



LEGAL AFFAIRS SERVICES

Parma, 28 October 2022
Ref. LV/CP/AS/mm (2022) – out-27236399

Stéphane Horel
Le Monde
Avenue Pierre Mendès, 67-69
FR-75013 Paris
France

E-mail: [REDACTED]@lemonde.fr

Re.: Your application for public access to documents of 15 September 2022

Our ref. PAD 2022/132

Dear Ms Horel,

I refer to your application of 15 September 2022, registered at EFSA as PAD 2022/132, by means of which you requested access to:

"1) Dossier AR-09-0336/SIT-schm. Dated: March 2007. Submitted by Solvay Solexis, Italy as referred to in EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF); Scientific Opinion on the safety evaluation of the substance perfluoro acetic acid, α -substituted with the copolymer of perfluoro-1,2- propylene glycol and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropoxy groups, CAS No. 329238- 24-6 for use in food contact materials. EFSA Journal 2010; 8(2):1519. [11 pp.]. doi:10.2903/j.efsa.2010.1519" (hereinafter referred to as "Dossier 1").

"2) Dossier on Perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt. April 2013. Submitted on behalf of Solvay Solexis SpA. as referred to in EFSA CEF Panel (EFSA Panel on food contact materials, enzymes, flavourings and processing aids), 2014. Scientific Opinion on the safety assessment of the substance, Perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4- yl)oxy]}, ammonium salt, CAS No 1190931-27-1, for use in food contact materials. EFSA Journal 2014;12(6):3718, 9 pp. doi:10.2903/j.efsa.2014.3718." (hereinafter referred to as "Dossier 2")

We have assessed your request in accordance with [Regulation \(EC\) No 1049/2001](#) on public access to documents (hereinafter the "PAD Regulation") and would like to provide you with a reply as follows.

In view of the fact that your request concerns a large number of documents in the ownership of third-parties, to be consulted in accordance with Article 4(4) of the PAD Regulation, EFSA would like to propose you as a fair solution in application of Article 6(3) of the PAD Regulation to provide you with replies in batches, along the case-by-case assessment of the documents in accordance with the PAD Regulation. We hope this is agreeable to you.

We are pleased to provide you with a full reply by means of this letter as regards **Dossier 1** (first batch). As regards Dossier 2, a second reply will follow **by 21 November 2022** at the latest (second batch).

1. Partial disclosure of Dossier 1 (first batch)

We would like to inform you that EFSA already disclosed Dossier 1 under previous PAD applications and we are granting you access to the Dossier 1 as previously released.

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

Having regard to the outcome of our consultation with the third-party document owner in accordance with Article 4(4) of the PAD Regulation, EFSA takes the view that certain information contained in the requested dossier is to be protected in accordance with Article 4(2), first indent, of the PAD Regulation relating to *"the protection of commercial interests of a natural or legal person, including intellectual property rights"*. Indeed, information masked in the documents released to you concern the tradenames, -information regarding the detailed composition/structure of the relevant substance, the quantity used in polymerisation of the test sample, the nature of the test sample, testing results (including their interpretation) and the manufacturing process of the relevant substance. Indeed, disclosure of this information risks enabling competitors to copy the details of the production methods and the technical specifications of the substance. Such a situation would result in an undue commercial advantage for the document owner's competitors and would leave their intellectual property rights unprotected.

EFSA has also ascertained whether any overriding public interest in disclosure may exist. Weighing specifically and actually any public interest in the release of that information against the legitimate interest of protecting the commercial interests of the applicant, and taking account of the fact that a very large proportion of the information contained in the requested dossier is disclosed to you, EFSA concluded that there is no such overriding public interest in disclosure at this stage.

- **Personal data protection - Article 4(1)(b) of the PAD Regulation**

Kindly note that personal data present in the requested dossier have been masked in accordance with 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 transmissions of personal data, Article 9(1)(b) of the EUDPR provides that "personal data shall only be transmitted to recipients established in the Union (...) if the recipient establishes that it is necessary to have the data transmitted for a specific purpose in the public interest". 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. Hence, 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 these documents were redacted manually, therefore EFSA cannot fully exclude the possibility that certain personal data are inadvertently disclosed to you. Should this be the case, we urge you to treat any such residual personal data with the utmost discretion in order to avoid undermining the privacy and integrity of the individual(s) concerned. We shall remind you about your responsibilities under the EUDPR in case of any further processing by you of any personal data inadvertently disclosed to you.

We hope you find the disclosed information useful. I must remind you that, in line with Article 16 of the PAD Regulation, all persons reproducing, redistributing, exploiting or making commercial use of

this information are expected to adhere to the terms and conditions asserted by any holder of copyright.

2. Confirmatory application

To exercise your right to appeal against this decision by a confirmatory application, you may write to EFSA at the address 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 to:

- [Connect.EFSA](#) Portal by selecting "*confirmatory application*" once your first request is closed: this is accessible only if you are registered in the system, or
- Introduce a new application in [Connect.EFSA](#) Portal (in case you are not registered in the Portal) mentioning the reference to your initial application in relation to which you would like an administrative review of the initial decision, 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: [REDACTED]@efsa.europa.eu

Should you require any information or clarification regarding the processing of your request in the meantime, please do not hesitate to contact us by writing to the following functional mail-box:
[REDACTED]@efsa.europa.eu.

Yours sincerely,

Luisa
Venier

Digitally signed by: Luisa Venier
DN: CN = Luisa Venier email =
[REDACTED]@efsa.europa.eu C
= IT O = EFSA OU = Legal
Affairs Services
Date: 2022.10.28 17:52:37 +
01'00'

Luisa Venier
Team Leader of Legal Processes Team
EFSA Public Access to Documents

Cc: V. Curtui (EFSA)

Encl.: Enclosure (PAD 2022_132) – FCM dossier – EFSA-Q-2007-068