Legal Affairs Services

Parma, 26 February 2025

Ref. LV/CP/mm (2025) – out-33816214

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Subject: Your application for public access to documents of 29 January 2025

Our ref. PAD 2025/030 (00015046)

Dear Mr Bauer-Panskus,

I refer to your application for public access to documents of 2 December 2024, registered by EFSA as PAD 2024/187 (00014193) and inserted in the Connect.EFSA tool, by means of which you requested access to "*all data and documents regarding the application EFSA-GMO-NL-2019-162 (soy leghemoglobin produced from genetically modified Komagataella phaffii, under Regulation (EC) No 1829/2003), including the unblackened version of the EFSA opinion*" (EFSA-GMO-NL-2019-162).

On 29 January 2025, by means of its letter ref. 33351195, EFSA provided you with a reply concerning the accessibility of part of the documents within the scope of your PAD application 2024/187 (00014193) due to the large number of documents falling in the scope of your PAD application and the stringent time limits to reply to requesters foreseen in the law. In the same letter, EFSA proposed you the fair solution of i) closing PAD 2024/187 (00014193) for which partial access on the Part II of the GMO application (EFSA-GMO-NL-2019-162) was provided and ii) processing the remaining documents in the scope by means of a new PAD application, registered as **PAD 2025/0030 (00015046)**, concerning **the remaining documents** in the scope of the initial request (hereinafter your "*PAD application*").

In the absence of a reply from you, EFSA is providing you with a reply related to as many documents as possible, on which EFSA was in a position to finalise its assessment by today, in accordance with point 2.2.3. of EFSA Guidance document for applicants submitting applications for public access to documents.

Your PAD application 2025/030 (00015046) has been processed in accordance with Regulation (EC) No 1049/2001 on public access to documents (hereinafter, "*the PAD Regulation*").

We are hereby pleased to provide you with partial access on your PAD application (1) and would like to address the follow-up of it (2).

1. Partial disclosure

In reply to your request pertaining to "*all data and documents regarding the application EFSA-GMO-NL-2019-162"*, we are pleased to grant you partial access to the remaining documents to the remaining parts of the public access version of the valid GMO application on Soy Leghemoglobin produced from genetically modified *Pichia pastoris* (EFSA-GMO-NL-2019-162), namely **Parts I, II, III, IV, V, VI, VII, and VIII.**

In addition, we are also providing the **list of the documents** submitted by the GMO applicant **with the additional information requested by EFSA** in the course of the risk assessment, so you can have a better overview of the documents EFSA received in relation to this GMO application and allow you to identify those of particular interest, as specified in Section 2 of this letter.

Please note that partial access means that certain information has been protected as detailed below:

- **Protection of commercial interests - Article 4(2), first indent of the PAD Regulation**

Following consultations with the third-party document owner, please kindly note that certain parts of the main text of the GMO application disclosed to you have been protected in accordance **with Article 4(2), first indent of the PAD Regulation** since their disclosure would cause significant harm to its competitive position. This provision requires the protection of information the disclosure of which would undermine the commercial interests of natural and legal persons, including intellectual property. The application of this exception takes full account of Article 30 of Regulation (EC) No 1829/2003.

Concretely, information redacted on the grounds of the protection of commercial interests relates *inter alia* to the strain numbers, the use level and the residual amount of DNA, DNA sequence information the disclosure of which could negatively affect the undertaking concerned which would therefore place that business operator at a competitive disadvantage with regard to the relevant markets in which it operates, in particular considering the particularity of this application which concerns micro-organisms.

EFSA also ascertained whether any overriding public interest in disclosure exists. Balancing specifically and actually any public interest in disclosure of this information with the legitimate interest of protecting the ongoing decision-making process and the relevant commercial interests at stake, EFSA concluded that at this stage no such overriding public interest in disclosing the documents exists.

- **Protection of personal data - Article 4(1)(b) of PAD Regulation**

Please be informed that **personal data**[1] present in the documents disclosed to you have been masked in application of the exception to disclosure set out in **Article 4(1)(b) of the PAD Regulation.**

This provision provides that EU bodies shall refuse access to information where the disclosure would undermine the protection of the "*privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data*". In accordance with settled case law of the Court of Justice of the European Union (CJEU), this exception to disclosure is to be interpreted as a reference to Regulation (EC) No 45/2001 - now repealed by Regulation (EU) 2018/1725 (hereinafter, "*the EUDPR*") - which becomes applicable in its entirety.

Regarding the transmission of personal data, Article 9(1) of the EUDPR provides that*: "personal data shall be only transmitted […] if […] the recipient establishes that it is necessary to have the data transmitted for a specific purpose in the public interest and the controller, where there is any reason to assume that the data subject's legitimate interests might be prejudiced, establishes that it is proportionate to transmit the personal data for that specific purpose after having demonstrably weighed the various competing interests".* In application of this provision, further clarified in the case law of the CJEU, EFSA shall determine whether there is any reason to assume that a transmission of the personal data might prejudice the legitimate interests of the concerned individuals and to balance the different interests at stake, based on any express and legitimate justification and convincing arguments you may be able to provide in order to demonstrate that it is necessary for you to receive these data for a specific purpose in the public interest within the meaning of the aforementioned provision.

[1] See in this respect, Article 3(1) of Regulation (EU) 2018/1725: "*'personal data' means any information relating to an identified or identifiable natural person ('*data subject*'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, identification number, location data, an online identifier or to one or more factors specific to physical, physiological, genetic, mental, economic, cultural or social identity of that natural person*".

Hence, only in the event that you are interested in receiving the personal data, EFSA invites you to submit to us your arguments as to why you consider it necessary to receive these data in accordance with Article 9(1)(b) of the EUDPR.

We should point out that personal data contained in the documents concerned were redacted manually, therefore EFSA cannot fully exclude the possibility that certain data are inadvertently disclosed to you. Should this be the case, we urge you to treat any such residual data with the utmost discretion in order to avoid undermining the privacy, integrity and commercial interests of the individual(s) concerned. We shall remind you about your responsibilities under the General Data Protection Regulation, i.e. Regulation (EU) 2016/679 (GDPR) in case of any further processing by you of any personal data inadvertently disclosed to you.

Please be reminded that in line with **Article 16 of the PAD Regulation** all persons intending to reproduce, redistribute, exploit or to make commercial use of the information released are expected to adhere to the terms and conditions remaining documents pertaining to the asserted by the respective copyright holder i.e. **Impossible Food Inc**.

Should you intend to use (i.e. reproduce, publish, redistribute, exploit, make commercial use) the documents concerned for purposes other than mere access pursuant to the PAD Regulation, you need to first verify whether they are protected by copyright/regulatory data protection provisions and contact the copyright and data holder.

2. Fair solution

As anticipated under Section 1 and in our previous fair solution letter (ref. 33351195), by means of this letter we are also providing you with the **list of the documents** submitted by the GMO applicant with the additional information requested by EFSA in the course of the risk assessment (EFSA-GMO-NL-2019-162). Please consider that the assessment of the accessibility of these documents falling within the scope of your PAD application would impose a high volume of work, as they amount to **415 documents and 11784 pages.** Therefore, a significant number of resources are required to reply to your PAD application, in particular in light of the large number of documents, the number of pages of some documents to be screened and the complexity of the concrete and individual assessment which must be carried-out for each document falling within the scope of your PAD application. Furthermore, this also includes carrying-out the **consultation with the relevant third-party document owner** concerned, in accordance with **Article 4(4) of the PAD Regulation**, which is a time-consuming process. The same consideration applies to the part of your request relating to the "*the unblackened version of the EFSA opinion*".

In this respect, within the deadline to process your PAD application 2025/030 (00015046), EFSA managed to screen and disclose to you 36 documents and 1158 pages and draw the list of the additional information in the scope of your request. Therefore, it was not possible to cover also the processing of the accessibility of the "*the unblackened version of the EFSA opinion*".

For these reasons, we would like to engage with you with a view to finding a fair solution in order to process your PAD application in a satisfactory way, whilst reconciling your interests with those of good administration, in accordance with Article 6(3) of the PAD Regulation, as implemented by Articles 4(7) and 4(8) of the Decision of the Management Board laying down practical arrangements for implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006.

Concretely, we would like to propose you to close your current PAD application, PAD 2025/030 (00015046), at this stage and, should you be interested in receiving any or some of the 415 listed additional information and/or "*the unblackened version of the EFSA opinion*", we propose you **to identify the documents you are interested receiving as a matter of priority**. We will consequently register a new PAD application and assess the accessibility of these priority documents within the deadline of the new PAD application. For this purpose, we kindly ask you to bear in mind that the total number of requested documents should not exceed what can be reasonably processed within the timeframe determined by Article 7 of the PAD Regulation.We trust on your understanding of the need to find the right balance in the handling of your PAD application with other tasks in the remit of EFSA and hope this finds your agreement.

We hope this finds your agreement and we would be grateful to receive your views in this respect by writing to: EFSA.public.access.to.documents@efsa.europa.eu.

Should you require any information or clarification regarding the processing of your PAD application in the meantime, please do not hesitate to contact us by writing to: EFSA.public.access.to.documents@efsa.europa.eu.

3. Confirmatory Application

To exercise your right to appeal against this decision of partial access by means of a confirmatory application, you may write to EFSA as detailed below. You have fifteen working days from receipt of this letter to appeal. In case you submit a confirmatory application, EFSA will inform you of the outcome of this re-examination of your request within fifteen working days of receipt, either by granting you access to the documents or by confirming the refusal. In the latter case, you will also be informed of any further appeal routes available.

Confirmatory applications must be sent:

- Via the Connect.EFSA Portal by introducing a new request in the online form or, if you are a registered user by selecting "confirmatory application" once your first request is closed, or
- Via e-mail to:
  EFSA
  Dirk Detken
  Head of Legal and Affairs Services
  Via Carlo Magno 1/A
  IT – 43126 Parma
  Italy

  E-mail: Dirk.DETKEN@efsa.europa.eu

Yours sincerely,

Luisa Venier

Digitally signed by: Luisa Venier
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Luisa Venier
Team Leader
EFSA Public Access to Documents

Cc: A. Afonso (EFSA)

Encl: (1)