BeeLife
European Beekeeping Coordination

Does EU Law on GMOs Enable a High Level of Environmental Protection to be Achieved?

Overview of the regulatory framework for GMOs and case study of pollinating insects

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INTRODUCTION

Under Article 191(2) of the Treaty on the Functioning of the EU (TFEU), European Union (EU) legislation requires a high level of environmental protection, of which pollinators are obviously a part. At the same time, there is currently a drive within the EU to strengthen their protection. The European Commission is developing policies to protect pollinators as effectively as possible.[1] A European citizens' initiative called "*Save the Bees and Farmers*" has been launched with the specific aim of protecting pollinators, and has collected more than a million signatures.[2] Projects funded by public authorities to improve the protection of pollinators are also underway (notably the IPol-ERA project, which aims to make progress in assessing the environmental risks of pesticides for pollinating insects, as well as the PollinERA and WildPosh projects).[3] This is therefore a highly topical issue.

Pollinators are living organisms that transfer pollen from plants by foraging. Pollinators play a crucial role in biodiversity and food production, ensuring the reproduction and diversification of plants.[4] In the context of this report, only insect pollinators will be discussed, including, for example, bees, butterflies, flies and beetles, and excluding pollinating birds and mammals. Pollinating insects are a very good bio-indicator for measuring the state of health of the environment. The main factors indicating poor environmental protection have a direct impact on pollinators and are among the reasons for their decline. These include "changes in land use, intensive agriculture, pesticide use, environmental pollution, invasive alien species, pathogens and climate change".[5] Conversely, pollinating insects play an important role in biodiversity and its balance. The two are intrinsically linked.

In this report we explore the issue of genetically modified organisms (GMOs) and their potential impact on pollinating insects. Directive 2001/18/EC[6] defines a GMO as "an organism, with the exception of human beings,

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[1] The European Commission launched the EU Pollinator Initiative in 2018. In addition, the European Green Pact and its EU Biodiversity Strategy 2030, which aims to reverse biodiversity loss in Europe, as well as other strategies such as the Zero Pollution Action Plan, the EU Forest Strategy and the Climate Change Adaptation Strategy, are helping to tackle threats to pollinators.

[2] Official website of the European Commission, "Save bees and farmers!": the million signatures collected in the European Citizens' Initiative signal to EU co-legislators the importance of maintaining environmental ambition, https://commission.europa.eu/index_fr [consulted on 1 June 2023], available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_23_2084

[3] Official EFSA website, Theme (concept) paper - Advancing the Environmental Risk Assessment of Chemicals to Better Protect Insect Pollinators (IPol-ERA), 2022, https://www.efsa.europa.eu/fr [consulted on 2 June 2023], available at: https://www.efsa.europa.eu/fr/supporting/pub/e200505; PollinERA official website https://pollinera-horizon.eu/; WildPosh official website https://wildposh.eu/

[4] Official website of the French Office for Biodiversity, *Pollinators,* https://www.ofb.gouv.fr [consulted on 1 June 2023], available at: https://www.ofb.gouv.fr/les-pollinisateurs

[5] IPBES, *Assessment Report on Pollinators, Pollination and Food Production, Summary for* Policy Makers, 2016, p. 10.

[6] 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, OJ L 106, 17.4.2001, p. 1-39.

in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."[7] This definition is accompanied by lists establishing which techniques of genetic modification are included or excluded from the scope of the directive.[8] The protection of pollinating insects depends on the legislation to which each player in the EU is subject, and therefore also on the legal framework applicable to GMOs. Here, we study EU law on GMOs to ascertain whether, how and to what extent this law ensures a high level of protection for the environment, and more specifically for pollinating insects. This includes primary and secondary legislation, but also the interpretation of the legislation and its evolution. This study provides a better understanding of current legislation in this area, and of the mechanisms it contains that contribute to the protection of the environment and pollinators. Indeed, by understanding these mechanisms, we can exercise greater vigilance in the future when assessing new legislative proposals that could have an impact on pollinators.

The aim is therefore to see how and to what extent EU law on GMOs can guarantee a high level of protection for the environment, and more specifically for pollinating insects.

Firstly, it will be seen that European GMO law is an old piece of legislation that deploys an arsenal of mechanisms to protect the environment (I), and secondly, that it is a law that is subject to fluctuations and dilemmas between economic interests and environmental protection (II).

PART 1

Long-standing legislation deploying an arsenal of mechanisms to protect the environment

In order to better understand the legal framework relating to GMOs, a general presentation of this long-standing legislation to which the precautionary principle applies should be given (Section 1), followed by a more detailed presentation of the protection mechanisms it contains and which enable it to effectively implement this principle (Section 2).

SECTION 1: Long-standing legislation including the precautionary principle

Legislation on GMOs goes back a long way, to a very early stage.[9] The first directives on the subject were adopted as early as 1990: **Directives 90/219/EEC**[10] **and 90/220/EEC.**[11]

At international level, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD) was adopted on 29 January 2000 by the Conference of the Parties. It establishes an international regulatory framework to reconcile environmental protection with the commercial imperatives of the biotechnology industry,[12] and incorporates the precautionary principle enshrined in Principle 15 of the Rio Declaration on Environment and Development.[13]

In order to renew the European legislative framework, which was in need of improvement, **Directive 2001/18/EC** was adopted in the EU in 2001, and is still **the main text relating to GMOs. Regulations (EC) no. 1829/2003 on genetically modified food and feed**[14] **and no. 1830/2003**[15] **on the traceability and labelling of GMOs complete the regulatory framework.** A GMO can only be placed on the market if it has received prior authorisation. Thus, when a GMO is intended for food or feed use, it is subject to the marketing authorisation procedure set out in Regulation 1829/2003. Directive 2001/18/EC lays down the authorisation

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[9] Estelle BROSSET, Le droit de l'Union européenne des OGM : entre harmonisation et renationalisation, Droit et biotechnologies, Les études hospitalières, 2012, pp. 41-75, p. 42.

[10] Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms, OJEC L 117, 8/05/1990, pp. 1-14.

[11] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of GMOs, OJEC L 117, 8/05/1990, pp. 15-27.

[12] Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes*, 2000, p. 1.

[13] Article 1 of the Cartagena Protocol.

[14] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268, 18.10.2003, pp. 1-23.

[15] 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, OJ L 268, 18.10.2003, pp. 24-28.

procedure for the placing on the market of GMOs for any other purpose.[16] Authorisation procedures for the cultivation of GMOs in the EU are subject to the requirements of Directive 2001/18/EC or Regulation 1829/2003 if the scope also includes food and feed. While the number of GMOs authorised for import into the European Union is relatively high,[17] only one GMO has been authorised for cultivation in the European Union: MON810 maize, i.e. maize plants producing active toxins from *Bacillus turingiensis* .

Even where the authorisation process is governed by Regulation 1829/2003, in the case of GMOs or foods containing or composed of GMOs, the application for authorisation must include a risk assessment (RA) carried out in accordance with the principles set out in Annex II of Directive 2001/18/EC, as well as a monitoring plan for environmental effects in accordance with Annex VII of Directive 2001/18/EC.[18] Regulation 1829/2003 therefore often refers to Directive 2001/18/EC. The framework also aims to establish harmonised procedures for assessing and approving GMOs through risk assessments, while promoting transparency. In addition, the framework requires clear labelling of products containing GMOs in order to provide consumers and industry professionals, such as farmers and feed operators, with accurate information to make informed decisions. In addition, the framework aims to ensure the traceability of GMOs placed on the market.[19]

It should be noted that in an area such as GMOs, where scientific knowledge is evolving rapidly, the regulatory framework established in the early 2000s can be considered particularly outdated.

Despite its age, the regulatory framework contains an arsenal of mechanisms to protect the environment, including pollinating insects. Indeed, the aim of the legal framework is to ensure the protection of human and animal health, as well as the environment, by implementing rigorous safety assessments at EU level before any GMO is placed on the market.[20]

Article 1 of Directive 2001/18/EC sets out its objective: to protect human health and the environment in accordance with the precautionary principle. The Court of Justice of the European Union (CJEU) has repeatedly stated that the importance of the objective pursued by a regulation, for example the protection of human health, "is such as to justify adverse economic effects, even if considerable".[21] **Recital 8 of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms also**

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[16] Official website of the Ministry of Agriculture and Food Sovereignty, GMOs: the regulatory framework, 2023 https://agriculture.gouv.fr [consulted on 1 June 2023], available at: https://agriculture.gouv.fr/ogm-le-cadre-reglementaire#:~:text=Les%20règlements%20(CE)%20n°,certains%20cas%20de%20présence%20accidentelle%20

[17] The list is available on the European Commission's website at https://webgate.ec.europa.eu/dyna2/gm-register/.

[18] Article 5(5) of Regulation (EC) No 1829/2003.

[19] European Commission website, *GMO legislation*, https://commission.europa.eu/index_en [consulted on 1 June 2023], available at: https://food.ec.europa.eu/plants/genetically-modified-organisms/gmo-legislation_en

[20] *Ibid.*

[21] ECJ, 17 July 1997, Affish BV v. Rijksdienst voor de keuring van Vee en Vlees, Case C-183/95, ECR p. I-04315, para. 43; General Court, 11 September 2002, Pfizer Animal Health SA v. Council of the European Union, Case T-13/99, ECR p. II-03305, para. 456; General Court, 11 September 2002, Alpharma Inc. v. Council of the European Union, Case T-70/99, ECR p. II-03495, para. 356.

explains that "the precautionary principle has been taken into account in the drafting of this Directive and must be taken into account in its implementation". Article 4§1 of the Directive also states that "Member States shall ensure, in accordance with the precautionary principle, that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs". Directive (EU) 2015/412[22] on the possibility for Member States to restrict or prohibit the cultivation of GMOs on their territory confirms that the precautionary principle "should always be taken into account in the context of Directive 2001/18/EC and its subsequent implementation".[23] Recital 3 of Regulation 1830/2003 on traceability and labelling of GMOs again refers to the precautionary principle, stating that "traceability should also facilitate the implementation of risk management measures, in accordance with the precautionary principle".

To better understand what this means, we need to take a closer look at this principle. The precautionary principle is a key concept in the European legal framework. Incorporated by the Maastricht Treaty in 1992, it is now enshrined in Article 191(2) of the Treaty on the (TFEU). The article states that "Union policy on the environment shall aim at a high level of protection (...). It shall be based on the precautionary principle (...)". This article therefore specifies that **the precautionary principle must serve as the basis for all European regulations with an impact on health and the environment.** The precautionary principle is not defined in the Treaties, but was explained in the Commission's communication on the precautionary principle in 2000.[24] According to the Communication, "recourse to the precautionary principle can only be had in the event of a potential risk", and it can "under no circumstances legitimise arbitrary decision-making".[25] Three factors must therefore be present: 1) identification of potentially negative effects, 2) scientific evaluation and 3) scientific uncertainty.[26] **We can therefore try to define it as the possibility for decision-makers to take precautionary measures when there is scientific uncertainty about a risk to the environment or human health.**[27]

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[22] 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 Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) on their territory, OJ L 68, 13.3.2015, pp. 1-8.

[23] Recital 2 of Directive (EU) 2015/412.

[24] Communication from the Commission on the precautionary principle, COM(2000) 1 final.

[25] *Ibid,* section 5.1, p. 13.

[26] *Ibid,* section 5.1, pp. 13-14.

[27] Didier Bourguignon, *Le principe de précaution, Définitions, applications et gouvernance,* 2015, p. 1.

The Commission Communication makes it clear that implementation of the precautionary principle "should start with a scientific assessment that is as complete as possible and, where possible, determine at each stage the degree of scientific uncertainty".[28] Measures based on the precautionary principle should then be "re-examined in the light of new scientific data".[29] Thus, contrary to what is sometimes argued, if one follows the official interpretations mentioned in the Treaties, legislation and other documents of the European Union, **the precautionary principle should not run counter to science or innovation, because it is precisely based on scientific evidence.**[30] The aim of the precautionary principle is to ensure that political decisions are based on science, and thus precisely to avoid decisions being based on unscientific assumptions.[31] According to the Commission, measures based on the precautionary principle should be proportionate to the level of protection sought.[32] In environmental matters, the level of protection sought is "high",[33] so the principle should give rise to strong protective measures.

Because of the uncertainty about the long-term effects of consuming or releasing GMOs into the environment, the precautionary principle necessarily applies to GMOs. The principle is applied by requiring testing and risk assessment, and must be followed when making decisions about their consumption or production. Risk assessment, combined with labelling and monitoring requirements, aims to ensure a high level of protection for the environment, animal health and human health. It is important to remember that the precautionary principle must be applied not only in risk assessment, but also in risk management and risk communication, which also means in the decision-making phase.[34]

SECTION 2: A multitude of mechanisms contributing to a high level of environmental protection

The regulatory framework provides for numerous mechanisms that contribute to the desired level of protection.

Risk assessment

One of the key points in ensuring a **high level of environmental protection for human and animal health is the environmental risk assessment (ERA).**

[28] Communication from the Commission on recourse to the precautionary principle, *op. cit,* section 6.1, p. 16.

[29] *Ibid,* p. 3

[30] Sven Ove HANSSON, How Extreme Is the Precautionary Principle? 2020, *Nanoethics* 14, pp. 245-257, online: https://doi.org/10.1007/s11569-020-00373-5

[31] *Ibid.*

[32] Communication from the Commission on recourse to the precautionary principle, *op. cit.* p. 3.

[33] TFEU, Article 191 para. 2.

[34] Summary of the Communication on the precautionary principle (COM(2000 1 final).

According to point A of Annex II of Directive 2001/18/EC on the deliberate release into the environment of GMOs, the objective of an ERA is "to identify and assess, on a case-by-case basis, the potential adverse effects of GMOs, whether direct or indirect, immediate or delayed, that the deliberate release or the placing on the market of GMOs could have on human health and the environment". The general principles and methodology to be followed to carry out the ERA for GMOs are described in Annex II of Directive 2001/18/EC on the deliberate release into the environment of GMOs; we will analyse this in more detail in Part 2.

It is important to understand not only who is responsible for this ERA, but also what follows from it. In the case of a GMO intended for food use, a company wishing to market a product containing or derived from GMOs must submit an application to a Member State. The application is then sent to the European Food *Safety* Authority (EFSA), which is responsible for assessing the environmental and health risks.[35] Following EFSA's opinion and consultation with the Member States, the European Commission prepares a draft decision. Following a vote by the Member States on the draft decision, if there is no qualified majority for or against, the Commission finally takes a decision authorising or refusing marketing. In the case of GMOs not intended for food use, the company submits the dossier to a Member State, which is itself responsible for drawing up an assessment report in which it gives an opinion on whether or not the GMO can be placed on the market. If the opinion is favourable, the European Commission consults the other Member States and the public. In the event of an unfavourable opinion, EFSA is consulted and submits the draft authorisation decision to the vote of the Member States.[36]

Traceability

Regulation (EC) No 1830/2003 establishes "a framework for the traceability of products consisting of or containing GMOs, and food and feed products produced from GMOs, in order to facilitate accurate labelling, the monitoring of environmental and, where appropriate, health effects, and the implementation of appropriate risk management measures, including, where necessary, withdrawal of products"[37] and thereby contributes to the application of the precautionary principle and a high level of protection. According to the definition given in Article 3, **"traceability" means the ability to follow GMOs and products produced from GMOs, at all stages of their placing on the market, along the production and distribution chain.** This is of fundamental importance, as **it enables the potential effects on health or the environment to be accurately monitored.** It also makes it possible to identify an unforeseen risk and therefore to withdraw the product in question.[38]

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[35] Official website of the Ministry of Ecological Transition and Territorial Cohesion, *Genetically modified organisms*, 2022, https://www.ecologie.gouv.fr [consulted on 1 June 2023], available at: https://www.ecologie.gouv.fr/organismes-genetiquement-modifies-ogm-0#scroll-nav__4

[36] *Ibid.*

[37] Regulation (EC) n°1830/2003, Article 1.

[38] European Commission website, *Traceability and labelling,* https://commission.europa.eu/index_en [consulted on 1 June 2023], available at: https://food.ec.europa.eu/plants/genetically-modified-organisms/traceability-and-labelling_en

According to Article 4 of the Regulation, traceability requirements imply that operators must provide their customers with an indication that the product (or certain ingredients) contains, consists of or is produced from GMOs, as well as information on the unique identifier[39] of these GMOs. In the case of products consisting of or containing mixtures of GMOs, intended solely for food or feed use or for processing, this information may be replaced by an operator declaration of use, accompanied by a list of the unique identifiers of all the GMOs that have been used to constitute the mixture. For products intended to be food and feed produced from GMOs, operators must ensure that an indication of each food ingredient, feed material or feed additive produced from GMOs is transmitted to the following operator.[40]

In addition, operators are required to ensure that the information received is transmitted in writing to the operators receiving the product and at all stages of the supply chain.[41] They must also set up systems to enable the information mentioned to be kept for five years and to identify the operator from whom the product was made available.[42]

Labelling and public information

Labelling is a key element of the **information given to the consumer, and undoubtedly the most accessible means of information.** It is therefore essential that controversial products are labelled **so that consumers can make a free choice as to what to consume.** Directive 2001/18/EC makes labelling compulsory for all GMOs at all stages of marketing.[43] Only in the case of "adventitious or technically unavoidable traces" of authorised GMOs that cannot be excluded can labelling be circumvented.[44] Regulations 1830/2003 and 1829/2003 contain more specific provisions on labelling. The former also makes it compulsory for products consisting of or containing GMOs to be labelled in writing, either on the pre-packaging or on the product label, indicating that the product contains GMOs.[45]

Regulation (EC) No 1829/2003 also contains provisions on the labelling of genetically modified food and feed, particularly in Articles 12 and 13 as regards food.[46] Thus, a wide range of information must be included on the label, including any characteristic or property where a food differs from its conventional equivalent in terms of, for example, its "nutritional value or nutritional effects" or its "implications for the health of certain sections of the population", or where it may give rise to ethical or religious concerns.[47] Similar provisions can be found for

[39] According to the definition given in Article 3 of Regulation (EC) No 1830/2003, it is "a simple numeric or alphanumeric code, which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and which provides a means of accessing specific information relating to that GMO".

[40] Regulation (EC) No 1830/2003, Article 5, para. 1.

[41] Regulation (EC) No 1830/2003, Article 4, paragraphs 1 and 2.

[42] Regulation (EC) No 1830/2003, Article 4, para. 4.

[43] Directive 2001/18/EC, Article 21.

[44] Directive 2001/18/EC, Article 21.

[45] Regulation (EC) No 1830/2003, Article 4, para. 6.

[46] Regulation (EC) No 1829/2003, Articles 12 and 13.

[47] Regulation (EC) No 1829/2003, Article 13 para. 2.

GM feed.[48] On the other hand, the European legal framework makes no provision for the labelling of products from "GMO-free" sectors.[49] However, the absence of a European legal framework has not prevented private "GMO-free" labelling initiatives from flourishing in several sectors (e.g. poultry) and Member States.

Directive 2001/18/EC contains other provisions on informing the public, further confirming its importance. Under Article 24, the European Commission shall immediately make the assessment reports available to the public, who shall then have a period of thirty days in which to submit comments. For GMOs that have been authorised or refused marketing authorisation, the assessment reports and opinions of the scientific committees consulted are made public.

Safeguard clauses

Article 23 of Directive 2001/18 provides that a Member State may provisionally restrict or prohibit the use and/or sale of a GMO as or in a product on its territory. **The safeguard clause therefore allows a Member State to partially apply an authorisation decision taken at Community level.**[50] However, this decision by a Member State must not be taken unjustifiably; there must be "precise" reasons for considering that this product, despite having been authorised in accordance with European legislation, presents a risk to human health or the environment. In addition, this must be based on new or additional information that has become available *after the* authorisation was given.

This clause is widely used by the Member States, many of which have banned the cultivation on their territory of the only GMO authorised for cultivation in the European Union: transgenic MON810 maize. At present, this GMO is only cultivated in Spain and Portugal,[51] proving that the precautionary principle is strongly applied by most Member States.

According to the Court, the safeguard clause is an expression of respect for the precautionary principle.[52] This possibility is enshrined in primary law, in Article 114(10) of the TFEU, which states that "harmonisation measures (...) shall, in appropriate cases, include a safeguard clause authorising Member States to take, for one or more non-economic reasons (...) provisional measures subject to a Union control procedure". Despite harmonisation at Community level, this means that Member States can continue to defend certain essential national interests, such as the protection of health and the environment.[53] It is therefore a mechanism that makes a major contribution to guaranteeing a high level of environmental protection.

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[48] Regulation (EC) No 1829/2003, Article 25.

[49] Official website of the Ministry of Ecological Transition and Territorial Cohesion, *Genetically modified organisms*, 2022, *op. cit.*

[50] Estelle BROSSET, Observations autour de la réforme et de la résistance du (au) droit des organismes génétiquement modifiés *in* Stéphanie MAHIEU, Katia MERTEN-LENTZ, *Sécurité alimentaire, nouveaux enjeux et perspectives,* Bruylant, 2013, p. 49.

[51] Official website of the Ministry of Ecological Transition and Territorial Cohesion, *Genetically modified organisms*, 2022, *op. cit.*

[52] ECJ, 21 March 2000, *Association Greenpeace France and others and Ministère de l'agriculture et de la pêche and others*, Case C-6/99, *ECR* p. I-1651, para. 44.

[53] Estelle Brosset, L'adaptation du droit français au droit de l'Union européenne en matière de mise en culture d'OGM : regard depuis le principe de précaution, *Revue juridique de l'Environnement*, 3, 2016, p. 556.

According to the Court, the safeguard clause is an expression of respect for the precautionary principle.

Monitoring and processing of new information

Another manifestation of the precautionary principle can be found in Article 20 of Directive 2001/18/EC, which states that **the notifier must immediately take the necessary measures to protect human health and the environment, and inform the competent authority if new information becomes available on the risks posed by a GMO.** In the 2000 ruling by *Association Greenpeace France and others and Ministère de l'agriculture et de la pêche and others*, the European Court of Justice (ECJ) explained that this is also an expression of respect for the precautionary principle.[54]

The monitoring plan referred to in Article 20, but also mentioned in Articles 13 and 19, is detailed in Annex VII. The purpose of a monitoring plan is "to confirm that any assumptions made in the environmental risk assessment regarding the occurrence and impact of potential adverse effects of the GMO or its use are correct", and "to identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment".[55]

Interestingly, data collected through monitoring should be interpreted in the light of other existing environmental conditions.[56] Thus, "where changes in the environment are observed, further assessment should be considered to establish whether they are a consequence of the GMO or its use".[57] A monitoring plan should include general monitoring for unanticipated adverse effects and, if necessary, specific monitoring targeted at the adverse effects identified in the environmental risk assessment.[58]

All these mechanisms provided for in the European legislative framework on GMOs contribute to the application of the precautionary principle, and to a high level of protection for human health and the environment.

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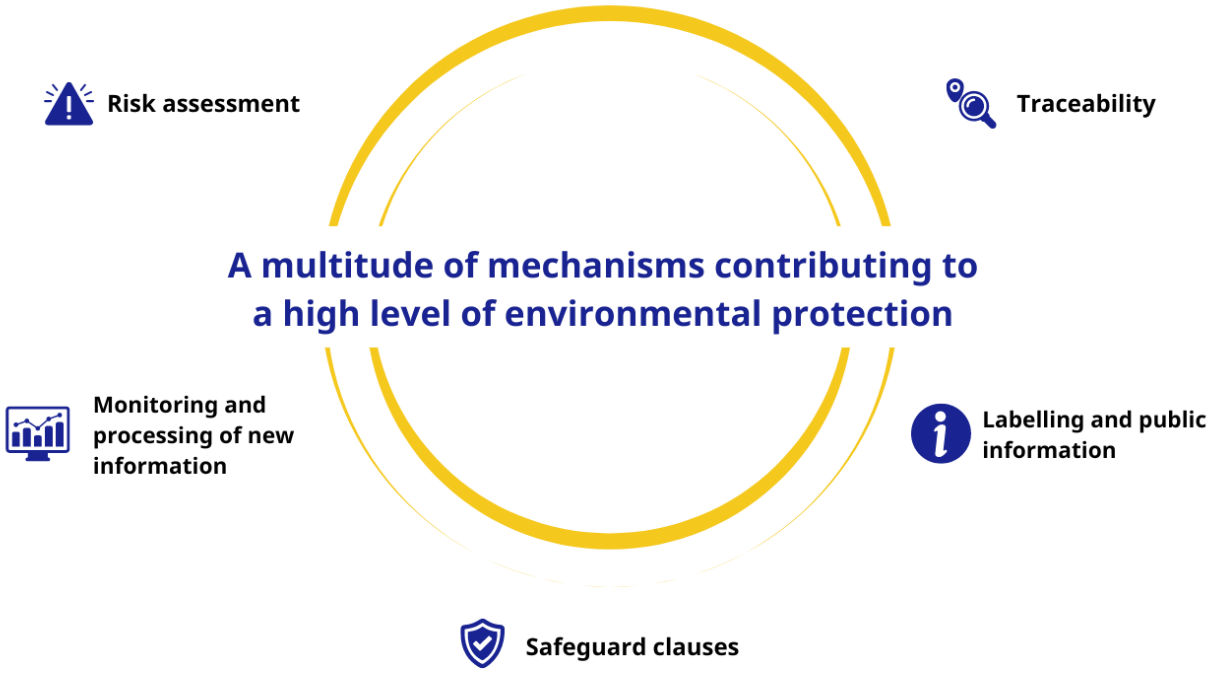
[54] ECJ, 21 March 2000, *Association Greenpeace France and others and Ministère de l'agriculture et de la pêche and others*, Case C-6/99, *op. cit.* para. 44. It should be noted that at the time of the judgment, the analogous article was Article 11 of Directive 90/220.

[55] Annex VII, Point A.

[56] Annex VII, Point B.

[57] *Ibid.*

[58] Annex VII, Point C, para. 3.



PART 2

A law subject to fluctuations and dilemmas: Legislative developments and rulings by the Court of Justice of the EU between economic interests and environmental protection

The law relating to GMOs has changed both in terms of its content (Section 1) and its interpretation (Section 2). This has implications for the protection afforded to the environment and therefore to pollinating insects.

SECTION 1: Legislative developments that have strengthened the protection of the environment and pollinators

Given the long history of GMO legislation, it has been necessary to amend it on several occasions. Since 2001, several directives have amended Directive 2001/18/EC, thereby affecting the protection afforded to the environment and pollinating insects.

Contributions of the 2015 and 2018 directives

In order to give Member States "more flexibility to decide whether or not they want GMOs to be cultivated on their territory, without undermining the risk assessment provided for in the authorisation regime for GMOs in

force in the Union, either during the authorisation procedure or subsequently",[59] Directive (EU) 2015/412 significantly amended Directive 2001/18/EC by including the possibility for a Member State to request that the geographical scope of an authorisation or renewal of authorisation for a GMO be amended so that all or part of the territory of that Member State must be excluded from cultivation.[60] Where no request has been submitted in accordance with the aforementioned provision, the Member State may still adopt measures restricting or prohibiting the cultivation of a GMO on all or part of its territory, provided that these measures are, inter alia, based on serious grounds, for example those relating to "environmental policy objectives".[61] The reasons that may justify a restriction or ban do not refer to scientific evidence; thus, Member States may restrict the cultivation of GMOs on their territory without providing scientific evidence to support their decision. This leaves plenty of room for other interests, such as social ones.[62] In addition, Member States where GMOs are cultivated must now adopt "appropriate measures in border areas of their territory to avoid any potential cross-border contamination of neighbouring Member States where the cultivation of such GMOs is prohibited".[63] In this way, the new Article *26a* of the Directive grants greater autonomy to European States, which can therefore be even more cautious in authorising the cultivation of GMOs on their territory.

On the other hand, the Directive does not allow Member States to take measures to restrict or prohibit GMOs based on risks that EFSA has already assessed.[64] In addition, the 2015 Directive only concerns the cultivation of GMOs, and therefore excludes the issue of GMO imports.[65]

Directive 2001/18/EC was also amended by Directive (EU) 2018/350.[66] This amended Annexes II, III, IIIB and IV of the original Directive. Section C of Annex II on environmental risk assessment (ERA) of Directive 2001/18/EC was amended by describing the general principles and methodology to be followed in carrying out the ERA. According to the directive, the objective of an ERA is "to identify and assess, on a case-by-case basis, the potential adverse effects of GMOs, whether direct or indirect, immediate or delayed, which the deliberate release or placing on the market of GMOs could have on human health and the environment".[67] According to the general principles set out in Annex II, the ERA "should be carried out in a transparent manner using a scientifically sound method based on available scientific and technical data",[68] and "should be carried out on a case-by-case basis, i.e. the information required may vary depending on the type of GMO concerned, its

[59] Directive (EU) 2015/412, recital 8.

[60] Article 26 *ter*, para. 1.

[61] *Ibid*, para. 3.

[62] Alessandra GUIDA, The precautionary principle and genetically modified organisms: A bone of contention between European institutions and member states. *J Law Biosci*, 19;8(1), 2021, online: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8132481/#fn11

[63] Article 26 *bis*.

[64] Alessandra Guida, The precautionary principle and genetically modified organisms: A bone of contention between European institutions and member states, *op. cit.*

[65] *Ibid.*

[66] Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms, OJ L 67, 9.3.2018, pp. 30-45.

[67] Directive 2001/18/EC, consolidated version, Annex II, A.

[68] *Ibid,* annex II, B.

intended use and the potential receiving environment, taking into account, inter alia, GMOs already present in the environment".[69] In addition, the ERA must be reviewed if new information concerning the GMO and its effects on human health or the environment becomes available.[70]

Whereas before 2018, the Annex only required vague information, from now on the ERA must identify "the intentional and unintentional changes resulting from the genetic modification" and assess "their potential to cause adverse effects on human health and the environment".[71] The long-term effects of a GMO must also be identified and assessed, i.e. "effects resulting either from a delayed reaction of organisms or their progeny to chronic or long-term exposure to the GMO, or from extensive use of the GMO in time and space".[72] In order to identify and assess the long-term effects of a GMO, **the ERA must take into account long-term interactions between the GMO and the receiving environment, characteristics of the GMO that become important in the long term, and data obtained in the context of repeated deliberate releases or placing on the market of the GMO over a long period.**[73] **Cumulative effects must also be taken into account**, which in this context refers to "the effect that the accumulation of authorisations would have on human health and the environment, in particular on flora and fauna, soil fertility, the degradation of organic materials by the soil, the human or animal food chain, biological diversity, animal health and problems linked to antibiotic resistance".[74] Account must also be taken of GMOs placed on the market in the past.[75]

These new elements introduced by the 2018 amendment can be seen as an improvement to the ERA, and help to ensure a high level of environmental protection.

The relevance for pollinating insects of the ERA currently required

The protection of pollinating insects necessarily involves the ERA, which potentially makes it possible to assess whether GMOs will have a negative impact on pollinating insect populations. Given the importance of the ERA for the protection of pollinating insects, it is worth taking a closer look at it in order to analyse it and identify the relevant provisions for their protection. To date, various provisions relevant to pollinating insects can be found in the legislative framework relating to GMOs. Firstly, and in very general terms, since the aim of an ERA is to assess the impact on the environment, it is undeniable that pollinating insects, which are obviously part of the environment, should be taken into account. According to the new section C.3 of Directive 2001/18/EC, there are 6 stages in an ERA: 1) problem formulation, 2) hazard characterisation, 3) exposure characterisation, 4) risk characterisation, 5) risk management strategies, 6) overall risk assessment and conclusions. The first step, namely problem formulation, must identify any changes in the characteristics of the organism linked to the genetic modification, and then identify the potential adverse effects on human health or the environment that

[69] *Ibid.*
[70] *Ibid.*
[71] Annex II, Section C.1, para. 1.
[72] Annex II, Section C.1, para. 2.
[73] *Ibid.*
[74] Annex II, Introduction.
[75] Annex II, Section C.1, para. 2.

are linked to the changes identified. These potential negative effects include "effects on the population dynamics of species in the receiving environment and the genetic diversity of each of these populations which may lead to a decline in biodiversity".[76] Any effect on bees or other pollinators should therefore be taken into account in accordance with these provisions.

Following the ERA, conclusions must be drawn regarding the potential environmental impact on receiving environments of the release or placing on the market of GMOs, as described in section D of Annex II. In the case of GMOs other than higher plants, some of the requirements concerning conclusions are relevant to pollinating insects. Indeed, according to section D, the conclusions concern, among other things, the "likelihood of the GMO becoming and spreading in natural habitats under the conditions of the proposed release(s)", the "possibility of gene transfer to other species", the "potential immediate and/or delayed effects that direct or indirect interactions between the GMO and target organisms may have on the environment". Even more explicitly, conclusions must also be drawn on the "potential immediate and/or delayed effects that direct or indirect interactions between the GMO and non-target organisms may have on the environment (...)", and the "possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct or indirect interactions between the GMO and target organisms or non-target organisms in the vicinity of the released GMO(s)". In the case of genetically modified higher plants (GMHP), the conclusions drawn must relate, among other things, to interactions between GMHP and non-target organisms.

As **pollinating insects are non-target organisms**, the conclusions must take them into account in both cases.

In addition, the information that must be included in the notification to the competent authority of the Member State where a GMO will be placed on the market and that may be necessary to carry out the environmental risk assessment is described in Annex III.[77] For GMOs other than higher plants, a large amount of information on the receiving environment is required. This includes the fauna and flora,[78] a description of target and non-target ecosystems likely to be affected,[79] and a comparison of the natural habitat of the recipient organism with the site or sites envisaged for the release.[80] Information on interactions with the environment must also be included: this includes the identification and description of non-target organisms likely to be affected by the release of GMOs and the expected mechanisms of any identified negative interactions,[81] or known or expected interactions with non-target organisms in the environment,[82] as well as any other potential interaction with the environment.[83]

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[76] Directive 2001/18/EC consolidated version, Annex II, C.3.

[77] Article 4 para. 2.

[78] Annex III A, para. III, B. 6.

[79] Annex III A, para. III, B. 7.

[80] Annex III A, para. III, B. 8.

[81] Annex III A, para. IV, B. 12.

[82] Annex III A, para. IV, B. 14.

[83] Annex III A, para. IV, B. 16.

For GMHPs, and for notifications under Article 13, information on interactions between the plant and non-target organisms, including an assessment of the potential for direct and indirect interactions between the GMHP and non-target organisms, including protected species, and adverse effects.[84] The assessment must take into account "the potential negative effect(s) on the ecosystem services concerned and on the species that provide these services".[85]

The ERA should therefore be adapted to these requirements in order to enable the notifier to provide this information. For example, **since the notifier must provide a great deal of information on the potential effects of the GMO on non-target organisms, the ERA should take account of pollinating insects.**

SECTION 2: Protection subject to fluctuations in the Court's interpretation

As Directive 2001/18/EC is old, it has undergone fluctuations, both in its content - as we have just seen - and in its interpretation by the CJEU. Moreover, as the European Commission states in its communication on the precautionary principle, "in order to give a more complete picture of the use of the precautionary principle in the European Union, it is important to examine the legislative texts, the case law developed by the Court of Justice or the Court of First Instance, and the policy guidelines that have emerged".[86] It is therefore clear that the precautionary principle and the environmental protection to which it contributes depend in part on the Court's interpretation of it.

The CJEU has sometimes handed down judgments prioritising economic interests over environmental protection, and has seemed reluctant to offer interpretations of a strong application of the precautionary principle in the context of biotechnology.[87] Indeed, **an analysis of four cases submitted to the Court has shown that the Court tends to favour international trade over the objective of a high level of environmental protection.**[88] In *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others* (Case C-236/01) of 2003, *Land Oberösterreich and Republic of Austria v Commission of the European Communities* (Joined Cases C-439/05 P and C-454/05 P) of 2007, *Monsanto SAS and Others v Ministre de l'Agriculture et de la Pêche* (joined cases C-58/10 to C-68/10) of 2011, *Giorgio Fidenato and Others* (case C-111/16) of 2017, none of the Member States has obtained the support of the CJEU in its application of the precautionary principle through measures banning GMOs on its territory.[89] In fact, the CJEU declared each of the attempted bans invalid.

This interpretation of the precautionary principle by the CJEU considerably affects the possibility of protecting the environment - and therefore pollinating insects - through the European legal framework.

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[84] Annex III B, para. II, B. 4(d)(i).

[85] Annex III B, para. II, B. 4(d)(i).

[86] Communication on recourse to the precautionary principle, *op. cit,* Annex III, para. 3.

[87] Alessandra Guida, The precautionary principle and genetically modified organisms: A bone of contention between European institutions and member states, *op. cit.*

[88] *Ibid.*

[89] *Ibid.*

However, in 2018, the Court handed down a ruling that changed the dynamic. In this emblematic case called *Confédération paysanne and others v Prime Minister and Minister for Agriculture, Food and Forestry* (Case C-528/16), the Court established that organisms obtained by mutagenesis constitute GMOs and are therefore, in principle, subject to the obligations set out in Directive 2001/18/EC. The case began when the French Conseil d'Etat referred questions to the CJEU for a preliminary ruling in order to clarify whether organisms obtained by mutagenesis constitute GMOs, as well as whether such organisms are excluded from the scope of the Directive only if they have been obtained using mutagenesis techniques that have been traditionally used and whose safety has long been proven. The status and fate of New *Genomic* Techniques (NGTs), the definition of which varies but which can be defined here as techniques capable of modifying the genetic material of an organism and which have appeared or have been developed since 2001,[90] including mutagenesis and cisgenesis, depended on the Court's answer to this preliminary question.[91]

Although Advocate General Michal Bobek suggested in his Opinion that the exemption provided for by the Directive "covers all organisms obtained by all mutagenesis techniques, irrespective of their use at the date adoption of that Directive",[92] the Court adopted a different interpretation. According to the Court, only organisms obtained "by means of mutagenesis techniques/methods which have traditionally been used for various applications and whose safety has long been proven"[93] are excluded from the scope of the Directive.

While the Advocate General's interpretation would have allowed, under certain conditions, the use and marketing of several NGTs[94] without being subject to the same strict regulations applicable to GMOs, the Court rejected this interpretation on the basis of recital 17 of the Directive, which states that organisms "obtained by means of certain techniques of genetic modification which have traditionally been used for various applications and whose safety has long been established" should be excluded from the scope of the Directive. The Court also relied heavily on the precautionary principle to justify its interpretation.[95] This judgement has been the subject of much comment. **Its impact is significant, because it means that in the current situation, NGTs are subject to the same requirements as "old GMOs", i.e. they are subject to the risk assessment described above, as well as to all the mechanisms that currently exist in the legislative framework to ensure a high level of environmental protection.** Industries willing to market NGTs regret the high costs and lengthy procedure to obtain an authorisation decision in the EU that this involves. On the other hand, the CJEU subsequently handed down a ruling in 2023 that disappointed environmental NGOs, stating that GMOs

[90] This is the definition given by the Commission in its document Commission Staff Working Document, Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16 of 29.4.2021 SWD(2021) 92 final, p. 2.

[91] Tomasz ZIMNY, Sławomir SOWA, Agata TYCZEWSKA, Tomasz TWARDOWSKI, Certain new plant breeding techniques and their marketability in the context of EU GMO legislation - recent developments, *New Biotechnology,* Volume 51, 2019, p. 53.

[92] Opinion of Advocate General Michal Bobek delivered on 18 January 2018, Case C-528/16, paragraph 168.

[93] CJEU, 25 July 2018, *Confédération paysanne and Others v Prime Minister and Minister for Agriculture, Food and Forestry,* Case C-528/16, ECLI: ECLI:EU:C:2018:583, para. 86.

[94] Tomasz ZIMNY, Sławomir SOWA, Agata TYCZEWSKA, Tomasz TWARDOWSKI, Certain new plant breeding techniques and their marketability in the context of EU GMO legislation - recent developments, *op.cit.* p. 54.

[95] Para. 50 to 53.

produced by random mutagenesis *in vitro* were exempt from the directive under certain conditions, like those produced by random mutagenesis *in vivo.*[96] This ruling has further fuelled the debate surrounding GMOs.

SECTION 3: Ongoing deregulation of new GMOs, reducing protection for the environment and pollinating insects

Following the 2018 judgement, the Council asked the European Commission to carry out a study on the status of NGTs in the EU, in the light of the judgement in question, and to submit a proposal, if necessary to take account of its results.[97] This study, published by the Commission on 29 April 2021, reconfirms that NGTs have so far been subject to the European legislative framework for GMOs, but highlights that, following the 2018 Court ruling, there have been many reports from the private and public sectors on the negative impacts of the current regulatory framework for the development of NGTs.[98] According to the study, while NGTs could contribute to a more competitive economy, the current legislation is not adapted to the scientific progress relating to NGTs, causes problems for its implementation and therefore causes regulatory uncertainties. In September 2021, the Commission launched an impact study on "legislation applicable to plants produced using new genomic techniques".[99] **The Commission's initiative aims to "propose a legal framework applicable to plants obtained by targeted mutagenesis and cisgenesis as well as to food and feed products containing such plants",[100] thus excluding them from current European legislation in this area. NGOs are therefore talking about a "deregulation" of NGTs.[101]**

Numerous NGOs,[102] including BeeLife,[103] have expressed concern that deregulation would result in the loss of the legal mechanisms detailed above, which are essential to help achieve the high level of environmental protection required by EU primary and secondary legislation. If these mechanisms are removed for NGTs - in particular risk assessment, traceability and labelling requirements - consumer information would also be

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[96] CJEU, 7 February 2023, *Confédération paysanne and others v Prime Minister and Minister for Agriculture and Food,* Case C-688/21.

[97] Council Decision (EU) 2019/1904 of 8 November 2019 inviting the Commission to submit a study in the light of the judgment of the Court of Justice in Case C-528/16 concerning the status of new genomic techniques in Union law, and a proposal, if appropriate to take account of the results of the study, OJ L 293, 14.11.2019, pp. 103-104.

[98] Commission Staff Working Document, Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, *op.cit*, p. 2.

[99] European Commission website, *Legislation applicable to plants produced using certain new genomic techniques*, https://commission.europa.eu/index_en [consulted on 1 June 2023], available at : https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-applicable-aux-vegetaux-produits-a-laide-de-certaines-nouvelles-techniques-genomiques_fr

[100] *Ibid.*

[101] Pollinis France website, *Deregulation of new GMOs: 340 organisations alert the Commission*, 2023, https://www.pollinis.org [consulted on 1 June 2023], available at : https://www.pollinis.org/publications/deregulation-des-nouveaux-ogm-340-organisations-alertent-la-commission/

[102] *Ibid.*

[103] BeeLife website, *Unscientific deregulation of GMOs puts bees and nature at risk and violates consumer rights,* 28 June 2023, *https://www.bee-life.eu* [accessed 21 July 2023], available at : https://www.bee-life.eu/post/unscientific-deregulation-of-gmos-puts-bees-and-nature-at-risk-and-violates-consumer-rights

affected. It involves losing the capability to step back (remove from the market), trace back or limit the risks or damages should any unwanted impacts arise from the cropping of NGT plants. Since the mechanisms put in place by the current legislative framework are expressions of the precautionary principle, *a contrario,* the absence of such mechanisms could pose a problem for the application of this principle, which is so fundamental to environmental law. Such deregulation would therefore call into question both the case law of the CJEU and the precautionary principle. The impact would be considerable, since it would affect around 95% of the new genetically modified plants currently under development.[104]

The European Commission finally published its proposal for a regulation on 5 July 2023 concerning plants obtained using certain new genomic techniques, and food and feed products thereof, and amending Regulation (EU) 2017/625.[105] However, a document was leaked almost 3 weeks earlier[106] that caused concern among stakeholders[107] (in particular environmental NGOs, but also representatives of organic farmers and distributors and consumers associations).

Firstly, it is not insignificant that the only mention of the precautionary principle in recital 10 of the leaked document has been removed from the final proposal. Recital 10, which stated that:

"The framework should share the objectives of the GMO legislation to ensure a high level of protection of human and animal health and of the environment in accordance with the precautionary principle and to ensure the smooth functioning of the internal market, while addressing the specificity of NGT plants (?)", now states only that "the legal framework for NGT plants should share the objectives of the Union GMO legislation to ensure a high level of protection of human and animal health and of the environment and the good functioning of the internal market for the concerned plants and products, while addressing the specificity of NGT plants (...)".

We need to take a closer look at what the "deregulation" of these new GMOs entails, in the light of what has been said above.

Complete deregulation of category 1 NGTs, leading to the loss of all environmental protection mechanisms

According to the proposed regulation, the rules applying to GMOs under European legislation should not apply to so-called category 1 NGTs,[108] i.e. NGTs that meet the criteria for equivalence to conventional plants under Annex I, or that are progeny of the NGT plant(s) referred to above, including progeny derived from crosses of

[104] European Non-GMO Industry Association website, *The advantages of current EU GMO legislation*, 2022, https://www.enga.org [consulted on 1 June 2023], available at : https://www.enga.org/newsdetails/the-advantages-of-current-eu-gmo-legislation

[105] European Commission, *Proposal for a Regulation of the European Parliament and of the council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625,* COM(2023) 411 final.

[106] Arc2020 website, *Leak - Draft NGT Regulation and Impact Assessment revealed*, 2023 https://www.arc2020.eu [consulted on 21 July 2023], available at : https://www.arc2020.eu/leak-draft-ngt-regulation-and-impact-assessment-revealed/

[107] BeeLife website, *Unscientific deregulation of GMOs puts bees and nature at risk and violates consumer rights,* 28 June 2023, *op. cit.*

[108] Article 5 para. 1.

these plants, provided that there are no other modifications that would make them subject to Directive 2001/18/EC or Regulation 1829/2003.

The criteria in Annex I are therefore fundamental, as they trigger the exclusion of GMOs from all the mechanisms for ensuring environmental protection under the current regulatory framework, and it is therefore appropriate to examine them in greater detail.

According to the Annex, **an NGT plant is considered equivalent to conventional plants when it does not differ from the recipient/parental plant by more than 20 genetic modifications.** The Commission offers no justification for this point, and the proposal therefore appears to be arbitrary and without scientific basis. Several environmental NGOs have openly criticised this point (see BeeLife and Co. press conference) and the scientific literature has shown that **changing one or more nucleotides in the genome of organisms can lead, for example, to changes in their translation and have potential functional consequences** such as increasing the risk of cancer in humans (Robert & Pelletier, 2018).

An NGT plant is considered equivalent to conventional plants when it does not differ from the recipient/parental plant by more than 20 genetic modifications.

Thus, the new regulatory framework applying to Category 1 NGTs would undermine all the legal mechanisms detailed above, which have been put in place precisely to help achieve the high level of environmental protection required by EU primary law.

Article 5(2) excludes the possibility of using NGTs in organic production, stating that Articles 5(f)(iii) and 11 of Regulation (EU) 2018/848 should apply to Category 1 NGTs. While the aim of this article is to reassure the organic farming sector, there would appear to be a contradiction. Article 11 of Regulation (EU) 2018/848 specifically states that operators may rely on product labels that have been affixed to that product or supplied in accordance with Directive 2001/18/EC, Regulation (EC) No 1829/2003 of the European Parliament and of the Council or Regulation (EC) No 1830/2003. **However, category 1 NGTs are not subject to the GMO regulations mentioned above. This raises the question of how operators (including consumers) can rely on non-existent labelling.**

Articles 9 and 10 of the proposal aim to ensure transparency regarding category 1 NGTs. Admittedly, a **database of decisions declaring plants to be NGTs in this category will ensure a degree of transparency, but what about consumer information?** Consumer information is only effective if consumers have the most

direct possible access to information about the product they are about to consume. **Clearly, the *average* consumer will not visit the database mentioned in the proposed regulation.** It should be remembered that access to information is a key element of environmental protection - the 1998 Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters bears witness to this.

It should be noted here that under the proposal, labelling would be retained for category 1 NGT seeds. According to the Commission, this would make it possible "to allow a choice at the beginning of the supply chain, to encourage the maintenance of organic production free of NGT and to preserve consumer confidence, an additional measure is proposed, in addition to the information contained in the public registers taken into account in the impact assessment: the indication of the use of NGT in the labelling of seeds".[109]

≠ Partial deregulation of category 2 NGTs, leading to uncertainty in environmental protection

Category 2 NGTs are subject to stricter rules to ensure better environmental protection. The same rules apply to them as to GMOs (unless the proposed regulation derogates from them), and there is provision for an ERA, as well as labelling and a monitoring plan. On the other hand, with regard to the placing on the market of a category 2 NGT product, a notifier who considers that the NGT does not require a monitoring plan may propose not to submit one - which is questionable, to say the least.[110]

Another provision that undermines environmental protection is Article 21, which states that **after the first renewal of a product, authorisation is valid for an unlimited period.** This limits the possibility of monitoring whether a product still warrants being on the market.

However, it is stipulated that Member States *must* take appropriate measures to avoid the adventitious presence of category 2 NGTs in other products.[111] The obligation on Member States is stronger than in the current GMO Directive, under which Member States *may* take such measures.[112]

On the other hand, the possibility that had been allocated to Member States since Directive (EU) 2015/412 to modify the geographical scope of an authorisation or renewal of authorisation for the cultivation of a GMO, so that all or part of the territory of that Member State may be excluded from cultivation, does not apply to Category 2 NGTs.[113] As a result, Member States lose a great deal of autonomy with regard to NGTs, and can no longer be as precautionary as they were under the current regulatory framework. **While they can currently**

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[109] European Commission, *Proposal for a Regulation of the European Parliament and of the council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625,* COM(2023) 411 final, p. 11.

[110] Article 14.

[111] Article 24.

[112] Article 26a of Directive 2001/18/EC.

[113] Article 25.

take restrictive measures for a variety of reasons, including social ones, they would no longer be allowed to do so if the new regulation came into force.

It is also important to note that the only provision referring, among other things, to pollinating insects is found in Annex II, Part 2, which deals with specific information for the environmental risk assessment of category 2 NGT installations concerning the identification and characterisation of hazards. Interactions with non-target organisms are mentioned.

Annex III describes the traits that NGT should have (Part 1) and should not have (Part 2). Part 1 contains some interesting points, in particular the fact that one of the traits that can justify an incentive is the fact that the NGT enables "more efficient use of resources, such as water and nutrients", or "a reduction in the need for external inputs, such as plant protection products and fertilisers". Since industries wishing to market an NGT will have to prove the existence of these traits, this provides a minimum of environmental protection. Conversely, under Part 2 of the Annex, the ability to be tolerant to herbicides is not a trait justifying the application of incentive measures, thus avoiding dependence on herbicides.

TABLE 1: Integration of environmental protection mechanisms for different types of GMO

	Old GMOs	NGT Category 1	NGT Category 2
Environmental risk assessment (ERA)	✓	✗	✓
Traceability	✓	✗	✓
Labelling	✓	**Only seeds**	✓
Public information	✓	**Access via database**	
Safeguard clause	✓	✗	✗
Surveillance plan	✓	✗	✓ **Unless the applicant considers it unnecessary**
Respect for the precautionary principle	✓	✗	?

TABLE 2: Developments in environmental protection under the GMO regulatory framework

Changes introduced by Directive (EU) 2015/412	Changes introduced by Directive (EU) 2018/350	Changes introduced by the Proposal for a Regulation COM(2023) 411 final
Member States where GMOs are cultivated shall adopt appropriate measures in border areas of their territory to avoid any cross-border contamination (new Article *26a*). A Member State may request that the geographical scope of the written authorisation or authorisation be amended so that all or part of the territory of that Member State is excluded from cultivation (new Article *26b*).	Amendment of Annexes II, III, IIIB and IV of Directive 2001/18/EC.	Removal of NGTs from the regulatory framework for GMOs.
➡ Greater autonomy for Member States ➡ Strengthening the precautionary principle	➡ Improving environmental risk assessment ➡ Strengthening the precautionary principle	➡ Less autonomy for Member States ➡ Cancellation of the precautionary principle

CONCLUSION

Although old, the current regulatory framework relating to genetically modified organisms (GMOs) has contained provisions expressing an application of the precautionary principle since its adoption. The precautionary principle takes on its full meaning in an area such as GMOs, where there is still scientific uncertainty about the risks to human and animal health and the environment. The provisions of the main directive on GMOs, Directive 2001/18/EC, have been adjusted over time, and now offer several mechanisms that best guarantee a high level of environmental protection, as required by Article 191 of the Treaty on the Functioning of the European Union (TFEU). This includes, as we have seen, the precautionary principle, taken into account both in the drafting of legislation and in its implementation, Environmental Risk Assessment (ERA), compulsory labelling, traceability, safeguard clauses, consumer information and monitoring mechanisms. Each of these protection mechanisms is essential.

Risk assessment (RA) is particularly relevant to the protection of pollinating insects, and has therefore been given special attention here. The regulatory framework requires the ERA to take account of the effects of GMOs on pollinating insects as non-target organisms.

However, new genomic techniques (NGTs), which are subject to the current regulatory framework in accordance with the ruling of the Court of Justice of the EU of 25 July 2018, are at the heart of current discussions. The European Commission adopted a proposal for a new legal framework applicable to plants obtained by targeted mutagenesis and cisgenesis that would remove them from the current legal framework on GMOs. It is therefore understandable that many fear that these new techniques will be "deregulated" and not be subject to the requirements and protection mechanisms that have been in place until now (e.g., should modifications of 1NGTs be unintentionally introduced in the environment and impact human or environmental health, including pollinators), even though they were put in place to achieve the level of protection sought and desired by the legislator.

OFFICIAL DOCUMENTS

At international level :

- United Nations Convention on Biological Diversity, adopted on 5 June 1992 in Rio de Janeiro, entered into force on 29 December 1993.
- United Nations, Rio Declaration on Environment and Development, 12 August 1992, A/CONF.151/26 (Vol. 1)
- United Nations, Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted in Montreal on 29 January 2000, entered into force on 11 September 2003.

At European Union level :

Treaties:

- Maastricht Treaty of 7 February 1992, *OJ C 191*, 29.7.1992, pp. 1-112.
- Treaty on the Functioning of the European Union of 13 December 2007 - consolidated version, *OJ C 202*, 7.6.2016, pp. 47-360.

Secondary legislation:

- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, *OJ L 268*, 18.10.2003, pp. 1-23.
- 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, *OJ L 268*, 18.10.2003, pp. 24-28.
- Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified microorganisms, *OJEC L 117*, 8/05/1990, pp. 1-14.
- Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of GMOs, *OJEC L 117*, 8/05/1990, pp. 15-27.
- 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, *OJ L 106*, 17.4.2001, p. 1-39.
- 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 Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) on their territory, *OJ L 68*, 13.3.2015, pp. 1-8.

- Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms, *OJ L 67*, 9.3.2018, pp. 30-45.
- Council Decision (EU) 2019/1904 of 8 November 2019 inviting the Commission to submit a study in the light of the judgment of the Court of Justice in Case C-528/16 concerning the status of new genomic techniques in Union law, and a proposal, if appropriate to take account of the results of the study, *OJ L 293*, 14.11.2019, pp. 103-104.

Case law:

- ECJ, 17 July 1997, *Affish BV v Rijksdienst voor de keuring van Vee en Vlees*, Case C-183/95, *ECR* p. I-04315.
- ECJ, 21 March 2000, *Association Greenpeace France and others and Ministère de l'agriculture et de la pêche and others*, Case C-6/99, *ECR* p. I-1651.
- Court of First Instance, 11 September 2002, *Pfizer Animal Health SA v. Council of the European Union,* Case T-13/99, *ECR* II-03305.
- Court of First Instance, 11 September 2002, *Alpharma Inc. v. Council of the European Union*, Case T-70/99, *ECR* II-03495.
- ECJ, 9 September 2003, *Monsanto Agricoltura Italia SpA and others v Presidenza del Consiglio dei Ministri and others*, Case C-236/01, *ECR* p. I-08105
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