



European Commission Inception Impact Assessment: Manipulating facts to better manipulate genes and reinforce the absolute oligopoly of the companies that control the European agri-food system

On 24 September, the European Commission published an "Inception Impact Assessment" on its proposal to **deregulate** GMOs derived from "genome editing" or cisgenesis. The Commission simultaneously claims to want to continue to apply the objectives of the current regulation. On the same day, it opened a four-week period for the collection of contributions until 22 October¹.

This Commission inception impact assessment uses the elements of language that have been constructed by communicators, experts and researchers from the biotech industry for 20 years. It attempts to assemble them into a narrative made up of undocumented assertions, unsubstantiated promises of the means to achieve them, approximate or grossly erroneous information, undefined new terms, and opinions aimed at justifying some very vague proposals, which may appear to non-specialists to be still open to discussion, but which poorly conceal the Commission's desire for deregulation.

For ECVC, the reality confirms on the contrary the need to strictly apply the current regulation to all GMOs without exception.

The Commission's inception impact assessment is based on the study it published on 29 April 2021. ECVC has already published an analysis of this study which goes into detail regarding the specific risks of new GMOs relating to health; the environment; biodiversity; traditional, peasant, organic and GM-free farming systems; the potential for abuses of positions of power; biopiracy and the erosion of cultivated biodiversity resulting from patents on new genetic modification techniques, modified genes or the corresponding genetic information; the risks of misleading consumers; questions of traceability; false promises that have never been fulfilled and without taking into account potential the impact on farmers' seed practices and alternatives.

These elements are not included in this new document, which is built around the Commission's new legal and semantic manipulations.

By carrying out its inception impact assessment exercise only in English, the Commission seems to want to reserve the debate for the research community and industrial actors who have

1 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-applicable-aux-vegetaux-produits-a-l%E2%80%99aide-de-certaines-nouvelles-techniques-genomiques_fr

adopted it as their only working language. Given that Ireland is the only European country where English is widely spoken as a first language, this is in clear contrast with the non-discrimination principle in the Charter of Fundamental Rights of the European Union (CFR). Citizens of the other 26 countries of the Union who do not understand this language but who still wish to know the rules with which they could be governed tomorrow and give their opinion on them have to make do with unofficial electronic translations, which are often approximate in nature, or spend internal resources on translations, reproducing existing power imbalances between the various parties and compromising the active, free, effective, meaningful and informed participation of the people and groups concerned in the associated decision-making processes. The lack of translations is a clear sign of the desire to dramatically reduce public debate on this important topic for our food systems.

1 - EU legislation on GMOs is adapted to scientific and technological progress

According to the European Commission, the problem is that "*the current legislation is no longer appropriate and needs to be adapted to scientific and technological progress for certain NGTs (new genomic techniques) and their products*". Such a statement demonstrates either ignorance of the content of this legislation or a desire to ignore it.

European Directive 2001/18/EC² gives a precise definition of GMOs: "*an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*". **The Commission never refers to this definition, which is the basis of EU law on GMOs.**

On the basis of this definition, the Directive establishes in its Annexes three categories of techniques:

- Annex 1A, a) a list of techniques producing GMOs subject to regulation. The legislator was careful to leave this list open to new techniques by specifying "*inter alia*". There is therefore nothing to prevent it from being supplemented by new techniques resulting from scientific and technological progress since 2001, whether current or future;
- Annex 1A, b) a closed list of techniques "*which are not considered to result in genetic modification*";
- Annex 1B: a closed list of techniques producing GMOs "*to be excluded from the Directive*".

These last two lists are closed because they only concern techniques already known at the time of adoption of the Directive. **The other techniques producing GMOs as defined in the Directive therefore all fall within its scope without exception.** The Commission's only task is therefore to determine which of the techniques not included in any of these lists do or do not produce GMOs within the meaning of this definition. It is not the role of the Commission to argue that the techniques do not produce GMOs without taking into account this definition.

2 - The terms of the directive are clear, giving rise to no legal uncertainty

In interpreting the third list (of techniques exempted from the scope of the Directive), the CJEU recalled Recital 17³ of the Directive, which states that the "*This Directive should not apply 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*". The

² <https://eur-lex.europa.eu/legal-content/FR/TXT/?uri=celex%3A32001L0018>

³ <https://curia.europa.eu/juris/document/document.jsf?text=&docid=204387&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=783263>

Commission considers that these terms are "*unclear or undefined*" which would lead to "*legal uncertainties*".

As regards to their definition, the Commission should look at the definition of GMOs in the directive instead of ignoring it. As for the lack of clarity, a simple examination of the facts removes the alleged ambiguity displayed by the Commission on the terms "*conventionally*" and "*long safety record*". Transgenesis is indeed clearly indicated in the list of Annex 1A(a) techniques producing GMOs. It was therefore not considered by the legislator as a technique "*conventionally been used in a number of applications and have a long safety record*", which the Commission does not dispute. It follows that all genetic modification techniques that appeared at the same time as or after transgenesis and were also mainly developed after 2001, like transgenesis, fall within the scope of the Directive. The CJEU confirmed this finding by specifying that Annex 1B (the third list) "*cannot be interpreted as excluding, from the scope of the directive, organisms obtained by means of new techniques/methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18 was adopted*".

The lack of clear legal understanding of the Directive among the institutions has led the European Commission, over a period of almost fifteen years, to organize various questionable committees of scientific experts (without any legal expertise) failing to understand which techniques do or do not fall within the scope of the directive. This has enabled it to justify why it refuses to carry out its task of harmonizing the application of the Directive within the single market. In the study⁴ it published at the end of April 2021, it attempted to modify the CJEU text by defining NTGs as techniques "*that have been developed since 2001*" in order to exclude techniques potentially appearing before that date and "*mainly developed*" after. Five months later, in its inception impact assessment, it abandoned this overtly visibly subterfuge, instead reintroducing it more subtly as shown below.

3 - All new mutagenesis techniques are currently subject to GMO legislation, not just "*targeted mutagenesis*" techniques.

Contrary to the Commission's claim, the Court of Justice of the EU did not state in 2018 "*that organisms produced by **targeted mutagenesis** are GMOs*". This term targeted mutagenesis does not appear anywhere in the CJEU judgment or in the press release that accompanied its publication. On the contrary, the press release⁵ states that "*Prior to the adoption of the GMO Directive, only **conventional or random methods of mutagenesis were applied in vivo** to entire plants. Subsequently, technical progress has led to the emergence **of in vitro mutagenesis techniques which make it possible to target the mutations** in order to obtain an organism resistant to certain herbicides.*"

The CJEU judgment is the only text with legal value. The Commission seems not to have read it. This judgment did not restrict its conclusions to "*organisms produced by targeted mutagenesis*". This new term put forward by the Commission, with no given definition, has never been mentioned until now. In its preliminary question to the CJEU, the French Conseil d'Etat cited "*new directed mutagenesis techniques implementing genetic engineering processes*" and not targeted mutagenesis. But the CJEU did not use either of these two terms in its conclusions, which state that:

- all mutagenesis techniques produce GMOs,

⁴ https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_fr

⁵ <https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf>

- only those that are "*conventionally used ... and have a long safety record*" are excluded from the scope of Directive 2001/18, while those "*emerging or mainly developed*" since 2001 are not excluded but instead fall within the scope of the directive.

These nuances of vocabulary are important. It is true that the targeted mutagenesis cited by the Commission, or directed mutagenesis cited in the words of the French Conseil d'État, is one of the techniques that are not excluded, but it is not the only one. By citing only "*targeted mutagenesis*", the Commission overlooks "*random in vitro mutagenesis techniques subjecting plant cells to chemical or physical mutagenic agents*" ("*in vitro mutagenesis*" in the rest of the text) identified by the French Conseil d'État, in application of the CJEU judgment, among the techniques falling within the scope of the Directive. This omission is not accidental. The Commission considers that these techniques have always been excluded, as it confirmed in its opposition to the injunctions of the Council of State, in response to a referral from the French government⁶.

However, these "*in vitro mutagenesis*" techniques appeared at the same time as transgenesis, shortly before the adoption of the Directive. These two techniques, like the "*targeted mutagenesis*" techniques, are still only applied today to *in vitro* plant cell cultures and their development came up against the same technical obstacle until the end of the 1980s: the regeneration of plant cells cultivated *in vitro* into new plants and the stabilization of these plants. It was not until the 1990s that this technical problem began to be solved for some species. These techniques could then start to be developed, but were mainly developed after 2001 thanks to the progress of genetic sequencing, marker-assisted selection and stabilization of plants of previously recalcitrant species.

Organisms produced by "*in vitro mutagenesis*" techniques are therefore subject to EU GMO legislation just like transgenic GMOs. It is perhaps not without reason that the European Commission is trying to oppose this obvious fact:

- these "*in vitro mutagenesis*" techniques have been developed almost exclusively to make varieties tolerant to herbicides. This is not in line with its communication, which repeats the old, unfulfilled promises of GMOs that would make it possible to abandon the use of pesticides, adapt to climate change or improve the quality of food;
- the techniques of cultivation and then regeneration of plant cells *in vitro*, which must be associated with any *in vitro* mutagenesis technique, leave identifiable signatures in the resulting plants⁷. This is not in line with the communication claiming that "*it will be difficult or impossible to differentiate them (plants resulting from these in vitro techniques) from plants from conventional breeding*".

4 - The techniques of directed or targeted mutagenesis all consist in introducing genetic material into plant cells.

The Commission claims that "*in targeted mutagenesis, the mutation(s) are induced in selected target locations of the genome without insertion of genetic material*". The Commission is playing with words to deny reality. All techniques of targeted mutagenesis consist of introducing into plant cells genetic material intended to induce mutations at a specific location

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<https://ec.europa.eu/growth/tools-databases/tris/fr/index.cfm/search/?trisaction=search.detail&year=2020&num=280&mLang=FR>

7 <https://bdspublishing.com/webedit/uploaded-files/All%20Files/Open%20Access/9781801462037.pdf>
<https://bdspublishing.com/webedit/uploaded-files/All%20Files/Open%20Access/9781801462044.pdf>

in the genome: oligonucleotides, nucleases, meganucleotides, crispr-cas9, etc. It is true that this genetic material is not, in principle, intended to remain in the cell once its mission has been accomplished. However, it is rare that no trace of it is found in plants modified in this way, which makes it possible to distinguish them from plants resulting from traditional selection. This introduction of genetic material is an unnatural way of genetically modifying plants through unnatural multiplication and recombination. These targeted mutagenesis techniques therefore all produce GMOs within the meaning of the directive's definition, which the Commission does not seem to want to consider.

5 - These techniques produce alterations in genetic material that are different from those obtained by natural mutations and conventional reproductive techniques

The Commission is still playing with words when it states that "*these techniques can produce alterations of the genetic material that can be obtained by natural mutations or conventional breeding techniques*". Admittedly, the description of the genetic modification claimed by the users of these techniques may be similar to the description of natural mutations or those obtained by conventional techniques. But on one hand, these techniques all cause multiple other so-called unintended genetic modifications. Some of these, known as off-target, are located in other parts of the genome than the claimed modification. Breeders can try to eliminate them by multiple backcrosses, but they can never eliminate them all. Some of these unintended modifications are inseparable from the targeted modification and therefore cannot be eliminated. Others can occur on the target itself, such as chromothripsis, which is an extremely damaging form of genomic rearrangement that results in the breakup of individual chromosomes and the subsequent reassembly of the pieces in a disordered order⁸. Just because these unintended changes are unidentified, and often unsought, does not mean they do not exist.

No natural mutation and no traditional technique can achieve such a range of genetic modifications. As the CJEU pointed out, "*the development of those new techniques/methods makes it possible to produce genetically modified varieties at a rate and in quantities quite unlike those resulting from the application of conventional methods of random mutagenesis*". Furthermore, cells isolated *in vitro* are deprived of any exchange with other cells organized within the same plant, contacts that regulate the reorganization of their genome following various mutagenic stresses. The genetic modifications that result from their exchanges with the only chemical substances in *in vitro* cultures are necessarily different from those that can occur naturally or as a result of traditional selection techniques that do not cross the natural barriers of evolution.

6 - It is possible to distinguish between plants produced by random *in vitro* or directed mutagenesis, or by cisgenesis, and plants produced by conventional breeding.

Contrary to what the Commission claims, these differences between natural genetic modifications or those resulting from traditional techniques and those produced by random *in vitro* or directed mutagenesis, or by cisgenesis, make it possible to distinguish between plants modified in this way as indicated in note 3 above. But for this to happen, the necessary technical protocols must be developed, a task that the European Commission has refused to carry out for more than 10 years. Not finding differences just because one refuses to look for them is in no way proof of the absence of differences.

8 <https://www.nature.com/articles/s41586-020-03064-z>

7 - There is no way of knowing *a priori* whether plants produced by random *in vitro* mutagenesis, directed mutagenesis or cisgenesis do not present new risks compared to plants produced by conventional mutagenesis or by conventional breeding techniques.

The interactions between the genetic modifications of an embryonic plant cell grown *in vitro* and the natural environment in which millions of plants resulting from regeneration and multiplication are disseminated are necessarily unpredictable. No one can assume *a priori* that they will not cause any damage to the environment or in terms of health. The same cannot be said of the genetic modifications regulated by a natural environment during the use of traditional plant breeding techniques which, moreover, are evaluated during the long natural multiplication operations preceding their wider dissemination.

Traditional breeding techniques respect the natural barriers of reproductive physiology or recombination of living organisms. Genetic engineering techniques overcome these barriers. Organisms and their products are designed according to the statistical laws of numerical models and are therefore cut off from the natural world, which obeys the laws of life and not computer algorithms. Genetic sciences, which focus exclusively on DNA, ignore epigenetics, which cannot be modelled by numerical algorithms, but which nevertheless ensures all the complex relationships of plants with their environment. As a result, plants derived from these techniques generate, as soon as they are disseminated in the natural environment, multiple unpredictable risks for the environment, health and biodiversity to which they are not adapted. The long-term consequences of the irreversible contamination of cultivated and wild biodiversity by these artificial genetic constructs are unknown.

The absence of evidence of these risks, especially when they have not been assessed, cannot be evidence of their absence. These risks result from the genetic modification process. The need to assess the risks of these elements must be based on that process of genetic modification and not the competitiveness or the promise of sustainability of the claimed trait.

8 - Not regulating "*in certain undefined cases*" is not regulating at all

The Commission is still playing with words when it says that "*in some cases*" these risks are not new and that it must therefore be decided "*on a case-by-case basis*" whether or not it is relevant to assess them, according to "*risk assessment and approval requirements proportionate to the risk involved*". But in order to know whether these requirements are proportionate to the risk, the risk must be known and therefore assessed on a case-by-case basis. This is exactly what the current EU GMO regulation provides for, and the Commission wishes to do the opposite: to decide on a case-by-case basis whether or not to subject plants derived from these techniques require a risk assessment. According to what criteria if there is no mandatory prior assessment? According to "*requirements proportionate to the risk*": the regulator in charge of applying such recommendations is at risk of going around in circles for a long time before making any decision on the relevance or irrelevance of an assessment.

And how will they know for which plants they need to judge the relevance of a risk assessment if it is no longer mandatory to declare the breeding processes? And if this obligation is maintained, how effective will it be if the Commission states in advance that "*for certain plants obtained by targeted mutagenesis or cisgenesis ... it will be difficult or impossible to differentiate them from plants from conventional breeding*"? First of all, this is nothing more than a self-fulfilling prophecy of the Commission's refusal to ensure it has the technical means to differentiate between them, as it did for transgenic GMOs following the adoption of the

directive in 2001. Additionally, this statement is all the more absurd given that numerous labels, quality signs, regulatory traceability obligations, etc., have amply demonstrated the effectiveness of documented traceability when it is accompanied by sufficient controls and dissuasive penalties in the event of fraud. How will the Commission respond to the concerns, which it acknowledges exist, of *“the coexistence with organic and GM-free agriculture as well as concerns on labelling and consumers’ right to information and freedom of choice”*? How will it ensure it reacts proportionally *“to the risk involved”*, if it does not know the existence or seriousness of said risk, without carrying out assessment? The regulator in charge of applying this policy is at risk, once again, of going around in circles for a long time before taking any decision.

This statement by the Commission on the alleged impossibility of distinction seems to be the best way to encourage operators not to declare anything in order to avoid the risk of having to comply with the obligations of applying for authorisation, evaluation, labelling, traceability, monitoring and the rules of coexistence. Especially since the Commission proposes to consider *“mechanisms to enable the applicant to identify the regulatory requirements applying to a specific product”*. We might as well do away with any semblance of public policy industry actors are allowed to identify the requirements it imposes on itself!

What the Commission is not yet admitting is that the only way out of such a contradiction is to no longer apply any specific regulations to GMOs and therefore to apply the same rules to all plants. Since it will still have to respond to social demands for public regulation of risks, it will also apply new standards and new evaluation constraints to all varieties derived from traditional breeding, and therefore not patented, restricting or eliminating their access to the market for the benefit of GMOs alone, which will be able to deal with some "lighter" constraints without difficulty thanks to their de facto monopoly and the return on investment offered by patents on genes or genetic information introduced into multiple varieties and species.

9 - What impact on biodiversity and on farmers' rights to seeds? The rhetoric of sustainability, the forgetfulness of history and the lack of independent expertise.

Although the inception impact assessment clearly indicates that there are concerns about the potential negative impacts of plants obtained through new genomic techniques on the environment and on biodiversity, throughout the text there is a promotion of these techniques as good for building sustainable food systems. But in fact, deregulation of the new genomic techniques is the perfect recipe to sabotage both the F2F Strategy and the EU Biodiversity Strategy. A few years ago, the industry was promoting transgenic plants as being good for the environment. History is repeating itself and we now know that there was nothing sustainable behind transgenic plants and that EU regulation, when properly implemented, is essential to protect European farming systems from the environmental risks of using these plants. American farmers are now struggling with superweeds and super diseases that are direct consequences of the use of these GM plants. The EU institutions are now replicating the propaganda messages about these techniques, most likely due to their lack of independent knowledge on the issue.

Deregulation of all new genomic techniques means no comprehensive case-by-case risk assessment, no methods of detection, identification and quantification of GMOs, no documentation to track GMOs and GMO products at all stages of the food chain, no consumer labelling of GMO products, no post-market monitoring and no register of where GMO crops are grown. This will make it impossible to see the impact on biodiversity and on the organic

sector which should be kept GM free and will then make it impossible to achieve the key objectives of the biodiversity strategy and F2F.

Nor does the inception impact assessment mention the impact of deregulation of new genomic techniques on farmers' rights to seeds, as recognised by Art. 9 of the binding *ITPGRFA*. Is the Commission aware of this Treaty and its obligations? The word *farmer* and the impact on their rights are never mentioned in the whole text. We find this simply unacceptable.

We believe that the Commission should commit itself in the coming years not to reforming EU legislation on GMOs, but rather to creating industry-independent expertise on this issue, both within its own services and within EFSA. Achieving the objectives of the F2F strategy and biodiversity is only possible by maintaining the current legislation.

The Commission's preliminary impact assessment consists of wrapping the introduction of uniform marketing rules for all plants, whether GMOs or not, in promises of sustainability, green objectives and simplification. On the one hand, under the pretext of competitiveness and innovation, we are removing all specific regulations on GMOs, in violation of the precautionary principle laid down in the European Treaties. On the other hand, under the pretext of the real risks generated by biotechnology-based agriculture and its products, we are maintaining new regulatory barriers that are disproportionate to the practices and products of traditional, peasant, organic and GMO-free agriculture. When more powerful and more numerous cars arrived on the roads, the safety constraints for cars were not reduced in order to impose them on hikers as well; on the contrary, they were reinforced while leaving hikers alone. Today, the European Commission seems to want to apply such an absurdity: to ease the biosafety rules for GMOs and apply them to conventionally bred plants.