INSIGHT

European Commission's Plans for a Special Regulation of Plants Created by New Genomic Techniques

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ABSTRACT: This *Insight* explains in detail, yet easily understandable, the contents of the European Commission's draft regulation on plants obtained by certain new genomic techniques and their food and feed. It critically comments on the underlying scientific considerations and discusses potential legal issues – the precautionary principle being one of them, though arguably not the most important one. Finally, the *Insight* summarizes the ongoing discussions and developments regarding the draft regulation. The Authors also hint at potential amendments, which might resolve some of the remaining problems.

KEYWORDS: environmental law – genetic engineering – new genomic techniques – genome editing – risk assessment – precautionary principle.

I. Introduction

On 5 July 2023 the European Commission has published a draft regulation on plants obtained by certain new genomic techniques (NGT).[1] It seems possible that the regulation will eventually – at least in principle – be agreed upon between the Council of the European Union, the European Parliament and the Commission as legislators. Being a regulation, these new rules according to art. 288(2) TFEU would in principle be binding in its entirety

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[1] Commission proposal for a Regulation COM(2023) 411 final of the European Parliament and of the Council of 5 July 2023 on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625.

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and directly applicable in all Member States of the EU. Therefore, the draft raised a lot of political discussion. This *Insight* strives to summarize the main elements of the draft and to discuss legal and scientific questions that arise from this envisaged regulation.

II. Context

In 2018, the Court of Justice of the European Union (CJEU) decided on organisms obtained by targeted mutagenesis techniques and found that all these organisms constitute Genetically Modified Organisms (GMO) in the sense of the Directive 2001/18/EC.[2] The judges in Luxembourg also held that the exemption clause in Annex I B(1) of said Directive for organisms created by mutagenesis techniques does not encompass organisms created by targeted mutagenesis techniques, *i.e*. techniques, which have not conventionally been used in a number of applications and do not have a long safety record.[3] This judgement has been interpreted by most commentators in the way that basically all genome edited organisms are regulated as GMO.[4] This means that any commercial use of genome edited organisms as field crops will require an authorization procedure. The same holds true for any deliberate releases of GMO for any other purpose than for placing in the market, *e.g*. field trials for research purposes. Obtaining authorizations for placing on the market is not only very costly – the Commission estimates costs being something in between 6 and 20 million EUR for single event GMO and between 17,5 and 28 million EUR for GMO to be commercially cultivated,[5] but also highly unpredictable in its practical outcome, keeping in mind the possibility for EU member states to opt out of cultivation of GMO according to art. 26(a) Directive 2001/18/EC. Costs for field trials also vary, although on a much lower level. In Germany for example, the fees for the decision of the competent authority alone (not including expenses for statements by the federal state authority, necessary duties like subsequent monitoring etc.) varies between 6400 and 25800 Euros according to section 1(8) *Besondere Gebührenverordnung BMEL*[6] in conjunction with section 8 of its Annex.

[2] Case C-528/16 *Confédération paysanne and Others v Premier ministre* ECLI:EU:C:2018:583 para. 38.

[3] *Ibid*. para. 51.

[4] KP Purnhagen, E Kok, G Kleter, H Schebesta, RGF Visser and J Wesseler, 'EU Court Casts new Plant Breeding Techniques into Regulatory Limbo' (2018) Nature Biotechnology 799; differently: P van der Meer, G Angenon, H Bergmans, H-J Buhk, S Callebaut, M Chamon, D Eriksson, G Gheisen, W Harwood, P Hundleby, P Kearns, T McLoughlin and T Zimny, 'The Status Under EU Law of Organisms Developed Through Novel Genomic Techniques' (2023) European Journal of Risk Regulation 93.

[5] Commission Staff Working Document SWD(2023) 412 final of 5 July 2023, Impact assessment report accompanying the document Proposal for a regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625.

[6] Federal Ministry of Food and Agriculture, Special Fee Ordinance for individually attributable public services in its area of responsibility, 13 July 2021.

In reaction to said CJEU ruling the Council of the European Union asked the Commission with Decision (EU) 2019/1904 to submit a study in light of the Court of Justice's judgment in case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study. In the study, the Commission concluded that the European GMO legislation had clear implementation challenges and that there were strong indications that it is not fit for purpose for some NGTs and their products, and that it needed to be adapted to scientific and technological progress.[7]

III. The draft regulation in detail

The draft regulation according to its art. 1 – note: all cited articles and recitals in this paper are those of the draft regulation, unless specified otherwise – only lays down specific rules for plants obtained by NGTs (NGT plants) and for the placing on the market of food and feed or other products containing, consisting of or produced from such plants and for deliberate release into the environment for any other purpose than placing on the market (*e.g.* research field trials). As can clearly be seen from recitals 8 and 9, these plants are legally considered GMO and according to recital 11 the draft regulation constitutes *lex specialis* with regard to the Union GMO legislation, meaning that the latter will not apply to NGT plants, insofar as the draft regulation applies.

NGT plants according to art. 3(2) are genetically modified plants obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool. The breeder's gene pool itself is legally defined in art. 3(6), encompassing the total genetic information available in one species and other taxonomic species with which it can be cross-bred, including by using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses. Compared to other hypothetical approaches to such a definition (*e.g.* limiting the breeders' gene pool to plants that can be cross-bred without the use of technology), this is a rather extensive approach.

III.1. Category 1 NGT plants

The NGT plants are subdivided into two groups: so called category 1 NGT plants (cat 1 plants) fulfil the criteria of equivalence to conventional plants as set out in Annex I and shall therefore mainly be treated like conventional plants. The equivalence criteria in Annex I allow for a limited set of genetic alterations, namely up to 20 genetic modifications of different types such as substitution/insertion of no more than 20 nucleotides or deletions of any number of nucleotides. What is also allowed among the 20 genetic modification is a targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool – but only if no endogenous gene is interrupted. Progeny of cat 1 plants remain cat

[7] Commission Staff Working Document SWD(2021) 92 final of 29 April 2021, Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16.

1 plants on the condition that there are no further modifications that would make it subject to Directive 2001/18/EC or Regulation 1829/2003 (art. 3(7)(a)).

Art. 5(1) holds that the rules which apply to GMOs in Union legislation shall not apply to cat 1 plants, hence these plants do not need to go through an authorization procedure with a risk assessment.

Indeed, most of the commercially relevant developments using NGT so far can be attributed to category 1: 217 publications between January 1996 and June 2019 comprising 231 market oriented-oriented studies on genome edited plant products have been identified by using a systematic review of publicly available literature and governmental databases such as those by the United States Department of Agriculture (USDA) using parameters that focus on ge-nome editing, traits relevant for crop market and that are distinct in the edited plant.[8] More than 85 per cent of those studies used a technology that resulted in what is now to be considered cat 1 plants. The EU SAGE database (as of December 2023) holding information on 836 genome editing plant products labels more than 91 per cent of those as "SDN1" edits (*i.e.* mutations in the form of changes in not more than a few base pairs, short deletions or insertions) which equals cat 1 like products as given in Annex 1 of the proposal.

However, a deliberate release (for testing purposes) as well as placing on the market is only possible after the status of cat 1 has been officially confirmed (art. 4(1)(a)). In case of deliberate releases this is done by the (locally concerned) competent EU member state authority and in case of placing on the market, it is done by the European Food Safety Authority (EFSA, arts 7(1) and 6(6)). In both cases, a draft decision is to be drawn up within 30 working days (arts 6(6) and 7(5)) from the application – this deadline cannot be prolonged to obtain additional information, because in case not all information have been filed, the application is to be rejected as inadmissible (arts 6(5) and 7(4)).

For deliberate releases, the other EU member states as well as the Commission get 20 days to comment (art. 6(7)) on the draft decision. If they do, then within 45 working days the COM, after consulting EFSA, must prepare a draft decision on the status of the NGT plant, which is then decided on in the committee procedure, requiring a majority vote by EU member states (art. 6(10)). For placing on the market, the Commission will prepare a draft decision within 30 days, which is then decided on in the committee procedure as well (art. 7(6)).

Unlike for authorizations for placing on the market of GMO under Directive 2001/18/EC or Regulation (EC) 1829/2003 where the committee procedure is an examination procedure (art. 5 of Regulation (EC) 182/2011), in which the (practically permanent) lack of a qualified majority requires the appeal committee and ultimately the Commission to take a decision, the verification of the NGT cat 1 status for placing on market for these

[8] J Menz, D Modrzejewski, F Hartung, R Wilhelm and T Sprink, 'Genome Edited Crops Touch the Market: A View on the Global Development and Regulatory Environment' (9 October 2020) Frontiers in Plant Science www.frontiersin.org.

plants only is dealt with in an advisory procedure (art. 4 of Regulation (EC) 182/2011, (see section V.1 of this *Insight*), needing only a simple majority and hence saving a lot of time and bureaucracy.

Plants officially recognized as cat 1 plants are being listed in a publicly accessible database (art. 9) and plant reproductive material, including breeding material, has to be labelled as "cat 1 NGT" (art. 10). Furthermore, cat 1 plants must not be used in organic production (art. 5(2)).

Apart from that, there are no more restrictions stemming from special legal provisions on genetic engineering. As explicitly mentioned in recital 22 of the proposal, cat 1 plants remain subject to any regulatory framework that applies to conventionally bred plants. This includes *e.g.* the official authorization of NGT plant varieties (cf. art. 4(1) of Directive 2002/53/EC). As also explicitly mentioned in recital 22, food products of NGT 1 plants featuring a significantly changed composition or structure that affects the nutritional value, metabolism or level of undesirable substances will be considered as novel food and therefore fall into the scope of Regulation (EU) 2015/2283 on novel foods and will be risk assessed in that context.

III.2 Category 2 NGT plants

Category 2 NGT plants (cat 2 plants), which are all NGT plants not being cat 1 plants (art. 3(8)), and their food and feed products are regulated entirely differently, as can be seen in art. 12. This article holds that the rules which apply to GMOs in Union legislation in so far as they are not derogated from by the draft regulation, shall also apply to cat 2 plants and their food and feed products.

There are notable differences for cat 2 plants and their food and feed products compared to GMO that are not NGT plants (*e.g.* transgenic plants) and therefore governed by the current European GMO regulation.

The scope of the environmental risk assessment is reduced compared to the legal status quo since the instructions for the risk assessment in Annex II hold that certain information on hazard identification and characterization (*e.g.* information on allergenicity, interaction with other organisms, potential gene transfer etc.) shall only be submitted if the specific characteristics and the intended use of the cat 2 plant in question or its product gives rise to a plausible risk hypothesis that can be addressed utilizing the specified information (Annex II Part 1 last paragraph). Hence, the risk assessment of cat 2 plants is adapted to their individual risk profile.

Plants belonging to cat 2 do not need a monitoring plan (arts 14(1)(h) and 19(3)(b)). if the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment do not render such a plan necessary.

The modalities to comply with analytical method requirements shall be adapted on duly justified request where it is not feasible to provide an analytical method that detects, identifies and quantifies the cat 2 plant (arts 14(1)(l) and 19(2)(2)).

The first renewal of the authorization shall be valid for an unlimited time period unless there are justified grounds based on the risk assessment to decide differently (arts 17 and 21).

The development of cat 2 plants containing traits relevant for sustainability as laid down in Annex III is incentivized with an expedited authorization procedure, with a waiver of fees for SMEs and a more detailed pre-submission advice by EFSA on request of the applicant regarding data requirements stemming from plausible risk hypotheses (art. 22) – herbicide tolerant plants however are always excluded from incentives (Annex III Part 2).

The mandatory labelling that applies for cat 2 plants just like for "conventional" GMOs may be supplemented by a specification of the trait(s) conveyed by the genetic modification (art. 23).

EU Member states cannot decide to opt-out of cultivation for authorized cat 2 plants (art. 25).

III.3 Provisions for delegated and implementing acts as well as guidance material

The draft regulation and its definitions laid down in art. 3 are not sufficiently clear for execution. Therefore, the proposal foresees the enactment of implementing rules in art. 27 by the Commission after consultation of EFSA in the committee procedure, *e.g*. on the methodology and information requirements for the environmental risk assessment of category 2 NGT plant.

More importantly, the Commission gets empowered to enact delegated acts (*i.e.* without the requirement for obtaining a qualified majority vote by EU member state first) to amend the criteria of equivalence of NGT plants to conventional plants as laid down in Annex I in order to adapt these criteria to scientific and technological progress as regards the types and extent of modifications which can occur naturally or through conventional breeding (art. 5(3)). This means, that the scope of cat 1 plants can eventually be accordingly enlarged, hence the number of plants not needing risk assessments would increase. Annex III, containing the traits for which regulatory incentives may or may not be granted when authorizing a cat 2 plant, could also be amended by a delegated (art. 22(8)) and the application. The proposal does not delegate the power to the Commission to amend Annex II, yet there are implementing acts foreseen for this Annex (art. 27(c)).

Lastly, art. 29(1) holds that EFSA shall before the date of application of the draft regulation publish detailed guidance to assist the notifier or the applicant in the preparation and the presentation of the notifications and the application referred to for the procedures mentioned above.

IV. Assessment of different scientific aspects in the regulation

IV.1. Scientific reasoning of equivalence criteria as given in Annex I

In order to justify thresholds for equivalence of cat 1 plants with conventionally bred plants as given in Annex I, a technical paper on the rationale for these criteria was published in October 2023.[9] In brief, the Commission analysed 90 scientific, peer-reviewed papers on plants obtained by conventional breeding methods and on genetic variations in these plants. The review analysed the type of mutation, the size range, and the number of occurrences per plant. The analysis refers to natural mutations and genomic alterations due to conventionally breeding, including products of random mutagenesis using chemicals or irradiation.

a) Number of genetic modifications per plant

Based on this analysis, the numerical limit of individual genetic modifications per plant was set to a number of 20 arguing that the probability to achieve specific and more extensive combinations of modifications by conventional breeding was rather low. From a breeder's perspective, however, conventional breeding methods are known where the number of genetic modifications easily exceeds a threshold of twenty: the mutation rate was estimated with one mutation per 300 000 basepairs when doing chemical mutagenesis (application of 1,5 per cent Ethyl methanesulfonate, a mutagenic chemical agent in rice). This might end up in 1400 mutations per rice genome (430 Mbp in size) when doing one application of that agent.[10] A recent study on genic presence/absence variations (PAVs) in barley in the context of building up a catalogue for such variations (barley pangenome) revealed more than 1.5 million structural variations when 20 barley accessions[11] were compared. The variations are to be considered the result of natural mutations and conventional breeding.[12] In addition it has been criticized *e.g.* by the ENVI committee of the European Parliament that the threshold of 20 genomic modifications does not consider the ploidy status of the plant, that is, the number of sets of more or less identical chromosomes that are found within the nucleus and that harbour genes that are alike.[13] The ploidy status does arise from fusion of the germ cells (diploid), in some

[9] Commission Services Technical Paper Document 14204/23 of 16 October 2023, Rationale for the equivalence criteria in Annex I to the proposal for a Regulation on plants obtained by certain new genomic techniques.

[10] SA Goff and others, 'A Draft Sequence of the Rice Genome (Oryza sativa L. ssp. japonica)' (2002) Science 92.

[11] An accession is a distinct, uniquely identifiable sample of seeds representing a cultivar, breeding line or a popula-tion, which is maintained in storage for conservation and use, cf. Food and Agriculture Organization of the United Nations, *WIEWS, World Information and Early Warning System on Plan Genetic Resources for Food and Agriculture* www.fao.org.

[12] M Javakody and others, 'The Barley Pan-Genome Reveals the Hidden Legacy of Mutation Breeding' (2020) Nature 284.

[13] Committee on the Environment, Public Health and Food Safety, Report A9-0014/2024 of 29 January 2024 on the proposal for a regulation of the European Parliament and of the Council on plants obtained

cases doubling of those by applying certain chemicals (many tetraploids) or the unification of genomes by other conventional breeding methods (hexaploids). In the latter case six almost identical genes must be altered to obtain one physiological effect. Therefore, a higher number of genomic alterations is necessary for polyploid plants than for diploid plants to cause a phenotypic change. This creates a regulatory imbalance in allowing more phenotypic alterations to get established in diploid versus polyploidy plants. What is true for genetic redundancy of a gene due to its presence on different chromosomes should be considered as well for redundancy that arises when the gene is present in multiple copies on the same chromosome: some genes exist as multiple copies in arrays or gene families dispersed on a single chromosome. An often-cited example are the genes encoding the protein gliadin in wheat where 45 identical genes encode this protein that is known to cause digesting disorders with some patients (coeliac disease) when consumed. To significantly reduce the amount of this protein and, hence, to achieve the alteration of a single trait, clearly more than 20 of these copies must be deleted. In addition, it is a contradiction *per se*, that deletions being subjected to no limitation in the number of nucleotides [Annex I (2)] could, theoretically, be used for removing this gene array, but single mutations aiming for achieving a similar effect cannot.

b) Number of nucleotides substituted or inserted per genetic modification

Conventional breeding and even natural mutations may cause larger genetic modifications than just 20 bp of substitution or insertion as held in Annex I (1). Natural insertion of DNA-segments up to 641000 bp in Arabidopsis have been reported.[14] Conventional breeding methods using introgression end up in exchange of chromosomal fragments even larger than this.[15] The Commission was well aware of this fact: In its technical report further publications on conventional breeding results are listed that describe large insertion, *e.g*. insertions spanning 2 Mbp after irradiation in soybean.[16] Larger insertions in introgression lines were also reported on within COM's technical paper.

c) The role of off targeting

The Commission clearly states in its technical paper that off-target modifications occurring in DNA sequence sharing sequence similarity with the targeted site are covered by the lim-

by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, proposed Recital 14(a) and explanatory statement.

[14] PD Fields and others, 'Complete Sequence of a 641-kb Insertion of Mitochondrial DNA in the Arabidopsis thaliana Nuclear Genome' (2022) Genome Biology and Evolution academic.oup.com.

[15] P Gramazio and others, 'Development and Genetic Characterization of Advanced Backcross Materials and An Introgression Line Population of Solanum incanum in a S. melongena Background' (2017) Frontiers in Plant Science www.frontiersin.org.

[16] YT Bolon and others, 'Genome Resilience and Prevalence of Segmental Duplications Following Fast Neutron Irradiation of Soybean' (2014) Genetics 967.

itation of 20 genomic modifications in total. Even with a limitation to sites that can be predicted by bioinformatic tools this obligation might be a burdensome hurdle for some crops. Especially those crops could fail to provide an unambiguous reference genome for applying bioinformatic tools where within a single variety a high degree of genomic variability exists. When interpreting off-target as unwanted mutations in genes not foreseen for modifications, clearly every conventional random mutagenesis treatment provides an abundance of unwanted modifications[17] which are not regulated due to the exemption provision of Annex I B of Directive 2001/18/EC. Hence, this risk is accepted in random mutagenesis and does not require regulation. EFSA clearly stated that off target in plants do not pose any additional risk when comparing to products of conventional breeding, especially conventional mutagenesis.[18] Given the fact that the Commission requested in its study[19] that breeding products with identical risk profiles must not be differently regulated, the inclusion of off target modifications within the 20 bp threshold is, therefore, debatable.

d) The role of cisgenesis

Annex I (3) of the draft proposal allows for any insertion of a contiguous DNA sequence existing in the breeders' gene pool or any substitution of an endogenous DNA sequence by such a sequence on the condition that it is targeted and does not interrupt an endogenous gene. On these grounds the draft proposal regulates the use of cisgenesis and intragensis. According to EFSA, cisgenesis means genetic modifications involving genetic material obtained from outside the host organism and transferred to the host using various delivery strategies; the incorporated sequences contain an exact copy of sequences already present in the species or in a sexually compatible species. If the transferred sequences contain, however, a re-arranged copy the sequence, the transfer is termed intragenesis.[20] On the grounds of EFSA's assessment that intragenesis may pose additional risks due to the new combination of genetic material,[21] the draft proposal excludes intragenesis from cat 1. Random cisgenesis is excluded as well according to COM's technical paper because it may interrupt endogeneous genes which may pose new hazards that require risk assessment. Only targeted cisgenesis leads to plants classified cat 1 plants. However, random cisgenesis has been used in the past by classical breeding and produced commercialized varieties.[22]

[17] IB Holme, PL Gregersen and H Brinch-Pedersen, 'Induced Genetic Variation in Crop Plants by Random or Targeted Mutagenesis: Convergence and Differences' (14 November 2019) Frontiers in Plant Science www.frontiersin.org.

[18] EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel), 'Applicability of the EFSA Opinion on Site-Directed Nucleases Type 3 for the Safety Assessment of Plants Developed using Site-Directed Nucleases Type 1 and 2 and Oligonucleotide-Directed Mutagenesis' (24 November 2020) EFSA Journal efsa.onlinelibrary.wiley.com.

[19] Commission Staff Working Document SWD(2021) 92 final cit.

[20] EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel), 'Updated Scientific Opinion on Plants Developed through Cisgenesis and Intragenesis' (18 October 2022) EFSA Journal efsa.onlinelibrary.wiley.com.

[21] *Ibid*.

[22] K Schneider and others, *Economic and Environmental Impacts of Disease Resistant Crops Developed with Cisgenesis* (European Union 2023) publications.jrc.ec.europa.eu.

Any targeted deletion would recombine endogenous DNA without the necessity to risk assess the junction area. Targeted deletion is allowed due to the provision in Annex I (2) of the proposal. Disruption of endogeneous genes is apparently also possible in this condition as the numbers of nucleotides for that deletion are not restricted. The exclusion of random cisgenesis is, therefore, scientifically not reasonable.

e) Opinion on the numerical and cisgenesis equivalence criteria
Taken together, it must be concluded that the number of 20 genetical modifications and of 20 bp substitutions or insertions per modification is rather at the lowest range of what is being observed in classical breeding. The threshold setting still displays inconsistencies when looking at chromosome number, gene families and off-targets. The same holds for the exclusion of random mutagenesis. Annex I, hence, must already in its current form be considered the result of a political compromise rather than being purely science based.

IV.2 Scientific reasoning of risk assessment criteria as given in Annex II

Annex II contains the foundational provisions for the environmental risk assessment (ERA) of cat 2 plants and cat 2 NGT food and feed. In its Part 1 it is laid down that the ERA shall be carried out in accordance with the principles of the Directive 2001/18/EC also valid for "old" GMOs. The risk assessment, however, shall be adapted to the risk profile of the cat 2 plants or cat 2 NGT food, for which inter alia the following factors are to be considered:

a) characteristics of the NGT plant, including the introduced trait, the function of the modified or inserted gene sequences

b) prior experience with consumption or cultivation of similar plants

c) intended condition of use of the NGT plant.

What always is required in the ERA is *i)*. A hazard identification and characterisation based on the information relating the recipient plant or the parental plant and a molecular characterisation, *ii)*. an exposure assessment with an evaluation of the likelihood of each identified potential adverse effect based on the characteristics of the receiving environment(s), the intended function, the dietary role, the expected level of use of the food and feed in the EU and the scope of the application for authorization and *iii)*. a risk characterization based on the beforementioned information including a quantitative or semi quantitative estimation of the risk and, where relevant, a description of the uncertainty for identified risks.

Part 2 and 3 of Annex II exhaustively list certain specific information for the hazard identification and characterisation that are only required if the specific characteristics and the intended use of the cat 2 plant or category 2 NGT food or feed give rise to a plausible risk hypothesis that can be addressed utilising the specified information. This includes inter alia information on persistence and invasiveness, potential gene transfer, interactions with other organisms, effects on human and animal health and an analysis

of agronomic, phenotypic and compositional characteristics. For food and feed uses this also includes information on toxicology, allergenicity and a nutritional assessment

This Annex II did not attract as much scientific reasoning in the present literature as Annex I. The reason probably is that EU legislation on GMOs is in principle applied to cat 2 plants including risk assessment which itself is science based. The derogations by the proposal aim at obtaining an assessment and a data requirement that is adapted to the risk profile of the cat 2 plant. Most of the criteria mentioned in part I and part II are known from conventional GMO risk assessment and are, for those, worked out very detailed in the respective EFSA guidelines. It remains to a coming implementing act to regulate the balance between risk profile and data requirements foreseen in those regulatory documents for cat 2 plants. Also, a guideline document could be feasible that connect traits (*e.g.* disease resistance, yield) with a risk profile adapted for those traits to conclude on data requirements to be taken into account for applications.

V. Assessment of different legal aspects in the draft regulation

V.1. Deliberate releases of cat 1 plants and committee procedure

As mentioned above, prior to deliberate releases (for testing purposes) of cat 1 plants, the verification for the status of category 1 must be done by the member states concerned. All EU member states and Commission can comment in this procedure, which at first glance seems reasonable, considering that this verification is binding also for a later placing on the market (art. 7(1)).

However, if such comments are made, this may give rise to a committee procedure which for classical GMO proved to be very problematic as member states regularly were unable to reach a qualified majority for or against an authorization.[23] That may, beside the official reasoning in recital 20 that the verification of cat 1 plant status is of technical nature and does not involve any risk assessment, be another reason why the draft regulation for the determination only foresees a advisory procedure (arts 6(10) and 7 (6) in conjunction with arts 28(2) and 4 of Regulation (EU) 182/2011). Within the advisory procedure, a simple majority is sufficient.

Nonetheless, with the current proposal, to give a purely hypothetical example, Cyprus could at least delay a deliberate release planned to only take place in Sweden, although it is obviously not concerned directly due to the geographical distance between Sweden and Cyprus.

It seems more reasonable to decouple the verification procedure for deliberate releases from the verification procedure for placing on the market, in the sense that placing on the market would always require a separate verification. That way, there would be no

[23] C Klika, J Kim and E Versluis, 'Why Science Cannot Tame Politics: The New EU Comitology Rules and the Centralised Authorisation Procedure of GMOs' (2013) European Journal of Risk Regulation 327.

need for a committee procedure initiated by EU member states not concerned with the deliberate release in question. It also wouldn't be too much of an additional burden, since for the placing on the market, the notifier could of course refer to the previous decision on the verification, which – depending on the specific case – might not really leave any questions open so that the EFSA could finish a draft decision rather quickly.

Furthermore, the result of a deliberate release can well be that the producer of the plant doesn't deem the plant commercially viable after all.

While understandable, it certainly is debatable that the proposal only foresees an advisory procedure for the status determination of a NGT plant. Art. 2(2)(b)(iii) of Regulation (EU) 182/2011 holds that the examination procedure applies to implementing acts relating to the environment, security and safety, or protection of the health or safety, of humans, animals or plants. Since the Commission apparently thinks that all genetically modified non-cat 1 plants are inherently risky (cf. risk assessment requirements for cat 2 plants), the determination of a cat 1 plant status is certainly safety relevant, because if that determination cannot be made, following that logic, it must be a risky plant.

V.2 Precautionary principle

Critics often claim that the draft regulation violated the precautionary principle,[24] because the CJEU has in essence pointed out in its judgements, the above mentioned one as well as in case C-688/21, that NGT due to the limited experience must be considered as inherently risky and even modifications of conventional mutagenesis techniques could lead to novel risks.[25]

However, the CJEU in its two judgments relied heavily on the wording of the Directive 2001/18/EC and its recitals, especially recital 17 according to which the Directive should not apply (only) to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record. Furthermore, the CJEU references recital 5 of Directive 2001/18/EC according to which the protection of human health and the environment required that due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms (GMOs) and recital 55 which holds that it was important to follow closely the development and use of GMOs. Lastly, it cites art. 4(1) of Directive 2001/18/EC that requires the EU member states in accordance with the precautionary principle, to ensure that all appropriate measures are taken to avoid adverse effects on

[24] For example TM Spranger, 'Expert Opinion on the Proposal for a Regulation on Plants Obtained by certain New Genomic Techniques and their Food and Feed, and Amending Regulation (EU) 2017/625' (30 October 2023) www.bfn.de. Likewise: G Winter, 'The European Union's Deregulation of Plants Obtained from new Genomic Techniques: A Critique and an Alternative Option' (4 March 2024) Environmental Sciences Europe enveurope.springeropen.com.

[25] Case C-688/21 *Confédération paysanne and Others v Premier ministre* ECLI: EU:C:2023:75 paras 43 ff and 51 ff.

human health and the environment which might arise from the deliberate release or the placing on the market of GMOs.

The CJEU has in its settled case law pointed out that the precautionary principle entails that, where there is uncertainty as to the existence or extent of risks, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent and that where it proves to be impossible to determine with certainty the existence or extent of the alleged risk, the precautionary principle justifies the adoption of restrictive measures.[26]

The verbs "may" and "justifies" are of importance in that sentence and should not be mistaken for the verbs "must" and "requires".

In other words, there is leeway for the European legislator how to deal with Novel Genomic Techniques, as long as the goal for a high level of environmental protection laid down in art. 191(2) TFEU is not undermined.

Therefore, should the legislator after detailed collection of information decide to side with the EFSA which doesn't see additional new hazards stemming from targeted mutagenesis[27] or cisgenesis[28] in comparison to conventional breeding and with the vast majority of the scientific community that finds the proposal to reflect the state of the art in science like the German Research Foundation and German National Academy of Sciences Leopoldina,[29] it is difficult to imagine that the CJEU would later find the draft regulation to violate the precautionary principle.

V.3. Cartagena protocol

An additional perspective into the discussion is added by the claim expressed in a legal opinion mandated by the parliamentary group of BÜNDNIS 90/DIE GRÜNEN (Greens) in Germany which holds that due to a lack of a risk assessment on a case-by-case basis, the draft regulation would violate the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CP).[30] As the legal opinion rightly points out, the draft regulation could eventually be declared void by the CJEU due to art. 216(2) TFEU if it violated the CP,

[26] Case C-616/17 *Criminal proceedings against Mathieu Blaise and Others* ECLI:EU:C:2019:800 para. 43.

[27] EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel), 'Applicability of the EFSA Opinion on Site-Directed Nucleases Type 3 for the Safety Assessment of Plants Developed using Site-Directed Nucleases Type 1 and 2 and Oligonucleotide-Directed Mutagenesis' cit.

[28] EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel), 'Updated Scientific Opinion on Plants Developed through Cisgenesis and Intragenesis' cit.

[29] R Bock, A Brakhage and H-G Dederer, 'Keeping Europe Up to Date – a Fit-for-Purpose Regulatory Environment for New Genomic Techniques' (19 July 2023) Leopoldina www.leopoldina.org.

[30] G Buchholz, 'Kommissionsvorschlag einer Verordnung über neue genomische Techniken (NGT): Zur Verletzung des Vorsorgeprinzips' (14 September 2023) www.gruene-bundestag.de.

because the CJEU following its settled case law interprets international agreements concluded by the EU.[31]

The Cartagena Protocol according to its art. 4 applies to the transboundary movement, transit, handling and use of all living modified organisms (LMO) that may have adverse effects on the conservation and sustainable use of biological diversity and according to art. 16 the parties of the CP, one of which being the EU,[32] shall regulate, manage and control risks identified in the risk assessment provisions of the CP associated with the use, handling and transboundary movement of living modified organisms. And indeed: according to Annex III(6), the risk-assessment should be carried out on a case-by-case basis.

However, it must be highlighted that according to Annex III(5) CP the risks associated with LMO should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment. This is the model of a comparative risk assessment.

In light of this, assuming cat 1 plants were LMO, one could try to argue that cat 1 plants have on an abstract level already been assessed by the legislator and found to be not riskier than their conventionally bred counterparts. And since a verification procedure for each cat 1 plant is in place, they are being dealt with on a case-by-case basis. After all, there are hardly any strict rules for the risk assessment in Annex III of the CP which is highlighted by the use of words like "as appropriate" [Annex III(8) CP], "depending on the case" [Annex III(9)]. Even the case-by-case risk assessment "should" only be done with information that "may vary in nature and level of detail from case to case" [Annex III(6) CP].

So, while there may be room for argumentation left in this regard, a necessary contradiction of the draft regulation to the CP would, however, be that cat 1 plants could be exported to third countries for deliberate release into the environment without the requirement for a notification and – if applicable – an authorization in advance as foresee in arts 4 to 6 Regulation (EC) 1946/2003, since the rules for GMO according to art. 5(1) of the draft regulation do not apply to cat 1 plants.

Therefore, if one really followed the opinion that NGT plants were LMO, it would be advisable to not exclude cat 1 plants from the requirements of Regulation (EC) 1946/2003.

Yet, it is held here, that cat 1 plants actually do not constitute LMOs. At first glance they certainly seem to: as has been said above, NGT plants are undoubtedly GMO (see section III of this *Insight*). And the first recitals of Regulation (EC) 1946/2003 on transboundary movements of genetically modified organisms make clear, that the regulation serves to transpose the obligations for LMO stemming from the CP into European Law and thereby uses in its art. 3(2) a GMO definition, that is almost the same as the general

[31] Case C-533/08 *TNT Express Nederland BV v AXA Versicherung AG* ECLI:EU:C:2010:243 para. 60.

[32] Convention on Biological Diversity, *Parties to the Cartagena Protocol and its Supplementary Protocol on Liability and Redress* bch.cbd.int.

GMO definition in art. 2(2) of the Directive 2001/18/EC which is central for the whole European genetic engineering law.

On the other hand, it is the opinion of the Commission that the LMO definition is (only) largely consistent with the European definition of a GMO and the genetic modification techniques applicable to each definition under the two instruments are not the same.[33]

The LMO definition of the CP indeed has a quite different wording compared to the GMO definition in European Law: LMOs are defined in art. 3(g) of the CP as any living organisms "that possess a novel combination of genetic material obtained through the use of modern biotechnology", with modern biotechnology meaning *inter alia* in vitro nucleic acid techniques "that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection" (art. 3(i) CP). Art. 2(2) of Directive 2001/18/EC defines a GMO as an "organism, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination". The simple claim that LMO equal GMO is therefore already doubtful from the different wording of the definitions.

Furthermore, it is highly questionable whether NGT plants are gained by the use of "modern biotechnology" in the sense of the definition in the CP: while NGT certainly have not been used in traditional breeding and selection, it seems hard to argue that NGT used for genetic modifications in the sense of Annex I of the draft regulation "overcome natural physiological reproductive or recombination barriers" as required by the definition in the CP. This is especially true for cases in which the use of NGT does not even cause a temporary integration *e.g.* to produce the CRISPR-tools in the target organism. On the contrary, as has been shown above, the GMO definition in the interpretation by the CJEU is much broader, as it encompasses all organisms that are being mutated, by whatever technique.[34]

Finally, to the knowledge of the authors, the CP's compliance committee,[35] which is responsible for taking measures with a view to promoting compliance and addressing cases of non-compliance has so far never decided on this crucial question and neither has the conference of the parties, although several members to the CP such as Brazil, Colombia, Japan, Kenya, Nigeria or the United Kingdom (England) all don't foresee risk assessments at least for some organisms obtained by NGT.

V.4. Amendment of Annex I via delegated act

As has been mentioned above, the scope of cat 1 plants can be broadened via a delegated act enacted by the Commission, without the requirement for a majority vote of the EU

[33] Commission Proposal for a Regulation COM(2002) 85 final of the European Parliament and of the Council on the transboundary movement of genetically modified organisms of 18 February 2002, Explanatory Memorandum.

[34] Case C-528/16 *Confédération paysanne and Others v Premier ministre* ECLI:EU:C:2018:583 para. 38.

[35] Convention on Biological Diversity, *The Compliance Committee* bch.cbd.int.

member states. This has been criticised since the instrument of delegated acts to amend the legislative act (here: the draft regulation) is according to art. 290 TFEU reserved for certain "non-essential" elements of the legislative acts and it could be argued that the criteria in Annex I are not a "non-essential" element, but instead the core of the whole regulation.[36]

Undeniably, Annex I is important. However, as has been pointed out in legal literature, the interpretation by the CJEU on what is considered to be essential in the sense of art. 290(1) TFEU, is not so clear.[37]

The CJEU has already held that provisions which, in order to be adopted, require political choices falling within the responsibilities of the European Union legislature cannot be delegated.[38] But it is remarked in legal literature that in the past the CJEU gave the Commission quite some leeway for using delegations and the interpretation of the word "essentiality" was less about democratic legitimation or but more about aspects of functionality.[39]

If the latter line of reasoning is followed, it might well be argued that political decisions have already been made in that cat 1 plants are necessarily those that are equivalent to conventional plants (art. 3(7)(a)) and Annex I can only be amended insofar as there is scientific and technological progress as regards the types and extent of modifications which can occur naturally or through conventional breeding (art. 5(3)). Hence, the scope of NGT 1 plants cannot be broadened at will, but only to retrace advances in conventional breeding and therefore, even if the first glance suggests otherwise, is indeed more a technicality than a foundational political decision.

On the other hand, as has been discussed above (see section IV.1 of this *Insight*), the equivalence criteria in its current form and numbers indeed seem to be like a political compromise – stressing this, one could also try to argue that the exact numbers indeed are a political decision after all that cannot be delegated to the Commission.

All in all, the delegation does raise some legal uncertainty. If this is to be avoided, a solution could be to avoid numerical limits altogether and instead work with abstract terms subject to implementing regulations by the Commission. This of course would again introduce the risk of delayed rulemaking and take away a good portion of the intended flexibility.

[36] Law Firm Artemisia, 'Legal Overview and Analysis of the Commission's Proposal for a Regulation on Plants Obtained by certain New Genomic Techniques, their Products, and their Food and Feed' (18 July 2023) corporateeurope.org.

[37] J Mendes, 'Delegated and Implementing Rule Making: Proceduralisation and Constitutional Design' (2013) ELJ 22.

[38] Case C-355/10 *Schengen Borders Code* ECLI:EU:C:2012:516 para. 65.

[39] M Nettesheim, *Das Recht der Europäischen Union*, Annotation of art. 290 TFEU (C.H. Beck 2023).

VI. Ongoing discussion

The draft regulation has raised quite a lot of debate. Negative critics mainly come from environmental NGOs and parts of the food sector: Friends of the Earth Europe think the nature is being put a risk[40] and similarly, IFOAM Organics Europe regards the draft as a "step backward for biosafety, freedom of choice and consumers' information"[41] while the European Non-GMO industry association highlights the risks for GMO-free production.[42]

Renowned scientific organisations and the seed industry on the other hand have a very positive attitude towards the draft regulation: The European Plant Science Organisation welcomes the draft proposal as being a "balanced compromise"[43] and supports most of its content. Similarly, Euroseeds regards the proposal and the NGT as a chance for more resilience and sustainability in a secure food production.[44]

Almost ubiquitous is the debate on patent law for NGT plants. The European Parliament in its first reading in February 2024 suggested to introduce an art. 4(a) (Amendment 33) into the draft proposal according to which NGT plants shall not be patentable, backed by art. 33(a) (Amendment 69) with a respective amendment of the Directive 98/44/EC.[45] In a newly suggested recital 1(a) (Amendment 167) this approach is claimed to be necessary, because allowing patent might give multinational seed companies even more power over farmers' access to seeds and in a context where large companies already have a monopoly on seeds and increasingly control natural resources, this could deprive farmers of all freedom of action by making them dependent on private companies. While socio-economically such a suggestion maybe has some merits, the draft proposal is certainly not the right place for such a reform of the patent system which should rather be dealt with in the European Patent Convention (an international agreement among 38 states, including all EU member states). Besides, what often seems to be neglected is the fact that patentability of a product

[40] Friends of the Earth Europe, *EU Commission's new GMOs Proposal Sacrifices Consumers' Rights and Puts Nature at Risk* friendsoftheearth.eu.

[41] IFOAM Organics Europe, *NGT Proposal a Step Backward for Biosafety, Freedom of Choice and Consumers' Information* www.organicseurope.bio.

[42] European Non-GMO Industry Association, *NGT Deregulation Proposal – GMO-free Food Production at Risk* www.enga.org.

[43] European Plant Science Organisation, *EPSO statement on the European Commission's Legal Proposal for a Regulation of the European Parliament and of the Council on Plants Obtained by certain New Genomic Techniques and their Food and Feed…* epsoweb.org.

[44] Euroseeds, *Planting the Seeds of Tomorrow: European Commission Unveils Game-Changing Proposals for Plant Breeding Innovation* euroseeds.eu.

[45] European Parliament, Amendments adopted on 7 February 2024 on the proposal for a regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD)).

does not depend on its use being authorised. Furthermore, patent experts warn that without adequate protection companies may not be able to invest in NGT.[46]

The Parliament in its first reading also suggested some important amendments to the matter itself: most notably, art.10 is revised so that cat 1 plants and products (*e.g.* foodstuffs) derived of these plants must be labelled and a document-based traceability must be established (Amendments 264 and 265). Furthermore, suggested changes to art. 6 (Amendment 37) demand that the cat 1 plant status may only be verified for plants, having at least one trait listed in Annex III Part 1, *i.e.* a trait that might contribute to sustainability. Even with these suggested changes it is clear that in principle the Parliament is in favour for the approach taken by the COM.

Of course, there are still some of open questions and pitfalls, which is also reflected by the lack of a qualified majority for an amended compromise draft in the European Council in December 2023.

As has already been mentioned elsewhere,[47] the authors, too, think that the proposal in principle is a big step in the right direction to streamline the Genetic Engineering Law with the scientific knowledge gained in the last 20 years and to enlarge the breeder's toolbox in challenging times.

[46] EPI, *European Parliament Votes for a Regulation on NGT Plants Supporting the Ban on Plant Patents* patentepi.org.

[47] G Vighi and N De Storme, 'Mind the (CRISPR) Gaps: The European Commission's Proposal for the Use of NGTs in the EU' (26 October 2023) www.embopress.org.