

(English version)

**Question for written answer E-000920/25
to the Commission
Martin Häusling (Verts/ALE)
(5 March 2025)**

Subject: GGSC opinion on NGTs — shift of safety assessment and liability risks from biotech companies to the food industry

The recent legal opinion by the Berlin law firm GGSC on the planned deregulation of new genomic techniques (NGTs) brought to light that the legislation proposed by the Commission will shift the safety assessment and liability risks for plants produced with NGTs and products derived from them from biotech companies to the food industry. The opinion points to the risk that the entire EU food sector might fall foul of the Commission's legislative proposal. ⁽¹⁾

1. How can food companies know whether they are placing on the market a NGT1 product that falls under the Novel Foods Regulation and for which they must carry out safety tests? How do they obtain the necessary information in this regard and how onerous is this?
2. What costs are involved with safety testing under the Novel Foods Regulation and what information does the Commission have on this?
3. How many NGT1 products does the Commission expect to be authorised under the Novel Foods Regulation over the next five years, and how does the Commission arrive at its estimate?

Submitted: 5.3.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(13 May 2025)**

It is the responsibility of food business operators to verify if the food they intend to place on the EU market falls in the scope of the Novel Food Regulation ⁽²⁾. Food obtained from Category c New Genomic Techniques (NGT) plants will fall under that regulation if it contains significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances as provided in its Article 3(2)(iv).

The Commission's proposal on plants obtained by certain NGTs contains transparency measures for Category c NGT plants: the foreseen public database will contain a description of the trait(s) and characteristics introduced or modified in a Category c NGT plant. This will support food business operators in the assessment of whether those traits give rise to the significant changes in the food that would qualify it as novel. It can be expected that food obtained from Category c NGT plants with such significant changes will be part of specialised supply chains as the purpose of developing such traits is to offer identifiable benefits to the consumer.

The Commission does not have specific information on the costs of safety testing under the Novel Food Regulation. Such costs depend on the type of novel food and the necessary tests to prove its safety ⁽³⁾.

The Commission estimated in its impact assessment ⁽⁴⁾ that of a total of 15 applications per year from the first year of operation of the regulation (two years after entry into force), 10 would be Category c NGT plants. It is not possible to predict how many of those would be intended for placing on the market as food and what proportion thereof would contain traits that would require an assessment of the food concerned under the Novel Food Regulation.

⁽¹⁾ https://www.ohnegentechnik.org/fileadmin/user_upload/08_presse/VLOG_GGSC-Rechtsgutachten_Haftung_bei_NGT-Deregulierung_Januar_2025.pdf.

⁽²⁾ <http://data.europa.eu/eli/reg/2015/2283/oj>.

⁽³⁾ The European Food Safety Authority has adopted technical guidance to support applicants in this regard: <https://www.efsa.europa.eu/en/efsajournal/pub/8961>.

⁽⁴⁾ SWD (2023)0412 final, Annex 3.