



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

Brussels, 4th February 2016

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,

A large rectangular area of the document has been redacted with a solid grey box, obscuring the signature and any text that might have been present below the signature line.

EMEA Crop Protection Regulatory Affairs Lead

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 178/2002¹ access of citizens to the documents held by EFSA is governed by Regulation (EC) No 1049/2001². 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 glyphosate³ in the framework of Regulation (EC) No 1107/2009⁴ and it's implementing Regulation (EU) No 844/2012⁵.

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

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 settling 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

Yours sincerely,

[Redacted signature]

Cc: [Redacted] (EFSA)

Mr [REDACTED]

European Food Safety Authority

By e-mail only

EFSA.public.access.to.documents@efsa.europa.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)

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.

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



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



Regulatory Affairs Manager

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 178/2002¹ access of citizens to the documents held by EFSA is governed by Regulation (EC) No 1049/2001². 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 glyphosate³ in the framework of Regulation (EC) No 1107/2009⁴ and it's implementing Regulation (EU) No 844/2012⁵.

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)

Study No.: 438623; Report No.: 7867

Date: 1993-04-07

GLP:

not published, TOX9750499

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.europa.europa.eu/RegData/DFR/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/cfsajournal/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 address]

Yours sincerely,

[Redacted signature]

Cc: [Redacted] (EFSA)

[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

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>

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 1049/2001¹ (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 2015². 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 it³.
- 2) As regards the information indicated in Article 63(2)(g) of Regulation (EC) No 1107/2009⁴ 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,



Cc: [Redacted] (EFSA)

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/docs/access.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.

[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.

1) 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 AIRE2 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 *Murfiz 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 partes 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

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 A/R2. 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 *Pitkington 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 compelling 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,



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.

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 its 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 glyphosate¹ 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 1049/2001² (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:

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/1302>

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,



Cc:  (EFSA)

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

Ref. [REDACTED] nm (2016) - out-15184596 22 JAN 2016

[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 178/2002¹ access of citizens to the documents held by EFSA is governed by Regulation (EC) No 1049/2001². 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 glyphosate³ in the framework of Regulation (EC) No 1107/2009⁴ and it's implementing Regulation (EU) No 844/2012⁵.

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

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)

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

By Email

Our Ref: MHE/MHE/60060-00003/53308287 v1

Without Prejudice

Brussels, 13 May 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 4 April 2016 which ADAMA received via e-mail on 4 May 2016 concerning a confirmatory application by the NGO Corporate Europe (CEO) (the "Confirmatory Application") following a request for access to the study [REDACTED] (2001) "Carcinogenicity Study with Glyphosate Technical conducted in Swiss Albino Mice" (the "Study"), submitted by our client, Adama, in the context of the renewal of glyphosate under Regulation 1107/2009 and Regulation 844/2012 ("AIR2").

You will find below our answers to the questions you raise. However, ADAMA would like to highlight that the Study is already part of a peer reviewed publication available online: 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.

First question: EFSA's peer-review of the active substance glyphosate was finalised on 30 October 2015 and the Conclusion published on 12 November 2015. 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.

In this regard, the disclosure of the Study will seriously affect the ongoing decision process related to glyphosate for the following reasons:

At this stage, glyphosate is still part of the internal inter-institution's decision-making process. It is consequently premature to disclose the Study as the substance is still subject to the comitology process with a vote expected on May 18-19. Assuming that glyphosate will be renewed as an active substance, products containing glyphosate will then undergo the next regulatory steps at Member State level. As indicated in our previous letter, there have been concerted campaigns of several NGOs and politicians calling for a ban of the substance. Additionally many articles and other publications, which are not based on scientific evidence and are plainly misleading and non-factual, have been published. This has seriously harmed the reputation of the substance and the products containing it and has putten undue political pressure on the ongoing regulatory process as evidenced by various leaked Commission documents. Releasing the Study to NGOs such as CEO, which to our knowledge is not a scientific authority equipped to properly evaluate a study of this nature, will further impact on the scientific debate and the independence of the institutions vis-à-vis external influence on the decision-making process.

This Study is part of a data package of 14 carcinogenicity studies evaluated by the BfR, Member State experts and the EFSA, which based on a weight of evidence approach, have concluded that glyphosate is unlikely to pose a carcinogenic risk when used appropriately. In the context of the sensationalised debate surrounding this molecule, the disclosure of a single Study to an NGO or to the public without safeguards to prevent misuse and/or misinterpretation means that there is a strong likelihood that the Study will be exploited individually and out of context by non-scientific bodies, which will further undermine the decision making process, lead to unbalanced and potentially biased views and conclusions and, in the process, stigmatise our client and its products.

Second question: As regards your argument related to the reputational damage of your company, EFSA would like you to clarify the direct causal link between the alleged damage and the release of the study concerned.

As stated above, NGOs and certain political parties are already creating excessive political pressure on what should be a science based regulatory process, as well as on regulatory authorities involved in the assessment of glyphosate. In our previous correspondence, we have listed some examples of non-factual and misleading media reports, a list that could be expanded on a daily basis. Such reports have created significant uncertainties for consumers, for example the completely incorrect claim that due to glyphosate, breast milk is no longer safe for infants or equally incorrect claims that industry has falsified studies in order to support the renewal of glyphosate. It goes without saying that Adama's reputation as an owner of 3 out of 14 studies being sought will be adversely impacted if the Study is released and exploited in the manner which is expected, i.e. to highlight carcinogenicity indications of these 3 studies v. the weight of the other evidence.

Further, the disclosure will undermine the protection of commercial interests of Adama, including its intellectual property.

As mentioned in our previous letters, the Study submitted by Adama is protected by intellectual property rights. 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 Adama's commercial interests, including intellectual property rights, while rendering the investments made in the development of the Study worthless.

In other words, Adama 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, Adama 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.

Third question: As regards the information indicated in Article 63(2)(g) of Regulation (EC) No 1107/2009 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.

The Study contains information such as the names and addresses of persons involved in testing on vertebrate animals. This data is covered by Article 63(2) of Regulation 1107/2009 which establishes a non-exhaustive list of types of information that is deemed to be confidential. In this respect, please note that the disclosure of a vertebrate animal Study would expose Adama and its personnel, as well as all those involved in the Study, to retaliation measures from third parties that are adverse to animal testing. The Study contains all details about the laboratory, individuals and sponsors of the Study, who will face such measures as shown by past experience involving animal protection activists.

Therefore, laboratories would be subject to the same mobbing tactics as other services retained by the Glyphosate Task Force which would certainly have an adverse business impact on them. We refer in this respect to the recent attack of CEO on Genius which is the communication company hired by the GTF to build and maintain the Glyphosate Information Portal (www.glyphosate.eu) Please see in this respect the article published on the following website: <http://corporateeurope.org/food-and-agriculture/2016/05/lobby-firm-works-both-sides-room>.

Fourth question: 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 veritable justification of each claim and evidence that if this information is disclosed that ADAMA's commercial interest will be undermined.*

The release of the Study for which access is sought would clearly provide the requestor and competitors with confidential information on the origin of the technical source of Glyphosate (links between a producer or importer and the applicant or the authorisation held), on how to conduct this study and on company's know-how and other sensitive business information in general. Granting access to said documents would also reveal information concerning Adama's strategy for renewal and related submission sent over to authorities in the context of ex parte proceedings.

In this respect, please note that the links between the producer and the applicant and/or the authorisation holder as well as the names and addresses of persons involved in testing on vertebrate animals constitute information which is protected under Article 63 and whose disclosure would undermine the protection of commercial interests, or the privacy and integrity of the individuals concerned.

Disclosure of links between the producer and applicant/authorisation holder are matters of commercial confidence since they relate to organisational and strategic decisions including those of procurement of the applicant. Disclosure of such links offers competitors inside information which can be used to remove competitive advantages gained via a strategic sourcing, procurement and regulatory strategy. Therefore, disclosing any part of the Study would undermine that confidentiality and defeat the purpose of Article 63 of Regulation 1107/2009 as it will harm the right of Adama to the protection of its business secrets.

Finally, as regards the names and addresses of individuals please see response to Question 3.

Fifth question: Please clarify the extent of the professional secrecy in the information contained in the study requested.

The release of raw data to the public would deprive Adama of a full return on costs and investment made in the Study. Releasing the Study including details of protocols to the public would allow competitors to copy its results and/or use them for the purpose of obtaining authorisations of competing products in the EU and outside the EU. Moreover, this would deprive Adama of its entitlement to data compensation from third parties wishing to rely on the Study for commercial purposes.

In addition, disclosure of the full scientific report to a third party having declared its intention to criticize the Study and attack the continued approval of Glyphosate in the EU would threaten Adama's Glyphosate business and commercial interests as a whole.

Sixth question: As regards data protection please specify which information in the study at hand is exclusive data owned by ADAMA and for which protection in terms of reuse or exploitation of the data can still be 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.

The Study is fully owned by ADAMA and could be used by competitors in dossiers to gain registrations outside the EU, especially in view of the significant costs for a carcinogenicity Study.

Giving access to the Study would seriously undermine the execution by Adama of its data protection rights which are granted to it by Article 59 of Regulation 1107/2009. Article 59 grants Adama an exclusive use right on its data that has been used within the framework of the renewal of glyphosate. Such data protection is essential for the purpose of allowing an entity such as Adama to recoup the significant investments made. It is obvious that this legal right, granted in Regulation 1107/2009, will be frustrated if Adama's proprietary information is given away for free on the market. To render nugatory such data protection would run contrary to the objectives of Regulation 1107/2009 and would constitute a serious

incursion upon our client's property rights which are protected under the EU Charter of Fundamental Rights.

*** **

In the light of the foregoing, we hereby formally oppose disclosure of the Study. We also confirm that Adama has no intention to publish the Study at this stage.

Without prejudice to the above arguments, should EFSA still consider granting access to the documents to CEO, Adama insists that its Study be made available only as part of the proposal made by the GTF in response 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. We believe that EFSA is already aware of the communications on this topic between the GTF and the Commission.

We also take this opportunity to remind you that the correct company name for our client is *Adama Deutschland GmbH* instead of *Adama Deutschland GmbH Northern*. May we kindly ask you to amend your records accordingly? We thank you on beforehand.

*** **

We remain of course at your disposal should you have any further questions.

Yours sincerely,



Joint Managing Partner

04 APR 2016

Ref. [REDACTED] mm (2016) - out-15665409

[REDACTED]
Joint Managing Partner
[REDACTED]

e-mail: [REDACTED]

On behalf of:

[REDACTED]
ADAMA Deutschland GmbH Northern
Edmund-Rumpler-Strasse 6
D-51149 Köln
Germany

e-mail: [REDACTED]

Re: Your letters of 1 April and 28 January 2016 related to the access to documents request on glyphosate concerning your mouse study

Ref.: PAD 2016/023

Dear [REDACTED],

Thank you for your letters of 28 January and 1 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 letters 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] (2001)

Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice

TOXI: 1559.CARCI-M FSG

GLP: Y, published: N 2309396 / ASB2012-11491,

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 letters, EFSA seeks clarifications to take a substantiated decision in reply to the pending confirmatory application under Regulation

(EC) No 1049/2001¹ (hereinafter the "PAD Regulation"). We kindly ask you to reply to the below questions linked to your claims:

- 1) EFSA's peer-review of the active substance glyphosate was finalised on 30 October 2015 and the Conclusion published on 12 November 2015². 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 it³.
- 2) As regards your argument related to the reputational damage of your company, EFSA would like you to clarify the direct causal link between the alleged damage and the release of the study concerned.
- 3) As regards the information indicated in Article 63(2)(g) of Regulation (EC) No 1107/2009⁴ 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.
- 4) 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 ADAMA's commercial interest will be undermined.
- 5) Please clarify the extent of the professional secrecy in the information contained in the study requested.
- 6) As regards data protection please specify which information in the study at hand is exclusive data owned by ADAMA 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 ADAMA 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.

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.

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.

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,



Cc: [REDACTED] (EFSA)

[REDACTED]

From: [REDACTED] [mailto:[REDACTED]@corporateeurope.org]
Sent: 10 December 2015 15:40
To: [REDACTED]
Cc: [REDACTED]
Subject: Re: ADols of scientific experts from national competent authorities

Dear [REDACTED], [REDACTED], [REDACTED]

I hope this email finds you well. Sorry to insist but I haven't received a response to my question on the DOIs of the authors of the glyphosate peer review, probably it slipped through? I was wondering whether it was all experts of the Mammalian toxicology group or whether it was only some of them, and/or other people as well? If so, and if it's not too burdensome, could you send me a complete list of names so that I can download the DOIs?

Also, I wanted to follow up on this question sent to you last 24/11 :

"Given the importance of the five above-mentioned studies, is EFSA considering their publication to enable an informed debate on such an important issue, all the more that, since glyphosate is no longer covered by patent protection and is widely used all over the industry, the usual argument about the need to protect commercially sensitive information is unlikely to apply here?"

This question referred to the 5 mouse studies that [REDACTED] insisted had played such an important role in reaching a different conclusion than IARC in the interpretation of the animal evidence but that IARC could not access in full because they were sponsored by industry and as such deemed to contain commercially sensitive elements.

EFSA's response to this question was the following:

"All versions/updates of the risk assessment report and the addendum regarding the IARC assessment are publicly available on EFSA's website.

This includes detailed information about the assessment and appraisal of all studies considered by EFSA and Member States as part of the peer review process, including studies submitted by industry. The documents, as you will see, run to several thousand pages.

Typically, the amount and type of information made available by EFSA about individual papers/studies is comparable to the amount of information contained within articles published in the open scientific literature (also bearing in mind that the raw data behind studies, including for so-called 'independent studies', is very rarely published in the open scientific literature).

For example, if you follow the link on our website to the documents I mention above, open the file 4302add_public.pdf, and go to page 1012 you will see extensive information and comments from the Rapporteur Member State on each of the long-term studies assessed regarding carcinogenicity.

The information published by EFSA about the studies assessed, including industry studies, is now in the public domain, allowing any organisation or individual to scrutinise the European peer review of glyphosate that was carried out by experts from all 28 MS. We would encourage anyone with an interest in our work to review this information."

The debate in Brussels last week between [REDACTED] from EFSA and [REDACTED]

[redacted] from IARC made clear that the level of information disclosed by EFSA in its published documents was insufficient and that access to these studies' raw data was necessary to enable a meaningful contradictory assessment of these studies between the two institutions.

I would therefore like to ask to have access, in line with EU Regulation 1049/2001 on access to documents, to these studies' full version including raw data.

Kind regards

[redacted]

[redacted]

Corporate Europe Observatory (CEO)

Rue d'Edimbourg 26

1050 Brussels - Belgium

[redacted]@corporateeurope.org

www.corporateeurope.org

phone: [redacted]

twitter: [redacted]

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05 FEB 2016

Ref. [REDACTED] (2016) - out - 15252298

[REDACTED]
Corporate Europe Observatory (CEO)
26, Rue d'Edimbourg
BE-1050 Brussels
Belgium

e-mail: [REDACTED]@corporateeurope.org

Subject: Your application for access to documents of 10 December 2015

Ref.: PAD 2015/143

Dear [REDACTED],

I refer to your e-mail submitted on 10 December 2015 by means of which you requested access to *"the 5 mouse studies' full version including raw data (...) that Mr Tarazona insisted had played such an important role in reaching a different conclusion than IARC in the interpretation of the animal evidence"* (hereinafter the "Studies") in accordance with Regulation (EC) No 1049/2001¹ (hereinafter referred to as the "PAD Regulation"). Having carefully considered your request, we regret to inform you that EFSA is not in the position to release the requested Studies to you.

EFSA interpreted that your request refers to the five long term toxicity and carcinogenicity mice studies that are mentioned in the section "Carcinogenicity" in the background document to the EFSA Conclusion published on 12 October 2016², notably:

- 1) 18-Month Oral Oncogenicity Study in Mice
- 2) Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice
- 3) Glyphosate Technical: Dietary carcinogenicity study in the mouse
- 4) A chronic feeding study of glyphosate (Roundup technical) in mice
- 5) Glyphosate - 104 week combined chronic feeding/oncogenicity study in rats with 52 week interim kill (results after 104 weeks)

EFSA has consulted the five owners of the Studies submitted in the frame of the renewal of the authorisation for the active substance Glyphosate under Regulation (EC) No 1107/2009³ and Commission Regulation (EU) No 1141/2010⁴ as amended by Commission Implementing Regulation (EU) No 380/2013⁵. In particular, in accordance with Article 4(4) of the PAD Regulation, EFSA liaised with the owners with a view to assessing whether these partially or entirely fall within the

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.

² Available at http://www.efsa.europa.eu/sites/default/files/4302_glyp_hosate_complementary.pdf

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

⁴ Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances, OJ L 322, 8.12.2010, p. 10-19.

⁵ Commission Implementing Regulation (EU) No 380/2013 of 25 April 2013 amending Regulation (EU) No 1141/2010 as regards the submission of the supplementary complete dossier to the Authority, the other Member States and the Commission, OJ L 116, 26.4.2013, p. 4.

exceptions to disclosure foreseen in the PAD Regulation. Four of the owners consulted replied to EFSA; one of the consultations is still pending.

The data owners provided justifications to support the refusal of the access request based on the following grounds:

These Studies are covered by the exception foreseen by Article 4(2) first indent of the PAD Regulation, namely the protection of "*commercial interests including intellectual property rights*" and their full protection is also the direct consequence of the qualification as confidential of information contained in the Studies under the terms of Article 63 of Regulation (EC) No 1107/2009.

As highlighted by the owners of the Studies, the Studies requested include protected know-how relating to the scientific and technical expertise in conducting these Studies, disclosure of which will undermine the competitive position of the companies.

These unpublished Studies are owned by the companies and contain property data that if released will jeopardise the exercise of their intellectual property.

These documents include business and data property of the owners and their disclosure will undermine their commercial interests.

Finally disclosure of the Studies would provide access to commercial information, resulting from an investment of the owners both in terms of time and resources, which could be used by potential competitors in particular outside the EU.

Having considered the arguments put forward by the owners of the Studies and after having carefully carried out a concrete examination of the Studies falling in your request, EFSA concludes that the Studies are protected in application of Article 4(2), first indent, of the PAD Regulation, namely the protection of "*commercial interests and intellectual property rights*". Please note that these Studies are also to be protected in application of Article 63 of Regulation (EC) No 1107/2009, as they classify as confidential information.

Moreover, EFSA has specifically undertaken the balance of interests at stake in application of the PAD Regulation, and concluded that no overriding public interest on disclosure applies to this request.

Indeed the public interest of accessing background information relating to the renewal of approval of this active substance, in accordance with Article 38(1)(c) of EFSA's Founding Regulation⁶, is granted by having published the relevant background documentations backing the EFSA's conclusions published at the following link <http://www.efsa.europa.eu/en/press/news/151119a>.

This includes as well the sanitised supplementary summary dossier for the ATR II renewal procedure where detailed descriptions of the toxicological studies are available (MII, section 3, pp 502f).

Therefore, given the fact that the accessibility of the Studies, in particular to competitors, would put at risk the commercial interests and intellectual property rights of the owners of the Studies, their disclosure would be disproportionate to the objective that is necessary to attain. In fact EFSA considers that the information granted to the public at large within this particular renewal process satisfies a good

⁶ 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.

level of transparency that is proportional to the protection of the commercial interests and intellectual property rights of the owners.

It follows that the Studies requested are not disclosed to you in application of the exceptions to disclosure provided for in the PAD Regulation, namely Article 4(2) first indent (protection of *"commercial interests including intellectual property rights"*) as combined with the provisions set out in Article 63 of Regulation (EC) No 1107/2009.

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

Further correspondence must be sent to:

EFSA

via Carlo Magno 1/A

I - 43126 Parma

e-mail: EFSA_public_access_to_documents@efsa.europa.eu

Cc: J.

[REDACTED]

From: [REDACTED] <[REDACTED]@corporateeurope.org>
Sent: 12 February 2016 15:18
To: EFSA.public.access.to.documents
Cc: [REDACTED]
Subject: PAD 2016/023 CA _ Re: PAD 2015/143_Reply_Your request of public access to documents of 10 December 2015

Follow Up Flag: Read
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Dear [REDACTED], dear [REDACTED],

thank you for your response to my access to documents request.

I understand - and expected - that the owners of these studies would not agree to the full disclosure of these documents in the name of the commercial interests exception foreseen in the 1049/2001 Regulation, and I understand and accept that EFSA is bound to respect their preferences in this domain.

However, I do not accept the suggestion that the whole content of the documents would be covered by this exception. Furthermore, I do not accept that the commercial interests at stake would be so sensitive as requiring being redacted: we are talking here about studies performed, for most of them, more than 15 years ago, on a product whose last related patent expired in 2000 and which now being manufactured by several different companies. The fact that the glyphosate renewal dossier was written and submitted by the Glyphosate Task Force, in itself a group including most contemporary manufacturers of glyphosate, is a strong indication that the content of these studies has already been shared among most relevant competitors, which makes the studies' owners' argument that secrecy would be needed to keep a competitive edge much less credible.

As a consequence, I am herewith appealing EFSA's decision to not publish a single word of these studies and urge you to:

- double-check the redacting requirements of the studies' owners;
- send me these studies with the actually commercially sensitive sections redacted.

I understand that the amount of work involved is going to be significant and I am ready to be flexible in terms of deadline; but not in terms of principle. Moreover, the public sensitivity of this particular dossier makes it a good case for testing EFSA's ambitions in terms of data transparency.

With kind regards,

[REDACTED]

Le 05/02/16 18:13, EFSA.public.access.to.documents a écrit :

> Dear [REDACTED],

>

>

>

> Please find attached the reply letter referenced 15252298 from [REDACTED]
[REDACTED] the Legal and Regulatory Affairs Unit of EFSA.

>
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>
> Yours sincerely,
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>
> [REDACTED]
>
> Public Access to document Team
>
> Legal and Regulatory Affairs Unit
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> Via Carlo Magno 1A
>
> I-43126 Parma
> Italy
>
> Tel. [REDACTED] Fax: [REDACTED]
> [REDACTED] [@efsa.europa.eu](mailto:[REDACTED]@efsa.europa.eu)
> [mailto:\[REDACTED\]@efsa.europa.eu](mailto:[REDACTED]@efsa.europa.eu)
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Researcher and Campaigner

Corporate Europe Observatory (CEO)

Rue d'Edimbourg 26

1050 Brussels - Belgium

@corporateeurope.org

www.corporateeurope.org

phone: 

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[REDACTED]

From: [REDACTED] <[REDACTED]@corporateeurope.org>
Sent: 17 February 2016 19:30
To: [REDACTED]
Cc: [REDACTED]; EFSA.public.access.to.documents; [REDACTED]
Subject: PAD 2016/023 CA _ addition to my confirmatory request on access to documents

Follow Up Flag: Read
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Dear [REDACTED],

cc [REDACTED] whom I am meeting tomorrow, [REDACTED]

I would like to add a precision to my confirmatory request on access to documents sent to you last Friday (2016-02-12 15:18). My original request was on five studies, and I would like to narrow my confirmatory request to the following three:

- "Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice" (2001), following OECD Guideline 451 & GLP – study owned by the Israeli pesticides company ADAMA Agan Ltd
- "Glyphosate technical: Dietary Carcinogenicity Study in the Mouse" (2009), following OECD Guideline 451 & GLP – study owned by the Australian pesticides company Nufarm
- "HR-001: 18-Month Oral Oncogenicity Study in Mice" (1997), following following OECD Guideline 451 & GLP – study owned by the Japanese pesticides company Arysta LifeSciences Corporation

You will see from an article I published today

<http://corporateeurope.org/efsa/2016/02/key-evidence-withheld-trade-secret-eus-controversial-risk-assessment-glyphosate>

that I am essentially asking EFSA to send me these studies with all items deemed a trade secrets redacted, in order to allow the scientific debate to progress. I understand this is a substantial work, but at the same time this is also the best opportunity EFSA has to demonstrate its good will in terms of data transparency so... It could also be an opportunity to measure the cost of such an action in the present legal conditions, in itself an important dimension of the debate. I therefore hope that EFSA will do its best to disclose these studies to me.

Kind regards

[REDACTED]

--

[REDACTED]

Corporate Europe Observatory (CEO)

Rue d'Edimbourg 26

1050 Brussels - Belgium

@corporateeurope.org

www.corporateeurope.org

phone: 

twitter: 

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[REDACTED]

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

[REDACTED]

[REDACTED]

[REDACTED]

By Email

[REDACTED]

[REDACTED]

Our Ref: CM1/MHE/60060-00003/53308287 v1

Without Prejudice

Brussels, 1 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] (2001) "*Carcinogenicity Study with Glyphosate Technical conducted in Swiss Albino Mice*" (the "Study"), submitted by our client, Adama, in the context of the renewal of glyphosate under Regulation 1107/2009 and Regulation 844/2012 ("AIR2").

By letter dated 28 January 2016 (copy attached) our client has already responded in full to the initial request for access to the Study, raising a series of objections against disclosure and outlining detailed argumentation why access should be rejected on the basis of (i) Article 4(3) the decision making exception, (ii) Article 4(2) protection of commercial interests and (iii) Article 63 of Regulation 1107/2009 regarding the confidentiality of data on plant protection products. Our client maintains these objections as no counter arguments have been raised thus far.

It is our assumption that EFSA has considered our argumentation and accepted it thus giving rise to this confirmatory application. However, we have not been provided with a copy of the EFSA decision that has resulted in the Confirmatory Application, and neither has the identity of the applicant and its initial request been disclosed as requested by us and therefore it is not possible for us to assess its legal basis properly. Further, we have not been provided with a copy of the Confirmatory Application and therefore are unable to respond to it in full.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



We therefore reiterate our request for access to these documents in order to provide a fully informed response thereto. Meanwhile, we wish to point out to the following reasons justifying a refusal to disclosure.

First, Articles 38 and 41 (1) of (EC) No 178/2002 you are referring to in your letter of 23 March 2016, do not authorize access to the full Study since pursuant to article 39 of Regulation (EC) No 178/2002 *"By way of derogation from Article 38, the Authority shall not divulge to third parties confidential information that it receives for which confidential information has been requested and justified, (...)*. As already stated this Study contained confidential information such as but not limited to the origin of the technical source of glyphosate and how to conduct this study (details of works) and thus constitutes an exception to the application of Articles 38 and 41 1).

Moreover, the public interest of accessing background of information relating to the renewal of the active substance glyphosate has been satisfied by providing to the public the necessary documentations backing the EFSA's conclusions in accordance to article 38.1 (c) of Regulation (EC) No 178/2002.

Second, our client's objections to disclosure as outlined in previous correspondence remain valid as the legal analysis of the argumentation which supports non-disclosure remains unaltered. Therefore our client continues to insist that there are no grounds to release this study in whole or in part.

On the contrary, releasing the study while the decision-making process is still ongoing would not only jeopardise the proper course of that process, but also expose our client to unjustified damage to its reputation as a company engaged in the manufacture and sale of glyphosate-based products.

It is within public knowledge or at least a factual presumption that certain findings on a chemical if placed out of context may create a stigma for that chemical and for the company selling it. The inevitable consequence is, therefore, the exact opposite of a fair process: i.e. that such companies will indeed be viewed as a business seeking to profit from a dangerous substance. One need only view latest developments in the press concerning glyphosate to understand the political climate and how the public perception may be influenced. We refer to a series of examples of popular reaction to the finding that the chemical substance glyphosate is potentially carcinogenic:

- a. Monsanto Weed Killer Glyphosate Herbicide Found In Popular Beer Brands (2/03/2016);
- b. Another 15 years? EU set to relicense glyphosate, deemed 'probably carcinogenic' by the WHO (25/02/2016);
- c. France Says "Glyphosate Could Be Carcinogenic to Humans" (17/02/2016);
- d. Glyphosate persistence raises questions (25/02/2016);
- e. Are Pesticides Causing The Birth Defects In Brazil? (03/02/2016);

Accordingly, our client maintains that the extreme political pressure that this particular generic active ingredient is subject to is undermining the whole basis for the proper and comprehensive scientific review and evaluation of plant protection products which is set out in the regulation and legislation that companies and EU evaluators are required to operate under for the benefit of the public and environment at large.

We therefore repeat our assertion that the applicant's request for access to the study at hand must be rejected because the study is still being assessed by the evaluators and remains subject to ongoing inter-institution decision-making process. Our client maintains that there is no legal basis for a right of criticism or review of scientific accuracy of third parties proprietary studies which were submitted in confidence to authorities. Release of this study prior to the final assessment by the Commission will undermine the decision making process and place a stigma for our client and its products. Therefore, we consider that

the request should be rejected based on the co-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').

Disclosure of this study to an NGO which has declared its intention to criticise and review the study in isolation to the totality of the carcinogenicity studies submitted in the dossier (14 in total) would give a completely unbalanced and potentially biased view and if used as part of a political agenda to undermine the regulatory system underpinning plant protection products and prejudice the reputation of our client and the industry as a whole.

The requirement under Article 10 of Regulation 1107/2009 referred to in Article 8 (1) to make the summary dossier available to the public excluding Article 63 data is sufficient without the need to make raw data available.

We refer again to the case law outlined in the earlier letter and submit that this sets adequate precedent for refusal to disclose.

Third, disclosure of the study would undermine our client'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.

Fourth, 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.

Fifth, we also wish to point out that the study at hand is not information relating to "emissions to the environment" since it was not conducted for determining the impact of the use of glyphosate on the environment. It was rather conducted on mouse in order to derive a relevant end point for human toxicity. Therefore, the exception relating to access to information relating to emissions to the environment is inapplicable to the case at hand, with the consequence that the study must not be disclosed.

Sixth, according to Article 16 of the PAD Regulation, the latter "shall be without prejudice to any existing rules on copyright which may limit a third party's right to reproduce or exploit released documents." In this respect we refer to Art 30 TRIPS covering confidential information and data protection, as well as Directive 2001/29¹ on copyright, as interpreted by the Court of Justice of the European Union (CJEU), which protects any literary work (and a scientific publication qualifies as a literary work) from unauthorised disclosure to and use by third parties

* * *

In the light of the foregoing, and of any other argument which might be added after receiving the details of the applicant and the justification for non-disclosure already provided by EFSA, as well as a copy of the Confirmatory Application, we hereby formally confirm our strong objection to disclosure and, we consider that the request should be rejected based on exceptions set out in Articles 4(1) b., 4 (2), 4 (3) and Article 16 of the PAD Regulation, article 39 of Regulation (EC) No 178/2002, as well as Article 39 of TRIPS agreements, Article 3 of Directive 2001/29 and Article 63 of Regulation (EC) No 1107/2009 and note that that our client remains willing to use all options available to it to resist disclosure including the request for interim measures.

¹ Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society, OJ 22.6.2001, L 167/10.

Meanwhile we request EFSA to send us a copy of the letter submitted by the requestor as well as the Confirmatory Application, together with the EFSA decision which prompted the confirmatory application to enable us to provide further comments thereto.

We also take this opportunity to draw to your attention that the correct company name for our client is Adama Deutschland GmbH and we ask you to amend your records accordingly.

*** **

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

Yours sincerely,

A rectangular area of the document has been redacted with a dark, textured grey fill, obscuring the signature of the Joint Managing Partner.

Joint Managing Partner

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

23 MAR 2016

Ref: [REDACTED] nm (2016) - out-15486045

[REDACTED]
ADAMA Deutschland GmbH Northern
Edmund-Rumpler-Strasse 6
D-51149 Köln
Germany

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 glyphosate¹ with reference:

[REDACTED] (2001)
Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice
TOXI: 1559.CARCI-M FSG
GLP: Y, published: N
2309396 / ASB2012-11491

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 1049/2001² (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:

- 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.

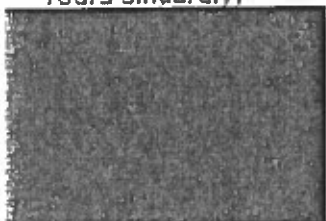
Please note that the PAD Regulation provides that, should only a part of the documents for which public access is requested fall into an exception to disclosure, the remaining parts shall be released.

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,



Cc: [redacted] (EFSA)

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

By Email

Our Ref: CM1/60060-00001/51467537
Your ref: 2015/143

Without Prejudice

Brussels, 28 January 2016

Dear Mr

Access to documents on glyphosate - Consultation under Article 4(4) of Reg. (EC) n. 1049/2001

This responds to your letter of 22 January 2016 concerning a request for access to documents made by a third party in relation to a study on the active substance glyphosate submitted by our client Adama in the context of the renewal of that substance under Regulation (EC) n. 1107/2009 and Regulation (EC) n. 844/2012 ("AIR3").

You informed our client that EFSA has received from an NGO ('the applicant') a request for access to a "*Carcinogenicity Study with Glyphosate Technical conducted in Swiss Albino Mice*" (the "study").

Our client 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 our client 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 co-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

Regulation 1107/2009 which operates as *lex specialis* 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 partes* 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 Adama, 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 Adama 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 Adama's commercial interests, including 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 A/R3. 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

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 358 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 Adama's study on glyphosate should be denied on grounds that it would harm Adama'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 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,
Joint Managing Partner

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.

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.

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

22 JAN 2016

Ref. [REDACTED] mm (2016) - out- 15181951

[REDACTED]
ADAMA Deutschland GmbH Northern
Edmund-Rumpler-Strasse 6
D-51149 Köln
Germany

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 178/2002¹ access of citizens to the documents held by EFSA is governed by Regulation (EC) No 1049/2001². 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-governmental 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 glyphosate³ in the framework of Regulation (EC) No 1107/2009⁴ and it's implementing Regulation (EU) No 844/2012⁵.

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] (2001)
Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice
TOXI: 1559.CARCI-M FSG
GLP: Y, published: N
2309396 / ASB2012-11491

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

Yours sincerely,

Cc: [REDACTED] (EFSA)

[REDACTED]

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

Paris, 13 May 2016

By Registered Email with return receipt ([REDACTED])
[REDACTED] Fax (+ [REDACTED]) and Registered Letter
with Acknowledgement of Receipt

Your ref. PAD 2016/023

Re: PAD 2016/023 CA- Additional clarifications for a substantiated decision to be taken by the EFSA in reply to the pending confirmatory application under Regulation (EC) No 1049/2001, in relation to our study on the active substance Glyphosate submitted in accordance with Regulation 2010/1141 (AIR2)

Dear [REDACTED]

We, as representative of Nufarm GmbH & Co KG (Nufarm), refer to your letter of 4 May 2016 that seek additional clarifications on some aspects of the confidentiality claims of our Client in relation to the study report "*Dietary carcinogenicity study in the mouse*" (2009) sent by Nufarm on behalf of the Glyphosate Task Force to the Rapporteur Member State Germany on 24 March 2011 (hereinafter referred as the "*Study*"), in the context of the renewal of glyphosate under Regulation (EC) No 1107/2009 and Regulation (EC) No 844/2012 (hereinafter referred as "*AIR2*").

In Nufarm's letters dated 28 January 2016 and 4 April 2016 (copies enclosed), Nufarm has already responded to the initial request for access to the Study, raising objections against disclosure, notably based on Article 4(2) first indent of Regulation (EC) No 1049/2001 (hereinafter referred as the "*PAD Regulation*") referring to protection of commercial interests.

Meanwhile, we hereby confirm Nufarm's initial position based on our previous arguments, which remain unaltered. However, in response to your last request, Nufarm would like to add additional clarifications.

- [REDACTED]
- a) First of all, it must be noted that the system of exceptions laid down in Article 4 of Regulation (EC) No 1049/2001, particularly in Article 4(2), is based on a weighing of two opposing interests in a given situation: on the one hand, the interests which would be favored by the disclosure of the documents at stake and, on the other hand, those which would be jeopardized by such disclosure.

That is to say that the decision taken on a request for access to documents directly depends on which interest must prevail in the matter at hand (Judgement of the Court (Fifth Chamber), 14 November 2013, Joined Cases C-514/11 and C-605/11 P, *LPN and Finland v Commission*).

Where the exception invoked is one of those set out in Article 4(2) of Regulation (EC) No 1049/2001, the Institution is under the obligation to examine and investigate the detailed reasons invoked in order to potentially disclose the information at stake.

In the present case, the Requestor merely argues that « given the importance of the five above-mentioned studies, is EFSA considering their publication to enable an informed debate on such an important issue (...) », without even further detail his overriding interest in such access.

Yet, as the EFSA reminds the Company in its letter sent 4 May 2016, it is essential for the Institution to be able to appreciate and evaluate the different interests in question in order to ensure a consistent and harmonious interpretation of EC Regulations.

From the analysis of the documents you kindly annexed to your last letter, such documents do not even contain details as the potential existence of an overriding public interest.

However, it appears that equal treatment between interested parties implies that not only the Company but also the Requestor are likely to give sufficient justifications on their respective interest as to permit the EFSA to take a “*substantiated decision*”.

Therefore, in the absence of a demonstration of an overriding public interest on disclosure applying to this request, it is, again, required, from the EFSA to not disclose the Study.

- b) Beyond, it shall be added that pursuant to Article 39 (2) of the TRIPS Agreement, it appears that any natural and legal persons shall prevent from any disclosure of information which:

“(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret”.

Yet, as you obviously know, it is necessary to interpret the provisions of Regulation (EC) No 1107/2009, especially Articles 63 (2) and 59 (1), in a balanced and proportional manner, so as to ensure that they do not contradict the provisions of Article 39 (2) of the TRIPS Agreement, which protect commercially valuable information, considered as “a body”, from public disclosure.

On the value of such provisions, the General Court clearly admitted that *“the provisions of the TRIPS Agreement, which is part of the WTO Agreement, signed by the Community and subsequently approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994), constitute an integral part of the European Union legal order. Where there are European Union rules in a sphere concerned by the TRIPS Agreement, European Union law will apply, which will mean that it is necessary, as far as possible, to adopt an interpretation in keeping with the TRIPS Agreement, although no direct effect may be given to the provision of that agreement at issue (see Case C-431/05 Merck Genériques – Produtos Farmacêuticos [2007] ECR I-7001, paragraph 35 and the case-law cited)”* (Judgement of the General Court (Second Chamber), 8 October 2013, Case T-545/11, *Stichting Greenpeace Nederland v. European Commission*).

In the light of the foregoing, it is thus necessary to ensure that Regulation (EC) No 1107/2009 is interpreted consistently with article 39 (2) of the TRIPS Agreement.

Yet, the content of the Study in question talks for itself, and pursuant to article 39 (2) constitute an assembly of components which has to be protected as an indivisible whole.

This means, on the one hand, that almost all the paragraphs of the content contain sensitive data, whether test material and experimental preparation or methods. Yet, such information is expressly *“deemed to undermine the protection of the commercial interests or of privacy and integrity of individuals”* under Article 63 (2) of Regulation (EC) No 1107/2009.

This relates to protected know-how relating to the scientific and technical expertise of the Company, which disclosure could undermine its market position.


On the other hand, no further information contained could be clearly understood without such a sensitive data, unless making an erroneous interpretation of the remaining content which could deeply jeopardized the position of Nufarm as well as the normal course of the procedure [See our related point on Article 4(3) of the PAD Regulation in our previous reply dated 4 April 2016].

Indeed, the secret information contained in the Study is understood *“as a body”* or only *“in the precise configuration and assembly of its components”* which makes it impossible to be isolated from the rest of the Study.

That is why the relevant background information backing the EFSA's conclusions as well as the sanitized supplementary summary dossier for the AIR II renewal procedure, where detailed descriptions of the toxicological studies are available, have been published.

For all the above-mentioned reasons, the Study cannot be deprived from its commercial sensitive information as listed in Article 63(2), which is exclusive data owned by Nufarm as regards Article 59(1) of Regulation (EC) No 1107/2009.

Furthermore, it is relevant to underline that Article 16 of the PAD Regulation referring to copyright expressly includes an exception to such a Regulation when copyright may limit a third party's right to reproduce or exploit released documents. Such Study, being covered by copyright, cannot be released.




Any disclosure of information contained in the Study at issue would seriously disturb the balance established by the European Union legislature, for companies which only have followed the renewal procedure for active substances provided for in the Regulation (EC) No 1107/2009.

Furthermore, it is worth noting that the General Court has clearly underlined that *"it may be impossible to give reasons justifying the need for confidentiality in respect of each individual document without disclosing the content of the document and thereby defeating the very purpose of the exception (Terezakis v Commission, paragraph 71). In the present case, the Commission clearly indicated that, independently of the position of the Member States, the exception upon which the Commission based its refusal is that provided for in the first indent of Article 4(2) of Regulation No 1049/2001. That is in accordance with the judgment of the Court of Justice in IFAW (paragraphs 68 and 99). In addition, as the applicant has correctly pointed out, the Commission actually adopted a succinct statement of reasons closely reflecting the words of the first indent of Article 4(2) of Regulation No 1049/2001"* (Judgement of the General Court (Second Chamber), 19 January 2010, Joined Cases T-355/04 and T-446/04, *Co-Frutta Soc. coop. v. European Commission*).

In essence, the EFSA is asked to ensure to cover the whole content of the Study by the exception of Article 4(2) of the PAD Regulation and Article 63 the Regulation (EC) No 1107/2009.

- c) However and beyond these self-sufficient legal basis and grounds, Nufarm is obviously particularly aware of the political questions surrounding a true public concern evoked, political issues raised by Commissioner Vytenis ANDRIUKAITIS in its letter dated April 4, 2016, sent to the Chair of the Board of the Glyphosate Task Force.

Consequently, Nufarm would like to draw, in this respect, the attention of the EFSA on the proposal of a data room with the 14 carcinogenicity studies available, within the terms, conditions and limits of the letter sent by Dr.  Board of the Glyphosate Task Force to Commissioner Vytenis ANDRIUKAITIS on the same date, April 4, 2016.

* * *

In the light of the foregoing, we hereby, and once again, confirm formally our objection for disclosure, except within the situation described in paragraph c) above.

We are looking forward to hearing from you.

In the meantime, we remain at your entire disposal.

Yours sincerely,



HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

04 APR 2016

Ref. [REDACTED] (2016) – out- 15664917

Christophe Hénin

[REDACTED]

e-mail: [REDACTED]

Copy to:

[REDACTED]

European Regulatory and
Development Lead
Nufarm GmbH & Co.KG
St Peter-Straße 25
4021 Linz
Austria

e-mail: [REDACTED]

Re: Your letters of 4 April and 28 January 2016 related to the access to documents request on glyphosate concerning your mouse study

Ref.: PAD 2016/023

Dear [REDACTED],

Thank you for your letters of 28 January and 4 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 letters 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]. (2009)

Glyphosate Technical: Dietary carcinogenicity study in the mouse

SPL 2060-0011 NUF

GLP: Y, published: N

2309412 / ASB2012-11492

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 letters, EFSA seeks clarifications to take a substantiated decision in reply to the pending confirmatory application under Regulation (EC) No 1049/2001¹ (hereinafter the "PAD Regulation"). We kindly ask you to reply to the below questions linked to your claims:

- 1) EFSA's peer-review of the active substance glyphosate was finalised on 30 October 2015 and the Conclusion published on 12 November 2015². 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 it³.
- 2) As regards the information indicated in Article 63(2)(g) of Regulation (EC) No 1107/2009⁴ 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 Nufarm'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 Nufarm 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 Nufarm 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.

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.

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.

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,



Cc: [redacted] (EFSA)

From: [REDACTED] [mailto:[REDACTED]@corporateeurope.org]

Sent: 10 December 2015 15:40

To: [REDACTED]

Cc: [REDACTED]

Subject: Re: ADols of scientific experts from national competent authorities

Dear [REDACTED], [REDACTED], [REDACTED]

I hope this email finds you well. Sorry to insist but I haven't received a response to my question on the DOIs of the authors of the glyphosate peer review, probably it slipped through? I was wondering whether it was all experts of the Mammalian toxicology group or whether it was only some of them, and/or other people as well? If so, and if it's not too burdensome, could you send me a complete list of names so that I can download the DOIs?

Also, I wanted to follow up on this question sent to you last 24/11 :

"Given the importance of the five above-mentioned studies, is EFSA considering their publication to enable an informed debate on such an important issue, all the more that, since glyphosate is no longer covered by patent protection and is widely used all over the industry, the usual argument about the need to protect commercially sensitive information is unlikely to apply here?"

This question referred to the 5 mouse studies that [REDACTED] insisted had played such an important role in reaching a different conclusion than IARC in the interpretation of the animal evidence but that IARC could not access in full because they were sponsored by industry and as such deemed to contain commercially sensitive elements.

EFSA's response to this question was the following:

"All versions/updates of the risk assessment report and the addendum regarding the IARC assessment are publicly available on EFSA's website.

This includes detailed information about the assessment and appraisal of all studies considered by EFSA and Member States as part of the peer review process, including studies submitted by industry. The documents, as you will see, run to several thousand pages.

Typically, the amount and type of information made available by EFSA about individual papers/studies is comparable to the amount of information contained within articles published in the open scientific literature (also bearing in mind that the raw data behind studies, including for so-called 'independent studies', is very rarely published in the open scientific literature).

For example, if you follow the link on our website to the documents I mention above, open the file 4302add_public.pdf, and go to page 1012 you will see extensive information and comments from the Rapporteur Member State on each of the long-term studies assessed regarding carcinogenicity.

The information published by EFSA about the studies assessed, including industry studies, is now in the public domain, allowing any organisation or individual to scrutinise the European peer review of glyphosate that was carried out by experts from all 28 MS. We would encourage anyone with an interest in our work to review this information."

The debate in Brussels last week between [REDACTED] from EFSA and [REDACTED]

[REDACTED] from IARC made clear that the level of information disclosed by EFSA in its published documents was insufficient and that access to these studies' raw data was necessary to enable a meaningful contradictory assessment of these studies between the two institutions.

I would therefore like to ask to have access, in line with EU Regulation 1049/2001 on access to documents, to these studies' full version including raw data.

Kind regards

[REDACTED]

[REDACTED]

Corporate Europe Observatory (CEO)

Rue d'Edimbourg 26

1050 Brussels - Belgium

[REDACTED]@corporateeurope.org

www.corporateeurope.org

phone: [REDACTED]

twitter: [REDACTED]

Sign up to CEO's e-newsletter:

<http://www.corporateeurope.org/subscribe-our-newsletter>

05 FEB 2016

Ref. [REDACTED] (2016) - out - 15252298

[REDACTED]
Corporate Europe Observatory (CEO)
26, Rue d'Edimbourg
BE-1050 Brussels
Belgium

e-mail: [REDACTED]@corporateeurope.org

Subject: Your application for access to documents of 10 December 2015

Ref.: PAD 2015/143

Dear [REDACTED],

I refer to your e-mail submitted on 10 December 2015 by means of which you requested access to *"the 5 mouse studies' full version including raw data (...) that Mr Tarazona insisted had played such an important role in reaching a different conclusion than IARC in the interpretation of the animal evidence"* (hereinafter the "Studies") in accordance with Regulation (EC) No 1049/2001¹ (hereinafter referred to as the "PAD Regulation"). Having carefully considered your request, we regret to inform you that EFSA is not in the position to release the requested Studies to you.

EFSA interpreted that your request refers to the five long term toxicity and carcinogenicity mice studies that are mentioned in the section "Carcinogenicity" in the background document to the EFSA Conclusion published on 12 October 2016², notably:

- 1) 18-Month Oral Oncogenicity Study in Mice
- 2) Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice
- 3) Glyphosate Technical: Dietary carcinogenicity study in the mouse
- 4) A chronic feeding study of glyphosate (Roundup technical) in mice
- 5) Glyphosate - 104 week combined chronic feeding/oncogenicity study in rats with 52 week interim kill (results after 104 weeks)

EFSA has consulted the five owners of the Studies submitted in the frame of the renewal of the authorisation for the active substance Glyphosate under Regulation (EC) No 1107/2009³ and Commission Regulation (EU) No 1141/2010⁴ as amended by Commission Implementing Regulation (EU) No 380/2013⁵. In particular, in accordance with Article 4(4) of the PAD Regulation, EFSA liaised with the owners with a view to assessing whether these partially or entirely fall within the

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.

² Available at http://www.efsa.europa.eu/sites/default/files/1307_glyphosate_complementary.pdf

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

⁴ Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances, OJ L 322, 8.12.2010, p. 10-19.

⁵ Commission Implementing Regulation (EU) No 380/2013 of 25 April 2013 amending Regulation (EU) No 1141/2010 as regards the submission of the supplementary complete dossier to the Authority, the other Member States and the Commission, OJ L 116, 26.4.2013, p. 4.

exceptions to disclosure foreseen in the PAD Regulation. Four of the owners consulted replied to EFSA; one of the consultations is still pending.

The data owners provided justifications to support the refusal of the access request based on the following grounds:

These Studies are covered by the exception foreseen by Article 4(2) first indent of the PAD Regulation, namely the protection of "*commercial interests including intellectual property rights*" and their full protection is also the direct consequence of the qualification as confidential information contained in the Studies under the terms of Article 63 of Regulation (EC) No 1107/2009.

As highlighted by the owners of the Studies, the Studies requested include protected know-how relating to the scientific and technical expertise in conducting these Studies, disclosure of which will undermine the competitive position of the companies.

These unpublished Studies are owned by the companies and contain property data that if released will jeopardise the exercise of their intellectual property.

These documents include business and data property of the owners and their disclosure will undermine their commercial interests.

Finally disclosure of the Studies would provide access to commercial information, resulting from an investment of the owners both in terms of time and resources, which could be used by potential competitors in particular outside the EU.

Having considered the arguments put forward by the owners of the Studies and after having carefully carried out a concrete examination of the Studies falling in your request, EFSA concludes that the Studies are protected in application of Article 4(2), first indent, of the PAD Regulation, namely the protection of "*commercial interests and intellectual property rights*". Please note that these Studies are also to be protected in application of Article 63 of Regulation (EC) No 1107/2009, as they classify as confidential information.

Moreover, EFSA has specifically undertaken the balance of interests at stake in application of the PAD Regulation, and concluded that no overriding public interest on disclosure applies to this request.

Indeed the public interest of accessing background information relating to the renewal of approval of this active substance, in accordance with Article 38(1)(c) of EFSA's Founding Regulation⁵, is granted by having published the relevant background documentations backing the EFSA's conclusions published at the following link <http://www.efsa.europa.eu/en/press/news/151119a>.

This includes as well the sanitised supplementary summary dossier for the AIR II renewal procedure where detailed descriptions of the toxicological studies are available (MII, section 3, pp 502f).

Therefore, given the fact that the accessibility of the Studies, in particular to competitors, would put at risk the commercial interests and intellectual property rights of the owners of the Studies, their disclosure would be disproportionate to the objective that is necessary to attain. In fact EFSA considers that the information granted to the public at large within this particular renewal process satisfies a good

⁵ 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.

level of transparency that is proportional to the protection of the commercial interests and intellectual property rights of the owners.

It follows that the Studies requested are not disclosed to you in application of the exceptions to disclosure provided for in the PAD Regulation, namely Article 4(2) first indent (protection of "*commercial interests including intellectual property rights*") as combined with the provisions set out in Article 63 of Regulation (EC) No 1107/2009.

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

Further correspondence must be sent to:

EFSA

Via Carlo Magno 1/A

I - 43126 Parma

e-mail: EFSA_public_access_to_documents@efsa.europa.eu

Cc: J.

[REDACTED]

From: [REDACTED] <[REDACTED]@corporateeurope.org>
Sent: 12 February 2016 15:18
To: EFSA.public.access.to.documents
Cc: [REDACTED]
Subject: PAD 2016/023 CA _ Re: PAD 2015/143_Reply_Your request of public access to documents of 10 December 2015

Follow Up Flag: Read
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Dear [REDACTED], dear [REDACTED],

thank you for your response to my access to documents request.

I understand - and expected - that the owners of these studies would not agree to the full disclosure of these documents in the name of the commercial interests exception foreseen in the 1049/2001 Regulation, and I understand and accept that EFSA is bound to respect their preferences in this domain.

However, I do not accept the suggestion that the whole content of the documents would be covered by this exception. Furthermore, I do not accept that the commercial interests at stake would be so sensitive as requiring being redacted: we are talking here about studies performed, for most of them, more than 15 years ago, on a product whose last related patent expired in 2000 and which now being manufactured by several different companies. The fact that the glyphosate renewal dossier was written and submitted by the Glyphosate Task Force, in itself a group including most contemporary manufacturers of glyphosate, is a strong indication that the content of these studies has already been shared among most relevant competitors, which makes the studies' owners' argument that secrecy would be needed to keep a competitive edge much less credible.

As a consequence, I am herewith appealing EFSA's decision to not publish a single word of these studies and urge you to:

- double-check the redacting requirements of the studies' owners;
- send me these studies with the actually commercially sensitive sections redacted.

I understand that the amount of work involved is going to be significant and I am ready to be flexible in terms of deadline; but not in terms of principle. Moreover, the public sensitivity of this particular dossier makes it a good case for testing EFSA's ambitions in terms of data transparency.

With kind regards,

[REDACTED]

Le 05/02/16 18:13, EFSA.public.access.to.documents a écrit :





> Dear [REDACTED],

>

>

>

> Please find attached the reply letter referenced 15252298 from [REDACTED]
[REDACTED] the Legal and Regulatory Affairs Unit of EFSA.

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>
> Yours sincerely,
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> Public Access to document Team
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> Legal and Regulatory Affairs Unit
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> Via Carlo Magno 1A
>
> I-43126 Parma
> Italy
>
> Tel.  Fax: 
> @efsa.europa.eu
> <<mailto:efsa@efsa.europa.eu>>
> www.efsa.europa.eu <<http://www.efsa.europa.eu/>>
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> [wAA&usg=AFQjCNE2bOYMFVSGnITwTtgfFRfvRnerCg](#)>
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Researcher and Campaigner

Corporate Europe Observatory (CEO)

Rue d'Edimbourg 26

1050 Brussels - Belgium



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[REDACTED]

From: [REDACTED] <[REDACTED]@corporateeurope.org>
Sent: 17 February 2016 19:30
To: [REDACTED]
Cc: [REDACTED]; EFSA.public.access.to.documents; [REDACTED]
Subject: PAD 2016/023 CA _ addition to my confirmatory request on access to documents

Follow Up Flag: Read
Flag Status: Flagged

Dear [REDACTED],

cc [REDACTED] whom I am meeting tomorrow, [REDACTED]

I would like to add a precision to my confirmatory request on access to documents sent to you last Friday (2016-02-12 15:18). My original request was on five studies, and I would like to narrow my confirmatory request to the following three:

- "Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice" (2001), following OECD Guideline 451 & GLP – study owned by the Israeli pesticides company ADAMA Agan Ltd
- "Glyphosate technical: Dietary Carcinogenicity Study in the Mouse" (2009), following OECD Guideline 451 & GLP – study owned by the Australian pesticides company Nufarm
- "HR-001: 18-Month Oral Oncogenicity Study in Mice" (1997), following following OECD Guideline 451 & GLP – study owned by the Japanese pesticides company Arysta LifeSciences Corporation

You will see from an article I published today

<http://corporateeurope.org/efsa/2016/02/key-evidence-withheld-trade-secret-eus-controversial-risk-assessment-glyphosate>

that I am essentially asking EFSA to send me these studies with all items deemed a trade secrets redacted, in order to allow the scientific debate to progress. I understand this is a substantial work, but at the same time this is also the best opportunity EFSA has to demonstrate its good will in terms of data transparency so... It could also be an opportunity to measure the cost of such an action in the present legal conditions, in itself an important dimension of the debate. I therefore hope that EFSA will do its best to disclose these studies to me.

Kind regards

[REDACTED]

[REDACTED]

Corporate Europe Observatory (CEO)

Rue d'Edimbourg 26

1050 Brussels - Belgium

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[REDACTED]

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

Paris, 4 April 2016

By Registered Email with return receipt [REDACTED]
[REDACTED] Fax [REDACTED] and Registered Letter with
Acknowledgement of Receipt

Your ref. PAD 2016/023

Re: PAD 2016/023 CA- Consultation under Article 4(4) Reg. - Confirmatory Application for Public Access under Article 7(2) of Regulation 1049/2001 to our study on the active substance Glyphosate submitted in accordance with Regulation 2010/1141 (AIR2)

Dear Mr [REDACTED]

We, as representative of Nufarm GmbH & Co KG (Nufarm), refer to your letter of 23 March 2016 informing our client about the confirmatory application for public access to Nufarm's study report '*Dietary carcinogenicity study in the mouse*' (2009) sent by Nufarm on behalf of the Glyphosate Task Force to the Rapporteur Member State Germany on 24 March 2011 (the "Study"), in the context of the renewal of glyphosate under Regulation (EC) No 1107/2009 and Regulation (EC) No 844/2012 ("AIR2").

In Nufarm's letter dated 28 January 2016 (copy enclosed) Nufarm has already responded to the initial request for access to the Study, raising objections against disclosure based on Article 4(2) first indent of Regulation (EC) No 1049/2001 (hereinafter "PAD Regulation") referring to protection of commercial interests.

In view of this Confirmatory Application, we suppose that EFSA has denied access to the Study concerned taking Nufarm's argumentation into consideration. However, we have not received copy of any request from the Requestor nor your decision to deny access and it is therefore not possible for us to analyse the legal grounds and the Requestor's contentions with a view to exercising Nufarm's right of defence.

Meanwhile, we hereby confirm Nufarm's position and in addition to arguments provided in Nufarm's letter of January 28, 2016, which remains unaltered and in response to your request based on Article 4 (4) of the PAD Regulation, Nufarm also invokes exceptions contained in:

- 1) Article 4(1) b. of the PAD Regulation, protecting privacy and the integrity of the individual.
- [REDACTED]

[REDACTED]

*"The Institution shall refuse access to a document where disclosure would undermine the protection of:
(...)
b) privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data."*

The Study contains all details about laboratory, individuals and sponsors of the study who could face retaliation measures from third parties which are against animal testing¹.

2) Article 4(3) of the PAD Regulation.

The Study has been submitted to EFSA for renewal assessment of the active substance glyphosate and relates to a matter where the decision has not been taken by the Institution.

The glyphosate active ingredient has been and is still subject of great media, political and public pressure. Releasing this Study before final assessment by the Commission could jeopardise the normal course of the procedure.

Disclosure of Nufarm's Study to the Requestor is not justified by scientific arguments and harms the integrity of the decision-making process with the competent authorities².

3) Pursuant to Article 39 of Regulation (EC) No 178/2002,

"By way of derogation from Article 38, the Authority shall not divulge to third parties confidential information that it receives for which confidential information has been requested and justified, (...).

Thus, articles 38 and 41 (1) of (EC) No 178/2002 you are referring to in your letter of 23 March 2016, could not authorize access to the full Study. As already stated, this Study contained confidential information such as but not limited to the origin of the technical source of glyphosate and how to conduct this study (details of works) and thus constitutes an exception to the application of Articles 38 and 41 (1).

Moreover, the public interest of accessing background of information relating to the renewal of the active substance glyphosate has been satisfied by providing to the public the necessary documentations backing the EFSA's conclusions in accordance to article 38.1 (c) of Regulation (EC) No 178/2002.

4) Article 39 of TRIPS agreements and Articles 59 and 63 of Regulation (EC) No 1107/2009 regarding the confidentiality of data on plant protection products.

Important investments are made on R&D to provide studies. These studies contain commercially confidential information which is the most important intangible business assets for agrochemical companies.

In order to protect such investments and stimulate incentives, data, studies and confidential information are protected namely under TRIPS agreement (Article 39) and Article 59 and 63 of (EC) No 1107/2009.

¹ See on the notion of personal data: Judgement of the European Court of Justice (Second Chamber), 16 July 2015, Case C-615/13 P, *Client Earth and others v EDPS*.

² Article 4(3) of the PAD Regulation enables the institutions to refuse access to documents that would risk to undermine the proper conduct of the procedures at stake (see Judgement of the European General Court, 13 November 2015, Joined Cases T-424/14 and T-425/14, *Client Earth v European Commission*; see also, as regards the obligation for EFSA to provide independent information: Article 22(2) and (7) of Regulation (EC) No 178/2002).

[REDACTED]

Article 39 of TRIPS agreement:

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

(...)

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except when necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

Nufarm's Study is not in the public domain. Thus, publication of Nufarm's Study will allow competitors to use the Study and will jeopardize data protection conferred by Article 39 of TRIPS Agreements and Article 59 of EC 1107/2009.

In principle, the purpose of Article 63 of (EC) No 1107/2009 is to protect confidential information against disclosure which would undermine the commercial interest or the privacy and integrity of the individual concerned.

Moreover, if Article 63 refers to Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information as a possible exception for its application, we precautionary would like to mention that this exception cannot apply to the Study of concern as it was conducted on mice and does not have any link with possible impact on environment.


Nufarm considers that the requirement under Article 10 of Regulation (EC) No 1107/2009 referred to in Article 8 (1) to make the summary dossier available to the public excluding Article 63 is sufficient without the need to make raw data available.

- 5) Article 16 of the PAD Regulation referring to copyright includes an exception to this Regulation when copyright may limit a third party's right to reproduce or exploit released documents. This Study is covered by copyright and thus could not be released.

Moreover and as already raised in Nufarm's previous letter, disclosure of the Study would undermine Nufarm's commercial interests and intellectual property rights in the Study including data protection, know-how and methodology used for conducting the study and would provide access to commercial information resulting from Nufarm's investments that could be used by competitors included outside the EU. Therefore, Nufarm considers that the request should be rejected also on grounds of the protection of commercial interests / intellectual property rights pursuant to Article 4(2) first indent of the PAD Regulation³.

Finally, we have not been provided with a copy of the Confirmatory Application or with the initial request and therefore are unable to respond to it in full. We therefore request for access to these documents in order to provide a fully informed response thereto.

³ See Judgement of the European General Court (Second Chamber), 19 January 2010, Joined Cases T-355/04 and T-446/04, *Co-Frutta Suc. coop. v European Commission*.



Meanwhile, Nufarm's hereby maintains objections to disclosure as outlined above and in its previous correspondence.

In view of the above, Nufarm considers that there are no grounds to release this study in whole or in part.

Therefore, we consider that the request should be rejected based on exceptions set out in Articles 4(1) b., 4 (2), 4 (3) and Article 16 of the PAD Regulation, article 39 of Regulation (EC) No 178/2002, as well as Article 39 of TRIPS agreements and Article 63 of Regulation (EC) No 1107/2009.

Disclosure of this study to an NGO without knowing what is the intention of use would give a completely unbalanced and potentially biased view of this Study which has to be reviewed in the light of all scientific elements contained in the dossier. Thus the risk is high if used to undermine the regulatory system underpinning plant protection products and prejudice the reputation of the entire industry.

* * *

In the light of the foregoing, and of any other argument to be added later on once we received more information on the nature and identity of the requesting party, we hereby confirm formally our objection for disclosure.

By the present letter, and in order to be able to provide further comments, Nufarm requests EFSA to send us a copy of the letter submitted by the requestor as well as the Confirmatory Application, together with the EFSA decision which prompted the confirmatory application .

We are looking forward to hearing from you.

In the meantime, we, of course, remain at your entire disposal.

Yours sincerely,



HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

23 MAR 2016

Ref. DD/CR/mm (2016) - out-15490692

Dr [REDACTED]
Nufarm GmbH & Co KG
St.-Peter Str. 25
AT-4021 Linz
Austria

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 its implementing Regulation (EU) N° 844/2012

Ref.: PAD 2016/023 CA

Dear Mr [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 glyphosate¹ with reference:

[REDACTED]

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 1049/2001² (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:

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,



Cc: [REDACTED] (EFSA)



To European Food Safety Authority,

Parma (I)

Nufarm GmbH & Co.KG

St. Peter-Straße 25

4021 Linz

Austria

www.nufarm.com

Re: PAD 2015/143 - application under Regulation (EC) No 1049/2001 asking for access to a study on the active substance Glyphosate submitted in accordance with Regulation 2010/1141 (AIR2).

Dear

Thank you for your e-mail and letter dated 22/01/2016 addressed to me informing Nufarm of the request for disclosure of information (data submission) sent by Nufarm on behalf of the Glyphosate Task Force to the Rapporteur Member State Germany on March 24th 2011.

Nufarm invokes Article 4(2), first indent, of Regulation 1049/2001 regarding the undermining of commercial interests, to resist the disclosure of parts of the data submission.

Specifically, Nufarm has a global Glyphosate herbicide business based on manufacturing outside the EU. Under the EU and global agrochemical legislative structure, the ability to register and sell product is based on the ability to demonstrate safety using scientific reports. This report therefore is of great commercial value to the business. The cost to Nufarm of generating the scientific report concerned in this request is in the region of 1.000,000€. Maintaining confidential control of this document is therefore paramount to the business. Within the PPP legislation, defined periods of data protection exist, but when this expires, it is only required that "data access" can be granted to another applicant which does not involve disclosure of the full reports.

Release of the full scientific reports to a third party would threaten this Glyphosate business and leave Nufarm at a commercial disadvantage. The difference between having the full copy of a scientific report as opposed to having data access to the report is very important. Having a full copy of the study report allows freedom to operate globally in a business sense and loss of control of its assets would threaten Nufarm's current business globally.

The release of the full study report would clearly provide third parties with detailed information considered as confidential on the origin of the technical source of Glyphosate (sponsor of the study) and on how to conduct this study ("details of work") and thus expose company know-how which is information of sensitive nature and of commercial interest (according to Article 4(2) of Regulation 1049/2001).

Nufarm would be willing to disclose the summary. However, as with that document Nufarm would request that it is permitted to produce a "sanitised" version according to Article 63(2) of Regulation (EC) No 1107/2009 and based on existing guidelines namely SANCO/10181/2013— rev. 2.1 13 May 2013 and EFSA guideline 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) prior to any release.

Yours sincerely,
Nufarm GmbH & Co. KG



NUFARM GMBH & CO KG
ST.-PETER-STRASSE 25
4021 LINZ/AUSTRIA

European Regulatory and Development Lead

Linz, January 28th, 2016

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

22 JAN 2016

Ref. [REDACTED] mm (2016) - out 15184942

[REDACTED]
Nufarm GmbH & Co KG
St.-Peter Str. 25
AT-4021 Linz
Austria

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 178/2002¹ access of citizens to the documents held by EFSA is governed by Regulation (EC) No 1049/2001². 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 glyphosate³ in the framework of Regulation (EC) No 1107/2009⁴ and it's implementing Regulation (EU) No 844/2012⁵.

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] (2009)
Glyphosate Technical: Dietary carcinogenicity study in the mouse
SPL 2060-0011 NUF
GLP: Y, published: N
2309412 / ASB2012-11492

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 Signature]

Cc: [Redacted] (EFSA)

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

Parma, 17 JUN 2016
Ref. DD/SG/CP/lm (2016) - out-15858014

[REDACTED]
Chair of the Board
Cc: [REDACTED]
Glyphosate Taskforce
c/o Monsanto Europe S.A./N.V. -
Agricultural Sector
Avenue de Tervuren 270-272
B-1150 Brussels
Belgium

e-mail: [REDACTED]
Cc: [REDACTED]

Subject: Consultation on an access to documents request related to 82 studies you submitted to EFSA for the renewal assessment of the active substance glyphosate in the framework of Regulation (EC) No 1107/2009 and its implementing Regulation (EU) N° 1141/2010

Ref.: PAD 2016/034

Dear Dr [REDACTED],

I am writing to you in the context of a request the European Food Safety Authority (EFSA) received from four Members of the European Parliament (MEPs). Under Regulation (EC) No 1049/2001¹ (hereinafter referred to as the "PAD Regulation"), they requested access to "*all studies used by EFSA to assess carcinogenicity of glyphosate and its representative formulation in their entirety, [...] all the historical control data used in that context*" and to "*all studies that you assessed concerning mechanisms of carcinogenicity*".

According to Article 41(1) of Regulation (EC) No 178/2002,² access of citizens to the documents held by EFSA is governed by the PAD Regulation.

EFSA considers that the studies falling within the scope of this request amount to 182 (Annex II³), 100 of which are published in the scientific literature.

EFSA is hereby consulting you pursuant to Article 4(4) of the PAD Regulation on the accessibility of the 82 studies you submitted to EFSA on behalf of the Glyphosate Task

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.

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 Annex II is the list of studies which has been extracted from the RAR from the Rapporteur Member State, so including the published and unpublished studies.

Force for the renewal assessment of the active substance glyphosate in the framework of Regulation (EC) No 1107/2009⁴ and that are not published in the scientific literature (**Annex II**). Since you are not the owner of all these studies, EFSA hereby kindly asks you to coordinate the consultation among all the members of the Glyphosate Task Force (GTF). Your reply will be processed by EFSA as a reply from the respective members of the GTF.

I would be grateful if you could share with me by the **8 July 2016** the reply of the members of the GTF on the release, full or partial, of the 82 studies, by completing the table enclosed in **Annex I** to the present letter for each of the studies listed in **Annex II**.

The GTF is kindly requested to complete electronically the table in **Annex I** by giving a verifiable and detailed indication and justification of any part of each study that in your view should not be released. Please also send an electronic copy of the full report for each study and, in the case you claim that some parts of the report are confidential, a sanitised electronic version of each study for which you submit confidentiality claims, together with the Annex I table explaining what you have sanitised and the grounds for confidential treatment. Please remove confidential data from the studies, using a redaction software tool that blackens the relevant text and fully removes the underlying information from the document. Please consider that you may not claim confidential treatment for details that are already in the public domain, or for which no verifiable justification under one of the exceptions provided for in Article 4 of the PAD Regulation applies. Finally, if some of the studies do not need sanitisation, please kindly provide EFSA with an electronic copy, indicating that they don't bear confidentiality claims.

You can reply by writing to:

EFSA

[redacted], Head of the Legal and Regulatory Affairs Unit

Via Carlo Magno 1/A

I - 43126 Parma

E-mail: EFSA.public.access.to.documents@efsa.europa.eu.

Yours sincerely,



Enclosures: 2

Cc: [redacted] (EFSA)

[redacted] (Monsanto)

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, as last amended.

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

Annex I – Justification table

EFSA Ref.: PAD 2016/034

Third party consultation on the disclosures of studies submitted for the renewal assessment of the active substance glyphosate

Title of study: [please include the reference to the study you are assessing]

Name of the third party consulted: [please include here the company member of the Glyphosate Task Force owner of the study concerned by this table]

Please do not include confidentiality claims on publicly available information (e.g. information published in the RAR or parts published in scientific literature)

Please indicate the grounds for protection by including information: (1) the legal basis (*e.g. Article 59, Article 63, of Regulation (EC) No 1107/2009, or any other legal requirement you consider should apply) ; (2) and why the protection is applicable under the PAD Regulation

Page number(s)	Element(s) of the document for which a request for confidential treatment is filed by the Glyphosate Task Force (Name, title of sections, page number)	Legal basis (please specify*)	Justification provided by the GTF for each confidentiality claim

Annex II : List of studies extracted from the RAR

	Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number	Data protection claimed Y/N	Owner ¹
1.	KIIA 5.4.1 (OECD)	Akanuma, M.	1995	HR-001: Reverse Mutation Test IET 94-0142 ALS GLP: Y, published: N 2309291 / ASB2012-11462	Y	ALS
2.	KIIA 5.4.1 (OECD)	Callander, R.D.	1996	Glyphosate acid: An evaluation of mutagenic potential using <i>S. typhimurium</i> and <i>E. coli</i> CTL/P/4874 SYN GLP: Y, published: N 2309313 / ASB2012-11473	Y	SYN
3.	KIIA 5.4.1 (OECD)	Flügge, C.	2009	Mutagenicity Study of Glyphosate TC in the <i>Salmonella typhimurium</i> Reverse Mutation Assay (<i>in vitro</i>) LPT 23916 HAG GLP: Y, published: N 2309303 / ASB2012-11468	Y	HAG
4.	KIIA 5.4.1 (OECD)	Flügge, C.	2010	Mutagenicity Study of Glyphosate TC in the <i>Salmonella typhimurium</i> Reverse Mutation Assay (<i>in vitro</i>) LPT 24880 HAG GLP: Y, published: N 2309305 / ASB2012-11469	Y	HAG
5.	KIIA 5.4.1 (OECD)	Jensen, J. C.	1991	Mutagenicity test: Ames salmonella assay with glyphosate, batch 206-JaK-25-1 Report: 12323, TOX9552371	Y	---
6.	KIIA 5.4.1 KIIIA1 7.6.3 (OECD)	Kier, L. D.; Stegeman, S. D.; Costello, J. G.; Schermes, S.	1992	Ames/salmonella mutagenicity assay of MON 2139 (Roundup herbicide formulation) EHL 91183 ! ML-91-440 ! MSL-11729 TOX1999-239	N	---
7.	KIIA 5.4.1 (OECD)	Kier, L. D.; Stegeman, S. D.; Costello, J. G.; Schermes, S.	1992	Ames/salmonella mutagenicity assay of MON 14445 (DIRECT Herbicide formulation) MSL-11731 ! EHL 91185/ML-91-442 TOX1999-320	N	---

¹ Only notifier listed

Annex II : List of studies extracted from the RAR

	Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number	Data protection claimed Y/N	Owner
8.	KIIA 5.4.1 KIIA 5.4.4 (OECD)	Kier, L. D.; Stegeman, S. D.; Costello, J. G.; Schermes, S.	1992	Ames/Salmonella mutagenicity assay of Rodeo MSL-11730 ! EHL 91184/ML-91-441 TOX9552373	N	---
9.	KIIA 5.4.1 (OECD)	Li, A. P.; Long, T. J.	1988	An evaluation of the genotoxic potential of glyphosate, Fundamental and Applied Toxicology 10 (1988)537 – 546 published: Y, TOX9500253	N	LIT
10.	KIIA 5.4.1 KIIA 5.4.4 (OECD)	Rank, J.; Jensen, A. G.; Skov, B.	1993	Genotoxicity testing of the herbicide roundup and its active ingredient glyphosate isopropylamine using the mouse bone marrow micronucleus test, Salmonella mutagenicity test, and Allium anaphase-telephase test Z82234	Y	---
11.	KIIA 5.4.1 KIIA 5.4.4 (OECD)	Rasmussen, E. S.	1997	Genotoxicity of Roundup/Glyphosate, Danish Environmental Protection Agency, AA036753, 7042-0110 ASB2013-9671	N	---
12.	KIIA 5.4.1 (OECD)	Riberri do Val, R.	2007	Bacterial reverse mutation test (Ames Test) for Glifosato Técnico Helm 3393/2007-2.0AM-B HAG GLP: Y, published: N 2309299 / ASB2012-11466	Y	HAG
13.	KIIA 5.4.1 (OECD)	Schreib, G.	2012	Reverse mutation assay using Bacteria (Salmonella typhimurium) with Glyphosate tech. 126159 ASB2014-9133		
14.	KIIA 5.4.1 (OECD)	Shirasu, Y.; Moriya, M.; Ota, T.; Ohta, T.	1978	Glyphosate: The report of mutagenic study with bacteria for CP 67573 - Microbial mutagenicity testing on CP67573 Report: ET-78-241, TOX9552368	N	---
15.	KIIA 5.4.1 (OECD)	Sokolowski, A.	2007	Salmonella typhimurium and Escherichia coli Reverse mutation assay with glyphosate technical (NUP-05068) 1061401 NUF GLP: Y, published: N 2309293 / ASB2012-11463	Y	NUF

Annex II : List of studies extracted from the RAR

	Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number	Data protection claimed Y/N	Owner ¹
16.	KIIA 5.4.1 (OECD)	Sokolowski, A.	2007	<i>Salmonella typhimurium</i> and <i>Escherichia coli</i> Reverse mutation assay with glyphosate technical (NUP-05070) 1061402 NUF GLP: Y, published: N 2309295 / ASB2012-11464	Y	NUF
17.	KIIA 5.4.1 (OECD)	Sokolowski, A.	2007	<i>Salmonella typhimurium</i> and <i>Escherichia coli</i> Reverse mutation assay with glyphosate technical (NUP-05067) 1061403 NUF GLP: Y, published: N 2309297 / ASB2012-11465	Y	NUF
18.	KIIA 5.4.1 (OECD)	Sokolowski, A.	2009	Glyphosate technical - <i>Salmonella typhimurium</i> and <i>Escherichia coli</i> Reverse Mutation Assay 1264500 SYN GLP: Y, published: N 2309315 / ASB2012-11474	Y	SYN
19.	KIIA 5.4.1 (OECD)	Sokolowski, A.	2010	<i>Salmonella typhimurium</i> and <i>Escherichia coli</i> Reverse Mutation Assay with Solution of Glyphosate TC spiked with Glyphosine 1332300 HAG GLP: Y, published: N 2309307 / ASB2012-11470	Y	HAG
20.	KIIA 5.4.1 (OECD)	Thompson, P.W.	1996	Technical glyphosate: Reverse mutation assay "Ames test" using <i>Salmonella typhimurium</i> and <i>Escherichia coli</i> 434/014 NUF GLP: Y, published: N 2309311 / ASB2012-11472	Y	NUF
21.	KIIA 5.4.1 (OECD)	Thompson, P.	2014	Glyphosate: Reverse mutation assay 'Ames test' using <i>Salmonella typhimurium</i> and <i>Escherichia coli</i> 41401854 ASB2014-9148	Y	
22.	KIIA 5.4.1 (OECD)	Vargas, A. A. T.; Bonetti, R.	1996	The <i>Salmonella typhimurium</i> reverse mutation by Glifos G.1.1 - 050/96 TOX1999-884	N	---

Annex II : List of studies extracted from the RAR

	Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number	Data protection claimed Y/N	Owner ¹
23.	KIIA 5.4.1 (OECD)	Wallner, B.	2010	Reverse Mutation Assay using Bacteria (<i>Salmonella typhimurium</i>) with Glyphosate TC BSL 101268 HAG GLP: Y, published: N 2309309 / ASB2012-11471	Y	HAG
24.	KIIA 5.4.2 (OECD)	Fox, V.	1998	Glyphosate acid: <i>In vitro</i> cytogenetic assay in human lymphocytes CTL/P/6050 SYN GLP: Y, published: N 2309321 / TOX2000-1995	Y	SYN
25.	KIIA 5.4.2 (OECD)	Jensen, J. C.	1991	Mutagenicity test: <i>In vitro</i> mammalian cell gene mutation test with glyphosate, batch 206- JaK-25-1, Report: 12325, published: N, TOX9552372	N	---
26.	KIIA 5.4.2 (OECD)	Kyomu, M.	1995	HR-001: <i>In vitro</i> cytogenetics test IET 94-0143 ALS GLP: Y, published: N 2309317 / ASB2012-11475	Y	ALS
27.	KIIA 5.4.2 KIIA 5.4.3 KIIA 4.4.4 (OECD)	Li, A. P.	1983	CHO/HGPRT gene mutation assay with glyphosate, Report ML-83-155 ! 830079, published: N, TOX9552369	N	---
28.	KIIA 5.4.2 (OECD)	Rossberger, S.	1994	Glyphosate: DNA repair test with primary rat hepatocytes, Report: 931564 ! 94-03-28 ro, published: N, TOX9400697/ TOX9551099	N	ADM
29.	KIIA 5.4.2 (OECD)	van de Waart, E. J.	1995	Evaluation of the ability of glyphosate to induce chromosome aberrations in cultured peripheral human lymphocytes (with independent repeat) Report: 141918, published: N, TOX9651525	N	---
30.	KIIA 5.4.2 (OECD)	Wright, N.P.	1996	Technical glyphosate: Chromosome aberration test in CHL cells <i>in vitro</i> 434/015 NUF GLP: Y, published: N 2309319 / ASB2012-11476	Y	NUF
31.	KIIA 5.4.3 (OECD)	Akanuma, M.	1995	HR-001: DNA Repair Test (Rec-Assay) IET 94-0141 ALS GLP: Y, published: N 2309325 / ASB2012-11477	N	ALS

Annex II : List of studies extracted from the RAR

	Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number	Data protection claimed Y/N	Owner
32.	KIIA 5.4.3 (OECD)	Clay, P.	1996	Glyphosate acid: L5178 TK+/- mouse lymphoma gene mutation assay CTL/P/4991 SYN GLP: Y, published: N 2309323 / TOX2000-1994	Y	SYN
33.	KIIA 5.4.4 KIIA 5.10 (OECD)	Alvarez-Moya, C., Silva, M.R., Arambula, A.R.V., Sandoval, A.I., Vasquez, H.C., Montes, R.M.G.	2011	Evaluation of genetic damage induced by glyphosate isopropylamine salt using Tradescantia bioassays Genetics and Molecular Biology 34 (1):127-130 34, 127-130 GLP: N, published: Y 2309560 / ASB2012-11538	N	LIT
34.	KIIA 5.4.4 KIIA 5.10 (OECD)	Amer, S.M., Aly, F.A.E., Farghaly, A.A., Ibrahim, A.A.E.	2006	<i>In vitro</i> and <i>in vivo</i> evaluation of the genotoxicity of the herbicide glyphosate in mice Bulletin of the National Research Centre (Egypt) 31, 427-446 GLP: N, published: Y 2309562 / ASB2012-11539	N	LIT
35.	KIIA 5.4.4 KIIA 5.10 (OECD)	Andre, V., Goff, J.L., Pottier, D., Lebailly, P., Peluso, M., Munnia, A., Gauduchon, P.	2007	Evaluation of bulky DNA adduct levels after pesticide use: Comparison between open-field farmers and fruit growers Toxicological & Environmental Chemistry 89, 125-139 GLP: N, published: Y 2309570 / ASB2012-11543	N	LIT
36.	KIIA 5.4.4 KIIA 5.5.3 KIIA 5.6 KIIA 5.7.2 KIIA 5.10 KIIIA1 7.6.3 (OECD)	Anonym.	2004	WORLD HEALTH ORGANIZATION and FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, Rome: Pesticide residues in food – 2004; Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20–29 September 2004, ASB2008-6266	N	LIT
37.	KIIA 5.4.4 KIIA 5.10 (OECD)	Benachour, N., Seralini, G.E.	2009	Glyphosate formulations induce apoptosis and necrosis in human umbilical, embryonic, and placental cells Chem Res Toxicol 22, 97-105 GLP: N, published: Y 2309606 / ASB2012-11561	N	LIT

Annex II : List of studies extracted from the RAR

	Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number	Data protection claimed Y/N	Owner
38.	KIIA 5.4.4 KIIA 5.10 (OECD)	Bolognesi, C., Bonatti, S., Degan, P., Gallerani, E., Peluso, M., Rabboni, R., Roggieri, P., Abbondandolo, A.	1997	Genotoxic activity of glyphosate and its technical formulation roundup Journal of Agricultural and Food Chemistry 45, 1957-1962 GLP: N, published: Y 2309628 / Z59299	N	LIT
39.	KIIA 5.4.4 KIIA 5.10 (OECD)	Bolognesi, C., Carrasquilla, G., Volpi, S., Solomon, K.R., Marshall, E.J.	2009	Biomonitoring of genotoxic risk in agricultural workers from five colombian regions: association to occupational exposure to glyphosate J Toxicol Environ Health A 72, 986-997 GLP: N, published: Y 2309630 / ASB2012-11570	N	LIT
40.	KIIA 5.4.4 KIIA 5.10 (OECD)	Bolognesi, C., Landini, E., Perrone, E., Roggieri, P.	2004	Cytogenetic biomonitoring of a floriculturist population in Italy: micronucleus analysis by fluorescence in situ hybridization (FISH) with an all-chromosome centromeric probe Mutation Research-Genetic Toxicology and Environmental Mutagenesis 557, 109-117 GLP: N, published: Y 2309634 / ASB2012-11572	N	LIT
41.	KIIA 5.4.4 KIIA 5.10 (OECD)	Bolognesi, C., Perrone, E., Landini, E.	2002	Micronucleus monitoring of a floriculturist population from western Liguria, Italy Mutagenesis 175, 391-397 GLP: N, published: Y 2309636 / ASB2012-11573	N	LIT
42.	KIIA 5.4.4 (OECD)	Carvalho Marques, M.F.	1999	A micronucleus study in mice for glifosate técnico Nufarm RF-G12.79/99 NUF GLP: Y, published: N 2309335 / ASB2012-11482	Y	NUF
43.	KIIA 5.4.4 KIIA 5.10 KIIIA1 7.6.3 (OECD)	Cavalcante, D.G.S.M., Martinez, C.B.R., Sofia, S.H.	2008	Genotoxic effects of Roundup (R) on the fish <i>Prochilodus lineatus</i> Mutation Research-Genetic Toxicology and Environmental Mutagenesis 655, 41-46 GLP: N, published: Y 2309662 / ASB2012-11586	N	LIT

Annex II : List of studies extracted from the RAR

	Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number	Data protection claimed Y/N	Owner ¹
44.	KIIA 5.4.4 KIIA 5.10 (OECD)	Cavas, T., Konen, S.	2007	Detection of cytogenetic and DNA damage in peripheral erythrocytes of goldfish (<i>Carassius auratus</i>) exposed to a glyphosate formulation using the micronucleus test and the comet assay Mutagenesis 22, 263-268 GLP: N, published: Y 2309664 / ASB2012-11587	N	LIT
45.	KIIA 5.4.4 KIIA 5.10 (OECD)	Chruscielska, K.; Brzezinski, J.; Grafstein, B.	2000	Glyphosate: Evaluation of chronic activity and possible far-reaching effects - Part 2. Studies on mutagenic activity Pestycydy, 2000, (3-4), 21-25 ASB2013-9830	N	LIT
46.	KIIA 5.4.4 KIIA 5.10 KIIIA1 7.6.3 (OECD)	Clements, C.; Ralph, S.; Petras, M.	1997	Glyphosate: Genotoxicity of select herbicides in <i>Rana catesbeiana</i> tadpoles using the alkaline single-cell gel DNA electrophoresis (comet) assay Environ. Molec. Mutagen., 29, 277-288 Z101728	N	LIT
47.	KIIA 5.4.4 KIIA 5.10 (OECD)	Coutinho do Nascimento; A. C.; Grisolia, C. K.;	2000	Comparative analysis between micronuclei tests in mice and in peripheral erythrocytes of <i>Oreochromis niloticus</i> in evaluation of mutagenic potential of the agrotoxins deltamethrin, dicofol, glyphosate, and Imazapyr ASB2013-11477	N	---
48.	KIIA 5.4.4 (OECD)	Costa, K. C.	2010	Amendment No. 1 to report: Evaluation of the mutagenic potential of Glyphosate technical by micronucleus assay in mice 3996.402.395.07 ASB2014-9284		
49.	KIIA 5.4.4 (OECD)	Costa, K. C.	2008	Evaluation of the mutagenic potential of Glyphosate Technical Micronucleus assay in mice Bioagri Laboratories Ltda., Brazil Data owner: HAG (original sponsor: Jingma Chemicals, Longyou Zhejinn, China) Report No.: RF - 3996.402.395.07 Date: 2008-09-29 Unpublished; ASB2012-11481		

Annex II : List of studies extracted from the RAR

	Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number	Data protection claimed Y/N	Owner ¹
50.	KIIA 5.4.4 KIIA 5.5.3 KIIA 5.10 (OECD)	Chruscielska, K.; Brzezinski, J.; Kita, K.	2000	Glyphosate: Evaluation of chronic activity and possible far - reaching effects - Part 1. Studies on chronic toxicity Pestycydy, 2000, (3 -4), 11-20 ASB2013-9829	N	LIT
51.	KIIA 5.4.4 KIIA 5.10 (OECD)	Chruscielska, K.; Brzezinski, J.; Kahlhom, D.	2000	Glyphosate: Evaluation of chronic activity and possible far - reaching effects - Part 3. Prenatal toxicity Pestycydy, 2000, (3-4), 27-31 ASB2013-9831	N	LIT
52.	KIIA 5.4.4 KIIA 5.10 (OECD)	Dimitrov, B.D., Gadeva, P.G., Benova, D.K., Bineva, M.V.	2006	Comparative genotoxicity of the herbicides Roundup, Stomp and Reglone in plant and mammalian test systems Mutagenesis 21, 375-382 GLP: N, published: Y 2309708 / ASB2012-11607	N	LIT
53.	KIIA 5.4.4 (OECD)	Durward, R.	2006	Glyphosate Technical: Micronucleus Test In The Mouse 2060/014 NUF GLP: Y, published: N 2309327 / ASB2012-11478	Y	NUF
54.	KIIA 5.4.4 (OECD)	Flowers, L. J.	1981	Ames/salmonella mutagenicity assay of MON 8080 MSL 1538 ! ML-80-294/800281 TOX1999-319	N	--
55.	KIIA 5.4.4 (OECD)	Flügge, C.	2009	Micronucleus Test of Glyphosate TC in Bone Marrow Cells of the CD Rat by oral administration LPT 23917 HAG GLP: Y, published: N 2309329 / ASB2012-11479	Y	HAG
56.	KIIA 5.4.4 (OECD)	Fox, V., Mackay, J.M.	1996	Glyphosate acid: mouse bone marrow micronucleus test CTL/P/4954 SYN GLP: Y, published: N 2309337 / TOX2000-1996	N	SYN
57.	KIIA 5.4.4 KIIA 5.10 (OECD)	Grisolia, C.K.	2002	A comparison between mouse and fish micronucleus test using cyclophosphamide, mitomycin C and various pesticides Mutation Research-Genetic Toxicology and Environmental Mutagenesis 518, 145-150 GLP: N, published: Y 2309776 / ASB2012-11834	N	LIT

Annex II : List of studies extracted from the RAR

	Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number	Data protection claimed Y/N	Owner ¹
58.	KIIA 5.4.4 KIIA 5.10 (OECD)	Guilherme, S., Gaivão, I., Santos, M.A., Pacheco, M.	2010	European eel (<i>Anguilla anguilla</i>) genotoxic and pro-oxidant responses following short-term exposure to Roundup®a glyphosate-based herbicide Mutagenesis 25, 523-530 GLP: N, published: Y 2309780 / ASB2012-11836	N	LIT
59.	KIIA 5.4.4 KIIA 5.10 (OECD)	Helal, A.D., Moussa, H.M.	2005	Chromosomal aberrations induced by glyphosate isopropylamine herbicide and trials for diminuting its toxicity using some chemical inactivators and antioxidant Veterinary Medical Journal Giza 53, 169-187 GLP: N, published: Y 2309794 / ASB2012-11841	N	LIT
60.	KIIA 5.4.4 KIIA 5.10 KIIIA1 7.6.3 (OECD)	Heydens, W.F., Healy, C.E., Hotz, K.J., Kier, L.D., Martens, M.A., Wilson, A.G.E, Farmer, D.R.	2008	Genotoxic potential of glyphosate formulations: Mode-of-action investigations Journal of Agricultural and Food Chemistry 56, 1517-1523 GLP: N, published: Y 2309802 / ASB2012-11845	N	LIT
61.	KIIA 5.4.4 KIIA 5.10 (OECD)	Holeckova, B.	2006	Evaluation of the <i>in vitro</i> effect of glyphosate-based herbicide on bovine lymphocytes using chromosome painting Bulletin of the Veterinary Research Institute in Pulawy 50, 533-536 GLP: N, published: Y 2309806 / ASB2012-11847	N	LIT
62.	KIIA 5.4.4 (OECD)	Honarvar, N.	2008	Glyphosate Technical - Micronucleus Assay in Bone Marrow Cells of the Mouse 1158500 SYN GLP: Y, published: N 2309339 / ASB2012-11483	Y	SYN
63.	KIIA 5.4.4 (OECD)	Jensen, J. C.	1991	Mutagenicity test: Micronucleus test with glyphosate, batch 206-JaK-25-1, Report: 12324, published: N, TOX9552374	N	---

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64.	KIIA 5.4.4 KIIA 5.10 (OECD)	Kale, P.G., Petty, B.T., Walker, S., Ford, J.B., Dehkordi, N., Tamasia, S., Tasie, B.O., Kale, R., Sohni, Y.R.	1995	Mutagenicity testing of 9 herbicides and pesticides currently used in agriculture Environmental and Molecular Mutagenesis 25, 148-153 GLP: N, published: Y 2309834 / 273986, ASB2012-11860	N	LIT
65.	KIIA 5.4.4 KIIA 5.10 (OECD)	Kaya, B.; Creus, A.; Yanikoglu, A.; et al.;	2000	Use of the Drosophila wing spot test in the genotoxicity testing of different herbicides ASB2013-9832	N	---
66.	KIIA 5.4.4 (OECD)	Kier, L. D.; Flowers, L. J.; Huffman, M. B.	1992	Mouse micronucleus study of Rodeo herbicide formulation MSL-11772 ! EHL 91201/91205/ML-91-438 TOX9552376	N	---
67.	KIIA 5.4.4 KIIIA1 7.6.3 (OECD)	Kier, L. D.; Flowers, L. J.; Huffman, M. B.	1992	Mouse micronucleus study of Roundup herbicide formulation MSL-11771 ! EHL 91200/91204 ! ML-91-434/ML-91-437 TOX1999-242	N	---
68.	KIIA 5.4 .4 (OECD)	Kier, L. D.; Flowers, L. J.; Huffman, M. B.	1992	Glyphosate: Mouse micronucleus study of DIRECT Herbicide formulation MSL-11773 ! EHL 91202/91206 ! ML-91-436/ML-91-439 TOX1999-322	N	---
69.	KIIA 5.4.4 KIIA 5.10 (OECD)	Knopper, L.D., Lean, D.R.S.	2004	Carcinogenic and genotoxic potential of turf pesticides commonly used on golf courses Journal of Toxicology and Environmental Health-Part B-Critical Reviews 7, 267-279 GLP: N, published: Y 2309864 / ASB2012-11871	N	LIT

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70.	KIIA 5.4.4 KIIA 5.10 (OECD)	Lebailly, P., Devaux, A., Pottier, D., De Meo, M., Andre, V., Baldi, I., Severin, F., Bernaud, J., Durand, B., Henry-Amar, M., Gauduchon, P.	2003	Urine mutagenicity and lymphocyte DNA damage in fruit growers occupationally exposed to the fungicide captan Occupational & Environmental Medicine 60, 910-917 GLP: N, published: Y 2309878 / ASB2012-11878	N	LIT
71.	KIIA 5.4.4 KIIA 5.10 (OECD)	Levine, S.L., Han, Z., Liu, J., Farmer, D.R., Papadopoulos, V.	2007	Disrupting mitochondrial function with surfactants inhibits MA-10 Leydig cell steroidogenesis Cell Biol Toxicol 23, 385-400 GLP: N, published: Y 2309890 / ASB2009-9030	N	LIT
72.	KIIA 5.4.4 (OECD)	Li, A. P.	1983	<i>In vivo</i> bone marrow cytogenetics study of glyphosate in Sprague-Dawley rats, Report: ML-83-236 / 830083, published: N, TOX9552375	N	---
73.	KIIA 5.4.4 KIIA 5.10 (OECD)	Lioi, M. B.; Scarfi, M. R.; Santoro, A.	1998	Genotoxicity and oxidative stress induced by pesticide exposure in bovine lymphocyte cultures <i>in vitro</i> Mutation Research 403 (1998) 13-20 ASB2013-9836	N	LIT
74.	KIIA 5.4.4 KIIA 5.10 (OECD)	Lioi, M. B.; Scarfi, M. R.; Santoro, A.	1998	Cytogenetic damage and induction of pro- oxidant state in human lymphocytes exposed <i>in vitro</i> to glyphosate, vinclozolin, Atrazine and DPX-E9636 Environmental and Molecular Mutagenesis 32: 39-46 (1998) ASB2013-9837	N	LIT
75.	KIIA 5.4.4 KIIA 5.10 (OECD)	Manas, F., Peralta, L., Raviolo, J., Ovandoa, H.G., Weyers, A., Ugnia, L., Cid, M.G., Larripa, I., Gorla, N.	2009	Genotoxicity of glyphosate assessed by the comet assay and cytogenetic tests Environmental Toxicology and Pharmacology 28, 37-41 GLP: N, published: Y 2309908 / ASB2012-11892	N	LIT

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76.	KIIA 5.4.4 KIIA 5.10 KIIIA1 7.6.3 (OECD)	Martinez, T. T.; Brown, K.	1991	Glyphosate: Oral and pulmonary toxicology of the surfactant used in Roundup herbicide Z80636	N	---
77.	KIIA 5.4.4 KIIA 5.11 (OECD)	Mensink, H.; Janssen, P.; WHO	1994	Environmental health criteria 159, Glyphosate TOX9500301	N	---
78.	KIIA 5.4.4 KIIA 5.10 (OECD)	Mladinic, M., Berend, S., Vrdoljak, A.L., Kopjar, N., Radic, B., Zeljezic, D.	2009	Evaluation of genome damage and its relation to oxidative stress induced by glyphosate in human lymphocytes in vitro Environmental and Molecular Mutagenesis 50, 800-807 GLP: N, published: Y 2309942 / ASB2012-11906	N	LIT
79.	KIIA 5.4.4 KIIA 5.10 (OECD)	Mladinic, M., Perkovic, P., Zeljezic, D.	2009	Characterization of chromatin instabilities induced by glyphosate, terbuthylazine and carbofuran using cytome FISH assay Toxicol Lett 189, 130-137 GLP: N, published: Y 2309944 / ASB2012-11907	N	LIT
80.	KIIA 5.4.4 KIIA 5.10 (OECD)	Monroy, C., Cortes, A., Sicard, D., de Restrepo, H.	2005	Cytotoxicity and genotoxicity of human cells exposed <i>in vitro</i> to glyphosate Biomedica 25, 335-345 GLP: N, published: Y 2309950 / ASB2012-11910	N	LIT
81.	KIIA 5.4.4 KIIA 5.10 (OECD)	Pastor, S., Creus, A., Parron, T., Cebulska-Wasilewska, A., Siffel, C., Piperakis, S., Marcos, R.	2003	Biomonitoring of four European populations occupationally exposed to pesticides: use of micronuclei as biomarkers Mutagenesis 18, 249-258 GLP: N, published: Y 2310004 / ASB2012-11991	N	LIT
82.	KIIA 5.4.4 (OECD)	Patel, N. N.	2012	Micronucleus test of Glyphosate TGAI in mice 120709 ! 485-1-06-4696 ! DR-0112-6927-003 ! 10001701-27-1 ASB2014-9277		

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83.	KIIA 5.4.4 KIIA 5.10 (OECD)	Paz-Y-Mina, C., Sanchez, M.E., Arevalo, M., Munoz, M.J., Witte, T., De- La-Carrera, G.O., Leone, P.E.	2007	Evaluation of DNA damage in an Ecuadorian population exposed to glyphosate Genetics and Molecular Biology 30, 456-460 GLP: N, published: Y 2310006 / ASB2012-11992	N	LIT
84.	KIIA 5.4.4 KIIA 5.10 KIIIA1 7.6.3 (OECD)	Peluso, M., Munnia, A., Bolognesi, C., Parodi, S.	1998	32P-postlabeling detection of DNA adducts in mice treated with the herbicide Roundup Environmental and Molecular Mutagenesis 31, 55-59 GLP: N, published: Y 2310014 / TOX1999-318	N	LIT
85.	KIIA 5.4.4 KIIA 5.10 (OECD)	Piesova, E.	2004	The Influence Of Different Treatment Length On the Induction Of Micronuclei In Bovine Lymphocytes After Exposure To Glyphosate Folia Veterinaria 48, 130-134 GLP: N, published: Y 2310026 / ASB2012-12001	N	LIT
86.	KIIA 5.4.4 KIIA 5.10 (OECD)	Piesova, E.	2005	The effect of glyphosate on the frequency of micronuclei in bovine lymphocytes <i>in vitro</i> Acta Veterinaria-Beograd 55, 101-109 GLP: N, published: Y 2310024 / ASB2012-12000	N	LIT
87.	KIIA 5.4.4 KIIA 5.10 (OECD)	Poletta, G.L., Larriera, A., Kleinsorge, E., Mudry, M.D.	2009	Genotoxicity of the herbicide formulation Roundup (R) (glyphosate) in broad-snouted caiman (<i>Caiman latirostris</i>) evidenced by the Comet assay and the Micronucleus test Mutation Research-Genetic Toxicology and Environmental Mutagenesis 672, 95-102 GLP: N, published: Y 2310028 / ASB2012-12002	N	LIT
88.	KIIA 5.4.4 KIIA 5.10 (OECD)	Prasad, S., Srivastava, S., Singh, M., Shukla, Y.	2009	Clastogenic effects of glyphosate in bone marrow cells of swiss albino mice J Toxicol GLP: N, published: Y 2310034 / ASB2012-12005	N	LIT

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89.	KIIA 5.4.4 KIIA 5.10 (OECD)	Raipulis, J., Toma, M., Balode, M.	2009	Toxicity and genotoxicity testing of Roundup Proceedings of the Latvian Academy of Sciences. Section B. Natural, Exact, and Applied Sciences. 63, 29-32 GLP: N, published: Y 2310040 / ASB2012-12008	N	LIT
90.	KIIA 5.4.4 KIIA 5.10 (OECD)	Rodrigues, H.G., Penha- Silva, N., Araujo, M.F.P, Nishijo, H., Aversi-Ferreira, T.A.	2011	Effects of Roundup Pesticide on the Stability of Human Erythrocyte Membranes and Micronuclei Frequency in Bone Marrow Cells of Swiss Mice Open Biology Journal 54-59 GLP: N, published: Y 2310046 / ASB2012-12010	N	LIT
91.	KIIA 5.4.4 (OECD)	Roth, M.		Glyphosate technical - Micronucleus assay in bone marrow cells of the mouse 1479200 I TK011298I ASB2014-9333		
92.	KIIA 5.4.4 KIIA 5.10 (OECD)	Salvagni, J., Ternus, R., Fuentefria, A.	2011	Assessment of the genotoxic impact of pesticides on farming communities in the countryside of Santa Catarina State, Brazil Genetics and Molecular Biology 34, 122-126 GLP: N, published: Y 2310060 / ASB2012-12017	N	LIT
93.	KIIA 5.4.4 KIIA 5.9 KIIIA 1 7.6.3 (OECD)	Sawada, Y., Nagai, Y.	1987	Roundup® poisoning - its clinical observation possible involvement - englische Version Journal of Clinical and Experimental Medicine (paper) 143, 25-27 GLP: N, published: Y 2309502 / Z35531	N	LIT
94.	KIIA 5.4.4 KIIA 5.10 (OECD)	Shaham, J., Kaufman, Z., Gurvich, R., Levi, Z.	2001	Frequency of sister-chromatid exchange among greenhouse farmers exposed to pesticides Mutat Res 491-, 71-80 GLP: N, published: Y 2310076 / ASB2012-12025	N	LIT
95.	KIIA 5.4.4 KIIA 5.10 (OECD)	Sivikova, K., Dianovsky, J.	2006	Cytogenetic effect of technical glyphosate on cultivated bovine peripheral lymphocytes Int J Hyg Environ Health 209, 15-20 GLP: N, published: Y 2310084 / ASB2012-12029	N	LIT

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96.	KIIA 5.4.4 KIIA 5.8.1 (OECD)	Stammberger, I.;	1992	Dodigen 4022: Chromosome aberrations in vitro in V79 chinese hamster cells 92.1024 ! 92.0337 TOX1999-325	N	---
97.	KIIA 5.4.4 KIIA 5.8.1 (OECD)	Stammberger, I.; Mayer, D.	1992	Dodigen 4022: Study of the mutagenic potential in strains of <i>Salmonella typhimurium</i> (ames test) and <i>Escherichia coli</i> 92.0487 ! 92.0336 TOX1999-324	N	---
98.	KIIA 5.4.4 KIIA 5.10 KIIIA1 7.6.3 (OECD)	Stegeman, S. D.; Kier, L. D.	1998	Mouse micronucleus screening assay of MON 0818 ML-89-463 ! EHL 89182 TOX1999-240	N	---
99.	KIIA 5.4.4 KIIIA1 7.6.3 (OECD)	Stegeman, S. D.; Li, A. P.	1990	Ames/salmonella mutagenicity assay of MON 0818 EHL 89178 ! ML-89-461 ! MSL-10625 TOX1999-241	N	---
100.	KIIA 5.4.4 (OECD)	Suresh, T.P.	1993	Glyphosate technical (FSG 03090 H/05 March 1990): Mutagenicity-micronucleus test in swiss albino mice, Report: 889-MUT.MN ! TOXI-889/1993 ! ES-GPT-MUT-MN, published: N, TOX9551100	N	---
101.	KIIA 5.4.4 (OECD)	Suresh, T. P.; Ponnanna, D.; Asha, M. et al.	1994	Glyphosate technical (FSG 03090 H/05 March 1990): Genetic toxicology - <i>In vivo</i> mammalian bone marrow cytogenetic test, Report: 890-MUT-CH.AB ! TOXI-890/1993 ! ES-GPT-MUT-CH.AB, published: N, TOX9400323 / TOX9551101	N	---
102.	KIIA 5.4.4 KIIA 5.10 (OECD)	Vigfusson, N.V., Vyse, E.R.	1980	The effect of the pesticides Dexon, Captan and Roundup on sister chromatid exchanges in human lymphocytes <i>in vitro</i> Mutation Research 79, 53-57 GLP: N, published: Y 2310114 / TOX970056 / ASB2012-12044	N	LIT
103.	KIIA 5.4.4 KIIA 5.10 (OECD)	Vlastos, D., Stivaktakis, P., Matthopoulos, D.P.	2006	Pesticide exposure and genotoxicity correlations within a Greek farmers' group International Journal of Environmental Analytical Chemistry 86, 215-223 GLP: N, published: Y 2310116 / ASB2012-12045	N	LIT

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104.	KIIA 5.4.4 KIIA 5.5.3 KIIA 5.10 KIIIAI 7.6.3 (OECD)	Williams, G.M., Kroes, R., Munro, I.C.	2000	Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans Regulatory Toxicology and Pharmacology 31, 117-165 GLP: N, published: Y 2310132 / ASB2012-12053	N	LIT
105.	KIIA 5.4.4 (OECD)	Zaccaria, C. B.; Vargas, A. A. T.	1996	A micronucleus study in mice for the product GILFOS G1206096 ! G.1.2 - 60/96 TOX1999-253	N	---
106.	KIIA 5.4.4 (OECD)	Zoriki Hosomi, R.	2007	Mammalian Erythrocyte Micronucleus Test for Glifosato Técnico Helm 3393/2007-3.0MN-B ASB2012-11480		
107.	KIIA 5.4.6 (OECD)	Suresh, T. P. et al.	1992	Glyphosate technical (FSG 03090 H/05, March 1990): Dominant lethal test in wistar rats Report: 888-DLT ! TOXI-888/1992 ! ES-GPT-DLT, published: N, TOX9551102	N	---
108.	KIIA 5.4.6 (OECD)	Wrenn, J. M.; Rodwell, D. E.; Jessup, D. C.	1980	Dominant lethal mutagenicity assay with technical Glyphosate in mice, Report: 401-064 ! IR-79-014, published: N, TOX9552377	N	---
109.	KIIA 5.5 (OECD)	Anon.	2015	Lesion-related incidence data. RITA database ASB2015-2532		
110.	KIIA 5.5 (OECD)	Eaton, G.; Johnson, F. N.; Custer, R. P.; Crane, A. R.	1980	The 1cr:Ha(ICR) mouse: a current account of breeding, mutations, diseases and mortality Lab. Animals 14(1980)17-24 ASB2015-2537		LIT
111.	KIIA 5.5 (OECD)	Giknis, M. L. A.; Clifford, C. B.	2010	Spontaneous neoplastic lesions in the Crl:CD1 (ICR) mouse in control groups from 18 month to 2 year studies Selected pages ASB2015-2529		
112.	KIIA 5.5 (OECD)	Greim, H.; Saltmiras, D.; Mostert, V.; Strupp, C.	2015	Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies Crit Rev Toxicol, 2015; 45(3): 183-208 ASB2015-2287		LIT

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113.	KIIA 5.5 (OECD)	Roe, F. J. C.; Tucker, M. J.;	1974	Recent developments in the design of carcinogenicity tests on laboratory animals Proc. Europ. Soc. Stud. Drug Tox., 15:171-177 (1974) ASB2015-2534		LIT
114.	KIIA 5.5 (OECD)	Sher, S. P.	1974	Review article - Tumors in control mice: Literature tabulation Toxicol. Appl. Pharmacol. 30(1974)337-359 Z22020		LIT
115.	KIIA 5.5 (OECD)	Son, W.-C.; Gopinath, C.;	2004	Early occurrence of spontaneous tumors in CD-1 mice and Sprague-Dawley rats Toxicologic Pathology, 32:371-374, 2004 ASB2015-2533		LIT
116.	KIIA 5.5 (OECD)	Taddesse- Heath, L.; Chattopadhyay, S. K.; Dillehay, D. L.; et al.;	2000	Lymphomas and high-level expression of murine leukemia viruses in CFW mice J. Virol. 74(2000)15:6832-6837 ASB2015-2535		LIT
117.	KIIA 5.5 (OECD)	Toth, B.; Rappaport, H.; Shubik, P.;	1963	Influence of dose and age on the induction of malignant lymphomas and other tumors by 7,12-Dimethylbenz(a)anthracene in Swiss mice J. Nat. Cancer Institute, 30(1963)4:723-732 ASB2015-2536		LIT
118.	KIIA 5.5 (OECD)	Tucker, M. J.	1979	The effect of long-term food restriction on tumours in rodents Int. J. Cancer: 23, 803-807 (1979) Z83266		LIT
119.	KIIA 5.5 (OECD)	Wood, E.;	2010	Historical Incidence of Malignant lymphoma in CD-1 Mouse ASB2015-2531		
120.	KIIA 5.5.1 KIIA 5.10 (OECD)	Milburn, G.M.	1996	Glyphosate Acid: One Year Dietary Toxicity Study in Rats CTL/P/5143 SYN GLP: Y, published: N 2309341 / TOX2000-1998	N	SYN
121.	KIIA 5.5.2 (OECD)	Atkinson, C., Strutt, A. V., Henderson, W., Fich, J., Hudson, P.	1993	Glyphosate - 104 week combined chronic feeding / oncogenicity study in rats with 52 week interim kill (results after 104 weeks) 7867 CHE GLP: Y, published: N 2309374 / TOX9750499	N	CHE

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122.	KIIA 5.5.2 KIIA 5.10 (OECD)	Brammer, A.	2001	Glyphosate Acid: Two Year Dietary Toxicity and Oncogenicity Study in Rats CTL/PR1111 SYN GLP: Y, published: N 2309368 / ASB2012-11488	N	SYN
123.	KIIA 5.5.2 (OECD)	Calandra, J. C.	1974	2-year chronic oral toxicity study with CP 67573 in albino rats B564 ! BTL-71-32 Z35230	N	---
124.	KIIA 5.5.2 (OECD)	Enomoto, A.	1997	HR-001: 24-Month Oral Chronic Toxicity and Oncogenicity Study in Rats, Vol. 1 (Seite 1-500) IET 94-0150 Vol.1 ALS GLP: Y, published: N 2309360 / ASB2012-11484	N	ALS
125.	KIIA 5.5.2 (OECD)	Enomoto, A.	1997	HR-001: 24-Month Oral Chronic Toxicity and Oncogenicity Study in Rats, Vol. 2 (Seite 501-1000) IET 94-0150 Vol. 2 ALS GLP: Y, published: N 2309362 / ASB2012-11485	N	ALS
126.	KIIA 5.5.2 (OECD)	Enomoto, A.	1997	HR-001: 24-Month Oral Chronic Toxicity and Oncogenicity Study in Rats, Vol.3 (Seite 1001-1500) IET 94-0150 Vol. 3 ALS GLP: Y, published: N 2309364 / ASB2012-11486	N	ALS
127.	KIIA 5.5.2 (OECD)	Enomoto, A.	1997	HR-001: 24-Month Oral Chronic Toxicity and Oncogenicity Study in Rats, Vol. 4 (Seite 1501-2051) IET 94-0150 Vol. 4 ALS GLP: Y, published: N 2309366 / ASB2012-11487	N	ALS
128.	KIIA 5.5.2 (OECD)	Stout, L.D., Ruecker, F.A.	1990	Chronic study of glyphosate administered in feed to Albino rats MSL-10495 MON GLP: Y, published: N 2309384 / TOX9300244	N	MON

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129.	KIIA 5.5.2 (OECD)	Suresh, T.P.	1996	Combined Chronic Toxicity and Carcinogenicity Study with Glyphosate Technical in Wistar Rats TOXI:886.C.C-R FSG GLP: Y, published: N 2309343 / TOX9651587 / TOX9600015	N	ADM
130.	KIIA 5.5.2 (OECD)	Wood, E., Dunster, J., Watson, P. Brooks, P.	2009	Glyphosate Technical: Dietary combined chronic toxicity / carcinogenicity study in the rat SPL2060-0012 NUF GLP: Y, published: N 2309391 / ASB2012-11490	Y	NUF
131.	KIIA 5.5.3 KIIA 5.10 (OECD)	Acquavella, J.F., Gustin, C., Alexander, B.H., Mandel, J.S.	2005	Implications for epidemiologic research on variation by pesticide in studies of farmers and their families Scandinavian Journal of Work Environment & Health 31, 105-109 GLP: N, published: Y 2309540 / ASB2012-11530	N	LIT
132.	KIIA 5.5.3 KIIA 5.10 (OECD)	Alavanja, M.C., Samanic, C., Dosemeci, M., Lubin, J., Tarone, R., Lynch, C.F., Knott, C., Thomas, K., Hoppin, J.A., Barker, J., Coble, J., Sandler, D.P., Blair, A.	2003	Use of agricultural pesticides and prostate cancer risk in the Agricultural Health Study cohort Am J Epidemiol 157, 800-814 GLP: N, published: Y 2309554 / ASB2012-11535	N	LIT
133.	KIIA 5.5.3 KIIA 5.10 (OECD)	Andreotti, G., Freeman, L.E.B., Hou, L., Coble, J., Rusiecki, J., Hoppin, J.A., Silverman, D.T., Alavanja, M.C.R.	2009	Agricultural pesticide use and pancreatic cancer risk in the Agricultural Health Study Cohort International Journal of Cancer 124, 2495- 2500 GLP: N, published: Y 2309572 / ASB2012-11544	N	LIT

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134.	KIIA 5.5.3 (OECD)	Atkinson, C.; Martin, T.; Hudson, P.; Robb, D.	1993	Glyphosate: 104-week dietary carcinogenicity study in mice 7793 ! IRJ 438618 TOX9552382	N	---
135.	KIIA 5.5.3 KIIA 5.10 (OECD)	Band, P.R., Abanto, Z., Bert, J., Lang, B., Fang, R., Gallagher, R.P., Le, N.D.	2011	Prostate Cancer Risk and Exposure to Pesticides in British Columbia Farmers Prostate 71, 168-183 GLP: N, published: Y 2309594 / ASB2012-11555	N	LIT
136.	KIIA 5.5.3 KIIA 5.10 (OECD)	Barale-Thomas, E.;	2012	Letter to the editor Food and Chemical Toxicology 53 (2013) 473-474 ASB2013-10998	N	LIT
137.	KIIA 5.5.3 KIIA 5.10 (OECD)	Berry, C.;	2012	Letter to the editor Food and Chemical Toxicology 53 (2013) 445-446 ASB2013-10988	N	LIT
138.	KIIA 5.5.3 KIIA 5.10 (OECD)	Blair, A., Freeman, L.B.	2009	Epidemiologic Studies in Agricultural Populations: Observations and Future Directions Journal of Agromedicine 14, 125-131 GLP: N, published: Y 2309618 / ASB2012-11566	N	LIT
139.	KIIA 5.5.3 KIIA 5.10 (OECD)	Carreon, T., Butler, M.A., Ruder, A.M., Waters, M.A., Davis-King, K.E., Calvert, G.M., Schulte, P.A., Connally, B., Ward, E.M., Sanderson, W.T., Heinemann, E.F., Mandel, J.S., Morten, R.F., Reding, D.J., Rosenmann, K.D., Talaska, G.	2005	Gliomas and farm pesticide exposure in women: The Upper Midwest Health Study Environmental Health Perspectives 113, 546- 551 GLP: N, published: Y 2309660 / ASB2012-11585	N	LIT

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140.	KIIA 5.5.3 KIIA 5.10 (OECD)	McDuffie, H.H., Pahwa, P., McLaughlin, J.R., Spinelli, J.J., Fincham, S., Dosman, J.A., Robson, D., Skinnider, L.F., Choi, N.W.	2001	Non-Hodgkin's lymphoma and specific pesticide exposures in men: cross-Canada study of pesticides and health Cancer Epidemiol Biomarkers Prev 10, 1155- 1163 GLP: N, published: Y 2309924 / ASB2011-364	N	LIT
141.	KIIA 5.5.3 KIIA 5.10 (OECD)	Engel, L.S., Hill, D.A., Hoppin, J.A., Lubin, J.H., Lynch, C.F., Pierce, J., Samanic, C., Sandler, D.P., Blair, A., Alavanja, M.C.	2005	Pesticide use and breast cancer risk among farmers' wives in the agricultural health study American Journal of Epidemiology 161, 121- 135 GLP: N, published: Y 2309720 / ASB2012-11613	N	LIT
142.	KIIA 5.5.3 KIIA 5.10 (OECD)	Eriksson, M., Hardell, L., Carlberg, M., Akerman, M.	2008	Pesticide exposure as risk factor for non- Hodgkin lymphoma including histopathological subgroup analysis Int J Cancer 123, 1657-1663 GLP: N, published: Y 2309722 / ASB2012-11614	N	LIT
143.	KIIA 5.5.3 KIIA 5.10 (OECD)	Farmer, D.R., Lash, T.L., Acquavella, J.F.	2005	Glyphosate Results Revisited Environmental Health Perspectives 113, A365-A366 GLP: N, published: Y 2309726 / ASB2012-11616	N	LIT
144.	KIIA 5.5.3 KIIA 5.10 (OECD)	Flower, K.B., Hoppin, J.A., Lynch, C.F., Blair, A., Knott, C., Shore, D.L., Sandler, D.P.	2004	Cancer risk and parental pesticide application in children of agricultural health study participants Environmental Health Perspectives 112, 361- 635 GLP: N, published: Y 2309734 / ASB2012-11620	N	LIT

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145.	KIIA 5.5.3 KIIA 5.10 (OECD)	Freeman, L.B.	2009	Evaluation of agricultural exposures: the agricultural health study and the agricultural cohort consortium Reviews on Environmental Health 24, 311-318 GLP: N, published: Y 2309740 / ASB2012-11623	N	LIT
146.	KIIA 5.5.3 KIIA 5.10 (OECD)	Fritschi, L., Benke, G., Hughes, A.M., Krickler, A., Turner, J., Vajdic, C.M., Grulich, A., Milliken, S., Kaldor, J., Armstrong, B.K.	2005	Occupational exposure to pesticides and risk of non-Hodgkin's lymphoma American Journal of Epidemiology 162, 849-857 GLP: N, published: Y 2309746 / ASB2012-11624	N	LIT
147.	KIIA 5.5.3 KIIA 5.10 (OECD)	George, J., Prasad, S., Mahmood, Z., Shukla, Y.	2010	Studies on glyphosate-induced carcinogenicity in mouse skin: a proteomic approach J Proteomics 73, 951-964 GLP: N, published: Y 2309766 / ASB2012-11829	N	LIT
148.	KIIA 5.5.3 KIIA 5.10 (OECD)	Grunewald, W.;	2012	Letter to the editor Food and Chemical Toxicology 53 (2013) 447-448 ASB2013-11001	N	LIT
149.	KIIA 5.5.3 KIIA 5.10 (OECD)	Hammond, B.; Goldstein, D. A.; Saltmiras, D.;	2012	Letter to the editor Food and Chemical Toxicology 53 (2013) 459-464 ASB2013-10995	N	LIT
150.	KIIA 5.5.3 KIIA 5.10 (OECD)	Hardell, L., Eriksson, M.	1999	A case-control study of non-Hodgkin lymphoma and exposure to pesticides Cancer 85, 1353-1360 GLP: N, published: Y 2309788 / ASB2012-11838	N	LIT
151.	KIIA 5.5.3 KIIA 5.10 (OECD)	Hardell, L., Eriksson, M., Nordstrom, M.	2002	Exposure to pesticides as risk factor for non-Hodgkin's lymphoma and hairy cell leukemia: Pooled analysis of two Swedish case-control studies Leukemia & Lymphoma 43, 1043-1049 GLP: N, published: Y 2309790 / ASB2012-11839	N	LIT

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152.	KIIA 5.5.3 KIIA 5.10 (OECD)	Heinemann, J. A.;	2012	Letter to the editor Food and Chemical Toxicology 53 (2013) 442 ASB2013-10987	N	LIT
153.	KIIA 5.5.3 KIIA 5.10 (OECD)	Karunanayake, C.P., Spinelli, J.J., McLaughlin, J.R., Dosman, J.A., Pahwa, P., McDuffie, H.H.	2011	Hodgkin Lymphoma and Pesticides Exposure in Men: A Canadian Case-Control Study Journal of Agromedicine 17, 30-39 GLP: N, published: Y 2309844 / ASB2012-11865	N	LIT
154.	KIIA 5.5.3 (OECD)	Knezevich, A. L.; Hogan, G. K.	1983	A chronic feeding study of glyphosate (Roundup technical) in mice 77-2061 ! (BDN-77-420) TOX9552381	N	---
155.	KIIA 5.5.3 (OECD)	Kumar, D.P.S.	2001	Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice TOXI: 1559.CARCI-M FSG GLP: Y, published: N 2309396 / ASB2012-11491	Y	ADM
156.	KIIA 5.5.3 KIIA 5.10 (OECD)	Landgren, O., Kyle, R.A., Hoppin, J.A., Freeman, L.E.B., Cerhan, J.R., Katzmann, J.A., Rajkumar, S.V., Alavanja, M.C.	2009	Pesticide exposure and risk of monoclonal gammopathy of undetermined significance in the Agricultural Health Study Blood 113, 6386-6391 GLP: N, published: Y 2309874 / ASB2012-11875	N	LIT
157.	KIIA 5.5.3 KIIA 5.10 (OECD)	Langridge, P.;	2012	Letter to the editor Food and Chemical Toxicology 53 (2013) 441 ASB2013-10986	N	LIT
158.	KIIA 5.5.3 KIIA 5.10 (OECD)	Lash, T.L.	2007	Bias analysis applied to Agricultural Health Study publications to estimate non-random sources of uncertainty J Occup Med Toxicol 2, 1-9 GLP: N, published: Y 2309876 / ASB2012-11877	N	LIT

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159.	KIIA 5.5.3 KIIA 5.10 (OECD)	Lee, W.J., Lijinsky, W., Heineman, E.F., Markin, R.S., Weisenburger, D.D., Ward, M.H.	2004	Agricultural pesticide use and adenocarcinomas of the stomach and oesophagus Occupational and Environmental Medicine 61 (9):743-749 61, 743-749 GLP: N, published: Y 2309888 / ASB2012-11883	N	LIT
160.	KIIA 5.5.3 KIIA 5.10 (OECD)	Lee, W.J., Colt, J.S., Heineman, E.F., McComb, R., Weisenburger, D.D., Lijinsky, W., Ward, M.H.	2005	Agricultural pesticide use and risk of glioma in Nebraska, United States Occupational and Environmental Medicine 62, 786-792 GLP: N, published: Y 2309886 / ASB2012-11882	N	LIT
161.	KIIA 5.5.3 KIIA 5.10 (OECD)	Monge, P., Wesseling, C., Guardado, J., Lundberg, I., Ahlbom, A., Cantor, K.P., Weideroass, E., Partanen, T.	2007	Parental occupational exposure to pesticides and the risk of childhood leukemia in Costa Rica Scandinavian Journal of Work Environment & Health 33, 293-303 GLP: N, published: Y 2309948 / ASB2012-11909	N	LIT
162.	KIIA 5.5.3 KIIA 5.10 (OECD)	Multigner, L., Ndong, J.R., Oliva, A., Blanchet, P.	2008	Environmental pollutants and prostate cancer: epidemiological data Gynecol Obstet Fertil 36, 848-856 GLP: N, published: Y 2309964 / ASB2012-11917	N	LIT
163.	KIIA 5.5.3 KIIA 5.10 (OECD)	Ndong, J.R., Blanchet, P., Multigner, L.	2009	Pesticides and prostate cancer: epidemiological data Bulletin Du Cancer 96, 171-180 GLP: N, published: Y 2309974 / ASB2012-11922	N	LIT
164.	KIIA 5.5.3 KIIA 5.10 (OECD)	Nordström, M., Hardell, L., Magnuson, A., Hagberg, H., Rask-Andersen, A.	1998	Occupational exposures, animal exposure and smoking as risk factors for hairy cell leukaemia evaluated in a case-control study TOX1999-687	N	---
165.	KIIA 5.5.3 KIIA 5.10 (OECD)	Ollivier, L.,	2012	Letter to the editor Food and Chemical Toxicology 53 (2013) 458 ASB2013-11000	N	LIT

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166.	KIIA 5.5.3 KIIA 5.10 (OECD)	Pahwa, P., Karunanayake, C.P., Dosman, J.A., Spinelli, J.J., McDuffie, H.H., McLaughlin, J.R.	2011	Multiple Myeloma and Exposure to Pesticides: A Canadian Case-Control Study Journal of Agromedicine 17, 40-50 GLP: N, published: Y 2309996 / ASB2012-11987	N	LIT
167.	KIIA 5.5.3 KIIA 5.10 (OECD)	Panchin, A. Y.;	2013	Toxicity of roundup-tolerant genetically modified maize is not supported by statistical tests Food and Chemical Toxicology 53 (2013) 475 ASB2013-10937	N	LIT
168.	KIIA 5.5.3 KIIA 5.10 (OECD)	Pilu, R.;	2012	Letter to the editor Food and Chemical Toxicology 53 (2013) 454 ASB2013-10992	N	LIT
169.	KIIA 5.5.3 KIIA 5.10 (OECD)	De Roos, A.J., Blair, A., Rusiecki, J.A., Hoppin, J.A., Svec, M., Dosemeci, M., Sandler, D.P., Alavanja, M.C.	2005	Cancer incidence among glyphosate-exposed pesticide applicators in the agricultural health study Environmental Health Perspectives 113, 49- 54 GLP: N, published: Y 2309704 / ASB2012-11605	N	LIT
170.	KIIA 5.5.3 KIIA 5.10 (OECD)	De Roos, A.J., Zahm, S.H., Cantor, K.P., Weisenburger, D.D., Holmes, F.F., Burmeister, L.F., Blair, A.	2003	Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men Occupational and Environmental Medicine 60 GLP: N, published: Y 2309706 / ASB2012-11606	N	LIT
171.	KIIA 5.5.3 KIIA 5.10 (OECD)	Schorsch, F.;	2012	Letter to the editor Food and Chemical Toxicology 53 (2013) 465-466 ASB2013-10996	N	LIT

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172.	KIIA 5.5.3 KIIA 5.10 (OECD)	Séralini, G.-E.; Clair, E.; Mesnage, R.; Gress, S.; Defarge, N.; Malatesta, M.; Hennequin, D.; Spiroux de Vendômois, J.;	2012	Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. Food and Chem Toxicol., in Press, ASB2012-15514	N	---
173.	KIIA 5.5.3 KIIA 5.10 (OECD)	Séralini, G. E.; Mesnage, R.; Defarge, N.; Gress, S.; Hennequin, D.; Clair, E.; Malatesta, M.; Spiroux de Vendômois, J.;	2013	Answers to critics: Why there is a long term toxicity due to a Rounduptolerant genetically modified maize and to a Roundup herbicide Food and Chemical Toxicology 53 (2013) 476–483 ASB2013-10985	N	LIT
174.	KIIA 5.5.3 KIIA 5.10 (OECD)	de Souza, L.;	2012	Letter to the editor Food and Chemical Toxicology 53 (2013) 440 ASB2013-10999	N	LIT
175.	KIIA 5.5.3 (OECD)	Sugimoto, K.	1997	HR-001: 18-Month Oral Oncogenicity Study in Mice IET 940151 ALS GLP: Y, published: N 2309415 / ASB2012-11493	Y	ALS
176.	KIIA 5.5.3 KIIA 5.10 (OECD)	Tester, M.;	2012	Letter to the Editor Food and Chemical Toxicology 53 (2013) 457 ASB2013-10994	N	LIT
177.	KIIA 5.5.3 KIIA 5.10 (OECD)	Tien, D. L.; Huy, H. L.;	2012	Comments on "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize" Food and Chemical Toxicology 53 (2013) 443–444 ASB2013-10984	N	LIT
178.	KIIA 5.5.3 KIIA 5.10 (OECD)	Trewavas, A.;	2012	Letter to the editor Food and Chemical Toxicology 53 (2013) 449 ASB2013-10989	N	LIT
179.	KIIA 5.5.3 KIIA 5.10 (OECD)	Tribe, D.;	2012	Letter to the editor Food and Chemical Toxicology 53 (2013) 467–472 ASB2013-10997	N	LIT

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180.	KIIA 5.5.3 KIIA 5.10 (OECD)	Wager, R.;	2013	Letter to the editor Food and Chemical Toxicology 53 (2013) 455-456 ASB2013-10993	N	LIT
181.	KIIA 5.5.3 KIIA 5.10 (OECD)	Weichenthal, S., Moase, C., Chan, P.	2010	A review of pesticide exposure and cancer incidence in the Agricultural Health Study cohort Environ Health Perspect 118, 1117-1125 GLP: N, published: Y 2310122 / ASB2012-12048	N	LIT
182.	KIIA 5.5.3 (OECD)	Wood, E., Dunster, J., Watson, P., Brooks, P.	2009	Glyphosate Technical: Dietary carcinogenicity study in the mouse SPL 2060-0011 NUF GLP: Y, published: N 2309412 / ASB2012-11492	Y	NUF

