10 Introducing the Roles of Soft Law Illustrated by a Regulatory Area in Environmental Law

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10.1 Soft Law in Environmental Law

According to legal literature, it was Lord McNair who was the first to use the term "soft law" in the late 1960s.[1] There are many more terms used for this concept, such as "non-binding international instruments", "informal international instruments", "non-binding agreements", "de facto agreements" but programmatic norms – with limitations – may also be interpreted as a term with a similar meaning.

"Soft law is an agreed-upon, non-contractual act, whereby the states settle their relationship with each other or with a field of law, and they orient their attitudes without creating legally enforceable obligations. Soft law is created as a result of negotiations, yet contractual law does not apply here. Its nature is rather political than legal (yet it may have legal implications)."[2] Considering the normative nature of "soft law", there are no paradigm-like statements. Without accurately defining its status, legal literature places it in the intersection[3] of law and politics. In *Hartmut Hillgenberg's* opinion, if not even the principle of estoppel can be applied to an agreement – even though this principle has no substantive force, it is still often referred to in international legal practice –, it comes to "soft law" and the mere "support" it may receive is good faith. Some say that "light law" – like a "quasi gentlemen's agreement" – implies moral obligations, others say that it is a

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1 Leyla Davarnejad, *In the Shadow of Soft Law: The Handling of Corporate Social Responsibility Disputes under the OECD Guidelines for Multinational Enterprises*, *J. Disp. Resol.*, 2011. Available at: https://scholarship.law.missouri.edu/jdr/vol2011/iss2/6. Jürgen Friedrich, *International Environmental "soft law"*, Max-Planck Institut für auslaendisches öffentlichen Recht und Völkerrecht, Beitraege zum auslaendischen öffentlichen Recht und Völkerrecht 247, Springer, Heidelberg, 2013.

2 Balázs Sándor Boros, 'A Nemzetközi Bíróság Statútuma 38. cikkének újragondolása avagy a soft law lehetséges helye a nemzetközi jog jogforrási rendszerében' (A new approach to Article 38 of the Statute of the International Court, or where the place of soft law is among the sources of international law), in: *Jog Állam Politika*, 2009/1; Nguyen Quoc Dinh, Patrick Dailler, Alain Pellet & Péter Kovács, *Nemzetközi jog* (International Law), Osiris Kiadó, Budapest, 1998, p. 198.

3 *See more in*: Hartmut Hillgenberg, 'A Fresh Look at Soft Law', *European Journal of International Law*, Vol. 10, No. 3, 1999; Daniel Thürer, 'Soft law', in: *Encyclopedia of public international law*, Vol. 4, Nort-Holland, Elsevier, 2000.

norm validated by politics and not by law. However, it is a – more or less – steady point of view that even though they are not legal norms, they have a serious influence on international relations and that they often become full value law.

Some say it cannot be recognized as law because "(…) these instruments or provisions are not laws in themselves, yet they have their unique interpretation in the general frames of the development of international law. Soft law is not clearly a law, even though a document does not need to be a treaty in order to exert influence on international politics."[4]

The role of soft law can be diversified (depending on its subgroups), it is mostly its function of facilitating legislation and law interpretation that is recognized. In this study we analyze the appearance and role of soft law in the field of environmental law.

International environmental conventions were preceded by environmental catastrophes that caused cross-border pollution. International environmental law, unlike other fields of international law, created a few novel characteristics during its progress. Burmese diplomat U Thant as the third Secretary-General of the UN, called the opinion of the global public to the following in 1969, at the 17th session of the UN's Economic and Social Council:

> "For the first time in the history of mankind, there is arising a crisis of worldwide proportions involving developed and developing countries alike, – the crisis of the human environment. It is becoming apparent that if current trends continue, the future of life on earth could be endangered. It is urgent, therefore, to focus world attention on those problems which threaten humanity in an environment that permits the realization of the highest human aspirations, and on the action necessary to deal with them."

Environmental rights have been mentioned in non-binding international documents for almost thirty years. First, it was mentioned in Principle 1 of the UN Conference on the Human Environment in Stockholm in 1972 – focusing on the quality of life as opposed to the dominance of consumer society – and in it, it is declared that: "Man has the fundamental right to freedom, equality and adequate conditions of life, in an environment of a quality that permits a life of dignity and well-being, and he bears a solemn responsibility to protect and improve the environment for present and future generations." It is the unity of law and duty and also, classical human rights, as a starting point, that characterize this approach. Twenty years later, Principle 1 of the Rio Declaration repeats and confirms the same: "Human beings are at the center of concerns for sustainable development. They are entitled to a healthy and productive life in harmony with nature." The so-called Plan of Implementation of the UN World Summit in Johannesburg in 2002, in line

4 Malcolm N. Shaw, *Nemzetközi jog* (International Law), Osiris, Budapest, 2001, p. 398.

with the poor results of the conference, does not seem to be very determined on the rights:

> "5. Peace, security, stability and respect for human rights and fundamental freedoms, including the right to development, as well as respect for cultural diversity, are essential for achieving sustainable development and ensuring that sustainable development benefits all."[5]

The Commission on Human Rights has adopted a resolution[6] on human rights and environmental protection, with respect to sustainable development. In this document, peace, security and stability (third generation problems) and the right to development are harmonized with sustainable development and it also calls for the realization of the Rio Declarations. The Commission confirmed[7] the above Resolution No. 2003/71 in 2005 again, which includes some noteworthy statements but which did not really take a step forward. Good governance is essential for sustainable development; respect for basic human rights also adds to sustainable development; it links environmental protection, the fight against poverty and improving the potentials of developing countries.

The Aarhus Convention[8] is remarkable among international documents, as it provides most of the procedural elements for the protection of the right to the environment.[9] According to Section 3 of the document[10] that analyzes the relationship between the Convention and human rights, "The Aarhus Convention is a new kind of environmental agreement. It links environmental rights and human rights. It acknowledges that we owe an obligation to future generations. It establishes that sustainable development can be achieved only through the involvement of all stakeholders. It links government accountability and environmental protection. It goes to the heart of the relationship between people and governments. The Convention is therefore not only an environmental agreement; it is also a Convention about government accountability, transparency and responsiveness. "Environmental agreements were entered into by the parties under the following unique circumstances: lack of mutual obligations, related or referred provisions from one instrument to another, framework structure, intermediate application, organizations with

5 Gyula Bándi, *Környezetjog* (Environmental Law), Szent István Társulat, Budapest, 2014, p. 97.
6 Human rights and the environment as part of sustainable development, Commission on Human Rights Resolution No. 2003/71.
7 Human rights and the environment as part of sustainable development, Human Rights Resolution No. 2005/60, April 20, 2005.
8 Act LXXXI of 2001 enacted the Aarhus Convention, adopted on 25 June, 1998 on access to information, public participation in decision-making and access to justice in environmental matters to Hungarian law.
9 Bándi 2014, p. 99.
10 Human Rights and the Environment: The Role of Aarhus Convention, Submission by the UN Economic Commission for Europe provided as input to the report being prepared by the Office of the High Commissioner for Human Rights pursuant to resolution E/CN.4/RES/2003/71, December 2003.

extensive mandates, novel law enforcement procedures and simplified means of modification or amendment."[11]

As seen above, the conferences held under the auspices of the UN and the declarations adopted in Stockholm, 1972, Rio de Janeiro, 1992 and Johannesburg, 2002, are milestones in the history of environmental law.[12] These "soft law" tools have critical importance in the development of environmental law both internationally and on the level of the European Union. The focus was on the relationship between people and their environment, primarily the realization of sustainable development.

Parallel to the UN's activities, the European Economic Community also took steps and in October 1972, the Paris summit of European Heads of State and Government took place. According to their statement, economic growth, which is not an ultimate goal in itself, is supposed to support the decrease in the differences in living conditions. In accordance with the European concept, we need to pay special attention to environmental protection in a way that progress may in fact be of service to humanity. The Paris summit called the attention of the European Commission to the need to elaborate an environmental action plan. The first action plan was adopted by the European Commission in November 1973 in the form of a declaration, which was followed by six more action plans as decisions, determining the framework of environmental ruling not only in directly effective legal instruments but also in those that were formulated later in soft laws. The direct goals of EU environmental policies contain principles concerning the legal regulation of genetic modification, maintaining a satisfactory ecological balance, protecting the biosphere and the reasonable use of our natural resources, furthermore, the prevention of the exploitation of these natural resources, which would strongly damage the ecological balance. The new approach of the fifth action program shows in the fact that

> "it initiates some changes in the current trends harmful to the environment in order to provide ideal circumstances for the social and economic prosperity and growth of present and future generations."[13]

11 Alexandre Kiss & Dinah Shelton, *Guide to International Environmental Law,* Martinus Nijhoff, Leiden/Boston, 2007, p. 74.

12 Participants of the Stockholm conference approved a declaration on environmental principles and its international tasks. The United Nations Environmental Program (UNEP) was created for harmonizing international efforts and guiding the cooperation. The Stockholm Declaration was the first to officially accept the right to a decent environment at an international level. In this declaration, governments solemnly committed to preserve and improve the human environment for present and future generations. Agenda 21, tasks for the 21st century, that is an overarching program of sustainable development, the Rio Declaration that describes the principles of sustainability and the principles of sustainable forestry was approved in Rio de Janeiro. The Convention on Biological Diversity and the Framework Convention on Climate Change, also called the "Rio conventions" were opened to sign.

13 *See* more in: Bándi 2014, p. 81.

Stopping the destruction of natural resources and biological diversity, in which are also affected by gene technology, are priorities in the program – as well as in the sixth and seventh action plans.[14]

In general, since the adoption of the Treaty of Lisbon, references to basic environmental principles have been applied in related court decisions as if these principles had been one of the articles of the Treaty, yet all principles had been integrated into the primary law from some soft law document. Here are a few examples from some of the numerous decisions, which show this phenomenon very well.

One of the first and most critical principles in environmental law is the "polluter pays" principle, which was created in a soft law document, in an OECD recommendation in 1972.[15] The European Economic Community took it over and defined it in a recommendation in 1975.[16] Rulings of the European Court of Justice refer to the polluter pays principle as Section 2 of Article 130r of the EC Treaty, for example in the *Stanley and Metson* case, where the European Court had to make a decision on British farmers' nitrate pollution.[17]

The principle of taking action at the source was first phrased in the UN conference held in Stockholm in 1972. In the *Vallon Waste* case,[18] the Court refers to it on the grounds of Article 130r(2) as the principle underlying the Community's actions related to the environment.

The principle of prevention has been a part of the Community's environmental policy since the First Action Program (1972). The *ARCO Chemie* case[19] is a well-known example for waste-related case law. The starting point in this case, as in many other waste-related cases, is the principle of prevention. "39. It should further be pointed out that, pursuant to Article 130r(2) of the EC Treaty (now, after amendment, Article 174(2) EC), Community policy on the environment is to aim at a high level of protection and is to be based, in particular, on the precautionary principle and the principle that preventive action should be taken."

14 The priority sectors were industry, energetics, transportation, agriculture and tourism. Regarding the industry-environment relationship, the program highlights the better use of resources and use of information to encourage better customer choices. These principles affected the regulations of gene technology as well.

15 Guiding principles concerning international economic aspects of environmental policies, C (72) 128.

16 Council Recommendation 75/436/Euratom, ECSC; EEC regarding cost allocation […] and action by public authorities on environmental matters.

17 Case C-293/97, reference to the Court by the High Court of Justice of England and Wales, Queen's Bench Division, for a preliminary ruling in the proceedings pending before that court between The Queen and Secretary of State for the Environment, Minister of Agriculture, Fisheries and Food, ex parte: H. A. Stanley and Others and D. G. D. Metson and Others, 29 April, 1999 (ECR 1999 I-02603).

18 Judgment of 9 July 1992 in Case C-2/90, *Commission of the European Communities v. Kingdom of Belgium*, [1992] ECR I-04431.

19 Judgment of 15 June, 2000 Joined Cases C-418/97 and C-419/97, *ARCO Chemie Nederland Ltd v. Minister van Volkshuisvesting and others*, [2000] ECR I-04475.

10.2 The Regulation of Coexistence, or Going from "Soft Law" to "Hard Law"

Most of the national environmental rules are directly linked to the fulfillment of the requirements of EU law. Thus, it becomes fully understandable why it is so important to be aware of the legal issues that come up in relation to applying EU law. It is known that directives are the most commonly applied rules in the EU's environmental policy,[20]

> "which apparently give freedom to the Member States in selecting their own methods or forms if the goal is reachable by these; however, it still uses such institutions or tools which, according to case law, the Member States are accountable for, with more or less accuracy. Of course, this does not mean that the autonomy of the Member States is hindered by serious limitations but standardization is almost obvious."[21]

> "With respect to the Member States' right that allows them to implement the environmental directives in a form and method of their own choice, it can be assumed that even though the Member States can still determine the distribution of responsibilities and competences in their own territories, all recurring cases where the differences between certain differences in the application of the Community environmental law led to delay, support the process of centralization."[22]

And the same author (Somsen) continues:

> "The European Court of Justice left little doubt as to that even less discretion remains for the Member States with regards to compliance with the environmental directives, especially when selecting the form and methods of transposition. The main reason is that most environmental directives expect achieving the results."[23]

So it is undoubted that the independence of the Member States does not mean complete freedom when adopting and applying the environmental laws of the EU.

20 Ludwig Krämer, *EC Environmental Law*, Sixth Edition, Thomson, Sweet and Maxwell, London 2007, p. 57.
21 Bándi 2014, p. 196.
22 Han Somsen, 'Discretion in European Community Environmental Law: an Analysis of ECJ Case Law', *Common Market Law Review*, 40: 2003, p. 1450.
23 Somsen 2003, p. 1452.

> "Some legal institutions are difficult to avoid, in the practical implementation of others, some constraints appear, and the third one plays a vital role in achieving the goals. If the Community system of environment law as a whole determines four-fifths of the national environmental law, it should be seen as a system, in the sense of what legal instruments and legal institutions are used, since it is impossible that this major constraint would not present itself in this field. This is all the more logical conclusion because the EU law can do nothing else but use elements that fit into the national law, to a smaller extent, striving for the unification of law by applying decrees or perhaps decisions, and to a greater extent, endeavoring for legal harmonization."[24]

An expert of international law clearly summarizes the point of the EU in this respect as: "... the European Union has an advantage in the sense that its Member States have in fact partially given up their sovereignty, therefore also giving up on some of the elements of their national power."[25]

The law on genetically modified organisms (hereinafter called: "GMO") is a sub-area of the regulation of biotechnology, which is a specific, marginal part of environmental law. GMO means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. This technology is often called "modern biotechnology" or "gene technology", sometimes "recombinant DNA technology" or "gene modification, gene manipulation."[26] This technology enables the transplantation of selected genes or internal transcribed spacers of a living organism into another living organism, even if they are not related species. "The concept of GMO is best defined by genetic modification or genetic engineering. GMO is a living organism whose genetic structure is modified in a way that nature is highly unlikely to recreate or only through a very long period of evolution."[27]

Below are the most significant EU laws of this field. The legal regulation of gene technology goes back to the 1990s. The first law on gene technology was Directive 90/220/EEC in 1990 on the deliberate release into the environment of genetically modified organisms. That was repealed by Directive 2001/18/EC on the release into the free environment of genetically modified organisms. At that time, the implementation of the Fourth Action Program (1987) of the European Community was in progress, which also recognized the fact that environmental protection is also a condition to further economic

24 Bándi 2014, p. 196.

25 Alexandre Kiss & Dinah Shelton, *International Environmental Law*, Transnational Publishers, 2000, p. 111.

26 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, Art. 2.

27 Ervin Balázs, *Genetically modified organisms – facts, expectations or fiction?*, Mindentudás Egyeteme, Semester 3, Lecture 7, 3 April 2006.

progress. The Directive introduced a preapproval procedure for genetically modified organizations. It prescribed that an environmental impact study be prepared before any GMO is placed on the market or released into the environment. For obtaining a license, applicants must submit detailed documentation, including information on the environmental impact study and the safety standards required by the study, as well as suggestions for the user guide and labelling instructions if it is about a product.

Council Directive 90/219/EC[28] on the contained use of genetically modified micro-organisms, amended by Council Directive 98/81/EC on the contained use of genetically modified micro-organisms, which indirectly affects the regulation of genetically modified seeds, also regulating their use for research and industrial purposes.

Regulation (EC) No. 1829/2003[29] regulates the matter of genetically modified food and feedstock, Regulation (EC) No. 1830/2003[30] provides regulation concerning the traceability and labelling of genetically modified organisms and the traceability of food products and feedstock produced from genetically modified organisms and amends Directive 2001/18/EC. Regulation (EC) No. 1946/2003[31] on transboundary movements of genetically modified organisms was also adopted in 2003.

The Council Regulation (EC) No. 870/2004 of 24 April, 2004 established a Community program on the conservation, characterization, collection and utilization of genetic resources in agriculture and repealing Regulation (EC) No. 1467/94 is also remarkable. The secondary law of the European Union clearly had a detailed legal background on GMOs.

At the same time, Member States clearly resisted the open-field use of GMOs. Municipalities in the Member States and contiguous areas in Europe declared themselves "GMO-free regions one after the other."[32] This phenomenon raised questions in the enforcement and application of the above laws and regulations, as it could also be interpreted as an excuse for the "GMO-free" territories not applying the EU law.

Member States that did not wish to authorize the open-field growing or placing on the market of a GMO in their own territory, which had already been authorized by the EU, had the following three legal options.

Article 23 of Directive 2001/18 allows the safeguard clause

28 Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

29 Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

30 Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

31 Regulation (EC) No. 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms.

32 *See* more in: https://www.gmo-free-regions.org/, and: http://gmo-free-regions-nrw.de/; http://www.gmo-free-europe.org/; http://www.firab.it/site/the-european-network-of-gmo-free-regions/; http://www.gmovapaa.fi/ajankohtaista/ulkomaan-uutiset/more-gmo-free-regions-in-romania.

> 1. "Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory."

In this process, the Member state had to apply security measures in case of a serious risk – for example, suspend or stop placing a product on the market – including informing the public. The Member State had to inform the European Commission and the other Member States as soon as they took measures on the grounds of this Article; they also had to give reasons attaching the verification of the environmental risk assessment, pointing out why and how the conditions of the consent had to be modified or how the consent had to be revoked, plus the new or additional information as the grounds for its decision, as the case may be. In the safeguard clause proceeding, a decision had to be made within 60 days.

Another lawful form of the Member States' "resistance" was the emergency measures according to Article 34 of Regulation 1829/2003/EC. It says

> "Where it is evident that products authorized by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorization arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) No 178/2002."

Thirdly, the notification proceeding set out in Sections 5 and 6 of Article 114 of the TFEU[33] was a good option for the Member States to propose new scientific evidence for protecting the environment or working environment.[34]

33 Consolidated Versions of the Treaty on the European Union and the Treaty on the Functioning of the European Union (2012/C 326/01).

Member States could refer to neither ethical nor religious reasons in all three proceedings and the reasoning exclusively had to be based on measurable risk assessment.

Hungary opted for the safeguard clause proceeding. The Minister of Agriculture and Rural Development started the safeguard clause proceeding on 20 January, 2005, based on the results of the environmental risk tests, against involving the open-field growing of the genetically modified MON 810 maize. The 2005 June statement of the European Food Safety Authority (hereinafter: "EFSA")[35] did not see the reasons of the moratorium well substantiated. In section 1. of Decision No. 53/2006 (XI.29.) the Hungarian Parliament asked the Government to continue the environmental impact assessments on genetically modified plants authorized at Community level, so the presumed negative effects in the Pannon Biogeographical Region can be revealed and all necessary steps can be taken within the safeguard clause proceeding to prevent the involvement of MON 810 maize in the open-field growing and maintain the Hungarian moratorium issued on 20 January, 2005, and therefore using all available diplomatic and legal instruments to change a possible unfavorable decision of the European Commission. The specialized committee that consisted of experts appointed by the Member States voted on the draft in September 2006 but the qualified majority required for the decision was still missing. 22 out of 27 member states voted against the Commission proposal and therefore, in favour of Hungary in 2007. As a result, the restriction could be maintained but Hungary had to provide more detailed documentation to the European Commission, so that the EFSA can also review it. However, neither the Commission nor the EFSA gave a response to the requested and received documentation. In 2009, a new voting was pushed by the Commission, where the result was the repeated maintenance of the moratorium.

This convinced the Member States of the necessity of collaboration. In June 2009, 13 Member States called the European Commission within the frames of soft law to develop a proposal that aims to let Member States make their own decisions when it comes to growing GMOs. The expectation was to develop national coexistence measures that serve to avoid the unwanted occurrences of GMOs amongst traditionally or by organic farming[36] grown plants.[37]

Member State initiation resulted in a stronger soft law instrument, as on 13 July, 2010, the Commission adopted recommendation No. 2010/C 200/01 for the Member States.

35 The European Food Safety Authority (EFSA), as an independent authority, was created by Regulation 178/2002/EC as an academic body independent from the other bodies of the Union whose most important task is to provide academic advice on the Community legislation and politics in every field that has any direct or indirect influence on food or feed safety.

36 Coexistence defines the rules of traditional, organic farming and open-field cultivation living next to each other.

37 Ágnes Kovács-Tahy, 'Az együtt-termesztés uniós szabályozásáról és annak vitájáról – A nemzeti együtttermesztési intézkedések kidolgozására vonatkozó iránymutatásokról szóló Bizottsági ajánlásról' (Ruling coexistence in the Union and its arguments – Commission Recommendation on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops), in: *Iustum Aequum Salutare*, Vol. VII, No. 2011/2, pp. 181-193.

Coexistence means the application of different cultivation cultures, while protecting their unique characters. This is a matter of "production organization."[38]

The Commission submitted a new GMO proposal agenda, whose purpose was – without amending the existing and science-based authorization system of the European Union – to allow the Member States to make their own decisions on whether they restrict GMO cultivation on their territory only partly or prohibit it fully. This agenda covered a communication and a proposed regulation, of which this latter one proposed the amendment of Directive No. 2001/18/EC. The Commission published a recommendation on coexistence as part of the agenda. According to this recommendation, the Member States should be offered more flexibility, so they can apply their own, regional, domestic features while adopting the regulation on coexistence.

> "The presidency has issued an informal document on the activities performed by the *ad hoc* council work group to promote the negotiations and to structure the tasks on the GMO agenda. The document summarized the key obstacles that occurred during the negotiations, and it also offered possible solutions to the concerns named by the Member States and their institutions."[39]

On March 14, 2011, the Environmental Council exchanged views based on the questions on the two aspects of the legislative proposal compiled by the presidency, focusing on the possible list of reasons. They made a new compromise proposal that each Member State accepted as good grounds for the further efforts to be taken by the Council. The presidency considered that although most delegations supported the presidency's compromise, it takes more time to clarify all matters and concerns brought up by some of the delegations. Then, after a discussion, on the June 21 session of the Environmental Council, the Ministers approved the progress report submitted by the presidency.

On July 5, 2011, the European Parliament voted for the amendment to the legislative proposal.[40] Nevertheless, the States arguing in favor of GMOs in the Council hindered the conclusion of the agreement for a long time. Negotiations only gained new momen-

38 Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops 2010/C, 200/01 Appendix.

39 *See*: Vidékfejlesztési Minisztérium, Biodiverzitás– és Génmegőrzési Osztály által kiadott közlemény (Communication issued by the Biodiversity and Gene Preservation Unit of the Ministry of Rural Development), Budapest, July 4, 2011; available at: http://biodiv.kvvm.hu/magyar-eu-elnokseg-biodiverzitas/eu-elnokseg-biodiv-gmo.pdf.

40 European Parliament legislative resolution of July 5, 2011 on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the production of GMOs on their territory. (COM (2010) 0375 – C7-0178/2010 – 2010/0208 (COD).

tum in 2012 when the scandal surrounding the authorization of the cultivation of maize 1507 GM showed the gaps in the EU GMO system.[41]

As a result of this process, an EU law was adopted in March 2015, which settled several decades of uncertainty in the Member States.[42] The new regulation preserved the system of centralized EU authorization but allowed a two-stage authorization to let Member States have their GMO-free agriculture. Directive (EU) 2015/412 provides a comprehensive legal framework that is fully applicable to GMOs for use of seed or other plant propagation material for cultivation in the Member States. It is a novelty that a Member State may, on the one hand, apply for an adjustment to the geographical scope of the application for authorization in the course of the authorization proceeding. This option gives the applicant biotechnology company the opportunity to adjust its application, *i.e.* to remove from its application the territory of the Member State requiring exemption. In case the company is required to respond within 30 days take into account the Member States' request formulated in a simple letter, their application for an EU authorization will be handled by making it clear to everyone that the company has not applied for permission in several Member States.

On the other hand, if the adjustment of the geographical scope has not been made as described above, or the Member State did not request such adjustment at all, such Member State may prohibit or limit the production of that particular plant after the GMO has been authorized (that means subsequently). The Directive gives examples of applicable reasons, *e.g.* arguments related to environmental policy, agricultural policy goals, urban and rural spatial planning priorities, land use considerations, socio-economic impacts, coexistence aspects, and public order as a basis for reference.

As a result of a long process, it was a regionally emerging social phenomenon that has achieved initial regulation in various "soft law" instruments, later as the will of the majority, at the level of a European Union directive.

41 In fact, only five of 28 EU Member States had granted this EU authorization, but it was still authorized.

42 Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.