**For the attention of:**

Ms Ursula von der Leyen, President of the European Commission
Mr Olivér Várhelyi, Commissioner for Animal Health and Welfare
Cc:
Mr Christophe Hansen, Commissioner for Agriculture and Food
Mr Michael McGrath, Commissioner for Democracy, Justice, the Rule of Law and Consumer Protection
Ms Jessika Roswall, Commissioner for the Environment, Water Resilience and the Competitive Circular Economy
Mr Stéphane Séjourné, Executive Vice-President for Prosperity and Industrial Strategy
Ms Ilze Juhansone, Secretary-General
The relevant Directorates-General, including DG Health & Food Safety, DG Environment, DG Agriculture and DG Research & Innovation
European Commission
Rue Breydel 4 / Breydelstraat 4
1040 Brussels, Belgium

**On behalf of the following organisations:**

*CNAFAL (Conseil national des associations familiales laïques), Collectif Vigilance OGM & Pesticides 16, FNAB (Fédération nationale d'agriculture biologique), FNE (France Nature Environnement), Follavoine, Générations Futures, GIET (Groupe International d'Études Transdisciplinaires), OGM Dangers, POLLINIS, Réseau Semences paysannes, Sciences citoyennes, SYNABIO (Syndicat des entreprises bio agroalimentaires)*

**Subject**: Concerns, requests for information and demands regarding the European Commission's Proposal for a Regulation on plants obtained through certain new genomic techniques and food and feed derived therefrom

20 February 2026

President Ursula von der Leyen,

Commissioner Olivér Várhelyi,

We, representatives of 13 environmental, consumers', and farmers' organisations from the organic and GMO-free sectors, hereby submit requests for information and demands to the European Commission regarding the circumstances of the drafting of the Proposal for a Regulation on plants obtained through certain new genomic techniques and food and feed derived therefrom, and amending Regulation (EU) 2017/625 (COM(2023) 411 final, 5 July 2023).

This European Commission Proposal for a Regulation on New Genomic Techniques (NGTs) – *hereinafter referred to as the Proposal* – provides for the exemption of a category of Genetically Modified Organisms (GMOs) derived from NGTs from the scope of Directive 2001/18/EC on GMOs, such that approximately 90% of future genetically modified plants will be exempted from the requirements for prior assessment and authorisation, risk management, traceability and labelling, thus hindering the freedom to choose whether to produce and consume with or without GMOs.

Having warned in vain for several years about the dangers of deregulating GMOs derived from NGTs, we are today officially expressing our deepest concerns regarding this Proposal. We have identified numerous shortcomings and failings in the way the Commission has prepared and drafted its legislative Proposal. This exemption for these new GMOs is in fact based on:

- paradigms lacking sufficient scientific basis, or even erroneous, despite numerous scientific studies and warnings that the Commission could not have ignored,
- shortcomings in consultations and impact assessments on fundamental issues, such as the classification criteria between NGT 1 and NGT 2, as well as inconsistencies in institutional expertise,
- a lack of consistency with existing legislation, with principles invoked by the Proposal itself, and with certain conclusions of its own scientific Agencies.

Furthermore, this Proposal fails to address two essential aspects: the patentability of GMOs derived from NGTs (and their impact on the additional cost of GM seeds, the availability of non-GM seeds and patent claims on native traits), as well as the coexistence of non-GM and organic farming sectors, both in the field and downstream.

These shortcomings reveal that the Commission has prioritised:

- a certain techno-solutionist approach to economic competitiveness and the ecological transition, to the detriment of health and the environment,
- the use of assumptions, *a priori* notions and scientifically unfounded paradigms, to the detriment of numerous contradictory studies warning of the dangers, risks and scientific shortcomings characterising the arguments used to justify deregulation,
- the demands of the biotechnology industries alone, to the detriment of the interests of other operators, consumers and citizens, taking for granted, without proof, the industry's promises regarding the benefits of NGTs.

We therefore consider that the Proposal was drawn up under conditions that violate several treaties, principles and fundamental rights of the European Union (EU), as well as the principles adopted by the Commission with a view to '*better regulation*', namely:

- *Precautionary Principle*: UNCED, Rio Declaration, 13 June 1992, Principle 15; Maastricht Treaty of 1992; TFEU, Article 191(2). On GMOs: Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 2000, Article 1; Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, Article 1, Annex II B; Regulation (EC) No 178/2002 on food safety, Articles 6.3 and 7.

- *Pursuit of a high level of human health protection in EU policies and actions*: Charter of Fundamental Rights of the EU, Article 35; TFEU, Article 168, particularly in the veterinary and phytosanitary fields, Article 168(4)(b); TFEU, Article 191(1).

- *Pursuit of a high level of environmental protection in EU policies and actions*: Charter of Fundamental Rights of the EU, Article 37; TFEU, Articles 12 and 191.

- *Pursuit of a high level of consumer protection*: Charter of Fundamental Rights of the EU, Article 38; TFEU, Articles 12, 114.3 and 169; Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, Articles 8, 14, 17 and 18.

- *The 'Do No Significant Harm' principle*: Regulation (EU) 2020/852 on the taxonomy defining sustainable activities within the EU; Communication from the European Commission, C(2025) 880 final.

- *Right to good administration (including adequate reasoning for legal acts)*: Charter of Fundamental Rights of the EU, Article 41; TFEU, Article 296; Communication from the European Commission, 'Better Regulation for Better Results – A Priority for the EU', 19 May 2015 COM(2015) 215 final; European Code of Good Administrative Behaviour (CEBCA) of the European Ombudsman, Articles 4, 6, 8, 9, 10, 11, 16, 18.

- *Principle of participation and information, and of the EU's functioning based on transparency, dialogue and consultation with citizens*: Aarhus Convention on Access to Information, Public Participation and Access to Justice in Environmental Matters, signed on 25 June 1998; TFEU, Article 15; Treaty on the Functioning of the European Union, Articles 10(3) and 11; Directive 2003/4/EC on public access to environmental information; Regulation (EC) No 1367/2006 on the implementation of the Aarhus Convention. And specifically on GMOs: Cartagena Protocol, Article 23; Aarhus Convention, Article 6a. And on food safety: Regulation (EC) No 178/2002, Section 1a.

- *Think Small First principle/priority for SMEs*: European Commission Communication, 'Better Regulation for Better Results – A Priority for the EU', 19 May 2015 COM(2015) 215 final.

- *Risk assessment based on the principles of excellence, independence, and transparency*: Pfizer case law of the CJEU (T-n°13/99).

- *Principle of adaptation to scientific knowledge:* TFEU, Article 191(3); CJEU, 21 March 2000, *Greenpeace France*, C-6/99, para. 44; Directive 2001/18/EC, Annex II, B.

- *Principle of proportionality*: Protocol to the TFEU on the application of the principles of subsidiarity and proportionality; TFEU, Article 5; CJEU case law (risk management measures 'proportionate' to the state of knowledge regarding risks).

- *Principle of legal certainty* (clarity, predictability, stability): general principle of EU law recognised by the CJEU (case law *Costa v Enel).*

- *Right to produce and consume with or without GMOs:* derived from Directive 2001/18/ EC.

Regarding the violation of these rights and principles, **our requests for clarification and explanations**, based on Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents, **as well as our concerns and demands, relate to the points set out in the following chapters**.

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## Chapter 1. Regarding the risks posed by GMOs derived from NGTs: the avoidance of studies demonstrating the existence of specific or non-specific, foreseeable and unforeseeable risks

Summary: *The Proposal's complete removal of any measures for the assessment and management of environmental and health risks for virtually all NGT derived GMOs under development is not based on comprehensive, independent and diverse scientific evidence, and seriously contravenes the precautionary principle enshrined in Directive 2001/18/EC, with which the Proposal is supposed to be* 'consistent*'. The Commission could not, however, ignore the numerous scientific studies warning of the risks, including systemic risks, associated with GM plants derived from NGTs. In accordance with the Precautionary Principle, the Commission should have initiated specific investigations into the foreseeable and unforeseeable risks involved and strengthened the specific and general surveillances' measures provided for in the GMO regulations.*

In the Proposal, research, risk assessment and risk management, whether foreseeable or not, are omitted for Category 1 plants derived from NGTs (GMO-NGT 1) – that is to say, almost all GMOs derived from NGTs set to be developed, as will be seen in Chapter 3 – in favour of a simple notification system without the possibility of any genuine, rigorous verification *a priori.* To justify this, the Commission relies on opinions issued, in particular, by the European Food Safety Authority (EFSA), which have failed to fully appreciate the risks to the organisms themselves as holobionts and their adaptation to the environment, to human and animal health, to the environment and, more generally, to ecosystems – risks which are, however, well documented in the scientific literature.

In this regard, we intend to demonstrate that the risks, even those that were foreseeable, were not properly addressed during the process of drafting the regulation and that the precautionary principle, to which the Commission is bound, is therefore not being respected in practice.

A- Shortcomings in the risk assessment

B- Focus on the total absence of a systemic assessment

### A- Shortcomings in the risk assessment

1- EFSA's scientific opinions downplayed the foreseeable risks

2- The European Commission simplified, and even ignored, certain conclusions of the EFSA

3- The European Commission has consistently ignored studies highlighting the risks

4 - The Proposal, despite a *pro forma* reference to it, does not respect the Precautionary Principle

5- The Proposal, despite a *pro forma* reference to it, does not respect the principle of '*Do No Significant Harm*'

6- Conclusion: principles not respected, demands and questions

## 1- EFSA's scientific opinions have downplayed the foreseeable risks

We will not address here the issue of unforeseen risks, which form part of the risk assessment process for any technology and the release of its products, including GMOs. It should be noted, however, that neither the EFSA nor the Commission emphasises the need to establish rules, procedures, and general surveillance networks concerning the release of products derived from NGTs to identify any unforeseen effects of these products.

The EFSA opinions (2012, 2020, 2022a, 2022b), cited by the Commission as scientific justifications for its Proposal, construct the erroneous general assumption that, due to the similarity in nature of the constituents of life (terrestrial, carbon-based, DNA with ATGC bases…), products derived from NGTs '*do not present additional risks*' compared to those derived from conventional breeding, which itself extends to *in vitro* techniques with unforeseeable unintended effects.

Such a hypothesis based on '***similarity***' leads to the absurd conclusion that **transgenic GMOs themselves, products of synthetic biology, and even products of xenobiology** under development for over 15 years — which are said to be similar in their mechanisms of reproduction and development[1] — would also be **equivalent** to **organisms resulting from the only evolution** currently known on our planet.

These studies do not comply with the Precautionary Principle, and do not themselves apply the risk assessment methodology in accordance with Directive 2001/18/EC, ignoring the complexity and unpredictability inherent in all life, and therefore even more so to the use of NGTs, despite the warnings in a wealth of scientific literature.

The studies published by EFSA demonstrate in particular:

a- A very limited scope of investigation, at the Commission's request

b- The disregard of off-target mutations and risks

c- A history of risk-free use cited, then disregarded

d- Negligence (or deliberate omission) on the part of the EFSA regarding studies alleging the existence of risks associated with NGTs

e- Questions regarding the independence of the invoked expert assessments

### a - A very limited scope of investigation, at the Commission's request

[1] On this very point see our statements in Chapter 7

In response to the Commission's highly restrictive mandates, EFSA **limited the scope of its studies** to:

- **solely the characteristics of the modified genetic sequence**. The repercussions on the genome, the pan-genome, and on the plant as whole organism interacting with various microbiomes (the consensus concept of the *holobiont*) were neither considered nor analysed by EFSA (contrary to the provisions of Directive 2001/18/EC), nor were effects at varying distances (e.g. different concepts of genes, non-linearly regulated pan-genomes, inter-tissue regulation, interactions with surrounding living organisms…) whether these involve coding sequences (some of which may contain regulatory elements within introns or exons) or non-coding sequences.

- **certain techniques,** whilst neglecting the entirety of NGT tools themselves obtained through complex genetic modifications, construction tools that are generally not replicated[2]. The EFSA has thus adopted an outdated approach, **focusing almost entirely on the – rather arbitrary – types of modification** (CRISPR-Cas9 and other Cas systems of interest, but also ZFNs, TALEN, Cre-Lox integrases...), **as well as on simple techniques, genes and enzymes** (ODM, siRNA, wild-type Cas, limiting itself to Cas9), **thereby intentionally omitting complex modifications of Cas nucleases** (modified into nickases, modifications for *Base Editing*, *Prime Editing*, gene fusions with methylases, integrases and transposases with complex effects not considered in the assessments) **or attempts to use systems with shorter half-lives** (mRNA, purified proteins)[3] with a view to reducing unintended modifications. **These restrictions do not even take into account** the impact of *in vitro* techniques, the biological origin of reagents which are, moreover, contaminated with DNA, and the most effective transformation systems based on a foreign biological system (*Agrobacterium*), both of which are sources of foreign DNA in modified pan-genomes that are not systematically screened for *via* ultra-deep sequencing.

This reductive approach reflects a **deliberate desire to restrict research and the identification of unintended modifications**, whereas, **as early as 2019**, studies raised the issue of complex modifications (*prime editing*, AI, directed *design*) and their impact—both genetic and epigenetic in the broad sense, as well as phenotypic[4]. As sources of new unintended modifications[5], **these complex modifications of the initial NGT tools were nevertheless completely ignored by the EFSA and subsequently by the Proposal.**

Furthermore, **the Commission did not request an assessment concerning unforeseen genetic modifications unlikely to occur in the context of conventional breeding** (or any other unregulated plant breeding process). This issue was therefore not the subject of a systematic study or a response from the EFSA that would meet the standards and practices of scientific research, if only through experimental evidence for various assertions and the replicability of the results put forward by stakeholders.

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2 To our knowledge, constructions generated by NGT tools have never been replicated by researchers, due to the complexity of carrying out such replication, even though the replicability of an experiment is the very essence of science and the basis of risk assessment.

3 The EFSA itself acknowledges this: '*An exhaustive list [of all possible scenarios] cannot be drawn up due to the wide variety of products that can be obtained through directed mutagenesis, cisgenesis and intragenesis*' (EFSA, October 2022).

4 Bertheau, 2019; Mundorf *et al.*, 2025.

5 According to David Liu of MIT (Broad Institute), creator of the *Base Editor* and *Prime Editor*, '*it is important to realise that there will probably never be a perfectly specific gene-editing agent, just as there has never been a perfectly specific drug that we have put into a human that does only what we want and does not engage any other molecule, any other site in the genome in that case'*. https://www.statnews.com/2022/11/15/perfection-too-high-a-bar-for-crispr-treatments-david-liu/

**b- The obscuring of off-target mutations and risks**

In an Opinion of 24 November 2020[6], the EFSA considered that, **in the light of carefully selected scientific publications,** '*the off-target mutations potentially induced by SDNs are of the same type as those mutations used in conventional breeding, including spontaneous mutations and those produced by physical and chemical mutagenesis*' (see our arguments on this point above). Asserting, without any supporting experimental evidence, that these off-target mutations are even **fewer** than in the case of conventional selection based on crossbreeding, the EFSA concludes that '*the analysis of potential off-targets would be of very limited value for the risk assessment*', **without any experimental evidence**. **The EFSA thus acknowledges**, *at the very least*, **its inability to predict the potential risks involved**, without calling for further studies, as required by the precautionary principle.

These conclusions consequently overlook a **vast and recognised body of scientific literature[7] which has demonstrated for years that the risks associated with *in vitro*, transformation and NGT techniques are numerous and significant**, even when limited solely to molecular aspects:

- Unintended off-target modifications and effects not detected by standard methods.
- Unintended modifications and effects on undocumented targets.
- Insertion of foreign DNA elements[8] that remain undetected in the absence of ultra-deep sequencing.
- Genomic and epigenetic tools based on complex chimeric genetic combinations of one or more copies of genes encoding nucleases, deaminases, methyltransferases, integrases, DNA repair inhibitor proteins, PAM delivery systems… not considered in risk assessment and regulation.
- Complex genomic rearrangements that may lead to loss of heterozygosity or chromosomal aberrations such as chromothripsis, with the production in offspring of micronuclei exhibiting non-Mendelian segregation.
- Epigenetic effects, epistatic and pleiotropic effects: the genome functions as a system of non-linear interactions, in which the effect of a modification depends heavily on its genetic, epigenetic and regulatory context.
- Unintended epigenetic (*sensu stricto*) and epitranscriptomic modifications, which are nevertheless well documented, including their effect on the expression of coding regions.
- Effects dependent on the genetic context (genetic background; see the growing importance of pan-genomes, millions of which are currently being sequenced in animals and plants).
- Unintended long-term or transgenerational effects (genetic but also epigenetic effects, for example, spanning at least 13 generations).
- Effects linked to the failure to consider the holobiont (and therefore the various internal and external microbiomes enabling, for example, plant tolerance to various biotic and abiotic stresses).
- Impact of the absence of coexistence procedures between GMO and non-GMO sectors, including organic farming.
- Systemic effects in agroecosystems (contamination of weeds, feral populations, herbicide-resistant weeds, etc.).

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6 EFSA, *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*, *EFSA Journal 2020*;18(11):6299, 14 pp.

7 See the bibliography in our Appendix 1.

8 Vectoring systems such as *Agrobacterium* or contaminating DNA resulting from the preparation of vectoring systems, or even all NTG tools (RNA, mRNA and Cas proteins/enzymes) derived from biological organisms such as yeasts, bacteria, etc.

Even when limiting the scope to molecular aspects alone, many publications on improving specificity and efficacy, and on reducing the number of off-target or unintended modifications on the target (*on-site*), demonstrate the widespread accidental side effects of *New Breeding Techniques* (NBTs, some of which have been renamed NGTs)[9].

To cite just a few authors, the literature clearly shows the negligence on the part of some biotechnologists - no doubt with the aim of promoting their techniques unhindered - of environmental effects on the expression of '*genes*' in response to biotic and abiotic stresses (Melotto *et al*., 2020). Similarly, it documents the fact that, even in the case of '*gene*' knockouts' via INDELs (insertions and deletions), unintended on-site modifications are observed[10]. It should also be noted that NGTs leave **transgenerational traces**[11] which are not considered in studies of unintended modifications, as these prove particularly difficult to investigate, both technically and financially. **These traces are therefore not considered in the EFSA opinions on SDN 1, 2 and 3, whose very premise is thus skewed**.[12]

Moreover, as Germini et al. (2018) very aptly pointed out, a comparison of techniques using the same plant models/pangenomes has never been carried out; this lack of verification raises questions regarding the undocumented assertions of the EFSA and the Commission.

More generally, the risks associated with NGTs are notoriously unpredictable as pointed out by the scientific literature[13].

More broadly, it should be noted that, despite the considerable capacity of EFSA's *staff* (permanent staff) and its ability to commission external studies, the Commission has been careful not to **ask EFSA to initiate genuine systematic literature reviews on the risks**, nor indeed on the concepts of '*continuity*' and **'***equivalence***'** put forward by the Commission (see Chapter 2). **This serious '*omission*' raises suspicions of a deliberate choice of informational and decision-making biases.** Taking all these elements into account would, however, have been essential for the assessment of the medium- and long-term impacts on the environment and health required by Directive 2001/18/EC.

### c- A history of safe use invoked, then forgotten

In its statement on the '*Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis*' of 30 September 2022, the EFSA makes the history of safe use (criterion 5: HoSU – *history of safe use*) one of the assessment criteria for these new GMOs. However, having acknowledged that these GMOs, derived from NGTs, do not have such a history – as indeed noted by the CJEU in 2018[14] - the EFSA ultimately recommends reducing the risk assessment to a bare minimum (in particular, no toxicological or food safety analysis would be required, barring exceptions that are difficult to determine).

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9 Rezza *et al*., 2019.

10 Tuladhar *et al*., 2019.

11 DNA damage leaves lasting traces on genome function, a phenomenon known as '*chromatin fatigue*', which has significant implications for ageing, disease and gene-editing technologies such as CRISPR (Bantele *et al.*, 2025). As highlighted by Faial (2025) '*Chromatin remembers past DNA damage*', including double-strand breaks caused by Cas.

12 Bantele *et al*., 2025.

13 GWAS studies show that it is very difficult (apart from a few rare cases) or even impossible to predict the phenotypic effects of genetic modifications (Grotzinger and Keller, 2022).

14 CJEU, judgment of 25 July 2018, Case C-528/16, *Confédération paysanne et al*.

### d- The EFSA's disregard for studies alleging the existence of risks associated with NGTs

In their various opinions[15], EFSA and its '*GMO Panel*' dismiss studies showing unexpected effects as: irrelevant, linked to '*poor practices*', or not generalisable, but **without incorporating them into a structured uncertainty analysis.** EFSA, through both its experts and its *staff* - **who ensure the continuity of the prevailing orthodoxy**[16] - thus only **considers the risk factors** highlighted by ANSES's opinions to **mere administrative categories**. It thereby avoids responding scientifically to scientific arguments**.** However, the **case law of the CJEU** consistently requires that **scientifically sound minority opinions** be considered. This is not the case here.

Furthermore, an examination of the '*minutes*' of the GMO Network meetings shows that **EFSA's opinions fall far short of reflecting the diversity of views held by national assessment bodies**, for example regarding **requests for systematic literature reviews and for greater consideration of the '*EFSA guidelines*' on risk assessment**[17]. The EFSA thus clearly appears to be playing a role in erasing differences in risk assessment requests and 'obfuscating the issue' when it disregards the rules.

**Under European risk law, the burden of proof regarding safety lies with the promoter of high-risk products, not with the critics.**

However, regarding NGTs:

- European authorities require critical studies to demonstrate a proven danger,
- any hypothetical risk is *a priori* disqualified because its assessment does not fit within the categories created by the EFSA and the Commission.

According to an analysis published in 2022 by Testbiotech[18], EFSA thus 'overlooked' 80% of the relevant publications submitted to it during the public consultation process. Similarly, according to Testbiotech, '*several publications provided by experts from EU Member States were not considered. Furthermore, even if publications were listed in the EFSA references, none of these were addressed in the reports to systematically examine unintended effects caused by NGT procedures*'.

Thus, to justify omitting a comprehensive risk assessment of GMOs derived from NGTs, **EFSA failed to consider a significant proportion of the scientific studies analysing the risks** associated with the use of plants derived from new genomic techniques in agriculture and their release into the environment[19]. **It left unanswered key questions** raised by important but overlooked studies, **notably those concerning the requirements and appropriate methods for detecting and assessing**, for instance, the direct and indirect effects, whether intentional or not, caused by organisms derived from

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15 EFSA Panel on Genetically Modified Organisms *et al.*, 2022; EFSA Panel on Genetically Modified Organisms *et al.*, 2020; European Food Safety Authority *et al.,* 2025; European Food Safety Authority *et al.*, 2021.

16 Demortain, 2011, 2017, Demortain and Borraz, 2015.

17 https://www.efsa.europa.eu/sites/default/files/2022-05/Minutes-13thGMONetwork-meeting.pdf

18 "New Genomic Techniques and unintended genetic changes: EFSA 'overlooked' most of the relevant publications", Testbiotech, 12 Dec. 2022. https://www.testbiotech.org/en/news/new-genomic-techniques-and-unintended-genetic-changes-efsa-overlooked-most-scientific-findings/

19 The risk of creating more persistent and invasive plants could be increased when widespread plants such as wild grasses, trees and herbs become the target of genetic modifications, see APHIS plant applications in the United States (Blackburn *et al.*, 2019; Blackburn, T. M., Bellard, C., and Ricciardi, A., 2019). It should be noted that exotic and invasive species are a major factor in the decline of biodiversity.

NGTs in ecosystems, or the specific effects, whether intentional or not, caused by NGT processes in terms of food, genetic, human, and animal safety (see the 2017 Parma conference).

### e- Questions regarding the independence of the expert assessments employed

**How can one explain such blindness** to the risks posed by GMOs derived from NGTs, despite these being well documented? It should be noted first and foremost that, regardless of the guidelines established, the **methods of recruiting and co-opting experts** are not without issue[20]. Furthermore, the **number of dossiers** (hundreds per year: GMO import authorisations, summary documents, guidelines…) addressed by the EFSA GMO Panel is **extremely high**, **especially given the very small number of experts**, although higher and more specialised than the **multidisciplinary European SAM** (Scientific Advice Mechanism). Even with the constant use of external experts, whose selection may be questioned, and even with calls for tenders for external reports, this small number does not allow for an in-depth examination of the proposed texts.

It is therefore EFSA's *staff* who gather the references, guide the content and draft most of the EFSA documents signed by this GMO Panel. It must therefore be acknowledged that the majority of EFSA's opinions and advice originate from the staff of permanent employees, in close coordination with Commission representatives, for whom adherence to the administrative framework takes precedence over the results of academic research. **This politicisation represents one of the factors behind the crisis of expertise**[21].

It should also be noted that within EFSA's current 'GMO panel', **many researchers are involved in the development of genetically modified plants**, some of whom have strong, recurring links with industry and actively campaign for the deregulation of GMOs[22]. The EFSA's purported expert mechanism, which provides for the selection of experts with a highly limited disciplinary diversity and strong ties to industry, runs every risk of leading to such biases.

The influence of **conflicts of interest** - whether industrial or simply career-related - on scientists' cognitive biases, the alteration of research agendas, and the publication of results favourable to those interests, even when publicly available, is a well-documented phenomenon regarding GMOs and, more generally, across all fields of research, **particularly when linked to regulation** and conflicts of interest[23]. **Unless they disavow their word, scientists do not change their opinions or mindset when they step out of the expert panel room**.

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20 Demortain, 2012.

21 Eyal, 2019, Bolsen and Druckman, 2015.

22 According to Testbiotech, nearly half of the 16 panel members are involved in the development of transgenic or NTG plants. In several cases, there has been or continues to be collaboration with industry, notably with Syngenta and Corteva. Five panel experts have filed patent applications for transgenic or NTG plants, often in collaboration with companies. The chair of the expert group on GMOs advises industry on risk assessment by the EFSA. Finally, many panel members are active in organisations such as EPSO, EU-SAGE and ARRIGE, which campaign for the deregulation of NTGs. Testbiotech, *Conflicts of interest taint the independence of EFSA – Experts linked to industry dominate the new GMO panel*, 5 September 2024. https://www.testbiotech.org/en/news/conflicts-of-interest-taint-the-independence-of-efsa/

23 Bero *et al.* 2016, 2018; Bhar and Denny, 2019; Fabbri *et al*. 2018; Guillemaud *et al.*, 2016, Resnik, 2007.

According to a joint statement[24] by 18 scientific experts on 5 December 2023, the many scientists who support the deregulation of this technique are involved in the development of NGTs and have a clear interest in accelerating their use and facilitating the commercialisation of GMO-NGT plants. Very often, **these scientists owe their careers to the development of these biotechnologies**, collaborate with companies in the sector, and, whilst they have not themselves set up start-ups, and are also involved in filing patents on the technology and derivative products.

### 2 - The European Commission has simplified, and even ignored, certain EFSA conclusions regarding the risks

In addition to the restrictive mandates given to EFSA by the Commission, as mentioned previously, several facts reveal **mismanagement** on the part of the Commission.

a- The Commission failed to highlight EFSA's inconsistency regarding the "history of safe use"

b - The Proposal is inconsistent with certain EFSA conclusions

c- The Commission reassures industry in the face of EFSA's nuanced opinions

#### a - The Commission failed to note the inconsistency in EFSA's approach regarding the '*History of Safe Use*' (HoSU)

As seen *supra*, having established that the HoSU was one of the assessment criteria for these new GMOs, and having acknowledged that GMOs derived from NGTs did not benefit from such a history, the EFSA recommended downplaying the risk assessment (EFSA Opinion, 30 Sept. 2022). The Commission should have highlighted this inconsistency, particularly considering the case law of the CJEU[25].

#### b- The Proposal is inconsistent with certain EFSA conclusions

The Commission, relying on EFSA's opinions, draws truncated conclusions (on this important point, we refer to our Annex 3, which provides more detailed examples of the Commission's selective interpretation of EFSA opinions).

- *On risk assessment*

Despite a broadly favourable stance towards streamlining risk assessment, EFSA recommended a **minimal case-by-case assessment** of the risks associated with GM plants derived from NGTs, even when they are deemed "*equivalent*" to conventional plants. Thus, whilst its 2012 study '*lumps together*'

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24 https://www.testbiotech.org/en/publikation/joint-statement-scientists-future-eu-regulation-NTG-plants-perspective-protection-goals/

25 CJEU, judgment of 25 July 2018, Case C-528/16, *Confédération paysanne and others*, confirmed by the judgment of 7 February 2023, Case C-688/21, *Confédération paysanne and others*: the exception relating to mutagenesis must be interpreted restrictively and applies only to methods traditionally used in a range of applications and long considered safe.

plants derived from conventional methods and those derived from cisgenesis, it nevertheless recommends a case-by-case risk assessment, as well as **considering the risks associated with large-scale release**[26].

Between 2012 and 2020[27], the EFSA published further opinions concluding that a risk assessment, even a simplified one, was necessary. Finally, in October 2022, the EFSA published a document setting out '*six main criteria to assist the risk assessment of these plants*' GMO- NGT. The EFSA also considered, without providing experimental evidence, '*plants produced by targeted mutagenesis, cisgenesis and intragenesis, **in some cases**, **do not pose new hazards** compared to plants produced with classical mutagenesis or conventional breeding techniques*'.

Regarding the risk assessment requirements set out in Directive 2001/18/EC, the Commission had even acknowledged, in its 2021 impact assessment[28], that it is only '***in some cases** [regulatory oversight and requirements] can be disproportionate or inadequate*'. **This important nuance has been omitted from the Proposal.** Furthermore, in the summary of this impact assessment published in July 2023, the Commission notes once again that '*EFSA also considered that **on a case-by-case basis**, a lesser amount of data might be needed for the risk assessment of plants produced by targeted mutagenesis and cisgenesis and therefore there is a need for flexibility in the data requirements for risk assessments. EFSA and other scientific bodies also concluded that, in targeted mutagenesis, off-target modifications are fewer than those occurring with most mutagenesis techniques and, where such changes occur, they are of the same types as those produced by conventional breeding*.' (summary of the impact assessment report of Sept. 2021, 5 July 2023, SWD(2023) 413 final).

It therefore follows from these various positions of the EFSA that:

- **a comprehensive risk assessment** of plants derived from NGTs **is necessary**.

- **in certain cases** — on an *ad hoc* basis, therefore, and not generally — certain plants derived from directed mutagenesis/cisgenesis/intragenesis **could** also **be obtained** through conventional breeding or may not present new risks when compared to classical mutagenesis or conventional methods.

**Ignoring the nuanced** (if not comprehensive) **conclusions of the EFSA**, the Proposal, however, asserts, contrary to the facts and scientific opinions, that the European Authority '*concluded that, as regards risks for human and animal health and the environment, there are **no specific hazards** linked to targeted mutagenesis or cisgenesis*'. The Commission can thus **falsely justify, in the same breath, that no further risk assessment will need to be carried out** for all GMOs derived from Category 1 NGTs (i.e.

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[26] EFSA (2012): '*The Panel is of the opinion that all these breeding methods can produce variable frequencies and severities of unintended effects. The frequency of unintended changes may differ between breeding techniques and **their occurrence cannot be predicted and needs to be assessed case by case**. Independent of the breeding method, undesirable phenotypes are generally removed during selection and testing programmes by breeders. The **risks to human and animal health and the environment will depend on exposure factor**s such as the extent to which the plant is cultivated and consumed*.'

[27] In its 2020 Opinion, the EFSA concluded that NGTs posed fewer risks than transgenesis, cisgenesis or intragenesis. It therefore recommends a risk assessment requiring fewer data but nevertheless carried out **on a case-by-case basis** depending on the new trait introduced: an **implicit recognition** that **dossiers** containing all the elements necessary for a comprehensive risk assessment **must be provided to the Agencies**.

[28] Ref. Ares (2021)5835503 – 24/09/2021. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_11592_2023_ADD_4

virtually all NGTs currently under development, see Chapter 3, §4), and that for GMOs derived from Category 2 NGTs, fewer risk data may be required[29].

- *On the applicability of the guidelines on the environmental risk assessment*

Regarding the applicability of the 2010 guidelines on the environmental risk assessment of genetically modified plants[30], the EFSA Scientific Panel on GMOs (2012a) states that all elements described in the guidelines may apply to cisgenic/intragenic plants, and that the relevance of applying specific elements of the guidelines is determined on a **case-by-case** basis. However, there is no trace of this '*applicability*' in the Proposal, even though it claims to be scientifically based on this EFSA study (2012a).

The Commission has thus presented the conclusions of its own scientific agencies in a partial (or rather distorted) manner to justify the absence of a risk assessment for NGT1, which may amount to a **selective, biased and partial presentation of the evidence**.

Thus, whilst it is indeed the legislator's responsibility to define the regulatory framework for GMOs (see §4), **the Commission cannot, however, 'scientifically' justify its Proposal by invoking opinions whose nuanced conclusions it disregards**. It must fully take responsibility for its political decisions that disregard scientific advice, whilst purely political are increasingly rejected by European citizens.

### c- The Commission reassures industry in the face of EFSA's nuanced opinions

Rather than paying heed to EFSA's nuanced conclusions, the European Commission has on the contrary, shown itself to be sympathetic to the concerns of biotechnology companies, which favour the abolition of any risk assessment. These companies had raised their concerns with the Commission following the EFSA's 2022 opinion stating that plants produced by certain NGTs did not present new risks '*in certain cases*'. In a letter to CropLife in January 2023, the Commission stated that EFSA's work '*on possible criteria for risk assessment also* ***feeds into this policy work as scientific advice*** *to the Commission for consideration.* ***This in no way prejudges what regulatory framework could eventually be proposed for NGT plants****. (...) A decision on whether risk assessment should be performed on NGT plants or not* ***is outside EFSA's remit, as you correctly noted***'.

## 3- The European Commission has consistently ignored scientific studies highlighting the risks

The Commission has sidestepped studies highlighting risks, even foreseeable ones, in the name of a purported constant improvement in NGT techniques and techniques relating to a purported '*improvement*' in '*conventional*' techniques.

a- The predominant reliance on studies that overlook risks

b- The suppression of studies demonstrating the existence of undesirable effects

[29] In particular: no health risk assessment, and only optional post-market environmental surveillance.
[30] EFSA GMO Panel, 2010.

### a- The predominant reliance on studies that overlook risks

Like the EFSA, **the European Commission relies heavily on studies that overlook both intentional and unintentional modifications and effects** – and thus overlook the risks – to justify *in the end* that there were '*no specific risks*'.

Analysis of the references used in the preparatory documents reveals an overwhelming predominance of studies demonstrating the technical feasibility of targeted modifications, comparisons of genetic or protein sequences, or general reviews concerning '*genome editing*'. Very few of the studies cited by the Commission aim to identify adverse effects or to test scenarios of environmental release. None address systemic effects (see *infra* Chapter 1-B).

As for the **numerous studies on the unintended effects** associated with NGTs and on the uncertainties regarding their phenotypic, environmental and health consequences, these are **either absent, marginalised, or simply dismissed** in the preparatory documents and expert reports: this constitutes a **confirmation bias in favour of the safety hypothesis, which becomes a founding postulate**.

The Proposal is thus based on a methodological confusion between the assessment of technical capability and the assessment of risks and hazards. The absence of observed risks in studies that do not seek them cannot constitute proof of their absence, especially when the Proposal rules on future products and practices about which we still know nothing.

The Commission is therefore committing a **manifest error of judgement:**

- by **equating an absence of negative data with proof of safety**,

- by treating technical capability studies as risk and hazard studies,

- by elevating a working hypothesis to the status of a scientific conclusion,

- and by implicitly asserting that this conclusion applies to an unknown future.

The Commission's preparatory documents, like the EFSA opinions, reveal that no dedicated experimental campaign has been conducted, contrary to the requirements of the precautionary principle, and that no comprehensive database of adverse effects exists:

- Impact Assessment SWD(2023) 412, section 'Evidence base': *'The evidence base for this impact assessment is largely built on existing studies, literature reviews, and scientific opinions. No new experimental studies were commissioned for the purposes of this impact assessment.'*

- Impact Assessment SWD(2023) 412, section 'Scientific knowledge and uncertainties': '*There is no comprehensive and systematic collection of data on unintended effects of genome editing techniques in plants*.'

- Impact Assessment SWD (2023) 412, section "*Limitations of the evidence*": "*Most available studies focus on the development and optimisation of the techniques rather than on the assessment of potential adverse effects*".

It should also be noted that the European Union has allocated only a very small – if any – portion to the risks posed by NGTs within its **research programmes** on NGTs[31]. In response to a written question from an MEP in 2021, the Commission was unable to cite **any project receiving EU funding for research into risks** caused by NGTs[32].

**b- The suppression of studies demonstrating the existence of undesirable effects**

**i) During the drafting of the Proposal, studies and warnings that the Commission could not ignore**

As seen *above,* **a wealth of literature has shown for years** that genetic manipulation, even the most precise, can lead to unintended modifications and thus undesirable effects, and pose risks at the level of the pan-genome used, the plant, the crop, and the environment in general, and consequently to their human and animal '*consumers*'.

**Before adopting its Proposal in July 2023, the Commission had therefore been duly warned and was thus fully aware of the shortcomings of its assertions and its Proposal**. In addition to the numerous scientific studies listed in our Annex 1, **scientists have repeatedly acted**, specifically and officially with the Commission, to inform it of the risks associated with the use of NGTs.

Thus, a **public statement by over 100 internationally renowned scientists**, in an open letter[33] published in November 2023, expressed serious concerns regarding the lack of scientific rigour and premature assumptions regarding safety. In their view, the fact that a plant exhibits *similar* characteristics does not mean that the process by which these new organisms are produced is no longer of significance: on the contrary, unintended modifications induced by the process may pose risks to health or the environment. Finally, the '*Call of the 100*' laments that the Commission appears to **confuse precision with safety**: NGTs are said to be safer because they are more precise. Yet unintended modifications are common with these new techniques for producing GMOs, such as CRISPR/Cas, both at the site of targeted intervention locus as elsewhere in the genome.

We may also mention the warning issued in the **official letter** sent on 30 March 2021 to the Vice-President of the European Commission, Mr Timmermans, **by 16 organisations** (and co-signed by around a hundred local European associations) from various sectors (food, environment, civil society, organic). This document highlighted the fact that NGTs can cause significant undesirable genetic and epigenetic changes, which may prove very different from what occurs naturally.

**Several national authorities and agencies** had also published opinions demonstrating the need for a case-by-case risk assessment, which is essential for techniques for which there is a lack of historical data. This is the case with institutional expert reports from France (ANSES) and Germany (BfN), as well as collective expert reports (COGEM, ENSSER). We should also mention the Note from the French Authorities dated 20 July 2022[34].

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31 See Commission Staff Working Document, *Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16*, §4-5-1.

32 https://www.europarl.europa.eu/doceo/document/E-9-2021-003643_EN.html

33 https://newgmo.org/2023/11/19/open-letter-serious-concerns-about-the-eu-commission-proposal-on-new-genomic-techniques/

34 Ref. SGAE/EEC/2022/504.

This case-by-case assessment had been deemed necessary by these bodies and expert groups both for the techniques themselves and for the final products – in line with Directive 2001/18/EC, which regulates GMOs precisely because of the use of genetic manipulation techniques.

**ii) Following the adoption of the Proposal in July 2023, several studies have corroborated the existence of specific risks associated with GMOs derived from NGTs**

However, the Commission has so far **still not requested a second opinion from EFSA regarding these new critical studies**, despite the significant methodological shortcomings and major potential environmental impacts highlighted by these studies.

Among these recent critical studies, particular mention should be made of those by Koller (2025), Koller and Cieslak (2023), Koller *et al.* (2024), Koller *et al*. (2023), Mundorf *et al*. (2025). Several expert agencies have also expressed serious concerns, including:

***ANSES**[35]/ Opinion (2022, 2023, 2024) on the risks and socio-economic issues associated with NGT plants, Collective Expert Report, January 2024. The Agency proposes a **case-by-case assessment** that considers both the precision of the technique used and the characteristics of the plant obtained once the genome has been modified, whilst also considering all potential toxicological, nutritional, agronomic and environmental consequences of the new characteristics. Certain risks identified for NGT plants are, fundamentally, not radically different from those arising from transgenesis techniques, but the level of exposure to the resulting plants could be much higher given the diversity of possible applications and pan-genomes.

***BfN**[36]/ (2021, 2022, 2023, 2024a, 2024b,) '*For a science-based regulation of plants from new genetic techniques'*, Policy Brief 2024: according to this study, it is impossible to rule out the potential risks of plants derived from NGTs solely on the basis of the size and number of modifications to the DNA sequence. Even minor changes may present high levels of potential risk to the environment and human health. NGTs can modify plants in ways that differ significantly from those achieved through conventional breeding.

***COGEM**[37]/ Collective expert report by IRD researchers for the Dutch COGEM on gene flow – '*Introgression of traits from NGT products into wild plants*' (COGEM *et al.* 2025).

***ENSSER**[38]/Analysis statement by ENSSER '*EU Commission's new GM proposal: no science no safety*'. Annex 1 on NGT "equivalence criteria" (October 2023). Scientists from the European Network for Social and Environmental Justice believe, following an analysis of existing scientific knowledge, that the Proposal fails to consider the unintended damage that new techniques such as CRISPR/Cas introduce into the genome.

***UmweltBundesamt**[39]/ Etude New Genetic Engineering – Possible Unintended Effects, November 2023. This latest study notably reviews the unexpected effects observed in tomatoes, rice and wheat derived from NGT.

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35 ANSES: French National Agency for Food, Environmental and Occupational Health & Safety.

36 BfN: Bundesamt für Naturschutz, German Federal Agency for Nature Conservation.

37 COGEM: The Netherlands Commission on Genetic Modification.

38 ENSSER: European Network of Scientists for Social and Environmental Responsibility.

39 UmweltBundesamt: Austrian Environment Agency. See also: https://www.ages.at/en/plant/future-crop-production.

It is also worth noting academic articles and institutional reports (Koller *et al*., 2024; Mundorf *et al.*, 2025) which highlight a **complete lack of integration of a rigorous risk assessment**, which, from a scientific perspective, clearly means that the proposed framework does not comply with the **precautionary principle**.

### 4 - The Proposal, despite a *pro forma* reference to it, does not comply with the Precautionary Principle

The European Commission, which makes a *pro forma* reference to the Precautionary Principle in its Proposal, disregards this principle enshrined in the Treaties and in the regulations governing GMOs. The Precautionary Principle is enshrined in the Treaties of the European Union (Maastricht 1992, TFEU, Article 191(2)). It follows from these Treaties and the case law of the Court of Justice of the European Union (CJEU) that, by virtue of the Precautionary Principle, **in the event of uncertainty regarding the existence or extent of risks to human health or the environment, protective measures may be taken without waiting for the reality and severity of these risks to be fully established, and research must be undertaken**.

The Precautionary Principle has a specific application in the field of GMOs. The **Cartagena Protocol** on Biosafety (2000), to which the EU and its Member States are signatories, requires that **risk assessments** be carried out on a **case-by-case basis** for GMOs prior to their placing on the market. Directive 2001/18/EC on GMOs structures the entire current framework for risk assessment, authorisation and management around the precautionary principle.

By concluding that there are no '*specific risks*' for certain categories of NGT plants **without relying on data from experimental protocols designed to actively identify such risks**, the Proposal is based on an insufficient assessment of risks, not only scientifically but also legally, thereby violating the precautionary principle.

- As a *lex specialis* of Directive 2001/18/EC, **the Proposal must ensure, in an effective and not merely *pro forma* manner, a high level of protection for human and animal health and the environment.** In this respect, the Proposal is not in line with the case law of the CJEU which, when examining the compatibility of Regulation (EC) No 1107/2009 on plant protection products with the Precautionary Principle, ruled that, in order to determine the compatibility of a regulation with the Precautionary Principle, it is not sufficient for that principle to be mentioned in a recital of the regulation.

  In this case, **the Commission did not even include the Precautionary Principle in the recitals of its proposal**. Yet these recitals fulfil the legislator's obligation to state the reasons for the Union's legal acts, in accordance with Article 296(2) TFEU, and constitute an important basis for the application and interpretation of legislation. **The Proposal is self-contradictory** because, on the one hand, it states that it takes account of the Precautionary Principle (explanatory memorandum) and aims to be consistent with the Directive on the release of GMOs, but, on the other hand, it does not include this objective in its recitals or in its articles.

  Not only is the Precautionary Principle not duly mentioned in the Proposal, but, more importantly, it is not respected in practice since the proposed regulatory provisions do not consider all the potential risks associated with the use and large-scale release of GMOs -NGTs, and provides for no precautionary measures regarding a broad category of NGTs, nor for research to reduce uncertainty. **The Proposal is therefore inconsistent** with secondary legislation designed, from the outset,

entirely around a Precautionary Principle implemented through risk assessment and management measures[40].

- As we have seen, the European Commission **has ignored, in a field characterised by uncertainty regarding risks, scientific opinions that do not corroborate its assumption of an absence of specific risk**s associated with NGTs. The anomalies observed (and not merely suspected) by Risk evaluation Agencies and leading research institutes were not sufficient to prompt the Commission to introduce precautionary measures (based in particular on prior case-by-case risk assessments), as well as rigorous post-marketing monitoring (specific and general surveillance) designed to document potential effects that may not have been identified during the assessment phase. *At the very least*, **the risks thus extensively documented should have compelled the Commission to acknowledge**, right from the recitals, **the existence of documented potential risks**, which would have led it **to clearly justify to the public the choice made** by the Commission **to accept the risks** entailed by the exemptions, in order to prioritise interests other than those of environmental and health protection.

  Indeed, whilst the legislator has discretion to apply (or not) the Precautionary Principle, for example by exempting, as in this case, a particular category of GMOs, it must do so **under three conditions, in order to be 'consistent' with the TFEU, the requirements of Directive 2001/18/EC and the principles of transparency and sufficient legislative justification**:

  1. having first undertaken a comprehensive risk assessment in accordance with the principles established by Directive 2001/18/EC, and not a limited assessment focusing solely on modified genetic sequences, whilst overlooking all unintended off-target effects of which it could not but have been aware,
  2. acknowledge in the body of the text (recitals, articles and/or annexes) the existence of specific potential risks,
  3. clearly justify in the Proposal why, in the absence of precautionary measures, these risks will be incurred, to the detriment of health and the environment. The Commission's reference to the alleged '*sustainability*' of NGTs, as will be seen in Chapter 4, does not appear in any way conclusive in this regard to offset the risk-taking.

Furthermore, with regard to risk assessment, particularly where risks are uncertain, the **Court of Justice of the European Union (CJEU) requires** a scientific assessment that is as comprehensive, thorough and objective as possible, carried out using a transparent methodology, based on the most reliable, recent and comprehensive, based on scientific opinions grounded in the principles of excellence, transparency and independence, and on a comparison of the most representative scientific theories[41]. **These case-law requirements were not met** during the drafting of the Proposal for risk assessment, as we have seen, and as is further demonstrated in the following chapters as well as in our Annexes 3 and 5.

- Finally, it should be noted that the requirements of the **Cartagena Protocol** (mandatory risk assessment, prior to release and cross-boundary transportation and carried out on a case-by-case basis) are not met by the Proposal when it provides for the general exclusion of Category 1 NGT plants from the scope of Directive 2001/18/EC, on the basis of purely formal criteria (see Chapter 3), unrelated to risks (nor to the expected benefits), without taking into account unintended changes and effects.

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40 Directive 2001/18/EC refers to the precautionary principle in Article 1 "Objectives": '*In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment* (...)'.

41 CJEU, Case T-13/99 *Pfizer Animal Health SA v Council*; *Council*; Case T-70/99 *Alpharma Inc. v Council*; Case T-74/00 *Artegodan GmbH and Others v Commission*; Case C-236/01 *Monsanto Agricoltura Italia SpA and Others*

**5- The Proposal, despite a *pro forma* invocation, does not comply with the principle of '*Do No Significant Harm*'**

Like the Precautionary Principle, the principle of "*Do No Significant Harm"*[42] is invoked by the Proposal merely *pro forma*. According to the explanatory memorandum of the Proposal, '*In full alignment with the '*do no significant harm*' principle, the preferred option includes procedures to ensure that NGT plants are only released or placed on the market if they are considered as safe as their conventional counterparts'.*

However, this principle is completely ignored by the Proposal insofar since, for approximately 90% of NGTs (as will be seen in Chapter 3), **no procedure exists to '*guarantee*' this equivalence of '*safety*'**:

- The verification procedures set out in Articles 6 and 7 offer no such guarantee. GM plants derived from Category 1 NGTs – that is, virtually all NGTs currently under development – will never be subject to an environmental and health risk assessment. Furthermore, the Commission's authorisation decisions will be taken based on partial information provided solely by the notifier, without information on the risks and without the technical or temporal capacity (very short deadlines) to genuinely verify the content and accuracy of such information[43].
- The decision to authorise a NGT Category 1 GM plant for field trials may subsequently be valid for placing it on the market throughout the Union[44]. With this automatic transfer of approval from one status to another, there will be no means of verifying, prior to wider dissemination – whether voluntary but uncontrolled – whether field trials have previously identified any risks, damage or failures, whether foreseeable or not.
- In the absence of any traceability measures, labelling (except for seeds) and post-marketing surveillance, in the event of observed harm, no procedure is in place to ensure that seed producers, farmers and consumers have access to plants derived from NGT 1 that are '*as safe*' as their supposed conventional '*equivalents*'.

**6 - Conclusion: principles that are not respected, claims and questions**

**Principles that are not followed**:

In conclusion to this Chapter 1-A, we consider that the way the European Commission drafted the Proposal for a Regulation on NGTs seriously contravenes the principles mentioned in the introduction, and in particular:

- *Precautionary Principle*: due to the Commission having **imposed a restricted mandate on EFSA** (and, more generally, a restricted administrative framework on European experts) for prior opinions; having **failed to request assessments** of unintended genetic modifications unlikely to occur in conventional breeding, assessments comparing techniques on the same plant models/pangenomes, and more generally a systematic review of the literature on risks; also due to **having relied solely on the opinions of EFSA and the JRC** within the restricted mandates, **without considering or**

42 The DNSH principle (*Do No Significant Harm*) is an EU principle set out in Regulation 2020/852/EU on taxonomy, which defines sustainable activities within the EU.

43 Articles 6 and 7 of the Proposal.

44 Explanatory Memorandum to the Proposal, p. 16.

**adequately reporting on the extensive literature, as well as the numerous warnings, opinions and scientific publications** sent directly to it to alert it to the risks posed by the release of GMOs-NGT, all of which were warnings **that the Commission could not ignore**; by relying solely on EFSA's assertion regarding off-target mutations without any experimental evidence; and, finally, by basing its Proposal scientifically on EFSA's opinions **without adopting EFSA's nuanced position** on the need for a risk assessment in certain cases.

- *Principles of excellence, transparency, and independence in scientific risk assessment*: for the reasons set out above.

- Due to the situation arising from the failure to observe the precautionary principle and the release of most NGT GMOs without risk assessment or monitoring: the *right to a healthy environment, the Principle of information and participation, and the Principle of free choice to produce and consume with or without GMOs*.

- *Requirement for duly justified legislation*: the Commission has chosen to ignore the warnings contained in a wealth of scientific literature on the risks; the bulk of the justification for the Proposal is based on this denial and is therefore not legitimate.

- *Principle of consistency*: with two elements with which the Proposal claims to be consistent, namely, on the one hand, Directive 2001/18/EC (during the drafting of the Proposal, no risk assessment of NGT GMOs was carried out in accordance with Directive 2001/18/EC and subsequent guidelines), and on the other hand, the principle of 'do no significant harm'.

- *Principles of transparency and information*: due to the lack of any means of verifying, prior to wider release, whether field trials have previously identified any risks, damage, or failures.

**Our questions and demands:**

We call on the European Commission to provide information, clarification, and action on the following points:

**a- Regarding the Precautionary Principle:**

To give due consideration to the precautionary principle, we ask the Commission:

- to mandate EFSA to provide a **comprehensive literature review of the generic potential of NGTs to cause specific unintended genetic modifications that are unlikely to occur with conventional breeding methods**, as it should have done during the drafting of the Proposal. This type of prior assessment is required by Directives 2001/18/EC and 2018/350/EU.

- to launch without delay a **research programme on the assessment of risk**s, overlooked by the Proposal, **related to microbiomes and complex modifications** (*prime editing*, AI, directed *design*, etc.). To this end, it is essential to diversify the **disciplines involved by drawing** not only on molecular biologists and a few population biologists, but also on specialists in agroecology, agronomy, developmental biology, ecology, environmental biosafety, environmental sciences, genetic toxicology, plant physiology, soil microbiology, technology assessment and veterinary medicine, as well as specialists competent to conduct independent and conflicting socioeconomic assessments.

**b- Regarding the EFSA and prior expert assessment:**

*Our questions:*

- How does the Commission justify disregarding EFSA's opinions recommending a risk assessment '*in certain cases*', in favour of an unfounded assertion in the Proposal that there is no specific risk whatsoever, even though these opinions are presented by the Commission as constituting the scientific justification for deregulating a significant category of NGT GMOs? More specifically, on what scientific grounds did the European Commission adopt the EFSA's opinion regarding the need for an assessment (at least *a minima*) of risks only for Category 2 NGTs, and not for Category 1 NGTs?

- To what extent has the European Commission ensured that the EFSA, in its opinions on the risks associated with GMOs derived from NGTs, has indeed taken into account, in its conclusions, the risk assessment principles set out in **Annex II of Directive 2001/18/EC**, which specifically requires an examination of long-term risks, given that EFSA itself acknowledges that the cultivation of NGTs lacks a sufficient track record (Opinion of 30 September 2022)?

*Our requests:*

We call on the European Commission:

- to **ask EFSA to broaden the disciplines represented within the "GMO Panel" and the external experts consulted**: economists, specialists in agroecology, agronomy, developmental biology, ecology, environmental biosafety, environmental sciences, genetic toxicology, plant physiology, plant population genetics, soil microbiology, technology assessment and veterinary medicine, as well as specialists competent to carry out independent and critical socio-economic assessments. To enable a more comprehensive approach to the risks and legislative impact of the Proposal, the expertise of statisticians and biologists otherwise involved in the development of biotechnologies would not suffice. This diversification of disciplines will also help to limit the conflicts of interest that inevitably arise within the EFSA when too many experts are involved in one way or another in the development of NGTs, often in cooperation with industry.

- to provide us with the **composition of EFSA's "GMO panel"**, as well as the declarations of interest of its members who adopted EFSA's opinions on NGTs in 2012 and again in 2022. Among the experts sitting on assessment bodies (such as EFSA) or advising the Commission, which of them hold patents on CRISPR tools, or are funded directly or indirectly by biotechnology companies or industry associations, or are involved in biotechnology start-ups?

- to provide us with access to the full minutes of meetings and to all documents and emails exchanged between the ***staff* of EFSA** and the experts, as well as between experts via the '*track-change*' feature used during the drafting of EFSA opinions (*scoping*, etc.) and the preparation of the Proposal, in order to assess the contribution of the *staff* within EFSA's expertise on GMOs.

- to provide us with all correspondence between the Commission and staff, as well as with members of the **SAM** (Scientific Advice Mechanism) and amongst its members during the preparation of SAM opinions concerning NGTs and their regulatory framework, as well as the identities of the members of the **SAPEA** (Science Advice for Policy by European Academies) who were consulted by the SAM on this occasion, and their declarations of interest.

**c- Regarding the interests considered:**

- According to the Explanatory Memorandum to the Proposal (p. 9), '*Various stakeholders (biotechnology/biotech industry, plant breeding/seeds, plant protection products/fertilisers, feed, ornamental plants sector and trade sector) believe that risk assessment is not needed when these plants could have been produced through conventional plant breeding or classical mutagenesis.'*. Regarding this risk assessment, **no university or research centre is mentioned, nor are consumer representatives, environmental associations, or farmers and seed producers affected** by the deregulation of NGTs. This passage suggests that the European Commission's position on risk assessment has been primarily shaped by economic actors with a vested interest in the development of biotechnology, despite its fundamental mission being to represent the European public interest[45].

- At the same time, the paradigms underpinning the proposal to deregulate GMOs obtained by NGT1 (notably the absence of specific risks associated with NGTs) correspond exactly to those championed by the biotechnology industry, without taking divergent scientific opinions into account in any way, and without even addressing the EFSA's doubts and recommendations in favour of a case-by-case risk assessment. However, according to the case law of the CJEU, the precautionary principle requires the competent authorities to take appropriate measures to prevent certain potential risks to public health, safety, and the environment, **by giving priority to the requirements relating to the protection of these interests over economic interests**.

We therefore call on the European Commission:

- to identify **the stakeholders** (biotechnology companies) who provided the '*opinions*' and information that may have led the Commission to dispense entirely with a case-by-case scientific risk assessment for NGT 1.

- to provide us with their names, the opinions they submitted and the email correspondence, or any other form of communication, with the Commission (including with the SAM – Scientific Advice Mechanism), specifying the arguments they used to convince the Commission not to carry out any risk assessment for NGT 1.

**d- Regarding studies conducted after July 2023:**

- What is the European Commission's current position regarding the studies mentioned *supra* (§3, b-ii) which highlight the specific risks associated with NGTs, including Category 1, and how does it intend to take them into account?

  See the studies by the following national expert agencies: ANSES (2024), BfN (2024), COGEM (2025), ENSSER (2023), Umweltbundesamt (2023) and Ages.

- Can the Commission refer these important studies to EFSA as soon as possible for an opinion, and explain why it has not done so previously?

[45] On lobbying tactics to deregulate NTG GMOs: https://corporateeurope.org/en/2021/03/derailing-eu-rules-new-gmos

### B/ Focus on the total absence of systemic assessment

Summary: *NTGs, and in particular CRISPR/CasX systems, are paving the way for major transformations in fields as diverse as health, agriculture, the environment, wildlife management, and quite simply life itself. New biotechnologies make it possible to modify, intentionally or unintentionally, the intimate functioning of living systems about which we have only very limited knowledge. Based on scientific knowledge of complex systems (see our Appendix 1-Bibliography, §2), we will show how the rapid, large-scale introduction of GMOs derived from NTGs could represent a major disruptive element in the organisation of ecosystems and societies. While their power and effectiveness are now well established at the molecular level, it remains crucial to recognise that these innovations interact with complex systems whose dynamics are non-linear, non-ergodic and sensitive to localised disturbances. Such dynamics escape conventional regulation because they cannot be confined and can have cross-border, unpredictable and irreversible consequences.*

In its Proposal, the European Commission presents GMOs-NTGs as if they were manufactured objects, using an analytical and reductionist approach that neglects the sustainability of ecosystems and societies. This perspective has led it to ignore, in the Proposal, the systemic risks associated with GMOs derived from NGTs. Biotechnology concerns **nothing less than living organisms, complex adaptive** systems of which humans, in particular, are a part, and which the Proposal disregards.

#### Genetic reductionism and the reality of living organisms

Using an analytical and reductionist approach, the Commission reduces a plant to a genetic sequence: a mutation would have the same general molecular nature (and, by implication, the same effect resulting in the same phenotype) regardless of how of obtaining it in any pangenome, and it is on this paradigm that it claims to base the equivalence between natural and artificial mutations.

However, a plant cannot be reduced in this way to its genome, and even less to a part of it, as we have seen in Chapter 1, §1. A genetic sequence cannot function on its own: it is essential that it has the pangenomic environment of the cell and the rest of the plant, which itself needs a wider environment (microbiota, soil, air, climate, biodiversity, etc.). Every plant is thus the product of an evolutionary history and is part of sociological practices. The reductionist view proposed by the European Commission makes no biological sense when the subject is an entire plant grown in nature, rather than cells grown in a laboratory (Mundorf 2025).

#### Complex systems: intertwined ecosystems and societies

'*Complex natural systems*', which include ecosystems and societies, including human societies (Vasconcelos 2023), are affected by biotechnologies and, in particular, by new techniques for artificial genome modification. Furthermore, societies and ecosystems are closely intertwined and, although they can be distinguished, they cannot be separated in terms of their nature and evolution. Thus, humans, in addition to being social beings acting on ecosystems systems, are living beings, part of ecosystems (Norgaard 1994, Berkes 1998, Laland 2000, Berkes 2003, Schweizer 2024, IPBES 2019, for example).

The challenges associated with complex natural systems concern not only individuals and their social activities, but also the way of life of humanity, and even its very possibilities for existence, at a time when everything suggests that we are close to a tipping point on a biosphere scale (Barnosky 2012, Steffen 2018, IPBES 2019, Richardson 2023, Rockström 2023). Humanity finds itself in an unprecedented historical situation: it is altering the conditions under which the planet functions without fully understanding the dynamics involved (Ceballos 2017, Lenton 2025).

**The biosphere in a critical zone and the need for sustainability**

'*The most worrying finding is that all the limits related to the biosphere, which provide the resilience of the Earth system, are close to or beyond high-risk zones. Planetary resilience is declining precisely when it is most needed to absorb increasing anthropogenic disturbances. There is therefore an urgent need for scientific and policy tools capable of reliably and regularly analysing the integrated Earth system and guiding decision-making processes to avoid a shift to less habitable states*.' (Richardson 2023)

In such a context, sustainability is not about optimising isolated sectors, but about keeping the ecosphere within its range of viability, despite irreducible uncertainty. The major problem currently facing humanity therefore concerns the impact of human activities on the organisation of the ecosphere as a complex adaptive system, this organisation already being clearly profoundly altered[46]. It is therefore within the framework of a **systemic** issue that techniques modifying the natural evolution of living beings must be evaluated.

**The Precautionary Principle, a relevant legal framework for radical**

In biology, '*natural evolution*', which gives rise to the world in which we live, is the context in which all issues must be considered (Dobhzansky 1973). This is particularly the case when new genomic techniques are likely to have a broad, profound and immeasurable impact on this adaptive evolution. The precautionary principle must be imposed in view of this systemic perspective, and its effective implementation requires risk assessment and management, as required by Directive 2001/18/EC.

To give an idea of the quantitative relationship between artificial mutations and natural evolution, we can consider a specific case: the maize genome (*Zea mays*). It contains approximately 2.3 billion base pairs (≈ 2.3 Gb). The number of possible combinations of base pairs is approximately $10^{1\,400\,000\,000}$ (10 to the power of 1.4 billion), compared to the number of atoms in the visible universe: $10^{8}$. With maize, we are therefore faced with an almost infinite number of possibilities, and this with only one maize pangenome.

This represents such a vast space of possibilities that no physical process can explore more than an infinitesimal fraction of it. Out of 10 to the power of 1.4 billion possible sequences, the vast majority are non-viable, a tiny fraction is functional, an even smaller fraction is adaptive, and an infinitesimal fraction is knowable.

The quasi-infinity is real mathematically, but biologically very constrained, and in a necessarily non-random way. In other words, the random selection of a combination has no real possibility of producing an element compatible with any living system whatsoever. Evolution does not draw randomly from the space of possibilities; it moves locally, through small variations around already viable genomes, each evolution being contingent, but confronted with the organisation of the system concerned, i.e. ontologically historical.

'Evolutionary chance' means: undirected variations, but within a highly structured space. The combinatorial immensity of the genome does not justify the trivialisation of genetic interventions: evolution only explores an extremely constrained subset of this space, while **NTGs allow for directed**

[46] « *Denying the crisis, simply accepting it and doing nothing, or even embracing it for the ostensible benefit of humanity, are not appropriate options and pave the way for the Earth to continue on its sad trajectory towards a Sixth Mass Extinction* » (Cowie 2022).

**leaps outside historically and ecologically proven** trajectories, made compatible with the whole via self-organising recursive phenomena.

We thus face:
- a complex non-linear system,
- a non-ergodic system (Magalam 2022, Marin 2025),
- effects dependent on multi-level interactions (genes, networks, phenotypes, agroecosystems),
- genotypes outside the historical learning domain (no comparable evolutionary data for intentional biotechnological constructions).

**Radical uncertainty, irreversibility and the need for surveillances**

When genetic intervention makes it possible to achieve states outside the space of evolutionarily accessible trajectories, **the absence of comparable biological precedents prevents any robust estimation of the long-term** consequences. This situation corresponds to **radical uncertainty** in the epistemological sense, **justifying the application of the precautionary principle** regardless of the apparent small scale of the modifications introduced.

If, despite everything, the decision is made to engage in the widespread use of new and increasingly rapid artificial genetic modifications, it is then necessary, at the very least, to ensure that the operating mode and its effects are reversible. Indeed, when a major risk is involved, the decision to take it can only be cautious and gradual, and must ensure that the authorised practices are reversible and avoid irreversible contamination.

**1- Contamination of genes from GMO-NTG**

It is impossible to 'recover' modified genes that have been introduced by pollination into other varieties or even other wild species. At the systemic level, this is referred to as an **ahistorical disruption of the dynamics of living** systems. The situation is all the more worrying given that **the criteria proposed by the European Commission allow plants classified in category 1, i.e. those that have not been assessed, untracked, to produce new proteins or RNAs that may have never been produced in nature** (Mundorf 2025). The Proposal does not provide for **any assessment of the safety of these products, which are currently unknown and unpredictable in their forms**, in relation to human, animal and plant health, ecosystems, societies and, more generally, the complex adaptive systems on which humans depend.

*Question*: What scientific method does the Commission have at its disposal to predict the safety of products that are currently unknown and unpredictable in their forms?

*Question*: Has the Commission assessed the systemic consequences of this leakage of artificially modified genes into ecosystems, including its sociological consequences?

*Question*: What methods, budgets and human resources does the Commission have, and will it have at its disposal to monitor the spread and condemnation of gene flows from GMOs-NTGs, including category 1?

2- **Co-evolution and path dependency**

For biotechnologies, the classic sociological description known as '*path dependency*' (Arthur 1989, Katz 1985, Pierson 2000) can be understood as follows: if biotechnologies benefit from *a priori* agreement on the part of political and industrial decision-makers, they will inevitably modulate (and

have already modulated) agricultural and industrial sectors, markets and regulations to their advantage. In the absence of flexible coexistence (see the conclusions of the European Co-Extra programme, which concluded that only coexistence in dedicated areas is viable), **this technological lock-in is detrimental to alternatives that are more compatible with European 'sustainability' objectives, particularly organic farming**. The promoters of NTGs are aware of this, as they advocate the authorisation of NTG products in organic farming (G6/CNRS 2024).

We can refer to the experience of the massive use of pesticides, which it is technically possible to stop drastically, but which is proving to be extremely difficult sociologically.

However, **path dependency and irreversibility** are not simply side effects of technological progress: they **are drivers of systemic vulnerability**. A risk assessment that does not take them into account underestimates fragility, misses tipping points and sets us on **paths that will be difficult, costly or impossible to correct**. The robustness of assessments and policies depends not only on the assessment of current and future threats, but also on paths that will be impossible to change tomorrow.

### Human intentionality and the breakdown of evolutionary regulations

Complex natural systems are ontologically historical and massively recursive (Eigen 1977, Hammond 2013, Kruzewski 2022, Tabilo Alvarez 2023, Jerab 2025, Truckovich 2025, Marwan 2025, Joseph 2025) in the sense that their ongoing evolution consists of bringing about a set of restrictions and facilitations (Longo 2012, 2013) that retroactively affect historically earlier levels of organisation. This recursion is the prevailing, essential phenomenon that ensures the coherence of natural systems.

Intentionality exists in animals and even plants, **but it remains within the overall natural evolutionary process**. A large part of emerging human intentionality operates **outside the evolutionary framework from which it originated, introducing breaks in the biological processes that evolution had slowly shaped**, **feedbacking on living systems at scales and timescales that exceed those of natural recursive phenomena**.

A process of empowerment-externalisation (of 'bubble') is at work, which remains connected to natural evolution but largely escapes the coherence normally produced by systemic evolution[47]. This dissociation of part of human activity forms a kind of externalised 'niche': it stems essentially from the fact that human knowledge develops without context and is abstracted from natural evolution and general ethics, retaining only a few moral constraints (Odling 1988, 2013, Laland 2010, Ellis 2015). Furthermore, technologies are geared towards the comfort and desires of individuals and groups, and hardly towards the coherence of human behaviour with the organisation of the systems on which they depend. This paradoxical empowerment of human thought there ensues rapid and targeted feedback loops, independent of natural evolution, which lead to the destruction of our own living conditions, as we are already seeing today.

The challenge of the modern world is not to develop technical responses built within this same externalised niche, which can only generate new problems due to the overall inconsistency of this niche

[47] According to the scientific literature, whilst human intentionality undeniably stems from natural evolutionary processes – notably through selection and neural plasticity – it now tends to operate within frameworks that exceed, or even bypass, the regulatory mechanisms inherent to biological evolution. By manifesting itself through technological, cultural or ethical choices, human intentionality introduces dynamics that no longer respond to the selective logic of adaptation, but rather reflect a relative autonomy from the initial evolutionary constraints.

with what allows us to live (Holling 1996), but rather to **recontextualise** human activities, particularly techno-scientific ones.

Biotechnologies, no more than pesticides, cannot constitute an adequate and sustainable response to the problems caused by the fundamental modern cultural inconsistency with natural evolution. By justifying the blind liberalisation of new technology products in agriculture in order to respond to climate change and the collapse of biodiversity, the European Commission is creating a formal contradiction in terms of an approach based on the organisation of natural systems.

**Modularity and co-evolution of complex natural systems**

The vast majority of complex natural systems are modular, i.e. they are made up of groups with a high density of connectivity, connected to others by a low density of links. When a disturbance occurs in such a system, it is most often confined within the module that receives it, without spreading to the entire system. The modular structure of networks is a determining factor in their resilience and sustainability.

When something new, such as the product of mutation, it is confronted with a densely connected and organised network. In most cases, it will be eliminated because it is not compatible with the module. When it is compatible, a co-evolution of the new element and the module begins, with the evolution also occurring in compatibility with the other modules. This co-evolution corresponds, in principle, to the emergence of a slight variation from the existing situation.

**When the transfer of elements from a module distant from the receiving module is artificial, it often causes significant disruption in the latter, because there has been no co-evolution within the module**, even though the new element is part of the same overall system. A typical example is the introduction, as a result of globalisation, of allogenic species, including pathogens. The list of examples is long.

**With regard to products of new biotechnologies:**

1- GMOs-NTGs 1 are not constrained in their variation by the Proposal in relation to the existing situation: 400 mutations and as many deletions as desired, on any part of the genome. There is therefore potentially the same type of deleterious effect on the organisation of natural systems as for allochthonous species, since they are not the result of local co-evolution.

2- GMOs-NTGs 1 can be radically new, even in relation to the ecosphere, since these techniques can be used to produce proteins and/or RNAs that have never existed in nature and have no chance of ever being produced. This would represent a major inconsistency at the systemic level.

3- GMOs-NTGs are an extension of intensive industrial agriculture based on the simplification of systems. Due to their speed of production and the scale of their introduction into the field, they reinforce these practices, particularly through the phenomenon of path dependency, which tends to eliminate alternatives. NTG GMOs particularly reinforce the practice of monoculture, which destroys systemic modularity (Zhang 2021, Hu 2025, Ma 2025) and historically produced biodiversity (see our Appendix 2). Such effects would lead to an increase in actions aimed at addressing these problems while posing others (pesticides, water use capture, various inputs, etc.), which would cause further nuisance and systemic disruption (Olesen 2007, Rogers 2016, Banerjee 2019, Ishimoto 2021, Ding 2024, Idbella 2025, Macfadyen 2025). It is **therefore wrong to present NTGs as part** of '*sustainable development*'.

*Question*: Does the Commission consider that the phenomena of co-evolution in the modules of the complex natural systems in which we live are negligible? If so, on what scientific basis? If not, how has it assessed, from this perspective, the effects of NTG products and these techniques themselves?

**Historicity of natural systems**

Complex natural systems are fundamentally historical in their entirety, their components and their connections. **Historicity is an ontological property of complex natural systems, insofar as their dynamics are based on processes of interaction, adaptation and emergence that structurally incorporate the effects of the past.**

The number of possible combinations of elements in a complex natural system (CNS) is so enormous that it can be considered virtually infinite. We have seen that this is already the case with the set of possible combinations of nucleotides in a single corn kernel. It is therefore impossible to generate a coherent system in one fell swoop, given that, even though the number of possible coherent systems is enormous for human beings, they are numerically minuscule compared to the raw potential. Complex natural systems can therefore only be created gradually, based on past events and through constant confrontation with what already exists. Furthermore, each modification is contingent and most often irreversible. The evolution of CNSs follows the arrow of time, like any dissipative structure (Prigogine 1968, 1981, Nicolis 1977). The evolution of CNSs is based both on a space of possibilities reduced by its history and on internal openings for emerging possibilities (Holland 1992, Longo 2017).

Overall, **this historicity implies, in particular, path dependencies, lock-in phenomena, enablers and attractors shaped by the history of the system**.

When a plant mutates naturally, this new unique specimen is confronted with an entire environment composed of abiotic materials and a wide variety of living beings, all in modules that are themselves connected to others. The situation is therefore numerically very unfavourable to the mutant. If it is 'accepted' by the system, a co-evolution begins between the plant and the system, mainly at the level of the initial modules. **This co-evolution historicises the randomness introduced by the mutation.**

**When *in vitro* cells are subjected to artificial mutagenesis processes, there is no confrontation with the natural environment and the mutations do not result from a natural process, which is clearly constrained** (Ossowski 2010, Weng 2019, Mundorf 2025). **The plants obtained are then multiplied, then planted *en masse*, in monoculture, on large areas of land that are also considerably impoverished by pesticides and herbicides and supported by inputs.** The confrontation with the environment takes place 'by force', in **networks of interactions that are considerably impoverished**.

The break with historicity represented by the introduction of plants derived from NTGs into nature reduces the resistance and resilience of the ecosystems into which they are introduced (see our Appendix 2). It is clear that, **from a systemic point of view, there can be no equivalence between a plant mutated *in vitro*, regardless of the technique used, and a plant derived from the selection of natural mutations**.

Question: Does the European Commission agree with the conclusion that it is not biodiversity per se (non-historical) biodiversity that confers stability and resilience (sustainability) on ecosystems, but rather systemic organisation, which translates into a certain biodiversity resulting from evolution?

**Acceleration, tipping points and systemic disruptions**

Complex natural systems are constantly evolving. But even though chance intervenes at all scales, this evolution is not random, and occurs at a certain pace, corresponding to the historical establishment of their organisations. Furthermore, complex systems never change at a single speed: they exhibit a stratification of temporal scales - from very slow processes (phylogenetic evolution, geomorphology) to rapid processes (behavioural or demographic responses) (Fronhofer 2023).

These speeds of evolution are not descriptive characteristics of the evolution of systems; they are an integral part of their organisation. **Artificially modifying them creates a risk of system** collapse: a change in stable state, an exit from the attractor of the dynamics (Perryman 2014, Crutchfield 2020) by crossing a threshold ('tipping point') (Scheffer 2001, 2012, Kéfi 2022, Vasconcelos 2023). The probability of tipping, of collapse, increases with the speed of change (Ritchie 2023, Panahi 2023), which can also trigger cascades of large-scale events (Fang 2025)[48].

**The effects of accelerating systemic change on biodiversity are well documented**, particularly in the context of climate change (IPCC 2021, 2022, Loarie 2009, Burrows 2011, Noah 2013, Radchuk 2019). The mechanisms described are not specific to climate change, but are very general: differences in evolutionary speeds at different scales lead to systemic disruptions with the disappearance of communities (rather than the disappearance of elements) and the creation of new communities (Williams 2007), leading to an alteration in the organisation of the systems concerned. The same is true for societies undergoing rapid technological acceleration, which creates interdisciplinary positive feedback loops leading to exponential evolution. Ray Kurzweil has long theorised this essential aspect of technological evolution (see, for example, Kurzweil 2005 and, before him, Meyer 1954).

Faced with such rapid change, individuals do not react in the same way or at the same speed, and, as in ecosystems, systemic disruptions arise with the formation of communities that are poorly connected to each other, generating their own ethics, their own language, and their own identity built in opposition to other communities, resulting in a loss of coherence with overall cohesion. As with ecosystems, human societies are becoming more fragile simply because of technological acceleration, whatever its nature. If biotechnologies are deregulated as proposed in the draft regulation, they will have an impact on both ecosystems and human societies at a fundamental level: life processes, food and culture.

### *A priori* valorisation of innovation

In the current cultural paradigm, innovation, associated with speed, is actively sought and valued, particularly in the field of biotechnology. See in particular:

- NGTs '*enable the rapid development* of *new plant varieties*' and bring '*greater speed in introducing the desired* genetic modifications' (European Commission 2023);

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[48] '*Recent theories have identified rate-induced transitions (RITs) as another important phenomenon that occur in dynamical systems (Ashwin et al. 2012, Kaur and Dutta 2022, Neijnens et al. 2021, Siteur et al. 2016, Wieczorek et al. 2010). RITs occur when a sufficiently high rate of change in external conditions - not (just) the magnitude of change - cause a regime shit. Here, we argue that RITs may be a common feature of CASs and occur when external environmental, technological, or social conditions change at a rate faster than the system's ability to adapt. As such, these RITs have significant implications for the stability and resilience of all CASs*.' (Vasconcelos 2023) (CAS = Complex Adaptative Systems).

- '*The EU's largest farm lobby, COPA-COGECA, welcomed the Commission's proposal, arguing that NGTs are 'part of the toolbox that enables breeders* ***to speed up*** *their breeding programmes and* ***bring faster*** *and better plant varieties to the market*' (European Parliament 2023);

- '*New Genomic Techniques (NGTs), such as genome editing using CRISPR-Cas, can* ***significantly improve the speed*** *and precision with which new plant varieties are created*' (ALLEA 2024);

- *'Gene editing also significantly* ***accelerates*** *the breeding process, which will allow us to develop improved seed products* ***much faster***' (Corteva 2024).

However, the concrete implications of this semantic space of innovation and speed are one of the major causes of the problems facing the contemporary world: biodiversity collapse, climate change, water cycle disruption, the emergence of infectious diseases, invasive alien species, destructive simplification of natural and cultivated environments, deterioration of soil, air and water quality, etc.

**Our demands:**

We call on the European Commission to immediately initiate:

- a **public and contradictory debate on systemic** risks, open to all stakeholders and citizens.
- a **research programme on the assessment of systemic** risks associated with GMOs (including those derived from NTG1) that have been overlooked by both the impact assessment (2021) and the Proposal. To this end, it is essential to **diversify the disciplines involved**, drawing not only on molecular biologists and a few population biologists, but also on specialists in agroecology, agronomy, developmental biology, ecology, environmental biosafety, environmental sciences, genetic toxicology, plant physiology, soil microbiology, technology assessment and medicine, particularly veterinary medicine.

## Chapter 2. On the '*equivalence*' between GM-NGT plants and conventional plants: the lack of any scientific basis and any explicit demonstration of this '*equivalence*'

Summary: *The Proposal exempts a considerable proportion of GM plants derived from NGTs from the obligations of Directive 2001/18/EC based on a principle of '*equivalence*' with plants derived from conventional breeding or which could '*occur naturally*'. This vague concept introduced by the Commission stems from a flawed and obsolete molecular approach, for which it has never commissioned any scientific study, even though NGTs represent a genuine technological breakthrough, with well-documented disruptive effects - which it could not have been unaware of - on both the modified plant and the holobiont.*

The European Commission justifies the deregulation of genetically modified plants derived from NGTs based on a purported '*equivalence*' between them and plants derived from conventional breeding or those that **may** '***occur naturally***'. A critical analysis of this concept of equivalence is essential, since it is on the claimed '*continuity*' that the Commission intends to legitimise the entire process of deregulating GMOs derived from NGTs 1.

Indeed, it is by relying on the assertion of '*equivalence*' that the Proposal bases the entire supposed legitimacy of the deregulation of NGTs and considers:

- that it is not necessary to investigate and assess specific risks to the environment and human health associated with their development and release: yet these risks are documented by an extensive body of literature (see Chapter 1).
- that it is unnecessary to impose management obligations, as well as traceability and labelling requirements, and thus post-marketing surveillance, which industry claims would be difficult to implement. Yet numerous studies show, as we shall see, that this distinction between NGT derived plants, and consequently their traceability and labelling, and thus their post-market management, are entirely feasible (see Chapter 5).
- it is legitimate to create a category of NGTs meeting certain 'equivalence' criteria: yet this classification has no scientific basis (see Chapter 3).

We intend here to demonstrate that the Proposal is based on a flawed and outdated approach, driven by a desire to make a self-fulfilling prophecy rather than by scientifically validated criteria. The assertion that GMOs derived from NGTs are equivalent to plants derived from conventional breeding or that may '**occur naturally**' is in fact **scientifically incorrect**, as evidenced by numerous scientific studies cited in our Appendix 1. **The Commission and EFSA could not, however, have been unaware of this extensive body of literature, including the results of their own research programmes** briefly summarised by Aguilar *et al*. (2013) **or commissioned reports** which are therefore not independent, if not outright 'corrected' (Brueller *et al*., 2012; Brueller *et al*., 2013).

The imprecise concept of '**equivalence**' is based on definitions that are themselves vague or ambiguous, as will be discussed in Chapter 7 on "**Vague definitions and semantic shifts**".

To provide a concise summary of the lessons drawn from the entire **bibliography in Annex 1**, the following main points regarding the issue of 'equivalence' should be noted:

1- The Proposal is based on a flawed and obsolete molecular approach.

2- NGTs represent a genuine technological breakthrough, a disruption which is, moreover, claimed by stakeholders.

3- NGTs cause disruptive effects on the modified plant, and therefore on the holobiont and its biotic and abiotic environment, effects never considered by the Proposal.

4- The Commission imports into the EU, without making this explicit, the American concept of a generalised "*substantial equivalence*", which is inconsistent with existing European legislation on GMOs.

5- Conclusion: principles not respected, claims and questions.

## 1- The Proposal is based on a flawed and obsolete molecular approach

a - An 'equivalence' never assessed by EFSA or the Commission

b- A principle of equivalence based on the study of a limited number of NGTs.

c- An obsolete approach based solely on the gene of interest.

### a- An 'equivalence' never assessed by EFSA or the Commission

It should first be noted that **the Commission has never mandated EFSA to investigate whether NGT plants are *substantially equivalent* to conventional or natural plants**, nor *a fortiori* according to which criteria and within what limits. It has thus **never requested assessments concerning unintended genetic modifications** unlikely to occur in the context of conventional breeding (or any other unregulated plant breeding process). This issue has therefore not been the subject of a systematic study or analysis by the EFSA that would meet the standards and practices of scientific research. No genuine Systematic Literature Review on the issue of '*equivalence*' (or on that of risks, as we have seen) was requested by the Commission, despite the expertise of EFSA's permanent staff and the Commission's ability to commission external studies. **This omission speaks volumes about the Commission's pre-determined choices**.

The Commission's scientific references to justify a principle of '*equivalence*' are based primarily on its "*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*", published in April 2021 (based on the opinions of certain experts and publications). This constitutes a consensus among carefully selected experts, without any conflicting views.

**The Commission's study does not systematically analyse the state of research but systematically adopts the administrative framework of the EFSA *staff* and the arguments of lobbies** (*staff* who, incidentally, contribute by publishing articles included in the literature subsequently cited in EFSA opinions). It does not make transparent the criteria for evaluating the material on which it is based but merely summarises and highlights certain carefully selected articles (*cherry-picking*). Its conclusions are biased as they are not based on a systematic analysis of the type found in a Systematic Literature

Review[49], and lack data to justify the conclusions. Furthermore, **several pieces of data presented as a hypothesis by the EFSA are subsequently taken up by the Commission as a scientifically founded assertion** (on this last point, see Chapter 7).

However, this study, and those of the EFSA on which it claims to rely, present numerous and significant conceptual, methodological, semantic, and logical weaknesses, as we will see.

### b- A principle based on the study of a limited number of NGTs.

It should be noted that the studies on which the Commission relies to reach its conclusions regarding 'equivalence' and risks focus entirely on a limited number of techniques and types of modification (see Chapter 1-A, §1, a).

### c- An outdated approach based solely on the gene of interest.

On reading the extensive literature cited in Appendix 1, the argument for equivalence is based on a **linear and additive view of the genome**, according to which a targeted modification would be **functionally equivalent** to a natural mutation arising from the existing gene pool. It should be recalled that **conventional selection** uses sets of **co-adapted variants**, whereas NGTs act on specific *loci* defined *a priori* within pan-genomes exhibiting quite different '*responses*.' The application of this principle is thus **based solely on molecular criteria that are scientifically outdated, as they take absolutely no account of effects on the phenotype** (see GWAS genotype-phenotype discrepancies). Like the arguments put forward by the biotechnology industries, the Commission's comparisons between plants obtained via NGTs and conventional ones, to conclude that they are equivalent, suggest that only the *gene of interest*[50], from which the desired function (the 'trait' or phenotypic characteristic) is hoped to be derived, is involved.

This approach overlooks the fact that it has been well known for many years that the **genome functions** as a **system of non-linear interactions**, in which the effect of a modification depends heavily on its genetic, epigenetic, and regulatory context (not to mention the epitranscriptome). **A plant cannot be reduced to the coding and regulatory sequences of the gene of interest** (see Chapter 4, which highlights the predominance of genetic background in resistance and tolerance to biotic and abiotic stresses) and to expression regulation that is virtually independent. The coding sequence indicates the type of *genetic information* contained within a particular DNA segment. It may itself give rise to several proteins (alternative splicing of mRNAs), contain regulatory elements within introns not expressed in the protein, and finally perform distinct functions depending on the cell cycle ('*moonlighting proteins*'). This multifunctionality of certain proteins is, once again, not considered by the EFSA opinions, for both knocked-out and inserted protein-coding sequences.

A gene or a group of genes (alleles and epialleles) do not have an intrinsically assigned function; their action and their expression regulation depend on context and co-evolutionary processes. **The genome is a complex, non-linear, connectivist system, and this is incompatible with the Commission's**

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[49] According to the principles developed by Environmental Evidence https://environmentalevidence.org/ or by the Cochrane Collaboration in the medical field (Scholten *et al.*, 2005).

[50] Bearing in mind that the definition of a gene is itself by no means settled in the reference literature.

**stated assumptions, which are fundamentally based on a 1970s conception of the organisation of 'genes' and (pan)genomes.**

However, to justify this equivalence, the Proposal therefore considers, in line with industry claims, only the coding sequence of interest—without its multiple possible translational and functional variants—and the desired mutation, in order to 'establish' that this sequence **could** have occurred naturally or through conventional breeding. Thus, other disruptive effects on the pan-genome considered as a whole and on the plant are not considered (DNA, RNA, proteins and hormones circulate between the tissues of living organisms – including humans – with a role in inter-cellular and inter-tissue signalling).

The Commission seeks to promote a simplistic and mechanistic view, whereas the use of NGTs involves constant modifications[51], extremely complex tools undergoing constant technical evolution, with software for predicting *off-targets*[52] that is insufficient, partial, and inconsistent, based on pan-genomic data that is not yet sufficiently 'cleaned' and is constantly evolving with the numerous ultra-deep pan-genome sequencing projects currently underway.

### 2- NGTs represent a genuine technological breakthrough, a disruption indeed claimed by stakeholders

**NGTs cannot under any circumstances be regarded as a continuation of conventional plant breeding** techniques. As a collection of disparate technologies, NGTs are even presented by their advocates as disruptive technologies and have therefore to be protected by patents due to their novelty.

**NGTs follow a logic that is the opposite of conventional plant breeding techniques**: they do not undergo a selection process co-evolving with the environment in the broadest sense, since they are created directly *in vitro* (based on the highly questionable assumption that we have full control over all the consequences associated with the mutated sequences or genes), and therefore lack a proven safety record, as the CJEU highlighted in 2018.

It is therefore paradoxical that the European Commission is attempting to draw – if we set aside the political considerations underpinning this approach – a parallel with conventional breeding techniques. Indeed, not only does this fail to reflect the practical reality of the method's logic and economics, but quite the contrary: **these methods represent a break with the process of variety creation whilst necessitating the retention of both older** (e.g., mass selection) **and more recent** (e.g., marker-assisted selection) selection methods. We are therefore far from achieving financial and time savings in variety development, since the mere transformation of Elite varieties remains highly problematic.

This is due to the fact that the gene pool prevails, as demonstrated by numerous agronomic factors, and that the Elite varieties required for 'cleaning' the pan-genomes of their biotechnological residues (through backcrossing according to precise schemes developed after lengthy observations) and for the preparation of commercial varieties must be maintained within the seed companies' '*gene pool*', a vague concept that has been severely misused by the Commission.

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51 DNA, then mRNA, then purified proteins to reduce the duration of action of double-stranded DNases.

52 But no prediction software for unintended on-target modifications, and only ultra-deep sequencing – rarely carried out due to cost – for foreign DNA insertions arising from vector systems and contaminants in NTG reagents, given that these are prepared from biological organisms.

To illustrate the major departure that NGTs represent from conventional production methods, two points should be noted:

i) Even without the insertion of additional genes, NGTs allow for **profound modification of parts of the genome that are completely inaccessible in conventional agriculture**.

In conventional farming, whole plant and animal cells are used, which have been shaped genetically and epigenetically by interactions with the biotic and abiotic environment, and thus by evolution. The mechanisms of Mendelian inheritance and gene regulation are not circumvented in it. However, the circumvention is made possible with NGTs, following directly in the footsteps of transgenesis, whose **tools, procedures** and '**laboratory varieties**' **NGTs use**. NGTs enable biological boundaries to be rapidly crossed and factors such as repair mechanisms, epigenetic mechanisms, genetic linkages, and the flow of information between plant tissues to be modified and circumvented…

ii) NGTs cause **mutations at a rate that is incommensurable on a human scale** and even on a planetary scale: the NHEJ system and, to a lesser extent, the MMEJ system must repair extremely rapidly double-strand breaks caused by highly efficient and rapid *Cas*, hence the transition to mRNAs and then to proteins to reduce the duration of action, which causes too many unintended modifications. (On the major systemic impact and co-evolutionary problems posed by the effect of this rapid mutation rate, see Chapter 1-B).

It should be noted that plants derived from random *in vivo* and *in vitro* mutagenesis are indeed genetically modified organisms, and not conventional plants, and therefore cannot serve as a basis for comparison with NGT plants within the framework of this distinction proposed by the European Commission.

**3- NGTs have disruptive effects on the modified plant, and therefore on the holobiont and its biotic and abiotic environment, effects never considered by the Proposal.**

It should be remembered that a gene does not express itself in isolation but within an immensely complex system (the other elements of the cell, the organism, the biotope, etc.), which is completely disregarded in this Proposal. The holobiont of an organism (that is to say, the holistic approach through the interaction of a multicellular organism such as a plant or an animal with its cutaneous, digestive, foliar, root microbiota…) has become, in all fields of biology, a fundamental element in understanding that organism, its capacity for resistance or sensitivity to various biotic and abiotic stresses, and thus, ultimately, co-evolution.

Consequently, GMOs derived from NGTs exhibit **elements of continuity with transgenic GMOs, which have been completely overlooked by the Commission.**

i) In most cases, the development of plants modified by NGTs involves the **same stages of genetic manipulation as those used to produce transgenic GMOs**: the highly stressful isolation of protoplasts, stressful cultivation in a synthetic medium, successive subculturing, transformation by agro-infection in the majority of cases or biolistics (particle guns coated with DNA), stressful regeneration of seedlings, acclimatisation of seedlings… which most often represent considerable stress on millions of cells, a **disruption that is beyond our control and which proves to be incomparable to conventional selection by crossbreeding**. The "*gene scissors*" themselves cause very profound genetic disruptions.

ii)This complexity gives rise to the **unintended and/or unexpected changes and effects** already mentioned, which not only pose potential risks (see Chapter 1), but also **render meaningless any notion of 'equivalence'** between plants derived from NGT and those from conventional cultivation (not to mention plants occurring 'naturally').

Like transgenesis, cisgenesis and intragenesis (whose definitions vary between JRC and EFSA documents, in both Category 1 and Category 2) are in fact techniques involving *in vitro* cultures that cause the disruptions already mentioned and well-documented (see Chapter 1 and Appendix 1 – Bibliography).

Let us recall the main possible effects:

- unintended modifications and effects (*off-target effects* /genomic modification in the wrong place, and *on-target effects* /modification of DNA introduced in the right place but not the correct sequences).
- insertions of foreign DNA derived from vectors such as *Agrobacterium* and NGT reagents contaminated with DNA from the organisms from which they were 'purified.'
- chromosomal aberrations such as chromothripsis (genetic 'chaos' involving the creation of micronuclei transmitted to offspring via non-Mendelian segregation), which are particularly feared in gene therapies with mosaicism.
- and an exceptionally substantial number of epimutations (changes in gene expression without altering the DNA sequence) which can lead to SMPs (Single Methylation Polymorphism).

These off-target and unintended effects of these NGTs can thus cause **genetic (genotype) and biological (phenotype) changes that do not occur naturally or in conventional breeding**.

iii) Among the unintended effects, it is important to note the unintended insertions of **foreign DNA**.

The European Commission asserts that NGT-type targeted mutagenesis leaves no foreign genetic material in the modified pan-genomes. **This assertion is completely erroneous**.

NGT genetic manipulations, whether Category 1 or Category 2, always leave residues of foreign DNA—of varying sizes and therefore varying degrees of detectability. Indeed, **NGTs do make use of foreign DNA**, and they do so **intentionally**:

*1-Reagents*

The reagents used by all NGTs (DNA, RNA, RNP) all leave traces of contaminating foreign DNA in the modified genomes, as recent studies attest[53].

*2-Transgenesis*

To introduce, for example, Cas9, which is a large molecule that is exceedingly difficult to introduce, the greatest efficiency is achieved through a conventional transgenesis procedure, using foreign DNA (from *Agrobacterium tumefaciens* or related bacteria, or their plasmids).

[53] To statistically eliminate foreign DNA (such as off-target modifications), backcrossing is carried out, ideally once a year for 14 years, a period most often reduced to 7 years. But in practice, operators only carry this out for 2 or 3 years, for cost reasons. Under these conditions, not all anomalies can be eliminated. And even if these backcrosses were carried out at least 14 times, only 90% of the plant would be statistically 'cleaned' (and thus only in theory). (Bertheau 2022b; Kawall 2020; Norris 2019, 2020; Ono et al., 2015; Ono et al., 2019).

And even if **subsequently** proper *backcrossing* is conducted, **fragments of foreign DNA will always remain**, as well documented[54]. NGT plants therefore contain numerous anomalies that have never been investigated due to an *a priori* assumption of precision. It is worth noting in passing that this intervention in the genome, which leaves scars (unintended effects) or fragments of foreign DNA, facilitates traceability… and patentability.

It should also be recalled that **these changes are never considered by the Commission** in its Proposal (see Chapter 1). Thus, the EFSA and the Commission do not address the fact that NGTs may unintentionally alter parts of the genomes (nucleus, chloroplasts, mitochondria...) and epigenomes of plants **which are not accessible to other methods**. Nor are the unintended effects of NGT applications sufficiently considered by the Commission's study, whether they result from intentional or unintentional modifications. The range of unintended modifications to plant organelles containing DNA is **not addressed at any point**, nor is the effect on intercellular, inter-tissue or inter-organism signals (endogenous and exogenous microbiota *vs*. the plant).

As noted by Germini *et al*. (2018) and various other authors subsequently, **no study has been conducted to rigorously compare (using ultra-deep sequencing) the pan-genomes** resulting from natural selection or from transgenesis or NGT techniques.

It is therefore without a sound scientific basis that, in an Opinion of 24 November 2020[55], the EFSA considers that, **in light of scientific publications,** ' *these publications also confirmed that the number of off-target mutations generated by SDN-based methods is lower than the numberof mutations observed in conventional breeding due to spontaneous or induced mutation*' and that these off-target mutations are even fewer than in the case of conventional breeding.

### 4 - The Commission is introducing into the EU, without explicitly stating so, the US concept of a generalised "*substantial equivalence*" that is inconsistent with existing European legislation on GMOs

First appearing in the United States and the OECD in the 1990s, and subsequently adopted by several countries, '*substantial equivalence*' is a concept that was intended from the outset to address a political and economic problem rather than a scientific one: how to regulate GMOs without blocking their entry onto the market[56].

According to this principle, if food derived from a GMO is *substantially equivalent* (note the lack of precision implied by the adverb) to its conventional counterpart, then it may be considered as safe, without the need for a specific, exhaustive assessment. **In the United States**, this approach led to GMOs

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54 Bertheau 2019, 2022b.

55 EFSA, '*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'*, EFSA Journal 2020;18(11):6299, 14 pp.

56 The United States has relied on this principle primarily to avoid hindering industry strategy and to grant greater freedom to agri-food companies, according to E. Millstone, E. Brunner & S. Mayer, *Beyond substantial equivalence*, *Nature*, 401, 6753, Oct. 1999: '***Substantial equivalence is a pseudoscientific concept because it is a commercial and political judgement masquerading as if it were scientific**. It is, moreover, inherently anti-scientific because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests. It therefore serves to discourage and inhibit potentially informative scientific research'*.

being regarded as *substantially equivalent* to their conventional counterparts, and therefore as not requiring any specific assessment.

**This approach was rejected by the EU in the 2000s in favour of a legislative framework based on the precautionary principle** (Directive 2001/18/EC). In fact, current regulations governing GMOs in the EU stipulate that, for food, any risk assessment must begin with a comparison of the risks associated with genetically modified plants with those of a related non-genetically modified plant, the former not being less safe than the latter.

Nevertheless, the European approach considers GMOs on a case-by-case basis, rather than applying a blanket ban to all GMOs as is the case in the United States, and as provided for in the Proposal on GMOs derived from NGTs n°1. Furthermore, EU regulations do not preclude further research into suspected risks.

Generally speaking, under European regulations, and with reference to the definition of a GMO used in Directive 2001/18/EC, GMOs fall within or outside the scope of application **depending on the type of method used and a proven safety record, and not on the basis of the product's *presumed* final characteristics** (and therefore even if, in theory, there are no longer any traces of genetically modified exogenous DNA in the final product).

According to the European approach prevailing to date (Directive 2001/18/EC and the 2023 regulations), **GMOs are therefore regulated because their release may have unforeseen and irreversible effects on humans or the environment**[57]. This involves, for example, preventing plants traditionally used for the production of food intended for human or animal consumption from exhibiting toxic effects due to genetic modifications, and ensuring that these plants themselves or similar ones, to which these traits are transmitted through cross-pollination, do not have unexpected adverse effects on human or animal health. It may also involve preventing the spread of GM plants which, like invasive conventional plants, may lead to significant changes in the ecosystem, such as the displacement or even extinction of existing species.

Furthermore, regarding the issue of coexistence between **GM plants** (whether NGT or not) and non-GM plants, it is essential to prevent genetically modified plants (whether NGT or not) intended for **pharmaceutical, industrial or environmental remediation purposes** (such as soil remediation) from cross-pollinating or contaminating food chains, as has been observed in the United States. Indeed, these **genetic modifications for non-food purposes are very commonly conducted on plants grown for food due to their ease of processing and subsequent mass production**.

The premise set out in the Proposal for a principle of equivalence for an entire category of GMOs, without any case-by-case risk assessment, therefore represents a **major upheaval in the European approach to the risks posed by biotechnological innovations**. The vague wording, lacking scientific basis or duly defined criteria for equivalence and continuity between plants derived from conventional breeding and products derived from NGTs, **opens the door** wide to **synthetic biology products, transgenic GMOs and xenobiology products** that have been under development for over a decade.

With this renewed concept of equivalence designed to avoid any risk assessment of GMOs derived from NGTs1 (i.e., virtually all NGTs currently under development, as will be seen in Chapter 3), the **Commission uses language that conveys a sense of certainty where science still finds, above all,**

[57] It should be noted that, in Directive 2001/18/EC, the precautionary principle appears as early as Article 1 'Objective', whereas in the Proposal, it is relegated to the explanatory memorandum.

**uncertainty**. This indicates a deliberate bias towards omission (selective evidence selection, or '*cherry-picking*') rather than rigorous argumentation on safety or risks.

In this respect, the Proposal is not consistent with the existing legislative framework, contrary to what the Commission asserts in the explanatory memorandum, and contrary to what the EU's principles of '***good administration***' require. The fact that the Proposal establishes the principle of equivalence as a postulate constitutes an unusual approach in science, and once again it politicises science[58].

### 5- Conclusion: principles not respected, claims and questions

**Principles not respected:**

In conclusion to this chapter, we consider that the way the Proposal for a Regulation on NGTs was drafted by the European Commission seriously contravenes the principles mentioned in the introduction, and in particular:

- *Principles of excellence and transparency in scientific assessment and the principle of adaptation to scientific knowledge*: notably due to the choice of an outdated molecular approach to justify a principle of equivalence, and in particular for having taken into account studies considering only the gene of interest and a limited number of techniques; by failing to make transparent the qualitative and quantitative criteria for assessing the material on which EFSA relies to justify a principle of equivalence; by failing to take into account the numerous studies that have for several years highlighted non-targeted and unintended modifications and effects, and, more generally, the disruptions caused by NGTs to the (pan)genomes and the plant as a whole; failing to commission studies on certain unintended and non-targeted effects, comparative studies on artificially modified and unmodified pan-genomes, or, more broadly, a Systematic Literature Review on the issue of equivalence.
- *Principle of legitimate justification of legislation and transparency*: for the same reasons as above. As the justifications for the Proposal are based on a scientifically unfounded principle of equivalence, they lose their legitimacy.
- *Principle of consistency*: no coherence with Directive 2001/18/EC, according to which GMOs fall within or outside its scope based on the type of method used and a proven safety record, rather than on the final characteristics of the product – the Proposal representing, in this respect, a major shift in the EU's approach to the risks posed by biotechnological innovations.

**Our demands:**

We urge the European Commission:

- to **recognise the scientifically unfounded nature of the principle of equivalence** between conventional plants and plants derived from NGT 1, a premise upon which the entire proposed deregulation process is based.
- to **initiate comprehensive studies** subject to cross-examination, enabling it to comply with the principles of excellence and transparency in scientific assessment and the principle of adaptation to scientific knowledge, considering the shortcomings mentioned *above*.

[58] On this issue, see Chapter 9 "Regarding the ethical issues raised by NTGs: a sidestepped debate on the structural choices of the Proposal".

**Our question:**

To what extent can it be argued that plants genetically modified using NGTs can be considered equivalent to plants that might have arisen naturally or through conventional breeding techniques, whilst at the same time accepting that these same plants can be patented, when essentially biological processes (including conventional breeding methods) are not patentable under European law?

It should be noted that native traits already present in conventional varieties are claimed in patents and that commercial and financial pressures, exerted by firms filing patents, lead to the withdrawal of varieties marketed prior to patenting.

## Chapter 3. Regarding the criteria distinguishing two categories of NGTs: arbitrary thresholds without a serious scientific basis, without prior debate or consultation

Summary: *The exemption in the Proposal for Category 1 NGT plants is justified solely on the basis that the type and number of DNA sequence changes would be like the type and number of DNA sequence changes available in the genetic pool of breeders. However, NGTs meeting these criteria could very well lead to modifications that cannot occur naturally and pose risks to humans and the environment, most of which are unidentified and undeclared. Without scientific basis, this classification into two categories, revealed only at the time of the Proposal's adoption, has not been subject to any rigorous and contradictory assessment.*

The Proposal distinguishes between two categories of GM plants derived from NGTs: NGT 1 plants, which would be completely excluded from European legislation on GMOs since they would be '*equivalent*' to plants derived from conventional agriculture or plants that have occurred naturally, and NGT 2 plants, which would continue to be covered by Directive 2001/18/EC, while benefiting from a simplified authorization procedure.

To this end, Annex I sets out '*equivalence criteria*' 'to ascertain if a NGT plant is equivalent to naturally occurring or conventionally bred plan' (according to the terms of recital 14 of the Proposal).

1- Reminder: a general principle of '*equivalence*' without any explicit and rigorous scientific basis.

2- The criteria in Annex I of the Proposal have no proven scientific basis agreed upon by consensus.

3- The risks associated with NGT 1 obscured by the Commission.

4- Equivalence criteria would allow the deregulation of some 90% of GMOs: could the Commission have been unaware of this?

5- A lack of prior scientific opinions and prior open consultations with Member States, stakeholders and citizens.

6- Conclusion: principles not respected, claims and questions

### 1- Reminder: a general principle of '*equivalence*' without explicit and rigorous scientific basis.

We saw earlier (Chapter 2) how the principle of equivalence between plants from conventional agriculture (or natural occurrence) and GM plants from NGT (regardless of the number of genetic modifications) was not only scientifically unfounded by the European Commission and EFSA but was also contradicted by numerous important scientific studies.

Since the principle of equivalence is not scientifically sound, it follows that the criteria, chosen to determine which GMOs are likely to be equivalent, cannot themselves be scientifically sound. Furthermore, equivalence criteria, whatever they may be, cannot in any way account for the differences between conventional plants and those derived from NGTs in terms of their genotype, phenotype, and

uses. Nor can they account for the unintended effects caused by NGTs, the assessment of which is never provided for in the Proposal.

It follows from this observation that, in principle, the legitimacy of a category 1 exempt from all the obligations of Directive 2001/18/EC is not based on any serious scientific consensus. Furthermore, the thresholds established by the criteria in Annex I of the Proposal are not based on any scientific consensus or internationally recognized biosafety standards, as demonstrated below.

### 2- The criteria in Annex I of the Proposal have no proven scientific basis for consensus.

#### a-A threshold of 20 nucleotides with no sound scientific basis.

Annex I of the Proposal establishes equivalence criteria to distinguish between Category 1 NGTs on the one hand and Category 2 NGTs on the other hand. However, these criteria have been chosen arbitrarily, without any proven scientific consensus. Presented as a simple operation of risk proportionality, this distinction is in fact not based on a clearly established biological threshold or a documented scientific consensus. The criteria used – number and type of modifications, hypothetical possibility of natural occurrence – do not correspond to identifiable biological discontinuities, but to normative dividing lines, defined *a priori* to meet regulatory simplification objectives.

In particular, the figure of 20 ('*A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications'* such as '*substitution or insertion of no more than 20 nucleotides*') does not appear to be a biological recommendation by EFSA, but rather an administrative crystallization of technical constraints resulting from the malicious misuse of technical considerations useful in the detection/identification of organisms.

**To explore this point further, our Appendix 3** shows how **sophistry and circular reasoning were constructed in stages to arrive at this threshold**. Indeed, based on a 2011 JRC study, which therefore contains several systematic biases, whether intentional or not, a 'technological lock' has been imposed on a limited number of detection techniques, a bias that was taken up by the ENGL network (2019) and used for subsequent self-referencing and circular reasoning by the JRC and the Commission[59].

We also refer to our **Annex 5**, which shows how, to justify the equivalence thresholds in the Proposal, **the Commission has misused certain JRC results that were not directly related to the issue of NGT thresholds**.

In any case, this NGT 1/NGT 2 categorization is in direct conflict with the principles of equivalence and continuity invoked by the Commission**. If NGTs are consistent with conventional selection and produce organisms equivalent to those that can be obtained naturally, then the introduction of a separate regulatory threshold loses all ontological coherence.**

**Conversely**, **if a break justifying specific regulation did indeed exist** beyond this threshold of 20, **it retroactively weakens the equivalence argument** used for NGTs 1.

[59] Including in the Commission's October 2023 technical document: *Regulation on new genomic techniques (NGT) - Technical paper on the rationale for the equivalence criteria in Annex I*, 2023/0226(COD).

b- From the point of view of **non-compliance with the principles of *good administration* associated with the principle of excellence in scientific** evaluation, two important points should be noted:

i) **These thresholds were only revealed at the time of publication of the Proposal** and were therefore not specifically subject to contradictory studies or prior scientific opinions (which is a problem, see *infra* §5).

However, **studies subsequent[60] to the Proposal denounced the lack of scientific justification for these criteria**.

Thus, in its opinion of **November 2023** on equivalence criteria[61], the **ANSES**, echoing the analysis of other scientists, considered the criterion concerning substitutions/insertions of up to 20 nucleotides and deletions[62] of unlimited size to be '***without scientific justification***'. Like other expert reports, ANSES thus shows that there is no link between the molecular criteria determining possible modifications and the level of risk associated with the modifications made:

- The associated risk is not directly proportional to the number of modifications, whatever they may be.
- The Commission's assumption that categories of plants that are equivalent in type, size, and number of genetic variations or modifications are equivalent in terms of characteristics and level of risk has no scientific justification.

ANSES points out that '*genetic variability or genetic variations observable in nature are the product of thousands of years of evolution, drift or natural selection*', also lists a series of imprecise or ambiguous terms and definitions. Many other scientists share this assessment.

(For more details, see Chapter 7 - 'Regarding the scientific concepts used: unclear definitions, vague concepts and semantic shifts in the service of a political agenda').

ii) When asked by the European Parliament, the **EFSA, in its response[63] to this ANSES opinion, sidestepped the issue by failing to respond to the ANSES's central criticism regarding the lack of scientific basis for the thresholds chosen (type/size/number of modifications)** (See our Appendix 4: "The EFSA does not respond to the ANSES's criticisms ANSES's criticism"). On this occasion, EFSA confirmed that the criteria in Annex I of the Proposal are **not intended to define risk levels**, but only **to classify plants according to arbitrarily chosen molecular criteria**.

For its part, in 2024, the German Federal Agency for Nature Conservation (**BfN**) published a study ('*For a science-based regulation of plants from new genetic techniques*') also affirming the lack of scientific validity of the criteria put forward by the Commission. It raises the following points:

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60 Since the criteria in Annex I of the Proposal were only made public when the Proposal was published in July 2023, agencies such as ANSES and the BnF were only able to give their opinion after that date.

61 ANSES (Nov. 2023). Opinion on the scientific analysis of Annex I of the European Commission's proposal for a regulation of 5 July 2023 on new genomic techniques (NGT) - Examination of the proposed equivalence criteria for defining NGT plants of category 1 (own-initiative opinion No 2023 -AUTO-0189). Maisons-Alfort, 34 p.

62 According to these criteria, an organism from which half of the genome has been removed in the laboratory would be equivalent to this organism with a complete genome.

63 Scientific opinion on the ANSES analysis of Annex I to EC proposal COM (2023) 411 (EFSA-Q-2024-00178).

- the criteria in Annex I of the Proposal are '*scientifically unjustified and contravene the precautionary principle*'.
- The numerical thresholds defined by the Commission are considered arbitrary and simplistic, as they '*completely ignore the most important factor: the genetic context*'. By proposing a simple numerical threshold, the European Commission equates genetic modifications with negligible effects with mutations to a vital gene, as if the consequences of these modifications were the same.
- On the more statistical aspect of the 20-modification threshold: in nature, the probability of achieving 20 targeted genetic modifications at specific locations in the DNA sequence is comparable to that of winning the lottery 20 times.

Finally, a wealth of scientific literature[64], published before and after the July 2023 Proposal, shows that:

- The **threshold criteria** (number of modifications, absence of foreign DNA, presumed equivalence) **do not correspond to scientifically established biological discontinuities**, but to regulatory constructs.
- There is no **validated analytical method** to determine whether an NGT modification could also be produced by conventional or natural processes.
- The concept of '*equivalence*' is often left **without precise operational definitions** in the regulations.
- The current proposals **sidestep the real biological complexity of genomic modifications**, making their categorisation arbitrary and potentially inconsistent with scientific precautionary principles.

### 3- Risks associated with NGT 1 obscured by the Commission.

The exemption for category 1 NGT plants is justified solely on the basis that the type and number of DNA sequence changes would be like the type and number of DNA sequence changes in the genetic information available in a species and other taxonomic species with which it can be crossed (**initial definition of the breeders' gene pool**).

These criteria do not consider other changes to the nuclear and organelle pangenomes and the holobiont. However, NGTs that meet the criteria of the Proposal could very well lead to 'unintended' changes in the plant (as seen in Chapter 1) that could not occur naturally or through conventional breeding and could pose risks to humans and the environment.

Areas of the nuclear pangenomes such as centromeres and telomeres are not accessible to natural crosses. However, for classification as a Category 1 NGT plant, the fact that the type and extent of the genetic modification occurs inside or outside such areas, which some describe as protected, is irrelevant. In conventional plants, such as those that have arisen naturally, these 'protected' areas of the genome cannot be reached: this does not prevent the Commission from asserting that plants derived from NGT 1 should be considered equivalent to those derived from conventional breeding or arising naturally.

**This** uniform linear stochastic approach to pangenomes by the Commission **is contrary to everything currently known about the organisation of living** organisms. It is entirely representative of a **political-**

[64] Bertheau, 2019, 2022b; Mundorf *et al*., 2025; Voigt, 2023; Winter, 2024; Zimny & Eriksson, 2020.

**economic approach to the distinction between genetic modification techniques**, and therefore **of the lack of realism and biological basis for the distinction between products derived from NGTs**.

It should also be noted that, for the Commission, the effects of molecular genetic modifications on the properties of the plant (the phenotype) also have no impact on its classification in category 1. **Once the criteria in Annex I are met, little does it matter whether an NGT plant is toxic to humans or animals, invasive to certain ecosystems or resistant to herbicides** due to genetic modification.

Take, for example, an NGT 1[65] rapeseed, developed for industrial use but toxic if used in human or animal food (e.g., rapeseed with a high erucic acid content intended for industrial use, whereas those intended for human consumption are 'double zero', i.e., without erucic acid). This toxic NGT rapeseed would meet the conditions for category 1 and classified as a category 1 NGT plant, its cultivation would not be regulated[66] (see the coexistence issues raised above regarding the lack of a coexistence framework in dedicated and therefore territorial areas, since it is fundamentally the result of political decisions). If this NGT rapeseed were to spread to neighbouring fields where rapeseed is grown for food or fodder or were to be mixed at the point of harvest, it could cause poisoning and death, the **origin would be difficult to discern in the absence of traceability**.

Conversely, an NGT product designed to remedy deficiencies, for example in pro-vitamins (e.g., variants of golden rice, bananas with biofortifiers), or soothing neurotransmitters (GABA tomatoes), could prove harmful if consumed unknowingly (due to the lack of traceability) by people who do not require medication.

In summary, in the absence of any prior risk assessment, it is conceivable that the toxicity of NGT rapeseed remains unknown at the outset. Similarly, in the absence of traceability, labelling and post-marketing surveillance, it could take months or even years before symptoms of poisoning could possibly be attributed to this NGT rapeseed or other NGT products for advanced pharmaceutical use, for example. In any case, the competent authority would not have the power to act because of the legislation resulting from Directive 2001/18/EC, as this regulation would no longer apply to Category 1 NGT plants.

### 4- Equivalence criteria that would allow for the deregulation of some 90% of GMOs currently under development: could the Commission ignore this?

These criteria, which were never scientifically evaluated before being proposed by the Commission, are likely to place almost all NGT plants in category 1, not to mention the opening to products derived from synthetic biology and xenobiology.

Two points demonstrate this observation:

#### a- Up to 400 possible genetic modifications.

[65] Example given by Georg Buchholtz, Legal Opinion, GGSC (2023), *Commission's proposal for a regulation on new genomic techniques (NGTs): violation of the precautionary principle*, pp. 33.

[66] See example of 'gold of pleasure' (*golden needle grass*), an NGT crop optimized for industrial purposes https://doi.org/10.1186/s12302-021-00482-2.

The European Commission proposes to classify GMOs with a maximum of 20 modifications of up to 20 nucleotide changes in category 1. GMOs with **up to 20 × 20, i.e., countless multi-local and multi-functional combinations of 20-to-400-point mutations each**.

And yet the Proposal only considers desired mutations, **whereas many mutations remain in the final product and foreign DNA will necessarily be introduced unintentionally**, if only through vectors and systematic contamination of NGT reagents (see Chapter 2, § 4).

Let us return to the criteria in Annex I of the Proposal: an NGT plant would be considered equivalent to a conventional plant if it differs from the recipient/parental plant by a maximum of 20 genetic modifications of up to 20 nucleotides of the types referred to in points 1 to 5, in any DNA sequence sharing a sequence similarity (**without any precise value for the degree of similarity**) with the target site that can be predicted using bioinformatics tools. The first two points are:

1. substitution or insertion of no more than 20 nucleotides.
2. deletion of any number of nucleotides (without size limit).

**These two points alone will allow almost all existing and future NGTs to fall into category 1**, which is exempt from any prior risk assessment and authorisation. In fact, 80 to 95% of known NGTs currently in development fall into category 1 (TestBioTech analysis). According to another study by the German agency BfN in 2024[67], **94% of plants derived from NGTs currently under development would belong to category 1** according to the criteria in Annex 1 of the European Commission. The Proposal would therefore ultimately mean that **the risks inherent in GMOs derived from NGTs would not be assessed for many of them**.

The few studies that have examined the criteria in Annex I are, by their very nature, posterior to the Proposal, since the Commission chose not to publish them or submit them for prior scientific evaluation. However, when setting these thresholds for the number of mutations, the Commission could not and should not have ignored **what was already stated in the literature**, namely that a difference of just one nucleotide (insertion, deletion, substitution) can alter the protein itself, as well as its function and regulatory system, for example through changes in chromosome positioning[68]. **The range of possibilities then becomes immeasurable**, especially if we consider various other elements such as intronic regulation, alternative splicing or moonlighting proteins, which 'work on the sly' (i.e., multifunctional proteins that are never studied as such in the petitioners' files).

### b- The concept of 'breeders' gene pool'

The 'breeder's gene pool' is a reference which, through the conceptual extension made by the EFSA and the Commission, would open the door to the introgression of sequences from almost all living organisms, either directly or through *'bridge crossing*'. Point 5 of Annex I to the Proposal provides that the threshold of 20 genetic modifications of 20 nt may apply to *'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.

What comes from the 'breeders' gene pool' (also known as germplasm) represented in the initial definition everything that the breeder holds in his collection of sexually compatible species. With the

[67] https://www.frontiersin.org/journals/genome-editing/articles/10.3389/fgeed.2024.1377117/full, BfN, 2024.
[68] Bertheau 2019, 2022b.

extension granted by the EFSA[69] and the Commission **to any species for which 'advanced techniques' would allow the 'conventional' crossing of the concept of the breeders' pool, the introgression of any sequence of living organisms would be accessible to companies. As a result, any living organism would be part of the breeders' pool.** In addition, crosses derived from these mutants will themselves fall under category 1, as will crosses of these crosses. In the common understanding, this therefore refers to species of any kind whose genome can be exploited, regardless of their initial taxonomic and phylogenetic[70] proximity.

The idea put forward by various authors and lobby groups is therefore to replace the known and relatively well-controlled problems in highly formalised conventional crosses, linked in particular to linkage drag (the dragging of unwanted sequences by linkage), with DNA insertions or modifications similar to sequences from closely related species, without considering the new problems caused (somaclonal variation, unintended on-target and off-target modifications, etc.).

These stakeholders focus (through '*attention capture'* and *'regulator capture*') solely on the origin of the model sequences, while forgetting that the reagents and methods of their delivery (e.g., *Agrobacterium*) introduce foreign DNA.

The Commission extends Jacobsen's scope of 'breeder's gene pool' beyond cisgenesis. It is therefore any 'genetic pool' that can be mobilised. As the EFSA pointed out in 2022, it is the techniques that guide what is acceptable and desirable: '*The new developments of site-directed modification of genomes offer the possibility to target the insertion of new sequences at specific loci in the genome. The introduction of sequences belonging to the gene pool of the species, other than a complete gene, was not envisaged and assessed in the 2012 EFSA Opinion (EFSA GMO Panel, 2012a), and is considered here for the first time. A fragment of genomic DNA that originates from a crossable species can be introduced in a plant as a single intact and continuous sequence. In addition, fragments of genomic DNA that originate from one or more crossable species can be combined and introduced in a plant.*'[71]

**With the extension to all genomic DNA from a transmissible species, any living species implicitly becomes a member of the germplasm via any species that can already be used as a bridge**. Since *Agrobacterium* allows such a bridge, products derived from transgenesis can therefore be exempted, especially if the phenotype associated with the modifications can be - more or less - predicted according to undefined models and reliabilities.

This cisgenesis also opens the door in the medium term to synthetic biology and xenobiology (Orzaez *et al*., 2010). The extension without known limits of this 'breeder's gene pool' by various techniques such as embryo rescue, induced polyploidy or the use of bridge species (single, double or more) clearly opens up access through various current techniques, which will develop to encompass all natural genomes and fields such as synthetic biology and xenobiology (see Chapter 7, §3, b, ii for further discussion on this point).

It should be noted that bridge species are used (single or double bridges) in conventional breeding in cases of pollen incompatibility, differences in DNA content or chromosome length, or significant differences in ploidy. However, these intermediate species can be unstable with chromosomal rearrangements and can introduce foreign sequences into cultivated varieties (van de Wiel *et al*., 2010).

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69 EFSA additional FAQ (2023) https://www.efsa.europa.eu/sites/default/files/2023-05/extented-faqs-on-ngts-ts.pdf

70 This can be verified in the chapter by (Jacobsen, 2013) following his earlier position (Jacobsen and Schouten, 2008, 2009).

71 EFSA (2022) *Updated scientific opinion on plants developed through cisgenesis and intragenesis*, 3.2.2.1.

More generally, it should be noted that the definition of 'breeders' gene pool' can cover an immeasurable number of future techniques, thanks to a clever term: the 'pool' is specified by the Proposal as '*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*'[72]. Furthermore, the lack of precision regarding 'advanced techniques' (date, type, definitions) opens the door to all kinds of abuses, particularly regarding foreign DNA inserted alongside mutations and epimutations resulting from related techniques and NGTs. The absence of effective comparisons of duration, difficulties and costs between techniques leaves the field open to all kinds of assertions by manufacturers, especially since the verification procedure for NGT 1 provides for such short deadlines that it is likely to take the form of a purely declaratory procedure.

In other words, **category 2 of NGT is only there to give the illusion that the proposed deregulation is not total**. But, in fact, **this category 2 seems destined to remain an empty shell**. The same would be true of Regulation 2001/18/EC, which would be emptied of its content and would concern less and less GMOs, which would become obsolete with the arrival of the new NGTs.

### 5- A lack of prior scientific opinions and prior consultation with Member States, stakeholders and citizens

We summarise here the **Commission's failures regarding the principles of good administration and scientific excellence**. The Commission proposes criteria distinguishing between NGT 1 and NGT 2 that have not previously been subject to:

- **any request for specific scientific opinion**, including that of the EFSA,

- **any impact assessment** by the Commission,

- **any consultation** with Member States, stakeholders and citizens.

As the EFSA points out, '*the criteria specifically proposed by the European Commission for NGT category 1 were developed by the European Commission itself*'[73]. The Commission may have been inspired by a 2022 EFSA opinion on assessing the risks associated with the use of plants modified by new techniques and, above all, diverting from the values of the 2011 JRC report on the differentiation capacity of two pangenomes with randomly distributed nucleotides, contrary to what is known about pangenomes.

However, no transparent consultation with European experts or stakeholders was organised on the criteria specifically proposed by the Commission.

**The legislative procedure therefore began in July 2023 without the usual prior scientific consultations and contradictory assessments**, and this **on a major point of the Proposal**, since it is these criteria that determine the scope of the total exemption that GMOs derived from NGT 1 "benefit" regarding Directive 2001/18/ EC.

On 3 December 2025, the trilogue adopted a provisional agreement on the Proposal containing a new version of the equivalence criteria. This presents a similar approach based solely on molecular criteria

[72] Article 3 §6 of the Proposal.

[73] EFSA press office to Inf'OGM, April 2024.

and does not consider the significant criticisms made by ANSES and BfN. The equivalence criteria adopted in the trilogue are therefore still unsatisfactory in terms of scientific rigour.

### 6- Conclusion: principles not respected, claims and questions

**Principles not respected:**

In conclusion to this chapter, we consider that the way the Proposal for a Regulation on NGTs was drafted by the European Commission seriously contravenes the principles mentioned in the introduction. More specifically, for failing to carry out an impact assessment, to seek specific scientific advice in a contradictory manner, including from the EFSA, or to officially consult Member States, stakeholders and citizens on the criteria distinguishing between NGTs 1 and NGTs 2 contained in Annex I of the Proposal; for having created so-called equivalence criteria arbitrarily, without robust scientific justification; for having created equivalence criteria such that GMO-NGTs 1 represent almost all GMO-NGTs in development (and even, in the long term, plants derived from synthetic biology and xenobiology), GMOs that may be released into the environment without assessment or risk management measures, the Commission has failed to comply with the following principles:

- *Principle of excellence in scientific assessment and principle of adaptation to scientific knowledge*
- *Principle of information and participation*
- *The European Commission's principles of '*better regulation*': principles of sufficient and legitimate motivation, consistency, transparency and good faith in the drafting of legislation*

Furthermore, the Commission failed to comply with the *principle of sufficient and legitimate motivation and legislative consistency* by providing for the possibility of amending the equivalence criteria by means of delegated acts. Indeed, Article 290(1) 1-1 TFEU provides that: '*A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain* ***non-essential*** *elements of the legislative act.*'. Considering the equivalence criteria as '*non-essential elements*' that may fall under Article 290 TFEU is inconsistent, if not contrary, to an exemption mechanism whose scope of application is based precisely on these criteria.

**Our demands**:

We call on the European Commission to:

- initiate consultations with Member States and stakeholders on the criteria set out in Annex I of the Proposal consultations with Member States and stakeholders, as well as impact studies and analyses that respond directly and comprehensively to the critical analyses of ANSES (2022, 2023, 2024), as well as that of the German agency BfN.
- Revise its Proposal to consider scientific opinions after its adoption, particularly regarding the criteria in Annex I, especially since these never were evaluated before. The Proposal would thus

be brought into line with the principle of adaptation to scientific knowledge[74], a principle particularly associated with the precautionary principle, especially in the field of GMOs[75].
- revise its Proposal to remove the possibility for the Commission to amend the equivalence criteria by means of delegated acts.

**Our questions:**

- Can the Commission provide us with the specifications for all requests for external reports (e.g., EFSA 2021, author: C. van der Vlugt), scientific studies, internal exchanges within the Commission, and exchanges between the Commission, experts (EFSA, SAM) and stakeholders, which led to the selection of the criteria contained in Annex I (internal and inter-party emails, text messages, document exchanges, etc.)?
- Can the Commission specify the reasons why it decided not to carry out a public consultation and biological and socio-economic impact studies specifically on the equivalence criteria in Annex I of the Proposal? How and by whom was this decision taken?
- Can the Commission justify the '*non-essential*' nature of the equivalence criteria in Annex I, which the Proposal provides for to be amended by delegated acts (Art. 5 §3)?
- How does the Proposal relate to the requirements of Regulation (EU) No 2015/2283? As revealed in a legal opinion to the European Parliament group Bündnis 90/Die Grüne[76], it appears that checking the status of NGT plants in category 1 does not make it possible to determine whether food produced from them falls within the scope of the Novel Food Regulation as novel foods. Only the general obligations of food and feed legislation would then apply to derived from NGT 1 plants that are not novel foods, and to all feed, including feed with novel properties. For products manufactured from NGT plants that are neither food nor feed, even the general product safety requirements would not apply.

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74 This principle, which requires periodic review of risk measures considering evolving knowledge, is particularly well suited to precautionary situations. Due to the scientific uncertainty surrounding the realization of the risk, new data may always invalidate or confirm the occurrence of a risk, thereby requiring a renewal of the assessment and modification of the management measures.

75 Dir. 2001/18/EC, Annex II, B: '(...) *If new information concerning the GMO and its effects on human health or the environment becomes available, the environmental risk assessment may need to be reviewed in order to: determine whether the risk has changed; determine whether it is necessary to modify the risk management measures accordingly*.' See also ECJ, 21 March 2000, *Greenpeace France*, C-6/99, §44.

76 Georg Buchholtz, Legal Opinion, GGSC (2023), *Commission's proposal for a regulation on new genomic techniques (NGT): violation of the precautionary principle*.

## Chapter 4. Regarding the 'sustainability' of GMOs derived from NGT: postulated but unproven benefits, in the absence of both biological and economic criteria

Summary: *The exemptions granted to GM plants derived from NGT compared to other GMOs are justified by the European Commission on the presumed basis of the overall superiority of NGT plants over other GMOs in terms of sustainability or food safety. However, relying on the promises of industry, the Commission provides no evidence of these benefits, the reality, or even the probability of which is not even a prerequisite for NGT plants to enjoy privileges. On the contrary, they could represent a major disruptive factor on a large scale for the organisation of ecosystems and societies. The emergence of resistance in pests, transmission of genes – possibly of industrial interest – to wild flora, toxicity to wildlife, extinction of existing species, etc., are tangible risks, but are never considered in the proposed text. As a result, GM plants derived from NGTs may be released without control even if they prove harmful to the environment and to a truly sustainable agricultural system.*

To justify the deregulation of NGT 1 GMOs, as well as a relaxation of the constraints on NGT 2 GMOs, the Proposal highlights the potential of NGT to respond to the challenges of agro-ecological transition[77]. According to the Proposal, these processes would make it possible to give seeds '*sustainable*' characteristics (resistance to certain diseases, tolerance to environmental stresses, reduced dependence on pesticides, and improved yields or nutritional quality).

This vague concept of sustainability (see Chapter 7 on 'Vague definitions and semantic shifts'), repeatedly mentioned in the Proposal, cannot hide the fact that the claimed benefits remain purely hypothetical to date. It is a simple umbrella term with no definition or qualitative and quantitative criteria provided by the Commission.

1. The Commission relies solely on the promises of industry (promises like those made in the 1990s for transgenic GMOs).
2. Numerous scientific studies show that NGT GMOs, far from being 'sustainable', pose a threat to agriculture and the environment through the loss of genetic diversity and the reduction of biodiversity.
3. 'Sustainability', cited as a legitimate reason for exempting NGT GMOs 1, is not, however, a condition for their uncontrolled release.
4. Conclusion: principles not respected, claims, questions

### 1- The Commission relies solely on the promises of industry.

The benefits associated with NGTs remain completely improbable hypotheses, as the Commission has provided no information to enable their real potential to be assessed[78]. In the Commission's impact assessment (2021), the data provided by industry does not demonstrate that the promises of 's*ustainable*'

[77] See in particular Recital 3 of the Proposal.

[78] Wilson, 2021.

NGTs' are achievable. The Commission's impact assessment even concludes that *'case-by-case*' studies are essential for risk assessment, adding: '*A purely safety-based risk assessment may not be enough to promote sustainability and contribute to the objectives of the European Green Deal and in particular the "farm to fork" and biodiversity strategies; benefits contributing to sustainability would also need to be evaluated, so an appropriate mechanism to accompany risk assessment may be required.'*

Since this conclusion by the Commission in 2021, we are not aware of any information that would enable us to know what factors led it to take this step and assert that, from now on, NGTs and their derivative products contribute to greater sustainability. This concept is also postulated without any precise definition or objective qualitative and quantitative criteria, far removed from the UN's sustainable development goals[79]. **A peremptory statement, not based on experimental data in the agricultural, biological, environmental and socio-economic fields, cannot replace a clearly argued demonstration**.

In the Commission's impact assessment, the data concerning only GMOs derived from NGTs currently on the market (e.g., pink pineapple, GABA tomato and Calyxt soybean[80]) or under development, are fragmentary, even biased: the expected benefits (such as the relaxing effect of the GABA tomato) are touted, even though there is a long way from the laboratory bench to successful field production, especially as unexpected effects are overlooked[81] (see also Chapter 3 on industrial rapeseed and biofortification products).

**The Commission should have carried out qualitative and quantitative assessments of the agricultural, biological, environmental and socio-economic impact** of the use of NGT GMOs on **cultivation, management and harvesting techniques** compared to non-GMO plants and, in any case, **considered existing academic studies**[82]. This shortcoming makes it **impossible to anticipate a potential increase in the use of insecticides, herbicides or pesticides**, which, despite initial promises, has characterised the development of transgenic GMOs, *as we will see below*. The structural choices made by the Proposal have therefore not been informed in this regard.

The **Commission bases its justification for deregulation solely on the promises of the biotechnology industry**. As highlighted in the Appeal of 100 Scientists in November 2023[83], the Commission, focused on the unsubstantiated promises of industry, gives the impression of using the argument of sustainability to convince politicians and citizens of the need to release GMOs derived from NGTs without risk assessment or control.

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79 Hüdig, 2022.

80 Currently on the market: Del Monte's Pinkglow pineapple; GABA tomato (with neurotransmitters believed to have a relaxing effect); Calyxt soybeans with high oleic acid content; mild-flavoured mustard (Mustard Greens, marketed by Pairwise under the brand name Conscious Foods); Arctic Apple with delayed oxidation (produced by Okanagan Specialty Fruits, Canada/USA, using RNAi)*; Innate* potatoes (developed by J.R. Simplot Company using RNAi gene silencing); *Purple Tomato* developed by Norfolk Plant Sciences (marketed in the United States and Australia). Several of these products containing foreign DNA sequences are considered GMOs.

81 See in UmweltBundesamt/AGES. Study by M. Eckerstorfer and A. Heissenberger, *New Genetic Engineering - Possible Unintended Effect,* November 2023. This study reviews the unexpected effects observed in tomatoes, rice and wheat derived from NGT.

82 USDA-ERS (2023): '*Between 1990 and 2020, the average price paid by farmers for seeds increased by 270%, while commodity price inflation was only 56%. Prices for genetically modified seeds (maize, soybeans, and cotton) increased by an average of 463%.*'

83 https://newgmo.org/2023/11/19/open-letter-serious-concerns-about-the-eu-commission-proposal-on-new-genomic-techniques/

This rhetoric of (unfulfilled) promises is not new. The European institution could indeed be wary **after 30 years of unfulfilled promises by the industry marketing GMOs**. Examples include:

- promises of 'golden rice' or drought-resistant rice that have never been commercialised,
- US GM maizes that was supposedly more drought-tolerant, but was surpassed by maize from CIMMYT's conventional breeding programme,
- pesticide resistance and a sharp increase in pesticide and herbicide use,
- disappointing yields that have never exceeded those of conventional varieties,
- a concentration of commercialised GMOs on a few traits, a few niches and a few varieties, despite initial promises, due to the importance of the genetic pool of Elite varieties.

These disappointments are well documented in the scientific literature[84] and reported in the press[85].

Ultimately, **the exemptions provided for in the Proposal from the precautionary requirements of Directive 2001/ 18/EC are not justified by any tangible sustainability benefits** for farmers, consumers and citizens[86].

### 2- Numerous scientific studies show that NGT-GMOs, far from being 'sustainable', represent a danger to agriculture and the environment through the loss of genetic diversity and the reduction of biodiversity

The concept of sustainability as set out - without definition or qualitative and quantitative criteria - by the Proposal shows that the Commission has ignored a whole area of academic research and avoided taking its findings into account. It should have considered the following points, summarised here from the scientific literature cited in our Annex 1:

a-Plants derived from NGT GMOs are not 'sustainable' as such.

b-NGTs could pose a danger to biodiversity that has never been assessed.

c- Deregulation of GMOs derived from NGTs will increase concentration in the seed sector, to the detriment of agricultural resilience.

#### a-Plants derived from NGT GMOs are not 'sustainable' as such

As we have seen above with the very short list of NGT GMOs on the market, despite more than 20 years of work, plants currently derived from NGT are aimed at

- either niche markets (pink pineapple, GABA tomato, delayed oxidation apple),

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84 See our Appendix 1 'Bibliography', and in particular: National Academies of Sciences, Engineering, and Medicine. 2016. *Genetically Engineered Crops: Experiences and Prospects*. Washington, DC: The National Academies Press, as well as the bibliography cited by the Test Biotech study of March 2023.

85 https://www.nytimes.com/interactive/2016/10/30/business/gmo-crops-pesticides.html

86 Winter, 2024.

- or markets that are already very crowded and therefore competitive with GM and conventionally bred varieties (e.g., Calyxt soybeans): the price of seeds will be an important factor in the success of these products, which are currently only marketed to a few companies.
- eventually, the majority of NGT GMOs target the fastest returns on investment. These are those with independent mono- or oligo-genic traits such as tolerance (stacked due to circumvention by weeds) to misused universal herbicides or tolerance to resistance to certain insects, even though the sustainability of 'horizontal' resistance (i.e. multigenic and more difficult to introgress using GMO-NGT techniques) to phytopathogens and holobiont parasites or the resilience of multi-line crops is unanimously recognised[87].

It is well known in plant breeding and phytopathology that **mono- and oligogenic solutions**, the only ones accessible to NGT even after the possible identification of genomic refuges ('*safe harbour*') and the creation of *landing pads* for repeated insertions, **are not biologically and agronomically sustainable**.

Furthermore, two important points should be noted:

i) It is wrong to claim that a plant could be sustainable *per se*. Sustainability or resilience comes from an agrarian/agricultural system as an ecosystem, from factors that are external to the plant (soil quality and richness, local biodiversity, local climatic conditions, the farmer's agricultural practices, etc.), as well as socio-economic factors such as the ability to develop seeds adapted to a local area. What matters in terms of yield or pest resistance is not so much a particular manipulated gene, but rather the gene pool and genetic and epigenetic diversity co-evolving with the environment.

Furthermore, even if it were possible to produce plants as promised by the European Commission (without any real evidence), it is impossible for such practices to be sustainable in themselves, since the sustainability of an agricultural system depends much more on its ecosystem than on the dissemination of genetically modified plants.

Indeed, **stress tolerances involve hundreds of genes, the expression of which depends on the genetic background** (gene pool) **and the contexts of the plant, the microbiota, and other living beings in the environment**. These tolerances do not involve the same sets of genes depending on the stage of cultivation (growth, grain filling, etc.). In addition, a gain in one area often leads to a loss in another: a certain tolerance to drought can lead to increased sensitivity to humidity, for example. The current ability of plants to adapt to extreme environmental conditions, which vary greatly in intensity and duration, depends on epigenetics and not solely on the genetics mobilised by NGTs with 'gene factors' that are generally poorly characterised or not characterised at all. This is particularly well illustrated in the case of drought resistance in maize. The genetic resources of maize selected by the CIMMYT international research centre are the only ones selected for Africa, as their tolerance to different forms of drought far exceeds and is more sustainable than that of GMO maize from GMO seed companies.

The trait of **drought resistance**, which is constantly mentioned to justify the proposed regulation, is therefore not within the scope of genetic engineering. Drought tolerance is a complex, polygenic trait involving hundreds to thousands of genes, with minor QTLs and epigenetic or environmental interactions. The factors involved at the germination stage, for example, differ from those involved in grain filling, while a plant's drought resistance depends on the severity and duration. Furthermore, these complex multigenic systems (in the form of QTLs and SNPs, with the study of 354 genes in maize linked to 365 SNPs, 369 in chickpeas, or thousands of SNPs in wheat) are highly dependent on the gene pool and the environment for their expression, and improved drought resistance can lead to yield declines

87 Orton, 2020.

during wet periods[88], just as a reduction in the gluten content of a cereal can decrease its drought resistance. The introduction of genes for resistance to abiotic stresses, such as drought or cold, can thus induce changes in plant architecture or even dwarfism[89].

Another problem in attempts to produce plants tolerant to various biotic stresses is that microbiota (bacterial and fungal microorganisms) are not considered despite their crucial importance for sustainable agriculture[90]. As for the claim that the promised improvements could occur naturally or through varietal selection, this would require, as we saw in Chapter 1-B, several million or even billion years.

ii) The use of NGTs, linked to an intensive production method focused on artificial monoculture productivity as much as possible, will reduce the genetic diversity cultivated, since the success of a variety will lead to its rapid and widespread use by farmers. This situation creates strong selection pressure on pests and pathogens and, due to the homogeneity of the gene pool[91], a high sensitivity to environmental changes and to pathogens or pests that have overcome the plants' defences. Inevitably, through the simple application of the rules of evolution, emerging diseases and pests develop (this is already the case with transgenic GMOs), forcing the use of more pesticides[92], as observed in third countries using GMOs with mono- or oligo-genic resistance. Indeed, only these resistances can be easily introduced by NGTs, which leads to the need for gene stacking, which is why the EFSA recommends seeking genomic refuges ('*safe harbour*').

More generally, the choice of traits studied is often dictated by convenience rather than by sound ecological or physiological hypotheses (for example, the most commonly measured plant traits worldwide are specific leaf area and plant height, which are easy to measure). It is therefore highly likely that these persistent choices of 'traits' will themselves limit possible technological developments against biotic and abiotic stresses, just as they already limit traditional selection. The use of local varieties ('*landrace*') such as Mediterranean tomatoes, which are particularly tolerant to drought, appears in many ways to be more interesting than biotechnologies[93].

This argument for the sustainability of NGT, in line with the economy of promise developed by biotechnology companies for decades, reinforces the '*path dependency'* of intensive agriculture, far removed from agroecology, which is recognised as the most sustainable option[94]. It has the advantage, for industries, of promoting the orientation of public and private research funds towards NGT, obscuring the associated risks, and legitimising their rent capture (accumulation of subsidies from the Common Agricultural Policy (CAP) and various national tax advantages).

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88 Blein-Nicolas et al., 2020; Islam et al., 2023; Jeandroz and Lamotte, 2017; Li et al., 2016; Mathew et al., 2019; Ruiz-Lozano et al., 2016, Sarkar et al., 2023.

89 Van Wallendael et al, 2019.

90 Favela 2021 et al., Melotto 2020 et al., Razzaq et al. 2021.

91 GMOs, whether derived from NGT or not, will be marketed as cultivars that meet VATE and DUS criteria, i.e., with a similar genetic and phenotypic background, much like clones.

92 See the extensive literature on the effect of '*selection pressure*.' GMO plants, including those derived from NGTs, are produced from limited genetic pools (e.g., Topaze rapeseed variety, see Bertheau 2022b) and the selection of a homogeneous phenotype (and therefore a homogeneous gene pool with current variety production techniques). Combined with intensive agriculture over large areas, this homogeneity of genetic resources not only reduces agricultural genetic diversity, but also promotes the selection of mutants among parasites, pathogens and pests that develop resistance, for example to Bt toxins in GM plants. This well-documented phenomenon then leads to increased use of pesticides (fungicides, insecticides), which is also harmful to environmental biodiversity and health, as observed, for example, in the United States.

93 Casals *et al.* 2021, Conesa *et al.*, 2020; Singer *et al.*

94 Blaix *et al., 2026, IPES-Food, 2022.*

Contrary to their untenable promises, the social and ecological innovations of agroecology in small-scale farming are effective, profitable, and equitable, make farmers less dependent on patents and inputs, pose no safety issues and enable agricultural systems to adapt to climate challenges while promoting social equity[95].

### b- NGTs could pose a danger, never assessed, to biodiversity

The significant risks associated with the potentially irreversible spread of GMOs derived from NGTs with adverse effects on health or the environment are not addressed at all in the Proposal (see Chapter 1). However, **plants derived from GTN are living organisms which**, like all other GMOs, **can reproduce and spread in the environment** (feral populations can be observed for many cultivated species). And like all other GMOs, they **can supplant natural or conventional plant species due to deliberate or accidental selective advantages derived from NGTs, thereby affecting existing food chains** (e.g., transfer of herbicide tolerance to related or wild plants).

As seen in Chapter 1-B, it should be remembered that uncontrolled, rapid[96] (given the ease of use of NGTs) and irreversible dissemination of genetically modified material would artificially increase the rate of evolution of complex natural systems. Such dissemination would also increase the contamination of food chains and the genetic resources of a centre of diversity (see, for example, maize in Mexico or sea beet in France). On a large scale, it could represent a major disruptive factor in the organisation of ecosystems and societies. The emergence of resistance in pests, gene transfer – possibly of industrial interest – to wild flora, toxicity to wildlife, extinction of existing species, etc., are tangible risks, but are never considered in the proposed text.

**In the absence of traceability tools and general monitoring networks and protocols** as provided for transgenic GMOs, the effects of the unintended release of NGT products would be difficult to discern before the systems break down.

### c- Deregulation of GMOs derived from NGTs will increase concentration in the seed sector, to the detriment of agricultural resilience

The development of patented plants derived from GMOs-NGTs will contribute to increased concentration in the seed sector. As summarised in this article[97] by Dr Kock, molecular biologist and former IP director of Syngenta: *'Once NGT varieties obtain a substantial market share (>50 per cent), access to and exchange of plant biodiversity could practically cease, and breeders would only breed within their own collections. This would substantially narrow the genetic diversity available to breeders, affect breeding progress, and lead to industry consolidation. Eventually, the EU could face a similar*

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95 FAO*, 2014;* Bezner Kerr *et al., 2021,* Ewert *et al. 2023;* UN FAO HLPE-FSN*, 2019,* Vikas and Ranjan*, 2024.*

96 The Commission touts the speed with which genetic modifications can be introduced using NGTs as a virtue. However, according to the case law of the CJEU (Case C 528/16), a higher speed of introduction and dissemination of GMOs does not argue in favour of deregulating the corresponding techniques, quite the contrary. In fact, a high speed of introduction of new organisms into agricultural ecosystems can subvert the adaptive capacity of surrounding ecosystems and limit the ability to respond to risks and hazards identified *ex post.*

97 Kock, Michael A., *EU Parliament on Patents for NGT-Derived Plants: Pawn Sacrifice or Sacrificed to the Pawns?* (27 February 2024). *Bio-Science Law Review,* SSRN: https://ssrn.com/abstract=4775666.

*situation to that in the United States, where two companies – Corteva and Bayer/Monsanto – control over 70 per cent of the corn seed market and 85 per cent of corn-related intellectual property.'*

This economic concentration will consequently lead to a decrease in seed genetic diversity, as well as a reduction in the supply of non-GMO seeds, as already observed for non-NGT GMOs by the European Co-Extra programme[98]. These deleterious effects will directly undermine the resilience of agricultural systems. At a time when agriculture is facing numerous ecological crises, maintaining the greatest possible genetic diversity of cultivated plants is essential to provide satisfactory responses.

### 3- However, '*sustainability*', cited as a legitimate reason for exempting NGT GMOs 1, is not *per se* a condition for their uncontrolled release.

The EU legislator is entitled to balance the precautionary principle with other objectives and principles and has regulatory leeway in this regard. Namely, the Commission justifies its proposal by citing advantages in terms of sustainability. However, it provides no documented scientific or socio-economic evidence of intrinsically greater sustainability advantages (or lower risks) associated with NGT GMOs compared to other GMOs, as we have seen.

Furthermore, **it does not include this sustainability criterion among the criteria required for an NGT to be classified as category 1**, and therefore to benefit from an exemption from the scope of Directive 2001/18/EC.

As a result, the Proposal contravenes both the precautionary principle and the principle of legitimate motivation for legislation. Plants derived from NGTs may thus be released without restriction even though they do not meet any of the sustainability objectives of the Proposal. **The total exemption of Category 1 NGT plants will effectively benefit, without restriction, NGT plants that are otherwise detrimental to the objectives of the Union, such as sustainability and biodiversity.**

The Proposal thus leads to this **paradoxical situation**: a Category 1 NGT plant that is herbicide-tolerant would be exempted from the requirements of the legislation on genetic engineering in the same way as any other Category 1 NGT plant, even though herbicide tolerance is explicitly mentioned in Annex III, Part 2, of the Proposal as a characteristic that excludes the granting of privilege to Category 2 NGT plants on the basis of their sustainability benefits[99].

### 4- Conclusion: principles not respected, claims, questions.

**Principles not respected:**

In conclusion to this chapter, we consider that the way the Proposal for a Regulation on NGTs was drafted by the European Commission seriously contravenes the principles mentioned in the introduction.

More specifically:

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98 Milanesi*, 2013.*

99 See on this point: G. Buchholz *et al*., *Legal Opinion, Commission Proposal on New Genomic Techniques (NGT): Violation of the Precautionary Principle*, 14 Sept. 2023.

- by failing to provide a clear, lasting definition of 'sustainability' in its Proposal that can be objectively assessed using qualitative and quantitative criteria, **even though it has already been admonished on this subject by the EU Ombudsman,**
- by failing to carry out prior assessments specifically concerning the impact of the use of -NGT on agricultural production systems and associated sectors using non-GMO plants,
- by not requiring that the putative social benefits inherent in an NGT plant be considered as one of the preconditions for exemption from the scope of Directive 2001/18/EC,

the Commission is contravening the *Precautionary Principle*, the *Principle of legal certainty* and the *Principles of good administration*, which require legitimate legislative justification and assertions based on scientific grounds that are recognised and consistent across different pieces of legislation.

**Our demands:**

We call on the European Commission to:

- define the characteristics of 'sustainable' agriculture, following debates and consultations allowing for the expression of opposing views.
- to conduct a scientific and socio-economic study that goes beyond simply analysing the sustainability of plants modified using NGTs: before the first GMOs-NGTs 1 and 2 products are placed on the market, it must undertake a comprehensive assessment of the expected sustainable benefits, but also of the collateral damage to the resilience of ecosystems and the socio-economic consequences, taking into account the spatial and temporal evolution of these plants in their environment, as well as the associated agricultural practices.

**Our questions:**

- Considering the evidence, we have provided regarding the unsustainability of NGT GMOs in several respects, what is the Commission's position?
- What measures does the Commission intend to put in place to ensure effective protection against the collateral damage and negative effects of GMOs-NGTs on the resilience of ecosystems, and to clarify liabilities?
- What guarantees does the Commission offer to ensure that the new promises made by industry regarding the sustainability of GMOs-NGTs do not remain empty? Are there plans to produce reports assessing the fulfilment of these promises over the coming years?

## Chapter 5 – Concerning the traceability of GMOs derived from NGTs: identification long obscured by the Commission and prolonged rejection of requests for adequate research programs

Summary: *The European Commission has long supported the argument that the identification of GMOs derived from NGTs was impossible, or at least sufficiently difficult to justify that GMO regulations could not apply to certain organisms derived from NGTs. Then, through a semantic shift, it claimed that these GMOs could not be technically distinguished, and ultimately were not biologically distinguishable from conventional plants, leading to a principle of 'continuity' and then 'equivalence'. Misunderstood technical points of detection thus allowed it to shift its arguments on the legal issue that GMO regulations were not applicable in the supposed absence of methods of detection. Recently, the Commission eventually acknowledged that their detection was feasible and funded two research programs on the subject. However, a carefully chosen agenda enable it to adopt its Proposal before the first results of these programs, which conclude that such detection is not only feasible but also desirable.*

The Proposal provides that genetically modified products derived from category 1 NGTs should be exempted from Directive 2001/18/EC, which makes traceability and labelling of GMOs mandatory. To justify this exemption, in particular, the Commission starts with a premise of '**undetectability**' (or '**too complex**' to detect) based on EU expert opinions whose biased reasoning can be criticized.

In doing so, the Proposal has deliberately and consistently ignored scientific studies that have shown for several years that such identification is entirely feasible and even desirable for reasons of food and environmental safety. Furthermore, the European Commission, which was slow to launch research programs on this issue, did not wait for their results before adopting its Proposal.

The Proposal aims to exempt GMOs derived from category 1 NGTs from any labelling and traceability requirements: a '**privilege**' that breaks with the **Precautionary Principle**, but also with the **polluter pays principle**, the **Principle of legal certainty**, the **Principle of transparency** and the **Principle of responsibility**.

1- The Commission pleads the difficulty of identifying GMOs derived from GTN as grounds for considering traceability and labelling measures to be inappropriate.

2- This assumption of 'undetectability' is based on biased opinions from EU experts and officials working on a legislative project aimed at deregulation.

3- The European Commission has ignored the numerous scientific studies that prove the possibility of identification and traceability.

4 - The Commission was slow to launch research programs and did not wait for their results before adopting its Proposal.

5- The Proposal exempts cat. 1 NGT from any labelling and traceability requirements: a 'privilege' that breaks with essential EU principles.

6- Conclusion: principles not respected, claims, questions.

**1- The Commission pleads the difficulty of identifying GMOs derived from NGTs as basis for considering traceability and labelling measures to be inappropriate.**

During the European debate on NGTs, the Commission has long pleaded its desire to ease regulations for a broad category of NGTs by claiming that the products obtained in this way are intrinsically undetectable or indistinguishable from those obtained through conventional breeding. This position is reflected not only in various documents prior to 2023, but also in the recitals of the Proposal, supporting that 'the current Union legislation on GMOs is not suitable for regulating NGT plants:'

Recital 7: (...) *the Union GMO legislation is difficult to implement and enforce for plants obtained by targeted mutagenesis and cisgenesis and related products. In certain cases, genetic modifications introduced by these techniques are indistinguishable with analytical methods from natural mutations or from genetic modifications introduced by conventional breeding techniques, whereas the distinction is generally possible for genetic modifications introduced by transgenesis.* (...)

This recital calls for two observations:

- while the Commission admits that this (alleged) lack of 'distinguishability' only applies '*in certain cases*', it then claims a generalised 'equivalence' for GMO-NGT 1 (i.e., almost all NGTs in development, as we saw in Chapter 3).
- The Commission reasons, wrongly, as if the alleged difficulty in identifying a GMO derived from NGTs removed any potential for them to pose risks to the environment and health.

This position on 'undetectability' or 'too complex' detectability, has helped to maintain a **political narrative of non-detectability and equivalence, a narrative that seems to have been useful to the Commission in justifying the removal of traceability and labelling** requirements. Labelling requirements are indeed perceived as likely to affect the acceptability of products by consumers.

**2- This assumption of 'undetectability' is based on biased opinions from EU experts and officials, serving a legislative project of deregulation**

The Commission relied on an erroneous analysis of the state of the scientific literature on GMO detection (JRC, 2011), as well as on an argument of biological equivalence presented as self-evident, without solid empirical evidence of the general impossibility of detecting specific genomic modifications, and regardless of the information available on these modifications.

Our **Appendix 3** provides details explaining how circular reasoning, self-referential loops and sophistry provided the Commission with its 'scientific' basis for justifying both the postulate of insurmountable difficulties in detecting at least some GMOs -NGT, and the establishment of certain criteria to distinguish between category 1 and category 2 NGTs.

It should be noted here that, in 2023, to justify this difficulty in identifying plants derived from NGTs from conventional plants, the Commission cites old studies dating from 2010 and 2011[100]. The

[100] EPEC (European Policy Evaluation Consortium), 2011; European Policy Evaluation Consortium (EPEC), 2011a; European Policy Evaluation Consortium (EPEC), 2011b; FCEC (Food Chain Evaluation Consortium), 2011; FCEC (Food Chain Evaluation Consortium) et al., 2010; Food Chain Evaluation Consortium (FCEC),

Commission thus considers that there has been no progress since then. And although these are **evaluations of public policy and not laboratory studies**, the Commission uses them in its 2023 proposal (see document *SWD(2023) 412 final*, page 13) to justify two critical points:

- The finding of inadequacy: these studies (framed by DG SANCO) conclude that the 2001 legislation is not adequate to keep pace with biotechnological innovation.
- The challenge of detection: the Commission emphasises – without mentioning the conditional language used by the experts – that these 2010 and 2011 reports already mention the *'**detection challenges** resulting from the fact that products of targeted mutagenesis **may** not differ from those obtained by conventional breeding'*.

The 2011 JRC technical study (JRC, 2011) is in fact the scientific basis that informed these two assessments and administrative frameworks. It was the JRC that provided the FCEC and EPEC/GHK assessors with the technical argument that, biologically, it would not be possible to distinguish between a 'natural' change and an 'induced' by new ('breeding') techniques (NBT[101] at the time).

A 'shift' took place between 2021 and 2023 with the introduction of the following sophism: what in 2010/2011 was only a technical limitation of detection (a **false finding of the inability of laboratories at a given moment**, see, for example, the results of the European Co-Extra program on the traceability and coexistence of GMO and non-GMO sectors[102], or the reports of the ENGL network on the detection of unauthorised and unknown GMOs) is transformed by the Commission in 2023 into a criterion of biological equivalence.

Here is a summary of how publications feed into each other to create this circular reasoning:

- 2010-11 (JRC/FCEC/EPEC/GHK): It is not technically possible to distinguish plants derived from NTGs from those derived from conventional agriculture if the modifications made by NTGs are minor.
- 2019[103] (ENGL): Since we cannot distinguish between them, we cannot apply GMO labelling.[104]
- 2021 (Commission Impact Assessment): the conclusions of the 2010-2011 evaluations of the GMO legislation as regards NGTs are confirmed: the impossibility of detection makes the current law unenforceable.
- 2023 (Proposed Regulation): Since they are indistinguishable (2011 argument), they are therefore equivalent to conventional products [semantic shift]. We therefore set the limit at 20 nucleotides (arbitrary figure) for the NGT1 category.

Analysis of the reports[105] of the **ENGL Steering Committee** and various other documents from the ENGL network reveals **strong technical tensions in response to the simplistic assertions of the**

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2009; Food Chain Evaluation Consortium (FCEC). Civic Consulting - Agra CEAS Consulting - Van Dijk Management Consultants – Arcadia International, 2011; Food Chain Evaluation Consortium (FCEC). Civic Consulting – Agra CEAS Consulting -Van Dijk Management Consultants - Arcadia International, 2011.

101 New Breeding Techniques, cf. COGEM 2007.

102 Bertheau, 2013a.

103 '*Assisted by the ENGL will need to review the minimum performance requirements [...] in view of the specific characteristics of genome-edited plants*' - this implicitly contradicts the idea of a complete lack of distinction, by calling for specific tools to distinguish NGT from conventional techniques. Source https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf

104 The ENGL experts note that current methods need to be revised for NGTs without recombinant DNA, as quantitative validation criteria (e.g., a 0.9% threshold) do not always apply, but emphasise that this is technically feasible in most cases through sequencing or appropriate screening.

105 https://gmo-crl.jrc.ec.europa.eu/ENGLabs#inline-nav-engl-meet

**Commission** on the non-detectability/non-discernibility of NGT products compared to conventionally bred plants.

**The Commission is thus transforming a technical challenge** (admittedly real in relation to commonly used techniques - unambiguous signature in real-time quantitative PCR – but technically and regulatory surmountable) **into an excuse for administrative deregulation aimed at aligning the EU with the standards of less protective countries** (United States, Brazil, China).

**The argument of undetectability has become the rhetorical and administrative pivot used by the Commission to overturn the legal regime for NGTs.** By seeking to have detection recognised as an 'insurmountable technical impossibility'[106], the Commission is seeking, through a strict and focused mandatory mandate ('*administrative framing of the mandate*' and '*terms of reference*') to make technical bodies (JRC, ENGL) and safety authorities (EFSA) accept profound paradigm shifts, supported in this by the '*scoping*' of European officials from these bodies who will 'hold the pen' of the experts.

**Getting equivalence in principle due to lack of evidence**: for the Commission, the limitations of control tools become proof of biological identity, rendering Directive 2001/18/EC obsolete. Rather than scientifically proving that the plant is safe (Precautionary Principle), the following argument is used: Since we cannot distinguish this plant from a conventional plant in the laboratory, it must be considered conventional. In other words, the argument of undetectability is used to make the removal of traceability obligations for operators 'rational' since (administratively) indistinguishable.

As with microorganisms, the Commission has once again extrapolated from very limited warnings ('certain point modifications', 'certain cases of unknown products') to a general conclusion about all NGT plants.

By getting the JRC and ENGL (and consequently the NRLs[107]) to accept - through close interactions between DGs (SANCO mandates and then SANTE in particular) and JRC staff (scoping, choice of bibliography, etc.) - that detection is 'too complex' or 'unreliable' and, in addition, 'costly', the Commission has shifted the burden of proof. We are thus moving towards the idea that modification has become 'natural/equivalent', and therefore that the developer no longer must provide these monitoring tools. This creates a grey area where contamination (in organic or 'GMO-free' sectors) becomes impossible to prove legally.

Let us recall here some deplorable and notable omissions. Thus, **comparing the effects of the techniques on the same plant pangenomes has never been done experimentally**, which represents a significant lack of verification from the point of view of the current legislative project. Yet it would make it possible **to highlight the types of scars and signatures of all examples of NGT** and to scientifically verify whether the '*matrix approach*' (the '*fingerprinting'* strategy of certain authors) of scars and signatures makes it possible to identify products derived from NGTs and their techniques, as is done by ISO and UPOV to identify varieties[108].

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[106] The argument regarding undetectability is based primarily on the biased report by Lusser et al. (2011), which, however, used the **conditional tense** and referred to only one of the available detection, identification and quantification strategies.

[107] National Reference Laboratories, i.e., the Member States' official control laboratories organised into a network, which are also members of ENGL.

[108] On this omission, see Germini et al. (2018), Bertheau (2022b) and Koller (2025), the last, despite his pro-NTG stance, implicitly acknowledges the limitations of exhaustive comparisons. This confirmation of the persistence of the gap (of effective comparison) noted by Germini is also acknowledged by other authors with

### 3- The European Commission has ignored the numerous scientific studies that prove the possibility of identification and traceability

Contrary to what the biotechnology industry and the Commission have long claimed, **it is entirely technically possible to identify plants derived from GMOs-NGTs**.

The detectability of products derived from new bioengineering techniques depends on methodological, bioinformatic and informational parameters, which are well understood and adaptable in many fields, and cannot in any case, even with the strategies and techniques available in 2010, be ruled out on general considerations without consulting independent scientists.

However, what is entirely feasible in other fields (biodefence, microbiology and even the European Co-Extra program[109], with or without DSS[110] and Artificial Intelligence software) has long been presented by the Commission as unfeasible in the controversial field of NGT GMOs.

However, **studies**, independent of the ENGL network supervised by the Commission's mandates, **have shown for years that the identification of GMOs derived from NGTs**, even those in category 1, **was not only feasible but also desirable**. Plants derived from NGTs are technically identifiable, **thanks to all the unintended adverse effects** induced by using these techniques **on the genome**: these techniques, however precise they may be[111], they encounter significant problems of reproducibility[112]. Traceability and labelling would therefore also be feasible if research and standardisation programs were funded, as they were for transgenic GMOs in the European FP4, FP5 and FP6 research programs[113].

Moreover, **biotech breeders can only protect their patents if they can identify their products**, in this case their GMO-NGT varieties. This is why standardisation is underway at ISO and UPOV level[114]. NGT1 seeds will be identified, not simply by documentary traceability (*i.e. stricto sensu*) but by techniques developed for patents and to fight possible counterfeiting, such as those currently being standardised by the same biotech breeders.

## What does the extensive literature reveal regarding the feasibility of identifying, quantifying and tracing GM plants derived from new genetic technologies?

Analysis of studies on the detectability of NGT GMOs[115] reveals that the argument of 'indiscernibility' confuses putative technical impossibility with the absence of accessible

pro-NTG narratives, as can be seen in the EFSA opinions (2020–2025), Petereit et al. (2022), or the 2024 report of the ENGL Steering Committee.

109 https://onlinelibrary.wiley.com/doi/book/10.1002/9781118373781

110 Decision System Support

111 *In vitro* cultures, seedling regeneration, acclimatisation, vectorisation of NGT tools and residual insertions, unintended effects on on-target and off-target sites that may lead to 'chromothripsis' (large rearrangements).

112 Bairu et al., 2011; Bertheau, 2019; Bertheau, 2022a; Bertheau, 2022b; Chu and Agapito-Tenfen, 2022; Editorial, 2017; Fossi et al., 2019; Henry et al., 2018; Shi et al., 2017. As noted in several articles cited in this letter, backcrossing with Elite varieties to introduce traits only removes some of the traces left by these techniques as a whole; for example, the signatures originate from the parental lines and the NGT techniques used.

113 QPCR-GMOFood, GMOchips, SIGMEA, Co-Extra.

114 On this issue, see Y. Bertheau, 2022b; de Lorenzo and Schmidt, 2018.

115 See Appendix 1

reference data, turning an organisational or political shortcoming into a supposed property of the modified organism (on this confusion, see our Appendix 3).

We refer in particular to the summaries by Yves Bertheau[116] (Bertheau, 2019, 2022a, 2022b, 2022c), who has demonstrated that it is entirely possible, thanks to the scars left on the genome by NGTs, to identify, for a given plant, its species, whether it is domesticated or not, whether it has been modified by an *in vitro* or an *in vivo* technique, and which pool of breeders it comes from (Bayer or other). **Artificial intelligence (AI) can even trace back to the names of the technicians** (depending on the use of a particular strain or plasmid) **and detect how much foreign DNA remains – which, it should be remembered, always contaminates the result**. This is true regardless of the technique used: CRISPR/Cas 9, ZFN or others.

For its part, the Agapito-Fenten team (Zanatta et al., 2023; Zanatta et al., 2025) has demonstrated that point mutations generated by genome editing can be detected and quantified by targeted PCR approaches, next-generation sequencing and comparative bioinformatic analyses, subject to clearly specified conditions. This work shows that **the detection of mutations resulting from genome editing is not only theoretically possible but can be implemented in a reproducible and operational** manner within a control framework, **provided that the authorities have minimum information on the modifications introduced, an obligation laid down in Directive 2001/ 18/EC** and related regulations.

Similarly, *fingerprinting* approaches, a name given to the *matrix approach* traditionally used for transgenic GMOs, are also possible (Fraiture *et al*., 2025). Fraiture's team's work provides decisive additional insight by analysing the detectability of organisms derived from NGTs **from the perspectives of the effective capabilities of official control laboratories**.

**Numerous articles on the best methods for reducing costs**, for example during sampling, or using qualitative methods to determine the analyte content of a sample in relation to a threshold such as that for GMO labelling[117], are also available in the literature.

The EU's Joint Research Centre (JRC) itself admits that if existing regulations are applied to NGT GMOs, **the availability of reference material**, as provided for in European regulations, **would make it possible to determine the presence of NGT GMOs** using these screening and fingerprinting techniques or techniques for detecting univocal targets[118]. The results of national programs such as Foodprint[119] and European programs such as Darwin also demonstrate that detection is possible when reference materials are available[120]. It should also be noted that the unavailability of CRMs[121] for controlling authorities will make it more difficult to carry out expert assessments in the event of disputes over patent ownership and the origin of undesirable events. As various recent health controversies have shown, self-monitoring by companies is far from guaranteeing the safety of citizens and consumers. **However**, despite requests from several

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116 Co-founder of the ENGL (European Network of GMO Laboratories), member of the ENGL Steering Committee, former chairman of AFNOR and head of the French delegation to CEN and ISO for the standardisation of detection and traceability methods, former coordinator of the European Co-Extra programme on improving coexistence between agricultural sectors.

117 Bertheau et al., 2002; Burns et al., 2007; Cankar et al., 2008; Kobilinsky and Bertheau, 2001; Kobilinsky and Bertheau, 2005; Miraglia et al., 2009.

118 Bellocchi et al., 2013.

119 https://www.norceresearch.no/en/projects/foodprint

120 Caprioara-Buda *et al.*, 2012; Corbisier *et al.*, 2007; Debode *et al.*, 2010; Linsinger *et al.*, 2007; Trapmann *et al.*, 2010; Trapmann *et al.*, 2002.

121 Certified Reference Material, as control genetic material.

Member States and NGOs, repeated for more than a decade, **this reference material has only relatively recently been made available by the Commission**.

In view of this abundant and convergent literature, the Commission's position on detectability may appear to be a denial that has been maintained for many years with a view to gaining acceptance for the deregulation of new GMOs. Its delay in launching research programs corroborates this intuition.

### 4- The Commission was slow to launch research programs and did not wait for their results before adopting its Proposal

For several years, Member States, the European Network of GMO Laboratories (ENGL) and several NGOs have been asking the Commission to launch research into strategies and methods for identifying new GMOs. However, between 2016 and 2021, of the €356 million that the EU is spending on new research on GMOs, only 1.6% was devoted to detection methods, risk assessment or monitoring[122].

**The Commission** refused **for a long time to fund a research program dedicated to the detection of NGTs**, led by the ENGL network, considering this issue to be **not a priority**[123]. As highlighted in 2021 by the newspaper Inf'OGM[124], the Commission was thus blinding Europe, both **by refusing twice, in 2013 and 2017, to fund ENGL's work on the detectability** of NBT/NGT products, thereby opposing political will to the scientific framing of this issue.

**It was only after a proliferation of scientific articles** demonstrating the theoretical and methodological feasibility of detection that the **Commission**, following ENGL's lead, recognised that detection was possible and **finally agreed to fund two targeted programs** (including the DARWIN project). At the end of 2022, the Commission launched a call for research proposals on the traceability of NGTs. In December 2023, it allocated €11 million to two research programs on the detectability and identification of GMOs/NGTs (DARWIN and DETECTIVE), **six months after adopting and publishing its Proposal, which partly justifies the deregulation of new GMOs on the grounds of difficulties encountered in their... identification!**

This timeline suggests that **the argument of undetectability was initially used as a political justification for structural regulatory choices, before being partially revised under pressure from scientific advances in detection, without however influencing the regulatory framework that had already been decided upon.**

The Proposal was therefore unable to consider the experimental results of programs launched too late, which risked undermining some of its paradigms. In fact, tasked with developing methods for the detection and traceability of products derived from NGTs, the DARWIN program issued an opinion in September 2025 with the evocative title '*The analytical detection of NGTs in food and feed is **feasible** - and **essential to maintain confidence and transparency**'*[125]. This study provides **further confirmation that all GM plants derived from NGTs are perfectly identifiable**, i.e., made distinct from plants derived from conventional agriculture or occurring naturally; and therefore, **traceable from the seed producer to the final consumer**, using the many techniques and strategies previously developed for

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122 European Commission, « 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 » (p. 35), 29 April 2021.

123 Inf'OGM, 2021 ; GMWatch, 2023.

124 https://infogm.org/article_journal/le-legislateur-rend-lunion-europeenne-aveugle/

125 DARWIN (2025), Analytical detection of NTGs in food and feed is achievable – and essential to maintain trust and transparency (Policy Brief).

transgenic GMOs or other detection targets (e.g., in biodefence). DARWIN even considers this detection to be essential in the name of the *Principle of transparency* and the *Principle of trust* of consumers and users.

Today, the argument of undetectability can no longer be used in good faith to justify a regulatory exemption. After several theoretical reviews confirming the possibility of detecting NGT GMOs, the most recent work has confirmed this finding on an experimental level and shows that detection is possible, reproducible and compatible with official controls. They explicitly invalidate the Commission's initial argument that NGT products are intrinsically undetectable.

### 5- The Proposal exempts NGT 1 GMOs from any labelling and traceability requirements: a 'privilege' that breaks with essential EU principles

According to the Proposal, GMOs derived from NGT 1 will not be subject to traceability and labelling requirements, whereas, as we have seen, traceability is both feasible and desirable - and, as noted in Chapter 3, the thresholds for category 1 are both arbitrary and very broad (approximately 90% of GMOs-NGT in development fall below these thresholds).

If these organisms prove to be dangerous after they are placed on the market, no effective protective measures can be taken, as they will no longer be identifiable due to the absence of labelling, traceability and specific and general monitoring measures. **Food business operators, farmers and consumers will no longer be able to refrain from using these plants, the risks of which will not have been assessed and reported before they are placed on the market**. This situation would seriously contravene the Precautionary Principle as laid down in the legislation resulting from Directive 2001/18/EC. It would also break with the principle of free choice to produce and consume with or without GMOs, which has prevailed until now, as well as with the Polluter Pays Principle, the Principle of legal certainty, the Principle of transparency and the Principle of responsibility.

Furthermore, the absence of any obligation to identify and label NGT 1 GMOs and the unavailability of CRMs give rise to serious **legal uncertainties** for a whole range of operators: **developers, distributors and users of category 1 NGT plants and products, as well as downstream companies in the food and feed sectors**. Indeed, they will be unable to know whether and to what extent they are liable for any damage that may result from the use of these organisms. And since GMOs-NGT 1 (except for seeds) will not be required to be labelled as such, food companies will not know whether and to what extent their foodstuffs have been produced from NGT 1 plants. This situation would clearly contravene the *Polluter Pays Principle,* the *Principle of legal certainty*, the *Principle of transparency* and the *Principle of responsibility*.

The Commission has not taken proper account of the **viewpoint of consumers and citizens**; it has not been given due consideration by the Commission. Yet they have expressed themselves clearly, on several occasions and in several countries of the European Union: they are calling for the labelling of all GMOs, including new GMOs, so that they can be informed and retain their freedom of choice regarding the food they buy and consume. For example, in a 2022 survey conducted for Greenpeace by Kantar, 92% of the French population wanted the presence of new GMOs to be indicated on food

packaging[126]. Several consumer associations in France and Europe have clearly expressed citizens' demand for traceability and labelling of all GMOs-NGTs[127]. This demand has not been heard.

### 6- Conclusion: principles not respected, demands, questions

Rather than scientific impossibility or insurmountable technical constraints, the argument of the undetectability of new GMOs is a matter of administrative goals (mandates) of the Commission intended to drive the JRC, ENGL and EFSA, then the Member States and the European Parliament, to accept political choices in favour of acceptation of 'equivalence' criteria and removing the obligations to declare or trace GMOs-NGT 1. This removal contravenes fundamental principles and rights and raises several claims and questions.

**Principles and rights not respected:**

In conclusion to this chapter, we consider that the way in which the Proposal for a Regulation on NGTs was drafted by the European Commission seriously contravenes the EU principles and rights mentioned in the introduction, and in particular the following principles:

- *Principles of information and participation*: because of the Commission's procrastination, Member States, the European Parliament, stakeholders and citizens have not been properly informed about the detectability of GMOs derived from NGTs, even though this important point is the basis for the Commission's justification for deregulating NGTs.
- *Principles of 'Better Regulation'*, the principles of legitimate legislative motivation and good faith and the principle of transparency, due to the Commission's delay in recognising the detectability of GMO-NGT (despite abundant literature demonstrating its feasibility), in launching related research programs, and in adopting the Proposal without waiting for the results of this research.
- *Principle of rigorous scientific assessment based on principles of excellence, independence and transparency, and Principle of adaptation to scientific knowledge*: for the same reasons as above.
- *Principle of legal certainty*: due to uncertainty regarding the responsibilities of the various operators in the event of dissemination, contamination and damage caused by NGT GMOs, including those in category 1.
- *Polluter pays principle and Principle of liability*: the absence of traceability and labelling will make it impossible, in the event of damage, to trace the chain of responsibility back to the operator who produced or used GMOs derived from NGTs.

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126 https://www.greenpeace.fr/espace-presse/sondage-nouveaux-ogm-91-des-francais-favorables-a-plus-de-transparence-dans-leur-caddie/.

127 Open Letter signed by: Association de défense, d'éducation et d'information du consommateur (ADEIC), Conseil national des associations familiales laïques (CNAFAL), Confédération syndicale des familles (CSF), Information et défense des consommateurs salariés (Indecosa-CGT), Association Léo-Lagrange pour la défense des consommateurs (ALLDC), *Le Monde*, 6 March 2025.

Open Letter signed by: AK (Austrian Federal Chamber of Labour), L. Oberndorfer, Head of Department Climate, Environment and Transport; ASUFIN (Asociación de usuarios financieros), P. Suárez, President; CECU (Federación de Consumidores y Usuarios), D. Sánchez Carpio, Director; Eurocoop, F. Fabbri, Sustainability and Food Policy Manager; POLLINIS, C. Labauge, GMOs & biotechnologies campaigner; UFC-Que Choisir, M-A. Stévenin, Présidente; ZPS (Slovene Consumers' Association), J. Bevc Bahar, Secretary-general, *The Brussels Times*, 14 October 2025.

- *Rights of consumers and 'GMO-free' farmers*:
  The exemption of almost all new GMOs from the traceability and labelling requirements of Directive 2001/18/ contravenes several principles and provisions of EU law:

  - The traceability of food throughout the production chain is a legal obligation under Article 18 of Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law.
  - The right to information for consumers is enshrined in the EU's operating treaties and in Article 8 of Regulation (EC) No 178/2002.
  - The high level of consumer protection is enshrined in Articles 114 and 169 of the TFEU and in Article 38 of the Charter of Fundamental Rights of the European Union, while the protection of consumer interests is enshrined in Article 8 of Regulation (EC) No 178/2002.
  - The coexistence of GMO and non-GMO sectors and the right to produce and consume with or without GMOs derived from Directive 2001/18/EC.

**Our demands and questions:**

We urge the Commission to:

- Provide us with its reasoned opinion on all points of the conclusions of the **DARWIN program** of September 2025, and to make public the follow-up it intends to give to the Proposal, particularly the provisions concerning category 1 NGTs.
- Explain why it has been slow to launch **research programs** on the identification of GMOs derived from NGTs, which have been requested by Member States, the ENGL (European Network of GMO Laboratories) and NGOs for several years.
- Clarify the adoption of a Proposal to deregulate new GMOs, justified by the supposed difficulties in identifying them, **without waiting for the results of the research programs it itself launched** to develop identification and detection methods.
- Send us its opinion on the letter sent in July 2025 to European legislators by **twelve laboratories** in Germany, Poland, Spain, Ukraine and France, calling for the obligation, prior to any release of NGT GMOs, the methods and materials necessary for their detection and identification must be provided[128].
- Revise the Proposal to ensure traceability and labelling for all operators and consumers. And if not:
  provide us with clarification regarding the effects of the absence of traceability and labelling requirements for NGT GMOs 1 **in the event of damage**, and in particular on:

  i) The need for identification and risk assessment based on product liability.
  ii) The indication of the party responsible for the damage: those who develop and market NGT 1 plants, or those who use them?
  iii) The identification of risks that can be covered, and the insurance that can cover them.

- Let us know how, without comprehensive traceability and labelling measures and certified reference material, which are essential for monitoring risks and contamination, it intends to respond in practical terms to the concerns of consumers and farmers who do not want to consume or produce GMOs, even those derived from NGTs 1.

[128] https://www.enga.org/newsdetails/european-laboratories-join-forces-to-make-urgent-call-to-eu-policy-makers-on-new-gmos/

## Chapter 6. Concerning the problems posed by patents on NGTs: an omission that affects the economic legitimacy of the Proposal

Summary: *Patents on NGTs - and more broadly the patentability of living organisms - are one of the blind spots of the Proposal, even though they pose significant threats to conventional farmers and seed producers, as well as to the EU's food sovereignty and security. By deregulating most GMO-NGTs without simultaneously providing for provisions on their patentability, the Commission is ignoring serious difficulties for a whole range of operators. Yet it had been duly alerted to these problems. The Proposal provides for a dedicated impact assessment later, whereas this should have been carried out before its adoption in July 2023.*

Plants derived from NGTs are patentable or possess patentable traits/sequences and are therefore covered by patents: the companies that develop them demand the right to patent them, while at the same time claiming that these same plants are similar to plants derived from conventional breeding. This is a glaring paradox, since plants derived from conventional breeding are not patentable under European law.

Furthermore, any conventional product that contains traits patented in third countries and is exported to third countries that recognise these patents is likely to give rise to disputes that are difficult to resolve in the absence of detection methods and certified reference material.

However, **despite the many concerns expressed during the preparation of the Proposal, the Commission does not address issues related to the intellectual property of NGT traits and plants containing them, such as patents**. The European Commission has merely announced a surprisingly belated assessment of the impact that the patenting of traits and plants and related licensing and transparency practices could have on innovation in the field of plant breeding, whether conventional or not, on breeders' access to genetic material and techniques, and on the availability of seeds for farmers.

During the current legislative process, the European Parliament has proposed various amendments aimed at limiting the risks associated with patents, including a ban on the patentability of plants derived from NGTs that are indistinguishable from plants derived from traditional breeding that cannot be patented, as well as restrictions on the extension of the scope of patents. The Council of the European Union, for its part, simply added measures intended to improve access to information and transparency, but these are not legally binding and are not accompanied by sanctions, and are therefore ineffective as they depend on the goodwill of companies to comply.

**The risks associated with patents** on NGTs, NGT traits and derived plants **are nevertheless significant for farmers and seed producers**, whether conventional or not. They could have an impact on the additional cost of GMO seeds, the availability of non-GMO seeds and patent claims on native traits.

For **farmers**, the draft regulation poses serious risks due to the patents granted on traits and plants, and their genetic sequences derived from these genetic techniques, because of the removal of the requirement to publish detection and identification methods in the current regulations. **Farmers would face legal uncertainty and the potential risk of abusive patent infringement lawsuits in the event of accidental contamination or if traditionally bred crops happened to share the same traits and**

**sequences as patented ones**[129]. Without access to patented detection and identification methods (and not just the claimed genetic modification described as identical to what exists in nature or can be obtained through traditional breeding), they will be deprived of any means of proving that they have not used the patented invention. They will be increasingly limited in their use of farm-saved and peasant seeds and may be forced to use patented GMO seeds.

Pressure, from breeders who have patented native traits, on conventional breeders has **already been documented**. This pressure has led to withdrawals from the market and thus to a reduction in cultivable genetic diversity.

**Seed producers** will also be directly affected by the impact of these patents. Their customers will **refuse to buy their traditionally bred seeds if they know that they risk abusive prosecution for infringement** if one of their genetic sequences is also covered by a patent held by another company and relating to a trait introgressed by one of the new genetic techniques[130].

Furthermore, as the EU is a member of the UPOV treaty, European law rightly allows seed producers to use their competitors' registered varieties to select new ones. However, there is no obligation to declare that a commercial seed is patented, nor is there a comprehensive database of patented genetic traits. **Small and medium-sized seed companies therefore say they are 'walking in a minefield' when they freely use available genetic resources**, including seeds from other companies, without knowing whether they contain one or more patented traits or are covered by a competitor's patent, **without knowing whether or not they contain one or more patented traits, or whether or not they are covered by a patent held by their competitors**.

In addition, with the accumulation of patented traits and the overlapping of patents held by different players, including those of *princeps* NGT patents, **seed producers will be forced to negotiate licences with all these players, cease their activities or agree to be bought out by them** when they cannot afford to negotiate and pay for these licences. They may also be **prosecuted for infringement** if the seeds they market have the same traits and sequences as those patented, even though they are native and have been transferred by crossing previously and independently of the patented invention. Finally, the question of **litigation** will arise in cases where only some of the patented traits of a stacked variety are found in other varieties due to insertions on different chromosomes. **The current dynamism of European seed producers will be doomed to decline in favour of a handful of multinationals**[131].

The same problem of patent interference arises for biotechnology start-ups/spin-offs when they want to market a product.

More generally, the increased dissemination of patented traits and plants in the environment poses **direct and irreversible threats to our agriculture and food supply**: **increased concentration in the seed**

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129 See '*patent grab'*: by describing a natural trait using the language of a NGT, a company can claim ownership of any plant possessing that sequence, whether it comes from a laboratory or a farmer's field. This is what the 'No Patents on Seeds!' coalition calls 'illegitimate appropriation.'

130 See '*leverage effect*': an NGT manufacturer uses its patents to block conventional competitors. A breeder working on a conventional variety suddenly finds himself a 'counterfeiter' if his plant naturally expresses the gene that the manufacturer has patented via an NGT technical description.

131 The biotechnology industry has the following characteristics: large multinationals, highly concentrated (around half a dozen companies), developing an integrated approach between research and the market, protecting their products with patents (which forces farmers to buy new seeds every year), promoting a highly intensive production method and focusing research on a limited number of plants considered to be more profitable for those who market them. In some cases, they link their GMOs to another product sold by the group (Monsanto-Bayer, for example, sells GM maize that is resistant to the weedkiller RoundUp™, which it also markets).

**sector** - as observed for transgenic GMOs - in the hands of a few transnational companies holding the overwhelming majority of patents, **disproportionate increase in the price of these GMO seeds**, as observed in the United States, and therefore in the **prices of food products for consumers**, increased dependence of farmers on inputs - pesticides or fertilisers mostly produced abroad, and, ultimately, a weakening of the EU's food sovereignty and security.

We echo the criticism of the 'Appeal of 100 Scientists' of December 2023[132], for whom '*The ability to patent seeds may be even more important than the introduction of the new traits themselves. Indeed, conventionally grown seeds cannot be patented as easily. [...] Genetically modified organisms may be the Trojan horse and open the door to possibly patenting all seeds in the future, not just genetically manipulated ones. A recent report by European environmental organisations shows that a search for the term 'CRISPR-Cas plant' in international patent application databases yielded no less than 20,000 results*[133]*. These are often* ***broad patent applications*** *covering all plants with a particular trait,* ***regardless of how the plants are obtained – including via conventional breeding techniques****.'*

These issues arise from the fact that current European patent law does not consider 'new' genetic modification techniques that had not been developed at the time of its adoption. Directive 2001/18/EC was able to fill this gap by making not only documentary traceability mandatory, but also the publication of methods for detecting and identifying genetically modified plants.

However, **the proposed regulation on NGTs removes these obligations without considering the impact of this removal on patent law.** It will thus allow the scope of patents on so-called 'native' genes (legal patents when these genes are isolated from their natural environment according to Article 3. 2 of Directive 98/44/EC) to extend to all organisms containing these genes and expressing their function, whether they are derived from the patented invention.

**Principles not respected:**

In conclusion to this chapter, we consider that the way the European Commission's Proposal for a Regulation on NGTs was drafted seriously contravenes the principles mentioned in the introduction, in particular: *the Principles of motivation of legal acts and good administration, objectivity, information, participation, legal certainty and transparency*.

Indeed:

1. Given the high importance of this issue of patents on NGTs, the traits used, and the plants derived for operators (whether engaged in NGTs or not), the Commission should have addressed it **within the framework of its Proposal**, instead of postponing it to a later date, especially since **many stakeholders had previously raised significant concerns**. By sidestepping this issue and thus obscuring the difficulties ahead in this text, the Proposal is therefore *not balanced in its reasoning and in the interests it defends*. It introduces a considerable element of uncertainty, making it impossible to predict the socio-economic impacts of its Proposal.
2. This concealment of the problems associated with patents on NGTs is also detrimental to the *Principles of information, participation, legal certainty and transparency*. **No prior impact assessment has been carried out concerning the freedom of action and responsibility of**

[132] https://newgmo.org/2023/11/19/open-letter-serious-concerns-about-the-eu-commission-proposal-on-new-genomic-techniques/

[133] Dolan et al. 2022. Report '*Exposed. How biotech giants use patents and new GMOs to control the future of food.*' GLOBAL 2000 – Friends of the Earth Austria, Friends of the Earth Europe, Corporate Europe Observatory (CEO), Arche Noah, IG Saatgut – InteressenGemeinschaft für gentechnikfreie Saatgutarbeit and Arbeiterkammer Wien.

**farmers and seed producers**, particularly in the event of partial[134] or complete contamination by traits and plants derived from NGTs, and concerning the takeover of seeds by large industrial groups. Furthermore, **if the ongoing negotiations between the European Parliament and the Council result in the adoption of articles relating to patents, these provisions will not have been subject to impact assessments or consultations with stakeholders and citizens**. Finally, it should be noted that the European Plant Organisation (EPO) has for some time shown a certain reluctance to apply European regulations[135] due to its independent status under the European Patent Convention (EPC), rather than under direct EU law.

3. The Proposal claims to consider **the interests of VSEs** (Very Small Enterprises) **and SMEs** (Small and Medium-sized Enterprises) (pp. 12, 14, 28, Articles 22-2-b, 22-4-d, and Legislative Financial Statement p. 4). However, it is clear from these texts that only SMEs wishing to develop or use patented products derived from NGTs will be affected by these supposed benefits and preferential treatment. No provision takes into account the interests of VSEs and SMEs (and in particular seed producers) that could suffer from the uncontrolled dissemination of plants derived from patented NGTs, without any justification from the point of view of their interests.

   However, in order to be able to duly justify its Proposal and to comply with its own *2015 guidelines for 'Better Regulation'* (*Think Small First* principle/priority for SMEs), the Commission was required to take into account the interests **of all micro-enterprises and SMEs** affected by its proposal and, if it did not consider this possible, to justify its decision[136].

**Our demand:**

We call on the Commission to supplement the rules implementing Directive 98/44/EC to consider the emergence of new genetic modification techniques that did not exist when it was adopted. This amendment will make it mandatory for seed producers wishing to patent their GMOs to clearly indicate in the patent how their product differs from any product that may be derived from essentially biological processes that cannot be patented, thereby making public the processes for detecting and identification of their GMOs/NGTs. This will apply equally to products derived from NGTs and products derived from patentable technical processes not covered by 2001/18/EC (mutagenesis, cell fusion).

**References:**

Seeds, right to life and farmers' rights, Report of the Special Rapporteur on the right to food, Michael Fakhri, United Nations, 2021

Crispr/Cas9: access to a minefield?, Inf'OGM, 2022

European Commission risks farmers' rights by ignoring impact of new GMO deregulation on European patent law, ECVC, 2022

134 Contamination (gene flow) by only a few traits from a variety derived from NGTs with stacked traits.

135 https://www.schlich.co.uk/epo-vs-eu-can-you-patent-a-gmo-per-se/ Decision T 1063/18 (Technical Board of Appeal, 2018) declares Rule 28(2) incompatible with Art. 53(b) EPC: products (plants) remain patentable, even if the processes are excluded. The EPO ignores and circumvents EU rules to maintain patentability.

136 EC guidelines on 'Better Regulation' 2015, p. 8: '*We will apply the "Think Small First" principle more thoroughly when preparing initiatives: taking the interests of small- and medium-sized businesses into account when designing and evaluating policies, and envisaging a lighter regime for them including an outright exemption for micro-businesses wherever it is possible and makes sense.* ***Where either is not possible****, for instance because it would not allow an effective achievement of the social, environmental and economic objectives of the proposed legislation,* ***the Commission will explain why***.'

Impacts of the commission's initiative to modify the regulation of certain plant GMOs on the application of European patent law, ECVC, 2022

Open letter: European Commission’s biased road to deregulation of new GMOs, 2022

Seeds and intellectual property, SEMAE Committee on Societal Issues, Opinion No. 2, 2023

Patents on GMOs-NGTs: State of play and solutions to protect farmers, small breeders, and the GMO-free sector, ECVC (European Coordination Via Campesina), 2025

Joint statement on the deregulation of new GMOs - Protect the business of small and medium-sized breeders, farmers, and the organic and non-GMO sectors in the EU, 2025

## Chapter 7. Regarding the scientific concepts used: unclear definitions, vague concepts and semantic shifts in the service of a deregulation project

Summary: *Throughout the process of drafting the Proposal, and in the Proposal itself, the Commission uses vague terms and concepts, without any scientifically validated metrics, which are repeated without clarification by the EFSA's GMO panel, despite being composed of scientists. Added to these inaccuracies are circular arguments to justify an 'equivalence' between conventional plants and GMO-NGT plants. This reasoning illustrates the refusal to make a clear distinction between varietal improvement and the chemical rewriting of life, which could facilitate the acceptability of organisms derived from synthetic biology in the future.*



### 1- 'Target site', 'similarity', 'gene', 'breeders' gene pool'…: ANSES requests clarification

In its November 2023 review of the equivalence criteria proposed for defining Category 1 NGT plants, ANSES noted '**major shortcomings**' **concerning several terms that should be clarified and explained**: 'target site', 'similarity', "gene" (a term whose definition is still widely controversial among scientists), 'breeders' gene pool' and 'contiguous DNA sequence'[137].

These terms remain ambiguous, despite an update to the EFSA FAQ in 2023[138], and are likely to be **revised in the future according to the needs of stakeholders**, for example in patent infringement lawsuits against companies that have marketed varieties with conventionally selected 'traits'.

ANSES requests clarification on the following points in particular:

- '*Conventional plants'*, for which no definition is given in the Proposal, as well as conventional breeding techniques: *'A **first major shortcoming is the lack of a definition of conventional plants with which the decision rule must make the comparison**.';*
- '*Target site*': '*No clarification is provided on this term in the proposed regulation.'* However, *'the ANSES Biotechnology Working Group considers that the definition of this site is decisive in the application of each of the proposed criteria. **In the absence of such a definition, the***

[137] ANSES (Nov. 2023). Opinion on the scientific analysis of Annex I to the European Commission's proposed regulation of 5 July 2023 on new genomic techniques (NGT) - Review of the proposed equivalence criteria for defining Category 1 NGT plants (self-initiative review No. 2023-AUTO-0189). Maisons-Alfort, 34 p. https://www.anses.fr/system/files/BIOT2023AUTO0189.pdf

[138] https://www.efsa.europa.eu/sites/default/files/2023-05/extented-faqs-on-ngts-ts.pdf

***Working Group warns of a risk of distortions between cases, linked to the interpretation of each applicant**.';*

- '*breeder's gene pool*': '*The Biotechnology Working Group highlights the lack of clarity in the definition of "breeder's gene pool", in particular the use of the term "genetic information", which should be clarified.'*

Other important clarifications are recommended by ANSES, including:

- explicitly excluding non-targeted *cisgenesis* from the NGT techniques covered,
- distinguishing more precisely between *intragenesis* and *cisgenesis* (the Community definition of intragenesis varies between Lusser (2011) and the more recent EFSA definitions recent, aimed at facilitating the distinction between NGT 1 and the expansion of sources of genetic sequences useful for an extended 'breeder's gene pool'),
- specifying the materials included in the insertions (the work of the JRC and EFSA used to establish the Proposal is more precise than the term 'genetic material' used in the Proposal itself).

With regard more specifically to the definition of **targeted mutagenesis**, a legal opinion[139] highlights an essential point: '*The Commission study of 29.04.2021 proposes to define 'targeted mutagenesis' as a generic term to describe newer techniques to induce mutations at selected target sites of the genome without using genetic material to be inserted. This suggests that by using this term, the Commission does not intend to establish legal minimum standards for target accuracy. Rather, all newer techniques mentioned in the study (ODM, RdDM, SDN-1 to SDN-3, CRISPR/Cas) are apparently to be summarized under this generic term,* ***irrespective of their respective target accuracy*****', as well as their unintended modifications and effects.**

### 2- Imprecise "sustainability" to justify deregulation

'***Sustainability***' is a scientific and economic term widely used in management and by manufacturing companies[140], with a multidimensional and highly variable value[141]. Its definition varies according to context and even more so according to preconceptions. The concept of sustainability refers to a logic of *'path dependency'*, both in business management and economics[142], and in its biased transpositions in science, agriculture and technology. Social criteria and the perceptions of farmers and consumers are largely overlooked in its implementation, regardless of the continent[143].

The concept of 'sustainability' entered the European legislative field with the adoption in December 2019 of the *European Green Deal*, which provided measures to enable consumers to choose '**reusable, durable and repairable**' products. However, the Commission's understanding of sustainability has proved **unclear and highly variable depending on the goals and topics addressed**, to such an extent that the **European Ombudsman declared that the Commission was at fault in this regard**[144].

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139 Legal opinion, Georg Buchholz et al., 14.09.23, quoted above, p. 36 and f. https://www.martin-haeusling.eu/images/Violation_of_precautionary_principle_by_NGT_proposal_EN.pdf.

140 De Oliveira et al., 2024.

141 Giovannoni and Fabietti, 2013; Ruggerio, 2021.

142 Taibi-Voigts et al., 2025.

143 Conti *et al*., 2021; Janker & Mann, 2020; Konefal *et al*., 2023; Orou Sannou *et al*., 2023; Saleh & Ehlers, 2025; Tomaš Simin *et al*., 2025; Varyvoda *et al*., 2025.

144 https://www.ombudsman.europa.eu/fr/recommendation/fr/21592.

Regarding NGTs, the European Commission's vague notion of sustainability has led it to justify the deregulation of GMOs-NGTs, presenting them as innovations aligned with 'green' objectives, without identifying rigorous verification criteria. The sustainability criteria for NGTs remain broad and non-binding, such as lists of fallacious positive traits (resistance to climate change) or negative traits (excluding herbicide tolerance), without systematic requirements, quantitative estimation or modeling or effective random checks (see Chapter 4).

**More broadly, the Commission uses language of consensus and excessive optimism[145].** It tends to present the Proposal as an almost inevitable step forward (Evgueny Morozov's techno-solutionism), promoting an image of innovation and sustainability without seriously quantifying or concretely demonstrating these benefits. This argument is often perceived as a **sophism appealing to novelty or innovation**: '*it's new, so it's better and more sustainable*'. Thus, official communications emphasise the unproven and promotional ideas that NGTs would help to produce plants that are 'more resilient to climate change' or 'require less fertiliser and pesticides' - statements that reflect a strategic vision but lack **precise or quantified indicators** in the text itself, when they do not contradict observations made in third countries on transgenic GMOs carrying similar traits.

***'Innovation'* is becoming a dogma**. The gradual replacement of the *Precautionary Principle* in the EU's priorities with a political objective of *innovation* reflects intense lobbying aimed at excluding all socio-ethical and environmental considerations from scientific assessment. This proximity to industrial players creates a **confirmation bias**: NGTs are declared equivalent because the economic model of the 'biofoundry' (living factory[146]) requires the free circulation and sale of these new biological objects.

### 3- Vague concepts and semantic shifts intended to legitimise the concept of "equivalence"

#### a- Deliberate confusion between technical control and biological control

It should be remembered that the **argument for equivalence** (between genetically modified plants derived from NGT and plants derived from conventional agriculture or that '***may appear naturally***') is based on a linear and additive view of the pangenomes, according to which a targeted modification would be functionally equivalent to a mutation arising from the existing gene pool. This approach overlooks the fact that the genome functions as a system of non-linear interactions, in which the effect of a modification depends heavily on its genetic, epigenetic and regulatory context (not to mention epitranscriptomics). Conventional selection mobilises sets of co-adapted variants, whereas NGTs act on specific loci / sequences defined *a priori*. The Commission implicitly recognises the complexity of living organisms, while adopting a framework of analysis that disregards this complexity when concluding equivalence, thus creating an **unresolved internal tension** (see Chapter 2).

**To reach this conclusion on equivalence**, the European Commission deliberately confuses technical control and biological control. Indeed, **the Commission highlights the precision of NGTs to justify their assimilation into natural processes. However, there is no corresponding evidence that this supposed technical precision is interpreted as a guarantee of biological control.**

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[145] On the importance of language and metaphors in promoting acceptance of biotechnology/NGT: Baldwin, 2017; Barke, 2003; Benevenuto *et al*., 2022; Chu and Agapito-Tenfen, 2022; Eyal, 2019; Hedgecoe, 1999; Hellsten, 2002, 2005; Krzywinski & Cairo, 2013; Lakoff and Johnsen, 1980; Maben, 2016; Nelkin, 2001; O'Keefe *et al*., 2015; Patel, 2009; Silvestro, 2016; Stelmach & Nerlich, 2015.

[146] Advanced technology platforms designed to accelerate the engineering of biological systems.

Indeed, the only thing that is precise is the target site and the desired genetic expression. However, **the precision of an intervention at the molecular level does not in any way prejudge the predictability of its effects at the level of complex** biological systems. Moreover, these new techniques allow for deeper intrusion into pangenomes, which vary between varieties and can rarely be replicated by laboratory technicians – even though replicability is the very foundation of any robust science.

This internal confusion leads to a paradox: since NGT intervention is presented as targeted and controlled, we are led to believe that there is no need for in-depth systemic assessment. This is a classic '**streetlight effect**', which, through its well-known **cognitive bias**, discourages further research into modifications and collateral effects, thereby reducing assessment requirements precisely where indirect effects are most plausible.

### b- Semantic shifts to make a principle of equivalence seem inevitable

#### i)A text characterised by semantic shifts

In its **explanatory memorandum**, the Proposal states that '***in certain cases, substantially equivalent*** *plants* ***can*** *be obtained with conventional breeding methods and with targeted mutagenesis and cisgenesis'*. In **recital 2** of the Proposal, this question becomes: '***NGT*** *(...)* ***can*** *result in organisms with modifications* ***equivalent to*** *what can be obtained by conventional breeding methods or in organisms with more complex modifications.*'

Two semantic shifts can be noted between these two sentences:

- the equivalence observable 'in certain cases' becomes a generalised equivalence,

- 'substantially equivalent' plants become 'equivalent' a few lines further on.

It should be noted that in both sentences, the use of the term '***may***' implies that this equivalence is **not recognised as certain** - which does not prevent the Proposal from establishing an exemption mechanism based on this uncertain equivalence.

However, a few lines further on, there is no longer any doubt, with recital 14 adding plants that '*appear naturally*' to plants derived from conventional (breeding) methods: '*NGT plants that could also occur naturally or be produced by conventional breeding techniques and their progeny obtained by conventional breeding techniques ('category 1 NGT plants') should be treated as plants that have occurred naturally or have been produced by conventional breeding techniques,* ***given that they are equivalent*** *and that their risks are comparable, thereby derogating in full from the Union GMO legislation and GMO related requirements in sectoral legislation.*'

More generally, the **concept of equivalence**, like the very similar concept of **continuity**, is therefore a form of **circular reasoning** where the main argument and the conclusion are based on the same premise - which weakens the argumentative force if it is not supported by external data:

*NGT 1 ≈ conventional → therefore risk-free → therefore no need for assessment → therefore equivalent.*

It is therefore a **declarative equivalence**, not empirically demonstrated, illustrating a **normative vagueness** masked by pseudo-scientific vocabulary, leading to **confusion between natural feasibility and safety**.

**ii) *Reductio ad absurdum* that undermines the concept of continuity**

By using **vague notions of equivalence and continuity, the Commission dissolves the criterion of regulatory** relevance. By pushing the logic of continuity to its ultimate consequences, the Commission's reasoning tends to dissolve the boundary between what falls within the scope of historically proven biological processes and what falls within the scope of recent technical interventions. This dilution weakens the very criterion of regulatory relevance, which is not to determine whether an event is conceivable in theory, but whether it is sufficiently characterised in its actual effects to justify a lighter assessment regime.

Indeed, **the equivalence invoked by the Commission only works at the cost of an abstraction that neutralises the ecological, evolutionary and holobiotic dimensions of life, while claiming a scientific** basis. This internal contradiction weakens the coherence of the Commission's argument rather than reinforce it. The argument can be formulated as follows, in the form of a **reduction to absurdity** of the Commission's implicit reasoning: by using the conditional tense to assert continuity and equivalence in principle between conventional selection and NGT, the European Commission adopts a line of reasoning based solely on the logical possibility of mutations, **regardless of their actual conditions of appearance**.

**At this level of abstraction, any discontinuity necessarily disappears, as the Commission wishes**. Based on the four bases of DNA (A, T, G, C), it is indeed possible, through simple combinatorial reasoning, to consider that all conceivable mutations belong to the same *continuum*, since we are reasoning about terrestrial life as it is, and not about another form of life based on different biochemical principles. **Synthetic biology and its products are therefore admissible to the NGT 1-NGT 2 *continuum* thus created.**

But this purely theoretically logical continuity can be pushed to the point of absurdity: strictly following the same reasoning, one could argue that organisms based on another type of 'DNA' (xeno-DNA), other forms of life could arise naturally. Thus, four additional new bases (P, Z, B and S) and the replacement of DNA deoxyribose with another molecule (cyclohexene, glycol) **could be** constituents of forms of DNA that could potentially produce food organisms[147]. Other substitutes for the ATGC bases of DNA are being actively studied[148] since years, which could lead to what some authors call the 'biotechnological singularity'[149].

It should also be noted that this **xenobiology**, which has been in development for nearly 20 years, is being actively pursued, for example, as a means of biocontainment for products under development in synthetic biology (to reduce accidental dissemination) or as therapeutic elements[150].

Life **could also** be based on atoms other than carbon, such as silicon, since these elements have the same number of valence electrons and would also be part of a 'natural' continuum, on the grounds that their components obey general physical and chemical laws. Consequently, **following the Commission's reasoning, these organisms would be eligible for NGT 1 or NGT 2 categories.**

147 Hamashima et al., 2018; Zhao and Zeng, 2018.
148 Chaput et al., 2025.
149 Wen et al., 2025.
150 Budisa, 2025; Gómez-Tatay and Hernández-Andreu, 2024; Schmidt, 2010; Shearer *et al*., 2024.

Such a conclusion shows the limitation of the European Commission's reasoning: **intentionally confusing conceptual continuity with actual biological continuity amounts to dissolving any relevant distinction between natural processes, technically induced processes, and purely theoretical scenarios**.

In other words, if everything is continuous when reasoning on the basis of a minimal molecular alphabet or general chemical properties, then the very notion of biological equivalence loses all operational value for assessing the risks and real effects of NGTs. This formulation shows that **the conditional used by the Commission does not scientifically secure equivalence** but **postulates it at the cost of an ontological** shift: from empirical biology to an abstract continuity that is no longer discriminatory for regulation.

However, numerous articles highlight the **danger of synthetic biology with these 'mirror cells'**[151] **which, according to the Commission's current reasoning, can be considered a continuation of conventional** selection[152].

Ultimately, **the argument of continuity and equivalence** used by the European Commission to justify the regulatory exemption of NGT1s is not a simple technical clarification, but **a major normative shift**. By substituting an assessment based on the evolutionary history and systemic trajectory of living organisms with an approach focused on functional and phenotypic similarity, **the Proposal conceptually paves the way for the gradual acceptance of organisms derived from synthetic biology, and all forms of life, including those derived from xenobiology**. This dynamic is not a rhetorical slippery slope effect, but a logical consequence of an **evaluation framework without an explicit ontological threshold**.

### 4- Conclusion: breaches of principles, claims

**Breaches of principles**:

In conclusion to this chapter, we believe that the way in which the Proposal for a Regulation on NGTs was drafted by the European Commission seriously contravenes the principles mentioned in the introduction, particularly the *Principles of adaptation to scientific knowledge and excellence in scientific evaluation*, as well as the *Principles related to 'Better Regulation'* which, in the name of transparency and legitimate legislative motivation, **require clear definitions, reasoning without confirmation bias, and solid scientific foundations that are open to debate**.

**Our demands:**

We ask the Commission to:

- clarify all terms identified by ANSES (2023) as unclear or ambiguous, and to define and publish definitions that identify the equivalence criteria that are considered by the ANSES opinion to be missing or insufficient.
- provide a clear and lasting definition of sustainability that does not vary according to the goals and subjects addressed by the legislator, following a process of contradictory and public consultation.

151 Cf. Katarzyna et al., 2024. https://www.science.org/doi/10.1126/science.ads9158.
152 Adamala et al., 2024.

- provide all exchanges between the Commission, European officials from EFSA and JRC, as well as within the Commission's DGs, concerning these vague definitions.

## Chapter 8. Concerning the organic farming sector: the failure to consider the 'major threat' NGTs pose to the organic sector

Summary: *The Proposal claims to respond to the challenges of agricultural innovation while preserving different production models. However, it ignores the concrete consequences of the spread of GMOs derived from NGTs, particularly for the organic farming sector. Even though the European Commission explicitly states in a preliminary study that these organisms constitute a 'major threat' to the viability of the organic and GMO-free sectors, the Proposal does not draw any operational conclusions from this finding.*

By exempting almost all NGT plants (category 1) from evaluation, authorisation, traceability, labelling and (specific and general) surveillances requirements, while prohibiting their use in organic farming, and in the absence of effective and reliable coexistence measures[153], the text places the entire financial, practical and socio-economic costs of coexistence on operators who choose not to use these new GMOs (GMO-free sectors and organic farming). These costs represent an existential threat to them.

This **reversal of the polluter pays principle** weakens the organic sector economically, restricts its supplies and threatens consumer confidence. Furthermore, the Proposal misleadingly presents the deregulation of NGTs as favourable to organic interests, in clear contradiction with the findings of the Commission itself and with the consistent positions of stakeholders in the sector.

1- A 'major threat' to the organic sector, brought to the Commission's attention, but ignored by the Proposal.

2- A misleading argument: the deregulation of GMOs-NGTs presented as favourable to the interests of the organic sector.

3- Principles not respected, our demands.

4- Positions and actions of operators in the organic sector.

### 1- A 'major threat' to the organic sector, brought to the Commission's attention, but ignored by the Proposal

The Proposal rightly points out in its explanatory memorandum that "The organic and GMO-free sectors call for the *status quo* to be maintained, with NGT plants remaining subject to the current GMO requirements, in particular as regards traceability and labelling, and for strengthened provisions on coexistence and harmonised rules on liability.".

This request has not been heeded. The Proposal does provide that the use of genetically modified plants derived from NGTs of categories 1 and 2 is prohibited in organic production (Article 5-2), in line with Regulation 2018/848/EU.

[153] Coexistence in **dedicated areas** according to the conclusions of the European research programme Co-Extra.

However, for **NGTs in category 1**, which, it should be noted, would represent **between 80 and 95% of NGTs** under development[154], **the conditions for their release pose a true existential threat to organic** farming. Indeed, in the name of their supposed equivalence with organic and conventional crops, genetically modified plants derived from NGT 1 are exempted by the Proposal not only from any prior authorisation and assessment, but also from labelling requirements beyond seeds, traceability and post-market monitoring.

These new conditions for release **place the cost of GMO/non-GMO coexistence on organic and non-GMO farming operators**. To comply with the ban on GMOs in organic products, operators in the organic sector will have to commit additional funds. To prove that these organisms are not used beyond the purchase of seeds, **they will have to finance the implementation of documentary traceability, analysis costs** if the methods are developed and publicly available free of charge, **losses** in the event of downgrading due to contamination.

It is much more complicated to obtain information from suppliers when it is not mandatory. In the case of processed organic foodstuffs, it is possible, under certain strict conditions, to use up to 5% non-organic agricultural ingredients. This last point will limit the possible sources of supply and increase their costs, as organic operators will have to source their supplies from specific channels.

**The simple labelling of commercialised seeds, as provided for in the Proposal (Articles 9 and 10), is therefore clearly insufficient** to '*support maintaining organic production free from NGTs and preserve consumer trust*', as the Commission claims in a performative manner.

It is unacceptable that, in order to favour a single economic sector, that of biotechnology, the Proposal **thus abandons the polluter pays principle** and **places the cost of the charges on operators who do not wish to use these new GMOs and whose agricultural methods offer a real advantage for the preservation of the environment and climate** for years.

However, in a preliminary study dated 29 April 2021, **the Commission was able to fully assess the issues** by listing all the difficulties, particularly when it noted that '*several stakeholders (organic/GMO-free operators GMO-free operators and NGOs) consider NGTs and their products to be a **major threat to the viability of the organic and GMO-free sectors, due to increased compliance and segregation costs, difficulties related to controls and certification, the potentially unavoidable presence of NGT products in their supply chains, higher prices for end products and a potential loss in consumer confidence***[155].'

It is therefore **with full knowledge of those facts** that the Commission has drawn up a proposal favouring the interests of the biotechnology sector to the detriment of the interests of the organic and GMO-free sector, even though the European Union has set itself the target of achieving 25% of Usable Agricultural Area cultivated organically by 2030 (Green Deal, 2020).

Maintaining the (lightened) application of Directive 2001/18/EC to **NGTs in category 2** cannot be considered a consolation prize for the organic sector. Indeed, it should be reiterated that the equivalence criteria, in addition to being scientifically unfounded, are so broad that category 2 is likely to represent

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[154] 94 %, according to the Bundesamt für Naturschutz (BfN, German Federal Agency for Nature Conservation), *New developments and regulatory issues in plant genetic engineering*, 2021 (see Chapter 3).

[155] Study on the status of new genomic techniques under EU law and in light of the judgment of the Court of Justice in Case C-528/16, 29/4/2021, SWD(2021) 92 final, p. 41.

only a small portion of the NGTs developed in the future, and Directive 2001/18/EC will become nothing more than an empty shell.

### 2- A misleading motivation: the deregulation of GMOs-NGTs presented as favourable to organic interests

Despite the 'threats' posed by GMOs derived from NGTs recognised by the Commission itself, the Proposal contains, in its explanatory memorandum, a paragraph that makes the Commission's understanding of the interests of organic operators very confusing. Is this a drafting problem, or a ploy to show that the Proposal nevertheless considers a broader spectrum of operators than just the biotechnology industries?

*Explanatory memorandum - Justification and objectives of the proposal*: '*the application of the current GMO legislation to NGTs is not conducive to the development of innovative products that are potentially beneficial for breeders, farmers, food business operators, consumers, and the environment. These problems affect numerous operators across the agri-food system, especially breeders, the agricultural biotechnology innovation and research sector, farmers, bio-based industry and consumers, traders, and Union and national authorities.* '[156]

However, the 'organic sector' have never considered the obstacle to the development of 'innovative products' such as those derived from NGTs to be a problem: the Commission's impact assessment even noted the opposite, as we pointed out *above*.

### 3 - Principles not respected, our demands

#### Principles not respected:

In conclusion to this chapter, we believe that the way in which the European Commission's Proposal for a Regulation on NGTs was drafted seriously contravenes the principles mentioned in the introduction, and in particular the following principles:

- *Polluter pays Principle*: the cost of GMO/non-GMO coexistence is borne by organic and non-GMO farmers, and not on operators using plants derived from NGTs (Non-GMO sector includes: conventional, GMO-free and Organic supply chains).
- *Principle of legitimate and transparent motivation of legislation* (good faith in the reasons, objectivity, and balance in the interests taken into account, in particular between, on the one hand, the interests of operators developing and cultivating GM/NGT plants, and, on the other, the interests of breeders, farmers, processors and retailers who do not want to bear the risk and cost of contamination by these GMOs.
- *Principle of consistency*:

  i) with EU legislation aimed at encouraging and developing organic farming,

[156] It should be noted that the wording of this paragraph suggests that the entities supposedly affected by 'these problems' ('farmers', 'consumers', 'traders', 'authorities') are viewed as a monolithic whole, without taking into account the diversity of interests and viewpoints within them, particularly with regard to the 'problems' mentioned.

ii) with the impact assessment (EC 2021) recognising NGTs as a 'major threat' to the organic sector.

**Our demands:**

We call on the Commission to initiate legislative proceedings without delay with the following objectives:

1. **Maintaining plants derived from NGTs under the full regime of Directive 2001/18/EC.** Maintain the application of existing GMO legislation to plants derived from new genomic techniques, for category 1 NGTs, to ensure a consistent framework for risk prevention, transparency and accountability.
2. **Subject NGTs to full traceability and labelling requirements.** Impose traceability and labelling requirements throughout the production and processing supply chain for all NGT plants and their products, beyond the seed stage alone, in order to enable organic and GMO-free operators to comply with their regulatory obligations.
3. **Establishment of effective rules for GMO/non-GMO coexistence.** Establish and harmonise binding coexistence rules at EU level to prevent contamination, including separation measures, specific territorial organisations (at least dedicated areas as previously in Germany and Portugal), monitoring and flow management, adapted to the specificities of organic sectors.
4. **Strict application of the Polluter pays Principle.** Make the costs of coexistence, contamination prevention, controls, analyses, and possible downgrading borne by operators who benefit from NGTs by developing, marketing or using NGT plants, and not by the organic and GMO-free sectors suffering their collateral effects.
5. **Establishment of a clear and effective liability regime.** Establish a specific liability regime covering economic damage suffered by organic and GMO-free operators in the event of contamination by NGT plants, including rapid and effective compensation mechanisms. Or even provide, as in France, a compulsory insurance scheme for producers of NGT products.
6. **Guarantee the maintenance of (GMO-free) organic production / supply chain.** Ensure, through effective regulatory measures, the practical possibility for organic operators to produce, process and market products free from any GMOs, including those derived from NGTs, in accordance with Regulation (EU) 2018/848.
7. **Consistency between the impact assessment and the Proposal.** Align the content of the Proposal with the findings and conclusions of the Commission's impact assessment, on the recognition of NGTs as a major threat to the viability of the organic and GMO-free sectors.
8. **Abandon any misleading presentation of NGTs as beneficial to the organic sector.** End the argument that deregulating NGTs would be beneficial for organic farming, as this claim is refuted by both industry stakeholders and the Commission's own analyses.

**4- Positions and actions of operators in the organic sector**

Opposition to NGTs comes from entire value chains, including economic operators.

1 -IFOAM Organics Europe

https://www.organicseurope.bio/what-we-do/gmos/

https://www.organicseurope.bio/news/european-organic-movement-resolution-no-hidden-gmos-system-based-approach-to-innovation/

https://www.organicseurope.bio/content/uploads/2023/11/IFOAMEU_policy_GMO_Final_BriefingNov2023.pdf?dd

2-Demeter / European citizens' petition: 420,000 signatures https://demeter.net/keep-new-gm-food-strictly-regulated-and-labelled/

3-Joint Response by NGOs and farmer and business associations to the Commission's document on new GMOs (September 2021)

https://www.slowfood.com/wp-content/uploads/2023/12/Response-to-EU-Commission-on-gene-editing-deregulation-plans-1.pdf

4-Slow Food – Working Document on New Genomic Techniques (June 2021)

https://www.slowfood.com/wp-content/uploads/2021/06/2PAGER_NEWGMO6.pdf

5-Biodynamic Federation – New GMOs: old claims and false promises (August 2023)

https://demeter.net/ wp-content/uploads/2023/09/230915_DEM_Leaflet_NGTs_EN.pdf

## Chapter 9. Ethical issues raised by NGTs: an eluded debate on the structural choices of the Proposal

Summary: *The development of NGTs raises fundamental ethical, philosophical and societal questions about the limits of human power over nature, the legitimate interests to be taken into consideration, and the social acceptability of manipulating and appropriating living organisms. While the EGE (European Group on Ethics in Science and New Technologies) recommends a 'broad and inclusive societal debate on genome editing', the European Commission has chosen to sidestep any ethical and societal questions about the choices made in the Proposal, choices that will nevertheless shape the future for generations to come.*

1- NGTs, cutting-edge technologies for manipulating living organisms, raise major ethical problems.

2- Despite the obvious challenges, ethical issues have been sidestepped by the European Commission.

3- Conclusion: principles not respected and demands.

### 1- NGTs, cutting-edge technologies for manipulating living organisms, raise major ethical issues.

Symbolising a real change of scale in the project to transform living organisms, GMOs raised ethical questions about the relationship between humans and nature: artificial intervention interferes with biological evolutionary processes. According to a mechanistic approach of science and nature, the manipulation of living organisms is accepted with no limits other than the available technology: new GMOs, derived from NGT, are therefore just one innovative technique among many that needs to be tested. But other perspectives exist, which attribute intrinsic value to nature, with the idea that humans have a certain responsibility towards it. From this point of view, genetic manipulation raises essential ethical questions, especially since this artificialization benefits a minority against the rights and freedoms of others.

As C. Byk summarises, '*man's accelerated mastery over living beings, and therefore over himself, his descendants and his species, makes the question of the legitimacy of the desired goal all the more acute. It is therefore no longer possible to avoid questioning the use of knowledge and applications of knowledge*'[157]. This questioning is particularly relevant when it comes to the manipulation of living organisms, according to this author: '*With biotechnology (...), the machine is no longer just a tool, an extension of the capacities of living beings and humans, it directly interferes with biological processes and their future*'. It is therefore necessary to seriously consider the '*social justifications for the massive investment, not only private but also public, in biotechnologies*'[158].

This question of **social utility and acceptability**, which was raised from the outset for GMOs, must be raised with even greater urgency for organisms derived from NGTs: these techniques intervene more

[157] C. Byk, Preface to the *International Journal of Bioethics*, 2006, vol. 17, no. 3, p. 11.

[158] S. Pouteau, *Biotechnologies: life in pieces and ethic in peril*, *Journal international de bioéthique*, 2006, vol. 17, n° 3, p. 15.

deeply in the genome and, due to their development's speed and lower cost, produce plants that are likely to spread widely in the environment, contributing to its disruption.

The framework proposed by the Commission in its Proposal is **not simply an administrative simplification: it confirms a change in our conception of life**. By relying on the concept of equivalence, the legislator adopts **a mechanistic and reductionist vision**, what Martin Heidegger called the '*seizure of nature'*: life is no longer an autonomous entity (the *autopoiesis* of Maturana and Varela), but a 'fund' (*Bestand*) of interchangeable information (Heidegger, 1938).

Once **living beings are reduced to software**, whose medium (DNA or XNA) is merely a technical detail, the boundary between *born of* nature and *made by* artifice collapses. As Hans Jonas pointed out in *The Imperative of Responsibility* (Jonas, 1979, 1984), the transition to a 'creative' biology turns humans into demiurges without a compass, where innovation becomes its own justification.

Thus, by **refusing**, with the principle of 'equivalence', to **mark a clear break between varietal improvement and the chemical rewriting of life**, the Commission is organising, *nolens volens*, the programmed obsolescence of 'nature' as a legal category. The law no longer serves as a safeguard, but as a lubricant for a process of permanent displacement. **If equivalence is enacted today for the deletion of a few bases, tomorrow it will be invoked for the insertion of synthetic nucleotides, in the name of competitiveness and 'ecological transition**'. We would thus move from **bioethics** (protecting life) to **techno-management** ('optimising' biological systems), where **society would be faced with the *fait accompli* of a completely reconfigured and patentable living organism**.

### 2- Ethical issues have been sidestepped by the European Commission.

In its study on the status of new genomic techniques, published on 29 April 2021, the Commission refers to a formal opinion from the EGE (European Group on Ethics in Science and New Technologies), entitled *Ethics of Genome Editing*, 19 March 2021[159].

However, in accordance with the Commission's mandate, this EGE opinion is **general** (on genome editing in general) and **cross-cutting** (humans, animals, plants) and does **not address the ethical questions arising from the specific regulatory choices made by the Proposal two years later.**

**No new ethical opinion** has been requested by the Commission on **the provisions and effects of the Proposal**, particularly on the ethical or societal issues that may arise from exemptions in risk assessment, traceability or labelling, or that may arise from issues raised by patents or equivalence criteria. However, these provisions represent important structural societal choices with potentially irreversible effects, choices that would have justified ethical consideration.

Even though an EGE advisory opinion is not mandatory in the field of biotechnology, the Commission should have, given the stakes for agriculture, the environment, consumers and citizens in general, consulted the EGE in advance on the main choices made in the Proposal.

In its 2021 opinion, the EGE had also called for '***broad and inclusive societal debate on genome editing***, *efforts towards joint monitoring and learning on regulatory and scientific developments, and an*

[159] EGE (2021) *Ethics of Genome Editing*. European Group on Ethics in Science and New Technologies. European Commission D-G for Research and Innovation. March. 112 pp.

*international commitment to global governance. The debate should be based on democratic principles,* ***take into account current and future generations****, and include local and European perspectives.*'

**This debate did not take place.**

This can be explained by the fact that the Commission constructed and presented its proposal as a **simple technical and regulatory adjustment - as if it intended to avoid any societal and ethical debate** that might delay its adoption. An analysis by Sheila Jasanoff, and particularly her proposal for a *Global Observatory for Gene Editing*, allows us to move beyond a purely institutional reading of the debate on NGTs and reveal its structural dimension. Jasanoff shows that existing frameworks for the governance of genomic technologies tend to compartmentalise the issues, treating them as technical or regulatory matters, **regulatory or sectoral**, when in fact they **involve fundamental collective choices about the definition of life, responsibility and our shared future**.

In its report on the socio-economic risks and challenges of NGTs, ANSES (2024) also considers that these issues are not solely scientific, technical and socio-economic in nature. Their resolution corresponds to **societal choices** and must therefore be subject to *'structured and democratic governance'*, and more specifically a **public debate involving citizens on the role of NGTs in agriculture**. Following the example of the Danish citizen consultations, such a debate on GMOs took place in France in 1998 within the framework of the OPECST[160]. Its **conclusions are still relevant today** (Joly *et al*., 2003).

By focusing the assessment on a vague and controversial notion of biological equivalence and on the management of immediately observable risks, the Commission is, on the contrary, reducing the scope of public debate and **making it difficult to see the ontological, political and intergenerational implications of genome editing.** The absence of transnational arenas specifically dedicated to critical and forward-looking reflection contributes to **obscuring major normative and political choices, which are presented as simple technical adjustments or as the inevitable consequence of scientific progress** alone.

### 3- Conclusion: principles not respected and demands

**Principles not respected:**

In conclusion to this chapter, we believe that the way in which the European Commission's Proposal for a Regulation on NGTs was drafted seriously contravenes the principles mentioned in the introduction, particularly **for having sidestepped any prior debate on the ethical issues** associated with the dissemination of GMOs -NGT, including category 1:

- *Principle of motivation of legal acts and good administration*,
- *Principle of information and participation*.

**Our questions:**

[160] French Office Parlementaire d'Evaluation des Choix Scientifiques et Techniques, https://www.lemonde.fr/archives/article/1998/06/23/les-citoyens-appellent-a-la-prudence-face-aux-plantes-transgeniques_3674286_1819218.html

- Could the Commission specify the reasons and motivations behind its decision not to conduct a prior public consultation and a genuine public debate open to opposing views on the ethical, philosophical and ethical aspects of its Proposal?
- How and by whom was this decision taken?

**Our demand:**

Following the example of the European Group on Ethics in Science and New Technologies (EGE), **we strongly call on the European Commission to organise a contradictory dialogue based on the structural normative choices underlying the Proposal, to make public and debate all the ethical, philosophical, deontological and societal** issues raised by the uncontrolled dissemination of GM plants derived from NGTs that it authorises, and raised, more generally, by the process of widespread deregulation of biotechnologies currently underway. We propose the format of a citizens' convention already used and advocated by the association '*Sciences citoyennes*'.

## Chapter 10. Our final request

In conclusion, we urge the European Commission to:

- respond to the demands and questions set out in this letter,
- comply with the main procedural requirements it has itself laid down in the Guidelines for Better Regulation,
- immediately suspend the ongoing legislative procedure concerning the proposed Regulation COM (2023)411 final,
- restart the legislative process from the beginning to take account of the fundamental issues raised, by initiating a directive procedure rather than a regulation procedure, thus ensuring compliance with the principle of subsidiarity and the right of Member States to adapt legislation on GMO-NGT to their national context.

Given the urgency and seriousness of the issues raised, given that the legislative procedure concerning the proposed Regulation COM(2023)411 final is still ongoing, given the risk that legislative measures may be adopted without the issues raised in this letter being duly taken into account, **if the Commission does not take appropriate action within 60 days of receipt of this letter, we reserve the right to pursue all available legal and administrative remedies, including**, in accordance with Article 228 TFEU, **the lodging of a formal complaint with the European Ombudsman**.

We would be grateful if you could acknowledge receipt of this letter.

Yours sincerely,

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On behalf of:

CNAFAL (National Council of Secular Family Associations)
Collectif Vigilance OGM & Pesticides 16
FNAB (National Federation of Organic Agriculture)
FNE (France Nature Environnement)
Follavoine
Générations Futures
GIET (International Group for Transdisciplinary Studies)
OGM Dangers
POLLINIS
Sciences citoyennes
Réseau Semences paysannes (Farmers' Seeds)
Synabio (Union of Organic Agri-Food Companies)

# Appendix 1 – Bibliography

## §1. General bibliography on GMOs and NGTs.


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## Appendix 2 – Biodiversity and stability of natural systems in relation to GMOs-NGTs

In the 1970s, following the work of Ilya Prigogine particularly, the theme of complex systems emerged, followed by adaptive systems. This raised questions about the stability, resilience, and adaptability of complex natural systems, which clearly maintain themselves despite their size and the disturbances they undergo.

At the time, whether system stability hinges on component diversity was hotly debated—even though the term "biodiversity" itself did not enter into the ecological discourse until the 1980s.

It is clear, for example, that the emergence of a pathogen in an ecosystem will cause less damage if it acts on a diverse and redundant functional group than if it attacks a genetically homogeneous group, as is the case with current industrial agriculture and forestry. However, with the pioneering work in this field by Gardner and Ashby[161] and then May[162], it appears that, beyond a certain threshold, increase in connectivity or variety of components reduces the stability of systems and even ends up destroying them. The stability of ecosystems would therefore not be straightfully **linked** to biodiversity understood as the diversity of species and genomes and, in the case of this work, non-historical biodiversity.

As Theodosius Dobzhansky wrote: '*Nothing in biology makes sense except in the light of evolution*.' The conclusions of Gardner & Ashby(1), May(2), and many others since then, concerned **random**, and not historical, evolution of diversity and connectivity.

What makes the **highly improbable** coherence of a complex natural system possible is that any element emerging in evolution is immediately confronted with the other elements of the system (classical co-evolution), in different ways depending on the scales and modules involved. In doing so, it produces at least local changes and persists if it proves to be compatible with the organisation of the system, which is thus constructed **step by step, historically**. This historicity means that every change, every bifurcation occurring over time could have not happened or could have been different: events in a complex natural system are **essentially contingent**.

Despite all this, although randomness is present at all stages and on all scales, these changes are not arbitrary, in the sense that randomness operates under restrictions and that any emergence is confronted with the totality of the system. '*This biodiversity*' (observed) could have been different from what it is at a given moment, but it cannot be arbitrary, as in the case of the aforementioned models where, in fact, an increase in biodiversity via elements not derived from this autonomous evolutionary process alters or even destroys the stability of the systems.

Indeed, tropical forest ecosystems, which have extremely high biodiversity, are stable and resilient. But so are temperate forest ecosystems with average biodiversity, and even the very poor ecosystems of deserts are stable and resilient.

What makes a complex natural system stable and resilient is **its organisation and the interactions between its components**, which, in the case of ecosystems, **translates** into a **certain type of** biodiversity. **This biodiversity**, historically shaped by the evolution of ecosystems, evokes **metastable states** where a local equilibrium persists over time despite underlying vulnerability (Bertolami and

[161] Gardner, M.R. & Ashby, W.R. (1970) *Connectance of large dynamic (cybernetic) systems: critical values for stability* Nature 238: 784

[162] May, R.M. (1972) '*Will a large complex system be stable?*' Nature 238: 413-414.

Nystrom, 2026; Garcia et al., 2022; van de Leemput et al., 2015). It is this biodiversity that has been observed and that must obviously be preserved to preserve their adaptability.

Due to the huge number of connections, it is completely impossible for an external entity to **intentionally** generate a being that is consistent with a complex natural system. **Introducing artificial beings into these systems would amount to increasing diversity at random. It therefore presents a considerable risk of destabilising the system** (Atlan, 2009)**.**

GMOs are precisely artificial living beings, random with respect to the organisation of the ecosystems and societies into which they are introduced. Programmes to introduce non-native plants (especially trees) that are supposed to be drought-resistant are just as ecologically destructive, for the same reasons. Generally, translocating organisms across regions requires rigorous assessment, not the blind approach prevalent today - even in biological control.

There is an urgent need to implement a comprehensive (systemic) assessment that considers the organisation of the complex natural systems on which we depend to guide public decision-making.

*Note by Frédéric Jacquemart (Nov. 2024), medical biologist, Doctor of Science, former Vice-President of the Economic, Ethical, and Social Committee (CEES) of the High Council for Biotechnology (HCB), former administrator of ANSES (agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail)*

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Lecointre Guillaume: Director of the 'Systematics and Evolution' Department at the National Museum of Natural History.
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## Appendix 3 - Circular reasoning and other fallacies leading to the choice of an arbitrary threshold of 20 nt to define category NGTs 1

Summary: *Technical issues surrounding the detection and identification of poorly understood genomes enabled the Commission to argue 'legally' that the regulations on GMOs were not applicable because there was no method for detecting GMO-NGTs. Circular reasoning, a sophism, enabled the administrative framework of the JRC, EFSA and ENGL, supervised by the JRC staff, to respond to the requests of the Commission (DG SANTE).* ***This process has encouraged vague and circular narratives about the continuity and equivalence between plants obtained by conventional breeding and NGT, which have led to the establishment, by the Proposal, of a totally arbitrary threshold of 20 nt*** *for the definition of GMOs-NGT 1.*



### 1- Introduction of the technological lock of technical impossibility.

The European Commission has long supported the argument that the identification of GMOs derived from NGTs is impossible, or at least sufficiently difficult and costly to justify that these GMOs cannot be distinguished from conventional plants.

The first mention of this impossibility of distinguishing between GMOs-NGT and varieties derived from conventional breeding appears in a **report by the JRC (Lusser *et al.*, 2011)**[163] on the use of PCR primers (average size of 20 nucleotides (nt or bp), PCR being a technique commonly used for the **unambiguous** detection and identification of organisms). This average primer size however varies depending on the amplification conditions, the type of primers (scorpion, etc.), the GC content, and the position of GC

[163] It should be noted that in 2011, the JRC considered (page 70) that cisgenesis and intragenesis are carried out using sequences from the genetic pool of the species: https://publications.jrc.ec.europa.eu/repository/handle/JRC63971. This definition evolved over time and with the institution (EFSA) concerned.

bases in 3', the use of primers, LNA[164] or PNA[165]... (known since the 1990s) and with or without the use of internal probes (such as MGB[166]) to the amplified fragment, which makes it possible to distinguish sequences differing by a single nucleotide, even if they are low in abundance (Alkan *et al.*, 2011; Amiteye, 2021; Ayukawa et al., 2017; Azizi et al., 2021; Bates and Taylor, 2001; Ben Ali et al., 2014; Chen and Schedl, 2021; Corrado, 2016; Dong *et al.*, 2017; Fanelli *et al.*, 2021; Ganal *et al.*, 2009; Heller, 2002; Jiang et al., 2025; Korir et al., 2013; Marques et al., 2003; Shi et al., 2015; Ye et al., 2015).

**These capabilities for detecting** multiplex point mutations, and therefore identifying polymorphisms, **could not be ignored by the authors of the 2011** report.

It is **surprising to note that the JRC report focuses, intentionally or not, solely on the size of the primers**, whereas the specificity of identifications results from several factors (including the internal probe used in certain PCR techniques or DNA chip/microarray probes).

The detection of SNVs[167] or SNPs (a single nucleotide difference between two genetically modified or unmodified pangenomes) is therefore achievable by sequencing and other techniques (see below) for the detection of human genetic diseases linked to point mutations[168].

No other molecular identification methods are discussed in this report, which abusively focused on the difficulty of detecting unknown modifications, **even though the ENGL network and the European Co-Extra programme have published guidelines on the detection of unknown GMOs** (Holst-Jensen et al., 2013; Holst-Jensen et al., 2009a; Holst-Jensen et al., 2011; Holst-Jensen et al., 2009b; Holst-Jensen et al., 2012). **This JRC study therefore contains several systematic biases**, whether intentional or not. It seems to **deliberately limit itself to the unambiguous detection techniques routinely used** by private laboratories and ENGL enforcement laboratories.

It should also be noted that this average size of 20 nt is commonly found in the OdM[169] directed mutagenesis technique, microRNAs and siRNAs.

The JRC thus established a technological lock to the detection of nucleic acid targets, a barrier that will be endorsed by the ENGL network (2019) and will be used for subsequent self-referencing and circular reasoning by the JRC, EFSA and the Commission.

ENGL, with the JRC staff writing based on an article by an ENGL member (Grohman *et al.*, 2019), will thus endorse that a sequence of less than 20 nucleotides is the specificity threshold for a PCR

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164 Locked Nucleic Acid. Also known as bridged nucleic acid (BNA), this is very useful for detecting single nucleotide variants (SNVs, SNPs). See https://en.wikipedia.org/wiki/Locked_nucleic_acid.

165 Peptide Nucleic Acid, https://en.wikipedia.org/wiki/Peptide_nucleic_acid.

166 Minor Groove Binder, DNA minor groove ligand.

167 Single Nucleotide Variation, Single Nucleotide Polymorphism.

168 Sickle cell disease, β-thalassaemia, hereditary spherocytosis, Fanconi anaemia, haemophilia A and B.

169 Oligonucleotide Directed Mutagenesis. **The effector part is less than 20 nt**.

primer/probe. Below 20 nt, there would be a risk of 'false positives' because the sequence could exist elsewhere by chance.

The resulting drift will be to assert the impossibility of guaranteeing the origin (natural *vs*. artefactual) of a small sequence as an argument for biological equivalence because, as the **ENGL member's report quite rightly points out**: '***These estimates are based on the simplifying assumption that the four bases are equally distributed and occur statistically independently. However, the complexity of the altered sequence, the amount of repetitive sequences, and the diversity of the genomes within a species are not taken into account***' (Grohman et al. 2019).

**2- The use of statistics to support an initial arbitrary choice**

This value of 20 bp was then reused by the JRC in a self-referential manner in a document with a turbulent history, to ensure that the minimum size of a sequence capable of differentiating between two pangenomes (between species or within the same species) is of 20 nt (Emons *et al.*, 2018)[170]. The report emphasises that for certain techniques (SDN-1, oligonucleotide-directed mutagenesis (OdM)[171], the final product would not contain - an ***a priori*** unverified assumption - foreign DNA and the induced mutations **would be** '*similar to those resulting from conventional mutagenesis or natural processes*.'

This assertion is again based on (i) the arbitrary choice of a contiguous sequence with (ii) the assumption that the nucleotides would be arranged randomly, a postulate that contradicts the well-known concept of the pangenome, as recalled in the aforementioned 2019 article (Matthews *et al*., 2024; Tettelin *et al*., 2005).

Indeed:

- Numerous tools (RAPD, SSR, etc.) can be used to distinguish pangenomes[172] without using contiguous linear sequences as for the differentiation of cultivated lines and varieties (cultivars); in addition, the use of *in vitro* culture techniques and pangenomes' modification techniques such

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[170] It should be noted that the report was published with Hendrik Emons, Director of the JRC's IRMM, as the first author, a surprising position in the list of authors, clearly signifying the preponderance of this senior European official in the drafting of the JRC's highly political note. Following the publication of an article on the Inf'OGM website expressing surprise at this, his name was demoted to last place among the authors.

[171] The OdM was later found not to work in plants, cf. the case of Cibus and its 300 'patents' based on experimental errors.

[172] Pangenomes were described as early as 2005 (Tettelin *et al*.) to classify genes into four categories. Analysis of the pangenome reveals that not all genes are distributed equally among individuals. The stratification of genes into 'core', 'softcore', 'dispensable' and 'private' categories provides a quantitative framework for: (i) prioritising functional genomic studies, (ii) linking genotype to phenotype, and (iii) distinguishing evolutionary selection from stochastic variation. Thus, large-scale studies have produced comprehensive catalogues of human variation, ranging from single nucleotide polymorphisms (SNPs) and indels (insertions and deletions up to 49 bp) to larger structural variants (SVs), many of which have been linked to diseases and other traits: Ebler, J., Ebert, P., Clarke, W. E., Rausch, T., Audano, P. A., Houwaart, T., Mao, Y., Korbel, J. O., Eichler, E. E., Zody, M. C., Dilthey, A. T., and Marschall, T. (2022). *Pangenome-based genome inference allows efficient and accurate genotyping across a wide spectrum of variant classes*. *Nature Genetics* **54**, 518–525.

as NGTs, or effective *Agrobacterium* vectorisation systems, systematically leave signatures and scars (which are more or less difficult to distinguish because they vary in size) that, together with the signatures of parental lines, make it possible to distinguish pangenomes modified by humans (Bertheau, 2019, 2022b, 2022c; Dickinson *et al.*, 2023; Neelakandan *et al.*, 2023; Thomson *et al.*, 2024).

Grohman and Commission's approach is a reductionist view of contiguity. Focusing on 20 contiguous nt is like trying to identify a book by looking at a single five-letter word. Pangenomic polymorphism and high-throughput sequencing (NGS) techniques have long made it possible to analyse multi-locus signatures.

Furthermore, NGTs sometimes leave specific fingerprints (DNA repair signatures, micro-insertions, or even the specific absence of certain motifs) that provide much more robust evidence of identity than a simple linear sequence.

- The study of pan-genomes (and therefore modified and unmodified genomes) shows that they can be distinguished by SNPs (SNVs) and indels as well as more significant modifications, such as chromosomal rearrangements. This is what could be called the illusion of randomness. The classical statistical approach treats the genome as a random Markov chain. However, we know that the genomic structure is highly organised (motifs, coding regions, linkage disequilibrium). The use of **flanking sequences** transforms a simple SNV (Single Nucleotide Variation) into a unique 'address' or 'signature.'

**It is not the bit of information alone that counts, but its precise location in the pangenome architecture!**

**We can therefore reconsider the limitations of the approach to pangenome differentiation by contiguity threshold and propose a redefinition of genomic specificity that differs from that of the JRC-ENGL without any assumptions about size (20 nt or other).**

The historical position of the ENGL-JRC and the JRC (2011), stipulating the impossibility of distinguishing between two pangenomes because of a sequence of less than 20 nucleotides (nt), therefore, deserves to be re-evaluated considering recent advances in pan-genomics and genome editing. JRC's and Grohman et al.'s (2019) conclusion assumes a stochastic distribution of nucleotides. This is a simplification that ignores the structured architecture of genomes. The specificity of a genomic variation, such as an SNV (Single Nucleotide Variation), does not reside exclusively in the altered sequence itself, but in its overall genomic context. The analysis of flanking sequences such as an SNV (Single Nucleotide Variation), does not lie exclusively in the altered sequence itself, but in its overall genomic context. Analysis of flanking sequences makes it possible to anchor a small variation in a single locus within the species' pangenome, exponentially increasing the power of discrimination compared to a purely sequential approach.

Furthermore, focusing exclusively on contiguous 20 nt sequences obscures the richness of structural polymorphism and the complex molecular signatures induced by genetic modification techniques (GMOs or NGTs). These interventions leave molecular imprints – or 'scars' – which, although sometimes subtle, follow non-random patterns that can be identified by high-throughput sequencing. **Consequently, the ability to distinguish between them now relies more on the precise mapping of polymorphisms within the pangenome and the identification of contextual signatures than on an arbitrary fragment length threshold such as that used in the unambiguous detection of transgenic GMOs**.

**The JRC's (2021) framing: 'statistical naturalness'**

Based on these biased and misused *a priori* assumptions and postulates, the members of the JRC and ENGL argued that a 20 nt sequence would have a near-zero probability of appearing twice independently by chance, but that below this length, the 'naturalness' of the change is statistically defensible (but neither certain nor obligatory…). This approach thus opened the door to the continuity and equivalence subsequently developed by the EFSA and the Commission.

In its market study and support for the impact assessment (JRC *et al*., 2021), the JRC uses the work of ENGL-JRC to assert, in essence: since they cannot be technically distinguished from natural mutations, they should be treated as such.

**The JRC report thus made it possible to shift from 'technical impossibility of detection' to 'biological similarity.'** It posits – contrary to what is known and used in plant breeding – that if a mutation is small (the 'bit of information' of 20 nt or an SNV and therefore implicitly presumed to be insignificant), it cannot be proven that it is of human origin without prior information (primer sequence, parental line) despite the signatures of the parental lines and scars from *in vitro* and NGT cultivation techniques and unintentional insertions of elements from vectorisation systems.

We have thus moved from an era of looking for a 'needle' (the 20 nt sequence) in a haystack, to an era where we are able to map the exact position of each strand of straw in the haystack. Maintaining the 2011 threshold today is a bit like refusing to use GPS on the grounds that compasses have a margin of error of a few degrees.

**3- The JRC's technological detection lock from the perspective of information theory**

Let us make a conceptual transition: moving from genomics to information theory and the dynamics of complex systems, we see that the ENGL-JRC's and Grohman et al.'s (2019) error is a classic error of **statistical reductionism**.

Their reasoning treats the signal (the 20 nt sequence) as an independent and identically distributed (**i.i.d.**) random variable, whereas living organisms – like chaotic systems – are governed by an underlying structure that makes 'noise' extremely informative.

The distinction between relevant information and background noise within a biological system cannot be reduced to a linear metric of fragment length (the EC's 20 nt threshold). This conventional approach assumes of maximum entropy, where the components of the system are distributed stochastically. However, genomes, like deterministic chaotic systems, exhibit fractal organisation and long-range correlations that contradict this postulate.

The identification of a genomic signature must be understood as a problem of **pattern recognition** within a constrained phase space (the pan-genome). Where a reductionist analysis sees a sequence of low statistical complexity, a systemic approach identifies a specific trajectory. The relevance of the information extracted then depends on three factors:

1. **The topology of the system:** The integration of the data into its macroscopic context (flanking sequences and/or structural signatures).
2. **Symmetry breaking:** Disturbances induced by engineering techniques (NGT) work as deterministic anomalies that differ from thermal noise in their non-random signatures.
3. **Temporal and spatial resolution:** The use of multidimensional data makes it possible to overcome local detection limitations and achieve Bayesian certainty about the origin of the signal.

In short, the 'noise' perceived by European regulatory authorities is in fact structured information whose resolution requires a paradigm shift: moving from an isolated probability of occurrence to a probability conditional on the overall system.

**It is a bit like trying to distinguish a fake painting**: an expert does not just look to see if the colour 'blue' exists elsewhere (the 20 nt sequence), they look at the **way** the brushstroke is linked to the structure of the canvas and the pressure of the hand (the pan-genomic context and technological scars).

## 4- From the 20 nt information threshold to SNV and NGT residues

The joint JRC-ENGL adherence to the 20 nt threshold is based on a conception of genomic information as a linear signal within white noise. This view ignores the drastic reduction in local entropy made possible by knowledge of pan-genomic structures. Mathematically, the ability to distinguish two genomes by a single nucleotide variation (SNV) can be formalised by the information gain (or Kullback-Leibler divergence, also known as *relative entropy*) between the expected distribution in a stochastic model and the observed distribution in a mapped locus.

Whereas a 20 nt sequence (JRC-ENGL approach) seeks to establish specificity through the statistical rarity of its combination, the analysis of an SNV flanked by sequences anchored in the pan-genome establishes specificity through the uniqueness of its topological position. In this paradigm, the 'noise' of the system is no longer an obstacle but a reference point: the flanking sequences serve as an addressing vector, transforming the SNV into a discrete state variable within a deterministic system. The same determinism is found in siRNA and OdM techniques.

Consequently, once high-resolution sequencing techniques make it possible to remove ambiguity about the environment of an SNV, the distinction between two lines or the identification of a biotechnological intervention (NGT) achieves maximum statistical certainty, invalidating the need for 20 nt contiguity. Relevance is no longer a function of the *length* of the signal, but of the *resolution* of the model within which it occurs.

## Distinction between evolutionary noise and technical signal. Distinguishability criteria: Bayesian analysis of the NGT signature

The distinction between natural polymorphism and modification induced by new genomic techniques (NGT) is based on the identification of deterministic constraints absent from stochastic evolutionary noise. While biological evolution operates on vast timescales with a probability distribution governed by selection and drift, genome editing (e.g., CRISPR-Cas) introduces a local symmetry break.

This technical signature can be modelled by a reduction in the search space: an isolated mutation loses its random nature when it is correlated with a specific recognition motif (such as a nearby PAM) or when it has a substitution profile (rare transversion) that contradicts the natural mutagenesis models of the locus and pangenomes under consideration (GC/AT content, telomeres, centromeres, etc.). By integrating pangenome data as a 'normalised noise' reference, it becomes possible to calculate a probability of technical origin.

Consequently, the argument of indistinguishability below 20 nt collapses in the face of the power of likelihood calculation: a single SNV, when placed in its functional and technical topology, constitutes

sufficient information to characterise a lineage with greater precision than the arbitrary thresholds proposed by the Commission's regulation (see also Mundorf et al. 2025).

| **Characteristic** | **Reductionist Approach (ENGL-JRC 2011, 2019, 2021)** | **Systemic & Pan-genomic Approach (Modern)** |
|---|---|---|
| **Unit of measurement** | Contiguous sequence length (**20 nt**) | Contextual bifurcation point (**1 SNV**) |
| **Statistical model** | Simple probability ($4^{-n}$) | Conditional probability (***P***(x ½***C***)) |
| **Vision of the genome** | Random string of characters (White noise) | Structured complex system (Attractor) |
| **Role of context** | Ignored (each fragment is isolated) | Determinant (flanking sequences = address) |
| **Proof of origin** | Absent (statistically insignificant) | Technical signature (PAM, repair profile) |
| **Reference tool** | Single reference genome (linear) approach already outdated in 2011 | **Pangenome** (multidimensional) |

**The end of the arbitrariness of 20 nt**

The **old dogma of 20 nt** was based on a vision in which we attempted to recognise an individual solely by the length of their shadow. **Today**, but with **articles published before 2011, thanks to pangenome mapping**, we no longer look at the shadow, but at the **fingerprints (SNVs) correlated with the exact geographical position (the flanking locus).**

**The information is no longer 'lost in chaos;' on the contrary, it is revealed by the very structure of this chaos.** A single nitrogen base change, when located at a technical control point (NGT target site) or in an ultra-specific region-specific region of a pangenome, carries a much greater informational load than any random 20 nt sequence.

**In short: specificity no longer depends on the *quantity* of letters read, but on the *quality* of the map used to locate them, as in "genome editing" with NGT techniques.**

## 5 - From the 20 nt technological lock introduced for detection to risk assessment

We are therefore witnessing – via the JRC, ENGL, EFSA and finally the Commission – a shift towards the 20 nucleotides of the NGT1 class, moving from detection using an inappropriate strategy and technique to an inappropriate statistical approach that does not take into account the pan-genomic context, and then to a misleading risk assessment.

The 20-nucleotide limit is also being recycled to respond to the challenge posed by sizes close to 20 nt, such as the classic TaqMann® quantitative PCR probes, CRISPR-Cas gRNAs, OdMs, microRNAs, etc. This average figure has not been chosen at random but is based on two pillars that have been diverted from their original use.

**The arbitrariness of the 20 nt threshold in the Proposal is even more striking as it corresponds to the functional length of the main vectors of biological and biotechnological specificity**. Whether it be the **sgRNAs** used in CRISPR-Cas9 systems, regulatory **siRNAs,** or PCR primers themselves, the scientific community agrees that a sequence of this size, when properly anchored, is sufficient to discriminate a single locus within complex genomes. And it is much smaller than 20nt.

**By maintaining this threshold as a limit of distinguishability, the regulatory framework directly contradicts the fundamental principles of molecular engineering**: if 20 nt are sufficient to *induce* a targeted modification, they must, by informational symmetry, be sufficient to *identify* it.

**Administrative summary:**

The ENGL-JRC published a report in 2019 stating that detection is impossible without prior knowledge of the modified sequence (ENGL, 2019). It cites the JRC (2011), i.e. the report of Lusser et al., which itself relied on an ENGL working group, to support the idea that these changes are 'nature-like'.

The reasoning of the proponents of the NGT 1 (New Genomic Techniques category 1) exemption follows a circular logic that can be broken down as follows:

● **Step 1 (Technical):** Below 20 nt (or for an SNV), the standard PCR method fails to prove technical origin (see Weidner 2022).

● **Step 2 (Semantics):** If the technical origin is not 'provable', the modification is declared '*equivalent to what can occur naturally*'.

● **Step 3 (Legal):** Since it is 'equivalent to natural', it is exempt from in-depth risk assessment, traceability, and labelling.

This shift transforms a **temporary metrological inability** into a **universal biological truth**.

To do this, the JRC staff (2021), which is responsible for participating in working groups and drafting reports, establishes an '*administrative framework'* which they then transform (with the EFSA staff and the support of Commission DG representatives) into a legal threshold. This process makes it possible to move from a technical parameter (the average size of a primer or RNA guide) to a safety/equivalence limit (NGT 1). The EFSA staff, in coordination with the Commission (mandate, terms of reference…), will then validate this threshold, not because of biological risk, which is completely absent from EFSA opinions, but because of '*probability of natural occurrence'*. In its impact assessment, the JRC (2011) echoes the conclusions of the ENGL working group consulted, stating that the impossibility of detection renders the current regulation (Directive 2001/18/EC) inapplicable.

The EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms *et al*., 2022a, b, c; EFSA Panel on Genetically Modified Organisms *et al.*, 2020; European Food Safety Authority (EFSA) *et al*., 2021), supported by the staff responsible for ensuring compliance with the accepted doctrine, is then asked to give an opinion on safety. It concludes that if the modifications are limited (in size and number, except for deletions with no size limits), the risk profile would be like that of conventional plants. It bases its opinion on the findings of "similarity " of the JRC-ENGL.

The SAM[173] will take up the story in a magnificent self-referential argument.

Through a clear misunderstanding of the application of this value (some alleles differ between pangenomes by a single nucleotide, a variation called SNP that is widely used by breeders), or through deliberate intent, the European mandate and the administrative framework of the JRC and EFSA staffs set this average value of 20 nt as the limit for differentiating between two pangenomes.

Finally, in 2023, the European Commission, following its limited mandate, proposed the NGT Regulation, setting the threshold at 20 modifications/nucleotides in Annex I of its Proposal, justifying this threshold by '*the state of the art in science*' (in reality, the compilation of previous reports by Commission components without hearing critical scientists and rejecting peer-reviewed academic literature, as the EFSA will do again with the AGES, ANSES and BfN reports). The Commission uses an **internal** '*expert consensus*' **without any contradictory** evidence.

Through the constant practices of self-referencing, circular reasoning, and maintenance of the European dogma by the *staffs* of EFSA, JRC and the Commission's Directorates-General, this average value thus shifted towards the size defining the NGT 1 class.

**6- The sophism of indistinguishability: conclusion on this regulatory shift**

The persistent focus on the 20 nt threshold now goes beyond the strictly analytical framework to bring about a major semantic shift in the governance of biotechnologies. By establishing the technical inability of PCR to distinguish between point mutations as a principle of biological equivalence, the regulatory proposals on category 1 of NGTs (NGT 1) deliberately confuse **identifiability** and **safety**.

This paradigm assumes that what is **undetectable by certain routine methods** would, **by extension**, be **free of new risks**. However, modern molecular biology demonstrates that the potential danger of a genetic modification does not depend on the length of the altered sequence, but on its function within the metabolic network. A single SNV can induce major pleiotropic effects[174] that cannot be masked by the 'noise' of the pan-genome during a rigorous assessment.

The use of the 20 nt threshold as a criterion for exemption from risk assessment therefore constitutes the exploitation of an obsolete technical limit to justify a legal vacuum. By refusing to incorporate systemic detection methods (fingerprinting, digital-PCR, targeted NGS), the **regulator** is **validating** a form of '**invisibility by decree**' that disconnects traceability from the reality of current scientific capabilities.

**However, the amalgamation of an average value derived from a detection technique did not prevent a Commission representative from acknowledging, during a hearing at the EESC (European Economic and Social Committee), that this value defining NGT 1 had been arbitrarily determined**.

[173] Scientific Advice Mechanism (SAM), which replaces the much-criticised Chief Scientific Adviser and the panel of experts from Member States who, despite several years of consultation, have been unable to agree on risk criteria.

[174] Following, for example, changes in nuclear chromosomal TADs (Topologically Associated Domains).

**7 - A minimum of adversarial procedure never seemed necessary to the EFSA, JRC and ENGL staffs: in 15 years, they did not consider several published results on available detection techniques that would have invalidated the administrative classification of NGTs**

We maintain that PCR (implicitly real-time quantitative PCR with TaqMann® probe for univocal detection) considered in 2011 in the JRC report is by no means the only method for identifying two pangenomes, of the same species or of more or less distantly related species, as demonstrated, for example, by the molecular marker-assisted selection used by the majority of conventional breeders (Barabaschi et al., 2016; Cooper et al., 2008; Jayakodi et al., 2021; Jayakodi et al., 2025; Shi et al., 2023). There are indeed techniques for identifying different organisms other than the one referred to, without explicitly mentioning it, by the JRC: namely, a univocal signature, generally linked to the insertion of an exogenous foreign sequence into a pangenome with a target sequence to be detected of less than 100 nt. Specificity is often linked to an internal probe within the amplified fragment used directly or in DNA chips.

Whether using LCR, multiplex PCR, SNPLex, electroanalysis or PCR with hybridisation techniques, for example, on probes, analysts are able to differentiate between organisms using the 'screening' identification technique of various targets of variable sizes less than 20 nt (Barany, 1991; Chaouachi et al., 2008; Chaouachi et al., 2007; De La Vega et al., 2005; Kc et al., 2016; Landegren et al., 1988; Van den Bulcke et al., 2013).

In short, a set of strategies mentioned in the literature as the '*matrix approach*', '*fingerprinting'* and '*modular approach*' with compatible modules, recently highlighted by the experimental demonstration of these strategies' ability to identify GMOs-NGTs (Angers-Loustau et al., 2014; Block et al., 2013; Bonfini et al., 2012; Fraiture et al., 2025; Van den Bulcke et al., 2013).

A screening approach, i.e. a convergent set of evidence, standardised at CEN (European Committee for Standardisation (CEN), 2014) level, based on both European (JRC) and national network databases, which also allows the information collected to be used to detect unknown and therefore unauthorised GMOs, if necessary, using software that is already available (Angers et al., 2016; Bonfini et al., 2012; Chaouachi et al., 2005; European Committee for Standardisation (CEN), 2014; Debode et al., 2013; Dong et al., 2008; Gerdes et al., 2012; Holst-Jensen et al., 2011; Kralj Novak et al., 2009; Mallah et al., 2017; Morisset, 2012; Morisset et al., 2014; Querci et al., 2010; Randhawa et al., 2014).

Such approaches, in the field or in the laboratory, are used in other fields such as microbiology or to combat bioterrorism or biohacking enthusiasts, possibly with the help of decision support systems (DSS) or artificial intelligence (IA), as in the US IARPA biodefence programme set up after the events of 11 September 2001 (Bertheau, 2022a; 2022b,; 2022c; Bohanec et al., 2016; Clark and Pazdernik, 2016; Dobnik et al., 2018; GAO (U.S. Government Accountability Office), 2011; Hedman et al., 2018; Latxague et al., 2007; Ledford, 2015; Marx, 2015).

Thus, through '*circular reasoning*' and various self-references, and despite the many available tools and strategies, the EFSA and the EC have validated the politically correct criteria that will distinguish between Category 1 of NGT plants (treated as conventional plants) and Category 2 plants (EFSA Panel on Genetically Modified Organisms et al., 2022).

Therefore, **the figure of 20 nt does not appear to be a biological recommendation by the EFSA, but rather an administrative crystallisation of political and technical constraints**.

However, this **circular reasoning[175] on the 20 nt does not explain where the exemption for unlimited deletions comes from**. **Are we to understand that coding sequences or cis-regulatory sequences could be deleted at will, i.e., several at a time, and this 20 times in a row?** Phenotypically, anything is then possible: from the interruption of coding regions, overlapping or not, to the shifting of the reading frame or the production of unknown proteins (knockouts, for example, can lead to the production of new proteins with unknown effects).

**Are these modifications acceptable anywhere in the genome**, i.e., outside ORFs (but neither the EFSA nor the Commission has defined what they mean by a gene, a controversial concept (Portin and Wilkins, 2017))? If so, the effect is unpredictable because it affects regulatory or modifying coding sequences such as sORFs[176], thereby changing the expression or activity of endogenous genes, the target gene (quantity, location, regulation) or even activating transposable elements.

**But neither the Commission nor the EFSA are new to contradictions, having broadened the meaning of intragenesis and only recommending in 2022** (EFSA Panel on Genetically Modified Organisms *et al*., 2022), then in a 2023 FAQ[177], to **carry out modifications in '*Genomic Safe Harbours*'** (GSH) that are so difficult to find in plants, without taking into account unintended epigenetic modifications (Cantos et al., 2014; Dong and Ronald, 2021; Dong et al., 2020; Rozov et al., 2022) when they should not be created (Van Vu et al., 2025).

To conclude:

The EFSA will thus officially, but belatedly, introduce the concept of **'Genomic Safe Harbours'** as the **ultimate criterion for simplifying risk assessment**. The concept of GSH is the ultimate proof that EFSA and the regulator *knew* full well that these plants are technologically identifiable (since GSH can be located) but chose to use this same technology to validate a legal '*natural equivalence.*'

[175] A practice of circular reasoning and self-referencing that is common for the Commission, as highlighted by the case of the definition of traditional selection methods with the EFSA based on a report from Wageningen University, itself based on an internal Commission document (https://infogm.org/gmo-cell-culture-techniques-are-not-traditional/).

[176] Short Open Reading Frame.

[177] https://www.efsa.europa.eu/sites/default/files/2023-04/faq-criteria-risk-assessment-ngt-plants.pdf

## Appendix 4 – Criteria in Annex I of the Proposal: EFSA does not address ANSES's criticisms

The French agency ANSES[178] has recently published several reports on NGTs (2023, 2024) and on the differences in assessment between ANSES and EFSA regarding GMO approvals (2022). The November 2023 report presents a scientific analysis of Annex I of the Proposed Regulation of 5 July 2023 on new genomic techniques (NGTs) and examines the proposed equivalence criteria for defining Category 1 NGT plants. This opinion concludes that these criteria (including the 20-nt threshold) are "without scientific justification", demonstrating that there is no link between molecular criteria determining modifications and the level of risk associated with the modifications made.
ANSES has commented on substitutions/insertions of up to 20 nucleotides and deletions of unlimited size, as follows:

- Substitutions/insertions of up to 20 nucleotides:
    - "The 'Biotechnology' Working Group emphasises that the size of the modification alone provides no information about its functional consequences. This limit on substitutions or insertions set at a maximum of 20 nucleotides has no biological significance or justification."
    - "The 'Biotechnology' Working Group concludes that there is no scientific justification for accepting (in the sense of equivalence) substitutions or insertions because of their size. Furthermore, the maximum threshold of 20 nucleotides for an insertion or substitution has not been shown to be particularly relevant for defining equivalence to conventional plants."

- Deletions of unlimited size
    - 'The "Biotechnology" Working Group considers that this criterion of unconditional deletion does not appear to be justified in the light of the literature.'
    - 'Regardless of their size, the **functional consequences** of these deletions should be characterised.'

However, in its response, the EFSA (2024) did not address the substantive criticisms. Indeed, in its opinion of July 2024, the EFSA (Panel on GMOs):

- Acknowledges that **criteria** (type, number of modifications) have been pr**oposed to determine genomic equivalence** between new NGT plants and conventional plants.
- Considers that such types and numbers of **modifications also exist** as natural mutations or those resulting from random mutagenesis, which, according to EFSA, **justifies genomic equivalence**.
- States that it has not identified any new hazards or risks associated with NTGs compared to traditional breeding, based on **previous scientific opinions**.

However, the EFSA:

- Does not directly address ANSES's central criticism regarding the lack of scientific basis for the chosen thresholds (type/size/number of modifications), thresholds which are based on the argument that similar mutations could occur naturally.
- Does not address in depth, or even sidesteps questions concerning the potential risks identified by ANSES, as well as the off-target effects or specific environmental impacts studied in the real-world cases presented by ANSES.

[178] French Agency for Food, Environmental and Occupational Health & Safety, Maisons-Alfort.

The EFSA opinion effectively amounts to a **semantic evasion**: whereas ANSES highlighted biological risks associated with NTGs, the EFSA staff **redirected the response** towards a purely '**nomenclature**' issue. It argues that the Commission's criteria neither serve nor aim to assess risk, but merely to classify plants.
**By shifting the debate from the scientific realm (risk) to the administrative realm (classification), the *staff* has neutralised ANSES's arguments to protect the equivalence criteria.** This 'non-response' from EFSA to ANSES can indeed be interpreted as a **rhetorical strategy**, quite common for discrediting scientific criticism: the aim is to shift the scientific debate on a risk (in this case, the ANSES's area of expertise) towards the construction of a regulatory classification (in this case, the administrative terrain favourable to the Proposal).
The EFSA opinion is, in any event, aligned with the Commission's '*terms of reference'* and the '*scoping'* conducted by the EFSA staff drafting the experts' report.

The 2024 EFSA opinion clearly shows that EFSA **does not endorse** the criteria adopted by the Commission in its Proposal, and that it even identifies significant methodological issues. This reflects a new and clearly discernible tension between the political considerations prevailing within the Proposal and the scientific opinions, both from EFSA and the ENGL network, on which it is supposed to rely.

It should also be noted that the EFSA was not consulted by the European Commission. Nor did it take up the matter on its own initiative, regarding the ANSES opinion of January 2024, which sets out, over 324 pages, the results of three years of research, the **risks and socio-economic issues associated with NGT plants**. Such a referral would, however, be more than legitimate given the sustainability claims put forward by the Commission in its Proposal.

ANSES (2022a). *OPINION of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) on the comparative analysis of the opinions of ANSES and EFSA regarding applications for authorisation to place genetically modified plants on the market under Regulation (EC) No 1829/2003. Reference No. 2020-SA-0063*. ANSES, Maisons-Alfort, France.

ANSES, Joly, P.-B., Dargemont, C., Behar-Cohen, F., Bonmatin, J.-M., Desquilbet, M., Ducrot, C., Kaufmann, A., and Lagrange, E. (2022b). *La crédibilité de l'expertise scientifique - Enjeux et recommandations.* ANSES, Maisons-Alfort, France. https://hal.inrae.fr/hal-04178142v1

ANSES (Nov. 2023). *AVIS de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail relatif à l'analyse scientifique de l'annexe I de la proposition de règlement de la Commission européenne du 5 juillet 2023 relative aux nouvelles techniques génomiques (NTG) – Examen des critères d'équivalence proposés pour définir les plantes NTG de catégorie 1 (Auto-Saisine No. 2023-AUTO-0189).* Maisons-Alfort, France. 34 pp. https://www.anses.fr/system/files/BIOT2023AUTO0189.pdf

ANSES (Jan. 2024). *Risques et enjeux socio-économiques liés aux plantes NTG. Avis de l'Anses. Rapport d'expertise collective (Saisine No. 2021-SA-0019).* Maisons-Alfort, France. 324 pp. https://www.anses.fr/system/files/BIORISK2021SA0019Ra.pdf

Dedieu, F., and Demortain, D. (2021). *Expertise agencies and the framing of knowledge derived from research.* In 'Seminar of the INRAE Directorate-General for Expertise and Public Policy Support,' Online, France. https://hal.science/hal-03309803

EFSA (July 2024), *Scientific Opinion on ANSES's analysis of Annex I to EC proposal COM (2023) 411 (EFSA-Q-2024-00178)*. EFSA Journal, 22(7), e8894. https://doi.org/10.2903/j.efsa.2024.889

## Appendix 5 – On the criterion of the threshold of equivalence regarding intentional genetic modifications versus natural mutations

**Regarding the concept of equivalence in relation to 'context':**

Equivalence is a relationship, not an intrinsic property of things. However, every relationship is defined in relation to a criterion, a purpose, and a framework of interpretation. Two elements are equivalent only by virtue of a specific aspect (function, value, use, measure, standard, intention). Outside this aspect, equivalence loses all meaning. Without context, the statement of equivalence is empty, as no principle allows us to select what counts as relevant for comparison. Thus, no equivalence is universal because no meaning is independent of a horizon of determination. An equivalence is therefore never isolated; it is always relative to a conceptual network.

At no point does the European Commission justify the extraordinarily narrow context it imposes: '*The criteria are based on the modifications resulting from the technique(s), i.e., on molecular characteristics. Furthermore, if a certain type and number of mutations can be introduced by both conventional breeding techniques and NGTs, also the type of traits associated with these mutations would not be different between the techniques. Therefore, for the purpose of assessing equivalence, the analysis of type and number of mutations is considered sufficient*'[179].

The implicit context is therefore that of the molecular biology laboratory, even though the Proposal concerns the release of whole plants into the open field, within society and ecosystems... The context in which the Commission introduces its concept of equivalence is therefore clearly entirely inappropriate to the subject at hand. The references to the JRC's work are also consequently irrelevant and cannot therefore constitute a justification for the proposed equivalence criteria.

Furthermore, as we will see, this work, which is supposed to underpin the proposed equivalence threshold, addresses a question that is not the one posed by the Commission. The consequences of this obvious error are immediately apparent within the very framework of the equivalence issue proposed by the Commission:

Take the example of maize, for which the 'Technical Paper' gives the natural mutation rate: 2.17 to 3.87 $\times 10^{-8}$, let us say $3.10^{-8}$ for simplicity's sake. With NGTs, such as CRISPR/Cas9, it is possible to induce three **precise and targeted** mutations, i.e., the replacement of a specific 'letter' (ATGC) with another at a specific location within the genome.

The probability of obtaining the same result through natural mutations is $3 \times 10^{-23}$, which is already impossible in practice. Without going as far as the 400 mutations tolerated by the Proposal to fall into Category 1, how long would it take to obtain 20 precise, desired mutations in maize?

Annual maize production, according to FAO figures for 2010–2023, is 1.2 billion tonnes. The average weight of a maize grain is 0.35g. The geometric law, which is mathematically sound, tells us the number of generations required before the first favourable event occurs, provided we know the probability of that event. Based on these figures, with the average rate of natural mutations of $3.10^{-8}$ per site and per

[179] Technical paper on the rationale for the equivalence criteria in Annex I, 16 Oct. 2023

generation, it is easy to calculate the time it would take to have a chance of the desired result appearing under natural conditions.

If we consider a descendant to be a mutant relative to its parent, the first favourable event will occur after $(1/10^{-8})^{20}$, or $10^{160}$ grains of maize. It should be noted that the number of atoms in the universe is $10^{80}$. Global maize production is estimated at $1.2 \times 10^9$ tonnes, or $3 \times 10^{15}$ grains. If $10^{160}$ grains are required for the first favourable event to occur, we must therefore wait $10^{160} / (3 \times 10^{15})$, or $3 \times 10^{144}$ years. With the age of the universe estimated at 14 billion years, we would therefore have to wait **$10^{134}$ times the age of the universe…**

The European Commission therefore asserts **the equivalence between something that is achievable** (this is even the project concerned by the liberalisation conducted under Category 1), **and something that is radically impossible to achieve in nature.**

This is called a contradiction. **In science, if a hypothesis leads to a contradiction, the hypothesis is discarded; this is the very basis of the scientific method**. This holds true even beyond the scientific method. If we want the Proposition to make sense, even in a common-sense, **we must therefore abandon the conditions of equivalence proposed by the Commission**.

It is worrying to note that the Commission's error, which **confuses the probability of any mutation with that of a specific and deliberate mutation**, was already brought to its attention in a letter addressed to DG SANTE by several NGOs co-signing this document, dated 5 April 2016 (reference below). The Commission is therefore knowingly perpetuating this scientifically unacceptable confusion.

This confusion highlights the problem of reducing the issue to an irrelevant context, as we have emphasised above. The relevant context when discussing life – which is the case with **bio**technologies – is that of the evolution of living beings. Shortly after this letter was sent to DG SANTE, a representative of Limagrain took up our arguments, thinking to turn them to his advantage, by declaring to French OPECST that his company had produced a wheat plant containing three specific and deliberate mutations, stating: '*One would have had to observe every wheat plant on the planet for 4 million years to find a plant exhibiting the three correct versions of the gene*'[180].

Limagrain thus acknowledged that it had achieved what was impossible to obtain through the selection of natural mutations. What is presented as beneficial progress **once again confirms the lack of equivalence**. This confusion was also echoed during the EESC's discussion sessions on the Proposal, sessions in which Mr Alexandre Huchelmann, Policy Officer at the European Commission, honestly stated, in response to criticism, that the limit of 20 genetic modifications had no scientific basis[181], in line with the opinion of ANSES.

Since it is impossible, as we have shown using the example of maize, to obtain numerous **targeted** changes simultaneously in a random manner, evolutionary trajectories operate through sequential accumulation and selection within a diverse ecosystem, which forms the basis of the historicity of natural systems (see Part B of Chapter 1 on the systemic approach).

To make this easier to understand, let us consider the cultural sphere, which, too, evolves in an similar way. It is, of course, impossible that one morning, Cro-Magnon wakes up saying '*Eureka, $E = mc^2$.*' If, by some impossible hypothesis, this is to happen, our man would not have gained 28,000 years, as Limagrain argues. He would have uttered, not a truth ahead of its time, but a complete incoherence

[180] He used the natural mutation rate we had employed: $10^{-7}$, which was a lower estimate than the rate published since then and which we now use for the calculation. In essence, this does not change much.

[181] This is, moreover, in line with the opinion of ANSES and Mundorf et al. (2025).

within his own environment. As with life itself, cultural evolution can only take place through a gradual process in which innovation co-evolves with all the systems involved. An immediate, artificial, deliberate coherence is completely impossible, given the unimaginable number of possibilities.

The 'time saved' achieved by CRISPR/Cas9 or TALEN is so exorbitant, so out of proportion to reality, so at odds with the natural evolution that gives meaning to life, that it inevitably produces a major inconsistency with the systems on which, once again, humanity depends.

While our artificial Cro-Magnon would have not even have been listened to in the society of his time, agricultural biotech crops are cultivated 'by force' and interact with complex natural systems in our society. It is impossible for such inconsistencies to be without major consequences. But the difficulty lies in the fact that it is impossible to predict the precise nature of these consequences, given that the dynamics of the systems on which we depend are of a complexity that is beyond our grasp. Avoiding taking a major risk, even without being able to describe the specifics, is in line with the very essence of the precautionary principle and the most basic common sense.

*Question*: Does the Commission agree with our probability estimates? If not, why?

*Question*: Does the Commission consider that a hypothesis whose development leads to a contradiction or absurdity should be abandoned? If not, why?

**Regarding the equivalence criteria and the threshold based on the size of the sequences under consideration (20 pb):**

This threshold is justified by scientific data produced by the JRC[182]: '*Another approach for looking at genome diversity is to evaluate the probability of whether a sequence is unique in the context of a whole genome. Whilst genome sizes can vary by orders of magnitude,* ***the calculated theoretical probability that a random sequence is unique in the genome of various crops boils down to a consistent narrow size range between 19 and 21 bases***'.

This passage offers no argument other than the invocation of a 'calculated theoretical probability.' We asked the author of the report, who eventually provided us with a reference[183]. In this article, the authors explain that they are seeking the minimum size of a nucleotide sequence that would allow this DNA sequence to be considered unique within a 'genome' of a given size. As a consequence, it would be identified as the result of a deliberate genetic modification technique. **This research therefore aims to detect plants that have been genetically modified**.

According to the authors, when considering genomes ranging from *Arabidopsis thaliana* (tiny) to *Triticum aestivum* (very large), probability calculations show that a sequence of 14 to 17 nucleotides, depending on the size of the organism's genome, is theoretically expected to be unique.

Neither the JRC nor the European Commission explain their methods of calculation, nor why, whilst they base their work on a publication that gives thresholds of 14 to 17, they consider that it justifies a threshold of 19 to 21…

The authors (Grohman *et al*.) state: '*These estimations are based on the simplifying assumption that the four bases are equally distributed and occur statistically independent. However, the complexity of the*

[182] https://op.europa.eu/en/publication-detail/-/publication/5a661f2b-a180-11eb-b85c-01aa75ed71a1/language-en
[183] Grohman et al. 2019 https://www.frontiersin.org/journals/plant-science/articles/10.3389/fpls.2019.00236/full

*altered sequence, the amount of repetitive sequences, and the diversity of the genomes within a species are not taken into account*.'

This is indeed a theoretical approach based on highly simplified assumptions, and in none of the documents is the method of calculation provided.

Such a scientific basis for a decision of this importance is already quite surprising, but the major problem is that **neither the JRC document nor this publication by Grohmann *et al.* addresses the question posed by the Commission**. The Commission uses the answers, in a theoretical and highly simplified context, to the question to know whether two identical sequences occur in a genome so as to answer the question of detecting genetically modified organisms.

**Using the answer to one question as the answer to another question that has little to do with it obviously results in nonsense.**

It is clear why the Proposal, disregarding the reality of biology and, in particular, the mutation rate (!), reaches the conclusion that GMOs and plants derived from natural mutation selection might be equivalent, in complete contradiction to what we have demonstrated (and, once again, we are in agreement with ANSES and Mundorf *et al.* (2025), in particular).

Such an error is surprising and serious, as, due to its scientific appearance, it has misled policymakers, who, for the time being, have endorsed this unfounded criterion of 20 nucleotides, and in the process, the entirely fanciful criterion of 400, above which only the NGT GMO would be classified as Category 2.