efsa
European Food Safety Authority

HEAD OF LEGAL AND REGULATORY AFFAIRS UNIT

24 MAY 2016

Ref. DD/CR/lm (2016) - out- 15751029

[redacted]
Monsanto Europe S.A.
Avenue de Tervuren 270-272
B- 1150 Brussels
Belgium

e-mail:
[redacted]

Subject: Public access request related to the correspondence between EFSA and Monsanto

Ref.: PAD 2016/046

Dear Mr [redacted],

I am contacting you following our previous consultations in the context of the public access request with our reference PAD 2015/143, by means of which we consulted you on the accessibility of a mouse study[1] you submitted to EFSA for the renewal assessment of the active substance glyphosate.

Firstly, I should inform you on the fact that the public access requestor, a non-governmental organisation, has submitted an additional public access request for the correspondence held between EFSA and your organisation related to the accessibility of the mouse study dealt with in the context of the separate public access requests referred to above. To avoid any doubt, to clarify that the present access request only concerns the correspondence between you and EFSA on the accessibility of the mouse study.

As you are aware of, according to Article 41(1) of Regulation (EC) No 178/2002[2] access of citizens to the documents held by EFSA is governed by Regulation (EC) No 1049/2001[3] (hereinafter the "PAD Regulation"). The Regulation applies to all documents held by EFSA, *i.e.* documents which it has produced or received, in all areas of its activity.
Pursuant to Article 4(4) of the PAD Regulation, EFSA is hereby consulting you on the accessibility of the following identified correspondence send by you to EFSA falling within the scope of the request:

- Reply letter of Monsanto to the EFSA consultation launched in the context of the public access request with our reference PAD 2015/143, dated 4 February 2016.

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1 [redacted] (1983) A chronic feeding study of glyphosate (Roundup technical) in mice 77-2061(BDN-77-420) TOX9552381

2 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1-24, as last amended.

3 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43-48, applicable to EFSA.

Please find enclosed a version of this letter in which the personal data and information that might undermine the privacy of persons identifiable in the correspondence (names, e-mail addresses, signatures, and phone numbers) already has been masked in the way EFSA intends to disclose it to the requester for public access. We would appreciate to receive your reply with the following information regarding the enclosed document:

- an indication of any parts of the correspondence which in your view should not be released as a disclosure would undermine your commercial interests or another interest of Article 4 of the PAD Regulation;
- the reason(s) why these parts should in your view not be released, substantiating the grounds for protecting the information.

Please note that the PAD Regulation provides that, should only a part of the documents for which public access is requested fall into an exception to disclosure, the remaining parts shall be released.

To enable EFSA to reply to the request for public access within the time period laid down in the PAD Regulation, we would appreciate to receive your reply **by 27 May 2016** at latest. If we have not received a reply by this date and/or in case of an insufficiently substantiated negative answer, EFSA will decide on the access request in accordance with the PAD Regulation.

Yours sincerely,

[redacted]

Enclosure: 1

MONSANTO

[redacted]
EMEA Crop Protection Regulatory Affairs Lead
☎ direct [redacted]
Fax direct [redacted]
e-mail [redacted]@monsanto.com

Registered address
Monsanto Europe S.A./N.V.
Haven 627
Scheldelaan 460
B-2040 Antwerp Belgium

Correspondence address
Monsanto Europe S.A./N.V.
Avenue de Tervuren 270-272
Tervurenlaan 270-272
B - 1150 Brussels Belgium

[redacted]
Public Access to Document Team
Legal and Regulatory Unit
European Food Safety Authority
Via Carlo Magno, 1A
I-43126 Parma

Brussels, 4th February 2016

Dear [redacted],

Re: Request for access to documents

In response to your email letter dated 22 January 2016 concerning receipt of a third party request for access to one of our studies on Glyphosate in EFSA's possession, namely,

[redacted] *A chronic feeding study of glyphosate (Roundup technical) in mice 77-2061 (BDN-77-420) TOX9552381* (the "**Study**"),

Monsanto hereby formally objects to the disclosure of the entirety of the Study.

The Study is privately owned by Monsanto and is used for the renewal of the approval of the active substance Glyphosate under Regulation 1107/2009, presently under review. Its disclosure may harm legitimate interests of Monsanto as it is prejudicial to the *"commercial interests"* of Monsanto (in the meaning of Article 4(2) of Regulation 1049/2001).

Based on Article 63 of Regulation 1107/2009, Article 4(2) of Regulation 1049/2001, we object the disclosure because **the Study contains confidential information which disclosure would undermine the protection of Monsanto's commercial interests**.

Furthermore, according to Article 4(2) of Regulation 1049/2001, the request for access to documents should be refused where the disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property. With unlimited disclosure of the Study, it may not be guaranteed that protected intellectual property rights of Monsanto will not be disproportionately damaged.

Our objections are also grounded by **legitimate economic interests protected by the confidentiality**.

The Study represents a material investment in time and money for Monsanto and its findings form part of the core data package and knowledge of relevant product. If the Study is made available to the public upon request, this will make investment efforts of businesses like Monsanto useless, because effectively anyone, including competitors, would then have access to key commercial information without any expense for possible use in and outside of the EU.

Additionally, **information about undertakings and trade secrets shall be kept confidential as commercial secrets** (protected, inter alia, under Article 41(2) of the Charter of Fundamental Rights of the European Union as well as relevant case law). It is the duty of the EU Institutions to balance the contribution which the information makes to the protection of public interest, notably disclosure for public health reasons, and the degree of damage to commercial secrecy resulting from the disclosure of that information (*see the Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04*). **Any disclosure** of the above information **should not be disproportionate given the seriousness of the damage it may cause**. The duty to consult third parties prior to disclosure is vested with the EU institution, including EFSA, with the purpose to ensure the procedure where legitimate commercial interests are not damaged by breach of confidentiality.

Article 63 of Regulation 1107/2009 **contains a non-exhaustive list of information which must be deemed to undermine the protection of the commercial interests**, and which should therefore be treated as confidential.

Inter alia, above information includes know-how (e.g., Monsanto's scientific approaches and justifications, suggested and applied testing methodology, etc.) relating to the scientific expertise and strategy, created by Monsanto when preparing the dossier for disclosure in confidence to EFSA. Accordingly, such Monsanto's know-how would be adversely affected if disclosed to the public.

In view of the above, Monsanto hereby requests to refuse in access to documents of the Study.

Without prejudice to the above arguments, should EFSA still consider granting access to the document to the third party, Monsanto would insist on making The Study available to the third party in a **closed data room**, **without any possibility to make copies, reproduction or communication of the information and under logistical conditions to be agreed with Monsanto**.

This would allow the third party to view The Study on a single occasion, without the possibility of referring to or using The Study for its own ends, while limiting the detrimental effects of the disclosure of The Study for Monsanto. Prior to the third party viewing The Study, Monsanto would request an opportunity to sanitise The Study based on the principles of Article 63 of regulation 1107/2009.

Thank you in advance for your consideration of the above arguments and appropriate action. Please keep us informed on the progress of this matter

Yours sincerely

[redacted]

EMEA Crop Protection Regulatory Affairs Lead

efsa
European Food Safety Authority

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

22 JAN 2016

Ref. [redacted]mm (2016) - out- 15184496

[redacted]
Monsanto Europe S.A.
Avenue de Tervuren 270-272
B-1150 Brussels
Belgium

e-mail:
[redacted]

Subject: Consultation on an access to documents request related to the study you submitted to EFSA for the renewal assessment of the active substance glyphosate in the framework of Regulation (EC) N° 1107/2009 and it's implementing Regulation (EU) N° 844/2012

Ref.: PAD 2015/143

Dear [redacted]

According to Article 41(1) of Regulation (EC) No 178/2002[1] access of citizens to the documents held by EFSA is governed by Regulation (EC) No 1049/2001[2]. The Regulation applies to all documents held by EFSA, *i.e.* documents which it has produced or received, in all areas of its activity (hereinafter the "PAD Regulation").

EFSA has received a request by a non-government organisation for public access to documents. The public access request concerns the study you submitted to the EFSA for the renewal assessment of the active substance glyphosate[3] in the framework of Regulation (EC) No 1107/2009[4] and it's implementing Regulation (EU) No 844/2012[5].

Pursuant to Article 4(4) of the PAD Regulation, EFSA is hereby consulting you on the disclosure of the study with the following references:

[redacted] (1983)
A chronic feeding study of glyphosate (Roundup technical) in mice
77-2061 (BDN-77-420)
TOX9552381

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1 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1-24, as last amended.

2 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43-48, applicable to EFSA. http://www.europarl.europa.eu/RegData/PDF/r1049_en.pdf.

3 European Food Safety Authority, 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302 pp. 107 doi:10.2903/j.efsa.2015.4302, available at: http://www.efsa.europa.eu/en/efsajournal/pub/4302

4 Regulation (EC) No 844/2012 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market, OJ L 309, 24.11.2009, p. 1-50.

5 Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, OJ L 252, 19.9.2012, p. 26-32.

EFSA would like to consult with you, to ascertain whether any exception to disclosure in the sense of Article 4 of the PAD Regulation may apply. We would appreciate to receive your reply with the following information regarding the study:

- an indication of any parts of the study which in your view should not be released as a disclosure would undermine intellectual property or another interest of Article 4 of the PAD Regulation;
- the reason(s) why these parts should in your view not be released, substantiating the grounds for protecting the information.

Please note that the PAD Regulation provides that, should only a part of the documents for which public access is requested fall into an exception to disclosure, the remaining parts shall be released.

To enable EFSA to reply to the request for public access within the time period laid down in the PAD Regulation, we would like to receive your reply **by 28 January 2016** at the latest. If we have not received a reply by this date and/or in case of an insufficiently substantiated negative answer, EFSA will decide on the access request in accordance with the PAD Regulation.

We would be grateful if you could inform us timely on your point of view, by replying to this e-mail.

You can reply by writing to:
EFSA Public Access Team
[redacted]

Yours sincerely,

[redacted]

Cc: [redacted] (EFSA)

efsa
European Food Safety Authority

HEAD OF LEGAL AND REGULATORY AFFAIRS UNIT

24 MAY 2016

Ref. [redacted] (2016) - out- 15752570

[redacted]
Regulatory Affairs Manager
Cheminova A/S
Thyborønvej 78
DK-7673 Harboøre
Denmark

e-mail: [redacted]

Subject: Public Access request related to correspondence between EFSA and Cheminova

Ref.: PAD 2016/046

Dear [redacted]

I am contacting you following our previous consultation in the context of the public access request with our reference PAD 2015/143, by means of which we consulted you on the accessibility of a mouse study[1] you submitted to EFSA for the renewal assessment of the active substance glyphosate.

Firstly, I should inform you on the fact that the public access requestor, a non-governmental organisation, has submitted an additional public access request for the correspondence held between EFSA and your organisation related to the accessibility of the mouse study dealt with in the context of the separate public access requests referred to above. To avoid any doubt, to clarify that the present access request only concerns the correspondence between you and EFSA on the accessibility of the mouse study.

As you are aware of, according to Article 41(1) of Regulation (EC) No 178/2002[2] access of citizens to the documents held by EFSA is governed by Regulation (EC) No 1049/2001[3] (hereinafter the "PAD Regulation"). The Regulation applies to all documents held by EFSA, *i.e.* documents which it has produced or received, in all areas of its activity.

Pursuant to Article 4(4) of the PAD Regulation, EFSA is hereby consulting you on the accessibility of the following identified correspondence send by you to EFSA falling within the scope of the request:

[redacted]

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1-24, as last amended.

[3] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43-48, applicable to EFSA.

- Reply letter of Cheminova to the EFSA consultation launched in the context of the public access request with our reference PAD 2015/143, dated 28 January 2016.

Please find enclosed a version of this letter in which the personal data and information that might undermine the privacy of persons identifiable in the correspondence (names, e-mail addresses, signatures, and phone numbers) already has been masked in the way EFSA intends to disclose it to the requester for public access. We would appreciate to receive your reply with the following information regarding the enclosed document:

- an indication of any further parts which in your view should not be released as a disclosure would undermine your commercial interests or another interest of Article 4 of the PAD Regulation;
- the reason(s) why these parts should in your view not be released, substantiating the grounds for protecting the information.

Please note that the PAD Regulation provides that, should only a part of the documents for which public access is requested fall into an exception to disclosure, the remaining parts shall be released.

To enable EFSA to reply to the request for public access within the time period laid down in the PAD Regulation, we would appreciate to receive your reply **by 27 May 2016** at latest. If we have not received a reply by this date and/or in case of an insufficiently substantiated negative answer, EFSA will decide on the access request in accordance with the PAD Regulation.

Yours sincerely,

[redacted]

Enclosure: 1

Cheminova A/S
Thyborønvej 78
DK-7673 Harboøre
Denmark
[redacted]
SE No. DK 12 76 00 43

Mr [redacted]
European Food Safety Authority

By e-mail only

EFSA.public.access.to.documents@efsa.europe.eu
[redacted]@efsa.europa.eu

Copy: [redacted]@efsa.europa.eu

28 January 2016

Dear [redacted]

Re: Request for access to documents

We write to you in reply to your letter sent by e-mail on 22 January 2016 (your reference: [redacted]/mm (2016)-out-15182433), in which you inform that you received a third party request for access to one of our studies on Glyphosate in EFSA's possession. The study ("The Study") in question is:

> [redacted] **(1993)**
> **Glyphosate - 104 Week Combined Chronic Feeding/Oncogenicity Study in Rats with 52 Week Interim Kill (Results after 104 Weeks)**
> [redacted]
> **Study No.: 438623; Report No.: 7867**
> **Date: 1993-04-07**
> **GLP**
> **Not published, TOX9750499**

Concerning the above request, Cheminova formally objects to the disclosure of the entirety of The Study.

It should be noted that The Study is privately owned by Cheminova and is used for the renewal of the approval of the active substance Glyphosate under Regulation 1107/2009, which is still currently under review.

The objections to disclosure are justified under Article 63 of Regulation 1107/2009 because The Study contains confidential information, as well as under Article 4(2) of Regulation 1049/2001 because the disclosure of the Confidential Data would undermine the protection of Cheminova's commercial interests.

Furthermore, as outlined below, EFSA's duty of confidentiality combined with the release of commercially sensitive information outweighs any public interest which might be purported to accrue. Consequently, the request must be rejected in its entirety.

Cheminova A/S
Thyborønvej 78
DK-7673 Harboøre
Denmark
[redacted]
SE No. DK 12 76 00 43

1. Exception to Public Access to Documents under Article 4(2) of Regulation 1049/2001

As provided by Article 4(2) of Regulation 1049/2001, the request for access to documents should be refused where the disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property.

As explained above, The Study is owned by Cheminova and is protected by intellectual property rights. On that basis, all summaries, assessments and other documents included in The Study may not be disclosed, as this could jeopardize the proper execution of the intellectual property right.

Confidentiality of the data at hand is also designed to protect a legitimate economic interest: specifically, the data represents a substantial investment in time and money for Cheminova and the findings form part of the core data package and knowledge of the product. It is a vital part of Cheminova's business to be able to protect the studies commissioned on its chemicals. If The Study was made easily available upon request, businesses would be reluctant to conduct research to register their substances since third parties including competitors would then have access to key commercial information for possible use in the EU and/or outside the EU where data protection/confidentiality rules might be more lenient and difficult to monitor and enforce.

Additionally, information about undertakings and trade secrets attracts confidentiality as commercial secrets. Commercial secrecy is given wide protection as a general principle of European Union law and is enshrined in Article 41(2) of the Charter of Fundamental Rights of the European Union. Furthermore, there are procedural safeguards to prevent serious damage from the improper disclosure of business secrets (Case C-53/85 Akzo Chemie BV and Akzo Chemie UK Ltd v Commission [1986] ECR 1965).

Furthermore, EU Institutions are required to balance on the one hand the contribution which the information makes to the protection of public interest, notably disclosure for public health reasons, and on the other hand the degree of damage to commercial secrecy resulting from the disclosure of that information (see the Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04). In such an instance, the disclosure of confidential information should not be disproportionate having regard to the seriousness of the commercial damage which the disclosure may cause.

Therefore, it is clear that Article 4(2) of Regulation 1049/2001 is applicable in the current case since the disclosure of the scientific information contained in The Study would be prejudicial to the "*commercial interests*" of Cheminova. Consequently, the request for access to documents should not be granted.

It should also be noted that, in respect of third-party documents, Article 4(4) of Regulation 1049/2001 requires institutions to consult third parties prior to disclosure. Therefore EU institutions such as EFSA have a duty to take due account of Cheminova's legitimate commercial interest in not disclosing the confidential Study.

2. Confidentiality under Article 63 of Regulation 1107/2009

Article 63 of Regulation 1107/2009 contains a non-exhaustive list of information which must normally be deemed to undermine the protection of the commercial interests or the privacy and integrity of the individuals concerned, and which should therefore be treated as confidential.

Information which should normally be treated as confidential includes protected know-how relating to the scientific expertise and strategy in the compilation of the dossier the disclosure of which would undermine Cheminova's commercial interests.

The scientific approaches and justifications relied upon by Cheminova in order to evaluate endpoints, as well as suggested and applied testing methodology, amount to proprietary scientific know-how

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Denmark
[redacted]
SE No. DK 12 76 00 43

belonging to Cheminova. Should such information be disclosed to third parties, this would reveal the know-how, registration and/or commercial strategy of Cheminova in defending the active ingredient, and undermine its competitiveness. The results of research and development undertaken by Cheminova, and its related know-how, would be adversely affected if disclosed to the public. Indeed, while Cheminova's research represents significant financial investment and time spent, that would be made worthless if it would become easily and freely accessible by third parties.

Cheminova therefore submits that the request for access to documents should not be granted since it contains confidential information which is the property of Cheminova.

3. Alternative: Closed Data Room

Without prejudice to the above arguments, should EFSA still consider granting access to the document to the third party, Cheminova would insist on making The Study available to the third party in a closed data room, without any possibility to make copies, reproduction or communication of the information.

This would allow the third party to view The Study on a single occasion, without the possibility of referring to or using The Study for its own ends, while limiting the detrimental effects of the disclosure of The Study for Cheminova. Prior to the third party viewing The Study, Cheminova would request an opportunity to sanitise The Study based on the principles of Article 63 of regulation 1107/2009.

In any case, Cheminova requests to receive the identity of the third party seeking access to The Study. This information might indeed be relevant for some of the arguments developed above, as well as for the closed data room alternative proposal.

We thank you for your consideration of the points raised in this letter and for an urgent reply.

Yours sincerely,
Cheminova A/S

[redacted]

Regulatory Affairs Manager

efsa
European Food Safety Authority

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

22 JAN 2016
Ref. [redacted]mm (2016)-out-15182433

[redacted]
Cheminova A/S European Reg. Office
8 Cardale Court, Cardale Park
Beckwith Head Road
HG3 1RY Harrogate
United Kingdom

e-mail:
[redacted]

Subject: Consultation on an access to documents request related to the study you submitted to EFSA for the renewal assessment of the active substance glyphosate in the framework of Regulation (EC) N° 1107/2009 and it's implementing Regulation (EU) N° 844/2012

Ref.: PAD 2015/143

Dear [redacted],

According to Article 41(1) of Regulation (EC) No 178/2002[1] access of citizens to the documents held by EFSA is governed by Regulation (EC) No 1049/2001[2]. The Regulation applies to all documents held by EFSA, *i.e.* documents which it has produced or received, in all areas of its activity (hereinafter the "PAD Regulation").

EFSA has received a request by a non-government organisation for public access to documents. The public access request concerns the study you submitted to the EFSA for the renewal assessment of the active substance glyphosate[3] in the framework of Regulation (EC) No 1107/2009[4] and it's implementing Regulation (EU) No 844/2012[5].

Pursuant to Article 4(4) of the PAD Regulation, EFSA is hereby consulting you on the disclosure of the study with the following reference:

[redacted](1993)
Glyphosate – 104 week combined chronic feeding / oncogenicity study in rats with 52 week interim kill (results after 104 weeks)
[redacted]
Study No.: 438623; Report No.: 7867
Date: 1993-04-07
GLP:
not published, TOX9750499

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1 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1-24, as last amended.

2 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43-48, applicable to EFSA. http://www.europarl.europa.eu/RegData/PDF/r1049_en.pdf.

3 European Food Safety Authority, 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302 pp. 107 doi:10.2903/j.efsa.2015.4302, available at: http://www.efsa.europa.eu/en/efsajournal/pub/4302

4 Regulation (EC) No 844/2012 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market, OJ L 309, 24.11.2009, p. 1-50.

5 Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, OJ L 252, 19.9.2012, p. 26-32.

EFSA would like to consult with you, to ascertain whether any exception to disclosure in the sense of Article 4 of the PAD Regulation may apply. We would appreciate to receive your reply with the following information regarding the study:

- an indication of any parts of the study which in your view should not be released as a disclosure would undermine intellectual property or another interest of Article 4 of the PAD Regulation;
- the reason(s) why these parts should in your view not be released, substantiating the grounds for protecting the information.

Please note that the PAD Regulation provides that, should only a part of the documents for which public access is requested fall into an exception to disclosure, the remaining parts shall be released.

To enable EFSA to reply to the request for public access within the time period laid down in the PAD Regulation, we would like to receive your reply **by 28 January 2016** at the latest. If we have not received a reply by this date and/or in case of an insufficiently substantiated negative answer, EFSA will decide on the access request in accordance with the PAD Regulation.

We would be grateful if you could inform us timely on your point of view, by replying to this e-mail.

You can reply by writing to:
EFSA Public Access Team
[redacted]

Yours sincerely,

[redacted]

Cc: [redacted] (EFSA)

efsa
European Food Safety Authority

HEAD OF LEGAL AND REGULATORY AFFAIRS UNIT

24 MAY 2016

Ref. DD/CR/lm (2016) – out- 15752115

[redacted]
Arysta Lifesciences SAS
Route d'Artix, BP 80
FR-64150 Nogueres
France

e-mail: [redacted]

Subject: Public access request related to the correspondence between EFSA and Arysta

Ref.: PAD 2016/046

Dear [redacted],

I am contacting you following our previous consultations in the context of the public access request with our reference PAD 2015/143 and its confirmatory application with our reference PAD 2016/023 CA, by means of which we consulted you on the accessibility of a mouse study[1] you submitted to EFSA for the renewal assessment of the active substance glyphosate.

Firstly, I should inform you on the fact that the public access requestor, a non-governmental organisation, has submitted an additional public access request for the correspondence held between EFSA and your organisation related to the accessibility of the mouse study dealt with in the context of the separate public access requests referred to above. To avoid any doubt, to clarify that the present access request only concerns the correspondence between you and EFSA on the accessibility of the mouse study and thus is without prejudice to the on-going consultations with you in the context of the separate public access case with our reference PAD 2016/023 CA.

As you are aware of, according to Article 41(1) of Regulation (EC) No 178/2002[2] access of citizens to the documents held by EFSA is governed by Regulation (EC) No 1049/2001[3] (hereinafter the "PAD Regulation"). The Regulation applies to all documents held by EFSA, *i.e.* documents which it has produced or received, in all areas of its activity.
Pursuant to Article 4(4) of the PAD Regulation, EFSA is hereby consulting you on the accessibility of the following identified correspondence send by you to EFSA falling within the scope of the request:

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1 [redacted] (1997). HR-001: 18 month oral oncogenicity study in mice IET 940151 ALS GLP: Y, published:N,2309415/ASB 2012-11493.

2 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1-24, as last amended.

3 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43-48, applicable to EFSA.

Reply letter of Arysta to the EFSA consultation launched in the context of the public access request with our reference PAD 2016/023, dated 14 April 2016

Please find enclosed a version of this letter in which the personal data and information that might undermine the privacy of persons identifiable in the correspondence (names, e-mail addresses, signatures, and phone numbers) already has been masked in the way EFSA intends to disclose it to the requester for public access. We would appreciate to receive your reply with the following information regarding the enclosed document:

- an indication of any parts of the correspondence which in your view should not be released as a disclosure would undermine your commercial interests or another interest of Article 4 of the PAD Regulation;
- the reason(s) why these parts should in your view not be released, substantiating the grounds for protecting the information.

Please note that the PAD Regulation provides that, should only a part of the documents for which public access is requested fall into an exception to disclosure, the remaining parts shall be released.

To enable EFSA to reply to the request for public access within the time period laid down in the PAD Regulation, we would appreciate to receive your reply **by 27 May 2016** at latest. If we have not received a reply by this date and/or in case of an insufficiently substantiated negative answer, EFSA will decide on the access request in accordance with the PAD Regulation.

Yours sincerely,

[redacted]

Enclosure: 1

[redacted]

From: [redacted] on behalf of EFSA.public.access.to.documents
Sent: 21 June 2016 12:05
To: [redacted]
Subject: FW: PAD 2016/023_Third consultation_Arysta Lifesciences SAS
Attachments: EFSA Ref.15663822_PAD 2016 023_Third consultation of Arysta LifeScience.pdf

From: [redacted]@arysta.com]
Sent: 25 May 2016 20:38
To: EFSA.public.access.to.documents
Cc: [redacted]
Subject: RE: PAD 2016/023_Third consultation_Arysta Lifesciences SAS

Dear [redacted],

In answer to the question whether or not Arysta intends to publish the study [redacted] (1997) *"18-Month Oral Oncogenicity Study in Mice"*, could you please be informed that the GTF responded to the request from the Commission concerning the potential publication of carcinogenicity studies with an offer to present all 14 carcinogenicity studies in a reading room, with certain conditions on the management of the reading room. The GTF proposed that the full study reports should be made available, with the information considered confidential in accordance with article 63 of Regulation 1107/2009 and any personal data which are subject to the EU data protection rules being removed.
We believe that EFSA may be already aware of the communications on this topic between the GTF and the Commission.

Being aligned with this position, regarding specifically the Arysta study, we will only consent to the release of our study as part of the full set of studies in the reading room. In addition, we would like to highlight the fact that our study was already part of a peer reviewed publication:
Greim H, Saltmiras D, Mostert V, Strupp C. Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies.
Crit Rev Toxicol. 2015 Mar;45(3):185-208. doi: 10.3109/10408444.2014.1003423. Epub 2015 Feb 26.

Should you have any further comment, please let us know.

Best regards

Arysta

[redacted]
Active substance Registration manager / Herbicide – Europe
[redacted]

De : [redacted]@efsa.europa.eu] **De la part de** EFSA.public.access.to.documents
Envoyé : mercredi 4 mai 2016 11:49
À : [redacted]@arysta.com>

efsa
European Food Safety Authority

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

04 APR 2016

Ref. [redacted]/mm (2016) - out- 15663822

[redacted]
Active substance registration manager
Arysta LifeScience
Route d'Artix
64150 Noguères
France

e-mail: [redacted]

Re: Your letter of 14 April 2016 related to the access to documents request on glyphosate concerning your mouse study

Ref.: PAD 2016/023

Dear [redacted]

Thank you for your letter of 14 April 2016 in which you outlined your concerns with respect to the request in question and you submit a request to certain documents held by the European Food Safety Authority (EFSA). I am writing to you to seek additional clarifications on some aspects of the confidentiality claims you put forward in your letter with respect to a mouse study you submitted to EFSA for the renewal assessment of the active substance glyphosate (hereinafter "your study") with reference:
[redacted] (1997)
HR-001: 18-Month Oral Oncogenicity Study in Mice
IET 940151 ALS
GLP: Y, published: N
2309415 / ASB2012-11493

First of all, in reply to your request in this sense, I am pleased to inform you that EFSA hereby grants you access to the following documents, enclosed to this letter:

- The first request for access to document from the NGO Corporate Europe (CEO) of 10 December 2015,
- EFSA's first reply following our consultation with you, of 5 February 2016,
- The CEO confirmatory application of 12 February 2016,
- The clarification e-mail to the confirmatory application, narrowing down the request to three mouse studies, sent on 17 February 2016.

In relation to the concerns outlined in your letter, EFSA seeks clarifications to take a substantiated decision in reply to the pending confirmatory application under Regulation (EC) No 1049/2001[1] (hereinafter the "PAD Regulation"). We kindly ask you to reply to the below questions linked to your claims:

[1] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43-48, applicable to EFSA.

1) EFSA's peer-review of the active substance glyphosate was finalised on 30 October 2015 and the Conclusion published on 12 November 2015[2]. As regards the on-going decision of the EC and Member States, we would like to receive substantiation why the release of this study would "*seriously*" affect it[3].
2) As regards the information indicated in Article 63(2)(g) of Regulation (EC) No 1107/2009[4] which "*shall normally be deemed to undermine the protection of the commercial interests or of privacy and integrity of individuals*" concerned, please clarify if there is an interest of these laboratories laid down in Article 4 of the PAD Regulation that is likely to be affected by the disclosure.
3) EFSA would need to know if according to your view the study could be released deprived from the commercial sensitive information as listed in Article 63(2). If this would not be the case, please indicate why the rest of the study is also covered by Article 63(2) of Regulation (EC) No 1107/2009. For this purpose, we would be grateful if you could detail the following:
   - The identification of elements to be kept confidential within the scope of Art. 63(2), line by line in the PDF version of your study;
   - The verifiable justification of each claim and evidence that if this information is disclosed that Arysta's commercial interest will be undermined.
4) Please clarify the extent of the professional secrecy in the information contained in the study requested.
5) As regards data protection please specify which information in the study at hand is exclusive data owned by Arysta and for which protection in terms of reuse or exploitation of the data can be still claimed as provided in Art. 59(1), last paragraph, of Regulation (EC) No 1107/2009. In this regard, please also specify your viewpoint how the sharing of the study for reassessment purposes, public scrutiny or academic use affects the protection of proprietary data under Article 59 of Regulation (EC) No 1107/2009.

Finally we would like to know if Arysta intends to publish the study in question, and if so when.

To enable EFSA to reply to the request for public access within the time period laid down in the PAD Regulation, we would like to receive your reply by **13 May 2016** at the latest.

If we have not received a reply by this date and/or in case of an insufficiently substantiated answer, EFSA will decide on the access request in accordance with the PAD Regulation and Regulation (EC) No 1107/2009.

Yours sincerely,

[redacted]

Cc: [redacted] (EFSA)

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[2] European Food Safety Authority, 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302 pp. 107 doi:10.2903/j.efsa.2015.4302, available at: http://www.efsa.europa.eu/en/efsajournal/pub/4302.

[3] In addition, please allow me to clarify that the EFSA's Management Board decision you mentioned in your first letter is not any longer in force. The valid decision was adopted on 16 September 2003, please see EFSA's Management Board Decision concerning Access to documents, of 16 September 2003, available at: http://www.efsa.europa.eu/sites/default/files/assets/docsaccess.pdf.

[4] 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, OJ L 309, 24.11.2009, p. 1–50, as last amended.

Arysta LifeScience

[redacted]
Head of Legal & Regulatory Affairs
European Food Safety Authority (EFSA)
Via Carlo Magno 1/A
43126 Parma
Italy

[redacted]
Arysta LifeScience
Active substance registration manager
[redacted]

By Email
[redacted]efsa.europa.eu
EFSA.public.access.to.documents@efsa.europa.eu

Without Prejudice

Noguères, 14 April 2016

Dear [redacted]

Re: Access to documents on glyphosate - Consultation under Article 4(4) Reg. 1049/2001 - Confirmatory Application for Public Access under Article 7(2) (ref: PAD 2016/023 CA)

We refer to your letter of 23 March 2016 concerning a confirmatory application by an unidentified third party (the "Confirmatory Application") following a request for access to the study [redacted](1997) *"18-Month Oral Oncogenicity Study in Mice"* (the "Study"), submitted by Arysta LifeScience, in the context of the renewal of glyphosate under Regulation 1107/2009 and Regulation 844/2012 ("AIR2").

Arysta LifeScience was not provided with a copy of that request, so it is not possible for us to assess its legal basis properly. It would seem from your letter that such request would be based on Regulation (EC) n. 1049/2001 concerning public access to documents held by EU Institutions ('PAD Regulation')[1]. We further understand that you have consulted Arysta LifeScience on the basis of Article 4(4) of the PAD Regulation.

As further explained below, we consider that the applicant's request must be rejected because the study at hand is still being assessed by the evaluators and remains subject to ongoing inter-institution decision-making process. Therefore, we consider that the request should be rejected based on the so-called 'decision-making' exception set out in Article 4(3) of the PAD Regulation, which protects the integrity of the decision-making process of the institution of the European Union ('EU').

[1] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents

Moreover, disclosure of the study would undermine Arysta LifeScience's commercial interests and intellectual property rights in the study including the know-how and methodology used for conducting the study. Therefore, we consider that the request should be rejected also on grounds of the protection of commercial interests / intellectual property rights pursuant to Article 4(2) of the PAD Regulation.

Lastly, we consider that the study contains a series of confidential information concerning the persons and laboratories involved in the test. Disclosure would harm the integrity of those persons and entities and therefore must be refused also on that basis.

Each of these grounds is further developed herein below, in turn.

i) **Exception under Article 4(3) of the PAD Regulation : disclosure would adversely affect the 'decision-making' process**

By way of background, access to documents held by Institutions is not an absolute right but is subject to some conditions and exceptions, like for instance the 'decision-making' exception.

In particular, under **Article 4(3) of the PAD Regulation** the *"[a]ccess to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not yet been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure"*. In accordance with the settled EU case-law, the impact on the decision-making process must be assessed on a case-by-case basis, depending on all of the specific circumstances in each specific case.

The scope of Article 4(3) has been clarified in the **EFSA's Management Board decision concerning access to documents.**[2] Specifically, pursuant to Article 2.1.e) thereof *"[t]he Authority shall refuse access to certain documents in application of [...] Article 4 of Regulation (EC) No 1049/2001 [...], and in particular where the disclosure would undermine [...] the Authority's decision-making process, internal or preliminary consultations and deliberations, with a view to safeguard the freedom of the scientific debate and guarantee the independence vis-à-vis external influence."* The study in question is part of an ongoing assessment conducted by EFSA in view of presenting an opinion to the Commission which will, in turn, make proposals for the adoption of regulatory measures that will affect the outcome of the administrative initiated by Arysta LifeScience in its capacity as notifier of glyphosate under the AIR2 programme. As such, the EFSA evaluation constitutes an intermediary and preparatory step for further actions taken at EU level. In this respect, preparatory documents held by the Agency (i.e., working documents, internal notes, documents used for preparing opinions and other documents related to preliminary consultations within the Authority) are overall excluded from disclosure.

The EFSA's Management Board decision explicitly provides for the **possibility to disclose preparatory documents only** in specific and well identified cases where Union legislation requires open consultation on a draft opinion or report and/or where specifically agreed by the Executive Director of the Authority in consultation with the Scientific Committee or a Scientific Panel, which is not the case. Nor is there a risk for public health since glyphosate is currently approved under Regulation 1107/2009 and the renewal process is still ongoing. Indeed, the study on glyphosate, subject to the applicant's

[2] Revision of the decision concerning access to documents, 20 October 2011, MB 20 10 11, item 11 doc 9; adopted pursuant to Article 41 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

access request, has been compiled and submitted to EFSA within the context of the renewal assessment of this active substance. Hence, at this stage, the study in question is clearly still part of the internal inter-institution's decision-making process. Its premature disclosure to third parties would certainly impact the scientific debate and the Agency's independence vis-à-vis external influence.

Regulation 1107/2009 which operates as *lex specialist* in relation to EFSA's process and timeframe for disclosure of documents, provides that certain information may be disclosed by EFSA at a certain stage of the process, i.e., once the evaluation is completed. Only at that time will all aspects of the evaluation be made final, and in turn, the final EFSA Conclusions may be disclosed. Allowing disclosure of sensitive reports earlier in the process would defeat the purpose of those provisions.

Moreover, as we understand it, no specific argument was provided by the applicants in relation to a public interest on the basis of which the 'decision-making' exception set out in Article 4(3) of Regulation 1049/2001 would have to be overridden. In any event, as already noted, the assessment is still ongoing and its outcome will be made public in due course, so there is no reason for disclosing prematurely parts of that assessment and/or studies underlying it. On the contrary, disclosure at this stage of the process would seriously undermine the decision-making process concerning the renewal of glyphosate.

In particular, disclosure of the study will have a substantial impact on the decision-making process inasmuch as it is part of a particularly intense debate concerning glyphosate where NGOs have expressed clear positions against that substance. The circumstances of the case are such that the applicant's will no doubt use the study to interfere with the evaluation at hand thereby adversely affecting the decision-making process (judgment in *Muñiz v Commission*, paragraph 75).

Access to documents submitted by the notifying parties to the Commission and EFSA during the renewal process would jeopardize the inter parties nature of that process, which the EU legislature sought to ensure in the context of the administrative review of plant protection products involving the obligation on the undertakings concerned to supply evaluators with complex and sensitive information to enable the assessment of their product. If persons other than those involved in that process were able to obtain access to those documents during the evaluation on the basis of Regulation No 1049/2001, the system introduced by that legislation would be undermined.

ii) **Article 4(2) of the PAD Regulation – disclosure would adversely affect the commercial interests of Arysta LifeScience, including its intellectual property**

Pursuant to Article 4(2) of the PAD Regulation, access to documents can be refused when disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property.

The study submitted by Arysta LifeScience is protected by intellectual property rights inasmuch as, on the one hand, it contains information and know-how about the way in which the study was conducted, and on the other hand, it is eligible for data protection under Article 59 of Regulation 1107/2009 once it is used by the Commission to derive a relevant end point. This means that the study is commercially valuable for the owner as it is eligible for protection and related compensation fees.

If that study was simply disclosed to the public, third parties could benefit from the information contained therein to prepare their own dossier submissions ahead of time and without following the normal data compensation process. This would adversely affect Arysta LifeScience's commercial interests, including

Arysta LifeScience

intellectual property rights, while rendering the investments made in the development of the study worthless. On that basis, the study as well as all summaries, assessments and other documents included in the study may not be disclosed, as this could jeopardize the protection of the owner's intellectual property rights.

Moreover, as mentioned, the methodology followed by the persons involved in the study is part of the owner's know-how and experience in the way it has prepared its submissions under the renewal process set out by AIR2. Such information and know-how if disclosed would give competitive advantage to third parties. For this reason, EU Courts have established that information involving commercially sensitive information and covered by professional secrecy is given wide protection under general principles of EU law and the fundamental right to the protection of business secrets enshrined in Article 339 TFEU, Article 7 of the Charter of Fundamental Rights of the European Union and Article 8 of the European Convention for the protection of Human Rights and Fundamental Freedoms.[3]

Confidentiality of the data at hand is also designed to protect a legitimate economic interest: specifically, the data represents a substantial investment in time and money for Arysta LifeScience and the findings form part of the core data package and knowledge of the product.

Arysta LifeScience must be able to protect the studies commissioned on its chemicals as part of its company assets. If studies were routinely disclosed to the public Arysta LifeScience and other companies engaged in research activities would no longer conduct research thereby jeopardizing their business as well as the overall system for the scientific review of plant protection products in the EU.

Moreover, disclosure in the EU would allow third parties, including competitors, to have access to valuable information contained in complex and expensive scientific studies in order to seek authorisation of competing products within and outside the EU, thereby undermining Arysta LifeScience's investments and intellectual property rights.

All EU Institutions are required to balance on the one hand the contribution which the information makes to the protection of public interest, notably disclosure for public health reasons, and on the other hand the degree of damage to commercial secrecy resulting from the disclosure of that information (see the Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04). In such an instance, the disclosure of confidential information should not be disproportionate having regard to the seriousness of the commercial damage which the disclosure may cause.

Therefore, it is clear that Article 4(2) of Regulation 1049/2001 is applicable in the current case since the scientific information contained in the study would harm the "commercial interests" of Arysta LifeScience while upsetting the balance between secrecy in ongoing proceedings and the obligation for the parties concerned to submit sensitive information to the evaluators. Consequently, the request for access to documents should be rejected on grounds of Article 4(2) of the PAD Regulation.

In this respect, the applicant has not explained what would be the "overriding" interest favouring disclosure as required by Regulation 1049/2001. This is all the more important as the study at hand is not per se "environmental information" since it relates to effects on mice falling under the toxicology section of the assessment as opposed to environmental fate. According to the case-law general considerations alone cannot provide an appropriate basis for establishing that the principle of transparency is of particularly pressing concern, and that, on the contrary it is the task of the party requesting information to make specific reference to circumstances showing that there is an overriding

[3] Case T-462/12 *Pilkington Group v Commission*, cited above, paragraph 45.

public interest to justify the disclosure of the documents concerned (see, to that effect, judgment in *LPN and Finland v Commission*, cited in paragraph 145 above, paragraphs 93 and 94 and the case-law cited). In the case at hand, no such argumentation was made. And in any event, the balancing of the interests at hand would be against disclosure.

In this respect, we draw your attention to two rulings issued by the President of the EU Court concerning the release of EFSA Conclusions (and by implication, studies used in support of such conclusions). In particular, the President of the EU Court considered that the release of an EFSA Conclusion containing commercially sensitive information (the nature of which was being disputed by EFSA) should not be disclosed as this could harm the notifier's commercial interests (see Case T-578/13 R, Luxembourg Industries v European Commission, and Case T-725/15R, Chemtura Netherlands BV v EFSA).

The present situation is comparable to the situation of those two cases as the applicant had sought the suspension of the EFSA Conclusion in similar circumstances as those applicable to the present case.

The present case is also comparable to certain parts of a case brought against another EU body, the European Chemicals Agency (ECHA) (Case T-245/11, ClientEarth and International Chemical Secretariat v ECHA). While the legal framework in that case is partly different, the reasoning regarding the need to balance the protection of commercial interests is similar. In that case, ClientEarth made a request to ECHA to disclose manufacturers and importers name and precise tonnage bands of 356 substances (including information related to substances allegedly carcinogenic and toxic to reproduction). ECHA refused to grant access to the information on various grounds, including that disclosure of that information was deemed to undermine the protection of commercial interest under Article 118 of the REACH regulation. The Court ruled in favour of ECHA on this point. When weighing the competing interests, the Court did not find any overriding public interest justifying the disclosure, and thus no breach of Art. 4(4) of the Aarhus Convention, such that ECHA correctly applied the "commercial interest" exception.

Analogously in the present case, access to Arysta LifeScience's study on glyphosate should be denied on grounds that it would harm Arysta LifeScience's commercial interests in the proper functioning of the ongoing renewal process as well as protection of its know-how and commercial secrets, in the absence of proved overriding interests in disclosure. Under such circumstances, the balance of the interests at stake leans towards the refusal of access to the reporting tables on glyphosate.

iii) **Exception of Article 65(3) of Regulation 1107/2009: disclosure would adversely affect the confidentiality of the identity of persons involved in animal testing**

Article 63(2) of Regulation 1107/2009 contains a non-exhaustive list of types of information that would normally be deemed to be confidential which includes, amongst others, names and addresses of persons involved in testing on vertebrate animals.

This is supported by the Commission's General guidance on information that may be removed.[4] This reflects a common understanding such that certain data on the content of the active substance, in

[4] General guidance on information that may be removed (blackened) from rapporteur Member State assessment reports before provision to third parties, rev 1-5 of August 2011.

particular as regards impurities, and physico-chemical data concerning the active substance attract confidential treatment.[5]

Accordingly, those particulars must be in any event removed from the studies as they would otherwise endanger the integrity of the concerned individuals.

*** *** ***

We look forward to hearing from you and meanwhile remain available should you have questions.

Yours sincerely,

[redacted]

EU Active substance manager

[5] See for example Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04 *ABNA Ltd and Others v Secretary of State for Health and Others* [2005] ECR I-10423, paragraph 82.

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European Food Safety Authority

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

23 MAR 2016

Ref. [redacted] (2016) - out-15489558

[redacted]
Arysta Lifesciences SAS
Route d' Artix, BP 80
64150 Nogueres
France

e-mail: [redacted]

Subject: **Consultation - Confirmatory application for public access to the study you submitted to EFSA for the renewal assessment of the active substance glyphosate in the framework of Regulation (EC) N° 1107/2009 and it's implementing Regulation (EU) N° 844/2012**

Ref.: PAD 2016/023 CA

Dear [redacted]

I am contacting you following our previous letter dated 22 January 2016, by means of which we consulted you on the accessibility of a mouse study you submitted to EFSA for the renewal assessment of the active substance glyphosate[1] with reference:

[redacted] (1997)
HR-001: 18-Month Oral Oncogenicity Study in Mice
IET 940151 ALS
GLP: Y, published: N
2309415 / ASB2012-11493

I would like to inform you that the public access requestor has submitted a confirmatory application in accordance with Article 7(2) of the Regulation (EC) No 1049/2001[2] (hereinafter "PAD Regulation").

In this regard we would like to confirm that EFSA is subject to obligations in terms of transparency and public access to documents deriving from both the Treaty on the Functioning of the European Union (TFEU), Article 15 and EFSA's Founding Regulation (EC) No 178/2002, Articles 38 and 41(1)[3].

Pursuant to Article 4(4) of the PAD Regulation, EFSA is hence contacting you for a further consultation on the possibilities of public disclosure of the above-mentioned study and specifically to ascertain whether any of the exceptions to disclosure of this document provided in Article 4 of the PAD Regulation may apply. We would appreciate to receive your reply with the following information:

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1 European Food Safety Authority, 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302 pp. 107 doi:10.2903/j.efsa.2015.4302, available at: http://www.efsa.europa.eu/en/efsajournal/pub/4302

2 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43-48, applicable to EFSA.

3 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1-24, as last amended.

- an indication of any parts of the study which in your view should not be released as a disclosure would undermine intellectual property or another interest of Article 4 of the PAD Regulation;
- the reason(s) why these parts should in your view not be released, substantiating the grounds for protecting the information.

Please note that the PAD Regulation provides that, should only a part of the documents for which public access is requested fall into an exception to disclosure, the remaining parts shall be released.

To enable EFSA to reply to the request for public access within the time period laid down in the PAD Regulation, we would like to receive your reply **by 4 April 2016** at the latest. If we have not received a reply by this date and/or in case of an insufficiently substantiated negative answer, EFSA will decide on the access request in accordance with the PAD Regulation.

We would be grateful if you could inform us timely on your point of view, by replying to this e-mail.

You can reply by writing to:
EFSA Public Access Team
EFSA.public.access.to.documents@efsa.europa.eu

Yours sincerely,

[redacted]

Cc: [redacted] (EFSA)

efsa
European Food Safety Authority

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

22 JAN 2016

Ref. [redacted]nm (2016) - out-15184596

[redacted]
Arysta Lifesciences SAS
Route d'Artix, BP 80
64150 Nogueres
France

e-mail:
[redacted]

Subject: **Consultation on an access to documents request related to the study you submitted to EFSA for the renewal assessment of the active substance glyphosate in the framework of Regulation (EC) N° 1107/2009 and it's implementing Regulation (EU) N° 844/2012**

Ref.: PAD 2015/143

Dear [redacted]

According to Article 41(1) of Regulation (EC) No 178/2002[1] access of citizens to the documents held by EFSA is governed by Regulation (EC) No 1049/2001[2]. The Regulation applies to all documents held by EFSA, *i.e.* documents which it has produced or received, in all areas of its activity (hereinafter the "PAD Regulation").

EFSA has received a request by a non-government organisation for public access to documents. The public access request concerns the study you submitted to the EFSA for the renewal assessment of the active substance glyphosate[3] in the framework of Regulation (EC) No 1107/2009[4] and it's implementing Regulation (EU) No 844/2012[5].

Pursuant to Article 4(4) of the PAD Regulation, EFSA is hereby consulting you on the disclosure of the study with the following reference:

[redacted] (1997)
HR-001: 18-Month Oral Oncogenicity Study in Mice
IET 940151 ALS
GLP: Y, published: N
2309415 / ASB2012-11493

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1 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1-24, as last amended.

2 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43-48, applicable to EFSA. http://www.europarl.europa.eu/RegData/PDF/r1049_en.pdf.

3 European Food Safety Authority, 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302 pp. 107 doi:10.2903/j.efsa.2015.4302, available at: http://www.efsa.europa.eu/en/efsajournal/pub/4302

4 Regulation (EC) No 844/2012 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market, OJ L 309, 24.11.2009, p. 1-50.

5 Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, OJ L 252, 19.9.2012, p. 26-32.

EFSA would like to consult with you, to ascertain whether any exception to disclosure in the sense of Article 4 of the PAD Regulation may apply. We would appreciate to receive your reply with the following information regarding the study:

- an indication of any parts of the study which in your view should not be released as a disclosure would undermine intellectual property or another interest of Article 4 of the PAD Regulation;
- the reason(s) why these parts should in your view not be released, substantiating the grounds for protecting the information.

Please note that the PAD Regulation provides that, should only a part of the documents for which public access is requested fall into an exception to disclosure, the remaining parts shall be released.

To enable EFSA to reply to the request for public access within the time period laid down in the PAD Regulation, we would like to receive your reply **by 28 January 2016** at the latest. If we have not received a reply by this date and/or in case of an insufficiently substantiated negative answer, EFSA will decide on the access request in accordance with the PAD Regulation.

We would be grateful if you could inform us timely on your point of view, by replying to this e-mail.

You can reply by writing to:
EFSA Public Access Team
[redacted]

Yours sincerely

[redacted]

Cc: [redacted] (EFSA)