

(English version)

**Question for written answer E-002948/25
to the Commission
Martin Häusling (Verts/ALE)
(17 July 2025)**

Subject: Soy leghemoglobin

Following the Commission reply that ‘the data submitted concerned the actual strain used for producing this soy leghemoglobin (MXY0541)’ ⁽¹⁾, I have further questions.

1. The European Food Safety Authority’s (EFSA) Panel on Genetically Modified Organisms (GMO) explicitly states that it evaluated 14- and 28-day rat feeding studies on LegHPrep derived from the GM yeast strain MXY0291 — not the strain intended for commercialisation (MXY0541). Why did the EFSA’s Panel on Food Additives and Flavourings (FAF) and GMO Panel analyse studies from an irrelevant strain and derive favourable safety conclusions?
2. The findings in Impossible Foods’ peer-reviewed 90-day study ⁽²⁾, which used the strains MXY0291 and NRRL Y-11430 rather than MXY0541, appear to be the same as the findings in the study analysed by the FAF Panel. Therefore, it seems that they are the same study and that the 90-day study that EFSA evaluated used an irrelevant strain. Will the Commission release the full details of the 90-day study that EFSA evaluated, including details of the GM yeast strain that was used, and if it is a different study from the 90-day peer-reviewed one, will it state that and explain how two different studies on LegHPrep that found similar adverse effects are not an indication of food safety risk?

Submitted: 17.7.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(12 September 2025)**

The safety of the soy leghemoglobin protein produced using the genetically modified yeast strain MXY0541 was thoroughly assessed by two scientific Panels of the European Food Safety Authority (EFSA) ⁽¹⁾, ⁽²⁾.

They confirmed the safety of this protein for its intended use, following established risk assessment methodologies, as the Honourable Member was already informed ⁽³⁾.

For the assessment, the applicant provided a 90-day feeding study in rats, as required by the Genetically Modified Organisms (GMO) legislation ⁽⁴⁾.

This study was conducted with a test item from the actual strain used for production (MXY0541), as stated in Section 3.8.1.1 of EFSA’s opinion ⁽⁵⁾.

EFSA considered this study to be adequate and concluded that no adverse effects were reported up to the highest doses tested of the protein.

The applicant provided additional feeding studies conducted with test items from strain MXY0291. EFSA assessed these supplementary studies in line with its task to consider all the information relevant for its assessment. EFSA also considered the peer-reviewed publication ⁽⁶⁾ referred to by the Honourable Member.

On 18 July 2025, the Commission adopted a decision on the request made by the applicant for confidential treatment of certain information in the dossier.

Following the decision, the Commission has requested EFSA to republish the opinion with some fewer elements redacted. Once published, the Commission will reopen the public consultation based on the updated version of the opinion.

¹ https://www.europarl.europa.eu/doceo/document/E-10-2025-001090-ASW_EN.html.

² <https://pmc.ncbi.nlm.nih.gov/articles/PMC10581837/>.

⁽¹⁾ The EFSA Panel on GMO.

⁽²⁾ The EFSA Panel on Food Additives and Flavourings.

⁽³⁾ In the Commission’s reply to Parliamentary Question E-001090/2025 https://www.europarl.europa.eu/doceo/document/E-10-2025-001090-ASW_EN.html.

⁽⁴⁾ <http://data.europa.eu/eli/reg/2003/1829/oj>.

⁽⁵⁾ <https://doi.org/10.2903/j.efsa.2024.9060>.

⁽⁶⁾ <https://pmc.ncbi.nlm.nih.gov/articles/PMC10581837/>.