# The EU GM Regulatory Framework on Green Biotechnology under Revision

A study on the legal challenges and legal possibilities to draft a futureproof regulatory regime on GM technologies and NGTs.

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# Table of Contents

**Chapter 1 Introduction**

This research project focuses on agricultural genetically modification (GM) technology as the European Commission (EC) prepares a revision of the EU GM regulatory framework on green biotechnology.

As things are now, Directive 2001/18 lays down authorization procedures concerning two scenarios: (1) deliberate release of GMOs in the environment (Part B: Articles 5-11) and (2) placing of GMOs on the market (Part C: Articles 12-24). Under each scenario, two types of authorization procedures are enshrined in the Directive arguably offering some degree of flexibility regarding GMO authorisation: (a) a standard procedure (Article 6 [release] and Article 15 [placing on the market] respectively) and (b) a differentiated/derogatory procedure (Article 7 [deliberate release] and Article 16 [placing on the market] respectively). In particular on deliberate release, the wording of Article 7 indicates that a simplified procedure, as compared to the standard authorization procedure established in Article 5 (junto Annex III), could be applied to certain GMOs (for which substantive experience has been obtained regarding releases in certain ecosystems and provided that they meet the requirements in Annex V of the Directive). Such a differentiated authorization procedure, established by a Commission implementing decision (subject to 'comitology') on a proposal by a national competent authority, entails primarily establishing of a minimum amount of technical information from Annex III necessary for evaluating any foreseeable risks from the release.

Biotechnology regulation and genetically modified organisms (GMOs) in Europe have a long history of controversy.[1] Macnaghten and Habets (2020) identify three factors that caused the controversy of agricultural GM technologies in Europe. First, the radical promises of GM technologies were not realized in practice. Promises such as contributing to sustainability, feeding the world, and providing better quality of food, were not met with the first generation of GM crops in the 90s and early 2000s.[2] Second, the scope of the EU GM regulation was restricted to risk assessment. Room for formal consideration of socio-economic or ethical considerations in the assessment processes was lacking.[3] Third, internationally, different regulatory approaches to GM were developed. For example, in the United States a more product-based approach has developed, whereas the EU primarily follows a process-based approach.[4] According to Macnaghten e.a. these regulatory differences did not cause the controversy directly, but it facilitated space for NGOs to question the adequacy of the regulatory regimes and 'feed' societal concerns. [5]It would lead to a loss of consumer choice if, due to international trade, GM crops would enter the food systems without knowing.

These three factors together increased the societal unease with agricultural GM technologies and decreased the trust of the broader public in science. Arguably, the unease of the public was and still is no longer solved only by providing (more) scientific information. As Macnaghten e.a. put it, the EU

[1] See R. Mampuys, *The deadlock in European GM crop authorisation as a wicked problem by design. A need for repoliticisation of the decision-making process* (2021) Thesis. Rotterdam: Erasmus University.

[2] Ph. Macnaghten, Ph. & M. Habets, 'Breaking the impasse: Towards a froward-looking governance framework for gene editing with plants', (2020) 2 (4), *Plants, People, Planet*, 353–365, available at <https://nph.onlinelibrary.wiley.com/doi/epdf/10.1002/ppp3.10107> accessed 16 December 2022.

[3] Yet Article 29 of Directive 2001/18 acknowledges the primary competence of the Member States regarding ethical issues (e.g. in the Netherlands COGEM plays an important role in this respect) and provides additionally for the possibility that the Commission consults committees specialized on ethical implications of biotechnology (created by itself) on 'ethical issues of a general nature'.

[4] See COGEM (2019), *Geen roos zonder doornen, CGM 191010-01*, available at <https://cogem.net/app/uploads/2019/11/CGM191010-01-Geen-roos-zonder-doornen.pdf> accessed 16 December 2022.

[5] Macnaghten e.a., 'Breaking the impasse' (n 2) p. 355.

regulatory approach has 'done little to provide socially robust knowledge'.[6] EU GM regulation strongly builds on safety considerations, while among the public all kinds of non-safety considerations do play a role in their attitude towards GM technologies and GM crops.[7] Partly, these considerations are addressed by regulations on traceability and labelling (e.g. Regulation 1830/2003[8]). Other considerations, currently, do not play a role in authorization.

After a long and rocky road, the current regulatory practice of the use of genetic modification (GM) technologies became deadlocked.[9] A first attempt to break through this deadlock is Directive 2015/412 enabling Member States (MS) to prohibit cultivation of GM crops on their territory.[10] This new Directive was expected to change MS voting behavior as MS could ban GM crops from their territory based on non-safety considerations such as co-existency, cultural values, social welfare, and biodiversity. Consequently, it was expected that the general authorization procedures could focus on risk assessment in order to protect human health and the environment. However, the Directive did not end the controversy,[11] one reason for this being arguably that GMOs authorized under EU law would still be in free circulation and reaching the territory of MS prohibiting GMO cultivation.

Then, in 2018, all eyes pointed at the European Court of Justice (CJEU), that would rule on the status of new mutagenesis techniques (NGTs).[12] The CJEU settled the question whether crops (or organisms in general) that have been produced by means of new mutagenesis fall under the scope of Directive 2001/18/EC on the deliberate release into the environment GMOs [13] and also under the exemption for mutagenesis techniques regulated in article 3 of the Directive (entailing that NGTs would not be subject to the authorization procedure laid down in the directive for GMOs). The CJEU ruled that organisms produced through mutagenesis techniques qualify as GMOs and therefore they do fall under the scope of Directive 2001/18; moreover, the Court decided that NGTs do not qualify under the exemption.[14] New mutagenesis techniques were not exempted, because, contrary to conventional techniques of mutagenesis, the new techniques are not considered to have a 'long safety record' (as referred to in recital 17 Directive 2001/18/EC). Although this judgement was not surprising from a

[6] Macnaghten e.a., 'Breaking the impasse' (n 2) p. 356.

[7] See R. Mampuys & L. M. Poort, 'Controversy first: factors limiting the success of Directive (EU) 2015/412 for national decision-making on the cultivation of GM crops' (2019) 11:2, *Law, Innovation and Technology*, 175-202, available at <https://www.tandfonline.com/doi/abs/10.1080/17579961.2019.1665794?journalCode=rlit20> accessed 16 December 2022.

[8] 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, p. 24–28).

[9] For a good overview of this long and rocky road we refer to H. Bergmans, L.M. Poort & R. Kleinjans, Research report *Analyse van de Europese Wet- en regelgeving over genetisch gemodificeerde organismen* (2016) The Hague: COGEM, CGM 2016-05, available at <https://cogem.net/app/uploads/2020/03/CGM-2020-03-ECGE-Eindrapport-uitspraak-europees-Hof.pdf> accessed at 16 December 2022, and Bergmans, H., L.M. Poort, W.J. Kortleven & R. Kleinjans (2020), Research Report *Uitspraak van het Europees Hof over gene editing en de ggo-regelgeving,* The Hague: COGEM, CGM 2020/03, available at <https://cogem.net/app/uploads/2020/03/CGM-2020-03-ECGE-Eindrapport-uitspraak-europees-Hof.pdf>accessed at 16 December 2022.

[10] 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 (OJ L 68, 13.3.2015, p. 1–8).

[11] See for further analysis, Mampuys e.a. 'Controversy first' (n 7).

[12] Case C-528/16, C*onfédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forê*t ECLI:EU:C:2018:583.

[13] 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 (J L 106, 17.4.2001, p. 1–39).

[14] Case C-528/16 (n 12) para. 54.

legal perspective and applauded by opponents of GMOs[15], it was experienced being a setback for stakeholders working with GM technologies. Proponents had high expectations of the Court's ruling as they experienced difficulties placing crops made with these new techniques on the market. Some proponents even argue that products of targeted mutagenesis do not even fulfil the criteria of a GMO.[16]

Nevertheless, the CJEU confirmed the status-quo and put the ball to the European Commission. Until today, that is the current legal state of affairs.

Although the ruling did not end the rocky road, it did cause some motion on the road. On 8 November 2019, the Council of the European Union requested the European Commission to perform a study on the status of New Genomic Techniques (NGTs) in light of the CJEU's judgment. The EC favors a differentiated status of NGTs and stimulating innovation as NGTs are said to contribute meeting the requirements of sustainable agriculture. Furthermore, arguably deviating from CJEU's approach in Case C-528/16,[17] the EC also seemed sensitive to the argument put forward by the stakeholders working with GM technologies that products of NGTs do not differ from products obtained by conventional methods.

The results of this study were published on the 29th of April 2021.[18] The EC conducted this research and consulted experts, Member States competent authorities, and EU-level stakeholders. The scope of this study included GM in agri-food, industry, and pharmaceutical applications. The study examined whether current regulation should be maintained for NGTs or whether it should be adapted (and if so, on what ground and in what way). The study identified several limitations of the current legislation to keep pace with scientific development. Furthermore, it showed various indications that the current legal framework cannot adequately accommodate NGTs. The EC mainly intends to analyze how to simplify the assessments procedures for NGTs. The study emphasizes the need for a follow up to examine whether the current legislation should be adapted and, if so, in what form to make it futureproof. Additionally, the argument is made that the development of NGTs can be relevant to live up to the goals of the European Green Deal[19] and the Farm to Fork Strategy[20]. It is indicated in the outcomes of the EC-study, that NGTs might contribute to a sustainable food system. That would allow facilitating a faster development of these techniques, while keeping up with a high level of public health and environmental protection. It should be noted, however, that the findings and approach on NGTs put forward in the EC's study were also met with criticism by NGOs and farmer and business associations.[21] The latter mainly uphold that lacking sound scientific basis 'for deregulating whole classes of new GM techniques and their Products' (…) 'the European Commission's attempt to deregulate new GM techniques is contrary to the Precautionary Principle and will threaten public health and the environment'.[22] They take accordingly the view that 'New GM techniques must be kept

[15] See Bergmans e.a. *Uitspraak van het Europees Hof over gene editing en de ggo-regelgeving* (n 9).
[16] Ibid, p.13.
[17] See Case C-528/16 (n 12) para. 47-51.
[18] European Commission, Food Safety, *EC study on new genomic techniques,* available at <https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en> accessed 16 December 2022.
[19] European Commission*, A European Green Deal*, <https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en> accessed 16 December 2022.
[20] European Commission, Food Safety, *Farm to Fork strategy* <https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en > accessed 16 December 2022.
[21] Demeter, *Biased from the outset: The EU Commission's "working document" on new GM techniques fails to uphold environmental and consumer protection standards* (September 2021) <https://demeter.net/wp-content/uploads/2021/09/Open-Letter_Biased-from-the-outsets_20210906.pdf > accessed 16 December 2022.
[22] Ibid, p 17.

under the existing GMO regulations, which must not be weakened but strengthened (via additional risk assessment guidance) in order to maintain and improve protection for human and animal health and the environment'.[23]

With this background, the EC prepares a revision of the GM regulatory framework that it intends to present in 2023. It struggles with some questions and requests all Member States to provide input.

[23] Ibid, p. 18.

*Figure 1 Overview Relevant GMO Regulation*

**Contained Use of GMOs**

- Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms
- Besluit genetisch gemodificeerd organismen Milieubeheer 2013
- Regeling genetisch gemodificeerd organismen Milieubeheer 2013

**Deliberate Release of GMOs**

- Directive 2001/18/EC (in particular Part B of the directive)
- Besluit genetisch gemodificeerd organismen Milieubeheer 2013
- Regeling genetisch gemodificeerd organismen Milieubeheer 2013
- Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred on the Commission

**Placing on the Market of GMOs or in products**

- Directive 2001/18/EG, Part C
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed **(GM food and feed)**
- 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 **(traceability and labelling)**
- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency **(medicinal products**)
- 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 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
- Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC

The EC will have to decide upon:

(1) should the new regulation be a Directive or a Regulation?

(2) what are the options for other 'legal' instruments?

Furthermore, main points for discussion with member states are:

(3) how to formulate (a simplified) risk assessment (RA) for NGTs?)

(4) considering the Green Deal and Farm to Fork strategy, the EC tends to include sustainability criteria, but struggles with the question on how to do so.

**Assignment**

The Dutch Ministry of Infrastructure and Water Management (I&W), department Biotechnology assigned us to perform a small study on the legal possibilities to draft a futureproof regulatory regime on GM technologies and NGTs. This study is twofold. To start, the researchers are asked to identify the conditions, the difficulties, and bottlenecks for EU GM regulation. This stocktaking will not include strong theoretical reflections of these difficulties, neither does it provide an historical overview of the GM regulation. Instead, this small study only identifies those factors that together state the background in which new regulation can be drafted, being either relevant marker points or lessons learned. The Ministry formulated some important markers relevant for regulation, such as the precautionary principle, sustainability, innovation, freedom of choice, and safety. The meaning and extent of those markers will be analyzed. Besides, general principles in EU-law such as conferral (legal basis), subsidiarity and proportionality issues will be discussed.

Second, the Ministry of I&W requested an overview of possible legal constructions (such as sunset clauses, evaluations, smart regulation, etc) and legal instruments (art. 288 TFEU) against the background of EU-law. This overview also consists of a small theoretical reflection upon these legal possibilities. The Ministry of I&W formulated a few points of attention that are relevant for a thorough analysis of these legal possibilities. Besides the points of discussion that the EC formulated, the Ministry emphasized that new regulation should be future proof. In doing so, the Ministry requested to consider options to accommodate ways to take off existing polarization and to bridge the diverse and controversial opinions. Such regulatory options range from adopting lighter soft law tools (e.g. recommendations, communications, guidelines) complementing and clarifying the existing GMO legal framework to adopting a hard law instrument such as regulation or directive (possibly with exceptions/derogations included to allow some flexibility for Member States), with a combination thereof in-between (e.g. fairly broad/generic directive/regulation supplemented with soft recommendations/guidelines for interpretative/implementation purposes).

**Approach and Methods**

**Research questions:**

**Part 1**

- What lessons can be learned from earlier attempts to break through the impasse in EU GM regulation?
- What are relevant principles, factors, and markers that need to be considered in the revision of EU GM regulation?

**Part 2**

- What are the legal possibilities to develop a sustainable and futureproof GM regulation against the background of EU law?
- To what extent can these legal possibilities adequately accommodate important markers, in view of the lessons learned?

**Deliverables**

- Overview of lessons learned and important markers.
- Exploration of adequate and feasible legal possibilities for revision of the EU GM regulation taking into account the lessons learned and the important markers, and against the background of EU law;
- A theoretical reflection upon the feasibility and adequacy of these possibilities.

We will, thus, not provide concepts for legal provisions. Neither will we single out the best possible legal option. We will present a reflection of several legal possibilities from both a European law perspective (are the options legitimized, what tools do EU-law offer) and a theoretical perspective (justification from decision- and law-making theory).

**Reading Guide**

This report consists of three chapters: this introduction and two substantive chapters. Chapter 2 prompts the conditions for revisions. It touches upon the lessons learned from previous regulatory attempts and failures; the policy-aims and contemporary challenges relevant for future regulation; and the basic principles of the general European regulatory framework. Chapter 3 explores the legal possibilities when taking these conditions for revision into account. This chapter elaborates on the regulatory and practical challenges attached to those possibilities. Further, it will explore lessons to be learned to come to a future-proof regulation.

**Chapter 2 Conditions for Revision**

In this chapter, the conditions which are relevant for a revision of the European GM legislation are gathered and placed in context. These conditions can be classified into three different categories: (1) retrospectively as lessons learned from the current stalemate of the existing regulatory framework; (2) prospectively as policy aims and new developments in technology and society; and (3) general conditions derived from EU law and general (legal) principles, such as subsidiarity, proportionality, and the precautionary principle.

*2.1 Lessons learned*

In the introduction, the history of EU GM legislation was characterized as a rocky road leading to a legal impasse and a practical deadlock. The European Commission attempted to address this stalemate by additional regulations, such as Directive 2015/412 (cultivation of GM-crops).[24] However, the EC, until now, has not been able to end the **ongoing controversy** around regulation of genetic modification technologies. Macnaghten e.a point out a few lessons for the future developments of GM crops. They argue for a socio-economic assessment of how GM crops demonstrate a benefit to either societal challenges or to local consumers.[25] Macnaghten e.a. merely base these lessons on the dynamics that contributed to the controversy of agricultural GM technologies. They show that the EC merely focused on risks and provision of scientific information on harms and risks, **ignoring the quest for socially robust governance**.[26] Also, Mampuys e.a note that the controversies that characterize the GM issue are not accommodated in the current regulatory framework. **Socio-economic and ethical considerations** such as 'co-existency' and 'freedom of choice' are excluded from the regulatory framework.[27] Mampuys e.a. elaborated on the opportunity that Directive 2015/412 offered in taking these non-safety considerations seriously. They argued that this Directive could open the road for a more tailor-made assessment framework. Member States could include their cultural-specific values and socio-economic considerations in the assessment on cultivation of GM-crops. Mampuys e.a envisioned that this eventually could break through the impasse as Member States may change their voting behavior in the EU risk assessment.[28] Retrospectively, we see that this directive did not resolve the EU stalemate as Member States did not change their voting behavior.[29] Arguably, what also plays a role here is, that even if a Member State avails itself of the opportunity offered by the directive, GMOs allowed for cultivation in other MS could reach the territory of the MS not cultivating them by virtue of the free movement of goods in the internal market.

The 'playing field' in which GM regulation should operate and in which new regulation is to develop is complicated and controversial. The stalemate is not to be resolved solely by providing more knowledge about safety and risks, as the underlying conflict is (also) cultural-specific and value laden. Opposing interests and intractable value conflicts define the multi-layer context of research

[24] Directive (EU) 2015/412(n 10).
[25] Macnaghten e.a., 'Breaking the impasse' (n 2) p. 356.
[26] Ibid, p. 356.
[27] Mampuys e.a., 'Controversy first' (n 7) p. 179-184.
[28] Ibid, p.176.
[29] Mampuys, *The deadlock in European GM crop authorisation as a wicked problem by design* (n 1) argues for repoliticising the GM issue and not 'hide' behind risk assessment as for some stakeholders and member states, it is not about risks only. In this line of argument, Poort e.a. made an argument for broadening the input for decision-making at an early phase of problem-definition. L.M. Poort, J.A.A. Swart, R. Mampuys, AJ Waarlo, P.C. Struik, & L. Hanssen, 'Restore politics in societal debates on new genomic techniques' (2022), *Agriculture and Human Values*,1-10, available at <https://link.springer.com/article/10.1007/s10460-022-10328-z> accessed 16 December 2022.

institutions, industry, NGOs, citizens, and Member States. There seems to be **no consensus** on how to regulate or how to harmonize regulation of GM technologies in agriculture within the EU. Moreover, there is a lack of consensus on the definition and range of the issue at stake here.[30] Consequently, decision-making appears to be **sensitive** for which simply offering an opportunity to exclude a Member State' territory for cultivation of GM crops is no way out.[31]

These findings can be interpreted as **a need to include socio-economic considerations into the assessment framework**. At the same time, the need for such a framework is not shared by all stakeholders. Some Members States, research institutions, and plant breeders do not consider non-safety elements as relevant for decision-making at all. Focusing on the products, proponents of NGTs emphasize that societal unease is merely caused by lack of knowledge about the risks. Moreover, unlike the CJEU in Case C-528/16, they even consider NGTs as technologies that should be excluded from the GM regulatory framework as their products do not differ from products obtained by conventional methods, and are thus equally safe; according to this view, NGT-based products are not genuinely GMOs and therefore they should not be subject to the GM authorization procedure laid down in EU legislation, this being in line with the precautionary principle.[32] Furthermore, as the COGEM in 2014 has notified,[33] it is very difficult to develop hard criteria in a socio-economic assessment framework (see Section 2.2).

[30] Poort e.a., 'Restore politics in societal debates on new genomic techniques' (n 29) p. 5-6.
[31] Mampuys e.a., 'Controversy first' (n 7).
[32] VNO NCW, *Toekomstpact Biotechnologie Nederland 2025* (feb 2021), available at <https://www.vno-ncw.nl/sites/default/files/toekomstpact_biotechnologie_nederland_2025.pdf> accessed 16 December 2022.
[33] COGEM, *Bouwstenen voor een beoordelingskader voor teelt van GG-gewassen* (2014), CGM/141222-01, available at <https://cogem.net/app/uploads/2019/07/CGM141222-01_Signalering-Bouwstenen-voor-een-beoordelingskader-voor-teelt-van-gg-gewassen_web.pdf > accessed 16 December 2022.

Consequently, if and how a broader assessment framework should be designed and what role it should play is up for discussion. Full harmonization might not be possible or realistic. Using legally binding acts might not be the most effective regulatory tool in the short (and thus long) run due to the sensitivity and the complexity of the issue. A more cautious long-term approach should be considered.

**Important lessons** that can be learned here are:

(1) the need to acknowledge the controversies and take non-safety considerations and viewpoints seriously; and

(2) to recognize the sensibility on a political level.

Based on these lessons we draw some **careful conclusions** on how to interpret these findings.

*First*, with a view to recognize the sensibility of decision-making on GM crops on a political level, we recommend drafting **a regulatory framework that offers flexibility on a national level** (provide options and derogations for Member States). A directive may, therefore, be a more suitable regulatory instrument than a regulation. This may include a socio-economic assessment framework (to accommodate controversies), but preferably not with hard criteria defined on an EU-level.

*Second*, to stimulate harmonization (though not fully), the EC could carefully offer **guidance** for interpretation and implementation of the EU regulatory framework through so-called **'soft law' instruments** (see Chapter 3).

### *2.2 'Futureproof': policy-aims and socially robust innovation*

After the decision of the ECJ (Case C-528/16) on the 25th of July 2018 that new mutagenesis techniques fall under the scope of Directive 2001/18 and therefore require authorization, the EC felt the urge to respond and to analyze the status of new genomic techniques (NGTs). **NGTs** are 'techniques that are capable of altering the genetic material of an organism and that have emerged or have been developed since 2001'[34] (after the implementation of Directive 2001/18). NGTs refer to a diverse group of techniques that all use different methods to alter genetic material of organisms. Due to the rapid development of the accuracy and efficiency of some NGTs it is possible to develop crops also obtainable by conventional methods.[35] For those NGTs, the EFSA did not identify new hazards compared to these conventional methods (or to established genomic techniques).[36] One might carefully conclude, and that is what the EC and proponents do, that these techniques could meet the same level of safety as those techniques that are exempted from risk assessment.[37] The current regulatory framework arguably does not facilitate **innovation** of these new techniques as the EU stalemate entails that NGTs are subject to the standard GMO authorization procedures laid down in

[34] EC study on new genomic techniques (n 18) p. 3.
[35] Site-directed nuclease type 1 and type 2 (SDN-1, SDN-2), ODM, cisgenesis; p. 3.
[36] EC study on new genomic techniques (n 18) p. 3.
[37] It should be noted however that opponents reject the full assimilation between NGTs and conventional methods on the ground that it risks blurring 'the lines (which are legally and scientifically clearly drawn) between GM and conventional breeding', *Biased from the outset* 2021 (n 21) p. 13.

Directive 2001/18 which are deadlocked. One side effect could be that the EU risks that biotech companies avoid the territory of the EU for research and exploitation.[38]

As mentioned in the introduction, the EC performed a study on the status of these NGTs for which the results were published in April 2021. This study comprised two phases of consultation. First, the study included a survey among Member States. Second, it included a targeted stakeholder's consultation on the use of NGTs in the Member States. The study strongly focused on the use of NGTs in the Member States and the challenges that stakeholders experience. As mentioned in the introduction, the study identified several limitations of the current regulation. It acknowledged that the current legislation cannot keep pace with rapid and future technological developments, which creates enforcements issues and legal uncertainty (Poort, e.a. 2022). The study calls for a follow-up examining the need for adaption of the current regulation to make it futureproof while maintaining the high level of safety. Currently, the EC undertakes this follow-up and prepares a revision of GM legislation.[39] One of the goals of the European Commission for revision is **to simplify** the assessment frameworks for NGTS that have no new hazards compared to conventional methods or established genomic techniques. The EC intends to facilitate innovation of NGT and to enable the biotech companies and research centers in developing these techniques. Opponents, however, fear that assigning a differentiated status for NGTs will open up the road for future NGTs for which little is known about the effects.[40]

During the summer of 2022, the EC held a targeted survey among Member States and a wide variety of stakeholders in which various scenarios are sketched.[41] A few of these scenarios were directed to the status of NGTs (targeted mutagenesis and cisgenesis) and included a proportionate risk assessment and pre-notification of products that are also obtainable by conventional methods. Some scenarios focused on sustainability and labelling of sustainable products. Member States and stakeholders were asked to respond to those scenarios. Furthermore, the EC opened a round of public consultation (April 2022 until July 2022).[42] The questionnaire of the public consultation also circled around the main elements of the scenarios.

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[38] See *Toekomstpact Biotechnologie Nederland 2025 (n 32).*

[39] In parallel, there is a new case pending before the CJEU Case C-688/21 *Confédération paysanne and Others* (OJ C, C/37, 24.01.2022, p. 19). In this case, the CJEU is called to answer two questions raised by the French Conseil d'Etat on the interpretation of Article 3 (1) of Directive 2001/18in light of in vitro random mutagenesis. In his Opinion, Advocate General Szpunar rephrased these questions, by deciding to address only the more general question as to whether in vitro random mutagenesis is included within the scope of Directive 2001/18; he advises the CJEU that this question should be answered in the negative. Though, this preliminary ruling does not concern NGTs, it might have a broader relevance, as the Advocate General also proposes that the Court should offer clarification to promote uniform application of the Directive. (Opinion of Advocate General Szpunarin Case C-688/21 *Confédération paysanne and others* (delivered on 27 October 2022) ECLI:EU:C:2022:841 – see also François-Xavier Millet, "A pathway to terra ferma in the GMO legal landscape (Case C-688/21 – Confédération paysanne II)" Op-Ed (16 November 2022) available at https://eulawlive.com/op-ed-a-pathway-to-terra-ferma-in-the-gmo-legal-landscape-case-c-688-21-confederation-paysanne-ii-by-francois-xavier-millet/# (accessed on 16 December 2022). It remains entirely to the CJEU to decide on the questions raised by the French referring court (most probably by mid-2023) by following or not the approach proposed by the Advocate General; moreover, one might expect that the Court could provide additional clarification as regards mutagenesis techniques/methods that have 'conventionally been used in a number of applications' and that have 'a long safety record'.

[40] N. Foote, 'Commission stands by gene editing survey slammed by NGOs' (EURACTIV, 5 October 2022) <https://www.euractiv.com/section/agriculture-food/news/commission-stands-by-gene-editing-survey-slammed-by-ngos/> accessed 16 December 2022.

[41] European Commission, Food Safety, *Stakeholders' consultation* <https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques/stakeholders-consultation_en> accessed 16 December 2022.

[42] European Commission, Legislation for plants produced by certain new genomic techniques <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/public-consultation_en > accessed 16 December 2022.

The revision of the GM regulation must be understood in the broader policy context of the Farm to Fork Strategy. The Farm to Fork Strategy is at the heart of the EU Green Deal and offers a comprehensive approach for **a sustainable food system**. The EU aims '*to reduce the environmental and climate footprint of the EU food system and strengthen its resilience, ensure food security in the face of climate change and biodiversity loss and lead to a global transition towards competitive sustainability from farm to fork and tapping into new opportunities'* (Farm to Fork Strategy, 2020, p. 7). The Strategy emphasizes the role that biotechnology can play in increasing sustainability by, for example, reducing the dependency of pesticides. According to the Strategy, NGTs can contribute to seed security and diversity, and therefore, increase the access to seeds that can adapt to the pressures of climate change (Farm to Fork Strategy, 2020, p. 10).

This foreseen role of NGTs and biotechnology in the Farm to Fork Strategy, emphasizes the need to stimulate innovation and accommodate a 'lighter' assessment framework for NGTs.[43] The Farm to Fork Strategy plays an important role in framing the thorough revision of GM regulation. Consequently, it appears that **sustainability** is becoming an important principle in EU GM policy, though not completely new.[44] In spite of its importance, sustainability remains a rather broad multisided concept with unclear contours. The most frequent definition used worldwide, and also within the EU,[45] pertains to 'sustainable development' understood by UN World Commission on Environment and Development as 'development that meets the needs of the present without compromising the ability of future generations to meet their own needs.[46] Within the EU specifically, sustainability is characterized by economic, social, and ecological goals.[47] In 2009, the COGEM has developed a framework of nine criteria around these goals that together can be used as a framework of sustainability criteria. These criteria are (1) social benefit, (2) welfare & economic benefit, (3) welfare & health, (4) food security, (5) culture values, (6) freedom of choice, (7) safety, (8) biodiversity, and (9) environmental quality (COGEM 2009).[48] In 2014, these criteria were updated to work towards an assessment framework for cultivation of GM crops in the context of Directive 2015/412. The COGEM has emphasized that it is difficult to develop strict legally binding criteria from these nine criteria. To start with, these criteria and goals that sustainability aspires can be contradictory with each other. Economic goals may conflict with ecological values and goals (COGEM 2009).

An additional point that is raised by the Dutch Ministry is that sustainability has a more overarching scope and contains a general policy-aim for the whole food system. The COGEM has explored sustainability explicitly for GM crops (2009; 2014), but not all nine criteria are exclusively relevant in context of GM crops. Several criteria refer to more general economic, social, and ecological challenges, such as food security and welfare & economic benefit. These criteria are relevant for a sustainable food system for which GM crops can play an important role, but these challenges exceed GM and relate to other elements of the food system or agriculture (as well). Would that plead for a more overarching assessment framework for the whole food system, or can sustainability criteria in GMO assessment be justified?

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[43] *Farm to Fork strategy* (n 20).

[44] Already in the Dutch *Integrale Beleidsnota biotechnologie*, Tweede Kamer, 2001-02 (*Kamerstukken II,* 2001-2002, 27248, nr.2), the Dutch House of Representatives emphasized the need for public debate about a sustainable food system.

[45] European Commission, 'Sustainable development' available at <https://ec.europa.eu/environment/sustainable-development/index_en.htm> accessed 16 December 2022.

[46] United Nations Brundtland Commission, Report of the World Commission on Environment and Development: Our Common Future (20 March 1987) available at <http://www.un-documents.net/our-common-future.pdf > accessed 16 December 2022

[47] *A European Grean Deal* (n 19).

[48] See COGEM, *Bouwstenen voor een beoordelingskader voor teelt van GG-gewassen* (n 33) for a thorough analysis of these criteria.

Although sustainability plays a role in GM-debate for decades, the role of sustainability in GM-policy has changed. Whereas sustainability was considered a way to elaborate on socio-economic considerations around GM crops[49], due to the Green Deal and the Farm to Fork strategy, today it plays a more central role, though it is still up for debate which role it can play more concretely (ideological and practical). A possible role allocated to sustainability is to simplify assessment frameworks for NGTs which are used to promote sustainability. Sustainability is, then, an aspiration and can therefore be an incentive to promote NGTs (and thus justify simplification of its assessment framework). Sustainability as an aspiration or a goal may require less hard criteria. However, it still needs a clear tailored working definition. Currently, sustainability has a broad scope including social, economic, and ecological goals. These goals may conflict with each other, as well as with the goal of a 'high level of safety of human health and the environment' enshrined in Directive 2001/18.[50] How then translate the variety of goals into a definition of sustainability that can justify simplification of NGTs assessment framework?

Another possibility would be to simplify assessment frameworks for NGTS which are produced in line with sustainability criteria (see the scenarios B sketched by the EC in the targeted survey). Sustainability, in this role, needs to be translated into minimum requirements. As such sustainability may offer an entry to include socio-economic considerations into the assessment framework. Sustainability could function as catalysator to acknowledge ongoing controversies but, at the same time, it may create further side-effect tensions between the sustainability goals. Furthermore, according to some, 'taking claimed benefits of a GMO into consideration in the regulatory evaluation will neither help sustainability nor increase the societal consensus around GMOs'.[51]

As the Farm to Fork Strategy emphasizes, the role that NGTs can play to stimulate sustainability are under the condition that NGTs are safe (p.10). Safety remains an essential consideration in GM regulation, which reflects the precautionary principle.[52] The **precautionary principle (PP)** has played a dominant role since the 90s (Rio Principle 15 of the 1992 UNCED conference). In the early 2000s, the PP was further developed and given substance in the Netherlands and in Europe. The European Commission and the Dutch government followed a moderate interpretation of precaution defining conditions to minimize safety risks (risk management), and at the same time facilitating development of GM technologies.[53] During the years, the PP's interpretation has become more rigid focusing on avoiding safety risks; such an understanding of the PP seems to have been endorsed by the CJEU in its Judgment in Case C-528/16,[54] and arguably relied upon by the opponents of EC's plans on NGTs.[55] Bouchaut et al. show that the PP has been operationalized in Europe to ensure safety focusing on known and acceptable (read: manageable) risks. There, is, however, hardly room for research with

[49] *Integrale Beleidsnota biotechnologie*, (n 44).
[50] See for instance Article 16 (2).
[51] *Biased from the outset* 2021 (n 21) p. 10.
[52] In this respect it is maintained that 'policy decisions based on societal values such as "benefits contributing to sustainability" can only be considered as an additional element within the approval process. They must not replace the current process-oriented risk assessment, labelling, traceability, and monitoring, as required by EU law for the whole food chain, from breeders to consumers', *Biased from the outset* 2021 (n 21) p. 10.
[53] See Bergmans e.a, *Analyse van de Europese Wet- en regelgeving over genetisch gemodificeerde organismen* (n 9) for a further elaboration of the history and role of PP in EU GM debate.
[54] Case C-528/16 (n 11) paras 50-54.
[55] The 'EU Commission's attempt to deregulate new GM techniques is contrary to the Precautionary Principle and will threaten public health and the environment. It will also endanger the non-GMO, conventional, and organic agricultural and industry sectors. There is no scientific basis for deregulating whole classes of new GM techniques and their products.' *Biased from the outset* 2021 (n 21) p. 17.

uncertainties involved.[56] In EU regulatory practice, uncertainties are considered as (unmanageable) risks and, thus, research involving uncertainties is not authorized. Consequently, innovation is hindered. Bouchaut et al. argue for social learning in which the PP allows for more room to learn about uncertain risks and on how to mitigate these risks.[57] Concretely, this understanding of the PP entails that research involving uncertainties would be authorized (in contained use) to get a better understanding of these uncertainties and to what extent these uncertainties involve (unacceptable) risks.

In June 2022, the RECIPES project has published its outcomes offering a Guidance for future application of the precautionary principle within the EU.[58] This project aimed to reconcile innovation and precaution. The RECIPES project visioned that the PP '*should ensure a high level of proactive protection of human health and the environment and stimulate societally desired innovation*'[59]. In offering guidance, the project included some case studies, such as gene technology and the development of NGTs. The RECIPES team closely works with stakeholders gathering their feedback and ensuring that the guidance aimed for in this project is acceptable and relevant for various stakeholders. On gene technology in agriculture the contributors concluded that the PP is mentioned in regulations, but its role is ambiguous. On the one hand, GMO authorization in Directive 2001/18 builds on a precautionary approach to minimize risks, on the other hand precaution is mentioned in public controversies.[60]

By offering guidance to bridge the assumed contradiction between innovation and precaution, the project distinguishes two roles of the PP: (1) being a compass, and (2) being a safeguard. As a compass, the PP can steer innovation into societally beneficial directions (p.6). This may imply accommodating broad involvement from an early phase in research and enable debates on the societal impact of risks (which may include agenda-setting). Furthermore, as a compass in research processes, the PP may introduce social debates on acceptability of scientific uncertainties and possible risks. In this way, the PP can be taken into account from the design-phase of new technologies (safety-by-design).[61]

In line with current interpretations of PP, the RECIPES team also visioned PP as a safeguard in future regulations for GMOs. Though, they broaden the scope of its safeguarding role in which they consider the need for explicit and transparent problem scoping. This would translate into broadening stakeholders' involvement in order to define the risks and uncertainties that should be addressed in RA.[62] This involves broadening risk assessment, but also moving beyond cost-benefit analysis and broadening decision-making about application of the precautionary principle. As a safeguard, the PP creates conditions to ensure safety, while at the same time work towards responsible innovation.[63] It must be emphasized here that risk assessment is not broadened by including non-safety

[56] B.F.H. J Bouchaut, H. de Vriend, H., & L. Asveld, 'Uncertainties and uncertain risks of emerging biotechnology applications: A social learning workshop for stakeholder communication' (2022) 27, *Frontiers in Bioengineering and Biotechnology*, p. 2 available at <https://doi.org/10.3389/fbioe.2022.946526 >accessed 16 December 2022.
[57] Ibid.
[58] The RECIPES team consists of various social scientists and legal scholars from both Norway and the Netherlands. Their project is funded by Horizon 2020. The project presents recommendations for future application of the PP in such way that it can bridge the assumed contradiction between innovation and precaution. See <https://recipes-project.eu/ > accessed 16 December 2022.
[59] RECIPES project, *Deliverables 3.3: Sector specific briefs* (June 2022) p. 1., available at <https://recipes-project.eu/sites/default/files/2022-07/D.3.3%20Sector%20Briefs-Final.pdf > accessed 16 December 2022.
[60] Ibid, p. 6. For controversies about the meaning of precaution, see also P. Craig, *EU Administrative Law* (3rd edn, OUP 2018) p. 721. This topic is further discussed in Section 2.3 of this report.
[61] RECIPES project, *Deliverables 3.3: Sector specific briefs* (n 59) p. 7.
[62] RECIPES project, *Deliverables 3.3: Sector specific briefs* (n 59) p. 6.
[63] RECIPES project, *Deliverables 3.3: Sector specific briefs* (n 59) p. 8.

considerations. The RECIPES project refers to broaden the discussion about the risks that may be relevant either acceptable or which are we, as a society, not willing to take.

The RECIPES project provides a new perspective on the application of PP by interpreting it in connection to responsible innovation and by giving responsibility for its application to a broader audience of stakeholders. This new perspective may contribute to breaking through the current impasse as it shines a different light on the current conservative approach to risks. The CJEU in its Judgment in Case C-528/16 on NGTs has related the precautionary principle to the exemption of mutagenesis and to an understanding of the long safety record as referred to in recital 17.[64] A different, more dynamic understanding of PP (as visioned by RECIPES) may provide room for defining long safety record (see further Chapter 3).

At the same time, we could question whether the broadening of the PP as suggested above has the potential consequence of overcomplicating things and opening up to accusations of diluting the current level of safety protection. The RECIPES project intends to offer guidance but is not an official statement of the legislature. In Chapter 3, we will elaborate on the consequences of this understanding of PP.

Remarkable is that the two principles (sustainability and PP) that were initially related to two different framings of the GM debate are nowadays both discussed in terms of broadening the assessment framework. These principles are not conflicting with each other and may even be supplementary. Risk assessment is directed to effects on the environment (environmental risk assessment), which may also include effects on sustainability. Sustainability also includes the environment in terms of ecological goals.

However, some criticisms are voiced on the promises of GMs on sustainable benefits:

*'Moreover, the scientific rigour of the GMO evaluation process would be severely compromised by basing any part of it on claims of benefits by GMO developers. The first generation of transgenic plants was promoted on the basis of claims that they would contribute to sustainability by reducing pesticide use and provide benefits to consumers. However, these promises have never materialized. Thirty years after their release onto world markets, there is still no consensus amongst scientists, industry, farmers, and food producers on the sustainability impact of transgenic plants in food production'*. (*Biased from the outset* 2021*,* p. 10.)

One last issue relevant subject is the **freedom of choice** that strongly relates to **traceability and labelling** of GM-crops. Opponents of GM technology argue that if NGTs are excluded from authorization, it is impossible to keep track on these products as labelling is, then, not required (Mampuys, 2021). That would risk infringing consumer rights such as the freedom of choice.[65]

[64] Bergmans e.a. *Uitspraak van het Europees Hof over gene editing en de ggo-regelgeving* (n 9) p. 48-49.
[65] *Biased from the outset 2021* (n 21) p. 15.

In the targeted survey of the EC (2022), traceability and labeling did play a role, although more related to sustainability. Two scenarios were sketched: (1) additional labelling of sustainable products or; (2) no labelling if sustainable.[66] The first scenario would encompass the introduction of a new labelling system, building on sustainability requirements. It, however, does not exempt NGTs from regulations of GM labelling. The latter involves that, sustainable products which are developed by NGTs do not require GM labelling. This scenario may contribute to a simplified procedure for NGTs as it does not have to follow procedures on labelling. In both scenarios it is necessary to formulate a clear definition of sustainability and define requirements for (not) labelling.

Relevant principles and policy- aims that need to be considered when revising EU GM legislation in agriculture are: (1) differentiated status for NGTs; (2) sustainability; (3) precautionary principle; (4) innovation and; (5) traceability and labelling. In Chapter 3, we will elaborate on ways to define and operationalize these principles and policy-aims, taken into account the diversity of interpretations and meanings in current practice.

### *2.3 EU law principles and basic rules*

From the perspective of EU law, several legal principles and rules should be observed by the EC on its way forward on NGTs. First, any legal instrument proposed by the EC must comply with **horizontal principles**, such as conferral, subsidiarity, proportionality (Article 5 TEU), as well as with the principle of sincere cooperation (generally enshrined in Article 4 (3) TEU and given specific expression in EU institutional relations in Article 13 (2) TEU within the framework of the principle of institutional balance). The **principle of conferral** (Article 5 (2) TEU) entails that any EU legal act must have a legal basis reflecting a competence conferred on the EU in the Founding Treaties. Once the existence of the EU competence is established, subsidiarity and proportionality govern the exercise of Union's competence.

The **subsidiarity principle** (Article 5(3) TEU) concerns areas in which the EU competence is shared with that of the Member States (as is the case here), and it essentially requires a comparative efficiency test demonstrating that the objectives of the envisaged action cannot be sufficiently achieved by the Member States, and that they can be better achieved by the EU, by reason of its scale and effects.[67] According to the **principle of proportionality** (Article 5(4) TEU), the action envisaged must not go beyond what is necessary to achieve its objectives (which must be in line with and contribute to the objectives of the EU Founding Treaties). According to Protocol No 2 on the Application of the Principles of Subsidiarity and Proportionality, each EU institution (including the European Commission) must ensure 'constant respect' for these two principles.

With regard to proposals for legislative acts, this entails on the procedural side, that the EC must consult widely at an early stage (before the proposal is put forward) and must give reasons for its chosen course of action.[68] What is more, all draft legislative acts must contain 'a detailed statement making it possible to appraise compliance with the principles of subsidiarity and proportionality', and the 'reasons concluding that a Union objective can be better achieved at Union level shall be

[66]Targeted survey for the impact assessment of new legislation on New Genomic Techniques available at <https://www.infogm.org/IMG/pdf/technopolisquestionnairenouveauxogm2022.pdf > accessed 16 December 2022.
[67] See P. Craig and G. de Burca, EU Law. Text, Cases and Materials (, 7th edn, OUP 2020) p. 125.
[68] Article 2 of the Protocol.

substantiated by qualitative and, whenever possible, quantitative indicators'.[69] Last but not least, the national parliaments of the Member States are enabled to express their views on the compliance of EU draft legislative acts with the principle of subsidiarity.[70] All this is meant to preserve the underlying idea behind the principle of subsidiarity, namely that as a rule, 'decisions must be taken as closely as possible to the citizens of the Union' (namely at state or local level, rather than at EU level).[71]

The **principle of sincere cooperation** entails mutual assistance and in full respect between the EU and its member states 'in carrying out tasks which flow from the Treaties'. On the EU institutional side, the 'mutual sincere cooperation' requirement is linked to the **principle of institutional balance** (mirroring to some extent the application of the principle of conferral on the EU institutional structure) according to which EU institutions must act 'within the limits of the powers' conferred on them by the Treaties; it implies that EU institutions must respect each other's powers and should refrain from actions that would encroach upon or undermine the powers of another EU institution.

On top of the horizontal principles discussed previously, the European Commission's way forward on NGTs must take into account more **substantive principles and legal parameters**, relevant in the field of GMOs. This covers most significantly the precautionary principle, the principle that preventive action should be taken, sustainability and free movement of goods. The **precautionary principle**, enshrined in Article 191 (2) TFEU, represents according to the Treaties, one of the fundamental guarantees for ensuring a high level of protection in the European Union's environmental policy. What is more, the precautionary principle was raised by the EU courts at the rank of an autonomous general principle of EU law applicable across Union's policies observing a high level of protection for the environment, health and consumer protection.[72] The EU courts further clarified that PP as a general principle of EU law requires 'competent institutions to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests'.[73] One important implication of this is that 'where there is uncertainty as to the existence or extent of the risks to human health, the institutions may take precautionary measures without having to wait until the reality and seriousness of the risks become fully apparent'.[74] Such precautionary measures must, however, comply with EU law, in particular with the principle that protection of health, safety, and the environment take precedence over economic interests, as well as the principles of proportionality and non-discrimination.[75] As could be seen, the CJEU in its Judgment in Case C-528/16 on NGTs seems to align to previous jurisprudence by favoring an understanding of the PP focusing on avoiding safety risks to human health and the environment. According to Craig, the PP remains subject to intensive debates, its precise meaning and application requiring particular attention being paid to the specific legal framework within which it is implemented.[76] EU courts indicate overall a preference for safety over economic interests in the application of the PP; yet they also seem to allow for some discretion for the competent authority to pursue a risk/benefit analysis when deciding on the authorization of a new (medicinal *in casu*) product.[77] Against this background, some recent views by scholars support a

[69] Article 5 of the Protocol.
[70] Articles 6-7 of the Protocol.
[71] Preamble of the Protocol.
[72] See Case T-13/99 *Pfizer Animal Health SA v Council* [1998] and Cases T-74, 76, 83-85, 132, 137 ECLI:EU:T:2002:209, and Joined Cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00 and T-141/00, *Artedogan and Others* v Commission [2002] ECLI:EU:T:2002:283.
[73] Artedogan and Others v Commission (n 72) para. 184.
[74] Artedogan and Others v Commission (n 72) para. 185; see also Craig, *EU Administrative Law* (n 59) p. 720.
[75] Artedogan and Others v Commission (n 72) para. 186.
[76] Craig, *EU Administrative Law* (n 60) p. 721.
[77] Artedogan and Others v Commission (n 72) paras. 187-192.

broader understanding of the precautionary principle, including also non-safety concerns in particular sustainability concerns.[78]

While highly relevant and topical, for the time being, **sustainability** remains, at least at EU level, a rather open-ended concept with no clearly defined content and boundaries. Therefore, the way in which sustainability should be linked to the precautionary principle, and what this should entail for the NGTs authorization issues remains a challenging question.

Finally, yet importantly, the placing on the EU internal market and the free movement of NGTs is another essential aspect of the envisaged regulatory framework. Backed up by the **principle of non-discrimination** on grounds of nationality and the removal of obstacles affecting the functioning of the internal market, **free movement of goods** can still be legitimately restricted by the Member States invoking derogations based on public health or public policy under Article 36 TFEU, or by relying on safeguard clauses[79] in secondary legislation authorizing Member States to take derogatory/provisional measures for non-economic reasons related to public health or the environment.

It should be noted that the integration and balancing of the various requirements/issues flowing from the above-mentioned substantive principles and standards within the envisaged regulatory approach and framework of NGTs is quite complex and requires careful consideration.

***Figure 2 EU law framework***

**1) Horizontal principles**

- Conferral, subsidiarity, proportionality
- Sincere cooperation
- Institutional balance

**2) Substantive principles/legal parameters**

- Precautionary principle, the principle that preventive action should be taken
- Sustainability
- Free movement of goods and non-discrimination

**Preliminary Assessment**

From the perspective of the principle of conferral, in view of the potential objectives and scope of European Commission's proposal for a new legislative act on NGTs amending Directive 2001/18, the appropriate legal basis could be Article 114 TFEU (same as in Directive 2001/18 and other legislative acts amending this directive over time) or could be a multiple legal basis (combining for instance Article 114 TFEU with Art 192 (1) TFEU [environment] and eventually with Article 43(2) TFEU

[78] See for instance the RECIPES project (n 57).
[79] See for instance Articles 114 (4)-(8) and (10) and 191 (2) TFEU; see also Article 23 of Directive 2001/18.

[agricultural markets]). Both solutions could work. Article 114 TFEU as a single legal basis would be in line with the past legislative practice concerning the amendment of Directive 2001/18. A multiple legal basis combining Articles 43 (2), 114 (1) and 192 (1) or Articles 114 (1) and 192 (1) could be desirable as it would better reflect the complex design and objectives of the GMO legal framework under consideration (touching not only on the placing of NGTs on the market, but also on their release into the environment, and reflecting the application of the precautionary principle as well as of a high level of safety, and ultimately also potentially affecting the common organization of agricultural markets); procedurally, the above mentioned Treaty provision could be easily be combined as they all provide the adoption of legislative acts according to the ordinary legislative procedure.

Regarding the subsidiarity principle, things might be more challenging in particular if the EC will aim at a more harmonized and binding approach in this area. The reasons for this can be summarized as follows: (1) the Member States and other stakeholders seem to be divided on the issue of NGTs, and there seems to be no scientific consensus yet on the risks associated with NGTs that do not have a long safety record; (2) the CJEU already established in Case C-528/16 that organisms obtained by means of techniques/methods of mutagenesis constitute GMOs, and therefore are subject to the authorization regime under Directive 2001/18, as they could entail risks for the environment or human health that are 'similar to those which result from the production and release of a GMO through transgenesis'[80]; and; (3) the EU legislator itself has acknowledged in the preamble of Directive 2015/412 that 'cultivation of GMOs is an issue which is more thoroughly addressed at Member State level'[81] and that 'it appears appropriate to grant Member States, in accordance with the principle of subsidiarity, more flexibility to decide whether or not they wish to cultivate GMOs on their territory'.[82] On the other hand, EFSA has stated that 'plants (and their products) derived from cisgenesis and targeted mutagenesis are equally safe as plants produced with classical mutagenesis or conventional breeding techniques';[83] it remains to be seen whether EFSA's view will pave the way to a more harmonized approach to NGTs, by convincing in particular the Member States to reflect this proposed legal status on NGTs in a future reform of Directive 2001/18.

Against this background, the EC should make a very sound case in an eventual evaluation study or impact assessment, including by relying on comprehensive and compelling scientific evidence and by duly taking into account the diversity of views and arguments on the subject-matter, as to the added value of new EU action in this area. Similarly, proportionality could become an issue, in particular if the EC is determined to propose a binding legal instrument like a directive or regulation on NGTs; GMOs are currently regulated by Directive 2001/18, so most likely Member States might feel that a directive, rather than a regulation would be preferrable to regulate NGTs; even if a directive would be preferred, it should still allow for sufficient flexibility for Member States, through derogations and safeguard clauses, to restrict or prohibit the use and/or sale of NGTs/based products on their territory,

[80] See also the pending case before the CJEU, Case C-688/21 *Confédération paysanne and Others* (n 37)*;* Opinion of Advocate General Szpunar in Case C-688/21 *Confédération paysanne and others* (delivered on 27 October 2022) ECLI:EU:C:2022:841.

[81] Recital 6 of the Preamble.

[82] Recital 8 of the Preamble.

[83] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms) E. Mullins, J.L. Bresson, ,T. Dalmay, ,I.C. Dewhurst, M.M. Epstein, L.G. Firbank, P. Guerche, J. Hejatko, F.J. Moreno, H. Naegeli, F. Nogué, J.J. Sánchez Serrano, G. Savoini, E. Veromann, F. Veronesi, J. Casacuberta, A. Fernandez Dumont, A. Gennaro, P. Lenzi, A. Lewandowska, I.P. Munoz Guajardo, N. Papadopoulou, & N. Rostoks, 'Updated scientific opinion on plants developed through cisgenesis and intragenesis' (2022), 20(10) *EFSA Journal*:7621, available at https://doi.org/10.2903/j.efsa.2022.7621 accessed 16 December.

See also the pending case before the CJEU, Case C-688/21 *Confédération paysanne and Others* (n 39).

in order to account for the sensitivities of some Member States.[84] From the perspective of the principles of sincere cooperation and institutional balance, a too daring approach by the EC (e.g. full harmonized regime excluding NGTs from the GMO normal authorization procedure under Directive 2001/18) might lead to allegations that the EC is seeking to circumvent CJEU's judgment in Case C-528/16.[85] For the same reason, the EC should also be cautious with reassessing the legal contours of the precautionary principle by integrating non-safety considerations (such as sustainability benefits) in the risk assessment phase rather than in the risk management phase. Additionally, if potential sustainability benefits cannot be readily balanced against the impact (risks) of NGTs on human health and environment due to the uncertainty surrounding these new technologies, the proposed legal instrument might risk not meeting the so-called 'proportionality stricto sensu' test.[86] An EU legal act ignoring these concerns, even if ultimately adopted, might be challenged before the EU courts and ultimately annulled by the CJEU.[87]

[84] Under the current legal framework, safeguard clauses enabling Member States to provisionally restrict or prohibit the use and/or sale of GMOs as or in a product on its territory usually based on new information/scientific evidence highlighting risks for human health/environment are enshrined in Article 23 of Directive 2001/18 and Article 34 of Regulation 1829/2003. Other derogations from free movement of goods and harmonization measures regarding the use and/or sale of GMOs are possible under the EU Treaty framework, in particular under Article 36 and Article 114 (4)-(6) TFEU (see also recital 7 of the preamble to Directive 2015/412).

[85] See Case C-528/16 (n 12) para 53.

[86] See for instance *Biased from the outset* 2021 (n 21) p. 10.

[87] Craig, *EU Administrative Law* (n 60) p. 721.

**Chapter 3 Possibilities for regulatory change**

In the previous chapter, the relevant background, policy-aims, and principles for revision of the agricultural GM regulatory framework were identified and listed. See below for an overview. In this chapter, we will explore several legal possibilities.

*Policy-aims:*

- Differentiated status for NGTS;
- Stimulate innovation of sustainable agriculture and food system while maintaining a high level of protection of human health and of the environment.

*Relevant general legal principles:*

- Subsidiarity
- Proportionality
- Precautionary principle

*Challenges related to the relevant principles*:

- How to translate social, economic, and ecological sustainability goals into a socio-economic assessment framework? Can these goals be translated into hard criteria, and can these goals be balanced?
- How to reconcile innovation and precaution? Do we need to consider uncertainties as (unacceptable) risks?

*General lessons learned:*

- The need to acknowledge the controversies and take non-safety considerations and viewpoints seriously;
- To recognize the sensibility on a political level.

*Recommendations:*

- Drafting a legislation that offers flexibility on a national level. A directive may therefore be more suitable than a regulation;
- If a socio-economic assessment framework is included, preferably not with hard criteria defined on an EU-level;
- Carefully offering guidance for interpretation and implementation of the framework via soft law instruments.

*3.1 Differentiated status for NGTs*

As already mentioned in the previous chapter, one of the main goals of the revision of GMO-regulation is to simplify the authorization procedure for NGTs. The EC-studies of both 2021 and 2022 concluded that the current regulatory framework cannot accommodate NGTs, neither is the current framework

futureproof, while at the same time NGTs are promising. The decision of the CJEU in 2018 (C-528/16), however, did not open the road for a differentiated status of NGTs. Instead, the CJEU reasons that NGTs cannot be exempted from Directive 2001/18/EC based on article 3, as these techniques cannot be assimilated to 'techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record' (recital 17 of the preamble to Directive 2001/18). The exemption was made for established genomic techniques that had a long safety record when the Directive was implemented. We concluded that the CJEU put the ball on the status of NGTs to the European Commission.

We think that a legal possibility to create a differentiated status of NGTs while at the same time ensuring safety of the environment is to regulate what it entails to have a **long safety record.** The current Directive should, then, be amended by a provision that techniques with a long safety record are also exempted from the Directive. Furthermore, the EC needs to regulate what it entails to have a long safety record. This could be done via a binding legal instrument (directive or regulation) amending Directive 2001/18, but could arguably also be left to a Commission delegated or implementing act, potentially complemented with additional EC recommendations/guidelines.

Bergmans e.a argue that the CJEU's decision on long safety record must be understood as 'having a history of safe use'.[88] Bergmans e.a claim that the technique of mutagenesis has not proven its safety as proving safety is scientifically impossible.[89] It is only possible to prove unsafety. The best possible scenario is to have a history of safe use. Having said that, Bergmans e.a. argue that it might be possible to build such a long safety record under Part B of Directive 2001/18, which regulates licensing procedures of deliberate release. These procedures are organized and regulated on a national level and leave room to, for example, simplify licensing by a generalized risk assessment on a national level.[90] For example, under Dutch law it is possible to apply for a 'vergunning onder vaste voorschriften' (art 26 Besluit GGO).[91] With this VOV-procedure environmental risk assessment for certain GM-products can be applied for similar GM-products and thus do not require a new risk assessment. Consequently, the procedure for authorization can be simplified and be speeded up. Bergmans e.a. acknowledge that this procedure is not yet used for deliberate release, but could pave the way for a relatively easy building of a safety record for NGTs.[92]

In Directive 2001/18, the legal basis for such a procedure in authorization of deliberate release can be found in article 7 of the Directive, that regulates the conditions for a differentiated procedure (see Section 1.1). This differentiated (read simplified) procedure is applicable if 'sufficient experience has been obtained of releases of certain GMOs in certain ecosystems' and provided that the GMOs concerned meet a number of criteria listed in Annex V of the Directive.[93] The initiative belongs to a national competent authority which submits a reasoned proposal to the Commission in this respect; the application of the differentiated procedure is decided by the Commission via an implementing act, adopted after the consultation of the relevant scientific committee; this implementing act must

[88] Bergmans e.a. *Uitspraak van het Europees Hof over gene editing en de ggo-regelgeving* (n 9) p. 67.
[89] Bergmans e.a, *Analyse van de Europese Wet- en regelgeving over genetisch gemodificeerde organismen* (n 9).
[90] Bergmans e.a. *Uitspraak van het Europees Hof over gene editing en de ggo-regelgeving (*n 9) p. 67.
[91] See for the procedure, Rijksinstituut voor Volksgezondheid en Milieu Ministerie van Volksgezondheid, Welzijn en Sport, IenW procedure vergunning onder vaste voorwaarden (VoV) available at <https://loketgentherapie.nl/ienw-procedure-vergunning-onder-vaste-voorwaarden-vov> accessed 16 December 2022.
[92] Bergmans e.a. *Uitspraak van het Europees Hof over gene editing en de ggo-regelgeving* (n 9) p. 67.
[93] Article 7(1) Directive 2001/18.

establish ' the minimum amount of technical information from Annex III necessary for evaluating any foreseeable risks from the release'.[94]

This scenario of a relatively simple adjustment of the Directive may contribute to simplify authorization of NGTs while at the same time ensuring its safety. The *solution* of building a long safety record can also overcome the criticism that exempting NGTs from the standard authorization procedure may open the road for future NGTs for which risks are not yet known. The (future) NGTs also require a long safety record. NGTs are not one kind of technique, but refer to a diverse group of techniques, using different methods.

Though we consider this scenario as a relevant one, we do see that this scenario still not answers the question on how to build such a long safety record. We think it is up to the EC or to the Member States to define criteria on building this long safety record. The criteria listed under Annex V of Directive 2001/18 for the application of the differentiated procedure laid down by Article 7 of the Directive could be a starting point in this respect (these criteria could perhaps be further clarified by the Commission via guidelines or other soft law instruments).

Furthermore, in this scenario the lessons learned on the issues related to the controversies and the sensitivity of GM-regulation are not (fully) addressed. In the next section, we will elaborate on a legal possibility that does address these lessons. Nonetheless, also in that scenario, the need to regulate how a long safety record can be established, is relevant to create room to differentiate between different genomic techniques.

*3.2 Socio-economic assessment framework*

One of the options for a thorough revision of GM regulation that is suggested and called for, is broadening the assessment framework. This call builds on several markers in the GM-debate. First, core of the issue here is partly caused by the restrictive framing of GM-regulation (environmental risk assessment), while the GM-debate is characterized by broader controversies (ethical and socio-economic considerations).[95] The need to acknowledge these controversies can be translated as a need for a broader, and thus, socio-economic assessment framework. What may be relevant socio-economic criteria as well as how to weigh them, is up for discussion. Member States differ and disagree on the role and scope of socio-economic assessment.

Second, sustainability plays a dominant role in debates on the food system and agriculture on EU-level. As has been explained in the previous chapter, sustainability contains social, economic, and ecological goals. The strength as well as the weakness of this concept is related to its broad scope. On the one hand, sustainability entails a comprehensive approach towards all those elements that are required to ensure a sustainable future. The food system can only be sustainable and, thus, be future proof if all these goals are met. On the other hand, a clear definition, clear criteria, and sharp boundaries of these goals are still lacking.

Nonetheless, the EC recognizes a strong narrative in sustainability to get 'everyone on board'.[96] This narrative contains several positive elements. To start, sustainability can be an incentive to simplify authorization for those genomic techniques that have a positive contribution to sustainability.

[94] Article 7 (1)-(3) Directive 2001/18.
[95] See for instance recital 9 of the Preamble to Directive 2001/18: "Respect for ethical principles recognised in a Member State is particularly important. Member States may take into consideration ethical aspects when GMOs are deliberately released or placed on the market as or in products."
[96] See *Targeted survey* (n 65).

Furthermore, sustainability can reflect the broader concerns that characterize the GM-debate, such as the socio-economic concerns.

Until now, however, it is discussed how to define what is sustainability. Point of discussion is how to translate all these diverse goals into hard criteria or one assessment framework?

The Norwegian approach is worthwhile exploring as broader socio-economic, ethical, and sustainability considerations are integrated in their GM regulatory framework. Although risk assessment still forms the basis of decision-making on authorization, their approach entails a more holistic way including all considerations.[97] One remark must be made here, Norway has never (or: not yet) put their regulatory framework into practice as no one applied for authorization of cultivation of GMOs under the Gene Technology Act. Nonetheless, their approach may provide valuable insights on how to broaden assessment.[98]

In Norway, the Norwegian Biotechnology Advisory Board is responsible for assessing sustainability, societal benefit, and ethics of GMOs.[99] Over the years the Board have published several reports on substantiating the considerations that play a role in the assessment.[100] They did so by formulating several control questions that could be directed to applicants for impact assessment. These questions are grouped into 1) product characteristics and 2) production and use of the product. In 2005, when the new Gene technology Act came into being, the Board translated assessment of social benefit into a cost-benefit analysis which was divided into eight phases (see below)[101].

***Figure 3 Eight steps of the Norwegian cost-benefit analysis***

1) Describe the GMO application and formulate goals
2) Identify possible outcomes of the application: full approval, rejection, or limited approval
3) Identify effects
4) Quantify the effects in numbers and value
5) Evaluate economic profitability
6) Conduct an uncertainty analysis
7) Describe distributional effects
8) Give an overall assessment and recommend measures

[97] Macnaghten e.a., 'Breaking the impasse' (n 2) p. 357-358.

[98] Also the COGEM has touched upon the Norwegian approach in their reports on socio-economic assessment of GMOs. See COGEM, *Sociaal-economische aspecten van ggo's. Bouwstenen voor een EU duurzaamheidsbeoordeling van genetisch gemodificeerde gewassen (2009),* CGM/090929-01, available at < https://cogem.net/app/uploads/2019/07/090929-01-Sociaal-ec-aspecten_webversie.pdf accessed 16 December 2022>: and COGEM, *Bouwstenen voor een beoordelingskader voor teelt van GG-gewassen* (n 33).

[99] Norwegian Biotechnology Advisory Board, *Societal Benefits and Genetically Modified Organisms* (2018), available at <https://www.bioteknologiradet.no/filarkiv/2018/10/2018-10-18-Rapport_Samfunnsnytte_Eng_lesevennlig-versjon.pdf>accessed 16 December 2022.

[100] See for example Norwegian Biotechnology Advisory Board, *Sustainability, Benefit to the Community, and Ethics* (2009) available at <https://www.bioteknologiradet.no/filarkiv/2010/07/2009_11_18_diskusjonsnotat_baerekraft_engelsk.pdf > accessed 16 December 2022; Norwegian Biotechnology Advisory Board, *Herbicide-resistant genetically modified plants and sustainability* (2014) available at <https://www.bioteknologiradet.no/filarkiv/2014/09/Herbicide-resistant_genetically_modified_plants_and_sustainability_NBAB.pdf> accessed 16 December 2022; Norwegian Biotechnology Advisory Board, *Societal Benefits and Genetically Modified Organisms* (n 99).

[101] Norwegian Biotechnology Advisory Board, *Societal Benefits and Genetically Modified Organisms (*n 99) p. 12.

In their latest report of 2018, the Norwegian Biotechnology Advisory Board recommended to distinguish three different tiers of cost-benefit analysis: 1) minimum requirements for analysis; 2) simplified analysis and 3) cost-benefit analysis. To determine the appropriate level of analysis, the Board has formulated various control questions related to uncertainties, to health and environmental risks, to long safety records, and to traits specifically relevant for the Norwegian territory.[102] Until now, these recommendations has not been put into practice. However, this proposal provides an interesting approach to tackle several issues that characterize the EU GM-debate.

The differentiation between levels of cost-benefit analysis by distinguishing three tiers in the regulatory framework gives room to differentiate between different genomic techniques and simplify procedures for those techniques that have a long safety record or have minimum safety risks. Furthermore, it may also give room to differentiate between levels of sustainability: absence of negative effects or positive effects. Positive effects would fall under the tier in which minimum requirements for analysis are formulated (tier 1), while absence of negative effects justifies a simplified analysis (tier 2).

A different way to go is that the control questions are formulated in such a way that, in case of positive contributions to sustainability, a simplified cost-benefit analysis can be performed (provided that the GM products fulfill requirements on either a long safety record or minimum safety).

This proposal still leaves the issue open that it is hard to translate the three sustainability goals into hard criteria. Besides, these proposal does not overcome the complexities of balancing these different (and sometimes contrasting) goals.

An option can be found in separating the three sustainability goals. The ecological goal goals as has been formulated in the Green Deal and the Farm to Fork Strategy, then, becomes a novel part of environmental risk assessment. In Norway environmental risk assessment is both a pre-condition and part of cost-benefit analysis.[103] While social and economic goals are only part of the cost-benefit analysis.

On EU-level, environmental risk assessment (ERA) got stuck, which can be explained by the lack of accommodation of the more socio-economic considerations which are, consequently voiced in context of authorization (see Chapter 2). If you split ERA from socio-economic assessment, ERA can really address environmental risks, including ecological sustainability. Safety, thus, remains a central issue and can be ensured. ERA being a first stage and a pre-condition can overcome the criticism that sustainability translated into a cost-benefit analysis may downplay safety by paving the way for introducing 'unsafe' products into the market in case these provide a high economic or social benefit.[104] This ERA is a first stage of the GM authorization procedure and can be performed on EU-level in a similar matter as the current authorization procedure (see figure 4).

[102] See for instance Norwegian Biotechnology Advisory Board, *Societal Benefits and Genetically Modified Organisms* (n 96) p. 14, and Norwegian Biotechnology Advisory Board 2018, *Proposal for Relaxation of Norwegian Regulations for Deliberate Release of Genetically Modified Organisms (GMO) with Applicability also for EU Legislation*, available at <http://www.bioteknologiradet.no/filarkiv/2019/03/2019- 04-16-Genteknologiloven-komplett-ENGELSK.pdf> accessed 16 December 2022.

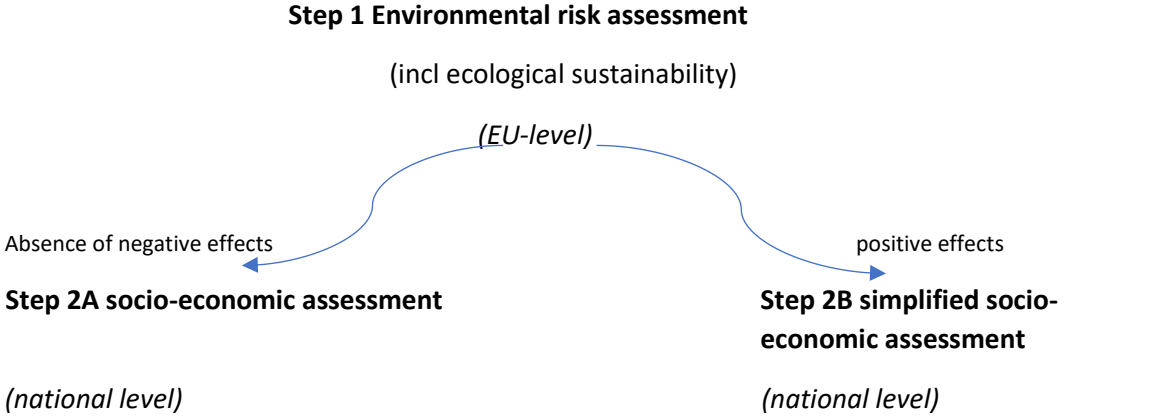
[103] See step 3, 4, and 6 of the eight steps of the cost-benefit analysis, figure 3.

[104] N. Foote, 'Commission stands by gene editing survey slammed by NGOs' (n 32).

This first stage is, then, followed by a set of control questions to determine the right level of socio-economic assessment. To accommodate the non-safety considerations adequately, we recommend performing this second stage on a national level. In this way, Member States can formulate country-specific control questions and identify their own relevant considerations for analysis. This approach gives room to cultural values and the country-specific social and economic situation and may overcome the political sensitivity as well as subsidiarity and proportionality concerns.

However, one way or the other, this scenario may overcomplicate procedures compared to the current ERA. For those favoring simplifications or even exemption of NGTs, this scenario may evoke resistance. The European Commission may have difficulties to get these stakeholders on board. We, therefore, strongly recommend being aware of the politically sensitivity of this scenario which may influence its effectiveness. Nonetheless, this scenario may still benefit multiple stakeholders involved, as it may break open the road for NGTs if these benefit sustainable food systems.

***Figure 4 Proposal for a renewed authorization procedure of GMOs***




*3.3 Legal Possibilities*

Several regulatory scenarios could be envisaged regarding the EC's way forward on NGTs. They are further sub-dived into 'shorter term' and 'longer term' scenarios with a view to integrate our reflection on the 'future-proof' dimension of the regulatory options available

*Shorter term scenario's*

1) **A first scenario (Baseline 00)** is a 'wait and see' scenario; it entails that the Commission is waiting with its NGT regulatory proposals/instruments until the CJEU will deliver its judgment in Case C-688/21 (probably by June 2023); though this judgment will mostly address random mutagenesis in vitro (not NGTs per se), it is expected nevertheless that it might bring additional clarifications regarding the 'long safety record' requirement. If this will be the case, it would be wise for the Commission to first reflect on and integrate CJEU's clarifications/criteria in its envisaged regulatory instruments/proposals before moving forward.
2) **A second baseline scenario (Baseline 01)** would envisage minimum interventions on the current regulatory framework on GMOs. More concretely, this would entail only intervention

by way of persuasive (non-legally binding) soft law instruments,[105] such as Commission recommendations and/or guidelines. Such soft law instruments could arguably be used for specifying the relevant risk assessment standards (potentially including ecological sustainability issues) as guidance documents for risk assessment in case of NGTs;[106] More specifically, they could be used to explain/clarify the requirements of 'sufficient experience obtained of releases of certain GMOs in certain ecosystems' in Article 7(1) as well as the criteria listed in Annex V of Directive 2001/18 under the simplified authorization procedure. Arguably, one could consider relying on such instruments in a more far-reaching manner, for instance for the purpose of clarifying the requirements and steps for a long safety record in case of NGTs conventionally used. Such a scenario would raise arguably rather lower concerns from the perspective of subsidiarity and proportionality.

3) **Another scenario** could entail the adoption by the Commission of a binding delegated act according to Article 27 of Directive 2001/18 by which Annex V could be amended in order to be adapted to technical progress with respect to NGTs; such an act could further adjust/detail for instance criteria 2 and 5 of the Annex with respect to NGTs (it could perhaps be complemented by a Commission soft law instrument on Article 7 (1), as mentioned under scenario 2).

4) **A more advanced regulatory scenario** could consist of amending the current legal framework on GMOs to account for the specific situation of NGTs. This would entail tabling a proposal for a directive amending Directive 2001/18 providing explicitly that NGTs with a long safety record are exempted from the Directive (this could be done by way of amendment of Article 3(1) or Annex I B of the Directive), and then providing (minimum) criteria and procedural standards for establishing a 'long safety' record (for instance in an annex of the amended directive); this could be further complemented by Commission non-binding soft law instruments further guiding the interpretation and application of the requirements in the amended directive.

5) **A derived version** of the previous scenario would entail adopting a regulation instead of a directive. A regulation would be most suitable to establish a more comprehensive and uniform regulatory framework on NGTs' long safety record, but it is likely to raise most opposition from the Member States and civil society in view of the controversies and sensitivities surrounding this subject matter; such an instrument would also raise highest concerns regarding compliance with subsidiarity and proportionality; some of these concerns could arguably be alleviated to some extent if the regulation would leave some flexibility/discretion for the Member States in combination with reliance on Commission soft law instruments supporting the interpretation and application of the main legal act).

[105] See on the persuasive force of European Commission's soft law instruments, C. Andone & F. Coman-Kund, 'Persuasive rather than 'binding' EU soft law? An argumentative perspective on the European Commission's soft law instruments in times of crisis', (2022) 10 (1) *The Theory and Practice of Legislation*, 22-47.
[106] See for instance *Biased from the outset* 2021 (n 21) p. 11.

*Longer-term future-proof scenario's*

6) The **most far-reaching scenario** scenario would entail amending the current legal framework on GMOs with a view to regulate the renewed two-step authorization procedure of GMOs put forward in this paper. Here several, sub-scenarios could be envisaged:

   a) Amending Directive 2001/18 via a directive
      i. The amending directive could regulate more extensively the two-step authorization procedure described previously (figure 4); this would have the advantage of creating EU wide uniform binding rules on NGTs authorization, but it would also meet challenges such as establishing the common ground for socio-economic assessment criteria across the EU against the background of the lack of a common understanding on this issue among the Member States, and linked to that it might also raise more serious issues as regards compliance with the subsidiarity and proportionality principles.
      ii. The amending directive could only provide for minimum harmonization as regards the renewed authorization procedure (in particular the second stage taking place at national level) leaving the Member States with sufficient discretion with regard to NGTs authorization (thus accounting for national sensitivities and disagreement on this issue); this could be further combined with derogations and safeguard clauses that Member States could invoke (for safety and non-safety related reasons) to preclude authorization and entry of NGTs in their territories; finally, certain aspects pertaining to the interpretation and application of the long safety record, criteria/conditions for socio-economic assessment on national level, who should perform the analysis, could be left to Commission delegated/implementing acts as well as complementary and formally less intrusive soft law instruments (recommendations, guidelines, communications).

   b) Amending Directive 2001/18 via a regulation
      This would be the most suitable legal instrument to establish a comprehensive and uniform regulatory framework on NGTs' renewed authorization procedure, but it is likely to raise most opposition from the Member States and civil society in view of the controversies and sensitivities surrounding this subject matter; such an instrument would also raise highest concerns regarding compliance with subsidiarity and proportionality. Some of these concerns could arguably be alleviated to some extent if the regulation would leave some flexibility/discretion for the Member States in combination with reliance on Commission soft law instruments supporting the interpretation and application of the main legal act.

*3.4 Lessons to be learned*

In the previous we have sketched several scenarios for either the shorter term or the longer term. The narrative of sustainability as has been introduced by the EC, has opened the road towards integration of socio-economic considerations in the authorization procedure. Our sixth scenario follows this road. However, we are aware of the lessons of the past that integration of socio-economic considerations may complicate things. We have elaborated on the Norwegian approach which has never been put into practice. Though, we see that the Norwegian approach does offer a source for inspiration when socio-economic considerations are discussed.[107] We, therefore, consider it worthwhile to further explore this road if the EC wants to hold on to the sustainability as a guiding principle in GM regulation.

Furthermore, a two-step authorization procedure may contribute to adapt to the complexity and the political sensitivity of GM-regulation. It, however, requires further research on the interpretation of sustainability in GM regulatory practice. A clear conceptualization is required if sustainability as a narrative can offer a way out of the existing impasse.

Poort e.a. have drawn critical conclusions on the approach of the EC in involving stakeholders. They have remarked that the questionnaire of the EC-study on NGTs which was published in April 2021 was one-sided, risking to that underlying viewpoints and other sorts of controversies remains hidden.[108] They argue against stakeholders involvement as window-dressing being a goal in itself instead of involving stakeholders to reach a certain goal.[109] A similar criticism has been made by several NGOs in a recent letter (4 October) to the Commissioner Stella Kyriakidis on the public consultation that closed in July 2022 and targeted survey that closed in October 2022. The NGOs stated that the survey was fundamentally flawed as the questionnaire was strongly biased. They raised concerns about the lack of transparency and call the targeted survey and the public consultation 'alarmingly one-sided'.[110]

Poort e.a. argue that for adequate decision-making it is essential to make underlying viewpoints explicit. They argue that stakeholder's involvement should be used to structure the policy problem that needs to be addressed, instead of solving it.[111] A broader scope of involvement is, therefore, required.

Fur the current revision, these are important lessons to consider. If the EC wants to break through the impasse and have all stakeholders on board, the EC will benefit from broadening the range of input and reflect upon this input when defining the problem before reaching its solution.

The precautionary principle as a compass, as envisioned by the RECIPES-team, may provide an interesting starting-point to involve stakeholders in structuring and defining the problem. That however would require further research as it requires a new understanding of PP on a European level. Follow-up research could elaborate on this new understanding in GM regulatory practice.

A similar line of thought can be followed for the need to define what it takes to build a long safety record. If we follow the precautionary principle as being a compass, stakeholders should also be involved in elaborating on the question what, as a society, we consider as 'safe'? Besides the need for

[107] See Macnaghten e.a., 'Breaking the impasse' (n 2), and COGEM, *Sociaal-economische aspecten van ggo's. Bouwstenen voor een EU duurzaamheidsbeoordeling van genetisch gemodificeerde gewassen* (n 97), COGEM, *Bouwstenen voor een beoordelingskader voor teelt van GG-gewassen* (n 33).
[108] Poort e.a., 'Restore politics in societal debates on new genomic techniques' (n 29) p. 2.
[109] Ibid, p. 2-3.
[110] N. Foote, 'Commission stands by gene editing survey slammed by NGOs' (n 40).
[111] Poort e.a., 'Restore politics in societal debates on new genomic techniques' (n 29) p. 2-3, 6.

scientific parameters,[112] it is relevant to open up debate on the risks society is willing to take and what is 'safe' (enough)? Also in this respect, PP can offer a starting point.

[112] See Opinion of Advocate General Szpunarin Case C-688/21 *Confédération paysanne and others* (n 39).

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# Appendix 1: Authorization scheme for deliberate release of GMOs

## Directive 2001/18/EC, part B

### *A) Standard Authorisation procedure*

*Article 6*

Standard authorisation procedure

1. Without prejudice to Article 5, any person must, before undertaking a deliberate release of a GMO or of a combination of GMOs, submit a notification to the competent authority of the Member State within whose territory the release is to take place.

2. The notification referred to in paragraph 1 shall include:

(a) a technical dossier supplying the information specified in Annex III necessary for carrying out the environmental risk assessment of the deliberate release of a GMO or combination of GMOs, in particular:

(i) general information including information on personnel and training,

(ii) information relating to the GMO(s),

(iii) information relating to the conditions of release and the potential receiving environment,

(iv) information on the interactions between the GMO(s) and the environment,

(v) a plan for monitoring in accordance with the relevant parts of Annex III in order to identify effects of the GMO(s) on human health or the environment,

(vi) information on control, remediation methods, waste treatment and emergency response plans,

(vii) a summary of the dossier;

(b) the environmental risk assessment and the conclusions required in Annex II, section D, together with any bibliographic reference and indications of the methods used.

▼M7

2a. The notification referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist under Union law.
▼B

3. The notifier may refer to data or results from notifications previously submitted by other notifiers, provided that the information, data and results are non confidential or these notifiers have given their agreement in writing, or may submit additional information he considers relevant.
4. The competent authority may accept that releases of the same GMO or of a combination of GMOs on the same site or on different sites for the same purpose and within a defined period may be notified in a single notification.

5. The competent authority shall acknowledge the date of receipt of the notification and, having considered, where appropriate, any observations by other Member States made in accordance with Article 11, shall respond in writing to the notifier within 90 days of receipt of the notification by either:

(a) indicating that it is satisfied that the notification is in compliance with this Directive and that the release may proceed; or

(b) indicating that the release does not fulfil the conditions of this Directive and that notification is therefore rejected.

6. For the purpose of calculating the 90 day period referred to in paragraph 5, no account shall be taken of any periods of time during which the competent authority:

(a) is awaiting further information which it may have requested from the notifier, or

(b) is carrying out a public inquiry or consultation in accordance with Article 9; this public inquiry or consultation shall not prolong the 90 day period referred to in paragraph 5 by more than 30 days.

7. If the competent authority requests new information it must simultaneously give its reasons for so doing.

8. The notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in this consent.

9. Member States shall ensure that no material derived from GMOs which are deliberately released in accordance with part B is placed on the market, unless in accordance with part C.

*ANNEX II*

**PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT**

▼M3

This Annex describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform the environmental risk assessment (e.r.a.) referred to in Articles 4 and 13. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 30(2) in order to facilitate the implementation and explanation of this Annex.

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With a view to contributing to a common understanding of the terms 'direct, indirect, immediate and delayed' when implementing this Annex, without prejudice to further guidance in this respect and in particular as regards the extent to which indirect effects can and should be taken into account, these terms are described as follows:

— 'direct effects' refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events;

— 'indirect effects' refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management.

Observations of indirect effects are likely to be delayed;

— 'immediate effects' refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect;

— 'delayed effects' refers to effects on human health or the environment which may not be observed during the period of the release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

A general principle for environmental risk assessment is also that an analysis of the 'cumulative long-term effects' relevant to the release and the placing on the market is to be carried out. 'Cumulative long-term effects' refers to the accumulated effects of consents on human health and the environment, including *inter alia* flora and fauna, soil fertility, soil degradation of organic material, the feed/ food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

**A. Objective**

The objective of an e.r.a. is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have. The e.r.a. should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used.

**B. General Principles**

In accordance with the precautionary principle, the following general principles should be followed when performing the e.r.a.:

— identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;

— the e.r.a. should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;

— the e.r.a. should be carried out on a case by case basis, meaning that the required information may vary depending on the type of the GMOs concerned, their intended use and the potential receiving environment, taking into account, i.a., GMOs already in the environment;

— if new information on the GMO and its effects on human health or the environment becomes available, the e.r.a. may need to be readdressed in order to:

— determine whether the risk has changed;

— determine whether there is a need for amending the risk management accordingly.

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## C. Methodology

Guidance issued by the European Food Safety Authority is available for the implementation of this section for Part C notifications.

### *C.1.* ***General and specific considerations for the e.r.a.***

#### 1. *Intended and unintended changes*

As part of the identification and evaluation of the potential adverse effects referred to in Section A, the e.r.a shall identify the intended and unintended changes resulting from the genetic modification and shall evaluate their potential to cause adverse effects on human health and on the environment.

Intended changes resulting from the genetic modification are changes that are designed to occur and which fulfil the original objectives of the genetic modification.

Unintended changes resulting from the genetic modification are consistent changes which go beyond the intended change(s) resulting from the genetic modification.

Intended and unintended changes can have either direct or indirect, and either immediate or delayed effects on human health and on the environment.

#### 2. *Long-term adverse effects and cumulative long-term adverse effects in the e.r.a. of Part C notifications*

Long-term effects of a GMO are effects resulting either from a delayed response by organisms or their progeny to long-term or chronic exposure to a GMO or from an extensive use of a GMO in time and space.

The identification and evaluation of the potential long-term adverse effects of a GMO on human health and on the environment shall take into account the following:

(a) the long-term interactions of the GMO and the receiving environment;

(b) the characteristics of the GMO which become important on a long-term basis;

(c) data obtained from repeated deliberate releases or placings on the market of the GMO over a long period.

The identification and evaluation of the potential cumulative long-term adverse effects referred to in the introductory part of Annex II shall also take into account the GMOs deliberately released or placed on the market in the past.

**3.** ***Quality of the data***

In order to carry out an e.r.a. for a notification under Part C of this Directive, the notifier shall collate already available data from scientific literature or from other sources, including monitoring reports, and shall generate the necessary data by performing, where possible, appropriate studies. Where applicable, the notifier shall justify in the e.r.a. why generating data by studies is not possible.

The e.r.a. for notifications under Part B of the Directive shall be based at least on already available data from scientific literature or from other sources and may be supplemented by additional data generated by the notifier.

Where data generated outside Europe is provided in the e.r.a., its relevance to receiving environment(s) in the Union shall be justified.

Data provided in the e.r.a for notifications under part C of this Directive shall comply with the following requirements:

(a) where toxicological studies carried out to assess risk to human or animal health are provided in the e.ra., the notifier shall provide evidence to demonstrate that they were conducted in facilities which comply with:

(i) the requirements of Directive 2004/10/EC; or

(ii) the 'OECD Principles on Good Laboratory Practice' (GLP), if carried out outside the Union;

(b) where studies other than toxicological studies are provided in the e.r.a., they shall:

(i) comply with the principles of Good Laboratory Practice (GLP) laid down in Directive 2004/10/EC, where relevant; or

(ii) be conducted by organisations accredited under the relevant ISO standard; or

(iii) in the absence of a relevant ISO standard, be conducted in accordance with internationally recognised standards;

(c) information on the results obtained from the studies referred to in points (a) and (b) and on the study protocols used shall be reliable and comprehensive and shall include the raw data in an electronic format suitable for carrying out statistical or other analysis;

(d) the notifier shall specify, where possible, the size of effect that each study performed intends to detect and justify it;

(e) the selection of sites for field studies shall be based on relevant receiving environments in view of the potential exposure and impact that would be observed where the GMO may be released. The selection shall be justified in the e.r.a.;

(f) the non-genetically modified comparator shall be appropriate for the relevant receiving environment(s) and shall have a genetic background comparable to the GMO. The choice of the comparator shall be justified in the e.r.a.

**4. *Stacked transformation events in Part C notifications***

The following shall apply to the e.r.a. of a GMO containing stacked transformation events in Part C notifications:

(a) the notifier shall provide an e.r.a. for each single transformation event in the GMO or refer to already submitted notifications for those single transformation events;

(b) the notifier shall provide an assessment of the following aspects:

(i) the stability of the transformation events;

(ii) the expression of the transformation events;

(iii) the potential additive, synergistic or antagonistic effects resulting from the combination of the transformation events;

(c) where the progeny of the GMO can contain various subcombinations of the stacked transformation events, the notifier shall provide a scientific rationale justifying that there is no need to provide experimental data for the concerned subcombinations, independently of their origin, or, in the absence of such scientific rationale, shall provide the relevant experimental data.

### *C.2.* ***Characteristics of the GMO and of the releases***

The e.r.a. shall take into account the relevant technical and scientific details regarding characteristics of:

— the recipient or parental organism(s),

— the genetic modification(s), be it insertion or deletion of genetic material, and relevant information on the vector and the donor,

— the GMO,

— the intended release or use including its scale,

— the potential receiving environment(s) into which the GMO will be released and into which the transgene may spread, and

— the interaction(s) between these characteristics.

Relevant information from previous releases of the same or similar GMOs and organisms with similar traits and their biotic and abiotic interaction with similar receiving environments, including information resulting from the monitoring of such organisms, shall be considered in the e.r.a., subject to Article 6(3) or Article 13(4).

### *C.3.* ***Steps in the e.r.a.***

The e.r.a. referred to in Articles 4, 6, 7 and 13 shall be conducted for each relevant area of risk referred to in Section D1 or in Section D2 in accordance with the following six steps:

**1.** ***Problem formulation including hazard identification***

The problem formulation shall:
(a) identify any changes in the characteristics of the organism, linked to the genetic modification, by comparing the characteristics of the GMO with those of the chosen non-genetically modified comparator under corresponding conditions of release or use;

(b) identify potential adverse effects on human health or the environment which are linked to the changes that have been identified under point (a) above;

Potential adverse effects shall not be discounted on the basis that they are unlikely to occur.

Potential adverse effects will vary from case to case, and may include:

— effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations leading to a potential decline in biodiversity,

— altered susceptibility to pathogens facilitating the dissemination of infectious diseases or creating new reservoirs or vectors,

— compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine,

— effects on biogeochemistry (biogeochemical cycles), including carbon and nitrogen recycling through changes in soil decomposition of organic material,

— disease affecting humans, including allergenic or toxic reactions,

— disease affecting animals and plants, including toxic, and, in the case of animals, allergenic reactions, where appropriate.

Where potential long-term adverse effects of a GMO are identified, they shall be assessed in the form of desk based studies using, where possible, one or more of the following:

(i) evidence from previous experiences;

(ii) available data sets or literature;

(iii) mathematical modelling;

(c) identify relevant assessment endpoints.

Those potential adverse effects that could impact the identified assessment endpoints shall be considered in the next steps of the risk assessment;

(d) identify and describe the exposure pathways or other mechanisms through which adverse effects may occur.

Adverse effects may occur directly or indirectly through exposure pathways or other mechanisms which may include:

— the spread of the GMO(s) in the environment,

— the transfer of the inserted genetic material to the same organism or other organisms, whether genetically modified or not,

— phenotypic and genetic instability,

— interactions with other organisms,

— changes in management, including, where applicable, in agricultural practices;

(e) formulate testable hypotheses, and define relevant measurement endpoints, to allow, where possible, a quantitative evaluation of the potential adverse effect(s);

(f) consider possible uncertainties, including knowledge gaps and methodological limitations.

**2.** ***Hazard characterisation***

The magnitude of each potential adverse effect shall be evaluated. This evaluation shall assume that such an adverse effect will occur. The e.r.a shall consider that the magnitude is likely to be influenced by the receiving environment(s) into which the GMO is intended to be released and by the scale and conditions of the release.

Where possible, the evaluation shall be expressed in quantitative terms.

Where the evaluation is expressed in qualitative terms, a categorical description ('high', 'moderate', 'low' or 'negligible') shall be used and an explanation of the scale of effect represented by each category shall be provided.

**3.** ***Exposure characterisation***

The likelihood or probability of each identified potential adverse effect occurring shall be evaluated to provide, where possible, a quantitative assessment of the exposure as a relative measure of probability, or otherwise a qualitative assessment of the exposure. The characteristics of the receiving environment(s) and the scope of the notification shall be taken into consideration.

Where the evaluation is expressed in qualitative terms, a categorical description ('high', 'moderate', 'low' or 'negligible') of the exposure shall be used and an explanation of the scale of effect represented by each category shall be provided.

**4. *Risk characterisation***

The risk shall be characterised by combining, for each potential adverse effect, the magnitude with the likelihood of that adverse effect occurring to provide a quantitative or semi quantitative estimation of the risk.

Where a quantitative or semi quantitative estimation is not possible, a qualitative estimation of the risk shall be provided. In that case, a categorical description ('high', 'moderate', 'low' or 'negligible') of the risk shall be used and an explanation of the scale of effect represented by each category shall be provided.

Where relevant, the uncertainty for each identified risk shall be described and, where possible, expressed in quantitative terms.

**5. *Risk management strategies***

Where risks are identified that require, on the basis of their characterisation, measures to manage them, a risk management strategy shall be proposed.

The risk management strategies shall be described in terms of reducing the hazard or the exposure, or both, and shall be proportionate to the intended reduction of the risk, the scale and conditions of the release and the levels of uncertainty identified in the e.r.a.

The consequent reduction in overall risk shall be quantified where possible.

**6. *Overall risk evaluation and conclusions***

A qualitative and, where possible, quantitative evaluation of the overall risk of the GMO shall be made taking into account the results of the risk characterisation, the proposed risk management strategies and the associated levels of uncertainty.

The overall risk evaluation shall include, where applicable, the risk management strategies proposed for each identified risk.

The overall risk evaluation and conclusions shall also propose specific requirements for the monitoring plan of the GMO and, where appropriate, the monitoring of the efficacy of the proposed risk management measures.

For notifications under Part C of the Directive, the overall risk evaluation shall also include an explanation of the assumptions made during the e.r.a. and of the nature and magnitude of uncertainties associated with the risks, and a justification of the risk management measures proposed.

**D. Conclusions on the specific areas of risk of the e.r.a.**

Conclusions on the potential environmental impact in relevant receiving environments from the release or the placing on the market of GMOs shall be drawn for each relevant area of risk listed in Section D1 for GMOs other than higher plants or Section D2 for genetically modified higher plants, on the basis of an e.r.a. carried out in accordance with the principles outlined in Section B and following the methodology described in Section C, and on the basis of the information required pursuant to Annex III.

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### *D.1.* ***In the case of GMOs other than higher plants***

1. Likelihood of the GMO to become persistent and invasive in natural habitats under the conditions of the proposed release(s).

2. Any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised under the conditions of the proposed release(s).

3. Potential for gene transfer to other species under conditions of the proposed release of the GMO and any selective advantage or disadvantage conferred to those species.

4. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO and target organisms (if applicable).

5. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMO and persons working with, coming into contact with or in the vicinity of the GMO release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any product derived from it, if it is intended to be used as animal feed.

8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).

9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific techniques used for the management of the GMO where these are different from those used for non-GMOs.

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### *D.2.* ***In the case of genetically modified higher plants (GMHP)***

'Higher plants' shall mean plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae).

1. Persistence and invasiveness of the GMHP, including plant to plant gene transfer

2. Plant to micro-organisms gene transfer

3. Interactions of the GMHP with target organisms

4. Interactions of the GMHP with non-target organisms

5. Impacts of the specific cultivation, management and harvesting techniques

6. Effects on biogeochemical processes

7. Effects on human and animal health.

*ANNEX III*

**INFORMATION REQUIRED IN THE NOTIFICATION**

Notifications referred to in Parts B and C of this Directive shall, as a rule, include the information set out in Annex III A, for GMOs other than higher plants, or in Annex III B, for genetically modified higher plants.

The provision of a given subset of information listed in Annex III A or in Annex III B shall not be required where it is not relevant or necessary for the purposes of risk assessment in the context of a specific notification, in view especially of the characteristics of the GMO, of the scale and conditions of the release or of its intended conditions of use.

The appropriate level of detail for each subset of information may also vary according to the nature and the scale of the proposed release.

For each required subset of information, the following shall be provided:

(i) the summaries and results of the studies referred to in the notification, including an explanation about their relevance to e.r.a., where applicable;

(ii) for notifications referred to in Part C of this Directive, Annexes with detailed information on those studies, including a description of the methods and materials used or the reference to standardised or internationally recognised methods and the name of the body or bodies responsible for carrying out the studies.

Future developments in genetic modification may necessitate adapting this Annex to technical progress or developing guidance notes on this Annex. Further differentiation of information requirements for different types of GMOs, for example perennial plants and trees, single celled organisms, fish or insects, or for particular use of GMOs like the development of vaccines, may be possible once sufficient experience with notifications for the release of particular GMOs has been gained in the Union.

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*ANNEX III A*

**INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS**

**I. GENERAL INFORMATION**

A. Name and address of the notifier (company or institute)

B. Name, qualifications and experience of the responsible scientist(s)

C. Title of the project

## II. INFORMATION RELATING TO THE GMO

### *A. Characteristics of (a) the donor, (b) the recipient or (c) (where appropriate) parental organism(s):*

1. scientific name,

2. taxonomy,

3. other names (usual name, strain name, etc.),

4. phenotypic and genetic markers,

5. degree of relatedness between donor and recipient or between parental organisms,

6. description of identification and detection techniques,

7. sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques,

8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts,

9. organisms with which transfer of genetic material is known to occur under natural conditions,

10. verification of the genetic stability of the organisms and factors affecting it,

11. pathological, ecological and physiological traits:

(a) classification of hazard according to existing Community rules concerning the protection of human health and/or the environment;

(b) generation time in natural ecosystems, sexual and asexual reproductive cycle;

(c) information on survival, including seasonability and the ability to form survival structures;

(d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonise other organisms;

(e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;

(f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

12. Nature of indigenous vectors:

(a) sequence;

(b) frequency of mobilisation;

(c) specificity;

(d) presence of genes which confer resistance.

13. History of previous genetic modifications.

### *B. **Characteristics of the vector***

1. nature and source of the vector,

2. sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO,

3. frequency of mobilisation of inserted vector and/or genetic transfer capabilities and methods of determination,

4. information on the degree to which the vector is limited to the DNA required to perform the intended function.

### *C. **Characteristics of the modified organism***

1. Information relating to the genetic modification:

(a) methods used for the modification;

(b) methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;

(c) description of the insert and/or vector construction;

(d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;

(e) methods and criteria used for selection;

(f) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.

2. Information on the final GMO:

(a) description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;

(b) structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;

(c) stability of the organism in terms of genetic traits;

(d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;

(e) activity of the expressed protein(s);

(f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;

(g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;

(h) history of previous releases or uses of the GMO;

(i) considerations for human health and animal health, as well as plant health:

(i) toxic or allergenic effects of the GMOs and/or their metabolic products;
(ii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
(iii) capacity for colonization;
(iv) if the organism is pathogenic to humans who are immunocompetent:

— diseases caused and mechanism of pathogenicity including invasiveness and virulence,

— communicability,

— infective dose,

— host range, possibility of alteration,

— possibility of survival outside of human host,

— presence of vectors or means of dissemination,

— biological stability,

— antibiotic resistance patterns,

— allergenicity,

— availability of appropriate therapies;

(v) other product hazards.

## III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

### *A.* ***Information on the release***

1. description of the proposed deliberate release, including the purpose(s) and foreseen products,

2. foreseen dates of the release and time planning of the experiment including frequency and duration of releases,

3. preparation of the site previous to the release,

4. size of the site,

5. method(s) to be used for the release,

6. quantities of GMOs to be released,

7. disturbance on the site (type and method of cultivation, mining, irrigation, or other activities),

8. worker protection measures taken during the release,

9. post-release treatment of the site,

10. techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment,

11. information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

### *B. Information on the environment (both on the site and in the wider environment):*

1. geographical location and grid reference of the site(s) (in case of notifications under part C the site(s) of release will be the foreseen areas of use of the product),

2. physical or biological proximity to humans and other significant biota,

3. proximity to significant biotopes, protected areas, or drinking water supplies,

4. climatic characteristics of the region(s) likely to be affected,

5. geographical, geological and pedological characteristics,

6. flora and fauna, including crops, livestock and migratory species,

7. description of target and non-target ecosystems likely to be affected,

8. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release,

9. any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

## IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE ENVIRONMENT

### *A. Characteristics affecting survival, multiplication and dissemination*

1. biological features which affect survival, multiplication and dispersal,

2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.),

3. sensitivity to specific agents.

### *B. Interactions with the environment*

1. predicted habitat of the GMOs,

2. studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses,

3. genetic transfer capability

(a) postrelease transfer of genetic material from GMOs into organisms in affected ecosystems;

(b) postrelease transfer of genetic material from indigenous organisms to the GMOs,

4. likelihood of postrelease selection leading to the expression of unexpected and/or undesirable traits in the modified organism,

5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify genetic stability,

6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.,

7. description of ecosystems to which the GMOs could be disseminated,

8. potential for excessive population increase in the environment,

9. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s),

10. identification and description of the target organisms if applicable,
11. anticipated mechanism and result of interaction between the released GMOs and the target organism(s) if applicable,

12. identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanisms of any identified adverse interaction,

13. likelihood of postrelease shifts in biological interactions or in host range,

14. known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens,

15. known or predicted involvement in biogeochemical processes,

16. other potential interactions with the environment.

## V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

### *A. **Monitoring techniques***

1. methods for tracing the GMOs, and for monitoring their effects,

2. specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques,

3. techniques for detecting transfer of the donated genetic material to other organisms,

4. duration and frequency of the monitoring.

### *B.* ***Control of the release***

1. methods and procedures to avoid and/or minimise the spread of the GMOs beyond the site of release or the designated area for use,

2. methods and procedures to protect the site from intrusion by unauthorised individuals,

3. methods and procedures to prevent other organisms from entering the site.

### *C.* ***Waste treatment***

1. type of waste generated,

2. expected amount of waste,

3. description of treatment envisaged.

### *D.* ***Emergency response plans***

1. methods and procedures for controlling the GMOs in case of unexpected spread,

2. methods for decontamination of the areas affected, for example eradication of the GMOs,

3. methods for disposal or sanitation of plants, animals, soils, etc., that were exposed during or after the spread,

4. methods for the isolation of the area affected by the spread,

5. plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

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*ANNEX III B*

**INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (GMHPs) (GYMNOSPERMAE AND ANGIOSPERMAE)**

## *I.* ***INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7***

### A. General information

1. Name and address of the notifier (company or institute)

2. Name, qualifications and experience of the responsible scientist(s)

3. Title of the project

4. Information relating to the release

(a) Purpose of the release

(b) Foreseen date(s) and duration of the release

(c) Method by which the GMHP will be released

(d) Method for preparing and managing the release site, prior to, during and post release, including cultivation practices and harvesting methods

(e) Approximate number of plants (or plants per $m^2$).

5. Information relating to the site of release

(a) Location and size of the release site(s).

(b) Description of the release site ecosystem, including climate, flora and fauna.

(c) Presence of sexually compatible wild relatives or cultivated plant species.

(d) Proximity to officially recognised biotopes or protected areas which may be affected.

**B. Scientific information**

1. Information relating to the recipient plant or, where appropriate, to the parental plants

(a) Complete name:

(i) family name
(ii) genus
(iii) species
(iv) subspecies
(v) cultivar or breeding line
(vi) common name.

(b) Geographical distribution and cultivation of the plant within the Union.

(c) Information concerning reproduction:

(i) mode(s) of reproduction
(ii) specific factors affecting reproduction, if any
(iii) generation time.

(d) Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species.

(e) Survivability:

(i) ability to form structures for survival or dormancy
(ii) specific factors affecting survivability, if any.

(f) Dissemination:

(i) ways and extent of dissemination

(ii) specific factors affecting dissemination, if any.

(g) Where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

(h) Potential interactions of the plant, that are relevant to the GMHP, with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

2. Molecular characterization

(a) Information relating to the genetic modification

(i) Description of the methods used for the genetic modification.
(ii) (ii) Nature and source of the vector used.
(iii) (iii) Source of the nucleic acid(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.

(b) Information relating to the GMHP

(i) General description of the trait(s) and characteristics which have been introduced or modified.
(ii) (ii) Information on the sequences actually inserted/deleted:

— size and copy number of all insert(s) and methods used for its/their characterisation,

— in case of deletion, size and function of the deleted region(s),

— subcellular location(s) of the insert(s) in the plant cells (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination.

(iii) Parts of the plant where the insert is expressed.

(iv) Genetic stability of the insert and phenotypic stability of the GMHP.

(c) Conclusions of the molecular characterization

3. Information on specific areas of risk

(a) Any change to the persistence or invasiveness of the GMHP, and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects thereof.

(b) Any change to the ability of the GMHP to transfer genetic material to microorganisms and the adverse environmental effects thereof.

(c) Mechanism of interaction between the GMHP and target organisms (if applicable) and the adverse environmental effects thereof.

(d) Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification and the adverse environmental effects thereof.

(e) Potential changes in agricultural practices and management of the GMHP resulting from the genetic modification and the adverse environmental effects thereof.

(f) Potential interactions with the abiotic environment and the adverse environmental effects thereof.

(g) Information on any toxic, allergenic or other harmful effects on human and animal health arising from the genetic modification.

(h) Conclusions on the specific areas of risk.

4. Information on control, monitoring, post-release and waste treatment plans

(a) Any measures taken, including:

(i) spatial and temporal isolation from sexually compatible plant species, both wild and weedy relatives and crops;
(ii) any measures to minimise or prevent the dispersal of any reproductive part of the GMHP.

(b) Description of methods for post-release treatment of the site.

(c) Description of post-release treatment methods for the genetically modified plant material including wastes.

(d) Description of monitoring plans and techniques.

(e) Description of any emergency plans.

(f) Description of the methods and procedures to:

(i) avoid or minimise the spread of the GMHPs beyond the site of release;
(ii) protect the site from intrusion by unauthorised individuals;
(iii) prevent other organisms from entering the site or minimise such entries.

5. Description of detection and identification techniques for the GMHP.

6. Information about previous releases of the GMHP, if applicable.

## *II. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 13*

### A. General information

1. Name and address of the notifier (company or institute).

2. Name, qualifications and experience of the responsible scientist(s).

3. Designation and specification of the GMHP.

4. Scope of the notification.

(a) Cultivation

(b) Other uses (to be specified in the notification).

**B. Scientific information**

1. Information relating to the recipient plant or, where appropriate, to the parental plants

(a) Complete name:
- (i) family name
- (ii) genus
- (iii) species
- (iv) subspecies
- (v) cultivar/breeding line
- (vi) common name.

(b) Geographical distribution and cultivation of the plant within the Union.

(c) Information concerning reproduction:
- (i) mode(s) of reproduction
- (ii) specific factors affecting reproduction, if any
- (iii) generation time.

(d) Sexual compatibility with other cultivated or wild plant species, including the distribution in the Union of the compatible species.

(e) Survivability:
- (i) ability to form structures for survival or dormancy
- (ii) specific factors affecting survivability, if any.

(f) Dissemination:
- (i) ways and extent of dissemination;
- (ii) specific factors affecting dissemination, if any.

(g) Where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

(h) Potential interactions of the plant, that are relevant to the GMHP, with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

2. Molecular characterisation

(a) Information relating to the genetic modification
- (i) Description of the methods used for the genetic modification.

(ii) Nature and source of the vector used.

(iii) Source of the nucleic acid(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.

(b) Information relating to the genetically modified plant

(i) Description of the trait(s) and characteristics which have been introduced or modified.

(ii) Information on the sequences actually inserted or deleted:

— size and copy number of all detectable inserts, both partial and complete, and methods used for its characterisation,

— the organisation and sequence of the inserted genetic material at each insertion site in a standardised electronic format,

— in case of deletion, size and function of the deleted region(s),

— subcellular location(s) of the insert(s) (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination,

— in the case of modifications other than insertion or deletion, function of the modified genetic material before and after the modification, as well as direct changes in expression of genes as a result of the modification,

— sequence information in a standardised electronic format for both 5' and 3' flanking regions at each insertion site,

— bioinformatic analysis using up-to-date databases, to investigate possible interruptions of known genes,

— all Open Reading Frames, (hereafter referred to as 'ORFs') within the insert (either due to rearrangement or not) and those created as a result of the genetic modification at the junction sites with genomic DNA. ORF is defined as a nucleotide sequence that contains a string of codons that is uninterrupted by the presence of a stop codon in the same reading frame,

— bioinformatic analysis using up-to-date databases, to investigate possible similarities between the ORFs and known genes which may have adverse effects,

— primary structure (amino acid sequence) and, if necessary, other structures, of the newly expressed protein,

— bioinformatic analysis using up-to-date databases, to investigate possible sequence homologies and, if necessary, structural similarities between the newly expressed protein and known proteins or peptides which may have adverse effects.

(iii) Information on the expression of the insert:

— method(s) used for expression analysis together with their performance characteristics,

— information on the developmental expression of the insert during the life cycle of the plant,

— parts of the plant where the insert/modified sequence is expressed,

— potential unintended expression of new ORFs identified under the seventh indent of point (ii), which raise a safety concern,

— protein expression data, including the raw data, obtained from field studies and related to the conditions in which the crop is grown.

(iv) Genetic stability of the insert and phenotypic stability of the GMHP.

(c) Conclusions of molecular characterization

3. Comparative analysis of agronomic and phenotypic characteristics and of composition

(a) Choice of conventional counterpart and additional comparators.

(b) Choice of sites for field studies.

(c) Experimental design and statistical analysis of data from field trials for comparative analysis:

(i) Description of field studies design

(ii) Description of relevant aspect of the receiving environments

(iii) Statistical analysis.

(d) Selection of plant material for analysis, if relevant.

(e) Comparative analysis of agronomic and phenotypic characteristics.

(f) Comparative analysis of composition, if relevant.

(g) Conclusions of comparative analysis.

4. Specific information for each area of risk

For each of the seven areas of risk referred to in Section D.2 of Annex II the notifier shall first describe the pathway to harm explaining in a chain of cause and effect how the release of the GMHP could lead to harm, taking into account both hazard and exposure.

The notifier shall submit the following information, except where it is not relevant in view of the intended uses of the GMO:

(a) Persistence and invasiveness including plant to plant gene transfer

(i) Assessment of the potential for the GMHP to become more persistent or invasive and the adverse environmental effects thereof;

(ii) Assessment of the potential for the GMHP to transmit transgene(s) to sexually compatible relatives and the adverse environmental effects thereof;

(iii) Conclusions on the adverse environmental effect(s) of persistence and invasiveness of the GMHP including the adverse environmental effect(s) of plant-to-plant gene transfer.

(b) Plant to micro-organism gene transfer

(i) Assessment of the potential for transfer of newly inserted DNA from the GMHP to microorganisms and the adverse effects thereof;

(ii) Conclusions on the adverse effect(s) of the transfer of newly inserted DNA from the GMHP to microorganisms for human and animal health and the environment;

(c) Interactions of the GMHP with target organisms, if relevant

(i) Assessment of the potential for changes in the direct and indirect interactions between the GMHP and target organisms and the adverse environmental effect(s);

(ii) Assessment of the potential for evolution of resistance of the target organism to the expressed protein (based on the history of evolution of resistance to conventional pesticides or transgenic plants expressing similar traits) and any adverse environmental effect(s) thereof;

(iii) Conclusions on adverse environmental effect(s) of interactions of the GMHP with target organisms.

(d) Interactions of the GMHP with non-target organisms.

(i) Assessment of the potential for direct and indirect interactions of the GMHP with non-target organisms, including protected species, and the adverse effect(s) thereof.

The assessment shall also take into account the potential adverse effect(s) on relevant ecosystem services and on the species providing those services.

(ii) Conclusions on adverse environmental effect(s) of interactions of the GMHP with non-target organisms.

(e) Impacts of the specific cultivation, management and harvesting techniques

(i) For GMHPs for cultivation, assessment of the changes in the specific cultivation, management and harvesting techniques used for the GMHP and the adverse environmental effect(s) thereof;

(ii) Conclusions on adverse environmental effect(s) of the specific cultivation, management and harvesting techniques.

(f) Effects on biogeochemical processes

(i) Assessment of the changes in the biogeochemical processes within the area in which the GMHP is to be grown and in the wider environment, and the adverse effects thereof;

(ii)

Conclusions on adverse effects on biogeochemical processes.

(g) Effects on human and animal health

(i) Assessment of potential direct and indirect interactions between the GMHP and persons working with or coming into contact with the GMHPs, including through pollen or dust from a processed GMHP, and assessment of the adverse effects of those interactions on human health;

(ii) For GMHPs not destined for human consumption, but where the recipient or parental organism(s) may be considered for human consumption, assessment of the likelihood of and possible adverse effects on human health due to accidental intake;

(iii) Assessment of the potential adverse effects on animal health due to accidental consumption of the GMHP or of material from that plant by animals;

(iv) Conclusions on the effects on human and animal health.

(h) Overall risk evaluation and conclusions.

A summary of all the conclusions under each area of risk shall be provided.

The summary shall take into account the risk characterisation in accordance with steps 1 to 4 of the methodology described in Section C.3 of Annex II and the risk management strategies proposed in accordance with point 5 of Section C.3 of Annex II.

5. Description of detection and identification techniques for the GMHP.

6. Information about previous releases of the GMHP, if applicable.

### *B) Differentiated (simplified) authorization procedure*

Article 7

Differentiated procedures

1. If sufficient experience has been obtained of releases of certain GMOs in certain ecosystems and the GMOs concerned meet the criteria set out in Annex V, a competent authority may submit to the Commission a reasoned proposal for the application of differentiated procedures to such types of GMOs.

2. Following its own initiative or at the latest 30 days following the receipt of a competent authority's proposal, the Commission shall,
(a) forward the proposal to the competent authorities, which may, within 60 days, present observations and at the same time;

(b) make available the proposal to the public which may, within 60 days, make comments; and

(c) consult the relevant Scientific Committee(s) which may, within 60 days give an opinion.

3. A decision shall be taken on each proposal in accordance with the procedure laid down in Article 30(2). This decision shall establish the minimum amount of technical information from Annex III necessary for evaluating any foreseeable risks from the release, in particular:

(a) information relating to the GMO(s);

(b) information relating to the conditions of release and the potential receiving environment;

(c) information on the interactions between the GMO(s) and the environment;

(d) the environmental risk assessment.

4. This decision shall be taken within 90 days of the date of the Commission's proposal or of receipt of the competent authority's proposal. This 90 day period shall not take into account the period of time during which the Commission is awaiting the observations of competent authorities, the comments of the public or the opinion of Scientific Committees, as provided for in paragraph 2.

5. The decision taken under paragraphs 3 and 4 shall provide that the notifier may proceed with the release only when he has received the written consent of the competent authority. The notifier shall proceed with the release in conformity with any conditions required in this consent.
The decision taken under paragraphs 3 and 4 may provide that releases of a GMO or of a combination of GMOs on the same site or on different sites for the same purpose and within a defined period may be notified in a single notification.

6. Without prejudice to paragraphs 1 to 5, Commission Decision 94/730/EC of 4 November 1994 establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC ( 2 ) shall continue to apply.

7. Where a Member State decides to make use or not of a procedure established in a decision taken in accordance with paragraphs 3 and 4 for releases of GMOs within its territory, it shall inform the Commission thereof.

*ANNEX V*

**CRITERIA FOR THE APPLICATION OF DIFFERENTIATED PROCEDURES (ARTICLE 7)**

The criteria referred to in Article 7(1) are set out below.

1. The taxonomic status and the biology (for example mode of reproduction and pollination, ability to cross with related species, pathogenecity) of the non-modified (recipient) organism shall be well-known.

2. There shall be sufficient knowledge about the safety for human health and the environment of the parental, where appropriate, and recipient organisms in the environment of the release.

3. Information shall be available on any interaction of particular relevance for the risk assessment, involving the parental, where appropriate, and recipient organism and other organisms in the experimental release ecosystem.

4. Information shall be available to demonstrate that any inserted genetic material is well characterised. Information on the construction of any vector systems or sequences of genetic material used with the carrier DNA shall be available. Where a genetic modification involves the deletion of genetic material, the extent of the deletion shall be known. Sufficient information on the genetic modification shall also be available to enable identification of the GMO and its progeny during a release.

5. The GMO shall not present additional or increased risks to human health or the environment under the conditions of the experimental release that are not presented by releases of the corresponding parental, where appropriate, and recipient organisms. Any capacity to spread in the environment and invade other unrelated ecosystems and capacity to transfer genetic material to other organisms in the environment shall not result in adverse effects.