Ref. Ares(2020)3092549 - 15/06/2020

EUROPEAN COMMISSION

Brussels, 7.2.2019
C(2019) 1060 final

PAN-Italia
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DECISION OF THE EUROPEAN COMMISSION PURSUANT TO ARTICLE 4 OF THE IMPLEMENTING RULES TO REGULATION (EC) NO 1049/2001[1]

Subject: **Your confirmatory application for access to documents under Regulation (EC) No 1049/2001 - GESTDEM 2018/3468**

Dear ,

I refer to your letter of 26 July 2018, registered on the same day, in which you submitted a confirmatory application in accordance with Article 7(2) of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents[2] (hereafter 'Regulation (EC) No 1049/2001').

1. SCOPE OF YOUR REQUEST

In your initial application of 14 November 2017, addressed to the Directorate-General for Health and Food Safety, you requested access to document '*Sulfoxaflor* Residues in Nectar and Pollen of Strawberry Plants_160355, reference Ares(2015)4088967' containing confirmatory information concerning the active substance *sufloxaflor*, which the applicant [in this case *Dow AgroSciences*] had to submit by 18 August 2017 in accordance with Implementing Regulation (EU) 2015/1295 of 27 July 2015'.

The Directorate-General for Health and Food Safety consulted the third party from which the requested document originates, *Dow AgroSciences*, in accordance with Article 4(4) of Regulation (EC) No 1049/2001. Following the opposition of *Dow AgroSciences* to the

1 Official Journal L 345 of 29.12.2001, p. 94.
2 Official Journal L 145 of 31.5.2001, p. 43.

disclosure of the document, the Directorate-General for Health and Food Safety refused access to the document on 18 July 2018, based on Article 4(2), third indent of Regulation (EC) No 1049/2001 (protection of commercial interests, including intellectual property).

Through your confirmatory application, you request a review of this position. You support your request with detailed arguments, which I address in the corresponding sections below.

2. ASSESSMENT AND CONCLUSIONS UNDER REGULATION NO 1049/2001

When assessing a confirmatory application for access to documents submitted pursuant to Regulation (EC) No 1049/2001, the Secretariat-General conducts a fresh review of the reply given by the relevant Directorate-General at the initial stage.

In this context, the Secretariat-General re-consulted *Dow AgroSciences*, based on Article 4(4) of Regulation (EC) No 1049/2001, with a view to assessing whether an exception in paragraph 1 or 2 could be applicable to the requested document, which originates from that third party.

While *Dow AgroSciences* opposed the disclosure of the requested document, based on Article 4(2), first indent (protection of commercial interests, including intellectual property), it drew attention to the fact that the decision-making process relating to the evaluation process of *sulfoxaflor* was still ongoing. It specified that the requested document was in the process of being evaluated. It also indicated that 'disclosing the content of the confirmatory data before the outcome of the evaluation process risk[ed] seriously undermining this process and preventing regulators from conducting this process in an objective and non-politicised manner, without external pressure and undue influence'.

As to the protection of its commercial interests, *Dow AgroSciences* explained that, together with its consultant, it had developed proprietary approaches that were novel for the conduct of the requested studies and went beyond the generic standards, which existed for only some of the individual stages of the study.

It also stated that it had, together with its consultant, invested considerable intellectual expertise in the methodology used, the disclosure of which would allow competitors to follow the specific approaches that had been developed. It explained that there were no specific and common test methods or guidelines. In its view, this was pure confidential business information – commercially crucial 'know-how'. It concluded that, since the requested study was entirely new and unique and had not been published in any public forum, disclosure would seriously undermine its intellectual property and commercial interests.

In addition, *Dow AgroSciences* claimed that the disclosure of the requested documents would undermine the confidentiality protection provided for in Article 63 of Regulation (EC) No 1107/2009[3], as well as the confidentiality protection stipulated in the guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009.[4]

Consequently, *Dow AgroSciences* fully opposed any disclosure of the requested document.

Following the confirmatory review and taking into account the reply of *Dow AgroSciences*, I can inform you that wide partial access is granted to the requested document, subject only to the redactions of personal data. The partial refusal is based on Article 4(1)(b) (protection of privacy and the integrity of the individual) of Regulation (EC) No 1049/2001, for the reasons set out below.

Please note, however, that the actual transmission of the document is subject to the absence of a request, by the third party author, namely *Dow AgroSciences*, for interim measures as referred to in paragraph 4.

3. PROTECTION OF PRIVACY AND THE INTEGRITY OF THE INDIVIDUAL

Article 4(1)(b) of Regulation (EC) No 1049/2001 provides that 'access to a document is refused where disclosure would undermine the protection of […] privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data'.

In its judgment in Case C-28/08 P *(Bavarian Lager)*,[5] the Court of Justice ruled that when a request is made for access to documents containing personal data, Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data[6] ('hereafter Regulation (EC) No 45/2001') becomes fully applicable.

Please note that, as from 11 December 2018, Regulation (EC) No 45/2001 has been repealed by Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free

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3 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, Official Journal L 309 of 24.11.2009, p. 1–50.

4 SANCO/5634/2009 rev. 6.1, available here: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_aas_guidance_confirmatory-data_rev6-1_201312_en.pdf.

5 Judgment of 29 June 2010 in Case C-28/08 P, *European Commission v The Bavarian Lager Co. Ltd*, EU:C:2010:378, paragraph 59.

6 Official Journal L 8 of 12 January 2001, page 1.

movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC[7] ('hereafter Regulation (EU) 2018/1725').

However, the case law issued with regard to Regulation (EC) No 45/2001 remains relevant for the interpretation of Regulation (EU) 2018/1725.

In the above-mentioned judgment, the Court stated that Article 4(1)(b) of Regulation (EC) No 1049/2001 'requires that any undermining of privacy and the integrity of the individual must always be examined and assessed in conformity with the legislation of the Union concerning the protection of personal data, and in particular with […] [the Data Protection] Regulation'[8].

Article 3(1) of Regulation (EU) 2018/1725 provides that personal data 'means any information relating to an identified or identifiable natural person […]'.

As the Court of Justice confirmed in Case C-465/00 (*Rechnungshof*), 'there is no reason of principle to justify excluding activities of a professional […] nature from the notion of private life'.[9]

The requested document includes names and contact details of natural persons, such as the names of the authors of the study or names of natural persons intervening in the preparation or validation of studies, their signatures or their contact details.

This information clearly constitutes personal data in the sense of Article 3(1) of Regulation (EU) 2018/1725.

Pursuant to Article 9(1)(b) of Regulation (EU) 2018/1725, 'personal data shall only be transmitted to recipients established in the Union other than Union institutions and bodies if '[t]he 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'.

Only if these conditions are fulfilled and the processing constitutes lawful processing in accordance with the requirements of Article 5 of Regulation (EU) 2018/1725, can the transmission of personal data occur.

In Case C-615/13 P *(ClientEarth*), the Court of Justice ruled that the institution does not have to examine of its own motion the existence of a need for transferring personal data.[10] This is also clear from Article 9(1)(b) of Regulation (EU) 2018/1725, which

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7 Official Journal L 205 of 21.11.2018, p. 39.

8 Quoted above, paragraph 59.

9 Judgment of 20 May 2003 in Joined Cases C-465/00, C-138/01 and C-139/01, preliminary rulings in proceedings between *Rechnungshof and Österreichischer Rundfunk*, EU:C:2003:294, paragraph 73.

10 Judgment of 16 July 2015 in Case C-615/13 P, *ClientEarth v European Food Safety Agency*, EU:C:2015:489, paragraph 47.

requires that the necessity to have the personal data transmitted must be established by the recipient.

According to Article 9(1)(b) of Regulation (EU) 2018/1725, the European Commission has to examine the further conditions for the lawful processing of personal data only if the first condition is fulfilled, namely if the recipient establishes that it is necessary to have the data transmitted for a specific purpose in the public interest. It is only in this case that the European Commission has to examine whether there is a reason to assume that the data subject's legitimate interests might be prejudiced and, in the affirmative, establish the proportionality of the transmission of the personal data for that specific purpose after having demonstrably weighed the various competing interests.

In your confirmatory application, you assert that '[t]he functioning of ecosystems we all depend on is a public interest' and that there is 'an overriding public interest in the process of approval of new insecticides such as *sufloxaflor* and the data it is based on'.

However, you do not refer in any way to the personal data included in the requested study, nor do you put forward any arguments to establish the necessity to have the personal data included in the documents transmitted for a specific purpose in the public interest. Therefore, the European Commission does not have to examine whether there is a reason to assume that the data subject's legitimate interests might be prejudiced.

Notwithstanding the above, there are reasons to assume that the legitimate interests of the data subjects concerned would be prejudiced by the disclosure of the personal data reflected in the documents, as there is a real and non-hypothetical risk that such public disclosure would harm their privacy and subject them to unsolicited external contacts.

As to the handwritten signatures appearing in the requested studies, which constitute biometric data, there is a risk that their disclosure would prejudice the legitimate interests of the persons concerned.

Consequently, I conclude that, pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access cannot be granted to the personal data, as the need to obtain access thereto for a purpose in the public interest has not been substantiated and there is no reason to think that the legitimate interests of the individuals concerned would not be prejudiced by disclosure of the personal data concerned.

I would also like to point out that Article 4(1)(b) has an absolute character and does not envisage the possibility to demonstrate the existence of an overriding public interest.

4. DISCLOSURE AGAINST THE EXPLICIT OPINION OF THE AUTHOR

According to Article 5(5) and (6) of Commission Decision of 5 December 2001 amending its rules of procedure[11], '[t]he third-party author consulted shall have a

[11] Commission Decision of 5 December 2001 amending its rules of procedure (notified under document number C(2001) 3714), Official Journal of 29.12.2001, L 345, p. 94.

deadline for reply which shall be no shorter than five working days but must enable the Commission to abide by its own deadlines for reply. In the absence of an answer within the prescribed period, or if the third party is untraceable or not identifiable, the Commission shall decide in accordance with the rules on exceptions in Article 4 of Regulation (EC) No 1049/2001, taking into account the legitimate interests of the third party on the basis of the information at its disposal. If the Commission intends to give access to a document against the explicit opinion of the author, it shall inform the author of its intention to disclose the document after a ten-working day period and shall draw his attention to the remedies available to him to oppose disclosure.'

At initial and confirmatory level, *Dow AgroSciences* objected to the disclosure of the requested document on the grounds that it would undermine the protection of its commercial interests, including intellectual property, and the decision-making process.

The European Commission informed the applicant that, according to Article 4(4) of Regulation (EC) No 1049/2001, a third party, other than a Member State, is consulted with a view to assessing whether an exception in paragraph 1 or 2 is applicable. The exception of Article 4(3) of Regulation (EC) No 1049/2001 cannot be invoked by a third party other than a Member State. Furthermore, the European Commission does not consider that its decision-making process would be seriously undermined by the disclosure of the requested study. As to the exception relating to the protection of the commercial interests, including intellectual property, of *Dow AgroSciences*, after a detailed examination of the requested study, the European Commission concluded that these interests would not be undermined by disclosure at this stage. It also concluded that, even if it could be considered that public disclosure at this stage would undermine the protection of the commercial interests, including intellectual property of *Dow AgroSciences*, such disclosure is justified, as there is an overriding public interest in its disclosure.

Since the decision to grant wide access is taken against the objection of the third party author expressed at initial and confirmatory level, the European Commission will inform the third party author of its decision to give wide partial access to the document requested. The European Commission will not grant such partial disclosure until a period of ten working days has elapsed from the formal notification of this decision to the third party author, in accordance with the provisions mentioned above.

This time period will allow the third party author to inform the European Commission whether it will object to the partial disclosure using the remedies available to it, i.e. an application for annulment and an application for interim measures before the General Court. Once this period has elapsed, and if the third-party author has not signalled its intention to avail itself of the remedies at its disposal, the European Commission will forward the redacted document to you.

5. MEANS OF REDRESS

Finally, I draw your attention to the means of redress available against this decision. You may either bring proceedings before the General Court or file a complaint with the European Ombudsman under the conditions specified respectively in Articles 263 and 228 of the Treaty on the Functioning of the European Union.

Yours sincerely,

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION

For the Commission
Martin SELMAYR
Secretary-General

Enclosure: (1)