

NGT legal framework in the EU: What can we expect?

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Commission proposal to regulate NGT

- Publication of the EC proposal on July 5th, 2023.
- EK proposes to divide NGT crops/products into two categories.
- Category 1 (“NGT 1”): equivalent to plants/products that can also be bred conventionally.
- E.g.: through natural mutations, classic mutagenesis through radiation or chemical mutagenesis (but so far always exempt from all GMO regulations), or changes that can occur through CRISPR/Cas or similar NGT methods.

Commission proposal to regulate NGT

- NO more approval, only notification necessary
- (IMPORTANT: Proof by notifier that there is no foreign DNA in the finished product)
- NO more labeling of products – only seeds and other reproductive material!
- NO more opt-out for NGT1 plants
- EC database with these plants
- NO use in organic production allowed
- NO NGT1 classification of herbicide-tolerant plants

Commission proposal to regulate NGT

- Category 2 (“NGT 2”): Plants/products with properties that would not be comparable to conventionally bred plants
- However: Evidence that no transgenic elements can be detected
- Genetic engineering regulations continue to apply.
- OPT-OUT is also possible
- NGT2 should be approved with a simplified risk assessment
- EC can change the definition of NGT1 and NGT2 at any time via DELRA!
- Voluntary sustainability labeling possible on NGT2

Genesis and important steps

- July 5, 2023: EC proposal
- July 10, 2023: first WP of the Council on the topic
- July 25, 2023: Presentation and discussion at AGRIFISH
- WP under ES presidency on July 26th/27th, September 11th/12th, September 25th/26th, October 4th/5th, November 14th and November 27th/28th, 2023
- First WP under BE presidency on January 11th/12th, 2024
- Second WP May 22nd/23rd, 2024

Genesis and important steps

- COREPER on February 7, 2024 did not produce a majority for a negotiating mandate.
- No qualified majority necessary for a negotiating mandate.
- On **February 7, 2024, EP voted** to adopt the Presidency's compromise text, but with **three essential amendments**.

Genesis and important steps

EP amendments

Art.10 (1):

Category 1 NGT plants, products containing or consisting of category 1 NGT plant(s) and 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 ‘New Genomic Techniques’**. In the case of plant reproductive material, it shall be followed by the identification number of the NGT plant(s) it has been derived from

Genesis and important steps

EP amendments

Art. 10 (1 a) new

Appropriate **document-based traceability** for NGTs shall be provided by the transmission and holding of information that **products contain or consist of NGT plants and product**, and the unique codes for those NGTs, at **each stage** of their placing on the market.

Genesis and important steps

EP amendments

Art. 4 a new

Exclusion from patentability

NGT plants, plant material, parts thereof, genetic information and the process features they contain shall not be patentable

Genesis and important steps

- ANSES has published a statement in which ANSES states that the equivalence criteria for classification in category 1 NGT are not scientifically based
- EP asked EFSA to provide a scientific opinion on the analysis by ANSES
- The EFSA GMO Panel concluded, that it is scientifically justified to consider category 1 NGT plants as equivalent to conventionally bred plants with respect to the similarity of genetic modifications and the similarity of potential risks.

Status Quo

- **There is currently no general approach from the Council**

So no trialogue at the moment

Key Players

- In strong favor for the proposal: Scandinavian countries, Baltic countries, Ireland, and Netherlands
- In favor: Malta, Cyprus, and Greece ?
- Abstain: Germany (most important),
- Against: Austria, Slovenia, Croatia, Hungary, Slovakia, Romania

but most important: Poland

Prospect

- Depends on further negotiations within the council
- **Depends extremely on the position of Poland**
- Poland has the next presidency: I would expect further negotiations within the council
- For all participants of this meeting: **You have to convince the government of your country to change its official opinion if it is in favor, because there are still a lot of open questions**

Presidency HU, PL and DK: Risk and Chances

- Hungary tried to restart the negotiations after presidency of Spain and Belgium
- Hungary sent a Non-paper to all member states including and supporting opinions from not-in-favor MS
- Based on the mostly negative feedback from the MS, Hungary stopped further negotiations so far
- I would expect that Poland will try to continue the negotiations

Presidency HU, PL and DK: Risk and Chances

- The next presidency after Hungary and Poland will be Denmark
- Denmark is an extremely strong supporter of the proposal from the Commission
- Therefore, I would expect that the adoption of the proposal by the Commission could be easily managed within the Danish presidency
- **Therefore, I just can reiterate my message, that you need to increase the pressure on your government to vote against deregulation of NGT**

Impact on organic and Non-GMO production

- Although, the proposal of the COM states clearly, that NGT are not allowed in organic production, this provides massive problems in daily practice
- Just an example: NGT products for Food may be regulated under the Novel Food regulation.
- But there is no Novel Feed regulation!!!!!!

Position of AT

- Austria always stated, that NGT has to be regulated as GMO
- Therefore, all these products, need to have a proper risk assessment, have to be labelled and traceability has to be assured
- Only this can ensure that the consumers be informed and have the freedom of choice

Problem of patentability

- Possible patenting of NGT products still not resolved, represents a problem for many MS
- EP tried to solve this problem with new Art. 4 a
- Newest compromise text from BE excludes patented plants from the definition of NGT 1.
- The extent to which this can be enforced is questionable, as the European Patent Convention would have to be changed and this is not the responsibility of the COM or the EP
- Still more discussions needed

**Thank you for
your attention**