed as genetic modification as long as the opposite cannot be undoubtedly proved. This practically means that these processes can still not be used in the agriculture. At the same time it does not oppose, but on the other hand promote

[36] The statement was made after a workshop took place at the initiation of the Commissioner and the National Society of Conservationists. The even called 'new plant breeding techniques and genetic engineering' took place on 19th February 2018. Both legislators and professional and civil organisations were represented. Parliamentary Commissioner for Future Generations: *Does genome editing constitute as genetic modification? The Parliamentary Commissioner for Future Generations on the precautionary principle,* standpoint – statement, 19th February 2018, source (2018.03.03.): http://www.ajbh.hu/-/genetikai-modositas-e-a-genszerkesztes-a-jovo-nemzedekek-szoszoloja-az-elovigyazatossag-elverol?inheritRedirect=true&redirect=%2F

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researches that study alternate ways of genetic engineering, since without them there could be no scholarlike and general commitment in the future either."

5. Final Conclusions

In total we can conclude that no general proposal which is acceptable to everyone in the scientific community has not yet been made. The collision of different scientific opinions can later contribute to the most advantageous solution of the problem. The phrase that says that putting two lawyers in a room means having to deal with three different legal opinions is still true, however, the same could easily be the case for scientists. In order to shape scientific opinion we need debates and exchanges of views like this. In the end we can only hope that both the EU and its Court of Justice and Hungary makes a decision which serves the best interests of the consumers and the environment and instead of aiming for the highest economic profit possible the best interests of future generations will be kept in mind. In the XXI century money is undoubtedly the biggest motivation for everyone, it is the engine of our world, nevertheless legislators have to look farther away. In the name of precaution we cannot forget that our decisions and laws have consequences and these consequences can mean that such genetically modified organisms enter the environment or even the plates of people that we don't even know every risk and long-term effect of. This would mean irreversible consequences. Humans are not the owners of the earth, at most we can enjoy its benefits. We cannot destroy it at the expense of future generations. We have to remember (and keep it in mind during legislation) that: "we do not inherit the earth from our ancestors, we borrow it from our grandchildren."

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