

(English version)

**Priority question for written answer P-000919/25
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) shows 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 be in breach of the Commission's legislative proposal ⁽¹⁾.

1. Does the Commission agree that large companies are able to cope more easily with the burdens imposed on them under the Novel Food Regulation than small and medium-sized enterprises, and that the latter are penalised as a result?
2. Has the Commission analysed the burden and costs for food companies of the requirement to carry out safety assessments on NGT1 plants under the Novel Foods Regulation, and what is the extent of this burden and of these costs according to the Commission?
3. Is the Commission planning an impact assessment in relation to its proposed legislation to regulate NGT, which seeks to shift the burden and cost of safety assessments of NGT1 plants from biotech companies to the food sector?

Submitted: 5.3.2025

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

The Commission recognises that regulatory requirements in general may be more burdensome for small and medium enterprises (SMEs).

For this reason, the Commission has adopted a number of measures aimed at creating a business-friendly environment ⁽¹⁾, facilitating access to finance ⁽²⁾, improving access to markets ⁽³⁾, fostering competitiveness ⁽⁴⁾, and innovation for SMEs ⁽⁵⁾.

As regards novel foods, some Member States are in addition providing financial and technical support for SMEs to prepare and submit novel food applications and others are exploring such possibility.

Furthermore, the European Food Safety Authority (EFSA) has recently published the second Call for Expression of Interest targeting Novel Food SMEs ⁽⁶⁾, aiming at raising awareness and facilitating access for SME applicants to the pre-submission advice service by the European Food Safety Authority, specifically in the area of novel foods.

The Commission carried out an impact assessment ⁽⁷⁾ prior to adopting its proposal on plants obtained by certain new genomic techniques (NGTs) ⁽⁸⁾, focusing on the burden and costs for food business operators and developers to bring NGT plants to the market, and not on additional potential requirements that might arise from other existing EU legislation applicable to Category c NGT plants and products.

According to the proposal, plants verified to be Category c NGT plants would be subject to other regulatory requirements as they apply to comparable plants obtained by conventional breeding.

The Commission notes that the Novel Foods Regulation ⁽⁹⁾ requires every operator to verify whether a food it intends to place on the market is novel or not and maintains a catalogue ⁽¹⁰⁾ with examples to support companies in this regard.

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

⁽¹⁾ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions entrepreneurship 2020 action plan reigniting the entrepreneurial spirit in Europe, COM/2012/0795 final (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52012DC0795>).

⁽²⁾ https://europa.eu/youreurope/business/finance-funding/getting-funding/access-finance/index_en.htm.

⁽³⁾ https://ec.europa.eu/growth/access-finance-smes/cosme-financial-instruments_en.

⁽⁴⁾ https://ec.europa.eu/growth/industry_en#competitiveness.

⁽⁵⁾ https://ec.europa.eu/growth/industry/policy/innovation_en.

⁽⁶⁾ <https://www.efsa.europa.eu/en/call/call-expressions-interest-efsas-advice-novel-food-smes-2025-edition>.

⁽⁷⁾ SWD(2023) 412.

⁽⁸⁾ COM(2023) 411.

⁽⁹⁾ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, OJ L 327, 11.12.2015, p. 1. See Article 4.

⁽¹⁰⁾ https://food.ec.europa.eu/food-safety/novel-food/consultation-process-novel-food-status_en.