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

submitted by

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A. Mandate for investigation

On 5 July 2023, the European Commission presented a 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 (hereinafter referred to as "the draft regulation"). By that proposal the Commission is seeking, in particular, to respond to the decision of the Court of Justice of the European Union ("the CJEU") in Case C-528/16 and, at the same time, to address the requirements and future outlooks that it formulated in the Commission Staff Working Document – which has already been analysed elsewhere – entitled "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" (hereinafter referred to as "the Commission Study").

The purpose of this expert opinion is to analyse the major changes to be introduced by draft regulation from a legal perspective. To that end, the key provisions of the draft regulation will be addressed in sequential order.

B. Individual evaluations

1. Scope of the draft regulation (Article 2 of the draft regulation)

Article 2 of the draft regulation provides that the regulation is to apply to NGT plants. This is because the Commission study concluded that Union genetic

engineering law was no longer fit for purpose in that respect. That central assumption underlying the limitation on the scope of application is set out and expanded upon under Recital 7 of the draft regulation. According to that recital, the Commission study had revealed inadequacies in the authorisation procedure and risk assessment requirements provided for under genetic engineering law. In that regard, it was also asserted that the applicable law was disproportionate and inadequate in relation to NGT plants; that was the case "given the amount of scientific evidence that is already available, in particular on their safety".

In the expert opinion on the Commission study, it was comprehensively demonstrated, however, that the Commission had, in that study, neither fulfilled its mandate for investigation nor followed a methodology that was transparent and sufficiently compliant with scientific standards. In particular, the Commission study disregarded both the applicable primary law and the case-law of the CJEU in Case C-528/16 (and now also Case C-688/21). It is therefore already apparent that a sufficiently valid basis – that is to say a basis that is scientifically founded and compliant with the law – is lacking for the entire draft regulation, but particularly vis-à-vis the change to be made under Article 2 thereof.

Furthermore, the basic assumption manifested in Article 2 of the draft regulation, i.e. that NGT plants are, by definition, to be regarded as lower risk than plants obtained by other genomic techniques, is diametrically opposed to the findings of the CJEU. In Case C-528/16 as well as Case C-688/21, the CJEU ruled that, in view

of the insufficient body of experience, unforeseeable risks were currently inherent in new genomic techniques. Moreover, in Case C-688/21 it was also specifically stated that even very small modifications to already established genomic techniques covered by the scope of the exemption could entail new risks in both qualitative and quantitative terms. In view of the fact the CJEU referred also to the primary-law precautionary principle in those remarks, it therefore follows that the draft regulation is also – as secondary legislation – in violation of higher-ranking law.

The above assumptions are also based on the fact that the draft regulation focuses solely on plants obtained using NGT; by reverse argument, other organisms such as fungi are excluded from its scope. Recital 9 sentence 1 of the draft regulation justifies this as follows: "Based on the current scientific and technical knowledge in particular on safety aspects, this Regulation should be limited to GMOs that are plants, i.e. organisms in the taxonomic groups Archaeplastida or Phaeophyceae, excluding microorganisms, fungi and animals for which the available knowledge is more limited." However, the "history of safe use" described in Recital 17 to Directive 2001/18/EC, which is based on the precautionary principle and has been defined in further detail by the CJEU, is conditional on the establishment of a decades-long body of experience. At the present time, it is therefore impossible to produce such a body of experience for all new (sic!) genomic techniques. NGT cannot therefore be classified as currently unsafe in respect of microorganisms, fungi

and animals on the one hand, but as already proven safe in the case of plants on the other hand.

2. Definitions (Article 3 of the draft regulation)

The legal definitions set out in Article 3 of the draft regulation contain various deficiencies, which will be addressed separately below in each case.

a. Breeders' gene pool

Article 3 (2) of the draft regulation defines an NGT plant as "a genetically modified plant 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 that temporarily may have been inserted during the development of the NGT plant". This must be criticised, first and foremost, on account of the fact that the usable gene pool for NGT production has been defined in the broadest possible terms. That is because, even if Article 3 (2) of the draft regulation is considered in isolation, the usable gene pool is not that of the individual company, but rather the gene pool of all breeders, and thus, ultimately, all forms of material available commercially or through "Material Transfer Agreements". On the condition and to the extent that the end product no longer contains "any genetic material", any gene pool may in fact be used.

This "maximum scope" is confirmed by the subsequent definition set out in Article 3 (6): ""breeders' gene pool" means 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”. The barely measurable scope of the modification possibilities that the foregoing definition creates could lead to the emergence of completely new risks. This runs counter to the basic assumptions adopted by the CJEU in Case C-528/16 and especially in Case C-688/21, because – even in cases where established techniques are used – applications in new contexts could give rise to completely new risks.

Along these same lines, there is also a misunderstanding that extends beyond the incorrect assumption – as already discussed in respect of Article 2 of the draft regulation – of an adequate history of safe use for targeted mutagenesis or cisgenesis. That is because Article 3 (2) of the draft regulation is intended to enable deregulation also in those cases where targeted mutagenesis and cisgenisis are combined – in any manner whatsoever. However, in Case C-688/21, the CJEU expressly found that new risks are presented even by combinations of technologies presumed to be safe.

b. Category 1 plants

Key definitions for NGT plants in categories 1 and 2 are subsequently laid down in Article 3 (7) and (8) of the draft regulation. Since category 2 plants are defined on the basis of what they are not, i.e. “as NGT plants other than a category 1 NGT plant”, the primary focus thus lies on the positive definition set forth under Article 3 (7) of the draft regulation. The stipulation in (b) that former genetic engineering law is to remain applicable in cases of modifications to

progeny of category 1 plants subject to Directive 2001/18/EC or Regulation (EU) No 1829/2003 is so self-evident that no further comment is necessary in this regard. By contrast, what is essential is the key change to be introduced under Article 3 (7)(a) of the draft regulation, which means that Union genetic engineering law would no longer be applicable in cases of equivalence to conventional plants. This "equivalence" is then defined as follows in Annex I:

"A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

1) substitution or insertion of no more than 20 nucleotides;

2) deletion of any number of nucleotides;

3) on the condition that the genetic modification does not interrupt an endogenous gene:

a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;

b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

4) targeted inversion of a sequence of any number of nucleotides;

5) any other targeted modification of any size, on the condition that the resulting DNA sequences already occur (possibly with modifications as accepted under points (1) and/or (2)) in a species from the breeders' gene pool."

The understanding accorded to the equivalence criterion here is worthy of criticism when considered from both a general and a specific perspective. From a general perspective, it must once again be highlighted that the assumption underpinning that approach – i.e. that "minor modifications" produce only minor effects which can, from a regulatory point of view in particular, be regarded as negligible – has not been scientifically proven and, most significantly, is incompatible with the findings of the CJEU - particularly in case C-688/21.

When considered more specifically, it becomes apparent that the definition contains further flaws, since, on closer inspection, the definition is not even limited to – presumed – minor modifications. That is because the upper limit of "20 genetic modifications" specified in the "major premise" of Annex I may explicitly refer to all of the types of modifications listed under points 1 to 5 cumulatively. That would mean that the "deletion of any number of nucleotides" as permitted under no. 2 would constitute a single genetic modification, such that "19 further potential modifications remain". In view of the fact that, conversely, Annex I no. 4 regards the "targeted inversion of a sequence of any number of nucleotides" as an additional singe genetic modification, this is ultimately an approach that fails to establish any

boundaries. Even heavily modified plants could be regarded as category 1 plants.

The breadth of the definition given to category 1 plants will result in a narrowing of the regulation's potential scope of application to category 2 plants. This approach is intended to result in the maximum possible degree of deregulation.

The definitions set out in Article (3)(9)-(14) of the draft regulation then extrapolate the concepts of NGT plants – more specifically category 1 plants and category 2 plants – to cover food, feed and other products, to the effect that the standards of genetic engineering law would no longer apply to any of those areas. The criticism set out above therefore applies *mutatis mutandis*.

c. SME

Article 3 (15) of the draft regulation then defines an SME (small and medium sized enterprise) as meaning an SME within the meaning of the Commission Recommendation of 6 June 2003 (2003/361/EC). That definition is of particular relevance given that the innovation-hampering effect that genetic engineering law allegedly has on SMEs has been prominently addressed as part of the Commission study – under heading no. 1.4.3 "Expected results and impact" – of the assessment accompanying the draft regulation, as well as in the draft regulation itself. Accordingly, the Commission is seeking to grant the administrative reliefs and benefits provided for under Article 22 (2)(b), (3)(b),

(4)(d) and (5)(b) to all SMEs covered by the definition set out in Article 3 (15) of the draft regulation.

However, this overlooks the fact that Article 2 (1) of Recommendation 2003/361/EC permits SMEs to have up to 250 employees and an annual turnover of up to 50 million euros, which is inconsistent with the concept of "single person start-ups". Above all, however, many SMEs have interconnections – sometimes of a complex nature – with large corporations and/or investors, which also prevents them from being automatically regarded as worthy of protection. Article 3 of Recommendation 2003/361/EC attempts to address those phenomena by defining upper investment limits, among other measures. Even in cases where those upper limits have not been exceeded, however, it is still perfectly possible, for example, that an SMU could make use of the research department at a large investor company. That also runs contrary to the protection worthiness claimed by the Commission.

3. Release of category 1 plants (Article 4 of the draft regulation)

The effect of Article 4 (1)(a) of the draft regulation will mean that category 1 plants may ultimately – upon receipt of the official certificate of equivalence provided for under Article 6 of the draft regulation – be released without any restrictions. Once that certificate has been issued, the alternative criteria set forth respectively in Article 4 (1)(a) and Article 4 (1)(b) of the draft regulation will mean that "progeny" are not required to undergo any further

official scrutiny, but can instead be released without any restrictions, provided that no further modifications have been made that would render them subject to Directive 2001/18/EC or Regulation 1829/2003 (Article 3 (7)(b) of the draft regulation).

In that regard, the fact that the draft regulation specifies the concept of "progeny" as a requirement but fails to provide a definition of that concept is worthy of criticism. This approach is perplexing considering that, in its study, the Commission criticised the alleged vagueness of numerous definitions laid down in Directive 2001/18/EC and concluded, primarily on that basis, that there was an apparent need for reform.

With regard to the resulting incompatibility with the precautionary principle, the fact that the Commission has not made a provision for any official inspections, but assumes instead that a one-time certification of equivalence justifies an assumption that the genetic modifications will be "perpetually stable", is also worthy of criticism.

4. Legal status of category 1 plants (Article 5 of the draft regulation)

a. General (Article 5 (1) of the draft regulation)

Article 5 (1) of the draft regulation stipulates that the rules of Union genetic engineering law are generally inapplicable to category 1 plants. As already explained herein and elsewhere with sufficiently detailed reasoning, that area-specific exemption is incompatible with the precautionary principle of Union

law. This is especially true in light of the settled case-law of the CJEU in Cases C-528/16 and C-688/21. Moreover, as a guiding principle of primary law, the precautionary principle cannot be modified by the secondary legislature.

b. The relationship with the Organic Basic Regulation (Article 5 (2) of the draft regulation)

In view of the objectives pursued by Regulation (EU) 2018/848 – the Organic Basic Regulation – Article 5 (2) of the draft regulation stipulates that the provisions laid down in Articles 5 (f)(iii) and 11 of the Organic Basic Regulation are to remain applicable to category 1 plants, notwithstanding the general deregulation. Use of category 1 plants is thus incompatible with organic production methods. Category 1 plants and products produced from them are not be used in food or feed, or as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, plant reproductive material, micro-organisms or animals in organic production. In this respect, three facets of the proposed regulation must be criticised:

Firstly, it is questionable whether an isolated applicability of Article 5 (f)(iii) and Article 11 of the Organic Basic Regulation is appropriate, as this would preclude the continued applicability of the labelling provisions laid down in Article 30 of the Organic Basic Regulation. Given that the Commission has itself pointed out that the use of NGT is "incompatible with the concept of organic production in Regulation (EC) 2018/848 and with consumers' perception of organic

products”, full compatibility with the Organic Basic Regulation must therefore be guaranteed.

Secondly, the Commission regularly refers to the alleged lack of appropriate methods for detecting NGTs. However, it is questionable whether the official certification of the claimed equivalence, as provided for under Article 6 of the draft regulation, will mean that organic producers are able to circumvent or prevent the use of category 1 plants with reasonable certainty. Under the Impact Assessment heading of its draft regulation, the Commission states: “To allow choice at the beginning of the supply chain to support maintaining organic production free from NGTs and preserve consumer trust, in addition to the information in public registries considered in the impact assessment, an additional measure is proposed: the indication of the use of NGTs in the labelling of seeds.” Furthermore, public registries and seed labelling are not sufficient on their own to adequately protect organic producers against contaminations with category 1 seeds.

Thirdly, the Commission’s approach contains another deficiency, in view of the fact that Article 5 (2) of the draft regulation still really regards category 1 plants as GMOs for the purposes of the specified provisions of the Organic Basic Regulation. The Commission’s approach is therefore inherently contradictory. An organism is either a GMO or it is not. Recognising certain consumer rights as justified on the one hand (and thus imposing obligations on organic producers in particular) while, on the other hand, emphasising the harmlessness of category 1 plants

and, in doing so, disregarding consumer rights (with a view to accommodating companies using genomic techniques), is therefore mutually incompatible.

a. Delegated acts (Article 5 (3) of the draft regulation)

Article 5 (3) of the draft regulation empowers the Commission to adopt delegated acts, in accordance with Article 26 of the draft regulation, amending the criteria of equivalence for NGT as set out in Annex I of the draft regulation. In that regard, Article 26 of the draft regulation probably meets the requirements laid down in Article 290 (1) subparagraph 2 sentence 1 TFEU. By contrast, however, Article 5 (3) of the draft regulation would violate Article 290 (1) subparagraph 1 and subparagraph 2 sentence 2 TFEU. Article 26 of the draft regulation is based explicitly on the "supplement" alternative ("adopt") referred to in Article 290 (1) subparagraph 1 TFEU, with the result that the only supplements permitted are those primarily manifested through specifying the rules contained in the relevant legislative act more clearly and in greater detail. It is clear from the case-law of the CJEU that, for example, the "the parameters for the evaluation and authorisation" of food-related products and the "fundamental safety rules" are included within the essential elements that must be regulated by the legislature itself. However, since the criteria for equivalence are not refinements of the applicable law but rather, according to the Commission's intention, the sole relevant criteria that will determine the (non-)applicability of genetic engineering law, they

are necessarily "essential elements" within the meaning of Article 290 (1) subparagraph 1 and subparagraph 2 2 sentence 2 TFEU.

The fact that some academic commentators maintain that Article 290 TFEU requires only that the "major fundamental political decisions on a matter" [own translation] are to be taken by the legislature has no bearing on the present assessment. That is because the case-law of the CJEU relied on in those particular cases concerns the – entirely undisputed – immateriality of accompanying conditions, which are merely intended to safeguard the core substance of the legislation: "That is not true of penalties, such as surcharges or exclusions, which are intended to underpin the options chosen by ensuring the proper financial management of the Community funds designated for their attainment." Irrespective of all dogmatic vagueness, it can thus be safely assumed that the decision on whether Union genetic engineering law is (in-)applicable to an entire technology area – regarded by the Commission itself as being of significant importance to the internal market – relates not to a marginal detail aspect but rather to the core substance of the entire subject of regulation. Article 5 (3) of the draft regulation is therefore incompatible with Article 290 (1) TFEU.

5. Labelling (Article 10 of the draft regulation)

The provision on labelling under Article 10 of the draft regulation is worthy of criticism from two angles.

a. Inconsistencies with the Organic Basic Regulation

It is first necessary to highlight the inconsistencies with the Organic Basic Regulation already discussed in relation to Article 5 (2) of the draft regulation. As already explained, the Commission considers that the labelling requirements of the organic farming industry can be adequately addressed by means of register entries and the specification laid down in Article 10 of the draft regulation, which is at issue here. However, this is likely to be in conflict with the fact that these requirements do not effectively prevent contaminations of GM-free cultivation areas, which means that the burden of the prohibition under Article 11 (1) of Regulation (EU) 2018/848 would be unilaterally shifted to organic producers. That applies all the more so in view of the fact that the reliability accorded to certain labels under Article 11 (2) and (3) of Regulation (EU) 2018/848 would not encompass labels affixed in pursuance of Article 10 of the draft regulation and, furthermore, the Commission has no plans to make a corresponding supplementary amendment to Article 11 (2) and (3) of Regulation (EU) 2018/848.

b. The proposed label "cat 1 NGT"

Notwithstanding the above argument, it must be asserted that the proposal for labelling plant reproductive material as "cat 1 NGT" is inadequate for three reasons:

Firstly, if the label contains only “cat 1 NGT” followed by the identification number, that is clearly a deliberate omission of the extra word “contains”, which, as experience shows, would lead to heightened awareness among consumers and other involved parties. Without the additional word “contains”, a label such as “cat 1 NGT 123456” could be seen as a mere reference number. The addition of “*enthält*” or “contains” is therefore essential.

Secondly, in view of the well-established use of the term “GMO”, it cannot be expected that the average consumer would immediately link “cat 1 NGT” to genetic engineering issues, thus preventing rather than enabling informed decision-making. Considering that the Commission itself assumes, in its draft, that category 1 plants are GMOs that are merely to be exempted from genetic engineering law (cf. Article 5 (1) of the draft regulation), there are no grounds, even in light of a systematic interpretation, for not including the term “GMO” in the labelling.

This ultimately leads to the final point of criticism, that is to say that the label “contains GMOs” is not only well-established but also firmly anchored in secondary law. It therefore follows that departing from that standard would confuse consumers and is ultimately also incompatible with the principle of coherency. The fact that a product contains GMOs must therefore be indicated using uniform terminology.

6. Status of category 2 plants (Article 12 of the draft regulation)

Article 12 of the draft regulation addresses the status of category 2 plants. In view of the fact that category 1 plants could, according to the provisions of Annex I of the draft regulation, include also plants that have undergone massive cumulative modifications, it is therefore to be expected that category 2 plants will exhibit the greatest qualitative and quantitative changes. Accordingly, the possibility of providing for exemptions from the general applicability of Union genetic engineering law – as created by Article 12 of the draft regulation – raises considerable concerns. Articles 19–22 of the draft regulation actually provide for numerous derogations from the applicable standards of genetic engineering law that are intended to apply in favour of category 2 plants.

In that regard, concerns arise that are even more serious than those arising in relation to category 1 plants; these relate to the applicability of the precautionary principle, as expressed in the formulation "history of safe use", and the case-law of the CJEU in Cases C-528/16 and C-688/21. The concerns raised in relation to category 1 plants thus assume an entirely new dimension in the case of category 2 plants, which cannot be assuaged by the fact that there is to be only a partial deregulation of category 2 plants, rather than a comprehensive deregulation.

7. Release of category 2 plants (Article 13 of the draft regulation)

For the purposes of deliberate release of category 2 plants, Article 13 (d) of the draft regulation provides for a risk assessment to be carried out in accordance with the requirements set out in Annex II of the draft regulation and in conformity with the implementing act adopted in accordance with Article 27 (c) of the draft regulation. In that regard, Part 1 of Annex II to the draft regulation would initially appear to provide satisfactory assurance of the required standards, since the provisions set out therein require observance of the principles referred to in Annex II of Directive 2001/18/EC. However, that assurance is completely undermined by the subsequent second paragraph of Annex II, Part 1 of the draft regulation:

"The type and amount of information necessary for the environmental risk assessment of category 2 NGT plants laid down in Annex III of Directive 2001/18/EC and for the food and feed safety assessment of category 2 NGT food and feed shall be adapted to their risk profile. Factors to be considered include:

a) the characteristics of the NGT plant, in particular the trait(s) introduced, the function of the modified or inserted genome sequence(s) and the function of any gene disrupted by the insertion of a cisgene or parts thereof;

(b) prior experience with the consumption of similar plants or their products;

(c) prior experience with the cultivation of the same plant species or plant species exhibiting similar traits or in which similar genome sequences have been modified, inserted or disrupted;

(d) the scale and conditions of the release;

(e) the intended conditions of use of the NGT plant."

For a variety of reasons, the effect of those provisions will lead to the elimination of any obligation to conduct a proper (*lege artis*) risk assessment: Firstly, the meaning of "adapted to the risk profile" is completely unclear. Even when considered in isolation, the understanding of "adapt" and the specifications assigned to the "risk profile" could result in the risk assessment procedure becoming so diluted that it has no substantial value. Secondly, the list of factors set out under points (a) to (e) appears to be in no way exhaustive, since the formulation stating that the aspects "to be considered include" clearly suggests a non-exhaustive list of examples. That creates further potential for debasement of the risk assessment.

Furthermore, the parameters listed under points (a) to (e) are "broadly formulated" and permeated with imprecise legal terms, of which the Commission is said to be generally critical. This would ultimately provide an authority that looked favourably on genetic engineering with numerous steering tools for "piloting" category 2 plants through the risk assessment process without any difficulties. It can reasonably be assumed that the Commission would use the implementing acts provided for under Article 27 (c) of the draft

regulation to further expand that abundant potential for deregulation.

In light of the settled case-law of the CJEU in Cases C-528/16 and C-688/21, the intended procedure would contravene primary law. That is because GMOs are to be released without an adequate risk assessment, despite the fact that the CJEU has expressly held that new genomic techniques present potential risks.

8. The notification procedure under Article 13 of Directive 2001/18/EC (Article 14 of the draft regulation)

Article 14 of the draft regulation is intended to modify the notification procedure laid down in Article 13 of Directive 2001/18/EC. This provision also exhibits numerous blind spots. That is evident, for example, in the breadth of possibilities granted to companies for the purposes of providing proof that a plant constitutes an NGT plant. Similarly, it once again appears that the "fine adjustments" to be carried out by the Commission in the form of an implementation act adopted under Article 14 (1)(d), read in conjunction with Article 27 (a), of the draft regulation creates yet more potential for further loosening of the legislative requirements.

To address the lack of detection methods that the Commission repeatedly alleged during the preliminary stages, Article 14 (1)(l) sentence 2 of the draft regulation contains the following options: "In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly

justified by the notifier, the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2)[…].” In the area of food and feed, that approach is accompanied by Article 19 (2) sentence 2 of the draft regulation: “In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the applicant or concluded by the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 during the procedure referred to in Article 20(4), the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2)[…].” Article 20 (4) of the draft regulation, cited therein, states: “The Union reference laboratory shall test and validate the method of detection, identification and quantification proposed by the applicant in accordance with Article 19(2) or assess whether the information provided by the applicant justifies the application of adapted modalities to comply with detection method requirements referred to in that paragraph.” Lastly, Article 29 (2) of the draft regulation requires the European Union reference laboratory, assisted by the European Network of GMO Laboratories, to issue detailed guidance to assist the notifier or the applicant regarding the application of Article 14 (1)(l), and Article 19(2).

At first glance, this appears to be a detailed provision aimed at closing the alleged gaps in the area of detectability. On a closer inspection, however, relevant errors and loopholes come to light. Firstly, as already explained in detail elsewhere, the applicant is required by law to develop appropriate detection methods when necessary. Moreover, in view of the requirement to protect trade and business secrets, the possibility of a company having no (internal) detection methods can reasonably be excluded. The assumption that companies would invest considerable amounts in conducting genetic research, producing NGT plants and bringing them to market, but without being able to provide evidence capable of standing up in court that a specific plant was its "own NGT plant", is therefore perplexing. Hence, the planned exemption from the obligation to provide an appropriate detection method, as set out in the specified provisions of the draft regulation, is, as such, unnecessary from the outset and should be rejected.

The role assigned to the reference laboratory (or, additionally, the European Network of GMO Laboratories) is also worthy of criticism. As the guidelines play a significant role in the practical implementation of the draft regulation, there is a risk that they will have a "quasi-legislative" effect. Even more important than the planned implementing acts of the Commission is the question of the necessity of a legal regulation and, ultimately, also the question of the democratic legitimacy of the corresponding measures.

9. Food and feed (Article 18 of the draft regulation)

With regard to food and feed, all of the concerns expressed above in relation to category 2 plants apply cumulatively vis-à-vis Article 18 of the draft regulation. Reference is therefore made primarily to the observations set out there. As already discussed, there are no grounds for the deregulation measures planned in respect of category 2 plants under Article 19 et seq. of the draft regulation.

10. Incentives for the development of category 2 plants (Article 22 of the draft regulation)

Article 22 of the draft regulation sets out a very wide range of incentives for companies seeking to develop category 2 plants with characteristics relevant for sustainability. At first glance, that appears to be a welcome proposal, especially in light of the fact that promises made over recent decades concerning the conceivable benefits of green genetic engineering have often failed to come to fruition. However, a perusal of Annex III, which specifies the traits referred to in Article 22 of the draft regulation, results in a certain disappointment, since the characteristics relevant for sustainability specified therein are largely well-known. Only the aspects of climate change and more efficient use of water, as referred to respectively in Part 1 (3) and (4) of Annex III, are comparatively “new”. More generally, Article 22, read in conjunction with Annex III, creates the impression that the Commission’s primary concern is to establish a link between the new genomic techniques and the

European Green Deal, which has thus far been lacking. That is because, although the Commission has repeatedly alleged such a link, it has been demonstrated elsewhere that there are in fact no links between the Green Deal and new genomic techniques. It is clear that the Commission is now seeking to make subsequent, cosmetic corrections.

Beyond those aspects, which are aimed more at making political corrections, questions of a legal nature arise as to whether introducing such incentives is, in itself, viable and whether the specifically offered incentives are compliant with the law. With regard to the first aspect, it should be noted that regulatory incentives are also offered to companies in other sectors for reasons of legal policy, and that there is a very broad margin for assessment and structuring in that respect.

By contrast, the specific form of the incentive comprising pre-submission advice from the authority, as set out in Article 22 (3)–(5) of the draft regulation, is worthy of criticism. Although the draft regulation seeks to avoid both prejudice and the partiality of individual employees of the authority, the planned overall procedure will mean, in effect, that the applicant is relieved by the authority of a significant portion of the effort involved in preparing the application. Not only does that turn the principles of administrative law on their head, it also raises the much more significant question as to why the applicants are deemed to require such assistance in this highly specific area but not, however, in any other (no less complex) areas involving communications governed by

Union law between private persons and public authorities.

It therefore appears that the Commission is ultimately seeking to substantially transfer the burden of preparing the application to the authorities and thereby effectively release the actual obliged parties from a significant share of their legal obligations. The actual extent of the assistance that will be provided by the authorities cannot be predicted on the basis of the draft regulation in its current state. That is because, under Article 22 (4)(c) of the draft regulation, the information to be provided to the public in accordance with the requirement for transparency will be published only in the form of a summary of the advice, for which no further specifications are given.

An alternative attempt to access the full information by invoking the Union right of freedom of information under Regulation (EC) No 1049/2001 would probably not succeed, in view of the fact that trade and business secrets and intellectual property rights are recognised therein as grounds for impeding access. A standard reference to trade and business secrets or intellectual property rights would therefore be all that was required in order to temporarily block information requests, or even reject them entirely. Consequently, the interested public would, in effect, be completely prevented from carrying out any checks.

Moreover, the cost savings realised by the applicant in indirect association with Article 22 of the draft regulation would probably be difficult to reconcile

with the principle that the polluter should pay under Article 191 (2) TFEU.

Lastly, it must also be pointed out that Article 22 of the draft regulation is to take effect simply by virtue of the fact that characteristics relevant for sustainability have been claimed, but without there being any requirement for further substantiation of that claim. Alongside the wording of the provision, that assertion is supported by the explanations given in Recital 33 of the draft regulation: "Regulatory incentives should be offered to potential notifiers or applicants for category 2 NGT plants and products containing traits with the potential to contribute to a sustainable agri-food system, in order to steer the development of category 2 NGT plants towards such traits. The criteria to trigger these incentives should focus on broad trait categories with the potential to contribute to sustainability [...] and should be based on the contribution to the value for sustainable cultivation and use [...]. The applicability of the criteria across the EU does not allow a narrower definition of traits to focus on specific issues or address local and regional specificities." However, if there is no requirement for a sound sustainability link, then the purported objective of Article 22 of the draft regulation will be reduced to absurdity.

11. Unintended contaminations (Article 24 of the draft regulation)

Article 24 of the draft regulation provides that Member States are to take appropriate measures to avoid the

unintended presence of category 2 NGT plants in products not subject to Directive 2001/18/EC or Regulation (EU) No 1829/2003. For three different reasons, that provision requires significant improvement.

Firstly, it appears inconsistent that the Commission is clearly seeking to specify even very small details of the deregulation itself, by means of delegated acts and implementation acts, while seeking, on the other hand, to delegate essential measures for avoiding the unintended presence of category 2 plants to the Member States. That apparent contradiction would probably make sense only if the Commission is assuming that Article 24 of the draft regulation will lead not to an indirect tightening of the requirements laid down in the draft regulation but, on the contrary, to further deregulation. In that scenario, it is likely that "NGT-friendly" Member States will show restraint in giving effect to Article 24 of the draft regulation. In the worst case scenario, the internal market would thus become contaminated with "unintendedly present" category 2 plants entering via the gateway of the relevant Member States, as a result of which the Commission would then be able to take the further step – justified on the basis of the, by then, irreversible facts – of proceeding with further deregulation, with reference to the internal-market harmonisation now required under Article 114 (1) TFEU.

Secondly, it is completely inadequate that addressing the extremely important issue concerning the unintended presence of category 2 plants is to require only that Member States take "appropriate measures". That is,

once again, an example of an imprecise legal term which has, in other contexts, been subject to harsh criticism from the Commission. Considering that the term "appropriate" usually has a subjective interpretation, it also carries the broadest possible meaning. The same applies to the term "measures". Considering that the Commission has intentionally refrained from issuing more detailed specifications or from providing an annexed (non-exhaustive) list of potential means, Article 24 ultimately proves to be a blank cheque for "NGT-friendly" Member States. On the other hand, it is of course conceivable that an "NGT-sceptic Member State" would implement strict measures that were actually effective. It is likely, however, that the Commission would take corresponding measures to counteract any de facto undermining of the regulatory philosophy underlying the draft regulation. That is because the Commission would construe such an approach on the part of a Member State as potentially prejudicial to the internal market, which would then be used as a reason for proceeding with further "harmonisation measures".

Furthermore, it can be concluded from both the wording of Article 24 of the draft regulation, as well as from a systematic interpretation of the draft regulation as a whole, that measures to prevent the unintentional presence of category 1 plants would no longer be possible in the Member States. Moving beyond questions of genetic engineering law in the narrow sense, significant considerations also arise in relation to consumer protection law, since the guiding principle of a "well-informed consumer" applies regardless of

whether and to what extent the contents of a product present health risks, for example.

12. Administrative review (Article 32 of the draft regulation)

Article 32 of the draft regulation gives the Commission an extensive right to intervene in decisions of EFSA (cf. Article 6 (10) of the draft regulation). All decisions taken by EFSA pursuant to the draft regulation and any non-exercise of its powers can be reviewed by the Commission on its own initiative, or at the request of a Member State or affected individuals, and the Commission can then call upon EFSA to retract its decision or remedy the shortcoming.

Considering that Article 6 (10) of the draft regulation designates the European Food Safety Authority as the competent authority for the purposes of Article 32 of the draft regulation, the key question therefore arises as to the scientific basis on which the Commission seeks to revise or correct decisions taken by EFSA; that is because the construct developed under the draft regulation assumes that the scientific expertise lies with EFSA in that respect. It therefore follows that the provision laid down in Article 32 of the draft regulation enables reviews and modifications of scientific assessments that are based on legal policy considerations; that is particularly so in view of the fact that the possible grounds on which the Commission could modify an assessment by the authority are not listed in detail, nor is the Commission required to give detailed reasons for its decision.

The fact that Article 32 of the draft regulation – while providing for the Commission to act on its own initiative, or at the request of a Member State or affected individual – fails to provide for a request to be made by a specialist authority that has – for example as a conduct authority – been "overruled" at national level by EFSA, is also worth of criticism. Considering the number of ways in which an administrative review can be initiated, it is surprising that that option has been left out.

Notwithstanding that point of criticism, it must of course be pointed out that, although the oversight provided for under Article 32 of the draft regulation is a new feature in the context of Directive 2001/18/EC, it is already well-established in other branches of Union law. Almost identical clauses can be found, for example, in the provisions governing materials intended to come into contact with food, or maximum residue levels of pesticides. Article 32 of the draft regulation is thus "importing" a control instrument into genetic engineering law that is already well-established in other branches of law, where – insofar as can be seen – it has not been subject to extensive criticism.

C. Summary of the main findings

The draft regulation lacks a valid basis, that is to say a basis that is scientifically founded and compliant with the law.

The basic assumption manifested in Article 2 of the draft regulation, i.e. that NGT plants are, by definition, to be regarded as lower risk than plants obtained by other genomic techniques, is diametrically opposed to the findings of the CJEU in Cases C-528/16 and C-688/21 and also violates the precautionary principle set out in primary law.

The fact that microorganisms, fungi and animals modified using NGT remain excluded from the scope of the draft regulation is evidence of the inherent risks associated with those technologies.

The breeders' gene pool that is usable under the draft regulation allows for an almost limitless transfer of material. This disregards the particular concomitant risks raised by the CJEU in Case C-688/21.

The equivalence criterion established for category 1 plants is unconvincing. In particular, Annex I of the draft regulation, which sets out criteria of equivalence in further detail, adopts a cumulative approach that completely fails to establish any boundaries. This means that, with appropriate planning, even heavily modified plants can be regarded as category 1 plants.

The privileged status that is to be accorded to SMEs overlooks the actual size of such companies and the

manifold interconnections with larger entities that are usually present.

Article 4 (1)(a) of the draft regulation will mean, in effect, that category 1 plants may ultimately, upon receipt of the official certificate of equivalence provided for under Article 6 of the draft regulation, be released without any restrictions; the same applies to their "progeny", for which no definition is given. As no official inspections are to be carried out, the Commission incorrectly assumes that a one-time certification of equivalence justifies an assumption that the genetic modifications will be "perpetually stable".

The draft regulation itself makes explicit reference to the incompatibility of organic production and category 1 plants. This creates tension between the draft regulation and the Organic Basic Regulation (EU) 2018/848. That is particularly so with regard to the merely isolated applicability of Article 5 (f) (iii) and Article 11 of the Organic Basic Regulation. It is also questionable whether the official certification of the alleged equivalence provided for under Article 6 of the draft regulation will mean that organic producers are able to circumvent or prevent the use of category 1 plants with reasonable certainty.

The planned further specifications for the criteria of equivalence, to be adopted by means of delegated acts, relate to "essential elements" as referred to in Article 290 (1) subparagraph 1 and subparagraph 2 sentence 2 TFEU. Article 5 (3) of the draft regulation is therefore incompatible with Article 290 (1) TFEU.

The planned provision on labelling set out under Article 10 of the draft regulation leads to inconsistencies with the Organic Basic Regulation. In view of its specific label proposal “cat 1 NGT” it is, moreover, an unsuitable approach, since the both the appropriate addition of “contains” and the established term “GMO” is to be omitted.

In the case of category 2 plants, concerns arise that are even more serious than those arising in relation to category 1 plants; these relate to the applicability of the precautionary principle, as expressed in the formulation “history of safe use”, and the case-law of the CJEU in Cases C-528/16 and C-688/21.

For the purposes of the deliberate release of category 2 plants, Article 13 (d) of the draft regulation provides for a risk assessment to be carried out in accordance with the requirements set out in Annex II of the draft regulation and in conformity with the implementing act adopted in accordance with Article 27 (c) of the draft regulation. In that regard, the effect of the second paragraph of Annex II, Part 1 of the draft regulation will, however, lead to the elimination of any obligation to conduct a proper (*lege artis*) risk assessment.

Article 14 of the draft regulation is intended to modify the notification procedure laid down in Article 13 of Directive 2001/18/EC and, in this respect, it perpetuates the Commission’s incorrect assumptions concerning a company’s obligations to provide proof. In addition, the role assigned to the reference laboratory

(or, additionally, the European Network of GMO Laboratories) is to be criticised, since the guidelines to be developed by that body have a "quasi-statutory effect".

Article 22 of the draft regulation sets out a very wide range of incentives for companies seeking to develop category 2 plants with characteristics relevant for sustainability. It appears that the Commission's primary concern is to establish a link between the new genomic techniques and the European Green Deal, which has thus far been lacking. From a legal perspective, the planned incentive comprising pre-submission advice from the authority is worthy of criticism. The planned relief for the applicant is unjustifiably selective, difficult to reconcile with traditional principles of administrative procedure and, furthermore, it conflicts with the principle that the polluter should pay (which is also relevant vis-à-vis responsibility for payment of costs), as referred to in Article 191 (2) TFEU.

The extent of support that is actually provided by the authorities would not have to be disclosed in detail, which is incompatible with the requirement for transparency under primary law.

Furthermore, Article 22 of the draft regulation is to take effect simply by virtue of the fact that characteristics relevant for sustainability have been claimed by the applicant, without there being any requirement for further substantiation of that claim. It cannot be expected that viable sustainability effects will be achieved on that basis.

Article 24 of the draft regulation provides that Member States are to take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18/EC or Regulation 1829/2003. This entails the possibility that individual "NGT-friendly" Member States will show restraint in giving effect to Article 24 of the draft regulation, with the result that the expected contaminations could be taken by the Commission – with reference to the internal-market harmonisation now required under Article 114 (1) TFEU – as a reason for proceeding with even further deregulation.

Although the administrative review intended under Article 32 of the draft regulation borrows from other branches of Union law, it nevertheless gives the Commission an extensive right of intervention with respect to EFSA, which raises questions concerning the technical competence of the Commission in that regard.