



Brussels
SANTE/E3/OO/nn(2024)10303528

Dear Mr Bauer-Panskus,

Subject: Your email of 4 December 2024 - public consultation on the EFSA's scientific opinion for authorisation of soy leghemoglobin produced from genetically modified *Komagataella phaffii* (EFSA-GMO-NL-2019-162)

I refer to your email of 4 December 2024 ⁽¹⁾ to Deputy Director General Claire Bury, requesting the Commission to suspend the ongoing public consultation on the scientific opinion of European Food Safety Authority (EFSA) regarding soy leghemoglobin produced from genetically modified *Komagataella phaffii* ⁽²⁾ until an opinion without any redacted text is made available.

On 15 November 2024, the public consultation of EFSA's opinion was launched in accordance with Article 6(7) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽³⁾. In conformity with this Article, EFSA "*shall make its opinion public, after deletion of any information identified as confidential (...)*" (emphasis added).

⁽¹⁾ Our reference: Ares(2024)8655300

⁽²⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2024. Scientific Opinion on assessment of soy leghemoglobin produced from genetically modified *Komagataella phaffii*, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2019-162). EFSA Journal, 2024;22:e9060, <https://doi.org/10.2903/j.efsa.2024.9060>

⁽³⁾ OJ L 268, 18.10.2003, p. 1

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The rules for the handling of confidentiality of applications under Regulation (EC) No 1829/2003 are those applicable at the date of submission of the application concerned. In the case of application EFSA-GMO-NL-2019-162, Article 30 of Regulation 1829/2003 before amendment by the Transparency Regulation ⁽⁴⁾ applies.

In this context, the Commission has not yet taken a decision on the confidentiality of this application in accordance with Article 30(2) of Regulation (EC) No 1829/2003, as applicable at the date of the submission of the application. Once that process is completed, should the Commission conclude that additional elements of the opinion should have been disclosed, we will reopen the public consultation based on an updated non-confidential version of the opinion.

I would also like to inform you that the deadline of the open public consultation is extended until 27 December 2024.

Yours sincerely,

Irene SACRISTAN SANCHEZ
Head of Unit

⁽⁴⁾ Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (L 231, 6.9.2019, p. 1).



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food Safety, Sustainability, and Innovation
Biotechnology

Brussels
SANTE.E.3/BV/nn (2025)3270500

Dear Mr Bauer-Panskus,

Subject: Your email of 20 February 2025 – Request regarding EFSA's Assessment of soy leghemoglobin produced from genetically modified Komagataella phaffii

I refer to your email of 20 February 2025 ⁽¹⁾ to Deputy Director General Claire Bury and myself, regarding your recent access to documents request to the European Food Safety Authority (EFSA) and our letter of 13 December 2024 ⁽²⁾ concerning EFSA's scientific opinion on soy leghemoglobin produced from genetically modified *Komagataella phaffii* ⁽³⁾. Ms Bury has asked me to reply on her behalf.

As regards your access to documents request to EFSA and EFSA's replies to it, any communication on this matter should be addressed to EFSA which is handling the relevant request.

In addition, I would like to reiterate that, as indicated in our reply of 13 December 2024 to your letter of 4 December 2024 ⁽⁴⁾, the Commission has not yet taken a decision on the confidentiality of this application in accordance with Article 30(2) of Regulation (EC) No 1829/2003, as applicable at the date of the submission of the application. Once that

⁽¹⁾ Our reference Ares(2025)1455602

⁽²⁾ Our reference Ares(2024)8949741

⁽³⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2024. Scientific Opinion on assessment of soy leghemoglobin produced from genetically modified *Komagataella phaffii*, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2019-162). EFSA Journal, 2024; 22:e9060, <https://doi.org/10.2903/j.efsa.2024.9060>

⁽⁴⁾ Our reference Ares(2024)8655300

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process is completed, should the Commission conclude that additional elements of the opinion should have been disclosed, we will reopen the public consultation based on an updated version of the opinion.

Yours sincerely,

Irene SACRISTAN SANCHEZ
Head of Unit