

EUROPEAN COMMISSION

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OUT OF SCOPE

Greenpeace European Unit Rue Belliard 199 1040 Brussels Belgium

DECISION OF THE EUROPEAN COMMISSION PURSUANT TO ARTICLE 4 OF THE IMPLEMENTING RULES TO REGULATION (EC) NO 1049/2001¹

Subject:	Your confirmatory application for access to documents under
	Regulation (EC) No 1049/2001 - GESTDEM 2018/3469

Dear
Door

I refer to your letter of 26 July 2018, registered on the next 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 documents² (hereafter 'Regulation (EC) No 1049/2001').

1. Scope of Your Request

In your initial application of 15 June 2018, addressed to the Directorate-General for Health and Food Safety, you requested access to the following documents:

- Sulfoxaflor_Honey Bee (Apis mellifera L.) Larval Toxicity Test (Repeated Exposure), reference Ares(2015)4088967 (hereafter 'document 1'); and
- *Sulfoxaflor_*Bumble Bees (Bombus terrestris L.) in Tomato Plants under Semi-Field Conditions, reference Ares(2015)408896 (hereafter 'document 2').

As you state in your application, these documents contain confirmatory information concerning the active substance *sufloxaflor*, which the applicant for the active substance

Official Journal L 345 of 29.12.2001, p. 94.

Official Journal L 145 of 31.5.2001, p. 43.

had to submit by 18 August 2017 in accordance with Implementing Regulation (EU) 2015/1295 of 27 July 2015³.

At the initial stage, the Directorate-General for Health and Food Safety consulted the third party from which the requested documents originate, *Dow AgroSciences*, in accordance with Article 4(4) of Regulation (EC) No 1049/2001. Following the opposition of *Dow AgroSciences* to the disclosure of the documents, the Directorate-General for Health and Food Safety refused access to the documents on 18 July 2018, based on Article 4(2), first indent of Regulation (EC) No 1049/2001 (protection of commercial interests, including intellectual property).

In 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 (EC) 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 documents, which originate from that third party.

While *Dow AgroSciences* opposed the disclosure of the requested documents 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 documents were 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 studies.

It stated also stated that it had, together with its consultant, invested considerable intellectual expertise in the methodology used, the disclosure of which would allow

Commission Implementing Regulation (EU) 2015/1295 of 27 July 2015 approving the active substance sulfoxaflor, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) 540/2011 (Text with EEA relevance), Official Journal L 199 of 29.7.2015, p. 8–11.

competitors to follow the specific approaches that had been developed. It explained that for the study contained in document 2, 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 1107/2009⁴, 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 1107/2009.⁵

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

Following the confirmatory review and taking into account the reply of *Dow AgroSciences* to the consultation carried out at confirmatory level, I can inform you that:

- wide partial access is granted to document 1, subject only to the redaction of personal data in accordance with Article 4(1)(b) (protection of privacy and the integrity of the individual) of Regulation (EC) No 1049/2001;
- partial access is granted to document 2, subject to the redaction of personal data and limited parts of the document that would reveal the specific 'know-how' of *Dow AgroSciences* in terms of testing methodology. These redactions are based on Article 4(1)(b) (protection of privacy and the integrity of the individual) and on Article 4(2), first indent (protection of commercial interests, including intellectual property) of Regulation (EC) No 1049/2001, for the reasons set out below.

Please note, however, that the actual transmission of the documents is subject to the absence of a request, by the third party author, namely *Dow AgroSciences*, for interim measures, as referred to in paragraph 5.

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'.

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.

SANCO/5634/2009 rev. 6.1, available here:
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides aas guidance confirmatory-data rev61 201312 en.pdf.

In its judgment in Case C-28/08 P (*Bavarian Lager*),⁶ 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 data⁷ ('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 movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC⁸ ('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'9.

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'. ¹⁰

The requested documents include names and contact details of natural persons, for example the names of the authors of the studies or names of natural persons intervening in the preparation or validations 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

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.

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

⁸ Official Journal L 205 of 21.11.2018, p. 39.

⁹ Quoted above, paragraph 59.

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.

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. This is also clear from Article 9(1)(b) of Regulation (EU) 2018/1725, which 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 studies, 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

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

reason to think that the legitimate interests of the individuals concerned would not be prejudiced by the disclosure of the personal data concerned.

3.1. Protection of commercial interests

Article 4(2), first indent of Regulation (EC) No 1049/2001 stipulates that '[t]he institutions shall refuse access to a document where disclosure would undermine the protection of [...] commercial interests of a natural or legal person, including intellectual property, [...] unless there is an overriding public interest in disclosure'.

Limited parts of document 2 are withheld in application of Article 4(2), first indent, of Regulation (EC) No 1049/2001 (protection of commercial interests, including intellectual property), as their disclosure would undermine the commercial interests, including intellectual property, of *Dow AgroSciences*.

The withheld parts contain information that can be qualified as specific expertise and 'know-how' of *Dow AgroSciences* in terms of testing methodology. Document 2 is a study for which no specific and common test methods or guidelines exist. The withheld parts describe methodologies in which considerable intellectual expertise was invested and which refer to specific commercially protected 'know-how'. The disclosure of these parts, at this stage, would seriously undermine the commercial interests of the firm concerned, including intellectual property, as it would reveal its specific 'know-how' in conducting a study for which no specific and common test methods or guidelines exist. Such disclosure would negatively affect its commercial activity, in particular *vis-à-vis* its market competitors.

Therefore, there is a real and non-hypothetical risk that the disclosure of this sensitive information would adversely affect the commercial interests of the concerned company.

I conclude that the disclosure of the withheld parts of document 2 would undermine the protection of the commercial interests of *Dow AgroSciences* within the meaning of Article 4(2), first indent, of Regulation (EC) No 1049/2001.

In your confirmatory application, you do not contest that the requested study may contain commercially sensitive information. You request the disclosure of both studies, based on the claim that the requested studies should be disclosed in accordance with the Convention on access to information, public participation in decision-making and access to justice in environmental matters¹². I examine the existence of a possible overriding public interest in disclosure under point 4.

institutions and bodies, Official Journal L 264 of 25.9.2006, p. 13–19.

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This Convention was approved on behalf of the European Community by Council Decision 2005/370/EC of 17 February 2005, Official Journal 2005 L 124, p. 1. It is applicable in EU law through Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community

4. NO OVERRIDING PUBLIC INTEREST IN DISCLOSURE

The exception laid down in Article 4(2), first indent of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosure. Such an interest must, firstly, be public and, secondly, outweigh the harm caused by disclosure.

In your confirmatory application, you claim that 'as pollinator populations are a part of biological diversity and thus an element of the environment and as the use of pesticides always includes emissions into the environment because pesticides, in the course of normal use, are intended to be released into the environment by virtue of their very function', the requested information must be released in accordance with Article 6(1) of Regulation (EC) No 1367/2006. You state 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. This applies in particular to studies dealing with the effects of the active substance *sulfoxaflor* on pollinators.'

You refer to the judgment of the Court of Justice in Case C-673/13 P¹³ to support your argument. This judgment interprets the concept of information relating to emissions into the environment, for which Article 6(1) of Regulation (EC) No 1367/2006 stipulates that an overriding public interest is deemed to exist with regard to the exceptions of Article 4(2), first and third indents of Regulation (EC) No 1049/2001, with the exception of investigations.

The Court of Justice interpreted the notion of information that relates to emissions into the environment as follows:

'In the light of the objective set out in the first sentence of Article 6(1) of Regulation (EC) No 1367/2006 of ensuring a general principle of access to "information [...] [which] relates to emissions into the environment", that concept must be understood to include, inter alia, data that will allow the public to know what is actually released into the environment or what, it may be foreseen, will be released into the environment under normal or realistic conditions of use of the product or substance in question, namely those under which the authorisation to place that product or substance on the market was granted and which prevail in the area where that product or substance is intended to be used. Consequently, that concept must be interpreted as covering, inter alia, information concerning the nature, composition, quantity, date and place of the actual or foreseeable emissions, under such conditions, from that product or substance.' 14

It is important to underline in this context that the Court acknowledged that 'the purpose of access to environmental information provided by [...] [Regulation (EC) No 1367/2006] is, inter alia, to promote more effective public participation in the decision-making process, thereby increasing, on the part of the competent bodies, the accountability of decision-making and contributing to public awareness and support for the decisions taken. In order to be able to ensure that the decisions taken by the

Judgment of 23 November 2016, Commission v Stichting Greenpeace Nederland and PAN Europe, Case C-673/13 P, EU:C:2016:889.

¹⁴ Ibid, paragraph 79.

competent authorities in environmental matters are justified and to participate effectively in decision-making in environmental matters, the public must have access to information enabling it to ascertain whether the emissions were correctly assessed and must be given the opportunity reasonably to understand how the environment could be affected by those emissions¹⁵ (emphasis added).

In the present case, please note that the decision has not yet been taken by the competent authorities, who are in the process of assessing the information provided by the applicant. Although the purpose of Regulation (EC) No 1307/2006, as explained by the Court of Justice, is to increase, on the part of the competent bodies, the accountability of decision-making and contribute to public awareness and support for the decisions taken, it is not to substitute the decision-making process of the competent institutions through a public review of the confirmatory information submitted by the applicant.

The Court of Justice has specified that 'the interpretation of "information on emissions into the environment" [...] does not in any way mean that all data contained in dossiers for authorisation to place plant protection products or biocides on the market, in particular, all data from studies carried out in order to obtain that authorisation, are covered by that concept and must always be disclosed. Only data relating to "emissions into the environment" are covered by that concept, which excludes, inter alia, not only information which does not concern emissions from the product in question into the environment, but also [...] information which relates to hypothetical emissions, that is to say emissions which are not actual or foreseeable from the product or substance in question under representative circumstances of normal or realistic conditions of use' 16.

The data generated as confirmatory information relates to the process of approval of an active substance. The European legislature has opted for a two-stage process for such approvals. Whereas the active substance is approved at EU level, the mere approval is not sufficient for a release into the environment. For this stage, a product authorisation at Member State level is required under Regulation (EC) No 1107/2009. The product authorisation takes account of the specific climatic and soil conditions in Member States, and the form of use of products may greatly vary from one Member State to another. Therefore, the European Commission considers that information on the active substance, which is not released as such into the environment, does not fulfil the criteria developed by the Court.

The General Court has confirmed this interpretation in its judgment of 21 November 2018, Stichting Greenpeace Nederland and Pesticide Action Network Europe (PAN Europe) v European Commission.¹⁷ It acknowledged that '[a]pproval of [an] active substance [...] does not in any way include authorisation for the isolated use of that substance. Use will be made of that substance only once it is included in a plant protection product authorised for placement on the market by a Member State. Therefore,

Judgment of the Court of 23 November 2016, Bayer CropScience SA-NV and Stichting De Bijenstichting v College voor de toelating van gewasbeschermingsmiddelen en biociden, Case C-442/14, EU:C:2016:890, paragraph 100.

EU:T:2018:817.

while it is true that an active substance [...] is inevitably released into the environment at some stage of its life cycle, that is the case only via a plant protection product subject to the authorisation procedure.' Therefore, the General Court concluded that 'it is only at the stage of the national authorisation procedure to place a specific plant protection product on the market that the Member State assesses any emissions into the environment and that specific information emerges concerning the nature, composition, quantity, date and place of the actual or foreseeable emissions, under such conditions, from the active substance and the specific plant protection product containing it'19.

Furthermore, the Court of Justice explicitly underlined the need not to render void any legitimate protection of commercial interests:

'(...) while [...] it is not necessary to apply a restrictive interpretation of the concept of "information [which] relates to emissions into the environment", that concept may not, in any event, include information containing **any kind of link**, even direct, to emissions into the environment. If that concept were interpreted as covering such information, it would to a large extent deprive the concept of "environmental information" as defined in Article 2(1)(d) of Regulation (EC) No 1367/2006 of any meaning. Such an interpretation would deprive of any practical effect the possibility, laid down in the first indent of Article 4(2) of Regulation (EC) No 1049/2001, for the institutions to refuse to disclose environmental information on the ground, inter alia, that such disclosure would have an adverse effect on the protection of the commercial interests of a particular natural or legal person and. It **would jeopardise the balance which the EU legislature intended to maintain between the objective of transparency and the protection of those interests also constitute a disproportionate interference with the protection of business secrecy ensured by Article 339 [of the Treaty on the Functioning of the European Union]**'²⁰ (emphasis added).

Full disclosure of the document 2, at this stage, would lead to a disproportionate undermining of the protection of the rights ensured by Articles 16 and 17 of the Charter of Fundamental Rights of the European Union and by Article 39(3) of the Agreement on Trade-Related Aspects of Intellectual Property Rights.

I therefore conclude that for the withheld (parts of) document 2, there is no public interest capable of overriding the public and private interests protected by Article 4(2), first indent, of Regulation (EC) No 1049/2001.

The fact that document 2 relates to an administrative procedure and not to any legislative act, for which the Court of Justice has acknowledged the existence of wider openness, ²¹ provides further support to this conclusion.

¹⁹ Ibid, paragraph 88.

¹⁸ Ibid, paragraph 82.

Judgment of 23 November 2016, *Commission v Stichting Greenpeace Nederland and PAN Euro*pe, Case C-673/13 P, cited above, paragraph 81.

Judgment of the Court of 29 June 2010 in Case C-139/07 P, Commission v Technische Glaswerke Ilmenau Gmbh, EU:C:2010:376, paragraphs 53-55 and 60; Judgment of the Court (Grand Chamber) of

Please note also that Article 4(1)(b) of Regulation (EC) No 1049/2001 does not include the possibility for the exceptions defined therein to be set aside by an overriding public interest.

The fact that after the registration of *sufloxaflor*, documents containing the detailed assessment made by the rapporteur Member State as well as the technical report by the European Food Safety Authority, including commenting tables by the Member States, the European Food Safety Authority and the applicant, are publicly available, only reinforces this conclusion.

5. DISCLOSURE AGAINST THE EXPLICIT OPINION OF THE AUTHOR

According to Article 5(5) and (6) of the detailed rules of application of Regulation (EC) No 1049/2001²², '[t]he third-party author consulted shall have a 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 levels, *Dow AgroSciences* objected to the disclosure of the requested documents 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, in accordance with Article 4(4) of Regulation (EC) No 1049/2001, third-party originators of documents held by the Commission are consulted with a view to assessing whether an exception in paragraph 1 or 2 could be applicable. The exception of Article 4(3) of Regulation (EC) No 1049/2001, pertaining to the protection of the decision-making process, 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 studies. As to the exception relating to the protection of the commercial interests, including intellectual property of *Dow AgroSciences*, the European Commission concluded, after a detailed examination of the requested studies, that these interests would not be undermined, at this stage, by their partial disclosure. It also concluded that the confirmatory data on *sufloflaxor* contained in the disclosed parts of the studies do not fall into any of the exceptions referred to in Article 4 of Regulation (EC) No 1049/2001. Hence, there is no need to assess the

²⁹ June 2010 in Case C-28/08 P, Commission v Bavarian Lager, cited above, paragraphs 56-57 and 63

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

possible application of an overriding public interest in the disclosure of the requested documents which, however, cannot be excluded, taking into account of the specific nature of the information contained in the documents concerning the safety and the environmental impact of approved products under the present circumstances.

Since the decision to grant wide access is taken against the objection of the third party author expressed at initial and confirmatory levels, the European Commission will inform the third party author of its decision to give wide partial access to the documents 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 documents to you.

6. 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

Enclosures: (2)