

Treaceability and Labelling of NGTs

Helene Schmutzler

November 2023

Analysis of legislative proposal



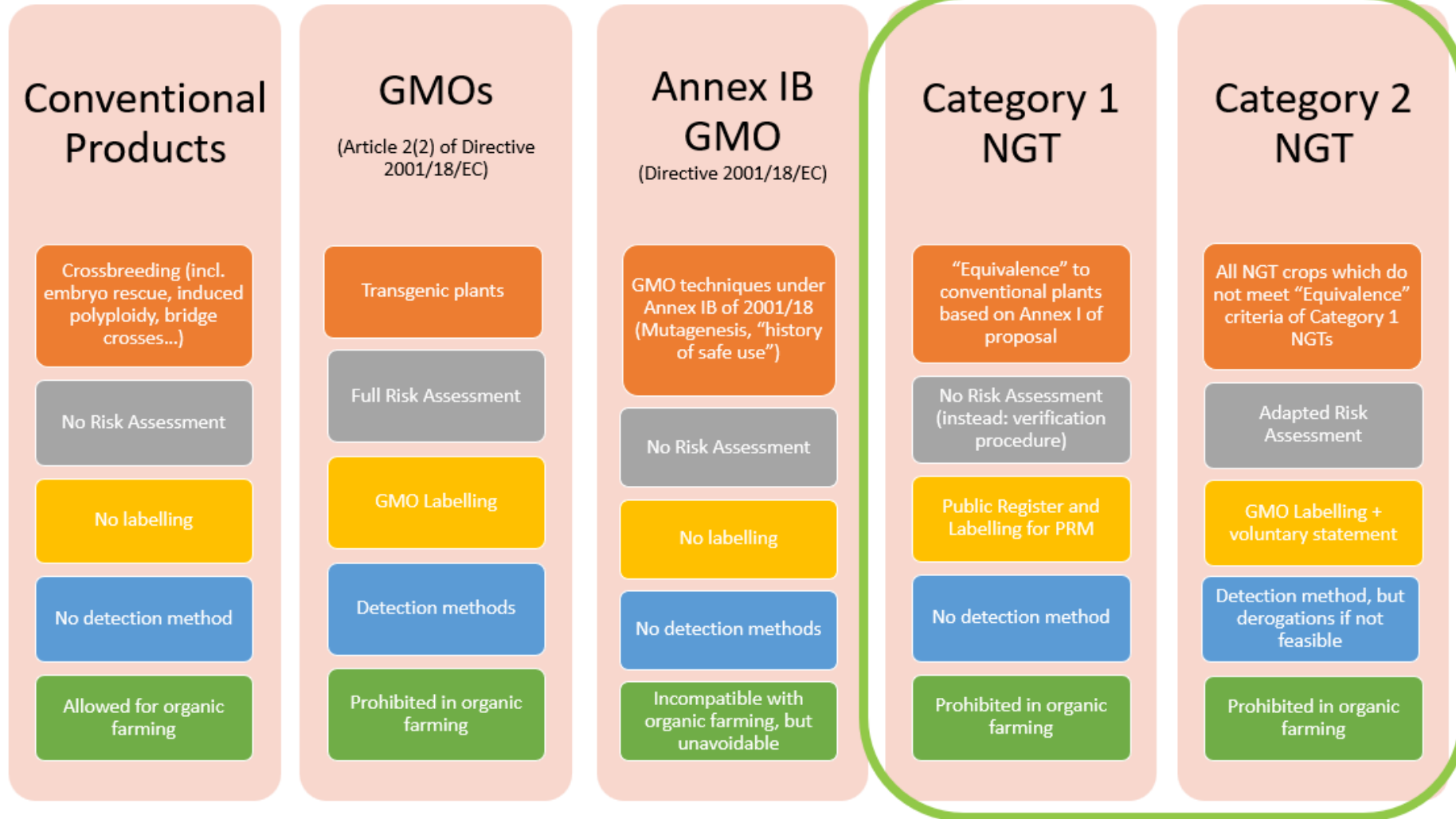
Brussels, 8 August 2023

Preliminary Analysis - Legislative Proposal on so-called “New Genomic Techniques”

This is a confidential, IFOAM Organics Europe member-only document, so please do not distribute it to external contacts. This document aims to provide a short overview of the main points of interest for the organic food and farming movement of the legislative proposal on so-called “New Genomic Techniques” (NGTs), published by the European Commission on July 5, 2023. It also refers to some helpful material for further reading and understanding.

Table of Contents

Preliminary Analysis - Legislative Proposal on so-called “New Genomic Techniques”	1
Prohibition of all GMOs in organic production	2
Annex I – Criteria of equivalence of NGT plants to conventional plants	3
Category 1 NGT plants – New Regulatory Framework and Transparency Provisions	5
Extensive Confidentiality Provisions for Category 1 NGT crops	6
Category 2 NGT plants – Adaptation of Current Framework	7
Narratives on Organic and Ally Communication	8
Proportionality Instead of Precaution	9
Patents	10
Next Steps – Co-Decision Process	10
IFOAM Organics Europe Resources on the topic of GMOs	11



Webinars with Background Information

- Webinar: “Upcoming EU proposal on NGTs: The Calm Before the Storm”
- Link to webinar [here](#).
- Webinar: “Legislative Process on NGTs: Advocacy Update”
- Link to webinar [here](#).

Agenda

- **Background**
 - What are GMOs and NGTs?
 - Organic & Genetic Engineering
 - False and Misleading Sustainability Claims
 - Patenting and Intellectual Property Rights
 - Current EU Regulatory Framework
- **Political State of Play on NGT Proposal**
- **IFOAM Organics Europe's Activities**
- **What is next and how can you support?**
 - Resolution on NGTs – General Assembly 2023
 - Other Supporting Activities
 - National Contexts?

Video call participants: Agnes Modrovich, Helene Schmutzler, Steven Jacobs, Erica Conversano.

Advocacy: European Commission

- Public consultation closed on 5 November 2023
- IFOAM Organics Europe contribution [here](#).

Timeline:

- In preparation**
- Baseline**
 - Feedback period: 24 September 2021 - 22 October 2021
- Public consultation**
 - Consultation period: 26 April 2022 - 22 July 2022
- Commission adoption**
 - Feedback period: 07 July 2022 - 08 November 2022

Video call participants: Helene Schmutzler, Mariel Huybrechts, Maximilian Engel, Arndt Steing, Lisa Brückmann, Eva Brückmann.

Advocacy: European Council

- Agricultural Ministers
 - Spanish presidency (July-December)
 - “matter of life or death”
 - In the member extranet, you can find the working schedule and upcoming meetings of the Council on the topic of NGTs.
 - Belgian presidency upcoming (Jan-June)
- Vote for general approach in December 10-11.

It is going to be difficult [...]”

DRIVING THE DAY

GENERAL APPROACH ‘DIFFICULT’ WITHIN SPANISH PRESIDENCY: The Spanish presidency had hoped to agree a general approach among member states on the new gene-editing (NGTs) rules proposal, which initially enjoyed broad support. That ambition has now shrunk to reaching “a solid agreement,” said Fernando Miranda Sotillos from the Spanish Ministry of Agriculture and Food during POLITICO’s [Sustainable Future Week](#) on Wednesday.

“It’s going to be difficult to get a general approach in the Council,” he said, adding that the proposal – which the Commission submitted in July — came “late” to the presidency.

Concerns persist: Miranda Sotillos noted ongoing concerns regarding the relaxation of EU rules on certain gene-edited organisms and seeds — such as coexistence with organic farming; the patentability of such seeds; and a verification process that equates some gene-edited crops (category 1) with conventional ones.

Advocacy: European Council

Letter: 20 July

- Call for traceability and co-existence measures

Brussels, 20 July 2023

To: Agriculture ministers of the European Union

Re: 25 July AGRIFISH Council exchange of views on the Commission's proposal on NGTs

Dear Agriculture Minister,

On 25 July at the Council of Agriculture ministers, you will hold an exchange of views with other Member States on the Commission's proposal on so-called "Novel Genomic Techniques".

On this occasion, **IFOAM Organics Europe urges you to call for maintaining traceability and the possibility of coexistence for the two categories of NGT plants proposed by the Commission**, the Category 1 NGT plants and Category 2 NGT plants.

IFOAM Organics Europe fully agrees with the prohibition of all NGTs from organic production, in line with the precautionary principle and the principles of organic farming. Indeed, the overwhelming majority of organic producers is against the use of NGTs in organic agriculture and wants their production process to remain free of gene editing technologies.

The alleged benefits of NGTs for sustainability or pest resistance are currently based on assumptions and industry promises, and the evaluation of the capacity of certain modifications to provide long-term resistance to pests or diseases needs to be assessed against alternatives and should be part of the risk assessment. Even if some plant varieties would be successfully genetically modified to develop a resistance towards a certain disease, this resistance is unlikely to last very long as diseases develop resistance themselves. Organic breeders and farmers know by experience that resistance

Letter: 5 September

- Call for holistic approach to "sustainability" in agriculture ([link](#))

Brussels, 29 August 2023

To: Agriculture ministers of the European Union

Re: 05 September AGRIFISH Informal Council exchange of views on "New technologies for more sustainable and resilient agriculture".

Dear Agriculture Minister,

On September 5th, at the Informal Meeting of the Council of Agriculture ministers, you will hold an exchange of views with other Member States on the topic of "New technologies for more sustainable and resilient agriculture".

On this occasion, **IFOAM Organics Europe urges you to maintain a system-based approach to innovation and sustainability in the food and farming sector. We need to transition away from input-intensive, short-term fixes, which include the promotion of specific technologies with unproven benefits and potential unintended effects and risks, such as genetic engineering.** This call is also in line with the [common letter](#) to Executive Vice-President for the European Green Deal Frans Timmermans from May 2023, signed by 300+ organizations which called for evidence-based decision-making for sustainable food systems.

Innovation in plant breeding is necessary but it should not be reduced to the use of gene editing technologies. A product or an agriculture production system cannot be declared "sustainable" solely on the basis of a given plant variety, let alone a trait. **The alleged benefits of NGTs for sustainability, spanning from pest resistance to drought resistance, are currently based on assumptions and remain merely theoretical industry promises.** Genetic engineering and the trait-focused approach to

Advocacy: European Council

Letter: 20 November

Brussels, 17 November 2023

To: Agriculture ministers of the European Union

*Re: Agriculture and Fisheries Council, 20 November 2023 – Points of reflection on agenda item
“Regulation on plants obtained by certain new genomic techniques and their food and feed products -
state of play”*

Dear Agriculture Minister,

On November 20th, at the Meeting of the Council of Agriculture ministers, there will be an update on the state of play and information on the legislative proposal on so-called “New Genomic Techniques” (NGTs) and their food and feed products by the Spanish presidency.

On this occasion, IFOAM Organics Europe would like to raise a few important points of consideration on the Commission’s legislative proposal on NGTs as well as the Council presidencies’ draft compromise text which was circulated in early October.

1) New briefing paper on the approach of sustainable innovation in the breeding sector

First of all, following up on the [IFOAM Organics Europe letter](#) to European agricultural ministers ahead of the Informal Council meeting on September 5th on the topic of “New technologies for more sustainable and resilient agriculture”, we would like to call your attention to our recently published [briefing paper](#), entitled “Sustainability in organic breeding: Improving the entire system or adjusting some genes?”. This briefing paper provides an overview of the organic food and farming movement’s understanding of sustainability in crop breeding. From this perspective, the European

- **1) We call to your attention the recently published briefing paper on the approach of the organic movement to sustainability in breeding, which stands in contrast to the notion promoted in the current legislative proposal.**
- **2) We call on you to maintain the prohibition of all NGTs from organic production and offer the adequate means to substantiate freedom of choice for producers.**
- **3) We raise our concerns about the arbitrary as well as legally, politically and scientifically unsound definitional changes introduced in the Council presidencies’ draft proposal in regards to the definition of “NGT plants”.**

Advocacy: European Council

(2) 'NGT plant' means a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool that temporarily may have been inserted during the development of the NGT plant;

WORKING DOCUMENT

From: Presidency
To: Delegations
Subject: Regulation on new genomic techniques (NGT) – Presidency compromise
text on Articles 1-11

Insight into the European Council Working Group

- Spanish presidency compromise proposal remains close to COM proposal
- MS are frustrated in Council Working Group on the chairmanship of the Spanish presidency
- Compromise text?
- Compromise content?
 - Deletion of opt-out for NGT2 (but no mandatory national coexistence measures)
 - Exclusion of herbicide-tolerant plants from Cat. 1
 - unchanged retention of Art. 5(2) (prohibition in organic farming) and Art. 10 (labelling down to seed level)
 - Likely no change on supply chain and consumer labelling

Blocking minority?



Voting rule

Qualified majority



Final result
Rejected

27 member states
Minimum "Yes" required for adoption: (55%) 15



% Population
Minimum "Yes" required for adoption: 65%



Advocacy: European Parliament

Preliminary Timeline

- AGRI Committee vote: 11 December
- ENVI Committee vote: 11 January
- Plenary vote: 15-18 January



Rough Mapping of MEP positions in committees

IFOAMEU_MEP Mapping_NGTs_102023 .XLSX

File Edit View Insert Format Data Tools Help

100% € % .0 .00 123 Calibri 11 B I A

H25

	A	B	C	D	E	F	G	H
1	Mapping of MEPs on NGT position							
2								
3	First Name	Last Name	Party	Nationality	Committee Affiliation (AGRI or ENVI)	Role in Committee	Position	Strategic Importance of MEP (low, medium, high)
11	Traian	Basescu	EPP	Romanian	ENVI	Member		
12	Aurélia	Beigneux	ID	French	ENVI	Member		NO
13	Hildegard	Bentele	EPP	German	ENVI	Member		
14	Stefan	Berger	EPP	German	ENVI	Substitute Member		
15	Sergio	Berlato	ECR	Italian	ENVI	Member	Pro-NGT	
16	Alexander	Bernhuber	EPP	Austrian	ENVI	Member		
17	Benoit	Biteau	Greens/EFA	French	AGRI	Shadow Rapporteur in AG against NGT-deregulation		
18	Franc	Bogovic	EPP	Slovenian	AGRI	Substitute Member	Pro-NGTs	
19	Daniel	Buda	EPP	Romanian	AGRI	Vice- Chair	Pro-NGTs	
20	Pascal	Canfin	Renew	French	ENVI	Chair in ENVI		
21	Catherine	Chabaud	Renew	French	ENVI	Substitute Member		
22	Asger	Christensen	Renew	Danish	AGRI and ENVI	Member in AGRI, Substitute Member in ENVI	Pro-NGTs	
23	Angelo	Ciocca	ID	Italian	AGRI	Member	Pro-NGTs	
24	Dacian	Ciolos	Renew	Romanian	ENVI and AGRI	Member in AGRI and ENVI Substitute Member		
25	Christophe	Clergeau	S&D	French	AGRI and ENVI	Substitute Member in bot against NGT deregulation		
26	Deirdre	Clune	EPP	Irish	ENVI	Substitute Member		
27	Lara	Comi	EPP	Italian	AGRI	Substitute Member		

Controversial Draft Report from EPP rapporteur

2023/0226(COD)

16.10.2023

*****|**

DRAFT REPORT

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

Committee on the Environment, Public Health and Food Safety

Rapporteur: Jessica Polfjärd

Organic Farming Remains GMO-free

- All GMOs, including Category 1 and 2 NGT plants remain prohibited in Organic Production
- Balancing act
- The alternative would be that NGTs would only be banned via the EU Organic Regulation
 - Would open the door to undesired changes on other aspects of the whole Organic Regulation
 - Would prevent the needed legal clarity and the establishment of safeguards of GM-free production, meaning that responsibility for ensuring this would lie with the organic industry itself (EU Organic Regulation)

Controversial Draft Report from EPP rapporteur

- Deletion of ban of Category 1 NGTs in organic

Amendment 16

Proposal for a regulation Article 5 – paragraph 2

Text proposed by the Commission

Amendment

2. *For the purposes of Regulation (EU) 2018/848, the rules set out in its Articles 5 (f) (iii) and 11 shall apply to category 1 NGT plants and to products produced from or by such plants.*

deleted

Or. en

Justification

The proposal establishes a verification process to verify if an NGT plant is meeting the equivalence criteria to be The prohibition for organic farmers to use conventional-like NGTs (Category 1) in their production is neither science-based nor politically justifiable. Moreover, the prohibition of GMOs is part of the organic farming regulation, but not the GMO Directive 2001/18. Already today certain private standards in the organic sector exclude seeds derived from certain conventional breeding methods based on transparent information from the breeding sector. It should therefore be left to the organic operators to decide which seeds to use in their production and all references to organics should be deleted from the NGT proposal.

IFOAM Organics Europe Reaction: Press Release



PRESS RELEASE

EUROPEAN PARLIAMENT SHOULD UPHOLD BAN FOR ALL NGTS IN ORGANIC IN RAPPORTEUR'S REPORT

BRUSSELS, 19 OCTOBER 2023 – IFOAM Organics Europe, the voice for organic food and farming in Europe, is strongly against the changes concerning organic in the rapporteur's [draft report on New Genetic Techniques](#) (NGTs). Crucially, the responsible rapporteur in the ENVI committee proposed to remove the ban of Category 1 NGTs in organic (Article 5(2)). Furthermore, in the draft report, important seed labelling provisions (Article 10) are deleted, which would have been a starting point for transparency at the breeding level.

In June 2023, an overwhelming majority of the European organic movement re-affirmed that the [organic production process should remain free of Genetically Modified Organisms](#) (GMOs). As the European Commission's proposal reflects, [the use of gene editing technologies is not aligned with the principles of organic agriculture](#). Using NGTs in food production can lead to unintended effects, has potential risks, and conflicts with the precautionary principle. Organic producers also want and must fulfil consumers' expectations that no old or new GMOs are used in the organic production process.

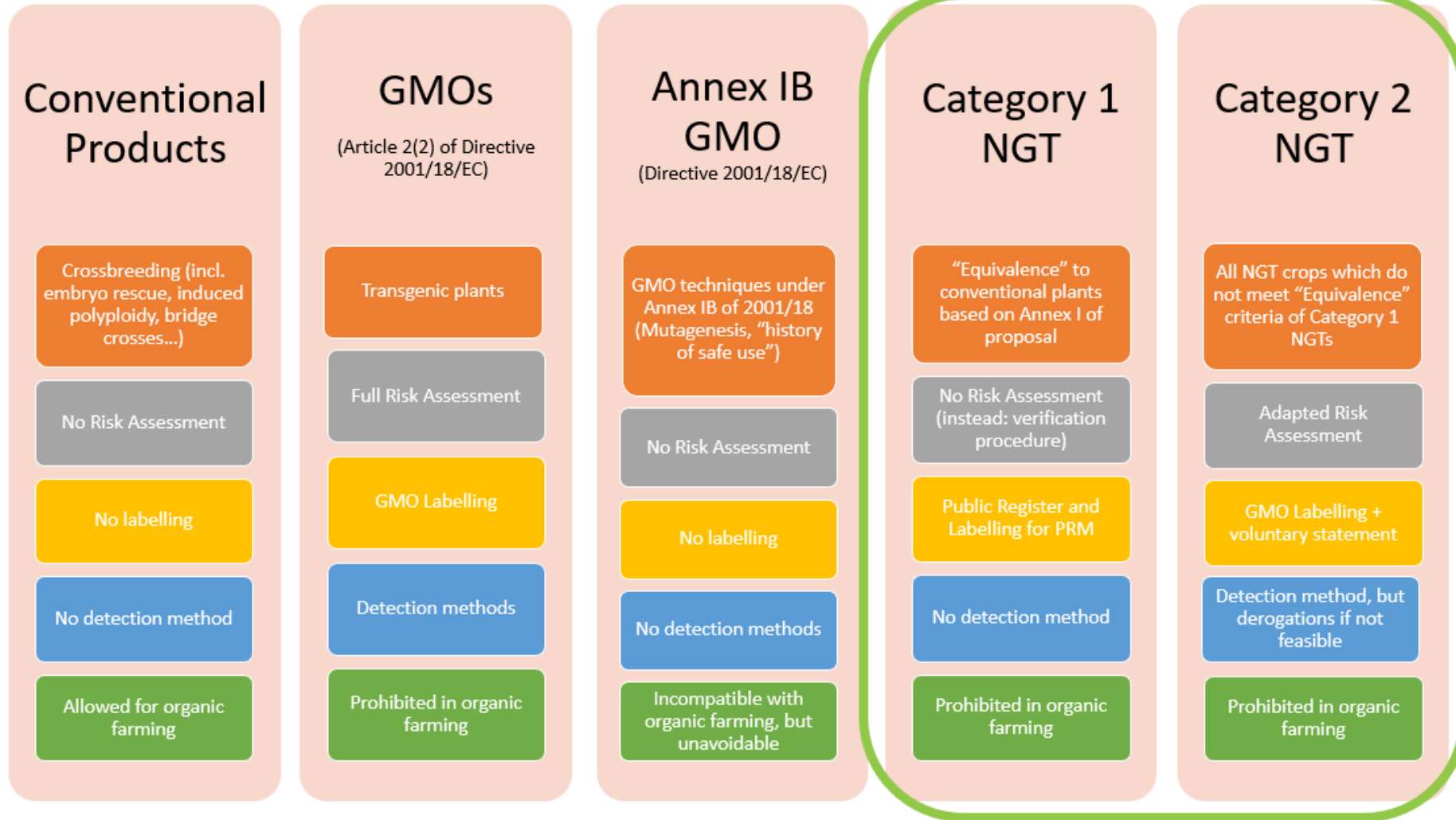
Guaranteeing the freedom of choice and the right of organic operators to produce without NGTs can only be effective if it is accompanied by the legal and technical means. These must be embedded in the NGT regulation, rather than in the EU Organic Regulation (2018/848) as some proponents of NGT deregulation argue. The organic movement is against reopening the EU Organic Regulation as this would open the door to undesired changes of other aspects of the long-negotiated regulation. On top of that, it would also prevent much-needed legal clarity

Advocacy: European Parliament

- Intense exchanges for amendment suggestions
- Deadlines passed (9 Nov AGRI; 15 Nov ENVI)
- 1193 amendments in ENVI Committee tabled
- NGO coordination
- IFOAM Organics Europe: 37 amendment suggestions
 - Tabled in ENVI by MEPs from Renew, EPP, S&D, and Greens
- AGRI and ENVI amendments:
 - Worse than COM proposal (both the compromise amendments and the individual amendments)
 - Except for patents

Advocacy: European Parliament

- [Letter](#) Outreach to all MEPs in October
- 3 key demands
 - ✓ the importance to maintain the explicit ban within the legislative proposal of all NGTs for the purposes of organic production...
 - ✓ ...which needs to be underpinned by the appropriate legal and technical framework, which is not currently the case in the Commission's proposal, namely full traceability for all NGTs and co-existence rules, and
 - ✓ our concerns connected to patents on conventional traits and plant material, which will be exacerbated by a new legislation on NGTs.



Traceability and Co-existence

Article 9

Database of decisions declaring the category 1 NGT plant status

1. The Commission shall establish and maintain a database listing the decisions declaring the category 1 NGT plant status adopted in accordance with Article 6(8) and (10) and Article 7(6).
The database shall contain the following information:
 - (a) name and the address of the requester;
 - (b) the designation of the category 1 NGT plant;
 - (c) a summarised description of the technique(s) used to obtain the genetic modification;
 - (d) a description of the trait(s) and characteristics which have been introduced or modified;
 - (e) an identification number, and
 - (f) the decision referred to in Article 6(8) or (10), and Article 7(6), as appropriate.
2. The database shall be publicly available.

Traceability and Co-existence

Article 10

Labelling of category 1 NGT plant reproductive material, including breeding material

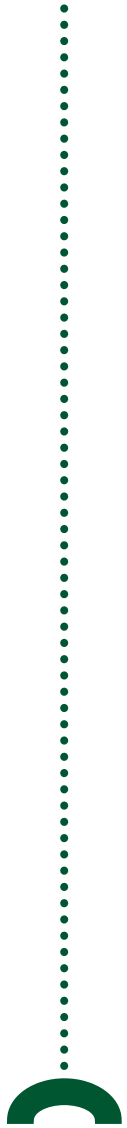
Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from.

Article 11

Confidentiality

1. The requester referred to in Articles 6 and 7 may submit a request to the Member State competent authority or to the Authority, as appropriate, to treat certain parts of the information submitted under this Title as confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6.

3 Scenarios for Category 1 NGTs



1st Scenario – Commissions' proposal

Public Register and Seed Labelling & Explicit Ban in Organic

- Confidentiality issues
- What about NGT products other than seeds?
 - Food additives, vitamins, 5% conventional margin, emergency derogations...
- B2B labelling self organized in organic supply chain?
- Contaminations without detection methods?
- Imports and international trade?
- Consumer and citizen perception



2nd Scenario – Organic & Labelling Out

**Public Register remains, but no seed labelling
 & no Explicit ban in Organic**

- Ban in Organic Regulation instead?
 - Repetition of pesticide dilemma?
 - Polluter pays principle?
 - Regulatory uncertainty
- Seed labelling missing -> public register as useful source for farmers and breeders?
- B2B, consumer perception, contamination, and confidentiality issues remain (Scenario 1)



3rd Scenario – Traceability without labelling

Traceability re-established for NGT 1, but no consumer labelling & Explicit Ban in Organic

- Traceability throughout the full supply chain
- Similar to NGT 2 provisions (and resulting problematique)
- No consumer labelling = no threshold (e.g. 0.9%) for labelling
- No detection methods available
- Member States may take co-existence measures, but on what basis in the absence of detection methods



