

1_PAD 2017/036 Glyphosate CEO

Correspondence with Knoell Consult GmbH

From: knoell.com>
Sent: 20 October 2015 12:32
To:
Cc:
Subject: AW: glyphosate
Importance: High

Sehr geehrter ,
diesen Freitag, 23.10, an dem Knoell für die Glyphosate Task Force den 'EFSA draft review report' über das EFSA Data Management System bekommen soll, bin ich leider verhindert werde nicht im Haus sein.
Ich möchte Sie bitten, Ihre mail mit den Zugangsdaten an folgende beiden Personen zu mailen:

Beide sind im e-mail header einkopiert und mit der Sache vertraut.

Vielen Dank für Ihr Verständnis.

Mit freundlichen Grüßen

Tel.:
Fax:
E-Mail: knoell.com
Dr. Knoell Consult GmbH, Marie-Curie-Straße 8, 51377 Leverkusen, Deutschland

Von: @efsa.europa.eu]
Gesendet: Montag, 19. Oktober 2015 13:32
An:
Betreff: glyphosate

Sehr geehrter ,

Könnten wir noch mal kurz telefonieren (heute oder morgen)?

Gruß

Scientific Officer
Pesticides / Regulated Products




European Food Safety Authority

Via Carlo Magno 1A

43126 Parma (Italy)

Tel.

www.efsa.europa.eu

twitter.com/EFSA_EU 

youtube.com/EFSAchannel 

From: knoell.com>
Sent: 30 October 2015 11:45
To:
Subject: AW: Glyphosat_Zeit zur Prüfung des review reports
Importance: High

Sehr geehrter ,

können Sie abschätzen, wann heute die Dokumente zur Verfügung stehen? - es ist bald mittag.
Bisher habe ich keine e-mail erhalten noch sind Dokumente auf das DMS hochgeladen..

Vielen Dank für Ihre Antwort.

Mit freundlichen Grüßen

Dr. Knoell Consult GmbH, Marie-Curie-Straße 8, 51377 Leverkusen, Deutschland

Von: @efsa.europa.eu]
Gesendet: Montag, 26. Oktober 2015 16:03
An:
Betreff: AW: Glyphosat_Zeit zur Prüfung des review reports

Sehr geehrter ,

Für die EFSA conclusion bekommen Sie 5 Tage, für die revidierte Monographie (revised RAR, oder final addendum),
sowie für den Peer Review Report 14 Tage.
Der Review Report ist ein Dokument der Kommission und wird erst zu Abstimmung vorbereitet.

Herzliche Grüße

Scientific Officer
Pesticides / Regulated Products
Via Carlo Magno 1A
43126 Parma (Italy)

www.efsa.europa.eu<<http://www.efsa.europa.eu>>

Von: [<@knoell.com>](mailto:@knoell.com)
Gesendet: Montag, 26. Oktober 2015 15:10:12
An:
Betreff: Glyphosat_Zeit zur Prüfung des review reports

Sehr geehrter ,
wir sprachen über die 14 Tage Zeit für Schwärzungsarbeiten des RAR + background information.
Wir gehen davon aus, dass wir das zeitlich hinbekommen.

Bezügl. des checks des review report haben wir jedoch aufgrund der Einbeziehung der vielen GTF Mitglieder Bedenken, dass wir es innerhalb der 5 Werktage hinbekommen.
Könnten Sie uns das Wochenende zusätzlich einräumen, sprich Rückantwort unsererseits Montag, den 9. November?

Vielen Dank für Ihre Rückmeldung.

Mit freundlichen Grüßen

Dr. Knoell Consult GmbH, Marie-Curie-Straße 8, 51377 Leverkusen, Deutschland

From: @knoell.com>
Sent: 02 November 2015 13:28
To:
Cc:
Subject: AW: glyphosate (AIRII): EFSA conclusion on the peer review of the risk assessment
Importance: High

Dear ,
I confirm receipt of the documents. We have started the work.
Could you please confirm that for background documents in folders 4302pr and termed

-
01 comments on assessment report and addendum 1

Or
02 reporting tables and commenting table on addendum 1

a sanitization is n o t requested for commenting tables referring to Vol 4 as they are not meant for publication?

Thanks and best regards

Dr. Knoell Consult GmbH, Marie-Curie-Straße 8, 51377 Leverkusen, Deutschland

Von: @efsa.europa.eu] **Im Auftrag von EFSA PESTICIDES PEER REVIEW**
Gesendet: Freitag, 30. Oktober 2015 15:57
An:
Cc: EFSA PESTICIDES PEER REVIEW;
Betreff: glyphosate (AIRII): EFSA conclusion on the peer review of the risk assessment

Dear Sir,

EFSA has now finalised and forwarded to the European Commission the EFSA conclusion on the risk assessment for the active substance **glyphosate** (AIRII). The conclusion text and the list of endpoints are provided as a merged document.

Please note that this pre-notification of the conclusion is exclusively addressed to the specified recipients, under embargo, for the purpose of consideration of any justified requests for removal of confidential information prior to publication on the EFSA website, and no further disclosure/publication to any third party can take place.

In the interests of efficiency, the EFSA conclusion and background documents are available for downloading from a unique project in our Document Management System (DMS) using the following username and using the link to set your personal password for access to the DMS project:

Link for password setting:

<https://sciencenet.efsa.europa.eu/sumt/pages/lostPassword.jsp>

Username:

DMS Project name and link:

<https://dms.efsa.europa.eu/otcs/livelink.exe?func=ll&objId=14793301&objAction=browse>

We would like to give you the opportunity to remove confidential data from the EFSA conclusion and background documents. This can be done electronically (preferred procedure) in the dispatched files, using a redaction software tool that blackens the relevant text and fully removes the underlying information from the document. The removal is crucial as EFSA will make the files, as prepared and provided by you, publicly available on its website after checking the eligibility of the applied sanitisations. In case the sanitisation cannot be performed with the proper software tool, we invite you to print the sanitised pages with blackened text and to provide EFSA with scans of these sanitised pages. For all deletions, justifications (individually indicating each sanitisation and referring to the electronic page number) must be provided using the template also available for download from the same unique project.

The sanitised documents or scans of the sanitised pages and the respective justifications should be uploaded in the same unique project from which the documents were downloaded (above link) as soon as possible and at the latest by:

- **regarding the sanitisation of the EFSA conclusion: 6 November 2015**
- **regarding the sanitisation of the background documents: 13 November 2015**

Upon uploading of the sanitised documents, a notification should be sent to the Pesticides Peer Review functional mailbox (pesticides.peerreview@efsa.europa.eu)

We would like to thank you for your support and assistance during the course of the peer review.

With kind regards,

Senior Administrative Assistant
Pesticides Unit/Scientific Evaluation of
Regulated Products Department



Via Carlo Magno 1A
43126 Parma (Italy)

Tel:

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twitter.com/EFSA_EU 

youtube.com/EFSAchannel 

From: @knoell.com>
Sent: 05 November 2015 16:46
To:
Subject: Glyphosate: Question regarding Vol4s from one of the TF members

Hallo ,

ich hoffe sie haben schon einen schönen Urlaub.

Wenn Sie wieder da sind hätte ich folgende Frage:

Ein Task Force Member kam heute auf mich zu und zweifelt, dass die Conclusion im „company specific“ Vol4 richtig sind, bzw. nimmt an, dass da etwas verwechselt wurde.

Gibt es eine Möglichkeit das zu besprechen? Wissen Sie evtl. an wen sich die Firma wenden könnte?

Vielen Dank und freundliche Grüße

Dr. Knoell Consult GmbH, Marie - Curie Str. 8, 51377 Leverkusen

From: @knoell.com>
Sent: 06 November 2015 16:36
To: EFSA PESTICIDES PEER REVIEW
Cc:
Subject: Comments on the EFSA Conclusion on Glyphosate
Attachments: Residues_Comments on EFSA conclusions_to EFSA.docx;
Analytical_EFate_Comments on EFSA conclusion_to EFSA.docx; EFSA 4302
Conclusions Glyphosate_EFSA_comments_20151106.pdf

Categories:

Dear ,

I would like to let you know that I have uploaded the commented EFSA Conclusion to the EFSA sharepoint. Furthermore I have attached it to this e-mail to make sure it is available for you in time.

I also attached specific outlining's on the Analytical Methods, E-fate and Residue part that came in during today (see word docs). In that cases the applicant found some mistakes in the EFSA conclusion. These comments are also repeated as comments in the commented EFSA conclusion pdf for your consideration. Anyhow I found it reasonable to attach the original comments again for a better overview.

As discussed with you this morning the company Dow Agrosience had some doubts regarding the conclusions drawn by the authorities in their specific Vol.4. I would like to ask you on their behalf to check again (if possible) if the source is in-line (equivalent) with the reference specification. Thank you very much in advance for considering this as well.

If there are any questions please do not hesitate to contact me.

I wish you a nice weekend and kind regards,

Dr. Knoell Consult GmbH, Marie - Curie Str. 8, 51377 Leverkusen

From: knoell.com>
Sent: 10 November 2015 17:43
To:
Cc:
Subject: AW: glyphosate - EFSA conclusion, public version

Dear ,

I would like to keep you updated that it is very unlikely that I will be able to give you a final reply today.

I have not received final feedback yet. I hope I will get the information by tomorrow morning as some of the colleagues are based in the US.

FYI: The companies Syngenta and Helm agreed to let the information about the source and the manufacturing route in.

Still I have no final feedback from the Task Force Lead. I stay on the ball and come back to you asap.

Best regards and have a good evening.

Dr. Knoell Consult GmbH, Marie - Curie Str. 8, 51377 Leverkusen

Von: @efsa.europa.eu]
Gesendet: Dienstag, 10. November 2015 11:50
An:
Cc:
Betreff: glyphosate - EFSA conclusion, public version

Dear ;

Thank you for the submission of your comments and your proposals for the removal of sensitive information from the EFSA conclusion on glyphosate. In general comments on the EFSA conclusion are not foreseen at this stage, unless they refer to factual errors or typos.

pp. 3, 18, 24, 85 of the conclusion: the conclusion has been amended to "bank infiltration.

p. 8 of the conclusion: the conclusion has not been amended with regard to the material that meets the FAO specification. This is commonly available information on the FAO website, dealing with the published specifications. Therefore, it is not considered confidential.

pp. 8 and 57 of the conclusion: The residue definition for monitoring in food of animal origin is defined as sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate. The method has an LOQ of 0.025 mg/kg for each individual compound in milk, egg and meat, as a consequence, the sum is 0.05 mg/kg as correctly reported in the mentioned part of the RAR. However the LOQs for glyphosate and N-acetyl glyphosate in liver, kidney and fat are 0.05 mg/kg for each compound, as a consequence the sum is 0.1 mg/kg, not as reported in the RAR.

The EFSA conclusion reports correctly the individual LOQs of each compound in each matrix.

pp. 8, 9 and 23 of the conclusion: The information that there is a data gap for one of the applicants is not considered confidential and it is common procedure to list the missing data for the individual applicants, as this is done as well for substances with a single applicant.

pp. 9 and 23 of the conclusion: the reference to the code for the method has been removed and the text was amended.

pp. 9 and 35 of the conclusion: meat has been added.

pp. 10 and 25 of the conclusion: The non-compliance of the material tested with the proposed specification as well as the number of sources is not considered confidential.

pp. 44, 46 and 53 of the conclusion: all your comments have been accepted.

Please find attached the amended version as it will be published on the EFSA website on 12 November 2015. In order to prepare the conclusion for publication, we kindly ask for your agreement that there is no further confidential information in the attached version, by this evening close of business at the latest.

Kind regards

Scientific Officer
Pesticides / Regulated Products



European Food Safety Authority

Via Carlo Magno 1A
43126 Parma (Italy)

Tel.

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twitter.com/EFSA_EU 

youtube.com/EFSAchannel 

From: @knoell.com>
Sent: 11 November 2015 08:36
To:
Cc:
Subject: AW: [UNSCANNED] RE: glyphosate - EFSA conclusion, public version

Dear ,

I have received the feedback from the task force now that they agreed to what is outlined.
So please proceed with the publishing.

Have a good day & kind regards,

Dr. Knoell Consult GmbH, Marie - Curie Str. 8, 51377 Leverkusen

Von: @efsa.europa.eu]
Gesendet: Mittwoch, 11. November 2015 08:04
An:
Cc:
Betreff: [UNSCANNED] RE: glyphosate - EFSA conclusion, public version

Dear ,

Thank you for your "interim report". The agreement of the two companies is already a good step forward.

Looking forward to your next message.

Kind regards

Scientific Officer
Pesticides / Regulated Products



European Food Safety Authority

Via Carlo Magno 1A
43126 Parma (Italy)
Tel.

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twitter.com/EFSA_EU 

youtube.com/EFSAchannel 

From: [@knoell.com](mailto:knoell@knoell.com)
Sent: 10 November 2015 17:43
To:
Cc:
Subject: AW: glyphosate - EFSA conclusion, public version

Dear ,

I would like to keep you updated that it is very unlikely that I will be able to give you a final reply today.

I have not received final feedback yet. I hope I will get the information by tomorrow morning as some of the colleagues are based in the US.

FYI: The companies Syngenta and Helm agreed to let the information about the source and the manufacturing route in.

Still I have no final feedback from the Task Force Lead. I stay on the ball and come back to you asap.

Best regards and have a good evening.

Dr. Knoell Consult GmbH, Marie - Curie Str. 8, 51377 Leverkusen

Von: [@efsa.europa.eu](mailto:efsa.europa.eu)
Gesendet: Dienstag, 10. November 2015 11:50
An:
Cc:
Betreff: glyphosate - EFSA conclusion, public version

Dear ;

Thank you for the submission of your comments and your proposals for the removal of sensitive information from the EFSA conclusion on glyphosate. In general comments on the EFSA conclusion are not foreseen at this stage, unless they refer to factual errors or typos.

pp. 3, 18, 24, 85 of the conclusion: the conclusion has been amended to "bank infiltration.

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pp. 44, 46 and 53 of the conclusion: all your comments have been accepted.

Please find attached the amended version as it will be published on the EFSA website on 12 November 2015. In order to prepare the conclusion for publication, we kindly ask for your agreement that there is no further confidential information in the attached version, by this evening close of business at the latest.

Kind regards

Scientific Officer
Pesticides / Regulated Products



European Food Safety Authority

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43126 Parma (Italy)

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twitter.com/EFSA_EU 

youtube.com/EFSAchannel 

From: knoell.com>
Sent: 16 November 2015 13:58
To:
Subject: AW: glyphosate - sanitised final addendum

Dear ,

thank you very much for the good news.
Yes, I agree with what you stated below.

Kind regards,

Dr. Knoell Consult GmbH, Marie - Curie Str. 8, 51377 Leverkusen

Von: @efsa.europa.eu
Gesendet: Montag, 16. November 2015 11:58
An:
Cc:
Betreff: glyphosate - sanitised final addendum

Dear ,

Thank you very much for your proposals for the removal of sensitive information from the Final Addendum for the active substance glyphosate. Your proposals have all been accepted and no changes were applied to the file. Therefore, we would like to publish the document by 19 November, as it has been sent to us, and as it is available in the EFSA project folder for glyphosate.

Could you kindly ask you for your agreement.

Kind regards

Scientific Officer
Pesticides / Regulated Products



European Food Safety Authority

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43126 Parma (Italy)

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twitter.com/EFSA_EU 

youtube.com/EFSAchannel 

From: @knoell.com>
Sent: 17 November 2015 14:46
To:
Subject: AW: Glyphosate - peer review report

Dear ,

thanks a lot for your comments and your message.

I have forwarded your e-mail to my colleagues and come back with an answer asap.

Kind regards,

Dr. Knoell Consult GmbH, Marie - Curie Str. 8, 51377 Leverkusen

Von: @efsa.europa.eu]
Gesendet: Dienstag, 17. November 2015 13:52
An:
Cc:
Betreff: Glyphosate - peer review report

Dear ,

Thank you for the submission of proposals for the removal of sensitive data from the peer review report and the excellent job you and the applicants did to sanitise the files. All of your comments have been taken into consideration and all your proposal have been accepted, with the exception to the metabolite AMPA, and the draft public documents are available in the project folder in the subfolder '05 draft public documents'.

There are some issues that I would like to highlight:

Referring to almost all the individually submitted justification forms, there were slight mismatches with regard to the number of blackened parts and/or the page numbers and the submitted redacted documents. This did not cause any major problem as the redacted files were available, and therefore the parts proposed for removal could easily be identified.

In _____, but the relevant parts in the document have not always been blackened. This has now be done by us.

Comments on the RAR and the addendum:

AMPA is a metabolite and therefore does not qualify for removal (see electronic page 18 of the French comments).

_____, but the relevant parts of the documents were not blackend. This has been done now.

Instead of the file '04 Glyphosate comments RAR_BE_2014-03-24.pdf' the file '03 Glyphosate comments RAR_DK_2014-03-23_sanitised.pdf' was submitted, which in fact doesn't need sanitisation.

_____, this has been removed in page 2 of the Belgium comment in accordance with the justification form.

We have envisaged to publish all back ground documents on Thursday this week and would therefore very much appreciate if you could confirm, what you agree to the documents provided in the relevant folder '05 draft public documents'

Kind regards

Scientific Officer

Pesticides / Regulated Products



European Food Safety Authority

Via Carlo Magno 1A
43126 Parma (Italy)

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twitter.com/EFSA_EU 

youtube.com/EFSAchannel 

From: knoell.com>
Sent: 18 November 2015 11:58
To:
Subject: AW: Glyphosate - peer review report

Dear ,

thank you very much for your feedback and the amendments you made.
We agree to what is outlined and the documents can be published that way.

Kind regards,

Dr. Knoell Consult GmbH, Marie - Curie Str. 8, 51377 Leverkusen

Von: efsa.europa.eu
Gesendet: Dienstag, 17. November 2015 13:52
An:
Cc:
Betreff: Glyphosate - peer review report

Dear ,

Thank you for the submission of proposals for the removal of sensitive data from the peer review report and the excellent job you and the applicants did to sanitise the files. All of your comments have been taken into consideration and all your proposal have been accepted, with the exception to the metabolite AMPA, and the draft public documents are available in the project folder in the subfolder '05 draft public documents'.

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, this has been removed in page 2 of the Belgium

comment in accordance with the justification form.

We have envisaged to publish all back ground documents on Thursday this week and would therefore very much appreciate if you could confirm, what you agree to the documents provided in the relevant folder '05 draft public documents'

Kind regards

Scientific Officer

Pesticides / Regulated Products



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2_PAD 2017/036 Glyphosate CEO

Correspondence with the European Crop Protection Association (ECPA)

From: On Behalf Of SHPlatformsecretariat
Sent: jeudi 12 novembre 2015 11:42
To: [@ecpa.eu](mailto:ecpa.eu)
Subject: UNDER EMBARGO - Glyphosate: EFSA updates toxicological profile

Dear stakeholders,

Today, 12 November at around 12:00 CET, EFSA will publish a Conclusion on the Peer review on glyphosate and a complementary technical document. It will be accompanied by a News Story and a non technical summary.

The documents are under embargo until **12/11/2015 at 12:00 CET** when they will be published on our website.

In line with EFSA's principle of openness and transparency we are happy to share with you some of the information we prepared on this occasion in light of the interest surrounding the topic. The pre-notification is meant to allow you to have sufficient time to get knowledgeable of the opinion and be in a position to respond to possible queries you may receive following its publication. Should you have any question, or wish to receive clarification on any aspects regarding this publication do not hesitate to contact me at .

We shall seek to publish on the embargo time indicated, **but we would also be grateful if you could wait until you see the material published on our website before undertaking any actions.**

Due to the sensitivity of the subject, the discussions with all parties were on-going until the minute, hence the timing of this pre-notification.

I hope this helps and please let me know if you have any questions.

Regards,

Stakeholder Consultative Platform Secretariat

Communications & External Relations Department

Via Carlo Magno 1/A
I-43100 Parma,
Tel:
Fax:
Email:

The documents are scheduled for publication on **Thursday 12 November 2015 at 12:00 CET. They are shared under embargo in advance for your information and not for wider distribution.** The documents are shared on a confidential basis in advance of final publication and are therefore not intended to be shared beyond recipients identified in the distribution list above until the final documents are actually published. There is always a possibility that there will be additional changes before the final version is published and that the actual date and/or time of publication, indicated by the embargo, may change. Please note that only the final, published version remains the reference document. The EFSA website should be checked for confirmation of final content and publication. Only documents which are published on EFSA's website can be cited/used.

3_PAD 2017/036 Glyphosate CEO

Correspondence with the German Federal Institute for Risk Assessment (BfR)

From:
Sent: 04 May 2015 10:05
To:
Subject: FW: A question regarding the glyphosate RAR

Ciao

Can you please answer to the question from

Thanks a lot

From: [mailto:...] **Sent:** Monday, May 04, 2015 09:20
To:
Subject: RE: A question regarding the glyphosate RAR

Good morning I and was good to meet you in Brussels.

Sorry for my late reply but I have been to the JRC for 2 days last week. I will collect the information and will reply to yourself today

Talk soon

From: [mailto:...] **Sent:** Wednesday, April 29, 2015 11:09
To: [...] a
Subject: A question regarding the glyphosate RAR

Dear

Today, I have a question that you, perhaps, might answer.

We are just preparing a manuscript dealing with potential effects of a glyphosate-containing herbicide on rumen metabolism and microbial communities in cattle rumen. It will be based on a preliminary report that we had briefly mentioned in the RAR on glyphosate yet and we have been asked sometimes since then when the results will become published.

Not for this report but for some other purposes, I would like to refer to the RAR in this paper but I am not sure if I am allowed to do that and how to do it best. To my understanding, the version of the RAR for the 2014 "Public consultation" (as prepared and edited by EFSA) is no longer available since it has never been on the Internet but was submitted only on request. Is it possible at the moment to ask EFSA for this report? If so, I could cite it with the remark "available on request from EFSA". Or is it still somewhere "hidden" on the EFSA website?

On one hand, I don't want to include references that are not readily accessible. On the other hand, we have emphasised, e.g. on the meeting in Brussels last week, that the scientific community should make more use of such comprehensive documents like a DAR or RAR as credible sources of information.

I would be glad to receive your thoughts on that.

The best that I might expect would be a clear advice in which way to cite the RAR.

Kind regards,

Bundesinstitut für Risikobewertung
Fachgruppe Toxikologie der Pestizide und Biozide
Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Unit Toxicology of Pesticides and Biocides
Department of Chemical Safety

Max-Dohrn-Straße 8-10,
10589 Berlin, Germany
Tel. +49 30 18412
Fax +49 30 18412
www.bfr.bund.de

From:
Sent: 07 May 2015 16:30
To:
Cc:
Subject: Request for clarification on certain studies on glyphosate

Dear

and I spent some time on this search but it was quite interesting.
What we found out, is the following:

We don't have any study by McConnell on file in the BfR. However, the document number 77-2061A is clearly related to study 77-2061 which is a long-term study in mice that was completed in 1983 and provided by Monsanto with Knezevich and Hogan being the principal authors. This study has got the BfR file number TOX9552381. It was reported in detail in the old DAR and is now considered still acceptable. Therefore, it was also mentioned in the RAR. Robert F. McConnell was apparently the study pathologist.

In 1985, a re-review of histological slides of the kidneys was performed on request of U.S. EPA but not by McConnell. This time, the pathologist was Marvin Kuschner. The result of this re-evaluation was recently reported by BfR in our preliminary response to the IARC assessment of glyphosate as carcinogenic and can be easily found there. I think that the question to EFSA might point into that direction.

MSL-1724 is on file in the BfR and has got the number Z35681. It is not an addendum to the pathology report but, instead, contains the complete three-generation study on rats by Schroeder (1981, TOX9552385). Apparently, it was provided in 1982 by Monsanto to support registration of glyphosate in West-Germany. At least, this purpose is indicated on the document. Therefore, it was not taken into account of previous EU evaluation. The pathology parts of MSL-1724 and of the original study are identical. The difference seems to be that additional analytical data on the diet is given in MSL-1724 but not in the original study report. Therefore, the number of pages is higher.

Anyway, the three-generation study by Schroeder (1981) must be considered not acceptable from a today's point of view and was not used for re-evaluation of glyphosate. This opinion of the RMS has not been questioned by any party during the commenting period. Thus, there is no need to go deeper into the details.

I hope this will answer your questions.

Kind regards,

Bundesinstitut für Risikobewertung
Fachgruppe Toxikologie der Pestizide und Biozide
Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Unit Toxicology of Pesticides and Biocides
Department of Chemical Safety

Max-Dohrn-Straße 8-10,
10589 Berlin, Germany
Tel. +49 30 18412
Fax +49 30 18412
www.bfr.bund.de

From: [REDACTED]
To: [REDACTED]
Subject: Antw: PEO tallowamine
Date: 11 June 2015 08:26:35
Attachments: [ATT00001.png](#)
[ATT00002.png](#)
[ATT00003.png](#)

Dear [REDACTED],

the major part of the toxicological information on POE tallowamines that is available to the RMS to can be found in Vol. 3 in Chapter B.6.13.3.(1). The studies addressed there were not part of the original GTF dossier but had been compiled in Germany before already and for other purposes. However, we felt it necessary to include this data in the RAR.

Furthermore, a number of in vitro studies have been performed (mainly by the Seralini group) proving a higher toxicity of PPP with POE talowamines as compared to the a.s. which were either part of the original dossier or were amended at later stages. They are reported on different sites of the RAR but I cannot recall at the moment the precise allocation. Of importance are, e.g., two studies of Mesnage et al. (2012 and 2013) that are cited under B.6.8.4 (at least in the version that has been prepared in advance of the PRAS meeting in February).

Kind regards,

[REDACTED]
Bundesinstitut für Risikobewertung
Fachgruppe Toxikologie der Pestizide und Biozide
Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Unit Toxicology of Pesticides and Biocides
Department of Chemical Safety

Max-Dohrn-Straße 8-10,
10589 Berlin, Germany
Tel. [REDACTED]
Fax [REDACTED]

www.bfr.bund.de

[\[REDACTED\]@bfr.bund.de](mailto:[REDACTED]@bfr.bund.de)

>>> [REDACTED] <[REDACTED]@efsa.europa.eu> 10.06.2015 18:08 >>>

Dear [REDACTED],

[REDACTED] to come back to our favourite issue. We are now preparing our statement on the POE tallowamines. Just a simple question to avoid digging into the dossier. Were there any supporting studies on the part on the PEO tallowamines you presented in the RAR?

Thanks already in advance

Best regards

[REDACTED]

[REDACTED]
Scientific Officer
Pesticides / Regulated Products



European Food Safety Authority

Via Carlo Magno 1A

43126 Parma (Italy)

Tel. [REDACTED]

www.efsa.europa.eu

twitter.com/EFSA_EU 

youtube.com/EFSAchannel 

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]
Subject: Antw: Glyphosate - was sonst
Date: 24 June 2015 10:14:11
Attachments: [ATT00001.png](#)
[ATT00002.png](#)
[ATT00003.png](#)

Dear [REDACTED],

I think I can explain:

You can't find the studies (industry studies and published papers) in the dossier of the Glyphosate Task Force because they were simply not part of it. As we tried to make clear in the RAR, Germany as the RMS (here: the BfR) has included in the RAR a tallowamine assessment that had been compiled in, I think, 2010 for national purposes. (Subsequent to this assessment, certain tallowamines in many glyphosate-containing herbicides have been in fact replaced by other surfactants, at least on the German market. I have no idea if companies did the same abroad.)

I can tell you that it was quite difficult to get access to the industry studies at that time. We felt it important to make this information publically available even though it was not relevant for the representative formulation that does not contain tallowamines.

To my understanding, a MS is free to introduce into the RAR additional information that was not part of the dossier. For the glyphosate RAR, we did the same with many papers that we had been aware of before or that were mentioned during the public consultation. They are reported now but were not submitted in the original dossier.

The "green" studies had been allocated by Monsanto to the dossier for other reasons and are referred to in other parts of the RAR, too.

Kind regards [REDACTED]
[REDACTED]

[REDACTED]
Bundesinstitut für Risikobewertung
Fachgruppe Toxikologie der Pestizide und Biozide
Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Unit Toxicology of Pesticides and Biocides
Department of Chemical Safety

Max-Dohrn-Straße 8-10,
10589 Berlin, Germany
Tel. [REDACTED]
Fax [REDACTED]

www.bfr.bund.de

[REDACTED] [@bfr.bund.de](mailto:[REDACTED]@bfr.bund.de)

>>> [REDACTED] <[REDACTED]@efsa.europa.eu> 23.06.2015 14:09 >>>

Dear colleagues,

Sorry to come back again to glyphosate.

On page 884 of the rev. RAR B.6, several studies are mentioned in table B.6.13-1:

[REDACTED], 1990 ASB2009-9027
[REDACTED], 1973 ASB2009-9026
[REDACTED], 1983 TOX2002-694
[REDACTED], 2007 ASB2010-365

[REDACTED], 2008 ASB2010-364
[REDACTED], 2007 ASB2012-2721
[REDACTED], 1989 ASB2009-9028
[REDACTED], 1990 ASB2009-9029
[REDACTED], 2003 ASB2012-11600

The “green” ones we found in the dossier, but for the other ones, we don’t have evidence that they have ever been included into an EU dossier.

The problem is, that we have or have not to confirm the access to these studies. Therefore I would like to crosscheck with you, whether these studies have or have not been in any of the EZ dossiers (the original one, the supplementary one and the updated one after the additional data request). I assume that these studies have been submitted under a national procedure?

Thanks already in advance and best regards

[REDACTED]

[REDACTED]

[REDACTED]
Scientific Officer
Pesticides / Regulated Products



Via Carlo Magno 1A
43126 Parma (Italy)
Tel. [REDACTED]

www.efsa.europa.eu

twitter.com/EFSA_EU 

youtube.com/EFSAchannel 

From: [REDACTED]
To: [REDACTED]; [REDACTED]
Cc: [REDACTED]
Subject: Antw: Re: glyphosate ongoing activities
Date: 02 July 2015 18:00:17
Attachments: [REDACTED]

as we discussed today I am sending you informally the PMRA monograph on glyphosate.
kind regards from the linat airport
[REDACTED]

[REDACTED]
Bundesinstitut für Risikobewertung
Leitung der Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Head of Department Chemical Safety

Max-Dohrn-Straße 8-10,
10589 Berlin, Germany
Tel.: [REDACTED]
Fax: [REDACTED]

www.bfr.bund.de

>>> [REDACTED] <[REDACTED]@bfr.bund.de> 01.07.15 22.22 Uhr >>>

Yes I will call you.

See you tomorrow
[REDACTED]

Sent from my iPhone

> On 01 Jul 2015, at 22:12, [REDACTED]
<[REDACTED]@efsa.europa.eu> wrote:
>
> Perfect. Could you please call me ([REDACTED]) after lunch?
> Many thanks and have a nice evening,
> [REDACTED]

> Verstuurd vanaf mijn iPhone

>
>> Op 1 jul. 2015 om 21:51 heeft [REDACTED]
<[REDACTED]@bfr.bund.de> het volgende geschreven:

>>
>> Dear [REDACTED]
>> Yes of course. We will Finishing about 1 pm. My Pick up is 4pm. We
can

>> have a short Diskussion After lunch.

>> See you

>> [REDACTED]

>> Von meinem iPhone gesendet

>>

>>>> Am 01.07.2015 um 20:58 schrieb [REDACTED]
>>> <[REDACTED]@efsa.europa.eu>:

>>>

>>> Dear [REDACTED],

>>>

>>> following the below email of my colleague [REDACTED], I kindly ask you
if

>> you would be available for a short discussion with [REDACTED] and myself on

>> the on-going glyphosate assessment tomorrow, 2 July?

>>>

>>> Could you please indicate when you would be available?
>>>
>>> I would like to thank you in advance for your time.
>>>
>>> Kind regards,
>>>
>>>
>>> _____
>>> From: [REDACTED]
>>> Sent: Tuesday, June 30, 2015 11:02 AM
>>> To: [REDACTED]
>>> Cc: [REDACTED]@bfr.bund.de
>>> Subject: glyphosate ongoing activities
>>>
>>> Dear [REDACTED] and [REDACTED]
>>>
>>> this morning I have had several telephone calls with the BfR ([REDACTED]
[REDACTED] and [REDACTED]), [REDACTED] will be in EFSA as a member of the
SC
>> Panel on 1 and 2 July. He asked me, whether it would be possible to
meet
>> with you to discuss the ongoing activities on glyphosate. He may
contact
>> you, [REDACTED] ([REDACTED]), once he will be in EFSA to arrange for an
>> appointment.
>>>
>>> I understood that Germany initiated steps for the CLH procedure and
>> was already asked by their ministry to have a thorough look into the
>> monograph of IARC, as soon as it will be available.
>>>
>>> [REDACTED] mobile phone number is: [REDACTED]
>>>
>>> If needed, I could participate in a short TC, but that might
>> jeopardise the flexibility to arrange for a spontaneous meeting with
>> [REDACTED].
>>>
>>> Have a nice day.
>>>
>>> [REDACTED]
>>>
>>> [REDACTED]
>>> Scientific Co-ordinator
>>> European Food Safety Authority
>>> Pesticide Risk Assessment Peer Review (PRAPeR)
>>>
>>> Via Carlo Magno 1A
>>> I-43126 Parma
>>> Tel: [REDACTED]
>>> Fax: [REDACTED]
>>> Email: [REDACTED]@efsa.europa.eu
>>> Website: <http://www.efsa.europa.eu>
>>

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]
Subject: Antw: Re: glyphosate ongoing activities
Date: 10 July 2015 07:27:39
Attachments: [REDACTED]

Good morning,

do you know the following activity?

<http://www.soilassociation.org/news/newsstory/articleid/8051>

Glyphosate scientific briefing
15 July 2015 08:00 - 15 July 2015 10:00

The Council Room, One Great George Street, Westminster, London SW1P 3AA

The Soil Association will host a scientific briefing on the recent report published by the WHO's International Agency for Research on Cancer (IARC), which found that glyphosate, the active ingredient in Roundup herbicide, is 'probably carcinogenic to humans'. Glyphosate is the most widely sold weedkiller in the world, and is widely used in farming, parks and gardens across the country. UK Government testing has found glyphosate to be one of the three most common pesticides found in British bread.

Three of the world's foremost experts will join us to lead the discussion:

[REDACTED] co-authored the WHO IARC report, and will talk about the work of the IARC, the investigation into glyphosate, the scientific evidence they considered and the conclusions they came to. [REDACTED] currently serves on a committee of the US National Academy of Sciences.

[REDACTED] will provide an overview of the global reaction to the IARC's report, including moves by some countries to ban glyphosate, reviews now being undertaken of glyphosate use and the implications for continued use in the UK. Claire is an editor at GMWatch.org.

[REDACTED] will talk about the significance of the IARC's findings, the overall health impacts of glyphosate, and what the UK Government should do in the light of these findings. [REDACTED] is a research associate in the Department of Medical and Molecular Genetics at King's College London, Faculty of Life Sciences and Medicine. He co-authored the only existing long-term toxicity study of a Roundup-tolerant GM maize, and of a complete formulation of Roundup herbicide.

Organic breakfast 8.00-8.30 Presentations and questions from 8.30-10.00
Attendance is free but prior booking is essential. Please register your attendance by emailing [REDACTED]@soilassociation.org or calling [REDACTED]
[REDACTED]

[REDACTED]
Bundesinstitut für Risikobewertung
Leitung der Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Head of Department Chemical Safety

Max-Dohrn-Straße 8-10,
10589 Berlin, Germany
Tel.: [REDACTED]
Fax: [REDACTED]
www.bfr.bund.de

>>> [REDACTED] <[REDACTED]@efsa.europa.eu> 01.07.2015
22:11 >>>
Perfect. Could you please call me ([REDACTED]) after lunch?
Many thanks and have a nice evening,
[REDACTED]

Verstuurd vanaf mijn iPhone

> Op 1 jul. 2015 om 21:51 heeft [REDACTED]
<[REDACTED]@bfr.bund.de> het volgende geschreven:
>
> Dear [REDACTED]
> Yes of course. We will Finishing about 1 pm. My Pick up is 4pm. We
can
> have a short Diskussion After lunch.
> See you
> [REDACTED]
> Von meinem iPhone gesendet
>
>> Am 01.07.2015 um 20:58 schrieb [REDACTED]
> <[REDACTED]@efsa.europa.eu>:
>>
>> Dear [REDACTED],
>>
>> following the below email of my colleague [REDACTED], I kindly ask you
if
> you would be available for a short discussion with [REDACTED] and myself
on
> the on-going glyphosate assessment tomorrow, 2 July?
>>
>> Could you please indicate when you would be available?
>>
>> I would like to thank you in advance for your time.
>>
>> Kind regards,
>>
>>
>>
>> From: [REDACTED]
>> Sent: Tuesday, June 30, 2015 11:02 AM
>> To: [REDACTED]; [REDACTED]
>> Cc: [REDACTED]@bfr.bund.de
>> Subject: glyphosate ongoing activities
>>
>> Dear [REDACTED] and [REDACTED],
>>
>> this morning I have had several telephone calls with the BfR
([REDACTED]
[REDACTED] and [REDACTED]), [REDACTED] will be in EFSA as a member of the
SC
> Panel on 1 and 2 July. He asked me, whether it would be possible to
meet
> with you to discuss the ongoing activities on glyphosate. He may
contact
> you, [REDACTED] ([REDACTED]), once he will be in EFSA to arrange for an

> appointment.
>>
>> I understood that Germany initiated steps for the CLH procedure and
> was already asked by their ministry to have a thorough look into the
> monograph of IARC, as soon as it will be available.
>>
>> [REDACTED] mobile phone number is: [REDACTED]
>>
>> If needed, I could participate in a short TC, but that might
> jeopardise the flexibility to arrange for a spontaneous meeting with
> [REDACTED].
>>
>> Have a nice day.
>>
>> [REDACTED]
>>
>> [REDACTED]
>> Scientific Co-ordinator
>> European Food Safety Authority
>> Pesticide Risk Assessment Peer Review (PRAPeR)
>>
>> Via Carlo Magno 1A
>> I-43126 Parma
>> Tel: [REDACTED]
>> Fax: [REDACTED]
>> Email: [REDACTED]@efsa.europa.eu
>> Website: <http://www.efsa.europa.eu>
>

From: [REDACTED]
To: [REDACTED]
Subject: Re: Glyphosat
Date: 18 September 2015 18:49:01

Hallo [REDACTED]

Leider habe ich Deine Emails erst jetzt gesehen. Die sind komischerweise an einen anderen Account gegangen.

Melde mich später

[REDACTED]

Von meinem iPhone gesendet

> Am 16.09.2015 um 07:34 schrieb [REDACTED] <J[REDACTED]@efsa.europa.eu>:

>

> Guten Morgen [REDACTED]

>

> Wir wollten uns doch kurz zusammensetzen. Wie sieht es heute aus?

>

> Gruß

>

> [REDACTED]

>

> [REDACTED]

> Scientific Officer

> Pesticides / Regulated Products

>

>

> Via Carlo Magno 1A

> 43126 Parma (Italy)

> Tel. [REDACTED]

> www.efsa.europa.eu

> twitter.com/EFSA_EU

> youtube.com/EFSAchannel

>

> -----Original Message-----

> From: [REDACTED] [[mailto:\[REDACTED\]@me.com](mailto:[REDACTED]@me.com)]

> Sent: 14 September 2015 21:58

> To: [REDACTED]

> Subject: Glyphosat

>

> Hallo [REDACTED]

> Bin gerade in Parma angekommen und bis Mittwoch beim Scientific Committee. Können wir uns nicht mal kurz zusammensetzen?

> Bis morgen

> [REDACTED]

>

>

> Von meinem iPhone gesendet

Von: efsa@efsa.europa.eu
An: "Flock Suzan (Suzan.Fiackebfr.bund.der <Suzan.Fiack@bfr.bund.de >
CC: 'efsa@efsa.europa.eu >
Datum: 28.01.2015 11:52
Betreff: FW: scientific meeting February 23 - registration request

Hallo Suzan,

War dieser Journalist mit euch im Kontakt? , will uns zu Glyphosate interviewen. Habt Ihr Erfahrungen gemacht?

Viele Grüße,

-Original Message -

From:
Sent: 27 January 2015 13:00
To: EFSA Press
Subject: scientific meeting February 23 - registration request

Dear

as I just explained by phone
we are working on a science documentary on glyphosate for ARTE France and ARDIWDR - especially about the current process of risk evaluation by BfR and EFSA

Glyphosate is a controversial topic, reaching from public concerns, to controversial scientific papers that recommend further research, to industry and farmers, who stress a need for glyphosate - but regarding the evaluation of risks and how carefully this process is handled, little is known within the public.

In this context we try to stress the intricacy of this scientific risk evaluation process - the integration of latest studies, the quality of studies, the iterative and thereby responsible evaluation process.

Experts of many Member States participate in this process, in "Arbeitsgruppen" and "Panels", which is why we would like to take the opportunity to show in an exemplary way during your expert panel on 23rd of February, how international, interdisciplinary and iterative this procedure is, before a report is summarized and passed from EFSA to the Commission.

We met Tand Solecki of BfR for a brief pretalk at Gruene Woche in Berlin where Mr Solecki made us aware of the EFSA glyphosate panel on Feb 23rd.

said a shooting can be arranged in close collaboration with your press team, though some restrictions will apply - and of course it might be good to have a brief talk also with your scientific officer at EFSA (in charge for Glyphosate).

We could then get back to each other, how to use this opportunity to bring some transparency to this process, e.g. by taking some images before and after the panel (not during the scientific meeting), and how to arrange a brief interview with your EFSA officer, to refer briefly the procedure of evaluation, and also to talk briefly to some members of your scientific expert panel, that they can refer how they tackled the evaluation procedure, how much work and effort is spent on this task, and how evidences, findings, but also critical issues are taken into consideration during the ongoing evaluation.

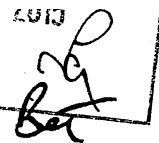
Before getting into more details at this stage, and as you could not find the event right away on your agenda, or possibly we noted down a wrong date, could you please confirm if this respective Glyphosate Panel expert group takes place on 23rd of February, or when it does take place?

with greetings from Berlin

yours

↑ Pras.

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our mind is like a parachute It works better when it's opened...

ASu

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Von: Suzan Fiack
An:
Datum: 02.02.2015 14:57
Betreff: Antw: Glyphosate

Hallo
uns liegt noch keine Anfrage vor. Allerdings wurde bei der folgenden öffentlichen Veranstaltung auch schon gedreht:
<http://www.bmel.de/SharedDocs/Pressemitteilungen/2015/025-KL-Pflanzenschutzmittelzulassung.html>
Besten Gruß,
Suzan

>>> @efsa.europa.eu > 02.02.2015 14:49 >>>
Hallo Suzan,

Habt ihr euch bezüglich Interviewanfrage "Glyphosate" entschieden, wie ihr verfahren wollt?
Viele Grüße,

Communications & External Relations Department
[cid:image001.jpg@01D03EF7.79FA10A0]
Via Carlo Magno 1A
43126 Parma, Italy
Tel. +39 0521 036
www.efsa.europa.eu <<http://www.efsa.europa.eu/>>
twitter.com/EFSA_EU <http://twitter.com/EFSA_EU> [cid:image002.jpge.01D03EF7.79FA10A0]
youtube.com/EFSAchannel <<http://youtube.com/EFSAchannel>>
[cid:image003.jpg@01D03EF7.79FA10A0]

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	BfR Berlin Registratur	
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Von:
An:
Datum: **23.03.2015 12:11**
Betreff: **Fwd: Glyphosat**

Bitte in den GG.

Von meinem iPhone gesendet

Anfang der weitergeleiteten E-Mail:

Vot @efsa.europa.eu>
Datum: **23. März 2015 12:07:32 MEZ**
An: "**Suzan Fiack**" <Suzan.Fiackebfr.bund.de>
Kopie: ' @efsa.europa.eu >
Betreff: Glyphosat

Hi Suzan,

Wir haben eine Medienanfrage zur Pressemitteilung der International Agency for Research an Cancer, veröffentlicht Freitag), die sagt, dass glyphosate als mögliche krebserregende Substanz eingestuft worden ist (Gruppe 2A)

<http://www.iarc.fr/en/media-centre/iarcnews/pdf/fvlonographVolume112.pdf>

Wir werden uns nicht groß äußern, erstens äußern wir uns nie zu laufenden Bewertungen und zweitens warten wir ja auf euren Bericht.

Unser Referatsleiter des Referats PESTIZIDE, , sagte, dass ihr den IARC Bericht berücksichtigen werdet ? Falls dass der Fall ist, würden wir das in unserer Antwort kurz erwähnen.

Viele Grüße,

24. März 2015

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Eingangsregistrierung Fwd: Article on Round up-glyphosate in Le Monde

Von: Suzan Fiack <suzan.fiack@bfr.bund.de >
An: Eingangsregistrierung@bfr.bund.de
Datum: 25.03.2015 18:44
Betreff: Fwd: Article on Round up-glyphosate in Le Monde
CC: 6.pol.domain@bfr.bund.de, Roland.Solecki@bfr.bund.de, 2 @mail.bfr.bund.de
Anlagen: Le d6sherbant Roundup class6 canc6roïne_Le Monde 25032015.pdf

Bitte in den GG.

Von meinem iPhone gesendet

Anfang der weitergeleiteten E—Mail:

Von: r7jefsa.europa.eu >
An: "Suzan Fiack" <Suzan.Fiack@bfr.bund.de>
Kopie: ' efsa.europa.eu > "EFSA Press"
<Press.Presseefsa.europa.eu>
Betreff: Article on Round up-glyphosate in Le Monde

Hi Suzan,

Heute Mittag hat Le Monde (sie publizieren Mittags) einen Artikel zu Glyphosate veröffentlicht. Ihr werdet erwähnt und kritisiert. Der Journalist ist uns bekannt.

Viele Grüße,

Eingangsregistrierung - FW: Glyphosat - BfR to publish English news story

Von: Aefsa.europa.eu
 An: :@bfr.bund.der
 @bfr.bund.de>, "Fiack Suzan (Suzan.Fiack@bfr.bund.der
 <Suzan.Fiack@bfr.bund.de >
 Datum: 26.03.2015 18:15
 Betreff: FW: Glyphosat - BfR to publish English news story
 CC: <@efsa.europa.eu>, '
 @efsa.europa.eu>
 Anlagen: eng-20150323 Glyphosat und Krebs-final_2_Stu.docx

Lieber

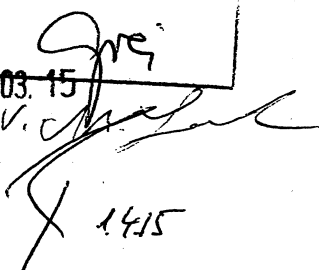
unsere wissenschaftlichen Kollegen in der Pestizid Unit haben auf einen Fehler in der Englischen Version aufmerksam gemacht (nicht in der Deutschen Version): Da der Peer Review Prozess noch nicht abgeschlossen ist, sollte die Textstelle: *"since other evaluations performed by supranational bodies such as the EFSA (2014, confirmed in an expert meeting in February, 2015), and the .IMPR of WHO and FAO (1114PR, 2004), and also by national regulatory agencies such as the U.S.EPA had concluded the contrary, i.e., that glyphosate was not carcinogenic."* dringend gelöscht werden.

Zusätzlich ist es auch nicht klar wie der Zusatz EFSA, 2014 zu verstehen ist, bzw. worauf er sich bezieht.

Viele Grüße,

BfR. Berlin Registratur · Bereich · Wissenschaft	„
27. MRZ 2015	2 23
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30. März 2015

31. 03. 15
 I. V. 
 14.15
 zu BfR
 mit ALG, L
 per
 und veröffentlicht
 in der deutschen Version
 (siehe Anlagen 23)
 1.4.15
 Z.d.A

elt

Von: efsa.europa.eu >
An: "'Fiack Suzan'" <Suzan.Fiack@bfr.bund.de >
CC: EFSA Press <Press.Press@efsa.europa.eu >
Datum: 31.03.2015 15:54
Betreff: RE: Glyphosat Arte

Hallo Suzan,

Wir hatten abgesagt mit der Begründung, dass der Zeitpunkt seiner Anfrage (Januar/Februar) zu früh war. Zu dem Zeitpunkt konnte die EFSA ja inhaltlich noch nichts sagen, da es ein laufendes Verfahren ist.

Bevor wir unsere Conclusion gemacht haben, werden wir auch keine Interviews geben.

Viele Grüße,

-----Original Message

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]
Sent: 31 March 2015 15:22
To: [REDACTED]
Cc: EFSA Press
Subject: Glyphosat Arte

Hallo

hat sich eben bei uns gemeldet und nach einem Interview (Anfang Juni) gefragt. Läuft eure Anfrage auch noch oder habt ihr abgesagt?

Mit freundlichen Grüßen
i.A.
Suzan Fiack

Dr. Suzan Fiack

Bundesinstitut für Risikobewertung
Fachgruppenleitung Presse- und Öffentlichkeitsarbeit Abteilung Risikokommunikation

Federal Institute for Risk Assessment
Head of Unit Press and Public Relations Department Risk Communication

Max-Dohrn-Straße 8-10, 10589 Berlin
Germany

Tel. +49 30 18412-4302
Fax +49 30 18412-4970

www.bfr.bund.de

Präs. i.V.	
01. April 2015	
BM. Berlin	Präs
Registrierung - Bereich - Wissen - haft	
01. APR. 2015	02.04.15 (i.V.)
Az.: 4114/11	i.V. 7.4.
Doc.-Nr.: 1 2,53--5S6	

2.8.15

VdSI23

Von: |@efsa.europa.eu >
An: ""Fiack Suzan"" <Suzan.Fiack@bfr.bund.de >
Datum: 04.05.2015 11:51
Betreff: RE: Antw: Glyphosat: Bald komplett verboten?

Danke, ich werde ihn mir anschauen.

- - Original Message - -

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]
Sent: 04 May 2015 11:48
To:
Subject: Antw: Glyphosat: Bald komplett verboten?

Hallo
morgen gibt es übrigens vermutlich einen Beitrag zu Glyphosat bei Frontal21.

Mit freundlichen Grüßen
i.A.
Suzan Fiack

Dr. Suzan Fiack

Bundesinstitut für Risikobewertung
Fachgruppenleitung Presse- und Öffentlichkeitsarbeit Abteilung Risikokommunikation

Federal Institute for Risk Assessment
Head of Unit Press and Public Relations Department Risk Communication

Max-Dohrn-Straße 8-10, 10589 Berlin
Germany

Tel. +49 30 18412-4302
Fax +49 30 18412-4970

www.bfr.bund.de

ffiefsa.europa.eu > 04.05.2015 11:20

>>

<http://www.agrarheute.com/glyphosat-bald-komplett-verboten>

Communications & External Relations Department [cid:image001.jpg@01 D0865C.59367A00]
Via Carlo Magno 1A
43126 Parma, Italy
Tel. +39 0521 036
www.efsa.europa.eu <<http://www.efsa.europa.eu/>>
twitter.com/EFSA_EU <http://twitter.com/EFSA_EU>
[cid:image002.jpg@01 D0865C.59367A00]

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Von: Eef sa . eur opa .eu>
An: Fiack Suzan <Suzan.Fiack@bfr.bund.de>
CC: @efsa.europa.eu>
Datum: 08.06.2015 10:58
Betreff: Re: Glyphosat

1-1i Suzan

Apols for not getting back to you sooner on this. the link to web page can be found here
h • <http://dar.efsa.europa.eu/klar-web/> rovision
frs no e most user nendly form, but if you sort by Member State then you will find glyphosate. By
clicking on the link it takes you to a form that you have to fill out and then EFSA provides you with the
report.
Hope that helps
Best

On 08 Jun 2015, at 09:29, Fiack Suzan <Suzan.Fiack@bfr.bund.de <mailto:Suzan.Fiack@bfr.bund.de >>
wrote:

Dear all,
just a short question: Is the report on glyphosat (RAR) available on
the EFSA website? If not, when do you expect to publish the revised
version?
Have a nice week!
Best regards,
Suzan

BfR Berlin	Präs
Registratur - Bereich - Wissenschaft	111
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Az.: Doc.-N. 6.00	

09.06.15
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Does glyphosate cause cancer?

BfR Communication, 23 March 2015

In its recent evaluation from March 2015, the International Agency for Cancer Research (IARC), as the leading cancer agency of the World Health Organization (WHO), came to a conclusion that should now be classified as a carcinogenic substance in

(probably based on limited evidence" in human
 studies and sufficient evidence in animal-experiments. This classification was, published in the Lancet journal on 20 March 2015.
 As of the active substance glyphosate in the framework of the evaluation, the European Institute for Risk Assessment (EFSA) responded to the human health risk assessment and assessed glyphosate as non-carcinogenic. It is also a national, European and other international organizations, for health and safety. The Joint meeting on Pesticides of the European Commission (JMPR) BFR is the basis for the classification by IARC. The published short report

The International Agency for Research on Cancer (IARC) is the specialized cancer agency of the World Health Organization. The main objective of the IARC is to promote international collaboration in cancer research. The evaluations of carcinogenic risk are made by international working groups of independent scientists and are qualitative in nature. No recommendation is given for regulation or legislation. For this reason, 17 experts from 11 countries met at the International Agency for Research on Cancer (IARC; Lyon, France) in March 2015 in order to assess the carcinogenic or potentially carcinogenic effects of 4 organophosphates and glyphosate. The working group classified glyphosate as "probably carcinogenic to humans". This assessments will be published as volume 112 of the IARC Monographs.

In the opinion of BfR, the classification of glyphosate as "carcinogenic in Group 2A" (probably carcinogenic to humans) as published in the 20 March 2015 issue of the "Lancet" Journal comes as a surprise, since other evaluations performed by supranational bodies such as the IARC (IARC, 2015), the JPR of WHO and FAO (JPR, 2004), and also by national regulatory agencies such as the U.S. EPA had concluded the contrary, i.e., that glyphosate was not carcinogenic. Unfortunately, the database on which the IARC evaluation is based is not known, since a background monograph that is usually produced by IARC following the evaluation meetings has not yet been released. Therefore, a comprehensive and scientifically sound consideration of the data and arguments that led to the IARC- conclusion is simply not possible at the moment.

Kommentar | **EFSA**: This should be deleted, as the peer review is not yet completed, the meeting reports have not been made publicly available and the EFSA conclusion is still in the drafting phase. Furthermore EFSA has not been mentioned in the German statement on the BfR website. In addition it is not clear to what the reference EFSA 2014 refers to.

"4 #C8-ti-orientar[]: This is entirely
e e-evaluation process is on-
a final conclusion is not

or this purpose, an extensive "Renewal Assessment Report" (RARE) was provided in 2013 and has been revised in 2014 and again in 2015. The 2013 report was circulated by EFSA to the EU Member States and was made available for public consultation in 2014. Revisions were made to take into account the several hundred comments and remarks. The toxicological and residue chapters of the report have been prepared by the Federal Institute for Risk Assessment (BfR). For this purpose, we have compiled the most comprehensive toxicological database, presumably worldwide, for glyphosate. This database comprises hundreds of studies that were performed by or on behalf of the many manufacturers of glyphosate and thousands of references from the open literature. This huge amount of data makes glyphosate nearly unique among the active substances in plant protection products. We think that the entire database must be taken into account for toxicological evaluation.

tion and risk assessment of a substance and not merely a more or less arbitrary selection of studies.

In the absence of more reliable information from IARC, BfR has tried to allocate the findings that are mentioned in the brief "Lancet publication to certain studies in our database and, by doing that, to put them into perspective.

The new IARC classification for glyphosate as a carcinogenic substance is based firstly on "limited evidence" in humans. This risk is derived from three epidemiological studies in the USA, Canada and Sweden based on a statistical correlation between exposure to glyphosate and an increased risk of non-Hodgkin lymphoma. However, this assessment was not confirmed in a very large cohort of the also cited "Agricultural Health Study" or in other studies. A recent publication from 2012 has reviewed the epidemiologic literature to evaluate whether exposure to glyphosate is associated causally with cancer risk in humans and the relevant methodological and biomonitoring studies of glyphosate. The review found non-consistent patterns of positive associations indicating a causal relationship between total cancer or any site-specific cancer and exposure to glyphosate. The current report of the BfR to the EU based on the evaluation of over 30 epidemiological studies came to the overall assessment that there is no validated or significant relationship between exposure to glyphosate and an increased risk of non-Hodgkin lymphoma or other types of cancer.

Secondly, IARC points to findings of studies based on animal experiments submitted by the producers of glyphosate as evidence for the carcinogenic effect of glyphosate. All these findings were also considered in the glyphosate assessments of the BfR, which did support the conclusion of the Joint Meeting on Pesticide Residues (JMPR) of the FAO/WHO responsible for the assessment of active substances in pesticides: "In view of the absence of a carcinogenic potential in animals and the lack of genotoxicity in standard tests, the Meeting concluded that glyphosate is unlikely to pose a carcinogenic risk to humans. The BfR does not have any information as to how many of the 11 long-term studies on rats and mice that were assessed as valid were available to IARC.

Moreover, IARC concluded that a glyphosate formulation promoted skin tumours. In general, testing of formulations should not be used for toxicological evaluation of active substances because co-formulants may alter the outcome to a large extent. Therefore, the claim, based on this 2-stage cancer model in mice, that a highly concentrated, skin-irritating formulation containing the active substance promotes skin tumours is not considered by the institutions in the EU to be evidence for the carcinogenic properties of glyphosate.

It is not possible to fully examine the indications for the genotoxic potential of glyphosate based on the short report published by IARC, in particular due to the fact that the assessment included studies using formulations that are not specified in any detail.

The fact that different bodies assess issues differently due to differing information and assessments of experimental data is part and parcel of the risk assessment process. The BfR will therefore perform a thorough review of the classification issued by IARC once the monograph becomes available.

Formatiert: Nicht unterstrichen

Formatiert: Nicht unterstrichen

Formatiert: Nicht unterstrichen

Registratur - RE: Pflanzengift in Muttermilch gefunden Das Erste

Von: . fsa.europa.eu >
 An: "'Fiack Suzan'" <Suzai.Fiack@bfr.bund.de>, "[REDACTED]@efsa" EFSA Press
 <Press.Press@efsa.europa.eu >
 Datum: 03.07.2015 11:20
 Betreff: RE: Pflanzengift in Muttermilch rtfiindtn I n. p r e
 CC: @efsa.europa.eu >

Thanks Suzan for the heads up!

Regarding [REDACTED], we likely will give him an interview in September.

Viele Grüße,

From: **Fiack Suzan** [Suzan.Fiack@bfr.bund.de]
 Sent: 03 Julv 2015 11:10
 To: ; EFSA Press
 Cc:
 Subject: **Pflanzengift in muttermilch** gerunaen j Das Erste

Dear all,
 on Tuesday there will be a report on glyphosate in breast milk and we expect further questions from the press and public.
http://www.mdr.detfakt/fald_glyphosat06.html
 Herre is a link to a BfR press release:
http://www.bfr.bund.de/en/press_information/2015/16/the_national_breastfeeding_committee_and_the_bfr_recommend_that_mothers_continue_to_breastfeed-194547.html

Mit freundlichen Grüßen
 i.A.
 Suzan Fiack

Dr. Suzan Fiack

Bundesinstitut für Risikobewertung
 Fachgruppenleitung Presse- und Öffentlichkeitsarbeit
 Abteilung Risikokommunikation

Federal Institute for Risk Assessment
 Head of Unit Press and Public Relations
 Department Risk Communication

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BfR Berlin Registratur		Präs
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Eingangsregistrierung - Glyphosate und IARC

Von: ,@efsa.europa.eu >
An: "Hack Suzan (Suzan.Fiack@bfr.bund.de)" <Suzan.Fiack@bfr.bund.de >
Datum: 21.07:2015 11:58
Betreff: Glyphosate und IARC

Hallo Suzan,

Bezüglich glyphosate: Wir warten immer noch auf die Monographie des IARC. Wenn wir die Monographie bekommen haben, wollen wir eine kurze Meldung auf unsere Webseite stellen und darüber informieren, dass wir: a) die Monographie erhalten haben und b) für unser Peer Review Verfahren berücksichtigen (wir haben ein Mandat der Kommission). Plant Ihr auch irgendeine Art der Kommunikation? Eventuell könnten wir aufeinander verweisen.

Viele Grüße,

Communications & External Relations Department

e saun

Euimpfbam Food Safe Atibordy

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43126 Parma, Italy
Tel. +39 0521 036
www.efsa.europa.eu
[twitter.com/EFSA EU](https://twitter.com/EFSA_EU) 

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Von: efsa.europa.eu >
 An: "Fiack Suzan" <Suzan.Fiack@bfr.bund.de >
 Datum: 29.07.2015 09:42
 Betreff: RE: Antw: Glyphosat - Bundesinstitut hat Hinweise auf krebserregende Wirkung

Danke! **JC-k**
 'wsP **irr am. do⁴.** ; ?%

---Original Message

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]
 Senta 29 Julv 2015 09:27
 To: _
 Subject: Antw: Glyphosat - Bundesinstitut hat Hinweise auf krebserregende Wirkung

Hallo),
 danke für die Info. Der Beitrag dazu ist nicht ausgestrahlt worden.

Anbei unsere Mitteilung dazu:

<http://www.bfr.bund.de/cm/343/bfr-hat-offen-ueber-alle-vorliegenden-informationen-zur-bewertung-der-kanzerogenitaet-von-glyphosat-berichtet.pdf>

Gruß,
 Suzan

> [|@efsa.europa.eu](mailto:efsa.europa.eu) > 29.07.2015 09:23

>>>

FYI:

http://www.mdr.de/nachrichten/glyphosat142_zc-e9a9d57e_zs-6c4417e7.html

[cid:image001.png@01D0C9E6.40246A50]

uommunications % external Keiations Department European Food Safety Authority Via Carlo Magno 1A
 43126 Parma - Italy
 Direct: +39 0521 036
 Email:

Zefsa.europa.eu >

twitter.com/EFSA_EU <<http://twitter.com/EFSA:EU>>

[cid:image002.jpg@01 DOC9EO.40246A501]

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Suzan Fiack - IARC und glyphosate in EU Food Policy

Von: t@efsa.europa.eu
An: "Fiack Suzan (Suzan.Fiack@bfr.bund.de)" <Suzan.Fiack@bfr.bund.de >
Datum: 31.07.2015 12:27
Betreff: IARC und glyphosate in EU Food Policy

Hi Suzan,

Ich nehme an, dass du die Spokeswoman bist die in EU Food Policy zitiert wird. Journalist:
. Viele Grüße,

IARC publishes details of its glyphosate cancer findings

The WHO's International Agency for Cancer Research (IARC) published on Wednesday the 92-page monograph concluding that glyphosate is "probably carcinogenic in humans". The IARC issued its conclusion in an article in the *Oncology Lancet* in March 2015 but this is the first time other scientists have been able to evaluate the monograph and look at the evidence the IARC provides. It says "there is limited evidence in humans for the carcinogenicity of glyphosate" and that "a positive association has been observed for non-Hodgkin lymphoma". The monograph concludes that experimental animals provide "sufficient evidence" of the carcinogenicity of glyphosate which is used in hundreds of plant protection products globally, including 750 in the US alone. The authors argue that the mechanistic data offer "strong evidence for genotoxicity and oxidative stress" in terms of how glyphosate would cause cancer. They say there is also strong evidence that glyphosate can operate in two key ways known to cause cancer in humans. The IARC highlighted one study that showed communities exposed to glyphosate-based formulations had chromosomal damage in blood cells. Markers of chromosomal damage were significantly greater after exposure than before exposure in the same individuals. The industry, represented by the Glyphosate Task Force (GTF), has attacked the monograph, saying the evaluation of limited data on glyphosate by IARC does not call into question earlier evaluations that the chemical is safe. These have been done across the world for over 40 years and have confirmed glyphosate poses no unacceptable risk to humans, animals or the environment, says GTF. Not actual exposure. It argues that the IARC's work is only looking at cancer hazards and that "crucially, its evaluation does not assess the risks associated with actual exposure". However, a cursory glance at the IARC monograph shows that it does look at the exposure of workers as well as levels of the chemical in fruit and vegetables eaten by consumers, including an EU study. But the GTF insists that the German authorities took all the studies considered by the IARC into account in their role as EU rapporteur for the safety assessment. The GTF says the IARC has done a hazard assessment not a risk assessment. As a result, "hazards can be identified but the likelihood or degree to which they cause harm cannot be measured". The German authorities, in their role as EU safety assessor for the renewal of the glyphosate authorisation, said they had considered the animal studies which IARC refers to in its conclusions on cancer. A spokeswoman for BfR, the Federal Institute for Risk Assessment, said it was too early to say whether it had considered all the studies considered by IARC, given that the monograph had only just been published. BfR highlighted that glyphosate could be more toxic in formulations than on its own. In a statement, it said that in the studies provided, the composition of what was tested was often not described. The spokeswoman said that there could be some other substances in the formulations which were more harmful. The next step is for an assessment of the monograph by the European Food Safety Authority, which will involve the German authorities. EFSA is not expected to complete the assessment until the autumn. It is expected to set up a group of experts including staff for the evaluation, which would not be done by a panel. Member states, including BfR, are expected to play a role

efsain

Communications & External Relations Department

European Food Safety Authority

Via Carlo Magno 1A

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Direct: +39 0521 036

Email: gefsa.europa.eu

twitter.com/EFSA_EU

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Registratur - RE: Glyphosat

Von: @efsa.europa.eu>
 An: "'Fiack Suzan'" <Suzan.Fiack@bfr.bund.de>
 Datum: 04.08.2015 11:40
 Betreff: RE: Glyphosat
 CC: EFSA Press <Press.Press@efsa.europa.eu>

Danke Suzan!

Der Artikel im Tagesspiegel war exzellent.

From: Abfr.bund.de
 Sent: 04 August 2015 11:36
 To:
 Cc: EFSA Press
 Subject: Glyphosat

Hallo

für euch zur Info:

Inte: www.bfr.bund.de cm 349 bfr-reviews-mono•ra•h-of-the-international-a enc -for-cancer-research-iacr-on-glyphosate-divergence-procedure-within-the-who-still-in-progress.pdf

Mit freundlichen Grüßen

i.A.

Suzan Fiack

Dr. Suzan Fiack

Bundesinstitut für Risikobewertung
 Fachgruppenleitung Presse- und Öffentlichkeitsarbeit
 Abteilung Risikokommunikation

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BfR Berlin Registratur		Präs
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Pressestelle - RE: Wtrlt: Krebsgefahr durch Glyphosat - foodwatch fordert: Keine neue Zulassung für umstrittenes Pflanzenschutzmittel - E-Mail-Aktion an EU-Lebensmittelbehörde EFSA

Von: EFSA Press <Press.Press@efsa.europa.eu >
An: "'Pressestelle" <Pressestelle@bfr.bund.de >, "Fiack Suzan (Suzan.Fiack@bfr.bund.de)" <Suzan.Fiack@bfr.bund.de >
Datum: 05.08.2015 12:43
Betreff: RE: Wtrlt: Krebsgefahr durch Glyphosat - foodwatch fordert: Keine neue Zulassung für umstrittenes Pflanzenschutzmittel - E-Mail-Aktion an EU-Lebensmittelbehörde EFSA
CC: EFSA Press <Press.Press@efsa.europa.eu >

Vielen Dank!

Foodwatch hat die alte deadline verwendet (13. August). Dpa hat eine Clarification rausgeschickt, foodwatch die Kampagne offline genommen.

Viele Grüße,

From: Pressestelle fPressestelle@bfr.bund.de]

Sent: 05 August 2015 12:24

To:

Cc: EFSA Press

Subject: Wtrlt: Krebsgefahr durch Glyphosat - foodwatch fordert: Keine neue Zulassung für umstrittenes Pflanzenschutzmittel - E-Mail-Aktion an EU-Lebensmittelbehörde EFSA

Zur Info.

Mit freundlichen Grüßen

i.A.

Suzan Fiack

Dr. Suzan Fiack

Bundesinstitut für Risikobewertung
Fachgruppenleitung Presse- und Öffentlichkeitsarbeit
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www.bfr.bund.de

Eingangsregistrierung - FW: MONITORING 18.08.2015: TESTBIOTECH: EU
COMMISSION DECLARES REPORT ON GLYPHOSATE RISK ASSESSMENT A
SECRET but Monsanto had access

Von: eefsa.europa.eu>
An: "Fiack Suzan (Suzan.Fiack@bfr.bund.de)" <Suzan.Fiack@bfr.bund.de>
Datum: 31.08.2015 16:04
Betreff: FW: MONITORING 18.08.2015: TESTBIOTECH: EU COMMISSION DECLARES
REPORT ON GLYPHOSATE RISK ASSESSMENT A SECRET but Monsanto had
access
Anlagen: image001.png; image002.png; image003.png

From:
Sent: 22 August 2015 11:11
To:
Cc: 1
Subject: Re: MONITORING 18.08.2015: TESTBIOTECH: EU COMMISSION DECLARES REPORT ON
GLYPHOSATE RISK ASSESSMENT A SECRET but Monsanto had access

Dear what Germany has and is preparing are addenda to the RAR submitted for the public consultation to cover the comments raised during the peer-review, the addenda are considered confidential (on-going decision process) until the adoption but then will be published as background documents of the EFSA conclusion. Industry is generally consulted as the addenda should include both IND and RMS views. We are aware of the IND publication and received a similar comment from Pan Europe which we explained as above.

Thus what is not mentioned in the text is that the documents will be published by EFSA with our conclusion and the real reason for keeping documents temporarily as confidential.

Sent from my iPhone

Bd. 118

On 21 Aug 2015, at 17:26,

@efsa.europa.eu > wrote:

Hi

Testbiotech published this text on their website referring to a letter the Commission. We weren't aware of it. Is this consistent with your knowledge?

wrote to 23 -9-

Best,

2. d. A. 8.9.15

EU COMMISSION DECLARES REPORT ON GLYPHOSATE RISK
ASSESSMENT A SECRET

... but Monsanto had access

Tuesday, 18. August 2015

BfR Berlin		Präs
Registratur - Bereich • Wissenschaft		
01. SEP, 2015		2
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The EU Commission is refusing to let independent experts have access to the report prepared by the German Federal Institute for Risk Assessment (BfR) on the risk assessment of glyphosate. In a letter to Testbiotech dated 10 August 2015, the Commission says that the documents made available to the European Food Safety Authority (EFSA) by the German government "are protected in their entirety" as confidential. The EU Commission can see "no overriding public interest" that would justify access. There is, however, clearly public interest in the matter since the International Agency for Research on Cancer (IARC) of the World Health Organisation (WHO) has already declared that glyphosate is probably carcinogenic to humans. However, the German Federal Institute for Risk Assessment (BfR), is claiming there would be no risk to human health.

As stated in the letter from the EU Commission, "disclosure of these documents at this stage of the process will be premature and would seriously undermine EFSA's on-going decision-making process". Nevertheless, it appears that Monsanto and other Producers of glyphosate have already had access since they reviewed an advanced draft of the report, dated January 2015. Soon afterwards, industry quickly published a scientific paper claiming that glyphosate would not be carcinogenic. This was then promptly picked up by the German authority for the final version of its report.

"According to the Commission, giving industry access to the report does not undermine the process of risk assessment of glyphosate, whilst giving independent experts access to the data apparently does," says Christoph Then for Testbiotech "Glyphosate is present in many food products, it is the most widely used herbicide in the world. If it is carcinogenic it could impact consumers' health substantially. Therefore, from the perspective of public interest, there is no doubt that transparency in risk assessment must be given a high priority."

Despite a court ruling made by the European Court of Justice in 2013 (Case T-545/11), which said that data relevant for the risk assessment of herbicides have to be made public, there is still no sign that the EU Commission and EU Member States are complying with this process to create more transparency.

Contact:

info@testbiotech.org

Trainee

External Relations-Communications Department

22

<image001.png.secure>

Via Carlo Magno 1A
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twitter.com/EFSA_EU <image002.png.secure>

youtube.com/EFSAchannel <image003.png.secure>

Eingangsregistrierung - FW: Latest BfR Draft Assessment Report regarding glyphosate

Von: gefsa.europa.eu>
An: "Fiack Suzan (Suzan.Fiack@bfr.bund.der <Suzan.Fiack@bfr.bund.de >
Datum: 31.08.2015 16:05
Betreff: FW: Latest BfR Draft Assessment Report regarding glyphosate

From:
Sent: 20 August 2015 11:45
To: 1
Subject: RE: Latest BfR Draft Assessment Report regarding glyphosate

Dear

The final version including the addenda produced during the peer review will be published as a background document to the EFSA Conclusion and will be available through the registry of questions after the sanitisation for confidential information.

KR,

From:
Sent: 20 August 2015 17:38
To:
Subject: Latest BfR Draft Assessment Report regarding glyphosate

Hi

a Journalist contacted me asking for the latest BfR report re glyphosate, she said on our DAR page <http://dar.efsa.europa.eu/dar-web/provision> is only the old version from 12/03/201 available.

Do you know if and if yes, when the newest version will be available on dar ?

Best regards,

ay

Suzan Fiack - RE: Umweltinstitut

Von: @efsa.europa.eu>
An: "'Fiack Suzan'" <Suzan.Fiack@bfr.bund.de >
Datum: 02.09.2015 17:10
Betreff: RE: Umweltinstitut
CC: efsa.europa.eu>, EFSA Press
 <Press.Press@efsa.europa.eu >

Hallo Suzan,


Ja, das hat sich auch bei uns gemeldet und per Public Access to Document Request Einsicht in den, wie sie es nennen, „Full assessment report on glyphosate as it was sent to EFSA by the German Bundesinstitut für Risikobewertung in April 2015," zu nehmen. Sie haben uns eine Frist von 14 Tagen gegeben.

Unsere juristische Abteilung wird sich damit befassen.

Unsere Lines to take:

The draft Renewal Assessment Report (RAR) for glyphosate has been published March 2014. The whole process is transparent, which is proven by the fact that 29 different Parties (individuals and NGOs) have provided comments which were taken into account in the revised RAR. Only the access to the revised RAR is refused for the time being, as this document is currently being finalized. After that step, the final RAR will be published together with full information on the version history in early November 2015. By refusing access to the revised RAR, it is intended to protect the integrity of the decision making process, in order to avoid that a risk management decision on a potentially risky substance would be delayed unnecessarily.

Viele Grüße,

From: Fiack Suzan [Suzan.Fiack@bfr.bund.de]
Sent: 02 September 2015 09:33
To: 
Cc: EFSA Press
Subject: Umweltinstitut

Hallo

2 5-

anbei sende ich dir wie bereits besprochen den Brief des
eine ähnliche Anfrage vorliegen? Wir planen erneut an die "zuständigen europäischen Behörden" zu
verweisen. Über eine Einschätzung würde wir uns freuen.
Beste Grüße aus Berlin,
Suzan

Habt ihr bereits

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Bunricsinstitut für Risikobeweriunci

Postfach 12 69 42

10609 Berlin

Tel. +49 :30 18412-0

+49 30 18412-4741

bfr(?übfr_btind_de

www.bfr.bund.de

Per F-Mail

Ihre Zeichen und Nachrichten vom	Gesch.-Z.: Bitte bei Antwort angeben	Tel.-Durchwahl/Fax	Datum	Org.-Einheit/Ansprechpartner/in
31.07.2015	2312-01 Az.8481048	4300	10.08.2015	23

Ihre Anfrage zum Prüfbericht zu Glyphosat

Sehr geehrter

vielen Dank für Ihre Anfrage an das Bundesinstitut für Risikobewertung (BfR).

Der erste Entwurf des überarbeiteten (revidierten) Bewertungsberichts auf Basis der Antragsunterlagen der Glyphosat Taskforce und eigenen Literaturrecherchen des BfR wurde nach dem Zeitplan der Europäischen Kommission bis Ende 2013 erstellt und vom Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) an die Europäische Behörde für Lebensmittelsicherheit (EFSA) übergeben. Die öffentliche Konsultation mit Fachleuten und Stakeholdern im Peer Review-Verfahren unter der Leitung der EFSA ist 2014 erfolgt. Das BVL hat in den revidierten Gesamtbericht die umfangreichen Kommentare und zusätzlich gelieferten Studien aus der Konsultation mit den Mitgliedsstaaten und der interessierten Öffentlichkeit eingearbeitet und diesen auftragsgemäß im Dezember 2014 an die EFSA weitergeleitet. Der überarbeitete Bericht liegt derzeit bei der EFSA. Bitte wenden Sie sich mit ihrer Anfrage zum Bewertungsbericht an diese.

Aktuelle Fragen und Antworten rund um die Diskussion zu Glyphosat können Sie unseren FAQ entnehmen:

<http://www.bfr.bund.de/cm/343/fragen-und-antworten-zur-gesundheitlichen-bewertung-von-glyphosat.pdf>

Mit freundlichen Grüßen

im Auftrag ,'

Eingangsregistrierung - Commission says EFSA justified in keeping glyphosate report under wraps

Von: 1@efsa.europa.eu
 An: "Fiack Suzan (Suzan.Fiack@bfr.bund.der <Suzan.Fiack@bfr.bund.de >
 Datum: 03.09.2015 10:25
 Betreff: Commission says EFSA justified in keeping glyphosate report under wraps
 CC: ' :@efsa.europa.eu>

Hi Suzan,

This might be of interest to you regarding request from Umweltinstitut and media. Agra Europe published this article yesterday evening. Viele Grüße,

Commission says EFSA justified in keeping glyphosate report under wraps

The European Commission has defended the European Food Safety Authority's (EFSA) decision not to release the final version of its assessment report on the controversial pesticide glyphosate until official publication, despite a complaint from a prominent non-governmental organisation (NGO).

EFSA is right not to release the report before its official publication to avoid undue interference in the decision-making process, the Commission said in a letter to IVIunich-based NGO Testbiotech, which had filed a complaint....

<https://www.agra-net.net/agra/agra-europeipolicy-and-legislation/biotechnology/commission-says-efsa-justified-in-keeping-glyphosate-report-under-wraps-490097.htm?CTR=DNART>

efsa«

Communications & External Relations Department
 European Food Safety Authority
 Via Carlo Magno 1A
 43126 Parma - Italy
 Direct: +39 0521 036
 Email: efsa.euroDa.eu

twitter.com/EFSA_EU

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7. Sep.

BfR Berlin Registratur - Bereich - Wissenschaft	Präs
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Bd. 10/18

7.2.147 10.9.15

Eingangsregistrierung - RE: Antw: Re: Commission says EFSA justified in keeping glyphosate report underwraps

Von: efsa.europa.eu
 An: "'neck Suzan'" <Suzan.Fiack@bitbund.de >, RAMSAY James
r@efsa.europa.eu

Datum: 07.09.2015 15:43

Betreff: RE: Antw: Re: Commission says EFSA justified in keeping glyphosate report underwraps

CC: EFSA Press <Press.Press@efsa.europa.eu >

Hi Suzan,

James meant the line the Commission is using. This is not a line the BfR could use, but 1 paste it below for your information. 1 also put the line we are using. 1 think it would be best if you refer requests to us.

EFSA lines to take:

The draft Renewal Assessment Report (RAR) for glyphosate has been published March 2014. Only the access to the revised RAR is refused for the time being, as this document is currently being finalized. After that step, the final RAR will be published together with full information on the version history in early November 2015. By refusing access to the revised RAR, it is intended to protect the peer review process, in order to avoid that a subsequent risk management decision on a potentially risky substance would be delayed unnecessarily.

Commission line to take:

Several NGOs (including Testbiotech), are in possession of the dossier as well as of the assessment report (RAR) of the dossier. The Commission strongly rejects the Gllegation that the Renewal Assessment Report (RAR) for glyphosate is kept secret and insists that the process was transparent. This is proven by the fact that 29 different parties (individuals and NGOs, including Testbiotech) have provided comments which were taken into account in the revised RAR. Only the access to the revised RAR at this moment in time was refused, as this document is currently being finalized. After that step, the final RAR will be published together with full information on the version history. By refusing access to the revised RAR, the Commission intends to protect the integrity of the decision making process, in order to avoid that a risk management decision on a potentially risky substance would be delayed unnecessarily

Viele Grüße,

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Handwritten notes and signatures:

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- 10
- 11

--- Original Message--

From: Fiack Suzan [Suzan.Fiack@bfr.bund.de]

Sent: 07 September 2015 11:28

To:

Cc:

Subject: Antw: Re: Commission says EFSA justified in keeping glyphosate report underwraps

Hi

thanks for your mail!. Which line do you mean?

Best,

Suzan

>>efsa.europa.eu > 05.09.2015 11:08 >>>

we can share the line that we have from the commission

Gcl. 4⁰ / 13

On 04 Sep 2015, at 21:14, Fiack Suzan

<Suzan.Fiack@bfr.bund.de <mailto:Suzan.Fiack@bfr.bund.de >>

wrote:

Hi

thank you for the Information. Is there anything more "official" for proving that EFSA and BfR) should not publish / or talk about the RAR?

Best,

Suzan

Von meinem iPhone gesendet

Am 03.09.2015 um 10:25 schrieb "[REDACTED]"

Wefsa.europa.eu <mailto:Wefsa.europa.eu>, efsa.europa.eu >>.

Hi Suzan,

This might be of interest to you regarding request from Umweitinstitut and media. Agra Europe published this article yesterday evening. Viele Grüße, | Commission says EFSA justified in keeping glyphosate report under wraps The European Commission has defended the European Food Safety Authority's (EFSA) decision not to release the final version of its assessment report on the controversial pesticide glyphosate until official publication, despite a complaint from a prominent non-governmental organisation (NGO).

EFSA is right not to release the report before its official publication to avoid undue interference in the decision-making process, the Commission said in a letter to Munich-based NGO Testbiotech, which had filed a complaint....

<https://www.agra-net.net/agra-europe/policy-and-legislation/biotechnology/commission-says-efsa-justified-in-keeping-glyphosate-report-under-wraps-490097.htm> ?CTR=DNART

<image001.png>

Communications & External Relations Department European Food Safety Authority Via Carlo Magno 1A
43126 Parma - Italy

Direct: +39 0521 036

Email:

@efsa.europa.eu >

twitter.com/EFSA_EU <http://twitter.com/EFSA_EU> <image002.jpg> This e-mail, including its attachments, is intended only for the use of the recipient(s) named above. Unless you are a named recipient (or authorised by a recipient), access to this e-mail message or any disclosure or copying of its content, or any action taken in reliance on it is unauthorised and may be unlawful.

Von: eefsa.europa.eu >
An: 'Plack Suzan'" <Suzan.Fiack@bfr.bund.de>,
 .Defsa.europa.eu>
CC: EFSA Press <Press.Press@efsa.europa.eu >
Datum: 07.09.2015 16:25
Betreff: RE: Antw: Re: Commission says EFSA justified in keeping glyphosate report underwraps

17.9.1

Viele Grüße,

-----Original Message-----

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]

Sent: 07 September 2015 11:28

To:

Cc:

Subject: Antw: Re: Commisston says EFSA justified in keeping glyphosate report underwraps

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Suzan

@efsa.europa.eu >>

05.09.2015 11:08 ;>>

we can share the line that we have from the commission

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<Suzan.Fiack@bfr.bund.de <mailto:Suzan.Fiack@bfr.bund.de <mailto:Suzan.Fiack@bfr.bund.de%3cmailto:Suzan.Fiack@bfr.bund.de>>>

wrote:

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32

Von: Suzan Fiack <suzan.fiack@bfr.bund.de>
An: @efsa.europa.eu
Datum: 15.09.2015 08:12
Betreff: EU verschiebt Glyphosat-Zulassung - Wirtschaft - Süddeutsche.de

Hi

it seems as if EFSA needs more time:

[http://www.sueddeutsche.de/wirtschaft/umstrittenes-acker-gift-eu-verschiebt-glyphosat-zulassung_-1.2648](http://www.sueddeutsche.de/wirtschaft/umstrittenes-acker-gift-eu-verschiebt-glyphosat-zulassung_-1.2648243)

243

Is this correct?

Suzan

Von meinem iPhone gesendet

Von: @efsa.europa.eu >
An: Fiack Suzan <Suzan.Fiackebtr.bund.de>, @efsa.europa.eu >
Datum: 15.09.2015 09:00
Betreff: RE: EU verschiebt Glyphosat-Zulassung - Wirtschaft - Süddeutsche.de

Hi Suzan

From our side the scheduled finalisation and publication is still end October/beginning November - so we have not requested more time for our assessment

I presume that the article refers to an extension for the time the Commission needs for the authorisation decision. With active substances, the Commission usually has 6 months after EFSA delivers its peer review to make a decision an authorisation and also has the discretion to extend this period if necessary.

We will check with Commission colleagues and if this is indeed the case request that SZ update their article to reflect the fact that the deadline extension is not prompted by EFSA's assessment.

Best,

- - Original Message

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]

Sent: 15 September 2015 08:12

To: '

Subject: EU verschiebt Glyphosat-Zulassung - Wirtschaft - Süddeutsche.de

Hi

it seems as if EFSA needs more time:

<http://www.sueddeutsche.de/wirtschaft/umstrittenes-acker-gift-eu-verschiebt-glyphosat-zulassung-1.2648243>

Is this correct?

Suzan

Von meinem iPhone gesendet

publish / or talk about the RAR?

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Suzan

Von meinem iPhone gesendet

Am 03.09.2015 um 10:25 schrieb "

Hi Suzan,

This might be of interest to you regarding request from Umweltinstitut and media. Agra Europe published this article yesterday evening. Viele Grüße, Jan Commission says EFSA justified in keeping glyphosate report under wraps The European Commission has defended the European Food Safety Authority's (EFSA) decision not to release the final version of its assessment report on the controversial pesticide glyphosate until official publication, despite a complaint from a prominent non-governmental organisation (NGO).

EFSA is right not to release the report before its official publication to avoid undue interference in the decision-making process, the Commission said in a letter to Munich-based NGO Testbiotech, which had filed a complaint...

<https://www.agra-net.net/agra/agra-europe/policy-and-legislation/biotechnology/commission-says-efsa-justified-in-keeping-glyphosate-report-under-wraps-490097.htm?CTR=DNART>

<image001.png>

Communications & External Relations Department European Food Safety Authority Via Carlo Magno 1A

43126 Parma - Italy

Direct: +39 0521 036

Email:

twitter.com/EFSA_EU <http://twitter.com/EFSA_EU> <image002.jpg> This e-mail, including its attachments, is intended only for the use of the recipient(s) named above. Unless you are a named recipient (or authorised by a recipient), access to this e-mail message or any disclosure or copying of its content, or any action taken in reliance on it is unauthorised and may be unlawful.

Eingangsregistrierung - FW: SZ and Glyphosate

Von: 1@efsa.europa.eu
An: "Fiack Suzan (Suzan.Fiack@bfr.bund.de)" <Suzan.Fiack@bfr.bund.de >
Datum: 15.09.2015 12:08
Betreff: FW: SZ and Glyphosate
CC: @efsa.europa.eu

Hi Suzan

Further to our exchange this morning, please see below for the latest from the Commission on glyphosate approval.

As 1 suspected, the extension refers to the period of time — after EFSA's assessment that will be required by risk managers to decide on approval/non-approval. EFSA's deadline of end October remains the same.

For any questions from media regarding deadline for *overall* approval, I would refer media to the Commission (DG SANTE). For any questions on EFSA's deadline for the peer review, you can say that this will be completed by end October.

Hope this clears things up! Thanks for making us aware of the SZ article.

Best,

From: 'pec.europa.eu'
Sent: 15 September 2015 11:35
To:
Cc: Team Media Relations
Subject: RE: SZ and Glyphosate

Hi

We cannot say that we will be extending the authorisation for 6 months until the assessment is carried out. But we can say the following:

- The Commission intends to extend the approval of glyphosate by 6 months. To this end, it plans to submit a draft act regarding the extension of the approval period to the Standing Committee on Plants, Animals, Food and Feed.
- The reason for the proposed extension is that the evaluation procedure is delayed, not least due to the decision to ask EFSA to include the IARC Monograph in its peer review of glyphosate. That Monograph became available only in late July 2015, and is currently under evaluation by the Member States and EFSA.
- Once EFSA will have finalised their Conclusion on glyphosate, further time is necessary for the Commission and Member States to discuss the appropriate risk management measures, and eventually to decide on a renewal of the approval, or a non-approval.
- The Commission has a legal obligation to extend the approval period of an active substance, if the reasons for delay are beyond the control of the applicant. That is the case for

glyphosate.

Not sure where the "summer '16" deadline comes from, but I can check with my colleagues in Berlin who briefed SZ.

I will also convey the EFSA line to them.

All the best and till soon,

European Commission
Spokesperson's Service
BERL 04/305
B-1049 Brussels/Belgium
Tel.: -
Mob.:

** The information contained in this e-mail cannot be quoted in my name*

From: reefsa.europa.eu
Sent: Tuesday, September 15, 2015 9:28 AM
To: (COMM)
Cc: Team Media Relations
Subject: SZ and Glyphosate

Dear both

We came across this article this morning in SZ on glyphosate. It's perhaps slightly misleading in that it may give the impression that EFSA needs until summer 2016 to complete its assessment.

<http://www.sueddeutsche.de/wirtschaftiumstritten-es-acker-gift-eu-verschiebt-glyphosat-zulassung,-1.2648243>

Do you guys have a line on the extension of the deadline for the approval that you could share with us?

From our side, the line stays the same — the original deadline of August for completion of the risk assessment was pushed back to the end of October to allow EFSA sufficient time to consider the recently published IARC paper. When EFSA's evaluation is complete it will provide its advice to the European Commission, which will take a decision in due course (by summer 2016??) regarding authorisation.

Thanks,

D.S.

y

38

Suzan Fiack - Media Monitoring: EU Food Policy - Glyphosate: MEPs back six month extension of authorisation

Von: - 1@efsa.europa.eu>
 An: "Fiack Suzan (Suzan.Fiack@bfr.bund.de)" <Suzan.Fiack@bfr.bund.de >
 Datum: 16.09.2015 10:03
 Betreff: Media Monitoring: EU Food Policy - Glyphosate: MEPs back six month extension of authorisation
 CC: @efsa.europa.eu>,
 „eu>

Hi Suzan,

Below a good summary of yesterday's debate at the European Parliament showing different views of MEPs towards the BfR. Please don't share with others in the BfR there is a copyright issue with the article. Best,

Glyphosate: MEPs back six month extension of authorisation

MEPs this afternoon supported the six month extension for the authorisation of glyphosate, as proposed by the European Commission in order to allow EFSA proper time to evaluate the herbicide's safety. An attempt by the far left GUE political group to send a political message to the Commission by opposing the extension was defeated in a vote in the Environment, Public Health and Food Safety Committee (ENVI).

MEPs have no power of veto, so a vote against the extension would have been a pure political gesture. In the debate before the vote, the German Socialist and former ENVI Committee chair, , said the Committee should hold a hearing with EFSA once its delayed verdict on glyphosate was published. He said the hearing should include IARC (International Agency for Research on Cancer), which said in March that the chemical was probably carcinogenic to humans.

A senior official from DG SANTE said the Commission would discuss EFSA's findings in November with member states and prepare a draft review measure either to renew the authorisation or not. She said there would be a decision by the beginning of 2016. EFSA is currently considering the recommendation of the German Federal Institute for Risk Assessment, BfR, which, as EU rapporteur on glyphosate, has concluded the herbicide is safe for current uses, and the IARC monograph.

The German Institute was criticised by the Socialist vice-chair of the committee, who said "nobody knows the committee at BfR which is responsible". !legal practices who supported the GUE motion, also accused DG SANTE of "illegal practices" for its action in delaying the reauthorisation decision since 2012. But the German MEP the coordinator for the centre-right EPP group, said the BfR "is not known for playing down risks". Fellow centre-right member - also said she trusted the BfR. 3rgued that what mattered was the level ot consumer exposure, a point also mode by the European Conservative and Reformist MEP, (vho said the IARC monograph was not a risk assessment. However, the Austrian Socialist MEP, said that, based on the precautionary principle, glyphosate should be banned.

Many MEPs expressed concern about its safety, including about its presence in breast milk. But even the Greens were in favour of the six month extension to properly assess and discontinue the chemical. "I hope EFSA will look at it properly," said Green MEP

The Commission implementing act will extend the authorisation for glyphosate for six months beyond the due expiry date of 15 December.

zio

Eingangsregistrierung - Fwd: Request Süddeutsche Zeitung, Glyphosate and WHO

Von: Suzan Fiack <suzan.fiack@bfr.bund.de >
An: Eingangsregistrierung@bfr.bund.de
Datum: 22.09.2015 09:44
Betreff: Fwd: Request Süddeutsche Zeitung, Glyphosate and WHO
CC: 6.pol.domain@bfr.bund.de, Leitung@bfr.bund.de, 2@mail.bfr.bund.de

Bitte in den GG

Von meinem iPhone gesendet

Anfang der weitergeleiteten E-Mail:

Von: 1@efsa.europa.eu
Datum: 22. September 2015 09:41:17 MESZ
An: "Suzan Fiack" <Suzan.Fiack@bfr.bund.de>¹¹(
efsa.europa.eu)
Betreff: RE: Request Süddeutsche Zeitung, Glyphosate and WHO

Thanks Suzan, that's helpful. **I think** we are more or less aligned in our understanding of the significance of the WHO report. Our response will be something along the lines of:

The report of the WHO Task Force does not have a bearing on the timing of the on-going EFSA evaluation of glyphosate.

This is because the IARC conclusions - and the studies upon which those conclusions are based - have already been considered by the BfR in its assessment of glyphosate and are currently being considered by EFSA in the final stage of the EU risk assessment.

EFSA's conclusions are likely to be published in November, after which the European Commission will decide on whether or not to approve glyphosate for use in the EU.

Best,

From: Fiack Suzan [<mailto:Suzan.Fiack@bfr.bund.de>]
Sent: 21 September 2015 19:13
To:
Cc:
Subject: Re: Request Süddeutsche Zeitung, Glyphosate and WHO

Hi,

please find a link to our background information.

<http://mobillfr.bund.de/cm/343/bfr-unterstuetzt-die-aktualisierung-der-glyphosat-bewertung-durch-impr.pdf>

(In German only at the moment)

I do not have the full report.

Best regards,
 Suzan

Von meinem iPhone gesendet

Am 21.09.2015 um 17:00 schrieb "

Hi Suzan,

BfR Berlin Registratur		23.09.15 Was
Registratur	22. SEP. 2015	24.09.15 23
Az.:		25. SEP. 2
DocForm-Nr.:	8550117	

Wgi. 30. OKT. 2016

1@efsa.europa.eu:

Thanks. That's ok. We are in touch with the Commission and will align our lines. Do you already have a response for this Journalist. Our initial reaction is that the WHO report will not have any bearing on our on-going peer review.

And: Do you have the full report?

From: Fiack Suzan [<mailto:Suzan.Fiack@bfr.bund.de>]
Sent: 21 September 2015 16:57
Cc: EFSA Press; Team Media Relations
Subject: Re: Request Süddeutsche Zeitung, Glyphosate and WHO

Hi,
 I am still in a meeting. I might be able to answer via email.
 Best,
 Suzan

Von meinem iPhone gesendet

Am 21.09.2015 um 16:38 schrieb "1

eefsa.europa.eu;

Hi Suzan
 Just following up on his email (he's in a meeting at the moment). Do you have a moment to discuss this over the phone this afternoon?
 Thanks,

From:
Sent: 21 September 2015 13:43
To: Fiack Suzan (Suzan.Fiack@bfr.bund.de)
Cc: Team Media Relations; EFSA Press
Subject: FW: Request Süddeutsche Zeitung, Glyphosate and WHO

Hi Suzan,

Am writing in English because of EFSA-colleagues in copy.

We received the below media enquiry from Süddeutsche Zeitung.
 According to the article, the BfR is going to publish a statement today. Can you please share it with us, once ready?

Many thanks,

From: '1'@sueddeutsche.de
Sent: 21 September 2015 11:42
To: EFSA Press
Subject: Request Süddeutsche Zeitung, Glyphosate and WHO

Dear

Background of my question is the criticism of the
 WHO to the glyphosate auditors

An expert committee has recommended a complete re-evaluation of risks and a reform of the whole regulatory framework for the examination of glyphosate.

This recommendation arises some questions that are related to EFSA . For this review the WHO also relates to the Federal Institute for Risk Assessment

Süddeutsche Zeitung has published the following article an Monday.

<http://www.sueddeutsche.de/wirtschaft/landwirtschaft-weltgesundheitsorganisation-rueffelt-glyphosat-pruefer-1.2655778>

My questions are now

How will EFSA respond to the WHO report ? The review 's running currently and the report of the BfR has exactly the shortcomings described by the WHO

What consequences do the recommendations of the WHO have for the EFSA principle ? 1s there an Obligation to implement the recommendation ?

What consequences do the recommendations have for the ongoing re-evaluation of glyphosate in the EU ? Has the report to be withdrawn and reevaluated?

Does that mean a further delay of the re-registration of glyphosate in the EU?

It would be very helpfull to have your answers soon.

**Thanks lot for your support
Vielen DANK**

Mit freundlichen Grüßen

SÜDDEUTSCHE ZEITUNG 1 Wirtschaftsredaktion
Hultschiner Str. 8, 81677 München
Telefon +49 (0)89 2183 Aobil
Mail: _____@sueddeutsche.de
Web: Sueddeutsche.de, _____
<image001.gif>

Antwort an die Süddeutsche Zeitung vom 27. November 2015

Die wissenschaftliche Bewertung des Wirkstoffes Glyphosat ist abgeschlossen und die zuständigen politischen Gremien können nun auf dieser Basis eine Entscheidung treffen. Durch die öffentliche Konsultation gab es für die Wissenschaft und Öffentlichkeit sowie andere EU-Mitgliedsstaaten die Möglichkeit, den Bericht zur Neubewertung von Glyphosat vorab zu kommentieren und weitere Studien einzureichen.

Der von Ihnen genannte offene Brief richtet sich an den EU-Kommissar nachdem eine fundierte Einschätzung der zuständigen wissenschaftlichen Institutionen der Risikobewertung erfolgt ist. Adressat des Briefes ist offenbar nicht die Wissenschaft - hier wären zudem auch andere Wege der Kommunikation; beispielsweise über wissenschaftliche Publikationen, üblich.

Unterzeichner des offenen Briefes ist nicht die Arbeitsgruppe IARC der Weltgesundheitsorganisation WHO oder die IARC selbst.

Die in dem offenen Brief getroffenen Aussagen zur Kanzerogenität von Glyphosat kann das Bundesinstitut für Risikobewertung (BfR) wissenschaftlich nicht nachvollziehen.

Die Einschätzung des BfR zur Frage der Kanzerogenität von Glyphosat wird von der Europäischen Behörde für Lebensmittelsicherheit (EFSA), den zuständigen nationalen, europäischen und anderen internationalen Institutionen einschließlich des WHO/FAO Joint Meeting an Pesticide Residues (JMPR) geteilt. Zu der Einschätzung kommen auch die amerikanische Umweltbehörde (US-EPA) und die kanadische Behörde (Canada Health).

Die WHO selbst hat eine „ad hoc expert task force“ mit der Aufgabe eingerichtet, die Gründe für die unterschiedliche Bewertung der Daten durch ihre eigenen Gremien, der IARC einerseits und des JMPR andererseits, aufzuklären. Es handelt sich dabei um ein wissenschaftliches Divergenzverfahren innerhalb der WHO, das noch nicht abgeschlossen ist.

Die EFSA und die EU-Mitgliedstaaten haben die Neubewertung von Glyphosat abgeschlossen. Die europäischen Experten bestätigen in der EFSA-Schlussfolgerung mehrheitlich die gesundheitliche Bewertung des Bundesinstituts für Risikobewertung (BfR), dass nach derzeitigem wissenschaftlichen Erkenntnisstand beim Menschen bei einer sachgerechten Anwendung in der Landwirtschaft keine krebserzeugenden, erbgutverändernden oder entwicklungsschädigenden Risiken von Glyphosat zu erwarten sind.

Das OECD Guidance Dokument 116 sieht vor, dass die Auswahl der verwendeten statistischen Methoden für die Auswertung der Daten bereits bei der Planung, d.h. vor Beginn der Studie durch den Studienleiter festzulegen ist. Das BfR hat aus Transparenzgründen in seiner Bewertung zusätzlich zu den von den Studienleitern ausgewählten statistischen Tests auch den von der PARC favorisierten und verwendeten Trendtest hinsichtlich seiner Aussagen überprüft. Grundsätzlich ist es aus wissenschaftlicher Sicht fragwürdig, Daten im Nach-

Trendtest hinsichtlich seiner Aussagen überprüft. Grundsätzlich ist es aus wissenschaftlicher Sicht fragwürdig, Daten im Nachhinein mit einer anderen statistischen Methode auszuwerten als dies bei der Konzeption der Studie festgelegt wurde.

Das gesetzliche Verfahren schreibt in Europa vor, dass der Antragsteller für die Datenerhebung der toxikologischen Studien für den beantragten Wirkstoff verantwortlich ist. Dies entspricht dem generellen Grundsatz, wie in anderen Zulassungsverfahren, z. B. im Arzneimittelrecht, dass der Hersteller bzw. Inverkehrbringer die Verantwortung für die Unbedenklichkeit der Produkte trägt und dies auch nachzuweisen hat. Alleiniges Kriterium für die Berücksichtigung von Studienergebnissen ist die wissenschaftliche Qualität und Evidenz der Studien.

Das BfR empfiehlt grundsätzlich, Diskussionen über wissenschaftliche Studien auf wissenschaftlicher Ebene, selbstverständlich auch wenn nötig kontrovers, zu führen. Ein integraler Bestandteil der Wissenschaft ist dabei der wissenschaftliche Publikationsprozess. Thesen oder Kommentare zu Studien können dem wissenschaftlichen Diskurs nur zugeführt werden, wenn diese publiziert wurden und die entsprechenden Schlussfolgerungen transparent nachvollziehbar sind.

Da die wissenschaftliche Bewertung des Wirkstoffes Glyphosat abgeschlossen ist, können die zuständigen politischen Gremien nun auf Basis der wissenschaftlichen Bewertung entscheiden.

Die Schlussfolgerungen und Dokumente sind für die Politik, Wissenschaft und Öffentlichkeit auf der Webseite der EFSA als zuständige Behörde transparent und offen nachvollziehbar.

www.efsa.eu

Alle veröffentlichten Dokumente des BfR zum Thema Glyphosat finden Sie hier:

<http://www.bfr.bund.de/de/a-z/index/lyphosat-126638.htm#migrant-2>

Bei weiteren Nachfragen wenden Sie sich bitte an die zuständige Europäische Behörde für Lebensmittelsicherheit (EFSA). www.efsa.europa.eu

Suzan Fiack - RE: Bundestag Glyphosat

Von: ee@fsa.eurona.eu>
An: "'Fiack Suzan'" <Suzan.Fiack@bfr.bund.de >, R @efsa.europa.eu >
Datum: 23.09.2015 16:57
Betreff: RE: Bundestag Glyphosat
CC: @efsa.europa.eu>

Thanks Suzan! I will follow the stream an Monday.

Best,

From: Fiack Suzan [Suzan.Fiack@bfr.bund.de]
Sent: 23 September 2015 16:47
To:
Cc:
Subject: Bundestag Glyphosat

Dear all,
there will be some media attention because of a public hearing in the Bundestag concerning glyphosate.
https://www.bundestag.de/blob/386966/86b239e35db73fc7d60c161ccae4b913/to_40_sitzung_oeffentliche_anhoerung_am28_09_2015-data.pdf
Best regards,
Suzan

Von: Suzan Fiack
An:
CC:
Datum: 23.09.2015 17:21
Betreff: Antw: RE: Bundestag Glyphosat

Hi
wir auch (siehe Seite 2).

Mit freundlichen Grüßen
I.A.
Suzan Fiack

Dr. Suzan Fiack

Bundesinstitut für Risikobewertung
Fachgruppenleitung Presse- und Öffentlichkeitsarbeit
Abteilung Risikokommunikation

Federal Institute for Risk Assessment
Head of Unit Press and Public Relations
Department Risk Communication

Max-Dohrn-Straße 8-10, 10589 Berlin
Germany

Tel. +49 30 18412-4302
Fax +49 30 18412-4970

www.bfr.bund.de

>>> @efsa.europa.eu > 23.09.2015 17:19 >>>

Hi Suzan,
Kurze Frage: Werden nur die vier Sachverständigen gehört (aus Brasilien, der Schweiz etc...) oder wird auch jemand vom BfR anwesend sein?

From: Fiack Suzan [<mailto:Suzan.Fiack@bfr.bund.de>]
Sent: 23 September 2015 16:47
To:
Cc:
Subject: Bundestag Glyphosat

Dear all,
there will be some media attention because of a public hearing in the Bundestag concerning glyphosate.
https://www.bundestag.de/blob/386966/86b239e35db73fc7d60c161ccae4b913/to_40_sitzung_oeffentlich_e_anhoerung_am28_09_2015-data.pdf
Best regards,
Suzan

Registratur - Zeitplan Glyphosat

Von: efsa.europa.eu
An: "pressestelle@bfr.bund.de <pressestelle@bfr.bund.de>, "Fiack Suzan (Suzan.Fiack@bfr.bund.de)" <Suzan.Fiack@bfr.bund.de>
Datum: 23.10.2015 14:56
Betreff: Zeitplan Glyphosat

Liebe Suzan, lieber , liebe Kolleginnen und Kollegen der BfR Pressestelle,

anscheinend zirkulieren im BVL und BfR einige Fehlinformationen bezüglich EFSA's Zeitplan für das Gutachten zu Glyphosat.

Wie in unserem Mandat von der EU Kommission festgelegt, ist unsere Deadline der 30. Oktober. Dies ist der Zeitpunkt an dem wir unser Gutachten an die Kommission schicken.

Eine Veröffentlichung auf der Webseite der EFSA wird erst im November erfolgen. Ein fixer Tag steht noch nicht fest, aber ich rechne mit der 46.KW.

Ich melde mich, sobald der Tag der Veröffentlichung feststeht.

Wir gehen davon aus, dass das BfR diese Information vertraulich behandelt.

Beste Grüße,

efsa.

Communications & External Relations Department
 European Food Safety Authority

Via Carlo Magno 1A
 43126 Parma - Italy
 Direct: +39 0521 036

Email efsa.europa.eu
[twitter.com/EFSA EU](https://twitter.com/EFSA_EU)

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Von: efsa.europa.eu
 An: Fiack Suzan <Suzan.Fiack@bfr.bund.de>, efsa.europa.eu >, EFSA Press <Press.Press@efsa.europa.eu >
 CC: efsa.europa.eu
 Datum: 28.10.2015 13:23
 Betreff: RE: Glyphosat EFSA Conclusion

Hi Suzan

I just tried to call your press office number. Is it possible to reach you by phone and I can talk through what we have planned.

Best,

Communications and External Relations Department

Via Carlo Magno 1A
 43126 Parma (Italy)
 Tel. +
 Mob
www.efsa.europa.eu
twitter.com/EFSA_EU
youtube.com/EFSAchannel

-Original Message--

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]
 Sent: 98 October 2015 13:18
 To: EFSA Press
 Cc:
 Subject: Glyphosat EFSA Conclusion

Dear all,

hope you are all fine. I just wanted to know the timetable and press and public relations activities with regard to the EFSA conclusion on glyphosate. Are there any activities planned?

All the best from Berlin,
 Suzan

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Von: ee@efsa.europa.eu >
 Fiack Suzan <Suzan.Fiack@bfr.bund.de>, ee@efsa.europa.eu >
 CC: l@efsa.europa.eu >
 Datum: 09.11.2015 13:49
 Betreff: RE: Press requests

Hi Suzan

The briefing we're holding is rather low key (technical briefing rather than press conference) and we're limiting it to a small number of journalists. Invitations are likely to go out this evening but I'd be grateful if you didn't publicise the fact that we're holding a briefing with any journalists that make enquiries at your end (it won't be announced on our website). Publication is still due for 12 Nov.

We'll share comms materials/lines with you beforehand (probably tomorrow) and then I'm available to discuss in case of any questions.

Best,

-----Original Message--

From: Fiack Suzan [<mailto:Suzan.Fiack@bfr.bund.de>]
 Sent: 09 November 2015 13:42
 To:
 Cc:
 Subject: Press requests

Dear all,
 we have already received some requests from the press because of the publication of the EU PerReview of glyphosate. Have you already invited the press? Is the invitation public, so that we can refer to your website?

Best,
 Suzan

BfR Berlin Registratur		Präs
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Az.:		
DocForMs-Nr.:	8702411	

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51**Eingangsregistrierung - Fwd: Glyphosate - comms material**

Von: Suzan Fiack <suzan.fiack@bfr.bund.de >
An: Eingangsregistrierung
Datum: 10.11.2015 16:19
Betreff: Fwd: Glyphosate comms material
Anlagen: image001.jpg; image002.jpg; image003.jpg; Glyphosate_Complementary information_FINAL.DOCX; Glyphosate_PeerNews.docx, GlyphosateLayman_final.docx; Q+A glyphosate prenotify.docx; 4302 Glyphosate conclusion.pdf

bitte in den GG

Von meinem iPhone gesendet

Anfang der weitergeleiteten E-Mail:

Von: f@efsa.europa.eu >
An: "Suzan Fiack" <Suzan.Fiackgbfr.bund.de>
a@efsa.europa.eu >
@efsa.europa.eu >

Betreff: Glyphosate - comms material

Dear Suzan

Finally (!) I'm able to share with you our (still not finalised) comms materials that are due for publication on Thursday. I have also attached the adopted version of the Conclusion. Please note that these docs are strictly under embargo until Thursday at midday.

In attachment, you will find:

1. Press release
2. Lay persons summary
3. EFSA explains carcinogenicity assessment of glyphosate (technical document)
4. Reactive lines-to-take (not intended for publication/distribution)

Docs are only available in English at the moment but nos. 1&2 will be translated into French before publication.

Hope this helps. Let me know if you have any questions.

Also, do you plan to do any comms on glyphosate Bither on Thursday or in the

coming days?

Best,

Communications and External Relations Department

[Description: cid:image004.jpg@01CF4E80.D6C6B1C0]

Via Carlo Magno 1A

43126 Parma (Italy)

Tel.

Mob _____

www.efsa.europa.eu <http://www.efsa.europa.eu/>

twitter.com/EFSAEU <<http://twitter.com/EFSAEU>> [Description:

cid:image005.jpg@01CF4E80.D6C6B1C0]

youtube.com/EFSAchannel <<http://youtube.com/EFSAchannel>> [Description:

cid:image009.jpg@01CF4E80.D6C6131C0]



Von: @efsa.europa.eu >

An: Fiack Suzan <Suzan.Fiack@bfr.bund.de >

CC: EFSA Press <Press.Press@efsa.europa.eu >, efsa.europa.eu >

Datum: 11.11.2015 10:53

Betreff: Re: QA glyphosate prenotify - rev BfR.docx

Thanks Suzan, we'll have a look but shouldn't be a problem to make changes as you suggest. **confirm**
later (travelling to BXL at the moment)
Best

Sent from my iPhone

On 11 Nov 2015, at 10:21, Fiack Suzan <Suzan.Fiack@bfr.bund.de <mailto:Suzan.Fiack@bfr.bund.de >> wrote:

Hi

thanks a lot for sharing the documents. Could you please have a look at the QA below. Our experts recommend to change two aspects which are important.

1) JMPR was 2004 and not 2011

2) The BfR did not agree with EFSA on the identification of a concern in relation to the non-finalised assessment of the potential of glyphosate for endocrine disruption. For birds and mammals, EFSA also disagreed with the refinement proposed by UBA and identified risk for certain representative uses.

See also file attached.

Best,

Suzan

<QA glyphosate prenotify - rev BfR.docx.secure>

Eingangsregistrierung - UNDER EMBARGO Glyphosate: EFSA updates toxicological profile

Von: EFSA Communications <EFSACommunications@efsa.europa.eu >
An: EFSA Communications <EFSACommunications@efsaseuropa.eu>
Datum: 11.11.2015 17:55
Betreff: UNDER EMBARGO - Glyphosate: EFSA updates toxicological profile
Anlagen: Glyphosate_Layman_FINAL.pdf; Glyphosate_Complementary information_FINAL.ppt Glyphosate_Peer_News Story_FINAL.pdf

Dear all,

Tomorrow 12 November at 12:00 CET, EFSA will publish a Conclusion on the Peer review on glyphosate and a complementary technical document.

It will be accompanied by a News Story and a non technical summary.

The documents are under embargo until 12/11/2015 at 12:00 CET when they will be published on our website.

For any further information on the Conclusion, please contact efsa.europa.eu.

For any further information on the News Story, please contact @efsa.europa.eu.

Due to the sensitivity of the subject, the discussions with all parties were on-going until the minute, hence the timing of this pre-notification.

Best regards,

EFSA Communications

Communication & External Relations Department
European Food Safety Authority (EFSA)
Via Carlo Magno IA
43126 PARMA

The documents are scheduled for publication on Thursday 12 November 2015 at 12:00 CET. They are shared under embargo in advance for your information and not for wider distribution. The documents are shared on a confidential Basis in advance of final publication and are therefore not intended to be shared beyond recipients identified in the distribution list above until the final documents are actually published. There is always a possibility that there will be additional changes before the final version is published and that the actual date and/or time of publication, indicated by the embargo, may change. Please note that only the final, published version remains the reference document. The EFSA website should be checked for confirmation of final content and publication. Only documents which are published on EFSA's website can be cited/used.

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www.efsa.europa.eu/en/news/alerts.htm

Von: @efsa.europa.eu>
An: Fiack Suzan <Suzan.Fiack@bfr.bund.de >
Datum: 12.11.2015 09:13
Betreff: Re: Antw: RE: Publication and link

Hi Suzan

No, they won't. Still undergoing sanitisation process. Only Conclusion today

Kind regards,

From: Fiack Suzan <Suzan.Fiack@bfr.bund.de >
Sent: 12 November 2015 09:11
To: ; EFSA Press
Subject: Antw: RE: Publication and link

Hi

thanks a lot. Will the RAR and the addendum also be published today? 1

have not seen the German translations, yet.

Best,

Suzan

), >>

@efsa.europa.eu > 12.11.2015 09:04

>>

Hi Suzan,

We will publish today at 12:00 (Mittagszeit) and the materials are under embargo until 12:00 (Mittag)

Everything will be published on EFSA's Startseite, and it should be quite visible on the first page. For linking, we have to see at 12:00 what's the real url is. For the time being I would give

www.efsa.europa.eu

Do you already have the German transiations? They are ready now.

- - Original Message

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]

Sent: 12 November 2015 09:01

To: Press

Cc:

Subject: Publication and link

Dear all,

do you already know when you will publish the documents (12 am?)? Dou

you already know the urls?

All the best,

Suzan

Von: EFSA Press <Press.Press@efsa.europa.eu >
An: 1@bfr.bund.de,
1@efsa.europa.eu >, EFSA Press <Press.Press@efsa.europa.eu >
Datum: 12.11.2015 09:26
Betreff: RE: Antw: RE: Publication and link
Anlagen: Glyphosate_Layman_FINALfinalLDE.pdf; Glyphosate_Peer_News
 Story_FINAL_DErev.pdf

Hallo Suzan,

Attached the German translations of the press release and the layman summary.

Best,

- - Original Message

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]
 Sent: 12 November 2015 09:11
 To: i; EFSA Press
 Subject: Antw: RE: Publication and link

Hi

thanks a lot. Will the RAR and the addendum also be published today? I have not seen the German translations, yet.

Best,

Suzan

»7;

@efsa.europa.eu > 12.11.2015 09:04

>>

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Everything will be published on EFSA's Startseite, and it should be quite visible on the first page. For linking, we have to see at 12:00 what's the real url is. For the time being I would give www.efsa.europa.eu

Do you already have the German translations? They are ready now.

- - Original Message----

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]
 Sent: 12 November 2015 09:01
 To: EFSA Press
 Cc:
 Subject: Publication and link

Dear all,

do you already know when you will publish the documents (12 am?)? Do you already know the urls?

All the best,

Suzan

EFSA erklärt Risikobewertung

Glyphosat

Glyphosat ist ein Wirkstoff, der breiten Einsatz in Pflanzenschutzmitteln findet. Auf Glyphosat basierende Pflanzenschutzmittel (d.h. Formulierungen, die Glyphosat und weitere chemische Stoffe enthalten) werden in Landwirtschaft und Gartenbau vor allem zur Bekämpfung von Unkräutern verwendet, die mit Kulturpflanzen konkurrieren. Die Ausbringung erfolgt in der Regel vor der Aussaat und zur Sikkation (Trocknung) vor der Ernte, was die Pflanzen schneller und gleichmäßiger reifen lässt.

Was hat die EFSA unternommen?

Die EFSA hat zusammen mit den EU-Mitgliedstaaten eine Risikobewertung und ein Peer-Review durchgeführt, die uns aktuellste wissenschaftliche Kenntnisse bezüglich der Toxizität von Glyphosat liefern. Die EFSA hat im Rahmen dieses Verfahrens eine Schlussfolgerung zu Glyphosat veröffentlicht. Die Schlussfolgerung wird in die Entscheidung der Europäischen Kommission über den Verbleib von Glyphosat auf der EU-Liste genehmigter Wirkstoffe einfließen sowie in die Bewertungen der Verwendung glyphosat-basierter Formulierungen im jeweiligen Hoheitsgebiet der einzelnen Mitgliedstaaten, die von diesen anschließend durchzuführen sein wird. (Siehe Kasten: "Wie wird die Sicherheit von Glyphosat in der EU bewertet?")

Die wichtigsten Ergebnisse der Bewertung

Nach Sichtung der enormen Menge an einschlägigen Daten gelangte eine Peer-Review-Expertengruppe der EFSA, die sich aus Wissenschaftlern der Behörde und von EU-Mitgliedstaaten benannten Vertretern zusammensetzte, zu folgendem Schluss:

- Die Toxizität von Glyphosat muss neu definiert werden. Darum wird eine Akute Referenzdosis (ARfD) von 0,5 mg/kg Körpergewicht vorgeschlagen - das erste Mal, dass eine solche Sicherheitsmaßnahme für Glyphosat eingeführt wird. Die EFSA wird diese ARfD bei ihrer Überprüfung der Rückstandshöchstgehalte für Glyphosat zugrunde legen, die zusammen mit den Mitgliedstaaten 2016 durchgeführt werden soll. Die annehmbare Anwenderexposition (Acceptable Operator Exposure Level - AOEL) wird ebenfalls auf 0,1 mg/kg Körpergewicht pro Tag angesetzt, und für Verbraucher wird entsprechend der ARfD eine zulässige tägliche Aufnahmemenge (Acceptable Daily Intake - ADI) von 0,5 mg/kg Körpergewicht pro Tag vorgeschlagen.
- Die Substanz ist wahrscheinlich nicht genotoxisch (d.h. DNA schädigend) oder stellt eine krebserregende Bedrohung für den Menschen dar. Es wird nicht empfohlen, Glyphosat als karzinogen gemäß der EU-Verordnung über die Einstufung, Kennzeichnung und Verpackung von chemischen Stoffen einzustufen. Insbesondere waren sich die Experten aus dem Mitgliedstaaten, mit einer Ausnahme, einig, dass weder die epidemiologischen Daten (d.h. solche in Bezug

auf den Menschen) noch die Befunde aus Tierstudien einen Kausalzusammenhang zwischen der Glyphosat-Exposition und einer Krebsentstehung beim Menschen aufzeigten.

Wie wird die Sicherheit von Pestiziden in der EU bewertet?

Nach EU-Recht werden Wirkstoffe in Pflanzenschutzmitteln in der EU nur genehmigt, wenn davon auszugehen ist, dass ihr Einsatz sich nicht schädlich auf die Gesundheit von Mensch und Tier oder die Umwelt auswirken wird.

Die Bewertung sowohl existierender als auch neuer Wirkstoffe erfolgt im Rahmen eines mehrstufigen Verfahrens:

1. Für jeden Stoff wird zunächst von einem Bericht erstattenden Mitgliedstaat (Rapporteur Member State - RMS) ein vorläufiger Bewertungsbericht (Draft Assessment Report - DAR) bzw. ein Bewertungsbericht zur Neubewertung (Renewal Assessment Report - RAR) erstellt. Bei Anträgen auf Erneuerung einer Genehmigung entscheidet die Kommission über die Benennung eines berichterstattenden Mitgliedstaats in Absprache mit allen Mitgliedstaaten und Industrievertretern.
2. Die Risikobewertung des RMS wird von der EFSA zusammen mit allen Mitgliedstaaten einem Peer-Review unterzogen.
3. Die EFSA erstellt einen Bericht ("Schlussfolgerung") bezüglich des Wirkstoffs. Die Schlussfolgerung der EFSA fließt ein in das Genehmigungsverfahren der Europäischen Kommission, die anschließenden Bewertungen von Pflanzenschutzmitteln durch die Mitgliedstaaten sowie die Prüfung der Rückstandshöchstgehalte in Lebensmitteln seitens der EFSA.
4. Die Europäische Kommission entscheidet, ob die Substanz in die EU-Liste der genehmigten Wirkstoffe aufgenommen wird. Dies bestimmt, ob der Wirkstoff in einem Pflanzenschutzmittel in der EU verwendet werden kann.
5. Die EU-Mitgliedstaaten bewerten bzw. Neubewerten die Sicherheit von den Wirkstoff enthaltenden Pflanzenschutzmitteln, die in ihrem jeweiligen Hoheitsgebiet in Verkehr gebracht werden.

Warum sagen einige Wissenschaftler, Glyphosat sei krebserregend?

Die Internationale Agentur für Krebsforschung (IARC) erklärte Anfang des Jahres, dass Glyphosat genotoxisch und „wahrscheinlich“ krebserregend für den Menschen sei.

Allerdings betrachtete der IARC-Bericht sowohl Glyphosat - den Wirkstoff an sich - als auch Glyphosat-basierte Formulierungen, wobei alle Formulierungen unabhängig von ihrer Zusammensetzung zusammengefasst wurden. Die EU Bewertung hingegen berücksichtigte ausschließlich Glyphosat. Die Mitgliedstaaten sind für die Bewertung jedes einzelnen Pflanzenschutzmittels verantwortlich, die in ihrem jeweiligen Hoheitsgebiet in Verkehr gebracht wird.

Der Grund hierfür ist, dass die EU und die IARC unterschiedliche Ansätze bei der Einstufung chemischer Stoffe verfolgen. Nach dem EU-System wird jeder einzelne chemische Stoff und jedes in Verkehr gebrachte Gemisch separat bewertet. Die IARC bewertet generische Substanzen, einschließlich Gruppen verwandter chemischer Stoffe, die berufs- bzw. umweltbedingte Exposition sowie kulturelle Gepflogenheiten und Verhaltensweisen.

Dies ist insofern wichtig, da einige Studien darauf hindeuten, dass bestimmte Glyphosat-basierte Formulierungen genotoxisch (d.h. DNA schädigend) sein könnten, während andere, die nur den Wirkstoff Glyphosat betrachten, diese Wirkung nicht zeigen. Es ist daher wahrscheinlich, dass die in einigen Glyphosat-basierten Formulierungen beobachteten genotoxischen Effekte mit anderen Bestandteilen oder „Beistoffen“ im Zusammenhang stehen. In ähnlicher Weise zeigen bestimmte Glyphosat-basierte Formulierungen eine höhere Toxizität als der Wirkstoff selbst, was vermutlich auf Beistoffe zurückzuführen ist. In ihrer Bewertung empfiehlt die EFSA, dass die zuständigen Behörden in den Mitgliedstaaten die Toxizität jedes einzelnen Pflanzenschutzmittels, und insbesondere dessen genotoxisches Potenzial, eingehender berücksichtigen und darauf eingehen sollten, wenn sie deren Verwendung in ihrem jeweiligen Hoheitsgebiet neu bewerten.

Die Unterscheidung zwischen Wirkstoff und Pflanzenschutzmittel-Formulierung erklärt größtenteils die unterschiedliche Gewichtung der verfügbaren Daten seitens EFSA und IARC. Für die EU-Bewertung waren mit Glyphosat durchgeführte Studien relevanter als Studien mit Formulierungen, die andere Bestandteile enthielten, insbesondere wenn die anderen Inhaltsstoffe nicht eindeutig identifiziert werden konnten.

Welche Daten wurden bei dieser Bewertung verwendet?

Die Überprüfung unter Leitung der EFSA berücksichtigte einen großen Bestand an wissenschaftlichen Erkenntnissen, einschließlich des IARC-Berichts. Neben den ursprünglich von den Antragstellern gemäß den gesetzlichen Anforderungen vorgelegten Studien wurden sämtliche verfügbaren und veröffentlichten Studien berücksichtigt.

Die IARC-Monografie umfasst eine Reihe epidemiologischer Studien, die in der vorläufigen Bewertung der EU fehlten; diese wurden jedoch später dem EU-Dossier hinzugefügt.

Insgesamt bewertete die EFSA mehr wissenschaftliche Erkenntnisse, einschließlich zusätzlicher Schlüsselstudien, die nicht von der IARC berücksichtigt wurden.

Wie wurden die Tierstudien zur Kanzerogenität interpretiert?

Das Peer-Review der EU gelangte zu dem Schluss, dass in keiner der behandelten Tiergruppen in den berücksichtigten neun Langzeitstudien an Ratten eine signifikante Zunahme der Tumorinzidenz zu beobachten war. Nach Interpretation der IARC hingegen zeigen zwei Studien statistisch signifikante karzinogene Effekte. Ebenso ermittelte die IARC in zwei Studien an Mäusen positive karzinogene Tendenzen, die im EU-Peer-Review als nicht signifikant bewertet wurden.

Die wesentlichen Unterschiede zwischen den Bewertungen von EFSA und IARC werden ausführlich in einem von der EFSA veröffentlichten speziellen Hintergrundpapier erläutert. Abgesehen davon, dass die EFSA eine größere Zahl an Studien auswertete, erachtete sie beispielsweise bei hohen Dosen beobachtete karzinogene Effekte als nicht aussagekräftig, da sie auf allgemeine Toxizität zurückzuführen sein könnten.

Was geschieht als nächstes?

Die Schlussfolgerung der EFSA wird einfließen in die Entscheidung der Europäischen Kommission über den Verbleib von Glyphosat auf der EU-Liste der genehmigten Wirkstoffe, d.h. über die Zulässigkeit seiner weiteren Verwendung in Pflanzenschutzmitteln in der EU.

Chronik

2012

Mai Deutschland als Bericht erstattender Mitgliedstaat (RMS) erhält Dossier zur Unterstützung der möglichen erneuten Genehmigung von Glyphosat.

2013

Dezember RMS übermittelt vorläufigen Bewertungsbericht zur Erneuerung (RAR) an EFSA.

2014

Januar Peer-Review beginnt. RAR wird zur Konsultation und Stellungnahme an Mitgliedstaaten und Antragsteller übermittelt.

März Beginn der 60-tägigen öffentlichen Konsultation.

Juli RMS wertet alle Kommentare aus.

August Vom Antragsteller werden zusätzliche Informationen angefordert.

2015

Februar-März EFSA organisiert Expertenkonsultation in den Bereichen Säugetiertytoxikologie, Rückstände, Umweltverhalten (Verbleib) und Ökotoxikologie

Juli Konsultation der Mitgliedstaaten zu Schlussfolgerungen aus Peer-Review beginnt.

IARC-Monografie wird veröffentlicht.

August RMS erstellt Bewertung der Monografie, die den Mitgliedstaaten zur Stellungnahme übermittelt wird.

September Nach Eingang der Stellungnahmen organisiert EFSA zweite Expertenkonsultation zu Kanzerogenität und Säugetiertytoxikologie.

- Oktober Die Genehmigung für Glyphosat wird vorläufig bis Juni 2016 verlängert, solange das EU-Peer-Review nicht abgeschlossen ist.
- Oktober Entsprechende Aktualisierung des Peer-Reviews und abschließende Konsultation mit Mitgliedstaaten.

Was ist darunter zu verstehen...

Wirkstoff

Unter Wirkstoffen sind jegliche chemischen Stoffe, Pflanzenextrakte, Pheromone oder Mikroorganismen zu verstehen, die gegen „Schädlinge“ an Pflanzen, Pflanzenteilen oder Pflanzenerzeugnissen wirken.

Akute Referenzdosis (ARfD)

Bei der ARfD handelt es sich um die auf der Basis des Körpergewichts geschätzte Menge einer chemischen Substanz in Lebensmitteln, die über einen kurzen Zeitraum (in der Regel bei einer einzelnen Mahlzeit oder an einem Tag) aufgenommen werden kann, ohne ein Gesundheitsrisiko darzustellen.

Beistoff

Pestizide werden in verschiedenen Formulierungen in Verkehr gebracht, die neben dem Wirkstoff verschiedene Beistoffe enthalten. Glyphosat kann in Kombination mit POE-Tallowaminen eingesetzt werden — Beistoffe, die das Eindringen des Wirkstoffs in die Pflanzen fördern.

Genotoxizität

Genotoxische Chemikalien schädigen die genetischen Informationen in Zellen (DNA), was Mutationen auslöst, die zu Krebs führen können.

Rückstandshöchstgehalte

Bei Rückstandshöchstgehalten (Maximum Residue Levels — MRL) handelt es sich um die jeweils höchste Konzentration eines Wirkstoffs, die den gesetzlichen Bestimmungen zufolge bei korrekter Anwendung von Pflanzenschutzmitteln in Lebens- bzw. Futtermitteln erlaubt ist. Die EFSA ist in der EU dafür zuständig, Rückstandshöchstgehalte vorzuschlagen.

Metaboliten

Metaboliten sind Abbauprodukte, die sich bilden, wenn ein Pflanzenschutzmittel mit Luft, Wasser, Boden oder lebenden Organismen reagiert. Sie werden im Rahmen der EFSA-Sicherheitsbewertungen von Pestiziden berücksichtigt.

Beweiskraft der Daten

Wenn zahlreiche Studien zu einem Thema vorliegen, hat es sich bewährt, alle verfügbaren Informationen einzubeziehen, um Übereinstimmungen und Widersprüche in den Ergebnissen zu ermitteln, und dann die Befunde hinsichtlich ihrer Aussagekraft und Relevanz abzuwägen.

COMMUNICATIONS & EXTERNAL RELATIONS

**UNDER EMBARGO until 12/11/2015 at 12.00 CET
NOT FOR FURTHER DISTRIBUTION**

Parma, 12. November 2015

N EWS STORY

Glyphosat: EFSA aktualisiert toxikologisches Profil

Die EFSA und die EU-Mitgliedstaaten haben die Neubewertung von Glyphosat einer chemischen Substanz, die breite Verwendung in Pflanzenschutzmitteln findet, abgeschlossen. Den Schlussfolgerungen des Berichts zufolge ist es unwahrscheinlich, dass Glyphosat eine krebserregende Gefahr für den Menschen darstellt, und es wird eine neue Sicherheitsmaßnahme vorgeschlagen, um die Kontrolle von Glyphosat-Rückständen in Lebensmitteln zu verschärfen. Die Schlussfolgerung wird in die Entscheidung der Europäischen Kommission über den Verbleib von Glyphosat auf der EU-Liste der genehmigten Wirkstoffe einfließen sowie in die von den EU-Mitgliedstaaten durchzuführenden erneuten Sicherheitsbewertungen glyphosathaltiger Pflanzenschutzmittel, die im jeweiligen Hoheitsgebiet der Mitgliedstaaten zum Einsatz kommen.

Eine Peer-Review-Expertengruppe, die sich aus EFSA-Wissenschaftlern sowie Vertretern von Risikobewertungsstellen in EU-Mitgliedstaaten zusammensetzte, hat für Glyphosat eine Akute Referenzdosis (ARfD) von 0,5 mg/kg Körpergewicht vorgeschlagen - das erste Mal, dass ein solcher Expositionsgrenzwert auf Glyphosat angewendet wird.

José Tarazona, Leiter des EFSA-Referats Pestizide, erklärte: „Es handelte sich hierbei um einen umfassenden Prozess - eine vollständige Bewertung, die eine Fülle neuer Studien und Daten berücksichtigte. Durch die Einführung einer Akuten Referenzdosis verschärfen wir die künftige Bewertung potenzieller Risiken durch Glyphosat. Was die Karzinogenität betrifft, so ist es unwahrscheinlich, dass dieser Stoff krebserregend ist.“

Wahrscheinlich nicht karzinogen

Die Peer-Review-Gruppe kam zu dem Schluss, dass Glyphosat wahrscheinlich nicht genotoxisch (d.h. DNA schädigend) ist oder eine krebserregende Bedrohung für den Menschen darstellt. Es wird nicht empfohlen, Glyphosat als karzinogen gemäß der EU-Verordnung über die Einstufung, Kennzeichnung und Verpackung von chemischen Stoffen einzustufen. Insbesondere waren sich die Experten aus dem Mitgliedstaaten, mit einer Ausnahme, einig, dass weder die epidemiologischen Daten (d.h. solche in Bezug auf den Menschen) noch die Befunde aus Tierstudien einen Kausalzusammenhang zwischen der Glyphosat-Exposition und einer Krebsentstehung beim Menschen aufzeigten.

Auf Ersuchen der Europäischen Kommission berücksichtigte die EFSA auch den von der Internationalen Agentur für Krebsforschung (IARC) veröffentlichten Bericht, in dem Glyphosat als wahrscheinlich krebserregend für den Menschen eingestuft wird.

Im Rahmen der Bewertung wurde ein großer Bestand an wissenschaftlichen Erkenntnissen berücksichtigt, darunter eine Reihe von Studien, die nicht von der IARC bewertet worden waren; dies ist einer der Gründe für die unterschiedlichen Schlussfolgerungen.

Neben der Einführung der ARfD werden in dem Review-Bericht weitere toxikologische Sicherheitsgrenzwerte zur Orientierung der Risikobewerter vorgeschlagen: Die annehmbare Anwenderexposition (Acceptable Operator Exposure Level - AOEL) wurde auf 0,1 mg/kg Körpergewicht pro Tag gesetzt, und für Verbraucher wurde der ARfD entsprechend eine zulässige tägliche Aufnahmemenge (Acceptable Daily Intake - ADI) von 0,5 mg/kg Körpergewicht vorgeschlagen.

Dr. Tarazona fügte hinzu, dass die EFSA die neuen toxikologischen Grenzwerte bei der Überprüfung der Rückstandshöchstgehalte für Glyphosat in Lebensmitteln verwenden wird, die zusammen mit den Mitgliedstaaten 2016 durchgeführt werden.

Nächste Schritte

Die Schlussfolgerung der EFSA wird in die Entscheidung der Europäische Kommission darüber einfließen, ob die Substanz auf der EU-Liste der genehmigten Wirkstoffe verbleibt. Dies ist eine Voraussetzung dafür, dass die Mitgliedstaaten die weitere Verwendung von Glyphosat in Pflanzenschutzmitteln in der EU zulassen können.

Eine Erläuterung der wichtigsten Ergebnisse der EFSA-Schlussfolgerung zu Glyphosat finden Sie in unserer eigens erstellten Zusammenfassung für Laien. Die EFSA hat ferner ein ergänzendes Dokument erstellt, das ausführlich auf einige der wissenschaftlichen Fragen eingeht, die während der Bewertung hervorgehoben wurden.

Hintergrund

Glyphosat ist ein chemischer Wirkstoff, der in einer Reihe von Pflanzenschutzmitteln breiten Einsatz findet und dessen Verwendung in Europa strengen gesetzlichen Vorschriften unterliegt. Das Peer-Review der EFSA erfolgte im Rahmen des gesetzlich vorgeschriebenen Verfahrens für die erneute Genehmigung der Verwendung von Glyphosat in Europa.

Gemäß dem Standardverfahren für solche Erneuerungen übergab der Antragsteller ein Dossier mit einschlägigen wissenschaftlichen Informationen an einen Mitgliedstaat - den sogenannten berichterstattenden Mitgliedstaat (RMS) - zur Durchführung einer ersten Bewertung. Das Dossier wurde von dem RMS, in diesem Fall Deutschland, bewertet und an die EFSA weitergeleitet, um die Daten und Schlussfolgerungen in der Akte abschließend zu bewerten. Dieses Verfahren wird von einer Peer-Review-Gruppe durchgeführt, die sich aus EFSA-Wissenschaftlern sowie Vertretern von Risikobewertungsstellen aller EU-Mitgliedstaaten zusammensetzt.

Was sind Rückstandshöchstgehalte?

Bei Rückstandshöchstgehalten (Maximum Residue Levels - MRL) handelt es sich um die jeweils höchste Konzentration eines Wirkstoffs, die den gesetzlichen Bestimmungen zufolge bei korrekter Anwendung von Pflanzenschutzmitteln in Lebens- bzw. Futtermitteln toleriert wird. Die EFSA ist in der EU für die Empfehlung von Rückstandshöchstgehalten zuständig und bewertet die Verbrauchersicherheit auf Grundlage der Toxizität des Pestizids, der voraussichtlich zu findenden Mengen in Lebensmitteln und der unterschiedlichen Verzehrsgewohnheiten der Europäer. Die

96 Sicherheitsbewertung erfolgt mittels toxikologischer Referenzwerte wie der Akuten Referenzdosis
97 (ARfD).

98 Was ist eine Akute Referenzdosis (ARfD)?

99

100 Bei der ARfD handelt es sich um die auf der Basis des Körpergewichts geschätzte Menge einer
101 chemischen Substanz in Lebensmitteln, die über einen kurzen Zeitraum (in der Regel bei einer
102 einzelnen Mahlzeit oder an einem Tag) aufgenommen werden kann, ohne ein Gesundheitsrisiko
103 darzustellen.

104 Für Medienanfragen wenden Sie sich bitte an:

105 Medienstelle der EFSA

106 Tel.: +39 0521 036 149

107 E-Mail: Presseefsa.europa.eu

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109

110

112

1331124 64

Eingangsregistrierung - Glyphosate: EFSA. updates toxicological profile

Von: Scientific Cooperation <ScientificCooperation@efsa.europa.eu >
 An: "Austria (Corporate)" <efsaefocalpoint@ages.at >, "Belgium (Corporate)" <efsaefocalpoint ~ health.belgium.be>, "Bulgaria (Corporate)" <EFSAefocalpoint ~ nvms.government.bg>, "Croatia (Corporate)" <efsa.focalpoint@hah.hr>, "Cyprus (Corporate)" <efsaefocalpoint ~ sgl.moh.gov.cy>, "Czech Republic (Corporate)" <efsa.focalpoint@mze.cz >, "Denmark (Corporate)" <FocalPoint.EFSA@food.dtu.dk>, "Estonia (Corporate)" <efsaefocalpoint ~ agri.ee>, "Finland (Corporate)" <efsaefocalpoint@evira.fi >, "France (Corporate)" <pointfocal@anses.fr>, "Germany (Corporate)" <efsa-focal-point@bfr.bund.de >, "Greece (Corporate)" <efsa ~ efet.gr>, "Hungary(Corporate)" <focalpoint ~ nebih.gov.hu>, "Iceland (Corporate)" <focalpoint ~ mast.is>, "Ireland (Corporate)" <focalpoint@fsai.ie >, "Italy(Corporate)" <italianfocalpoint@iss.it >, "Latvia (Corporate)". <efsa@bior.gov.lv >, "Lithuania (Corporate)" <efsa.focalpoint@vet.lt>, "Luxembourg (Corporate)" <focal.point ~ osgca.etat.lu>, "Malta (Corporate)" <efsa-fp.mccaa ~ mccaa.org.mt>, "Netherlands (Corporate)" <VWAEFSAefocalpoint@vwa.nl>, "Norway (Corporate)" <EFSAFocalpoint-norway@vkm.no>, "Poland (Corporate)" <efsa ~ gis.gov.pl>, "Portugal (Corporate)" <efsaefocalpoint@asae.pt >, "Romania (Corporate)" <efsa.focalpoint@ansvsa.ro >, "Slovak Republic (Corporate)" <efsa.focalpoint ~ land.gov.sk>, "Slovenia (Corporate)" <efsa.mkgp ~ gov.si>, "Spain (Corporate)" <pfefsa@msssi.es >, "Sweden (Corporate)" <efsa.focalpoint@slv.se >, "United Kingdom (Corporate)" <efsa.focalpoint ~ foodstandards.gsi.gov.uk>, "FYR of Macedonia (Corporate)" <focalpoint ~ fva.gov.mk>, "Serbia (Corporate)" <fpefsaserbia ~ minpolj.gov.rs>, "Switzerland (Corporate)" <efsaefocalpoint@blv.admin.ch >, "Turkey (Corporate)" <efsaefocalpoint ~ tarim.gov.tr>

Datum: 12.11.2015 18:22

Betreff: Glyphosate: EFSA updates toxicological profile

CC: Scientific Cooperation <ScientificCooperation@efsa.europa.eu >

Dear Focal Points,

We would like to inform you that EFSA has published a Conclusion on the Peer review on Glyphosate and a Complementary Technical document. A News Story and a Non-Technical Summary have also been published. You may find this Information on the following EFSA links:

- Conclusion: <http://www.efsa.europa.eu/en/efsajournal/pub/4302>
- Complementary document: http://www.efsa.europa.eu/sites/default/files/4302_glyphosate_complementary.pdf
- News: <http://www.efsa.europa.eu/en/press/news/151112>
- Summary: <http://www.efsa.europa.eu/en/corporate/pub/glyphosatel51112>

Thank you for disseminating this information through the relevant national organisations/experts/stakeholders.

With our very best regards,

*Advisory Forum and Scientific Cooperation Unit
Communications & External Relations Department*



*Via Carlo Magno 1A
43126 Parma (Italy)
Tel. +39 0521 036*

www.efsa.europa.eu

[twitter.com/EFSA EU](https://twitter.com/EFSA_EU)

youtube.com/EFSAchannel UZ)

Von: Y@efsa.europa.eu >
 An: Fiack Suzan <Suzan.Fiack@bfr.bund.de>
 Datum: 13.11.2015 12:21
 Betreff: RE: Antw: RE: Publication and link

Hi Suzan

tried to call. I wanted just to catch up and see what your impression was of coverage in Germany following our glyphosate publication. I'm free this afternoon but it's not urgent and we can also speak next week if it's more convenient for you.

Best,

---Original Message---

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]
 Sent: 12 November 2015 09:23
 To: F
 Subject: Re: Antw: RE: Publication and link

Hi,

is it ok to mention that the document was sent to the Commission on the 30. Oktober 2015? I remember an information on efsa's website, but could not find it.

Mit freundlichen Grüßen

i.A.

Suzan Fiack

Dr. Suzan Fiack

Bundesinstitut für Risikobewertung
 Fachgruppenleitung Presse- und Öffentlichkeitsarbeit Abteilung Risikokommunikation

Federal Institute for Risk Assessment
 Head of Unit Press and Public Relations Department Risk Communication

Max-Dohrn-Straße 8-10, 10589 Berlin
 Germany

Tel. +49 30 18412-4302
 Fax +49 30 18412-4970

www.bfr.bund.de

x>>

efsa.europa.eu > 12.11.2015 09:13 >>>

Hi Suzan

No, they won't. Still undergoing sanitisation process. Only Conclusion today Kind regards,

From: Fiack Suzan <Suzan.Fiack@bfr.bund.de>

Sent: 12 November 2015 09:11

To: EFSA Press

Subject: Antw: RE: Publication and link

Hi

thanks a lot. Will the RAR and the addendum also be published today? I have not seen the German translations, yet.

Best,

BfR Berlin Registratur		Präs
Registratur	11. JAK 2016	2
		3.01.16

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Suzan

>>

i@efsa.europa.eu > 12.11.2015 09:04

>>

Ni Suzan,

We will publish today at 12:00 (Mittagszeit) and the materials are under embargo until 12:00 (Mittag)

Everything will be published on EFSA's Startseite, and it should be quite visible on the first page. For linking, we have to see at 12:00 what's the real url is. For the time being I would give www.efsa.europa.eu

Do you already have the German translations? They are ready now.

-----Original Message---

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]

Sent: 12 November 2015 09:01

To: **EFSA Press**

Cc:

Subject: Publication and link

Dear all,

do you already know when you will publish the documents (12 am)? Do you already know the urls?

All the best,

Suzan

Registratur - RE: Monsanto verfälscht eigene Studien zu Glyphosat I Umweltinstitut München

Von: | efsa.europa.eu>
 An: "'Fiack Suzan" <Suzan.Fiack@bfr.bund.de>,
 |@efsa.europa.eu>
 Datum: 19.11.2015 11:34
 Betreff: RE: Monsanto verfälscht eigene Studien zu Glyphosat I Umweltinstitut München
 CC: @efsa.europa.eu>

Hi Suzan,

We will publish around 13:00 today.

BTW: this journalist [REDACTED] (he approached you and me during the Grüne Woche) is back with an Interview request. How did you deal with him in the end? We think we will grant him an Interview.

Best,

From: Fiack Suzan [Suzan.Fiack@bfr.bund.de]

Sent: 19 November 2015 11:31

To,

Cc:

Subject: Monsanto verfälscht eigene Studien zu Glyphosat I Umweltinstitut München

Hi all,

just for your information.,

http://www.umweltinstitut.org/aktuelle-meldungen/meldungen/monsanto-verfaelscht-eigene-studien-zu-glyphosat.html?utm_source=CleverReach&utm_medium=email&utm_campaign=Newsletter

Could you please let us know, when the addendum etc. will be published on your website?

Best regards from Berlin.

Suzan

Mit freundlichen Grüßen

i.A.

Suzan Fiack

Dr. Suzan Fiack

Bundesinstitut für Risikobewertung

Fachgruppenleitung Presse- und Öffentlichkeitsarbeit

BfR Berlin Registratur		P
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Abteilung Risikokommunikation

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Department Risk Communication

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Germany

Tel. +49 30 18412-4302

Fax +49 30 18412-4970

www.bfr.bund.de

43

Suzan Fiack - RE: Gift im Acker - WDR Fernsehen

Von: t@efsa.europa.eu
An: "Fiack Suzan" <Suzan.Fiack@bfr.bund.de >, .
ee@efsa.europa.eu
Datum: 19.11.2015 11:54
Betreff: RE: Gift im Acker - WDR Fernsehen
CC: l@efsa.europa.eu

Did he ask you for an Interview?

From: Fiack Suzan [Suzan.Fiackgbf@rld.de]
See: 19 November 2015 11:53
To:
Cc:
Subject: Gift im Acker - WDR Fernsehen

has already produced for German TV station WDR:
http://www1.wdr.de/fernsehen/dokumentation_reportage/die-story/sendungen/glyphosat-100.html
Best regards,
Suzan

M4

Eingangsregistrierung - Fwd: Antw: RE: Urgent: preliminary assesement report

Von: Suzan Fiack <suzan.fiack@bfr.bund.de >
 An: Eingangsregistrierung
 Datum: 26.11.2015 16:23
 Betreff: Fwd: Antw: RE: Urgent: preliminary assesement report

fclt

Bitte in den GG.
 Gruß,
 Suzan Fiack

Von meinem iPhone gesendet

Anfang der weitergeleiteten E-Mail:

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2. DEZ. 2015

Von: efsa.europa.eu
 Datum: 26. November 2015 14:53:56 MEZ
 An: "Suzan Fiack" <Suzan.Fiack@bfr.bund.de>, I
 "EFSA Press" <Press.Press@efsa.europa.eu>
 Kopie: efsa.europa.eu
 Betreff: RE: Antw: RE: Urgent: preliminary assesement report

bei., 4wel-tt
 ;:2(2^{let}
 EFfil

Hi Suzan,

iLkf

according to the website it was available from 12/03/2014 and is still available.
You can still reffst it, but of course it is outdated.

23

This was the very first version before public consultation and NOT including the IARC addendum.

BTW: The leaked IARC addendum, as published on the website of FAKT is electronically blackened and afterwards scanned.

2.1
12.15

Question: How did you distribute the IARC addendum as a background paper to the attendees of Hensel's public hearing?

23, 9-

I am assuming you sent a blackened electronic version to the participants, meaning someone of the participants printed it and leaked it to FAKT. They then scanned it again to put it on their website.

Best,

-- Original Message-----

From: Fiack Suzan [<mailto:Suzan.Fiack@bfr.bund.de>]
 Sent: 26 November 2015 13:00
 To: EFSA Press

3d.2/7

75

Cc

Subject: Antw: RE: Urgent: preliminary assesement report

Hi

thank you. How long was it available? Was it possible to get it upon request till 2015?

Thanks!

Suzan

@efsa.europa.eu >

26.11.2015 12:57

Hi Suzan,

I've checked it. The Rapporteur Member State assessment report submitted for the EU peer review of glyphosate used in plant protection products was published on our website here:

<http://dar.efsa.europa.eu/dar-web/provision>

It was published on 12/03/2014.

Best,

- - Original Message - -

From: Fiack Suzan [<mailto:Suzan.Fiack@bfr.bund.de>]

Sent: 26 November 2015 12:24

To: - EFSA Press

Cc:

Subject: Urgent: preliminary assesement report

Dear all,

co'uld you please let us know, if the preliminary assessment report (basis for the public consultation) from Germany was always available upon request.

If not, could you please let me know, from wehn to when it was available.

need the answer as soon as possible.

Thank you!

Suzan

10/11/15

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Suzan Fiack - RE: Lunchdebate zum Stand des EU-Zulassungsverfahrens für Glyphosat - Martin Häusling

Von: efsa.europa.eu
An: 1@efsa.europa.eu, "Fiack Suzanw
<Suzan.Fiack@bfr.bund.de>, EFSA Press <Press.Press@efsa.europa.eu>
Datum: 27.11.2015 10:18
Betreff: RE: Lunchdebate zum Stand des EU-Zulassungsverfahrens für Glyphosat -
CC: -- efsa.europa.eu

are also taking part in an Exchange of Views in the ENVI Committee earlier in the morning of the same day. IARC will be present there too.

<http://www.europa.europa.eu/sidesigetDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bCOM%2bPARL.%2bENVI-0.1-20151201-1%2b01%2bDOC%2bXML%2bV0%2f%2fEN&Ianguage=EN>

Best,

From:
Sent: 27 November 2015 09:40
To: 'Fiack Suzan'; EFSA Press
Cc:
Subject: RE: Lunchdebate zum Stand des EU-Zulassungsverfahrens für Glyphosat -

Hi Suzan,

Yes, we are invited and (Head of EFSA's Pesticides Unit) will be at site.

Viele Grüße,

From: Fiack Suzan [<mailto:Suzan.Fiack@bfr.bund.de>]
Sent: 27 November 2015 09:29
To: ; EFSA Press
Cc:
Subject: Lunchdebate zum Stand des EU-Zulassungsverfahrens für Glyphosat -

Hi all,

are you aware of the following event:

<http://martin-haeuslin.eu/termine/1141-lunchdebate-zum-stand-des-eu-zulassungsverfahren-fuer-glyphosat.html>

Best regards,

Suzan

Suzan Fiack - FW: EFSA Glyphosate Recommendations

Von: ,@efsa.europa.eu>
 An: "Fiack Suzan (Suzan.Fiack@bfr.bund.de)" <Suzan.Fiack@bfr.bund.de >
 Datum: 27.11.2015 16:50
 Betreff: FW: EFSA Glyphosate Recommendations
 Anlagen: EFSA-Glyphosate-Letter.pdf

FYI

From: Chris Portier
 Sent: 27 November 2015 09:57
 To: CAB ANDRIUKAITIS WEBPAGE; ANDRIUKAITIS Vytenis
 Cc: URI_ Bernhard; eeuropari.europa.eu; ieitungebfr.bund.de; Directoreiarcfr:JonesjimeEpa.gov; EFSA PESTICIDES PPR; oststelle@bmel.bundide;
poststelle@bvi.bundide; helmuttschiersky@bvi.bund.de
 Subject: EFSA Glyphosate Recommendations

Dear Commissioner Andriukaitis,

Attached to this email is a letter from 96 prominent epidemiologists, toxicologists, statisticians and molecular biologists from 25 countries. We have banded together and write to you at this time to express our deep concern over the recent European Food Safety Agency (EFSA) decision that the widely used herbicide, glyphosate "is unlikely to pose a carcinogenic hazard to humans." We ask that you read our letter and share it with those who will be advising you on accepting or rejecting EFSA's decision. We would greatly appreciate your sharing this with the members of the Standing Committee on Plants, Animals, Food and Feed before their next meeting on December 10, 2015. I will be in Brussels from November 30 to December 2. If you believe it would be helpful for me to discuss these concerns with you or your staff in person, please send email to this address or call

Thank you for your attention to this important issue.

Sincerely,

Prof. Christopher J. Portier

cc: Mr. Phil Hogan, European Commissioner for Agriculture and Human Development
 Dr. Ladislav Miko, Deputy Director-General, DG Health & Food Safety
 Dr. Bernhard Uri, Executive Director, EFSA
 Dr. Giovanni La Via, Chair, ENVI Committee
 EFSA Panel on Plant Protection Products and their Residues
 Mr. Christian Schmidt, Minister of Food and Agriculture
 Dr. Helmut Tschiersky, President of the Federal Office of Consumer Protection

We reviewed these two differing decisions on the human carcinogenicity of glyphosate and conclude that the IARC WG decision is by far the more credible. The IARC WG decision was reached relying on open and transparent procedures by independent scientists who completed thorough conflict-of-interest statements and were not affiliated or financially supported in any way by the chemical manufacturing industry. It is fully referenced and depends entirely on reports published in the open, peer-reviewed biomedical literature. It is part of a long tradition of deeply researched and highly credible reports on the carcinogenicity of hundreds of chemicals issued over the past four decades by IARC and used today by international agencies and regulatory bodies around the world as a basis for risk assessment, regulation and public health policy.

In contrast, the BfR decision is not credible because it is not supported by the evidence and it was not reached in an open and transparent manner.

Accordingly, we urge you and the European Commission to disregard the flawed EFSA finding on glyphosate in your formulation of glyphosate health and environmental policy for Europe and to call for a transparent, open and credible review of the scientific literature.

The IARC Working Group Decision

The International Agency for Research on Cancer (IARC) Monographs Programme identifies environmental causes of cancer in humans and has evaluated more than 950 agents since 1971. The Monographs Programme evaluates chemicals, drugs, mixtures, occupational exposures, lifestyles and personal habits, physical agents and biological agents. Monographs are written by an ad hoc Working Group (WG) of international scientific experts over a period of about 12 months ending in an eight-day meeting. The WG evaluates all of the publically-available scientific literature on a given substance and, through a transparent and rigorous process^[3], reaches a decision on the degree to which the scientific evidence supports that substance's ability to cause or not cause cancer.

For Monograph 112^[4], 17 expert scientists evaluated the carcinogenic hazard for 4 insecticides and the herbicide glyphosate^[5]. The WG concluded that the data for glyphosate meets the criteria to be identified as a *probable human carcinogen*. This finding stirred great debate globally on the safety of glyphosate and led to a careful evaluation by numerous agencies of the IARC monograph results when they became available on July 29, 2015.

The BfR Addendum

In October, 2015, the EFSA reported[non their evaluation of the Renewal Assessment Report^[2] (RAR) for glyphosate. EFSA concluded that "glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential". Addendum 1 (the BfR Addendum) of the RAR^[2] discusses the scientific rationale for differing from the IARC WG conclusion.

We have serious concerns with regard to the scientific evaluation in the BfR Addendum and feel that it is misleading regarding the potential for a dose-dependent carcinogenic hazard from exposure to glyphosate. Since the BfR Addendum is the Basis for the European Food Safety Agency (EFSA) conclusion, it is critical that we express these concerns. We are also concerned about some of the implications of the BfR Addendum regarding the use of human data in identifying carcinogenic hazards.

Our comments to the BfR Addendum will focus on the human evidence, the animal laboratory evidence and the mechanistic evidence.

The Human Evidence

The BfR agrees with the IARC WG that there is "*limited evidence* in humans for the carcinogenicity of glyphosate". In the IARC review process, *limited evidence* is assigned if "A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence."³¹ The EFSA conclusion that "glyphosate is unlikely to pose a carcinogenic hazard to humans" is inappropriate when available data support the determination of *limited evidence* of carcinogenicity in humans. The BfR Addendum (p. ii) characterizes the IARC interpretation as "precautionary" and that the BfR takes a more "cautious view" of this classification because "no consistent positive association was observed", "the most powerful study showed no effect" and that the studies "could not differentiate between the effects of glyphosate and the co-formulants". We will consider the first two arguments here and discuss the third argument at the end of this letter.

The finding of *limited evidence* by the IARC WG was for non-Hodgkin lymphoma (NHL). High-quality cohort studies are particularly valuable for determining the carcinogenicity of an agent because their design can facilitate exposure assessment and reduce the potential for certain biases. The Agricultural Health Study⁶¹ (AHS) was the only cohort study available providing information on the carcinogenicity of glyphosate. The study had a null finding for NHL (RR 1.1, 0.7-1.9) with no apparent exposure response in the results. The BfR refers to this study as "the most powerful study" and notes that it was "negative" for NHL.

Several potential limitations of case-control studies are laid out in epidemiology textbook^{71, 81}. The BfR uses these limitations to label all of the case-control studies as unreliable. This gives the impression that all of the studies are equal in quality and unusable for an overall evaluation. This is not the case: well-designed case-control studies are recognized as an efficient alternative to cohort studies⁸. An IARC WG carefully evaluates all of the available epidemiology data, looking at the study's strengths and weaknesses. This is key to determining whether the positive associations seen in case-control studies are a reliable indication of an association or simply due to chance or methodological flaws. To provide a reasonable Interpretation of the findings, an evaluation needs to properly weight studies according to their quality rather than simply count the number of positives and negatives. The meta-analyses cited in the IARC Monograph⁹¹ and done by the WG

are excellent examples of an objective evaluation of the existence of a consistent positive association; both meta-analyses showed a statistically significant association. The BfR provided no justification for their evaluation of "no consistent positive association". Finally, despite the potential advantages of prospective cohort studies versus case-control, there are fewer cases to include in analyses, depending on the follow-up time resulting in limited statistical power. There were only 92 NHL cases included in the AHS unadjusted analysis and fewer in adjusted analyses, compared to 650 in a pooled case-control analysis from the United States[iml.

The final BfR conclusion (p. 21) that "there was no unequivocal evidence for a clear and strong association of NHL with glyphosate" is misleading. IARC, like many other groups, uses three levels of evidence for human data[³]. *Sufficient evidence* means "that a causal relationship has been established" between glyphosate and NHL. IARC does not state that the evidence is *sufficient*. BfR concludes that the IARC designation of *limited evidence* was not applicable because there was not "an unequivocal and consistent excess". In fact, that is the equivalent to the criteria for *sufficient evidence*, not *limited evidence*. Thus BfR's conclusion is equivalent to concluding there is not *sufficient evidence*. Legitimate public health concerns arise when "causality is credible", i.e., when there is *limited evidence*. BfR's language is misleading and not internationally acceptable and thus fails to meet EC Guidelines.

Evidence from Animal Carcinogenicity Studies

We find the conclusions of the BfR regarding the animal carcinogenicity data to be scientifically unacceptable. The IARC WG review found a significant positive trend for renal tumors in CD-1 micet¹¹], a rare tumor although no comparisons of any individual exposure group to the control group were statistically significant. A significant positive trend means that the pattern seen in the data supports an increasing risk with increasing dose. The WG also identified a significant positive trend for hemangiosarcoma in male CD-1 mice[¹²], again with no individual exposure group significantly different from controls. Finally, the WG also saw a significant increase in the incidence of pancreatic islet cell adenomas in two studies in Sprague-Dawley rats[¹³⁻¹⁵]. In one of these rat studies, thyroid gland adenomas in females and liver adenomas in males were also increased. Thus, glyphosate was positive for malignant tumors in both of the mouse studies examined and for benign tumors in two of the live rat studies examined. By the IARC review criteria[³], the evidence in the mouse constitutes *sufficient evidence* in animals and the increased incidences of benign tumors constitutes additional support.

The BfR agreed, stating (p. 43) "it is obvious that IARC concludes on '*sufficient evidence* of carcinogenicity' because the above criteria for this conclusion are fully met." The IARC WG reached this conclusion using data that were publicly available in sufficient detail for independent scientific evaluation (a requirement of the IARC PreambleE³]). Based on the BfR Addendum, it seems there were three additional mouse studies and two additional rat studies that were unpublished but available for review. BfR reported on two additional studies with a positive trend for renal tumors, one in CD-1 mice[¹⁶], and one in Swiss-Webster mice[¹⁷]. One of these studies[¹⁶] also reported a positive trend for hemangiosarcoma. Moreover, BfR reported two studies in CD-1 mice showing significant trends for malignant

lymphoma^[16,18] For all of the mouse tumors described above, a positive trend was seen against the concurrent control.

However, in all studies in CD-1 mice, including those reviewed by the IARC, the BfR dismisses the observed trends in tumor incidence because there are no individual treatment groups that are significantly different from controls and because the maximum observed response is reportedly within the range of the historical control data (Table 5.3-1, p. 90). Care must be taken in using historical control data to evaluate animal carcinogenicity data. In virtually all guidelines^[3,19], scientific reports^[Mand publications]^[21-23] on this issue, the recommended first choice is the use of the concurrent controls. For instance, the Preamble to the IARC Monographs states, "is generally not appropriate to discount a tumor response that is significantly increased compared with concurrent controls by arguing that it falls within the range of historical controls...". When using historical control data, they should be from studies in the same timeframe, for the same exact animal strain, preferably from the same laboratory or the same supplier and preferably reviewed by the same pathologist^[19]. This was not the case for the historical control database used by BfR. one of the mouse studies^[n] was clearly done before this historical control database was developed, one study^[16] used Crj:CD-1 mice rather than Crl:CD-1 mice, and one study^[12] did not specify the substrain and was reported in 1993 (probably started prior to 1988); hence only a single study^['] used the same mouse strain as the historical controls, but was reported more than 10 years after the historical control dataset was developed. Interestingly, the historical control data used by the BfR^[24] was from studies in seven laboratories using the Charles River Laboratory CD1 mice. It is important to note that there is a second report^[25] by the same authors with a larger control database using the same mouse strain from 11 laboratories over the same time period (1987-2000) showing very different results. For example, the 2000 publication^[24] shows five and four studies out of 46 with renal adenomas (no more than two in any one study) and renal adenocarcinomas (one in each study) respectively whereas the 2005 report^[25] shows only one study each out of 54 studies with a single renal adenoma and a single renal adenocarcinoma; all other studies had no renal tumors.

Given this evidence, it is clear that BfR differed from standard scientific practices in order to reach their conclusions. BfR reported seven positive mouse studies with three studies showing increases in renal tumors, two with positive findings for hemangiosarcomas, and two with positive findings for malignant lymphomas. BfR additionally reported two positive findings for tumors in rats. Eliminating the inappropriate use of historical data, the unequivocal conclusion is that these are not negative studies, but in fact document the carcinogenicity of glyphosate in laboratory animals.

Mechanistic Information

The BfR Addendum dismisses the WG finding that "there is strong evidence that glyphosate causes genotoxicity" by suggesting that unpublished evidence not seen by the IARC WG was overwhelmingly negative and that, since the studies that were reviewed were not done under guideline principles, they should get less weight. To maintain transparency, IARC reviews only publicly available data. Thus the use of confidential data submitted to the BfR makes it impossible for any scientist not associated with BfR to review this conclusion with scientific

confidence. Further skewing their interpretation, the BfR did not include evidence of chromosomal damage from exposed humans[²⁴] that was highlighted in the IARC Monograph.

The BfR confirms (p. 79) that the studies evaluated by the IARC WG on oxidative stress were predominantly positive but does not agree that this is strong support for an oxidative stress mechanism. They minimize the significance of these findings predominantly because of a lack of positive controls in some studies and because many of the studies used glyphosate formulations and not pure glyphosate. The WG concluded that (p. 77) "Strong evidence exists that glyphosate, AMPA and glyphosate-based formulations can induce oxidative stress". From a scientific perspective, these types of mechanistic studies can play a key role in distinguishing between the effects of mixtures, pure substances and metabolites and we encourage the BfR to carefully review this science.

Finally, we strongly disagree that data from studies published in the peer-reviewed literature should automatically receive less weight than guideline studies. Once a chemical or its formulations are on the market, the majority of the research done on these chemicals will be done by research laboratories using various models to address specific issues related to toxicity that will often not have testing guidelines associated with them. These peer-reviewed and published findings have great value in understanding mechanisms of carcinogenicity and should be given appropriate weight in an evaluation based on study quality and not just guideline studies.

General Comments

Science moves forward based on data, careful evaluation of those data and a rigorous review of the findings and conclusions. One important aspect of this process is transparency and the ability to question or debate the findings of others. This ensures the validity of the results and provides a strong basis for decisions. Many of the aspects of transparency do not exist for the RAR[²] or the BfR Addendum. For example, citations for almost all of the references, even those from the open scientific literature, have been redacted from the document. The ability to objectively evaluate the findings of a scientific report requires a complete list of the cited supporting evidence. As another example, there are no authors or contributors listed for either document, a requirement for publication in virtually all scientific journals. This is in direct contrast to the IARC WG evaluation listing all authors, all publications and public disclosure of pertinent conflicts of interest prior to the WG meeting[²⁶].

A second important aspect of the scientific process is a careful evaluation and analysis of the facts. Several guidelines have been devised for analyzing carcinogenicity data, most after consultation with scientists from around the world. One of the most widely used guidelines is the OECD guidance on the conduct and design of chronic toxicity and carcinogenicity studies[¹⁹] which is cited in the BfR Addendum. This OECD guidance is in contradiction to the methods used by the BfR for both historical controls and for trend analysis; the two reasons given by the BfR for dismissing these data. Thus, BfR uses the

.concept of testing guidelines to exclude substantive scientific evidence from their risk assessment and ignore OECD guidelines in addressing the important issues of historical controls and trend analyses.

Due to the potential public health implications of this extensively used pesticide it is essential that all scientific evidence be freely available, reviewed openly in an objective manner, and that financial support, conflicts of interest and affiliations of authors be fully disclosed. Many aspects of the evaluation conducted by the BfR and EFSA do not meet this fundamental objective criteria and raise significant questions of validity.

Summary

The IARC WG concluded that glyphosate is a "probable human carcinogen" putting it into IARC category 2A due to *sufficient evidence* of carcinogenicity in animals, *limited evidence* of carcinogenicity in humans and *strong* mechanistic data.

- The IARC WG found an association between non-Hodgkin lymphoma and glyphosate based on the available human evidence.
- The IARC WG found significant carcinogenic effects in laboratory animals for two tumor types in two mouse studies and benign tumors in two rat studies.
- Finally, the IARC WG concluded strong evidence of genotoxicity and oxidative stress for glyphosate, entirely from publicly available research, including findings of DNA damage in the peripheral blood of exposed humans.

In their RAR, BfR concluded (vol. 1, p. 160) "classification and labeling for carcinogenesis is not warranted" and "glyphosate is devoid of genotoxic potential".

- BfR agreed with the IARC on *limited evidence* in humans but then dismissed the association as "insufficiently consistent" with no justification.
- Using an inappropriate historical control dataset in an incorrect manner and ignoring established OECD guidelines cited in their report, BfR dismissed evidence of renal tumors in 3 mouse studies, hemangiosarcoma in 2 mouse studies and malignant lymphoma in 2 mouse studies. Thus, BfR incorrectly discarded all of the glyphosate-induced carcinogenic findings in animals as chance occurrences.
- The BfR ignored important laboratory and human evidence of genotoxicity.
- The BfR confirmed that glyphosate induces oxidative stress and dismissed this finding for lack of any other finding because they had dismissed all of the other evidence.

The most parsimonious scientific explanation of the cancers seen in humans and laboratory animals supported by the mechanistic data is that glyphosate is a *probable* human carcinogen. On the Basis of this conclusion and in the absence of

contrary evidence, it is reasonable to conclude that glyphosate formulations should also be considered probable human carcinogens.

We believe that the arguments promoted by the BfR to negate the human, animal and mechanistic evidence are fundamentally and scientifically flawed and should be rejected. We strongly object to the almost non-existent weight given to studies from the literature by the BfR. and the strong reliance on non-publicly available data in a limited set of assays that define the minimum data necessary for the approval of a pesticide. We believe that the IARC WG evaluation of *probably carcinogenic to humans* accurately reflects the results of the published scientific literature on glyphosate and, on the face of it, the unpublished studies to which the BfR refers. Conversely, the BfR evaluation, and consequently the EFSA evaluation, do not reflect the available science.

Thus, repeating our earlier request, we urge you and the European Commission to disregard the flawed EFSA finding on glyphosate in your formulation of glyphosate health and environmental policy for Europe and to call for a transparent, open and credible review of the scientific literature.

The views expressed in this letter are the opinion of the scientists who are listed below and DO NOT imply an endorsement or support for these opinions by any organizations to which they are affiliated.

Sincerely,

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Durban, South Africa

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Dr. Maria Grazia Petronio
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 Local Health Authority-Empoli, Florence, Italy
 Professor of Environmental Hygiene
 School of Specialization "Hygiene and Preventive Medicine
 University of Pisa, Italy
 Vice-President for Central Italy Area of International Society of Doctors for
 Environment, Italy

Dr Roberta Pirastu
 Researcher
 Department of Biology and Biotechnology "Charles Darwin"
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Prof. Miquel Porta, MD, MPH, PhD
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 (IMIM) and School of Medicine
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Former Division Head at the German Cancer Research Center, Heidelberg
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Hoseo University,
Asan, Korea

Dr. Paola Zambon
Past Director Veneto Tumor Registry
University of Padua
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Prof. Dr. Hajo Zeeb

Head, Department of Prevention and Evaluation, Leibniz-Institute for
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Prof. Shu-Feng Zhou, MD, PhD
Associate Dean for International Research and Chair
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Tampa, Florida, USA

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Suzan Fiack - RE: Lunchdebate zum Stand des EU-Zulassungsverfahren für Glyphosat

Von: i@efsa.europa.eu
An: "Fiack Suzan" <Suzan.Fiack@bfr.bund.de>, @efsa.europa.eu, EFSA Press <Press.Press@efsa.europa.eu >
Datum: 27.11.2015 09:40
Betreff: RE: Lunchdebate zum Stand des EU-Zulassungsverfahren für Glyphosat -
T
CC: @efsa.europa.eu

Hi Suzan,

Yes, we are invited and (Head of EFSA's Pesticides Unit) will be at site.

Viele Grüße,

From: Fiack Suzan [Suzan.Fiack@bfr.bund.de]
Sent: 27 November 2015 09:29
To: , EFSA Press
Cc:
Subject: Lunchdebate zum Stand des EU-Zulassungsverfahren für Glyphosat

Hi all,
are you aware of the following event:
<http://martin-haeusling.euitermine/1141-lunchdebate-zum-stand-des-eu-zulassungsverfahren-fuer-glyphosat.html>
Best regards,
Suzan

Von: @efsa.europa.eu>
 An: Fiack Suzan <Suzan.Fiack@bfr.bund.de >
 CC: EFSA Press
 <Press.Press@efsa.europa.eu>
 Datum: 28.11.2015 11:13
 Betreff: Re: 151121_Glyphosat_final_.docx

Yes, important distinction, it's not an official IARC paper. I would like to read IARC's lines regarding this 'private endeavour' of Poitier.

Sent from my iPhone

> On 27 Nov 2015, at 23:00, Fiack Suzan <Suzan.Fiack@bfr.bund.de > wrote:

> Dear
 > thanks a lot. This sounds reasonable. You might change IARC to "this
 > open letter", as the letter is not from IARC. Just a thought.
 > Have a nice weekend.
 > Best,
 > Suzan

> Von meinem iPhone gesendet

>>> Am 27.11.2015 um 22:07 schrieb
 >>> @efsa.europa.eu>:

>> Thanks v much Suzan. We're taking a slightly more minimalist approach
 > for the time being, given that we will have the opportunity to expand on
 > our position in the European Parliament on Tuesday. We will likely
 > follow many of the same arguments that you do though...

>> Here are our lines:

>> From an initial review of the letter it doesn't seem that IARC are
 > bringing any new scientific elements or arguments that haven't already
 > been assessed by EFSA and the Member States as part of the EU peer
 > review of glyphosate.

>>> We look forward to the opportunity we have in the European Parliament
 > on 1 December<x-apple-data-detectors://1> to explain our work face to
 > face with IARC.

>> best regards

>> Sent from my iPhone

>>> On 27 Nov 2015, at 20:11, Fiack Suzan
 >>> <Suzan.Fiack@bfr.bund.de <mailto:Suzan.Fiack@bfr.bund.de > wrote:

>> Dear
 >> please find attached our answers to the S?ddeutsche Zeitung, which I
 > will send them Sunday morning.
 >>

>> Mit freundlichen Gr??en
 >> i.A.

» Suzan Fiack
>>

» Dr. Suzan Fiack

» Bundesinstitut für Risikobewertung
» Fachgruppenleitung Presse- und Öffentlichkeitsarbeit
» Abteilung Risikokommunikation

» Federal Institute for Risk Assessment
» Head of Unit Press and Public Relations
» Department Risk Communication

» Max-Dohrn-Straße 8-10, 10589 Berlin
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» Tel. +49 30 18412-4302
» Fax +49 30 18412-4970

» www.bfr.bund.de <<http://www.bfr.bund.de>>

» <151121_Glyphosatfinal_.docx.secure>

Von: eeefa.euroDa.eu >
An: "'Fiack Suzan' <Suzan.Fiack@bfr.bund.de >,
i@efsa.europa.eu >
CC: EFSA Press <Press.Press@efsa.europa.eu >
Datum: 30.11.2015 11:38
Betreff: RE: Open Letter

Hi Suzan,

I would not share the open letter, but the "easy way" would be to refer to this article in Die Zeit, which links to the open letter:
<http://www.zeit.de/wissen/umwelt/2015-11/glyphosat-pflanzenschutzmittel-krebs-risiko>. The uploaded the open letter an their own website: <http://www.zeit.de/wissen/umwelt/2015-11/glyphosat-offener-brief.pdf>

Viele Grüße,

- - Original Message - -

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]
Sent: 30 November 2015 11:31
To:
Cc: EFSA Press
Subject: Open Letter

Hi all,
do you know, if the "open letter" is open to the public? Is there a link?
There are requests from the media who want us to send them the letter.
How do you deal with this?
Thank you!
Suzan

Von: @efsa.etimna eu>
 An: Fiack Suzan <Suzan.Fiack@bfr.bund.de>, _
efsa.europa.eu >, EFSA Press <Press.Press@efsa.europa.eu>
 CC: Leitung <Leitung@bfr.bund.de>, 2 <2@bfr.bund.de>, 6 <6@bfr.bund.de>
 Datum: 03.12.2015 16:53
 Betreff: RE: FAQ IARC

Hi Suzan - yes please feel free to send to us and we will have a look to check consistency with our
 lines/comms
 Thank you,

- - -Original Message -

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]
 Sent: 03 December 2015 13:08
 To: EFSA Press
 Cc: Leitung; 2; 6
 Subject: FAQ IARC

Hi ,

we plan to actualise our frequently asked questions regarding the different assessments of the
 carcinogenic effect of glyphosate by BfR and IARC.

Would it be possible for EFSA to check, if they are in line with EFSA's communication material? We plan
 to send you the documents today or tomorrow in German language.

What do you think?

Best regards,
 Suzan

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Von: i@efsa.europa.eu >
An: Fiack Suzan <Suzan.Fiack@bfr.bund.de>, efsa.europa.eu >, EFSA Press <Press.Press@efsa.europa.eu>
CC: efsa.europa.eu >
Datum: 04.12.2015 14:32
Betreff: RE: Antw: RE: 151203_FACUARC_NEU_NEU_Vorlage_Leitung_ak.docx

check from our side and come back to you asap.
Best, .

-- Original Message
From: Fiack Suzan [<mailto:Suzan.Fiack@bfr.bund.de>]
Sent: 04 December 2015 14:29
To: EFSA Press
Cc:
Subject: I-ZE: Antw: RE: 151203 JACUARC_NEU_NEU_Vorlage_Leitung_ak.docx

We would publish after we revised your comments. What would be realistic?

>> i@efsa.europa.eu > 04.12.2015 14:25 >>>
When are you planning to publish? Well have to consult also with scientific colleagues and I'm not sure right now what their availability is.
Best.

-- Original Message
From: Fiack Suzan [<mailto:Suzan.Fiack@bfr.bund.de>]
Sent: 04 December 2015 14:23
To: , EFSA Press
Cc:
Subject: Antw: RE: 151203 JAQIARC_NELLNEUVorlage_Leitung_ak.docx

Yes.
Do you think you can already check the German version?

Mit freundlichen Grüßen
i.A.
Suzan Fiack

Dr. Suzan Fiack

Bundesinstitut für Risikobewertung
Fachgruppenleitung Presse- und Öffentlichkeitsarbeit Abteilung Risikokommunikation

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>>

@efsa.europa.eu> 04.12.2015 14:20 >>>

Thanks Suzan - are you planning to produce an English version also?

Best,

From: Fiack Suzan [mailto:Suzan.Fiack@bfr.bund.de]

Sent: 04 December 2015 14:12

To: F EFSA Press

Subject: 151203_FAQ_IARC_NEU_NEU_Vorlage_Leitung_ak.docx

Hi all,

please find attached as already mentioned our FAQ.

Thanks for having a look an them!

Best,

Suzan

Registratur - RE: Antw: RE: 151203_FACLIARC_NEILINEU_Vorlage_Leitung_ak.docx

Von: 1@efsa.europa.eu>
An: "Fiack Suzan" <Suzan.Fiack@bfr.bund.de>, <1@efsa.europa.eu>
Datum: 07.12.2015 10:02
Betreff: RE: Antw: RE: 151203 FAQIARC NEU NEU Vorlage Leitung_ak.docx
CC: EFSA Press <Press.Press@efsa.europa.eu>, <1@efsa.europa.eu>
Anlagen: BfR FAQ comments Stu jo.docx, Geänderte Kopie von BfR FAQ comments Stu jo.docx

Hi Suzan,

Attached the FAQs with some minor comments from the Scientific Unit and me.

Viele Grüße,

BfR Berlin Registratur		r)
Registratur	12. JAN. 2016	D...)
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-----Original Message -----

From: Fiack Suzan [[L uzan.Fiack@bfr.bund.de](mailto:Suzan.Fiack@bfr.bund.de)]

Sent: 04 December 2015 19:20

To:

Cc: EFSA Press;

Subject: Re: Antw: RE: 151203_FAQ JARC_NEU_NEU_Vorlage_Leitung_ak.docx

Thank you!

Have a nice weekend.

Suzan

L.d.A

0221. (.6

> Am 04.12.2015 um 18:40 schrieb

1@efsa.europa.eu >

> Hi Suzan - haven't heard back from our scientists yet but presume Monday should be ok.

> I am out of the Office an Monday/Tuesday next week so ask Jan to get back to you

> Have a nice weekend

> Best, .

> Original Message -----

> From: Fiack Suzan [<mailto:Suzan.Fiack@bfr.bund.de>]

> Sent: 04 December 2015 14:29

> To: F

EFSA Press

> Cc:

> Subject: RE: Antw: RE: 151203_FAQ JARC_NIEU_NEU_Vorlage_Leitung_ak.docx

//

> We would publish after we revised your comments. What would be realistic?

>>> efsa.europa.eu 04.12.2015 14:25 >>>

> When are you planning to publish? Well have to consult also with scientific colleagues and I'm not sure right now what their availability is.

> Best, .

> Original Message - - -

> From: Fiack Suzan [<mailto:Suzan.Fiack@bfr.bund.de>].

> Sent: 04 December 2015 14:23

> To: EFSA Press

> Cr

> Subject: Antw: RE: 151203_FACLIARC_NEU_NEU_Vorlage_Leitung_ak.docx

> Yes.

> Do you think you can already check the German version?

> Mit freundlichen Grüßen

> i.A.

> Suzan Fiack

> Dr. Suzan Fiack

> Bundesinstitut für Risikobewertung

> Fachgruppenleitung Presse- und Öffentlichkeitsarbeit Abteilung
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> Fax +49 30 18412-4970

> www.bfr.bund.de

>>> efsa.europa.eu 04.12.2015 14:20 >>>

> Thanks Suzan - are you planning to produce an English version also?

> Best,

> From: Fiack Suzan [<mailto:Suzan.Fiack@bfr.bund.de>].

> Sent: 04 December 2015 14:12

> To: 7.FSA Press

> Subject: 151203_FAQ_IARC_NEU_NEU_Vorlage_Leitung_ak.docx

> Hi all,

108

- > please find attached as already mentioned our FAQ.
- > Thanks for having a look an them!
- > Best,
- > Suzan



Fragen und Antworten zur unterschiedlichen Einschätzung der krebserzeugenden Wirkung von Glyphosat durch BfR und IARC

FAQ des BfR vom 1. Dezember 2015

Kommentär

Nach Abschluss der wissenschaftlichen Diskussion bei der EFSA im Februar 2015 im Verfahren zur erneuten Prüfung des Pflanzenschutzmittelwirkstoffes Glyphosat wurde die Internationale Agentur für Krebsforschung (IARC) der WHO den Wirkstoff als „wahrscheinlich krebserzeugend für den Menschen“ (kanzerogen Gruppe 2A) ein-

Kommentar 1 1: This ts not correct. The expert.s' meeungs took place between Fibr. arid March, but thescien-tific discussion in EFSA went oribe-vond that periód.

Die Einschätzung der IARC stimmt aufgrund ihres Einflusses auf die Bewertungen des BfR, der EFSA und den zuständigen nationalen Behörden mit den internationalen Institutionen einschließlich des WHO/FAO (JMPR) überein. Die WHO selbst hat eine Ad-hoc-Kommission eingerichtet, die Gründe für die unterschiedliche Bewertung der Daten durch ihre eigenen Gremien, der IARC einerseits und des JMPR andererseits, aufzuklären. Es handelt sich dabei um ein wissenschaftliches Divergenzverfahren innerhalb der WHO, das noch nicht abgeschlossen ist.

Das Bundesinstitut für Risikobewertung (BfR) kam nach erneuter Prüfung seiner Bewertung des gesundheitlichen Risikos zum Ergebnis, dass sich nach dem derzeitigen Stand des Wissens bei bestimmungsgemäßer Anwendung von Glyphosat kein krebserzeugendes Risiko für den Menschen ableiten lässt. Die Experten aus den Behörden der 28 EU-Mitgliedstaaten und die Europäische Behörde für Lebensmittelsicherheit (EFSA) haben ebenfalls alle Unterlagen geprüft. Das Ergebnis der abschließenden Expertendiskussion war Grundlage der EFSA-Schlussfolgerung (EFSA Conclusion), die in Übereinstimmung mit der Einschätzung des BfR steht.

Das BfR hat Fragen und Antworten zur unterschiedlichen Einschätzung der krebserzeugenden Wirkung von Glyphosat durch BfR und IARC zusammengestellt.

Was sind die Ursachen der unterschiedlichen Bewertung von IARC und BfR?

Die Internationale Agentur für Krebsforschung (IARC) verwendet Kr **19.71eingeführtes** **ys-**
tem der **KlaSeiferung:4)hier9Ader** **igeliSC,114fted,,weiWriii in:der EU ,e,in,fortentwickeltes,**
weltweitabgestimm **t,Globalized Harmonized System" eingeführt wurde, das mit der CLP-**
Verordnung (Regulation an Classification, Labelling and Packaging of Substances and Mix-
tures) gesetzlich vorgegeben ist

Kommentar: []: That is a good argument. Can someone check whether this is true, that IARC did not change the procedure since 1971?

Die IARC führt eine rein gefahrenbezogene Analyse durch, die keine Empfehlung für Regierungen und Behörden darstellen soll. Die gefahrenbezogene Klassifizierung von Karzinogenen benennt die Eigenschaft eines Wirkstoffes, Krebs zu erzeugen. Eine solche Klassifizierung berücksichtigt jedoch nicht die Wahrscheinlichkeit, dass Krebs tatsächlich erzeugt wird, wenn dies von der Höhe der Aufnahmemenge abhängig ist.

Dagegen nimmt das BfR im Genehmigungsverfahren für Pestizid-Wirkstoffe eine risikobezogene Bewertung vor. Diese berücksichtigt neben der gefahrenbezogenen Analyse eines Stoffes auch die geschätzte Exposition, also die tatsächliche Aufnahmemenge des Stoffes, und ermittelt aus diesen Informationen das Risiko, an Krebs zu erkranken. Die rechtlich verbindliche gefahrenbezogene Klassifizierung erfolgt in der EU nach einem separaten Verfahren der CLP-Verordnung durch die Europäische Chemikalienbehörde (ECHA). Ein Bewertungsverfahren für Glyphosat nach der CLP-Verordnung wurde vom BfR **initiiert**.

Wie bewertet das BfR die Einschätzung der IARC?

Das Bundesinstitut für Risikobewertung (BfR) hat die Ende Juli 2015 veröffentlichte Monographie der IARC zur gesundheitlichen Bewertung von Glyphosat geprüft und in einem Addendum für die Neubewertung von Glyphosat im Rahmen der EU-Wirkstoffprüfung zusammengefasst. Nach umfassender Prüfung durch Experten aus den Behörden der 28 EU-Mitgliedstaaten und die Europäische Behörde für Lebensmittelsicherheit (EFSA) wurde in der abschließenden wissenschaftlichen Bewertung mehrheitlich festgestellt, dass sich nach dem derzeitigen Stand des Wissens bei bestimmungsgemäßer Anwendung von Glyphosat kein krebserzeugendes Risiko für den Menschen ableiten lässt.

Welche Gründe führen zu der Bewertung der IARC, dass Glyphosat wahrscheinlich krebserregend (kanzerogen) sei?

Bei der Frage einer möglichen Kanzerogenität von Glyphosat hat die IARC epidemiologische Untersuchungen am Menschen, publizierte Industriestudien an Ratten und Mäusen, sowie mechanistische Studien mit dem Wirkstoff und verschiedenen, nicht näher benannten glyphosathaltigen Pflanzenschutzmitteln ausgewertet, die öffentlich verfügbar sind. Die IARC kommt durch die vorliegenden epidemiologischen Studien zu dem Schluss, dass es begrenzte Hinweise („limited evidence“) für einen statistisch signifikanten Zusammenhang zwischen der Exposition gegenüber Pflanzenschutzmitteln, die auch Glyphosat enthalten, und einem erhöhten Risiko für Non-Hodgkin Lymphome geben könnte.

Die IARC führt als entscheidende Belege für eine wahrscheinlich kanzerogene Wirkung („sufficient evidence“) dieses Pestizidwirkstoffes tierexperimentelle Studien der Industrie mit dem Wirkstoff Glyphosat an. Diese Studien lagen der IARC nicht im Original vor. Alle zuständigen Behörden, die diese Studien im Original vorliegen hatten, kamen zu dem Schluss, dass sich daraus kein kanzerogenes Risiko für den Menschen ableiten lässt. Hierzu gehören unter anderem die US-EPA und das JMPR-Panel der WHO.

Diese tierexperimentellen Befunde waren dem BfR bekannt und bereits anhand der der IARC nicht vorliegenden Originalstudien im Bewertungsbericht (Renewal Assessment Report, RAR) im Rahmen der EU Wirkstoffprüfung aufgeführt worden.

Bezieht sich die Bewertung der IARC auf den Wirkstoff Glyphosat, welcher derzeit im EU-Genemigungsverfahren erneut bewertet wird?

Nein, die IARC hat eine gemeinsame Bewertung des Wirkstoffes, des Hauptmetaboliten als auch verschiedener glyphosathaltiger Pflanzenschutzmittel vorgenommen. Die Bewertung der glyphosathaltigen Pflanzenschutzmittel erfolgt dagegen in der EU erst in einem zweiten Schritt, dem zonalen Zulassungsverfahren, wenn eine Genehmigung des Wirkstoffes erfolgt ist. Es wurde festgestellt, dass bei vielen in der Wissenschaft diskutierten Studien und Veröffentlichungen zur möglichen Kanzerogenität und Genotoxizität als auch in den epidemiologischen Studien der Wirkstoff Glyphosat nicht isoliert, das heißt als Reinsubstanz, sondern nur in der Formulierung, das heißt als handelsübliches Produkt mit verschiedenen anderen Komponenten, verwendet wurde. Da die Toxizität der Beistoffe höher sein kann als die des Wirkstoffes Glyphosat und bei Publikationen in wissenschaftlichen Zeitschriften häufig die genaue Zusammensetzung nicht beschrieben wird, ist die Aussagekraft der Studien mit glyphosathaltigen Mitteln für die Wirkstoffprüfung im Rahmen des EU-Genemigungsverfahrens gering.

Hat das BfR in seinem Bewertungsbericht die gleichen Studien und Quellen ausgewertet wie die IARC?

Bei den Langzeitstudien an Nagern, die von der IARC mit „sufficient evidence in animals“ eingeschätzt wurden, fließen in die IARC-Bewertung drei Befunde aus von der Industrie finanzierten tierexperimentellen Studien ein. Diese Studien wurden bereits von der US-EPA

und des JMPR-Gremiums der WHO beurteilt mit dem Ergebnis, dass ein kanzerogenes Risiko von Glyphosat für den Menschen nicht zu erwarten ist.

Alle Befunde, auf die die IARC ohne Einsicht in die Originaldaten und Verwendung eigener statistischer Verfahren, die nicht durch GLP und die Versuchsplanung nach OECD-Richtlinien abgedeckt sind, Bezug nimmt, wurden vom BfR im Bewertungsbericht (RAR) vom April 2015 sowie im Addendum zum Bewertungsbericht vom 31. August 2015, gemeinsam mit zahlreichen weiteren Kanzerogenitätsprüfungen an Ratten und Mäusen anhand der Originaldaten beurteilt, die nicht öffentlich zugänglich sind. •

Bei den Daten zur Epidemiologie, die von der IARC mit „limited evidence in humans“ eingeschätzt wurden, hatte das BfR die Kernstudien bereits im überarbeiteten Bewertungsbericht (RAR) vom April 2015 berücksichtigt. Im Addendum zur Einschätzung der IARC-Monographie vom August 2015 hat das BfR weitere Studien bewertet, die die IARC aufgeführt hatte. Diese zusätzlichen Studien führen in Bezug auf die Schlussfolgerungen der Epidemiologie, in denen das BfR grundsätzlich mit der IARC übereinstimmt, zu keiner veränderten Gesamtbewertung.

Weiterhin enthält der RAR zahlreiche OECD-Leitlinien-konforme Studien, die der IARC nicht zur Verfügung standen. Hierbei handelt es sich insbesondere um Studien zur Mutagenität, die gemäß den gesetzlichen Anforderungen mit dem reinen Wirkstoff durchgeführt wurden. Studien, die entweder mit Pflanzenschutzmitteln unbekannter Zusammensetzung durchgeführt wurden, bei denen die Prüfung an Fischen oder Pflanzen erfolgt oder deren Methodik nicht eindeutig nachvollziehbar bzw. validiert ist, wurden nicht in den ursprünglichen RAR integriert.

Im Addendum zum Bewertungsbericht, das den zuständigen europäischen Behörden übersandt und mittlerweile von der EFSA veröffentlicht wurde, wurden vom BfR und den anderen EU-Mitgliedsstaaten alle von der IARC zitierten und im RAR vorher noch nicht enthaltenen Studien vollständig geprüft.

Entspricht es den OECD-Leitlinien, abgeschlossene Studien mit einer anderen statistischen Methode auszuwerten als dies bei der Konzeption der Studie festgelegt wurde?

Ein technischer Leitfaden der OECD (Guidance Document 116) sieht vor, dass die Auswahl der verwendeten statistischen Methoden für die Auswertung der Daten bereits bei der Planung, das heißt vor Beginn der Studie vorzunehmen ist. Dafür werden neben paarweisen statistischen Vergleichen auch Trendtests vorgeschlagen. Das BfR hat aus Transparenzgründen in seinem Addendum zusätzlich zu den in den Originalstudien verwendeten statistischen Tests auch den von der IARC favorisierten Trendtest hinsichtlich seiner statistischen Aussagen geprüft. Jedoch ist eine statistische Signifikanz nach dem technischen Leitfaden der OECD nicht generell mit einer biologischen Relevanz gleichzusetzen.

Hat das BfR bei der Bewertung der Kanzerogenität von Glyphosat etwas übersehen?

Nein. Bereits im Rahmen der öffentlichen und fachlichen Konsultation der EFSA zu Glyphosat ist eine Kommentierung durch die Öffentlichkeit, Wissenschaft, Politik, Wirtschaft und Nichtregierungsorganisationen zu den bis November 2013 recherchierten Bewertungsunterlagen erfolgt. Als die Befunde der IARC nach Abschluss der EFSA-Expertendiskussion bekannt geworden sind, hat die Kü-Kommission **derb EFSA ein zusätzliches** das-Mändk erteilt,-1 die **Befunde des IARCse** •

och zu berücksichtigen und den Bewertungszeitraum verlängert. Somit sind im abschließenden Bewertungsbericht der EFSA und im Addendum des BfR alle Befunde, welche in der IARC-Monographie aufgeführt sind, geprüft, dargelegt und abschließend diskutiert worden. Die Experten aus den Behörden der EU-Mitgliedsstaaten und die Europäische Behörde für Lebensmittelsicherheit

Kommentar [j] = Could be as the mandate for EFSA.

(EFSA) haben somit in der EFSA-Schlussfolgerung (EFSA Conclusion) bei der Bewertung der Kanzerogenität von Glyphosat keine relevanten Befunde, die bis Juli 2015 publiziert worden sind, übersehen und somit die gesetzlichen Anforderungen im Zulassungsverfahren für den Wirkstoff angewendet

Wie schätzt das BfR den „Offenen Brief“ einiger Wissenschaftler an den EU-Kommissar für Gesundheit und Lebensmittelsicherheit ein?

Unterzeichner des offenen Briefes ist nicht die IARC selbst. Der „Offene Brief wurde von Christopher Portier verfasst, der an der Erstellung der IARC-Monographie zu Glyphosat als eingeladener Spezialist ("invited specialist") nicht aber als Mitglied („member) beteiligt war. Der Initiator und Verfasser des Briefes ist aktives Mitglied des Environmental Defense Fund, einer US-amerikanischen Nichtregierungsorganisation. Er richtet sich also nicht im Namen der IARC, sondern gemeinsam mit anderen Wissenschaftlern, die seinem Aufruf gefolgt sind, an den für das weitere Verfahren zuständigen EU-Kommissar. Nach Einschätzung des BfR sind darin keine neuen wissenschaftlichen Erkenntnisse aufgeführt, die nicht bereits von der EFSA und den europäischen Mitgliedstaaten im Rahmen der EU-Wirkstoffprüfung bewertet wurden.

Die in dem Brief getroffenen Aussagen zur Kanzerogenität von Glyphosat stehen im Widerspruch zu den Bewertungen der zuständigen nationalen und internationalen Institutionen einschließlich des WHO/FAO Joint Meeting on Pesticide Residues (JMPR). Die gesundheitliche Bewertung des Pflanzenschutzmittelwirkstoffes Glyphosat ergibt nach Prüfung aller vorliegenden Studien durch diese Institutionen, dass bei bestimmungsgemäßer Anwendung ein krebserzeugendes Risiko für den Menschen nach derzeitiger Datenlage unwahrscheinlich ist. Zu der Einschätzung kommen bislang auch die amerikanische Umweltbehörde (US-EPA) und die kanadische Behörde (Canada Health).

Das BfR empfiehlt grundsätzlich, auch und gerade kontroverse Diskussionen über wissenschaftliche Studien auf wissenschaftlicher Ebene transparent zu führen. Ein unverzichtbarer integraler Bestandteil der Wissenschaft ist dabei der wissenschaftliche Publikationsprozess. Thesen oder Kommentare zu Studien können dem wissenschaftlichen Diskurs nur zugeführt werden, wenn diese publiziert wurden und die entsprechenden Schlussfolgerungen transparent nachvollziehbar sind.

Da die wissenschaftliche Bewertung des Wirkstoffes Glyphosat durch die zuständige EU-Behörde und die zuständigen Behörden der Mitgliedstaaten abgeschlossen ist und alle danach publizierten Artikel und Briefe keine neuen Untersuchungsergebnisse geliefert haben, können die zuständigen politischen Gremien in der EU nun auf Basis der wissenschaftlichen Bewertung entscheiden.

Wird die Qualität der wissenschaftlichen Bewertung von Glyphosat durch das BfR durch die unterschiedlichen Schlussfolgerungen in Frage gestellt?

Nein, es gehört zum Alltag der Risikobewertung und ist Teil der wissenschaftlichen Arbeit, dass verschiedene Gremien aufgrund unterschiedlicher Informationen und Einschätzungen von epidemiologischen Daten und experimentellen Prüfungen Sachverhalte unterschiedlich einschätzen.



Fragen und Antworten zur unterschiedlichen Einschätzung der krebserzeugenden Wirkung von Glyphosat durch BfR und IARC

FAQ des BfR vom Dezember 2015

Nach Abschluss der wissenschaftlichen Diskussion bei der EFSA im Februar 2015 im Verfahren zur erneuten Prüfung des Pflanzenschutzmittelwirkstoffes Glyphosat stufte die Internationale Agentur für Krebsforschung (IARC) der WHO den Wirkstoff als „wahrscheinlich krebserzeugend für den Menschen, Kanzerogen Gruppe 2A“ ein.

Die Einschätzung der IARC stimmt aufgrund ihres Bewertungsansatzes nicht mit den Bewertungen des BfR, der EFSA und den zuständigen nationalen, europäischen und anderen internationalen Institutionen einschließlich des WHO/FAO Joint Meeting on Pesticide Residues (JMPR) überein. Die WHO selbst hat eine „ad hoc expert task force“ mit der Aufgabe eingerichtet, die Gründe für die unterschiedliche Bewertung der Daten durch ihre eigenen Gremien, der IARC einerseits und des JMPR andererseits, aufzuklären. Es handelt sich dabei um ein wissenschaftliches Divergenzverfahren innerhalb der WHO, das noch nicht abgeschlossen ist.

Das Bundesinstitut für Risikobewertung (BfR) kam nach erneuter Prüfung seiner Bewertung des gesundheitlichen Risikos zum Ergebnis, dass sich nach dem derzeitigen Stand des Wissens bei bestimmungsgemäßer Anwendung von Glyphosat kein krebserzeugendes Risiko für den Menschen ableiten lässt. Die Experten aus den Behörden der 28 EU-Mitgliedstaaten und die Europäische Behörde für Lebensmittelsicherheit (EFSA) haben ebenfalls alle Unterlagen geprüft. Das Ergebnis der abschließenden Expertendiskussion war Grundlage der EFSA-Schlussfolgerung (EFSA Conclusion), die in Übereinstimmung mit der Einschätzung des BfR steht.

Das BfR hat Fragen und Antworten zur unterschiedlichen Einschätzung der krebserzeugenden Wirkung von Glyphosat durch BfR und IARC zusammengestellt.

Was sind die Ursachen der unterschiedlichen Bewertung von IARC und BfR?

Die Internationale Agentur für Krebsforschung (IARC) verwendet r¹ **kih kibiuäg, kifigioie Weregenschaften iehrehe'in** ein fortentwickeltes, weltweit abgestimmtes Globalized Harmonized System eingeführt wurde, das mit der CLP-Verordnung (Regulation on Classification, Labelling and Packaging of Substances and Mixtures) gesetzlich vorgegeben ist.

Die IARC führt eine rein gefahrenbezogene Analyse durch, die keine Empfehlung für Regierungen und Behörden darstellen soll. Die gefahrenbezogene Klassifizierung von Karzinogenen benennt die Eigenschaft eines Wirkstoffes, Krebs zu erzeugen. Eine solche Klassifizierung berücksichtigt jedoch nicht die Wahrscheinlichkeit, dass Krebs tatsächlich erzeugt wird, wenn dies von der Höhe der Aufnahmemenge abhängig ist.

Dagegen nimmt das BfR im Genehmigungsverfahren für Pestizid-Wirkstoffe eine risikobezogene Bewertung vor. Diese berücksichtigt neben der gefahrenbezogenen Analyse eines Stoffes auch die geschätzte Exposition, also die tatsächliche Aufnahmemenge des Stoffes, und ermittelt aus diesen Informationen das Risiko, an Krebs zu erkranken. Die rechtlich verbindliche gefahrenbezogene Klassifizierung erfolgt in der EU nach einem separaten Verfahren der CLP-Verordnung durch die Europäische Chemikalienbehörde (ECHA). Ein Bewertungsverfahren für Glyphosat nach der CLP-Verordnung wurde vom BfR initiiert.

Mentor : Wird bei Veröffentlichung aktualisiert

Kommentar i ;his is not correct. The experts' meetings took place between Febr. and March, but the scientific discussion in EFSA went on beyond that period.

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Wie bewertet das BfR die Einschätzung der IARC?

Das Bundesinstitut für Risikobewertung (BfR) hat die Ende Juli 2015 veröffentlichte Monographie der IARC zur gesundheitlichen Bewertung von Glyphosat geprüft und in einem Addendum für die Neubewertung von Glyphosat im Rahmen der EU Wirkstoffprüfung zusammengefasst. Nach umfassender Prüfung durch Experten aus den Behörden der 28 EU-Mitgliedstaaten und die Europäische Behörde für Lebensmittelsicherheit (EFSA) wurde in der abschließenden wissenschaftlichen Bewertung mehrheitlich festgestellt, dass sich nach dem derzeitigen Stand des Wissens bei bestimmungsgemäßer Anwendung von Glyphosat kein krebserzeugendes Risiko für den Menschen ableiten lässt.

Welche Gründe führen zu der Bewertung der IARC, dass Glyphosat wahrscheinlich krebserregend (kanzerogen) sei?

Bei der Frage einer möglichen Kanzerogenität von Glyphosat hat die IARC epidemiologische Untersuchungen am Menschen, publizierte Industriestudien an Ratten und Mäusen, sowie mechanistische Studien mit dem Wirkstoff und verschiedenen, nicht näher benannten glyphosathaltigen Pflanzenschutzmitteln ausgewertet, die öffentlich verfügbar sind. Die IARC kommt durch die vorliegenden epidemiologischen Studien zu dem Schluss, dass es begrenzte Hinweise („limited evidence“) für einen statistisch signifikanten Zusammenhang zwischen der Exposition gegenüber Pflanzenschutzmitteln, die auch Glyphosat enthalten, und einem erhöhten Risiko für Non-Hodgkin Lymphome geben könnte.

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Diese tierexperimentellen Befunde waren dem BfR bekannt und bereits anhand der der IARC nicht vorliegenden Originalstudien im Bewertungsbericht (Renewal Assessment Report, RAR) im Rahmen der EU-Wirkstoffprüfung aufgeführt worden.

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Nein, die IARC hat eine gemeinsame Bewertung des Wirkstoffes, des Hauptmetaboliten als auch verschiedener glyphosathaltiger Pflanzenschutzmittel vorgenommen. Die Bewertung der glyphosathaltigen Pflanzenschutzmittel erfolgt dagegen in der EU erst in einem zweiten Schritt, dem zonalen Zulassungsverfahren, wenn eine Genehmigung des Wirkstoffes erfolgt ist. Es wurde festgestellt, dass bei vielen in der Wissenschaft diskutierten Studien und Veröffentlichungen zur möglichen Kanzerogenität und Genotoxizität als auch in den epidemiologischen Studien der Wirkstoff Glyphosat nicht isoliert, das heißt als Reinsubstanz, sondern nur in der Formulierung, das heißt als handelsübliches Produkt mit verschiedenen anderen Komponenten, verwendet wurde. Da die Toxizität der Beistoffe höher sein kann als die des Wirkstoffes Glyphosat und bei Publikationen in wissenschaftlichen Zeitschriften häufig die genaue Zusammensetzung nicht beschrieben wird, ist die Aussagekraft der Studien mit glyphosathaltigen Mitteln für die Wirkstoffprüfung im Rahmen des EU-Genehmigungsverfahrens gering.

Hat das BfR in seinem Bewertungsbericht die gleichen Studien und Quellen ausgewertet wie die IARC?

Bei den Langzeitstudien an Nagern, die von der IARC mit „sufficient evidence in animals“ eingeschätzt wurden, fließen in die IARC-Bewertung drei Befunde aus von der Industrie finanzierten tierexperimentellen Studien ein. Diese Studien wurden bereits von der US-EPA

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Alle Befunde, auf die die IARC ohne Einsicht in die Originaldaten und Verwendung eigener statistischer Verfahren, die nicht durch GLP und die Versuchsplanung nach OECD-Richtlinien abgedeckt sind, Bezug nimmt, wurden vom BfR im Bewertungsbericht (RAR) vom April 2015 sowie im Addendum zum Bewertungsbericht vom 31. August 2015, gemeinsam mit zahlreichen weiteren Kanzerogenitätsprüfungen an Ratten und Mäusen anhand der Originaldaten beurteilt, die nicht öffentlich zugänglich sind.

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Weiterhin enthält der RAR zahlreiche OECD-Leitlinien-konforme Studien, die der IARC nicht zur Verfügung standen. Hierbei handelt es sich insbesondere um Studien zur Mutagenität, die gemäß den gesetzlichen Anforderungen mit dem reinen Wirkstoff durchgeführt wurden. Studien, die entweder mit Pflanzenschutzmitteln unbekannter Zusammensetzung durchgeführt wurden, bei denen die Prüfung an Fischen oder Pflanzen erfolgt oder deren Methodik nicht eindeutig nachvollziehbar bzw. validiert ist, wurden nicht in den ursprünglichen RAR integriert.

Im Addendum zum Bewertungsbericht, das den zuständigen europäischen Behörden übersandt und mittlerweile von der EFSA veröffentlicht wurde, wurden vom BfR und den anderen EU-Mitgliedsstaaten alle von der IARC zitierten und im RAR vorher noch nicht enthaltenen Studien vollständig geprüft.

Entspricht es den OECD-Leitlinien, abgeschlossene Studien mit einer anderen statistischen Methode auszuwerten als dies bei der Konzeption der Studie festgelegt wurde?

Ein technischer Leitfaden der OECD (Guidance Document 116) sieht vor, dass die Auswahl der verwendeten statistischen Methoden für die Auswertung der Daten bereits bei der Planung, das heißt vor Beginn der Studie vorzunehmen ist. Dafür werden neben paarweisen statistischen Vergleichen auch Trendtests vorgeschlagen. Das BfR hat aus Transparenzgründen in seinem Addendum zusätzlich zu den in den Originalstudien verwendeten statistischen Tests auch den von der IARC favorisierten Trendtest hinsichtlich seiner statistischen Aussagen geprüft. Jedoch ist eine statistische Signifikanz nach dem technischen Leitfaden der OECD nicht generell mit einer biologischen Relevanz gleichzusetzen.

Hat das BfR bei der Bewertung der Kanzerogenität von Glyphosat etwas übersehen?

Nein. Bereits im Rahmen der öffentlichen und fachlichen Konsultation der EFSA zu Glyphosat ist eine Kommentierung durch die Öffentlichkeit, Wissenschaft, Politik, Wirtschaft und Nichtregierungsorganisationen zu den bis November 2013 recherchierten Bewertungsunterlagen erfolgt. Als die Befunde der IARC nach Abschluss der EFSA-Expertendiskussion bekannt geworden sind, hat die Kl.1-Kommission der EFSA ein zusätzliches das-Mandät erteilt, die Befunde des IARCse auch zu berücksichtigen und den Bewertungszeitraum verlängert. Somit sind im abschließenden Bewertungsbericht der EFSA und im Addendum des BfR alle Befunde, welche in der IARC-Monographie aufgeführt sind, geprüft, dargelegt und abschließend diskutiert worden. Die Experten aus den Behörden der EU-Mitgliedsstaaten und die Europäische Behörde für Lebensmittelsicherheit

Kommentar Could be
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Wie schätzt das BfR den „Offenen Brief“ einiger Wissenschaftler an den EU-Kommissar für Gesundheit und Lebensmittelsicherheit ein?

Unterzeichner des offenen Briefes ist nicht die IARC selbst. Der "Offene Brief" wurde von Christopher Portier verfasst, der an der Erstellung der IARC-Monographie zu Glyphosat als eingeladenem Spezialist („invited specialist“) nicht aber als Mitglied (member) beteiligt war. Der Initiator und Verfasser des Briefes ist aktives Mitglied des Environmental Defense Fund, einer US-amerikanischen Nichtregierungsorganisation. Er richtet sich also nicht im Namen der IARC, sondern gemeinsam mit anderen Wissenschaftlern, die seinem Aufruf gefolgt sind, an den für das weitere Verfahren zuständigen EU-Kommissar. Nach Einschätzung des BfR sind darin keine neuen wissenschaftlichen Erkenntnisse aufgeführt, die nicht bereits von der EFSA und den europäischen Mitgliedstaaten im Rahmen der EU-Wirkstoffprüfung bewertet wurden.

Die in dem Brief getroffenen Aussagen zur Kanzerogenität von Glyphosat stehen im Widerspruch zu den Bewertungen der zuständigen nationalen und internationalen Institutionen einschließlich des WHO/FAO Joint Meeting on Pesticide Residues (JMPR). Die gesundheitliche Bewertung des Pflanzenschutzmittelwirkstoffes Glyphosat ergibt nach Prüfung aller vorliegenden Studien durch diese Institutionen, dass bei bestimmungsgemäßer Anwendung ein krebserzeugendes Risiko für den Menschen nach derzeitiger Datenlage unwahrscheinlich ist. Zu der Einschätzung kommen bislang auch die amerikanische Umweltbehörde (US-EPA) und die kanadische Behörde (Canada Health).

Das BfR empfiehlt grundsätzlich, auch und gerade kontroverse Diskussionen über wissenschaftliche Studien auf wissenschaftlicher Ebene transparent zu führen. Ein unverzichtbarer integraler Bestandteil der Wissenschaft ist dabei der wissenschaftliche Publikationsprozess. Thesen oder Kommentare zu Studien können dem wissenschaftlichen Diskurs nur zugeführt werden, wenn diese publiziert wurden und die entsprechenden Schlussfolgerungen transparent nachvollziehbar sind.

Da die wissenschaftliche Bewertung des Wirkstoffes Glyphosat durch die zuständige EU-Behörde und die zuständigen Behörden der Mitgliedstaaten abgeschlossen ist und alle danach publizierten Artikel und Briefe keine neuen Untersuchungsergebnisse geliefert haben, können die zuständigen politischen Gremien in der EU nun auf Basis der wissenschaftlichen Bewertung entscheiden.

Wird die Qualität der wissenschaftlichen Bewertung von Glyphosat durch das BfR durch die unterschiedlichen Schlussfolgerungen in Frage gestellt?

Nein, es gehört zum Alltag der Risikobewertung und ist Teil der wissenschaftlichen Arbeit, dass verschiedene Gremien aufgrund unterschiedlicher Informationen und Einschätzungen von epidemiologischen Daten und experimentellen Prüfungen Sachverhalte unterschiedlich einschätzen.

Susanne Kaus - EFSA IEP daily summary notification

Von: <noreplyefsa.europa.eu >
An: . i@bfr.bund.de>
Datum: 12.03.2015 17:02
Betreff: EFSA IEP daily summary notification

Dear subscriber,

The following documents have been uploaded to the IEP:

1 - New data from a BfR human study - no cyanide risk resulting from the consumption of Marzipan and persipan STA DE en 03-03-2015.html

Located in: **11.New and harmonised approaches for risk assessment of food and feed (EFSA's Scientific Committee)IBotanicals/**

2 - International BfR Symposium - Experts discuss continuing international harmonisation of terminology in developmental toxicologyTEC DE en 05-06-2014.html

Located in: **11.New and harmonised approaches for risk assessment of food and feed (EFSA's Scientific Committee)/Others/**

3 - More knowledge needed to ensure safe use of botanicals in food TEC DE en 06-01-2015.pdf

Located in: **11.New and harmonised approaches for risk assessment of food and feed (EFSA's Scientific Committee)/Botanicals/**

4 - No health risk for consumers from Bisphenol A exposure - the BfR endorses the conclusion of the new EFSA assessment STA DE en 19-02-2015.pdf

Located in: **09.Food contact materials enzymes flavourings and processing aids (CEF)/Food contact materials/Bisphenol A (BPA)/**

5 - Antimicrobial Resistance in Livestock and Food - Its Significance for Human Medicine and Options for Action in Risk Management STA DE en22-01-2015.pdf

Located in: **03.Biological hazards (BIOHAZ) and Animal Diseases Transmissible to Humans (Zoonoses) /Foodborne zoonoses/**

6 - Chemical decontamination procedures - no substitute for integrated hygiene concepts STA DE en 11-06-2014.html

Located in: **03.Biological hazards (BIOHAZ) and Animal Diseases Transmissible to Humans (Zoonoses) IFoodborne zoonoses/**

7 - EU active ingredient test for glyphosate - current situation and outlook TEC DE en 14-01-2015.html

Located in: **14.Plant protection products and their residues (PPR & PRAPeR)/**

« This is an automated email sent by EFSA. If you have any Problems, please contact servicedesk@efsa.europa.eu, >>

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unlawful. If you are
not the intended recipient, please let the sender know immediately.

- EFSA IEP daily summary notification

Von: <noreply@efsa.europa.eu >
An: ;@bfr.bund.de >
Datum: 30.03.2015 18:02
Betreff: EFSA IEP daily summary notification

Dear subscriber,

The following documents have been uploaded to the IEP:

- 1 - Does glyphosate cause cancer STA DE en 23-03-2015.pdf
Located in: 14.Plant protection products and their residues (PPR & PRAPeR)/

The following documents have been deleted:

- 1 - Does glyphosate cause cancer_STA_DE_en_23-03-2015.html
Located in: 14.Plant protection products and their residues (PPR & PRAPeR)/

-z< This is an automated email sent by EFSA. If you have any problems. please contact servicedesk@efsa.europa.eu. >>

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EFSA IEP daily summary notification

Von: <noreply@efsa.europa.eu >
An: @bfr.bund.de >
Datum: 07.04.2015 18:01
Betreff: EFSA IEP daily summary notification

Dear subscriber,

The following documents have been uploaded to the IEP:

1 - BfR-contribution to the EU-approval process of glyphosate is finalised STA DE en 02-04-2015.pdf

Located in: **14.Plant protection products and their residues (PPR & PRAPeR)/**

« This is an automated email sent by EFSA. If you have any problems, please contact servicedesk@efsa.europa.eu . >>

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not the intended recipient, please let the sender know immediately.

Von: EFSA-Focal-Point
An: pointfocal
CC: EFSA, Scientific Cooperation
Datum: 01.06.2015 17:18
Betreff: Antw: French Request for information on exposure and body burden to glyphosate and its metabolites (N° 23/2015)
Anlagen: _Glyphosate Exposure Body Burden French Request _Reply BfR.doc

Dear French Focal Point Team, dear , dear
Please find attached the completed template regarding your request on exposure and body burden to glyphosate and its metabolites.

If you have any further questions, please do not hesitate to contact us.

Kind regards
on behalf

Federal Institute for Risk Assessment (BfR)
EFSA Focal Point Germany
Max-Dohrn-Straße 10
10589 Berlin, Germany

>>>

Von: pointfocal <pointfocal@anses.fr>

J

3.ro>,

eu>,

Datum: 28.04.2015 162b

Betreff: French Request for information on exposure and body burden to glyphosate and its metabolites (N° 23/2015)

Dear Focal Points,

Please find attached a French multilateral request for information on exposure and body burden to glyphosate and its metabolites (number 21/2015).

We would be grateful if you could give us some information related to this request by the 1st June 2015.

Thank you in advance for your support and any information you may provide.
With kind regards,

EFSA National Focal Point
Direction des affaires européennes et internationales
European and International Affairs Department
) : 00 33 (0)1 49 77
8 : pointfocal@anses.fr

Agence nationale de sécurité sanitaire
Alimentation, Environnement, Travail
French agency for food, environmental and occupational health & safety
www.anses.fr

4

Attention : l'Anses change d'adresse à compter du 10 novembre 2014
allial ■■■ rease nate: new postai address for ANSES from 10 November 2014:
33 4 rue Pierre et Marie Curie - 94701 Maisons-Alfort Cedex - France

mmonammirpAnses fr

<https://twitter.com/Ansesfr>



efsa

European Food Safety Authority

Advisory Forum & Scientific Cooperation Unit

FOCAL POINT NETWORK
REQUEST FOR EXCHANGE OF INFORMATION ¹

PART 1- REQUEST

Requesting Institution: ANSES

Country: FRANCE

Date of request: 28/04/2015

Request Number²: 23/2015

Title of request	Request for information on exposure and body burden to glyphosate and its metabolites
Description of request (including background)	<p>Background: The herbicide glyphosate is currently undergoing the renewal of approval procedure according to Regulation EC n°1107/2009.</p> <p>The International Agency for Research on Cancer (IARC), the specialised cancer agency of the World Health Organization has assessed the carcinogenicity of five organophosphate pesticides, and classified the herbicide glyphosate as probably carcinogenic to humans (Group 2A). A summary of the final evaluations together with a short rationale have now been published online in The Lancet Oncology, and the detailed assessments will be published as Volume 112 of the IARC Monographs.</p> <p>Within this framework, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has recently been requested by its five ministries to examine the work led by the IARC concerning glyphosate, and will soon receive a similar request by a French approved consumers association.</p> <p>In this context, we would be very interested to gather all the data available in your respective countries concerning glyphosate/metabolites contaminations, exposure of population and results of biomonitoring.</p> <p>We would be grateful if you could send us some information regarding the following specific questions:</p> <p>Question(s):</p> <ul style="list-style-type: none">- Are you aware of current national works or studies on glyphosate or its metabolites (Y/N)?- Do you have any data (biomonitoring data, scientific publications, etc.) available at national level concerning exposure and body burden of general population, bystanders and workers to glyphosate and to its metabolites, through different sources of exposure (food, inhalation, skin exposure, etc.)? (Y/N)- Do you have any data on food or water contaminations (or residues) by glyphosate and its metabolites? (Y/N)- In case, could you spare them with us?
Addressee(s) of request	TO: all focal points Other addressee(s) requested action ³ : CC: scientificcooperation@efsa.europa.eu
Reply to request to be sent ⁴	TO: pointfocal@anses.fr ; gerard.lasfargues@anses.fr CC:
Timeline for submission of	01/06/2015

¹ The scope of this template is to allow sending out requests for exchange of information to the Focal Point network in a harmonised way. The template should be completed by Focal Points / EFSA. It includes a text field for replies by other Focal Points / EFSA. The template may also be used by the requestor to summarise all replies received following the sending out of a request.

² Number/Full Year (number to be selected from Excel file uploaded on ScienceNet on this link).

³ Even if not in CC on this request.

⁴ Name and email of person(s) receiving reply.

Advisory Forum & Scientific Cooperation Unit

replies	
Remit(s) of request ⁵	<input type="checkbox"/> Animal health and welfare (AHAW) <input type="checkbox"/> Biological hazards (BIOHAZ) Contaminants (CONTAM) <input type="checkbox"/> Plant health (PLH) <input type="checkbox"/> Feed (FEEDAP) <input type="checkbox"/> Nutrition (NDA) <input type="checkbox"/> Food ingredients and packaging (ANS, CEF) <input type="checkbox"/> Genetically Modified Organisms (GMO) Pesticides (PPR) <input type="checkbox"/> Other area falling within EFSA's remit <input type="checkbox"/> Not within EFSA's remit
Request concerns ⁵	Risk assessment <input type="checkbox"/> Risk management <input type="checkbox"/> Risk communication
Title(s) or link(s) to background document(s) ⁶	

⁵ More than one option can be selected

⁶ In case the documents are not published, please add the documents in hyperlink version in the form

PART II— REPLY TO REQUEST**Replying Institution:** Federal Institute for Risk Assessment (BfR)**Country:** Germany**Date of request:** 29/05/2015

Regarding your request we would like to provide you with the following information:

The draft assessment report including all information you requested was transmitted to EFSA and is available under the following http://corporateeurope.org/sites/default/files/attachments/glyphosate_rar_08_volume_3ca-cp_b-6_2013-12-18_san.pdf.

Meanwhile, EFSA has obtained the revised version of the draft assessment report.

Recently the BfR published four communications regarding glyphosate:

1) BfR Communication No 012/2015: EU Commission discusses critical issues in the assessment of the active substances in plant protection products
<http://www.bfr.bund.de/cm/349/eu-commission-discusses-critical-issues-in-the-assessment-of-the-active-substances-in-plant-protection-products.pdf>

2) BfR Communication No. 008/2015: BfR-contribution to the EU-approval process of glyphosate is finalised
<http://www.bfr.bund.de/cm/349/bfr-contribution-to-the-eu-approval-process-of-glyphosate-is-finalised.pdf>

3) BfR Communication No. 007/2015: Does glyphosate cause cancer?
<http://www.bfr.bund.de/cm/349/does-glyphosate-cause-cancer.pdf>

4) BfR communication No. 002/2015: <http://www.bfr.bund.de/cm/349/eu-active-ingredient-test-for-glyphosate-current-situation-and-outlook.pdf>
<http://www.bfr.bund.de/cm/349/eu-active-ingredient-test-for-glyphosate-current-situation-and-outlook.pdf>

Title(s) or link(s) to background document(s)⁶	http://corporateeurope.org/sites/default/files/attachments/glyphosate_rar_08_volume3ca-cp_b-6_2013-12-18_san.pdf http://www.bfr.bund.de/cm/349/eu-commission-discusses-critical-issues-in-the-assessment-of-the-active-substances-in-plant-protection-products.pdf http://www.bfr.bund.de/cm/349/bfr-contribution-to-the-eu-approval-process-of-glyphosate-is-finalised.pdf http://www.bfr.bund.de/cm/349/does-glyphosate-cause-cancer.pdf http://www.bfr.bund.de/cm/349/eu-active-ingredient-test-for-glyphosate-current-situation-and-outlook.pdf
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PART III — SUMMARY OF RESPONSES TO ORIGINAL REQUEST

Replying Institution:

Country:

Date of summary:

Title(s) or link(s) to background document(s) ⁶	

This III Part of the form is to be filled in by the Institution responsible for the original request

Von: AFwGComms Secretariat <AFwGCommssecretariat@efsa.europa.eu >
An: "efsa-focal-point@bfr.bund.dew <efsa-focal-point@bfr.bund.de >
Datum: 15.06.2015 10:01
Betreff: RE: Antw: AGENDA 47th AFCWG meeting_Bucharest, 16-17 June 2015

Many thanks

From: efsa-focal-point@bfr.bund.de [mailto:efsa-focal-point@bfr.bund.de]
Sent: 15 June 2015 09:13
To: AFwGComms Secretariat
Cc: 2; 21; Fiack, Suzan
Subject: RE: Antw: AGENDA_47th AFCWG meeting_Bucharest, 16-17 June 2015

Dear AFCWG Team, dear
Please find attached the presentation of Suzan Fiack with the title "Key Country Issues Germany: Challenges in Risk Communication".

Kind regards
an behalf

Federal Institute for Risk Assessment (BfR)
EFSA Focal Point Germany
Max-Dohm-Straße 10
10589 Berlin, Germany

[cid:image001.jpg@01D0A752.227F0150]

>>

Von:

AFwGComms Secretariat
<AFwGCommssecretariat@efsa.europa.eu <mailto:AFwGCommssecretariat@efsa.europa.eu >>

An:

"sefsa-focal-point@bfr.bund.de "
<efsa-focal-point@bfr.bund.de <mailto:efsa-focal-point@bfr.bund.de >>

Datum:

12.06.2015 15:43

Betreff:

RE: Antw: AGENDA_47th AFCWG meeting_Bucharest, 16-17 June 2015

Thanks a lot

What shall I put on the agenda as a title of her presentation?

Thanks,

From: efsa-focal-point@bfr.bund.de <mailto:efsa-focal-point@bfr.bund.de >
[mailto:efsa-focal-point@bfr.bund.de] <mailto:[mailto:efsa-focal-point@bfr.bund.de] >
Sent: 12 June 2015 12:29
To: AFwGComms Secretariat
Subject: Antw: AGENDA47th AFCWG meeting_Bucharest, 16-17 June 2015

Dear Team,

As usual, we prepared the key issues for the upcoming AFCWG meeting. We would like to inform you that Suzan Fiack would share the key issues with the group intending to add some additional slides to illustrate the topic with examples, e.g. the discourse on glyphosate and the appropriate communication of press and media statements.

Please find attached the Key Country issues of Germany for uploading to the DMS.

With kind regards
On behalf

Federal Institute for Risk Assessment (BfR)
EFSA Focal Point Germany
Max-Dohrn-Straße 10
10589 Berlin, Germany

[cid:image001.jpg@O1D0A752.227F0150]

>>>

Von:

AFwGCc)mms Secretariat

<AFwGCommssecretariat.efsa.europa.eu <mailto:AFwGCommssecretariat@efsa.europa.eu >>

An:

Datum:

03.06.2015 16:01

Betreff:

AGENDA_47th AFCWG meeting Bucharest, 16-17 June 2015

Dear all,

hope this email finds you well. As the meeting is approaching we would like to make sure you have not missed the FINAL version of the agenda which is available on the DMS by clicking on the link below

47TH Meeting_of the_Advisory_Forum_Communication_Working_Group FINAL.doc

<https://dms.efsa.europa.eu/otcs/cs.exe/properties/14258567>

We look forward to meeting you in Bucharest!

Have a good day,

Secretariat of the Advisory Forum Communications Working Group

[cid:image002.jpg@01D0A752.227F0150]

From:

Behalf Of AFwGComms Secretariat

Dear AFCWG members and observers,

As promised, please find on the DMS (and here attached) all logistic information **regarding** meeting's venue<<https://dms.efsa.europa.eu/otcs/cs.exe/properties/14261644> >, accommodation<<https://dms.efsa.europa.eu/otcs/cs.exe/properties/14259093> > and social event<<https://dms.efsa.europa.eu/otcs/cs.exe/properties/14261644>>.

Few highlights:

Meeting's venue

Capital Plaza Hotel

Bulevardul Iancu de Hunedoara 54, Bucuresti

011745, Romania

Tel:+40 372 080 080<javascript:void(0)>

Website<<http://www.capitalplaza.ro>>

More info on how to reach the venue in the attached document.

Accommodation

For your convenience EFSA has block-booked rooms at the meeting venue Hotel Capital Plaza Hotel. The cost for a single room is 85 Eur.

The deadline until which the rate provided for block booking is valid and after which reservation can only be confirmed upon availability is 25/05/2015.

In order to block your room, please fit in the reservation form<<https://dms.efsa.europa.eu/otcs/cs.exe/properties/14259093>>.

Social event

For the evening of 16 June 2015, a networking dinner will take place in Locanta Jaristea Restaurant. The restaurant is located in the very heart of Bucharest. A bus will be organised to

Dear AFCWG members and observers,

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Social event

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The meeting will consist of two half-day sessions and will run from 14h00 to 19h00 on 16 June and from 09h00 to 13h30 on 17 June.

Please find on the new DMS (Data Management System) the draft agenda<<https://dms.efsa.europa.eu/otcs/cs.exe/properties/14105061> > which will be shortly uploaded on Yammer for your comments and further Inputs.

On the DMS you will also find the link to the official invitation<<https://dms.efsa.europa.eu/otcs/cs.exe/properties/14105435> > and reimbursement guide<<https://dms.efsa.europaseu/otcsks.exe/properties/14081565> >, as well as all logistical details regarding registrations<<https://dms.efsa.europa.eu/otcs/cs.exe/properties/14081667> > and flights<<https://dms.efsa.europa.eu/otcs/cs.exe/properties/14081669> >.

Deadline for registrations and requests for prepaid flight ticket: 22 May 2015

Details on meeting venue, accommodation and social event will follow in a separate email. Kindly note that, as always, we will block a certain number of rooms at a hotel close to the meeting's venue.

PROBLEMS ACCESSING THE NEW DOCUMENT MANAGEMENT SYSTEM (DMS)?

As you know, to access the documents in the new DMS you need to log into the system with your username and password (this is a security measure to avoid unauthorised access to documents). Should you have technical Problems accessing the DMS or need a new account and password, please notify the EFSA Service Desk<<mailto:servicedesk@efsa.europa.eu> >, available Monday to Friday from 08:00 to 18:00.

QUERIES, COMMENTS, NOT ATTENDING?

Please let us know. The AFCWG Secretariat is available for any questions you may have.

We look forward to seeing you in Bucharest!

Best regards,

Secretariat of the Advisory Forum Communications Working Group

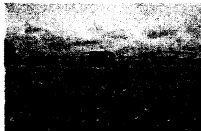
[cid: image002.jpg@O I DOA752.227F0150]

Key Country Issues Germany: Challenges in Risk Communication

Suzan Fiack
Department Risk Communication

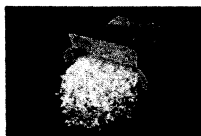
Examples

Communication an Glyphosate



Peer Review of Glyphosate

Communication an Arsenic in Rice



BfR Opinion, June 2015

Coherent Wording in Scientific Opinions and Related Publications



The Weight of Wording

Communication on Glyphosate



- **C** is the most widely used substance in pesticides worldwide to prevent unwanted crop cultures ("weed control product")
- **A**griculture
Annual production (drug) worldwide > 600,000 tonnes
- Germany: designated **Rapporteur Member State (RMS)** for the draft risk assessment report (DAR)
- Exceptionally high media attention
- Public debate, huge amount questions to BfR

Suzan Fiack, 16. June 2015, AFCWG, Bukarest

Seite 3 **rt BfR**

BfR Symposium on the Health Assessment of Glyphosate-Containing Pesticides January 2014

BfR Symposium with contributions from

- **EFSA**
- **Federal Office of Consumer Protection and Food Safety (BVL)**
- **Federal Research Centre for Cultivated Plants — Julius Kühn Institute (JKI)**
- **University of Veterinary Medicine Hannover, Foundation (TiHo)**



BfR Press Release

BfR FAQ

Suzan Fiack, 16. June 2015, AFCWG, Bukarest

Seite 4 **rt BfR**

Current BfR Publications regarding glyphosate

- > **Does glyphosate cause cancer? Diverging assessments within WHO should be clarified by experts (BfR Communication No 016/2015, Internet Publication 8 June 2015)**
<http://www.bfr.bund.de/m/343/loest-glyphosat-krebs-aus-divergierende-bewertungen-innerhalb-der-who-sollen-durch-expertengruppe-aufgeklaert-werden.ixtf>
- > **Does glyphosate cause cancer? (BfR Communication No 007/2015, Internet Publication 23 March 2015)**
<http://www.bfrbund.de/cm/349/does-glyphosate-cause-cancer.pdf>
- > **EU Commission discusses critical issues in the assessment of the active substances in plant protection products (BfR Communication No 012/2015, Internet Publication 13 March 2015)**
<http://www.bfr.bund.de/cm/349/eu-commission-discusses-critical-issues-in-the-assessment-of-the-active-substances-in-plant-protection-products.pdf>
- > **BfR-contribution to the EU-approval process of glyphosate is finalised BfR recommends the consideration of the Report of the International Agency for Research on Cancer (IARC) in the EU-Approval process (BfR Communication No 008/2015, Internet Publication 2 April 2015)**
<http://www.bfr.bund.de/cm/349/bfr-contribution-to-the-eu-approval-process-of-glyphosate-is-finalised.pdf>

Does glyphosate cause cancer? Diverging assessments within WHO should be clarified by experts

- > Evaluation of glyphosate by relevant national, European and other international institutions, including the WHO / FAO Joint Meeting on Pesticide Residues (JMPR) not carcinogenic
- > Meeting of the International Agency for Research on Cancer (IARC) of WHO in Lyon (March 2015) with experts on glyphosate
 —3 probably carcinogenic to humans (carcinogen group 2A)
- > Evaluation of the IARC scientifically not comprehensible until the detailed report with the reasons for the conclusions will be released in July 2015

WHO has recently set up an "ad hoc expert task force" for clarifying the reasons for the diverging assessments of IARC and the JMPR (divergence within the WHO)

Arsenic in Rice in the German media: Not a new topic

Gift im Korn

Poison in the grain

Reis ist ein Grundnahrungsmittel. Doch es **ist** ein **grausiger Verdacht**: Das Getreide, das die halbe Menschheit ernährt, könnte aufgrund einer Anreicherung von Arsen Krebs verursachen.

17. Mai 2010

Das Leben von drei Milliarden Menschen hängt an Reis. Vor allem in Asien ist er das Grundnahrungsmittel. Doch Forscher bewegen zurzeit ein grausiger Verdacht. Könnte das Getreide, das die halbe Menschheit ernährt, Krebs verursachen? Mehrere Studien zeigen, dass sich in Reis und Reisprodukten wie Kleie erhöhte Arsen-Mengen finden - mindestens zehnmal so viel wie in Weizen und anderen Getreiden.



Rice cakes belong to the (special) waste

17. Mai 2012

Reiswaffeln gehören in den (Sonder-) Müll



Sie sind also nicht zu essen, sondern gehören in den (Sonder-) Müll. Reiswaffeln sind kalorienarm, glutenfrei und werden oft als Diätnahrung empfohlen. Sie bestehen aus Reis und Wasser. In der Herstellung werden jedoch oft Schadstoffe eingesetzt, die in den Waffeln verbleiben. Diese Schadstoffe sind für die Gesundheit gefährlich. Die einzige Möglichkeit, sie zu entfernen, ist das Waschen der Waffeln. Dies ist jedoch nicht praktikabel. Daher sollten Reiswaffeln in den (Sonder-) Müll gegeben werden.

Suzan Fiack, 16. June 2015, AFCWG, Bukarest

Seite 7 **rfr: 113fr**

Inorganic arsenic compounds are classified as carcinogenic in humans

Arsenic occurs naturally in the earth's crust, is released through natural and anthropogenic processes such as the smelting of copper and lead and the use of fossil fuels, enters soil, groundwater and surface water, and can then be absorbed by plants.

In food, arsenic occurs both in the form of organic compounds (e.g. in fish and seafood) and inorganic compounds.



Inorganic arsenic compounds are classified as carcinogenic in humans.

In addition, when consumed over long periods of time, even in relatively small amounts, they can result in skin changes and vascular and nerve damage, as well as being toxic to development and contributing to cardiovascular problems.

Quelle: ad,nfodienst

Dietary exposure to inorganic arsenic

Dietary exposure to inorganic arsenic in the European population
EFSA Journal 2014;12(30597) [68 pp.].

EFSA has updated its analysis of the occurrence of arsenic in food in Europe.

Food, particularly grain-based processed products such as wheat bread, rice, milk and dairy products, and drinking water are the main sources of exposure for the general population in Europe.

BfR Opinion 1 Press release 1 FAQ June 2015



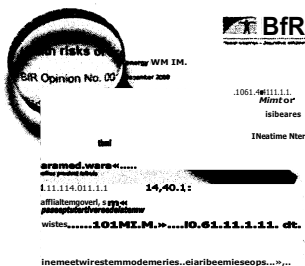
The BfR has assessed the health risk of the population of Germany on the basis of values measured by the federal states on arsenic levels in rice and rice products.

The daily intake of inorganic arsenic was calculated for the different groups of the population, such as infants, toddlers, children and adults, according to their dietary habits.

Suzan Fiack, 16. June 2015, AFCWG, Bukarest

Seite 9  BfR

Conclusions of the BfR health assessment



The intake level of inorganic arsenic compounds through rice and rice products is relative high.

Depending on dietary habits, rice can make a significant contribution to the overall consumption of inorganic arsenic compounds.

A safe intake level not associated with an increased risk of cancer cannot be defined for the carcinogenic effect of inorganic arsenic compounds.

Levels of inorganic arsenic compounds in foods should be reduced to an unavoidable minimum (ALARA principle).

The data on rice products available to date shows that the levels in some of the analysed rice products are higher than in grains of rice.

Suzan Fiack, 16. June 2015, AFCWG, Bukarest

Seite 10 OFT  BfR

Press release

The BfR recommends investigating possibilities of minimising the levels of arsenic in rice products (11. June 2015)



Quelle: alcfinfodlenst

"The reasons for the higher levels in certain rice products as compared to grains of rice need to be clarified," said the President of the Federal Institute for Risk Assessment (BfR), Professor Dr. Dr. Andreas Hensel.

Suzan Fiack, 16. June 2015, AFCWG, Bukarest

Seite 11

BfR

Consumers cannot tell how much arsenic is in their food

Consumers cannot tell how much arsenic is contained in their food.

In light of this, the BfR welcomes the European Commission's decision to introduce maximum Limits for inorganic arsenic in rice and rice products at a European level.

The following recommendations by the BfR will remain valid even after the introduction of maximum Limits.



Bitte eine Quelle angeben: Woepphoto

Suzan Fiack, 16. June 2015, AFCWG, Bukarest

Seite 12

BfR

Consumer recommendations



The BfR recommends consuming products such as rice cakes or rice flakes/rice pudding in moderation and varying these products with products based on other cereals.

Parents are advised not to feed their babies or toddlers exclusively with rice-based drinks such as rice milk or food such as rice pudding.

Consumers who suffer from coeliac disease or have an adverse reaction to Blüten should avoid focusing solely on rice and rice products when choosing gluten-free cereals. In addition to rice, they could add other gluten-free cereals such as maize, millet, buckwheat, amaranth or quinoa to their diet.

Nevertheless, rice should remain part of a balanced diet

When selecting food items, consumers should observe the general recommendation on a varied and diverse diet, and should vary the types of cereal they consume, if possible.

Suzan Fiack, 16. June 2015, AFCWG, Bukarest

Seite 13 **rTc. BfR**

The Weight of Wording

VKM



An overview of previous risk assessments of "other substances"

Report from the Scientific Committee of the European Food Safety Authority

EFSA

EFSA Journal 2014;12(12):3692

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www.BfR.de

BfR
Bundesinstitut für
Risikoanalyse

Flavouring substances in baby food

BfR opinion No 034/2014, 27 June 2014

Varying species of fish twice a week



Rapid advice 06-2015 of the Scientific Committee of the EFSA on a assessment of the risk of introduction of the highly pathogenic avian influenza virus in Belgium, particularly the H5N8 strain via wild birds, taking into account the current epidemiological context: evaluation of the period of increased risk.

anses

ANSES
Agence nationale de sécurité
alimentaire et de la santé

The European Union

12 February 2015

EFSA
European Food Safety Authority

"The use of 'European Union' and 'Food' and the concept of 'European Union' in the text are related to the interpretation of 'Europe'"

Nanofood
unwrapping

EFSA
European Food Safety Authority

efsa.

European Food Safety Authority

STATEMENT OF EFSA

Evaluation of the increase of risk for public health related to a possible temporary derogation from the maximum level of dryweight of water-soluble substances and from the maximum level of water-soluble substances

European Food Safety Authority

EFSA
European Food Safety Authority

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European Food Safety Authority

Healthy Eating
and Active Living for
Adults, Teenagers and
Children over 5 Years

EFSA
European Food Safety Authority

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Suzan Fiack, 16. June 2015, AFCWG, Bukarest

Seite 14 **BfR**



MANY TRANKS FOR YOUR ATTENTION

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Key Country issues on the national agendas for the
47th AFCWG meeting

Bucharest, 16-17 June 2015

Country: **Germany (BfR)**

Date: **12 June 2015**

Issues, scientific opinions, activities, meetings and events on the agendas of the National Agencies

Main Issue Risk and crisis communication	Hygiene Keeps You Healthy - The BfR is recommending that you observe the wies of kitchen hygiene on World Health Day (BfR Press Release 09/2015, Internet publication 2 April 2015) http://www.bfr.bund.de/en/press_information/2015/09/hygiene_keeps_you_healthv-193808.html
	Consumer tips on protection against foodborne infections (BfR Consumer Tips, Internet publication 2 April 2015) http://www.bfr.bund.de/cm/350/verbrauchertipps_schutz_vor_lebensmittelinfektionen_im_privathaushalt.pdf
	Publication of all presentations and the book of abstracts of the advanced training for staff in the public health sector 2015 (BfR web item, Internet publication 15 March 2014) Presentations http://www.bfr.bund.de/de/uebersicht_aller_praesentationen_zur_fortbildungungsveranstaltung_fuer_den_oeffentlichen_gesundheitsdienst_2015-194046.html
	Abstracts http://www.bfrbund.de/cm/343/fortbildung-fuer-den-oegd-2015-abstracts.pdf
	Publication of a questionnaire regarding the joint research project "Zoonoses and Food Safety Along Global Supply Chains (ZooGloW)" addressed to general practitioners (BfR Questionnaire, Internet publication 1 April 2015) http://www.bfr.bund.de/cm/343/xiyadgvcw89w73w67ep3hgh_umfrage_zooglow.html
	Publication of information on the EFSA@EXPO — The EFSA's second scientific conference "Shaping the future of food safety, together", Milan, 14-16 October 2015 with the contribution of BfR scientists (BfR Web link, Internet publication 24 April 2015) http://www.bfr.bund.de/de/veranstaltung/efsa_konferenz_zur_lebensmittelsicherheit_im_rahmen_der_expo_2015shaping_the_future_of_food_safety_together.html

n EFSA's remit only

	<p>d safety together-193965.html</p> <p>Publication of the English version of the A-Z Index with catch words for food safety related terms for the search on the BfR web site products (BfR Web Item, Internet publication 20 February 2015) http://www.bfr.bund.de/en/home.html</p>
Topic No 1 Biological hazards	<p>Pathogens in food: Improvements required to protect against Campylobacter, EHEC and Listeria - BfR publishes report "Zoonotic Pathogens in Germany" (BfR Press Release 10/2015, Internet publication 7 April 2015) http://www.bfr.bund.de/en/press_information/2015/10/pathogens_in_food_improvements_required_to_protect_against_campylobacter_ehec_and_listeria-193815.html</p> <p>Causative agents for zoonoses in Germany for the year 2013 (BfR-Wissenschaft 02/2015, ISBN 978-3-943963-27-4, Internet Publication 15 April 2014) http://www.bfr.bund.de/cm/350/erreger-von-zoonosen-in-deutschland-im-jahr-2013.pdf</p> <p>Publication of questions and answers on protection against foodborne infections in private households (BfR FAQ, Internet Publication 4 February 2015) http://www.bfr.bund.de/en/questions_and_answers_on_protection_against_foodborne_infections_in_private_households-194152.html</p> <p>Publication of selected FAQs on poultry meat (BfR FAQ, Internet Publication 19 March 2015) http://www.bfr.bund.de/en/selected_faqs_on_poultry_meat-54623.html</p> <p>EU Zoonoses Report — Number of cases of campylobacteriosis is unchanged, further increase of listeriosis (BfR Communication No. 004/2015, Internet Publication 18 February 2015) http://www.bfr.bund.de/cm/343/eu-zoonosenbericht-zahl-der-campylobacteriose-faelle-unveraendert-hoch-weitere-zunahme-bei-listeriosen.pdf</p> <p>Health is indivisible: Humans, animals and environment in the focus of food safety - BfR expert symposium dedicated to the control of foodborne zoonoses (BfR Press Release 05/2015, Internet publication 27 February 2015) http://www.bfr.bund.de/en/press_information/2015/05/health_is_indivisible_humans_animals_and_environment_in_the_focus_of_food_safety-193372.html</p> <p>Publication of the presentations of the One Health Symposium in March 2015 (BfR Web Item, Internet Publication 16 March 2015) http://www.bfr.bund.de/de/veranstaltung/one_health_gesundheit_von_mensch_tier_und_umweltbfr_fachsymposium-192922.html</p>
Topic No 2 Nanotechnology	<p>How can the safety of nanomaterials be ensured? "Nano" week at the German Federal Institute for Risk Assessment (BfR) on the state of safety research and health assessment of nanomaterials (BfR Press Release 06/2015, Internet publication 3 March 2015) http://www.bfr.bund.de/en/press_information/2015/06/how_can_the_safety_of_nanomaterials_be_ensured-193478.html</p>
	<p>Publication of the presentations of the 1st Joint Symposium on</p>

	<p>Nanotechnology (BfR Web Item, Internet publication 5 March 2015)</p> <p>Day 1: http://www.bfr.bund.de/en/overview_of_the_presentations_at_the_1st_joint_symposium_on_nanotechnology_on_5_march_2015-193865.html</p> <p>Day 2: http://www.bfr.bund.de/en/overview_of_the_presentations_at_the_1st_joint_symposium_on_nanotechnology_on_6_march_2015-193872.html</p>
Topic No 3 Contaminants, food ingredients, undesirable substances, veterinary drugs	<p>Rice and rice products contain 'high levels of inorganic arsenic - The BfR recommends investigating possibilities of minimising the levels of arsenic in rice products (BfR Press Release 14/2015, Internet publication 11 June 2015) http://www.bfr.bund.de/en/press_information/2015/14/rice_and_rice_products_contain_high_levels_of_inorganic_arsenic-194366.html</p> <p>Publication of updated frequently asked questions about arsenic contents in rice and rice products (BfR FAQ, Internet Publication 11 June 2015) http://www.bfr.bund.de/cm/343/fragen-und-antworten-zu-arsengehalten-in-reis-und-reisprodukten.pdf</p> <p>International collaborative study for the determination of pyrrolizidine alkaloids in honey and herbal tea by SPE-LC-MS/MS ((BfR-Wissenschaft 01/2015, ISBN 978-3-943963-26-7, Internet Publication 8 May 2015) http://www.bfr.bund.de/en/publication/bfr_wissenschaft_2015-193804.html</p> <p>New data from a BfR human study: no cyanide risk resulting from the consumption of marzipan and persipan (BfR Communication No 006/2015, Internet Publication 11 March 2014) http://www.bfr.bund.de/cm/349/new-data-from-a-bfr-study-no-cyanide-risk-resulting-from-the-consumption-of-marzipan-and-persipan.pdf</p> <p>Publication of a scientific article regarding toxicokinetics of seven perfluoroalkyl sulfonic and carboxylic acids in pigs fed a contaminated diet (BfR Web Link, Internet Publication 13 February 2015) http://pubs.acs.org/doi/ipdf/10.1021/jf405827u</p> <p>Publication of a scientific article regarding the transfer of perfluorooctane sulfonic acid (PFOS) from contaminated feed to dairy milk (BfR Web Link, Internet Publication 13 February 2015) http://www.sciencedirect.com/science/article/pii/S0308814613004810</p> <p>Publication of a scientific article regarding Absorption, Distribution, and Milk Secretion of the Perfluoroalkyl Acids PFBS, PFHxS, PFOS, and PFOA by Dairy Cows Fed Naturally Contaminated Feed (BfR Web Link, Internet Publication 13 February 2015) http://pubs.acs.org/doi/pdfplus/10.1021/jf3046801</p>
	<p>Omics methods: Towards a better prediction of the effects of substances at very low doses (Joint press release by the UFZ and BfR 08/2015, Internet Publication 16 March 2015)</p>

Subject	
	<p>http://www.bfr.bund.de/en/press-information/2015/08/omics-methods-towards-a-better-prediction-of-the-effects-of-substances-at-very-low-doses-193495.html</p> <p>Relating scientific article: Pathway and Time-Resolved Benzo[a]pyrene Toxicity on Hepa 2c7 Cells at Toxic and Subtoxic Exposure (BfR Web Link, Internet Publication 13 February 2015) http://pubs.acs.org/doi/abs/10.1021/pr500957t</p>
<p>Topic No 4 Pesticides Biocides Chemicals</p>	<p>Does glyphosate cause cancer? — Diverging assessments within WHO should be clarified by experts (BfR Communication No 016/2015, Internet Publication 8 June 2015) http://www.bfr.bund.de/cm/343/loest-glyphosat-krebs-aus-divergierende-bewertungen-innerhalb-der-who-sollen-durch-expertengruppe-aufgeklaert-werden.pdf</p> <p>Does glyphosate cause cancer? (BfR Communication No 007/2015, Internet Publication 23 March 2015) http://www.bfr.bund.de/cm/349/does-glyphosate-cause-cancer.pdf</p> <p>EU Commission discusses critical issues in the assessment of the active substances in plant protection products (BfR Communication No 012/2015, Internet Publication 13 March 2015) http://www.bfr.bund.de/cm/349/eu-commission-discusses-critical-issues-in-the-assessment-of-the-active-substances-in-plant-protection-products.pdf</p> <p>BfR-contribution to the EU-approval process of glyphosate is finalised BfR recommends the consideration of the Report of the International Agency for Research on Cancer (IARC) in the EU-Approval process (BfR Communication No 008/2015, Internet Publication 2 April 2015) http://www.bfr.bund.de/cm/349/bfr-contribution-to-the-eu-approval-process-of-glyphosate-is-finalised.pdf</p> <p>Publication of the presentations of the BfR-Workshop on data availability in REACH registrations "Mind the Gap - Data Availability in REACH Registrations" on 2 March 2015 (BfR Web Item, Internet Publication 17 March 2015) http://www.bfr.bund.de/en/overview of the presentations at the workshop on data availability in reach registrations mind the gap data availability in reach registrations on 2 march 2015-193519.html</p> <p>Abstracts: http://www.bfr.bund.de/cm/349/mind-the-gap-data-availability-in-reach-registrations-abstracts.pdf</p>
<p>Topic No 5 Toxicology</p>	<p>Regulatory Toxicology in the 21st century — Challenges, perspectives and possible solutions (BfR Communication No 015/2015, Internet Publication 8 June 2015) http://www.bfr.bund.de/cm/343/regulatorische-toxikologie-im-21-jahrhundert-herausforderungen-perspektiven-und-loesungsansaetze.pdf</p>
<p>Topic No 6 Exposure assessment</p>	<p>Publication of a feasibility study regarding the validation of exposure models for consumer exposure assessment (BfR Study, Internet publication 10 May 2015) http://www.bfr.bund.de/cm/343/Nalidierung-von-Expositionsmodellen-zur-Abschaetzung-der-Verbraucherexposition-Machbarkeitsstudie.pdf</p>

	<p>Publication of a report prepared on behalf of the BfR on the examination of standard models for the estimation of consumer exposure assessment (BfR Study, Internet publication 10 May 2015) http://www.bfr.bund.de/cm/343/Pruefung-von-Standardmodellen-zur-Schaetzung-der-Verbraucherexposition.pdf</p>
	<p>Publication of the record of the 15th BfR Consumer Protection Forum on possible health risks arising from aluminium found in food and products: Aluminium in everyday life: a health risk (BfR Record, Internet publication 30 April 2015) http://vimeopro.com/erlesen/bfr/video/114417070</p>
	<p>Publication of the website on the Total Diet Study with BfR as project partner coordinated by ANSES under the European Union's Seventh Framework Programme for research, technological development and demonstration (BfR Web Item, Internet publication 5 May 2015) http://www.bfr.bund.de/de/total_diet_study_exposure_tds_exposure-193091.html</p>
Topic No 7 Food Fraud	<p>Adulterated foods investigated: modern analytical methods verify that foods are genuine - BfR hosts the European conference of Food Law Enforcement Practitioners (FLEP) (BfR Press Release 04/2015, Internet publication 18 February 2015) http://www.bfr.bund.de/en/press_information/2015/04/adulterated_foods_investigated_modern_analytical_methods_verify_that_foods_are_genuine-193079.html</p>
Topic No 8, Nutrition	<p>Publication of updated frequently asked questions about folate and folic acid (BfR FAQ, Internet Publication 2nd April 2015) http://www.bfr.bund.de/en/frequently_asked_questions_about_folate_and_folic_acid-70348.html</p> <p>Publication of a research report of the Senate of the Federal Research Institutes in the portfolio of the Federal Ministry of Food and Agriculture (BMEL) including BfR contributions with focus on allergens in food (BfR Web Item, Internet publication 23 February 2015) http://www.bmelv-forschung.de/fileadmin/dam/uploads/ForschungsReport/FoRep2013-2/FoRep-2-2013_final_web.pdf</p>
Topic No 9 Breast feeding	<p>The recommendation of the National Breastfeeding Committee remains unchanged: babies should be breastfed exclusively for the first four to six months - Opinion of the National Breastfeeding Committee on the change of the S3 guideline on allergy prevention (BfR Press Release 12/2015, Internet publication 30 April 2015) http://www.bfr.bund.de/en/press_information/2015/12/the_recommendation_of_the_national_breastfeeding_committee_remains_unchanged_babies_should_be_breastfed_exclusively_for_the_first_four_to_six_months-194126.html</p> <p>Update of the S3-Guidance allergy prevention differs from the breast feeding recommendations of the National Breastfeeding Committee (National Breastfeeding Committee Opinion, Internet Publication 30 April 2015) http://www.bfr.bund.de/cm/343/update-der-s3-leitlinie-allergiepraevention-weicht-von-stillempfehlung-der-nationalen-stillkommission-ab.pdf</p>
Topic No 10	<p>Publication of a guidance on the analysis of the transfer of</p>

Food contact materials

substances from food contact materials made of **paper, cardboard** or **paperboard** (BfR Guidance, Internet Publication 26 March 2015)
<http://www.bfr.bund.de/cm/343/untersuchung-der-stoffuebergaenge-von-bedarfsgegenstaenden-aus-papier-karton-und-pappe.pdf>

Publication of methods for the **analysis** of **paper, cardboard** or **paperboard** for food contact materials and other commodities (BfR Methods, Internet Publication 30 March 2015)
http://www.bfr.bund.de/de/methodensammlung_papier_karton_und_pappe-32620.html

No health risk for consumers from **Bisphenol A exposure** (BfR Communication No 005/2015, Internet Publication 5 March 2015)
<http://www.bfr.bund.de/cm/349/no-health-risk-for-consumers-from-bisphenol-a-exposure-the-bfr-endorses-the-conclusion-of-the-new-efsa-assessment.pdf>

Publication of updated frequently asked questions on **bisphenol A** in consumer products (BfR FAQ, Internet Publication 19 February 2015)
http://www.bfr.bund.de/en/faqs_on_bisphenol_a_in_consumer_products-60837.html

Publication of updated frequently asked questions about **PET bottles**, English version (BfR FAQ, Internet Publication 10 February 2015)
http://www.bfr.bund.de/en/selected_questions_and_answers_on_pet_bottles-60846.html

Topic No 11
Laboratory animals

More **research** on the **protection** of **test animals** needed - BfR recommends further development of the 3R principle on the occasion of World Laboratory Animal Day (BfR Press Release 11/2015, Internet publication 24 April 2015)
http://www.bfr.bund.de/en/press_information/2015/11/more_research_on_the_protection_of_test_animals_needed-193975.html

Severity Assessment of **genetically altered animals** (BfR Communication No 029/2014, Internet Publication 07 March 2015)
<http://www.bfr.bund.de/cm/349/severity-assessment-of-genetically-altered-animals.pdf>

Database AnimalTestInfo: German initiative for **more transparency** in **animal experiments** - Information on the purpose of animal experiments and the expected levels of distress caused to animals now provided to the public (BfR Press Release 07/2015, Internet publication 9 March 2015)
http://www.bfr.bund.de/en/press_information/2015/07/database_animal_testinfo_german_initiative_for_more_transparency_in_animal_experiments-193452.html

Related scientific article: **Laboratory animals**: German initiative opens up animal data (BfR Web Link, Internet publication 9 March 2015)
<http://www.nature.com/nature/4journal/v519/n7541/full/519033d.html>

Publication of frequently asked questions about the **database AnimalTestInfo** comprising generally understandable non technical summaries regarding experimentation on animals (English version) (BfR FAQ, Internet Publication 24 March 2014)
http://www.bfr.bund.de/en/animaltestinfo_database-193572.html

	<p>Publication of the award of the 34th price for research in the area of animal protection by the Federal Ministry of Food and Agriculture (BMEL) (BMEL award, Internet Publication 20 March 2015) http://www.bmel.de/SharedDocs/Downloads/SharedDocs/SharedDocs/Tierschutzforschungspreis.html</p> <p>Call for proposals for the scientific development of alternatives to animal experiments (BfR Call for proposals, Internet Publication 29 April 2015) http://www.bfr.bund.de/de/ausschreibungen_von_forschungsvorhaben-415.html</p>
Topic No 12 Research	<p>Publication of the BfR research programme 2014-2016 (Update) (BfR Web Item, Internet Publication 27 May 2015) http://www.bfr.bund.de/cm/349/research-programme-of-the-bfr-2014-2016.pdf</p>
Topic No 13 Independence	<p>Publication of updated frequently asked questions and answers on Ensuring the Independence of the Federal Institute for Risk Assessment (BfR) (BfR FAQ, Internet publication 27 February 2015) http://www.bfr.bund.de/de/fragen_und_antworten_zur_sicherung_der_unabhaengigkeit_des_bundesinstituts_fuer_risikobewertung-129744.html</p>
Topic No 14 GLP	<p>Good Laboratory Practice (GLP) - Test Facilities / Test Sites in the Monitoring Programme, GERMANY (as to May 2015) (BfR list, Internet Publication 2 June 2015) http://www.bfr.bund.de/cm/349/good-laboratory-practice-GLP-test-facilities-ir_ito_nme-erman_rpcif_</p> <p>Publication of the GLP•Monitoring Authorities in Germany (federal Länder) (BfR list, Internet Publication 13 April 2015) http://www.bfr.bund.de/cm/349/1aender-authorities_0df</p>

Updating Scientific Opinions	
Date (Internet publication)	Topic
11 June 2015	<p>Arsenic in rice and rice products BfR Opinion No. 018/2015 http://www.bfr.bund.de/cm/343/arsen-in-reis-und-reisprodukten.pdf</p>
11 June 2015	<p>EU Maximum levels for inorganic arsenic in rice and rice products should be supplemented by consumption recommendations for the protection of infants, toddlers and children Updated BfR Opinion No. 017/2015 http://www.bfr.bund.de/cm/343/eu-hoechstgehalte-fuer-anorganisches-arsen-in-reis-und-reisprodukten-durch-verzehrsempfehlungen-zum-schutz-von-saeglingen-kleinkindern-und-kindern-erlaenzen.pdf</p>
8 May 2015	<p>Microplastic Particles in Food BfR Opinion No. 013/2015 http://www.bfr.bund.de/cm/349/microplastic-particles-in-food.pdf</p>
7 April 2015	<p>Two bitter apricot kernels per day are the limit for adults - children should refrain from consuming apricot kernels altogether BfR Opinion No. 009/2015 http://www.bfr.bund.de/cm/349/two-bitter-apricot-kernels-per-day-are-the-limit-for-adults-children-should-refrain-from-consuming-apricot-kernels-together.pdf</p>

18 June 2015	BfR, Marienfelde	<p>Seminar "Early detection of teratogenic effects of substances in a fish embryo test for reproductive toxicity" (FERT) organised by the "Centre for Documentation and Evaluation of Alternative Methods to Animal Experiments (ZEBET"</p> <p>Programme:</p> <p>http://www.bfrbund.de/de/veranstaltung/88_zeb_et_seminar_frueherkennung_von_fortpflanzung_sgefaehrdenden_substanzeffekten_in_einem_fis_chembryo_reproduktionstoxizitaets_test_fert_mit_dem_medaka_oryzias_latipes_-194194.html</p>
17-28 August 2015	BfR, Marienfelde	<p>4th BfR-Summer Academy on Risk Assessment and Risk Communication in Food Safety</p> <p>Programme:</p> <p>http://www.bfr.bund.de/cm/34914-th-bfr-summer-academy-flyer.pdf</p> <p>Description:</p> <p>http://www.bfr.bund.de/cm/349/4-th-bfr-summer-academy-description.pdf</p> <p>Registration:</p> <p>http://www.bfr.bund.de/cm/349/4-th-bfr-summer-academy-application-form.pdf</p>
2-4* September 2015	BfR, Marienfelde	<p>DACH-Conference on Epidemiology 2015 — Veterinary Epidemiology 3.0 — complex problems — simple answers?</p> <p>http://www.bfr.bund.de/de/veranstaltung/dach_epidemiologietagung_2015-194200.html</p>
14-18 September 2015	Seminarfis Campus Hotel. Address: Takustr. 39, 14195 Berlin, Germany	<p>14th international Conference on Trichinellosis</p> <p>Conference Website:</p> <p>http://www.bfr.bund.de/en/ict_berlin_2015.html</p>
4 November 2015	BfR, Marienfelde	<p>3rd Symposium "Foodborne Viruses"</p> <p>Programme:</p> <p>http://www.bfr.bund.de/cm/343/3-bfr-symposium-lebensmittel-assoziierte-viren.pdf</p> <p>Registration:</p> <p>https://www.bfr.bund.de/de/anmeldeformular/3_bfr_symposium_lebensmittel_assoziierte_viren_4_november_2015-194186.html</p>

- EFSA IEP daily summary notification

Von: <noreply@efsa.europa.eu >
An: <@bfr.bund.de>
Datum: 16.06.2015 18:01
Betreff: EFSA IEP daily summary notification

Lear subscriber,

The following documents have been uploaded to the IEP:

1 - [Does glyphosate cause cancer Expert group to address diverging assessments within the WHO STA DE en 08-06-2015.html](#)

Located in: **14.Plant protection products and their residues (PPR & PRAPeR)/**

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- EFSA IEP daily summary notification

Von: <noreply@efsa.europa.eu >
An: ;@bfr.bund.de >
Datum: 02.07.2015 18:01
Betreff: EFSA IEP daily summary notification

Dear subscriber,

The following documents have been uploaded to the IEP:

1 - [Risk assessment of antibiotic resistant bacteria in food producing animals RA NO en 08-06-2015.html](#)

Located in: **03.Biological hazards (BIOHAZ) and Animal Diseases Transmissible to Humans (Zoonoses) /**

2 - [Risk assessment of dietary cadmium exposure in the Norwegian population OPNO en 15-06-2015.html](#)

Located in: **04.Contaminants in the food chain (CONTAM)/Contaminants in food/Metals/**

3 - [Risk assessment of the metabolite M44 of bixafen, one of the active substances in Aviator, Xpro EC 225 OP NO en 11-06-2015.html](#)

Located in: **14.Plant protection products and their residues (PPR & PRAPeR)/**

4 - Evaluation of glyphosate contents in breast [milk and urine STA DE en 26-06-2015.pdf](#)

Located in: **14.Plant protection products and their residues (PPR & PRAPeR)/**

5 - [Risk assessment of Malakite with the active substances dithianon and vimethanil OP NO ns 11-06-2015.html](#)

Located in: **14.Plant protection products and their residues (PPR & PRAPeR)/**

The following documents have been deleted:

1 - Risk assessment of cadmium in the Norwegian population_RA_NO_en_01-05-2010.html

Located in: **04.Contaminants in the food chain (CONTAM)/Contaminants in food/Metals/**

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- EFSA IEP daily summary notification

Von: <noreply@efsa.europa.eu >

An:

Datum: 05.08.2015 18:01

Betreff: EFSA IEP daily summary notification

Dear subscriber,

The following documents have been uploaded to the IEP:

1 - BfR reviews monograph of the International Agency for Cancer Research (IARC) on glyphosate divergence procedure within the WHO still in progress STAJDE en 30-07-2015.pdf

Located in: **14.Plant protection products and their residues (PPR & PRAPeR)/**

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**- Scrapie: no evidence of threat to humans under real-life conditions; DRVs:
magnesium and phosphorus**

Von: EFSA Highlights<highlights@efsa.europa.eu>

An: @bfr.bund.de>

Datum: 05.08.2015 17:45

Betreff: Scrapie: no evidence of threat to humans under real-life conditions; DRVs: magnesium and phosphorus

Scrapie: no evidence of threat to humans under real-life conditions

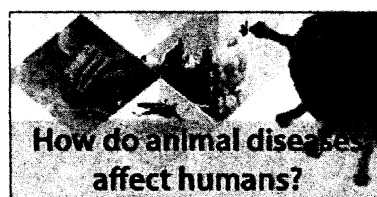
Scrapie: no evidence of threat to humans under real-life conditions

Recent scientific evidence reviewed by EFSA does not change the conclusion of a 2011 ECDC-EFSA joint scientific opinion: there is no scientific proof that Classical scrapie can be transmitted from animals to humans under real-life conditions.

Topic: TSEs

rgi Interactive infographic

Transmissible Spongiform Encephalopathies (TSEs) are a group of diseases that affect the brain and nervous system of humans and animals. The diseases are characterised by a degeneration of brain tissue giving it a sponge-like appearance.



igi • News

Glyphosate: EFSA assesses IARC findings

Glyphosate: EFSA assesses IARC findings

EFSA is to assess the findings of a report by the International Agency for Research on Cancer (IARC) which concludes that the herbicide glyphosate is probably carcinogenic to humans.

0 30 July 2015

Dietary reference values: magnesium and phosphorus

Dietary reference values: magnesium and phosphorus

EFSA has proposed adequate intakes for magnesium and phosphorus as part of its ongoing review of dietary reference values in the European Union.

0 28 July 2015

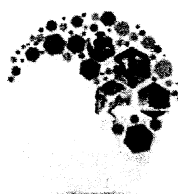
le Topic: Dietary reference values

Video

A balanced diet is one that provides adequate amounts of energy and nutrients for health and well-being. Dietary Reference Values (DRVs) are the complete set of nutrient recommendations and reference values, such as population reference intakes, the average requirement, adequate intake level and the lower threshold intake.



Nutrition: dietary reference values



EFSA's Second Scientific Conference Shaping the Future of Food Safety, together Milan, 14, 15 16 October 2015

Upcoming Events

Revisiting the International Estimate of Short-Term Intake (IESTI) Joint EFSA/FAO/WHO Stakeholder Meeting and Scientific Workshop

Geneva, 7 September 2015

PRAPER

58th plenary meeting of the ANS Panel

Parma, 8 September 2015

0 ANS

92nd plenary meeting of the AHAW Panel

Parma, 22 September 2015

AHAW

Latest Publications

Scientific Opinion on a request for a review of a scientific publication concerning the zoonotic potential of ovine scrapie prions

• 5 August 2015

Scientific Opinion of the BIOHAZ Panel

Occurrence of Pyrrolizidine Alkaloids in food

0 3 August 2015

0 External Scientific Report

Scientific support for preparing an EU position in the 47th Session of the Codex Committee on Pesticide Residues (CCPR)

0 31 July 2015

Scientific Report of EFSA

Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for fluroxypyr in light of confirmatory data

0 31 July 2015

0 Technical report

Preparatory work for the scientific opinion on welfare assessment of dairy cows in small scale farming systems

0 31 July 2015

0 External Scientific Report

EFSA scientific assistance to EC on the internal review submitted under Regulation (EC) No. 1367/2006 on the application of the provisions of the Aarhus Convention against Commission Decisions to authorise genetically modified soybeans 305423, MON 87705 and MON 87769

31 July 2015

0 Technical report

Description and interpretation of submitted data and subsequent analysis obtained from the preparatory work for the scientific opinion on welfare assessment of dairy cows in small scale farming systems

0 31 July 2015 0 External Scientific Report

Data collection on Combined Toxicity of Multiple Chemicals for Animal Health and Ecological Risk Assessment

• 30 July 2015 , C External Scientific Report

Scientific Opinion on the modification of the terms of the authorisation of OPTIPHOS® (6-phytase) as a feed additive for pigs for fattening

0 29 July 2015 0 Scientific Opinion of the FEEDAP Panel

Identification and analysis of the main drivers for Ebola virus spillover

0 29 July 2015 External Scientific Report

Scientific Opinion on Dietary Reference Values for phosphorus

0 28 July 2015 0 Scientific Opinion of the NDA Panel

Outcome of a public consultation on the Draft Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on Dietary Reference Values for phosphorus

0 28 July 2015 0 Technical report

Scientific Opinion on the safety and efficacy of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) for minor ruminant species for meat and milk production

0 27 July 2015 0 Scientific Opinion of the FEEDAP Panel

Outcome of a public consultation on the Draft Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on Dietary Reference Values for magnesium

• 27 July 2015 0 Technical report

Scientific Opinion on Dietary Reference Values for magnesium

0 27 July 2015 0 Scientific Opinion of the NDA Panel

Data collection on exposure assessment scenarios for operators exposed to pesticides

0 24 July 2015 External Scientific Report

Response to comments on the Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on the scientific substantiation of a health claim related to an equimolar mixture of the CLA isomers c9,t11 and t10,c12 (marketed as Clarinol® and Tonalin®) and "contributes to a reduction in body fat mass" pursuant to Article 13(5) of Regulation (EC) No 1924/2006

• 24 July 2015 Technical report

Conclusion on the peer review of the pesticide risk assessment of the active substance thifensulfuron-methyl

0 23 July 2015 0 Conclusion on Pesticides

Calls and consultations

Public consultation on the active substance Picoxystrobin

Deadline: 2 October 2015

C Public consultation

Committed to ensuring that Europe's food is safe

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European Food Safety Authority

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Von: EFSA-Focal-Point
An: AFwGCommssecretariat@efsa.europa.eu
CC: , Fiack, Suzan
Datum: 28.09.2015 17:01
Betreff: Antw: 48th AFCWG meeting in Parma: Draft Agenda for Input

Dear Team,

Thank you very much for sharing the draft agenda for the upcoming AFCWG meeting with us. We would like to express the interest of Dr. Fiack to present some slides regarding agenda item 6 "Science Matters Master Classes: Glyphosate, Endocrine Disruptors".

We thank you in advance for taking our suggestion into consideration.
The key country issues will be prepared by the BfR as usual.

With kind regards
on behalf

on behalf of the German AFCWG member

Federal Institute for Risk Assessment (BfR)
EFSA Focal Point Germany
Max-Dohrn-Straße 10
10589 Berlin, Germany

>>>

Von: AFwGComms Secretariat <AFwGCommssecretariate@efsa.europa.eu>

An:

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|
.

JIT

Datum: 21.09.2015 12:07

Betreff: 48th AFCWG meeting in Parma: Draft Agenda for input

Dear all, please find attached a draft of the agenda for the upcoming AFCWG meeting which will follow the Crisis Simulation Exercise. The time for the meeting is slightly less than normal as we will start later in the afternoon of Thursday 5 November and I would like to finish by lunch on Friday 6 November to ensure timely return voyages.

The objectives of this meeting are:

Work on strengthening the AFCWG's integration into the AFSCO Unit (Advisory Forum and Scientific Cooperation), which is now part of the Communications Department. Key members, including the Head of Unit of AFSCO Stef Bronszwaer, will join us to lead this active discussion.

Deepen our understanding and build alignment on current issues that may impact our work — on complex, often controversial topics. For this meeting I hope to cover Glyphosate and Endocrine Disruptors, but this is not yet confirmed. Your suggestions are welcome. I will invite a scientific expert on the topic and will follow up with a communications discussion.

Progress on AFCWG projects updates and input on projects including the Crisis Comms Guidelines, Risk Comms Guidelines, research (EU

Insights) and more!

Please send your input and recommendations for the meeting by Monday 28 September COB. In addition, if you would like to contribute to the Key Country Issues segment, please let us know in the coming weeks (we will send a reminder).

Thank you in advance and look forward to seeing you all again soon — it will be a very full couple of days in Parma!

With kind regards,

Communications & External Relations

Via Carlo Magno 1 A
43126 Parma (Italy)
Tel. +39 0521
www.efsa.europa.eu
<http://intranet/ivelink/killisapi.dll/www.efsa.europa.eu>
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44

- EFSA IEP daily summary notification

Von: <noreply@efsa.europa.eu>
An: @bfr.bund.de>
Datum: 14.09.2015 18:01
Betreff: EFSA IEP daily summary notification

Dear subscriber,

The following documents have been uploaded to the IEP:

1 - BfR review of the IARC monograph of glyphosate brought into the European assessment process STA DE en 08-09-2015.pdf

Located **14.Plant protection products and their residues (PPR & PRAPeR)/**

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Von: Scientific Cooperation <ScientificCooperation@efsa.europa.eu >

An:

Betreff:

%.,UupLattivii

Datum: 07.10.2015 17:30

Betreff: EFSA review of a publication by the Seralini lab

Dear Focal Points,

We are pleased to inform you that the European Commission recently asked EFSA to analyse the results of a study entitled 'Laboratory rodent diets contain toxic levels of environmental contaminants: Implications for regulatory tests' by Mesnage et al. (2015) published in PLoS One and unpublished data found on the farmwars.info website.

The study published in PLoS One in July (PLoS ONE 10(7): e0128429. doi:10.1371/journal.pone.0128429) reports the presence of pesticides, heavy metals, polychlorinated dibenzo-p-dioxins and dibenzofurans, and GMOs in laboratory rodent feeds whilst the data reported on the farmwars.info website indicate the presence of glyphosate in three different rodent diets (<http://farmwars.info/?p=14095>) . In its scientific report published on October, EFSA observed that the levels of pesticides, heavy metals and dioxins reported were only just above the Limits of detection in the feed samples but below regulatory levels and concluded that no new scientific elements were identified that would Impact on the validity of regulatory feeding tests in the EU.

The full EFSA's report can be found at this

link<http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4258.p

We would appreciate your support in disseminating this information through the relevant national networks and organizations.

With our very best regards,

behalf of Scientific Cooperation

Advisory Forum and Scientific Cooperation Unit
Communications and External Relations Department

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<[http://www.google.it/url?q=https://about.twitter.com/pressibrand-assets&sa=U&ei=jwM8U6W01-14aPOKydgRA&ved=OCBOQ9QEwAA&usg=AFQjCNHdUflp_sk_-mqb1hUTePVgcZ7RNg](https://www.google.it/url?q=https://about.twitter.com/pressibrand-assets&sa=U&ei=jwM8U6W01-14aPOKydgRA&ved=OCBOQ9QEwAA&usg=AFQjCNHdUflp_sk_-mqb1hUTePVgcZ7RNg)

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<[http://www.google.it/url?q=http://commons.wikimedia.org/wiki/File:Solid_coloryou_Tube logo.png&sa=U&ei=6wM8U5CxSqSO4ATxnYH4Cg&ved=0CB8Q9QEwAA&usg=AFQjCNE7bOYMFVSGnITwfTgfFRfvRnerCg](http://www.google.it/url?q=http://commons.wikimedia.org/wiki/File:Solid_coloryou_Tube_logo.png&sa=U&ei=6wM8U5CxSqSO4ATxnYH4Cg&ved=0CB8Q9QEwAA&usg=AFQjCNE7bOYMFVSGnITwfTgfFRfvRnerCg)>

Von: Scientific Cooperation <ScientificCooperation@efsa.europa.eu>
An:
<efi

Datum: 12.11.2015 18:22
Betreff: Glyphosate: EFSA updates toxicological profile

Dear Focal Points,

We would like to inform you that EFSA has published a Conclusion on the Peer review on Glyphosate and a Complementary Technical document. A News Story and a Non-Technical Summary have also been published. You may find this information on the following EFSA links:

* Conclusion: <http://www.efsa.europa.eu/en/efsajournal/pub/4302>

Complementary document:
http://www.efsa.europa.eu/sites/default/files/4302_glyphosate_complementary.pdf

News: <http://www.efsa.europa.eu/en/pressinews/151112>

Summary: <http://www.efsa.europa.eu/en/corporate/pub/glyphosate151112>

Thank you for disseminating this information through the relevant national organisations/experts/stakeholders.

With our very best regards,

Advisory Forum and Scientific Cooperation Unit
Communications & External Relations Department

[Description: Description: cid:image001.jpg@O1CF4F1E.E87FB350]

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cid:image002.jpg@O1CF4F1E.E87FB350]

<http://www.google.it/url?q=https://about.twitter.com/press/brand-assets&sa=U&ei=jwM8U6W
OH4aPOKydgRA&ved=0CBOQ9QEwAA&usg—AFQjCNHDUfJp_sk_-mciblhUTePVgcZ7RNg

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cid:image003.jpg@O1CF4F1E.E87FB350]

<http://www.google.it/url?q=http://commons.wikimedia.org/wiki/File:Solid_color_You_Tube_lo
go.png&sa=11&ei=6wM8U5CxSqSO4ATxnYH4Cg&ved=0CB8Q9QEwAA&usg—AFQjCNE2b
OYMFVSGn1TwfTgfFRfvRnerCg>

52

- Glyphosate toxicological profile updated; European Antibiotic Awareness Day 2015; Xylella: workshop

Von: EFSA Highlights <highlights@efsa.europa.eu >

An: ;@bfr.bund.de>

Datum: 12.11.2015 18:57

Betreff: Glyphosate toxicological profile updated; European Antibiotic Awareness Day 2015; Xylella workshop

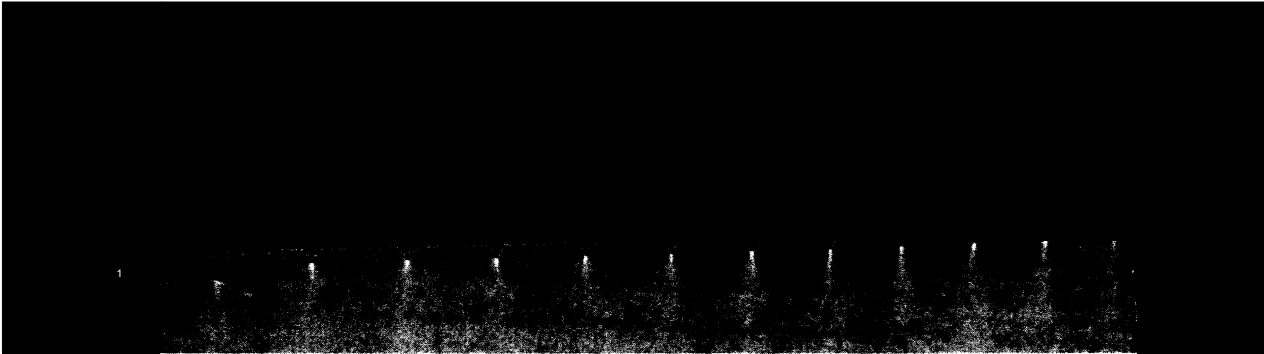
53



European Food Safety Authority

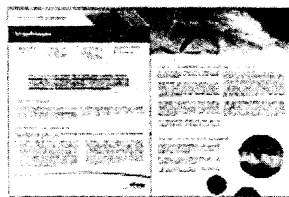
EFSA HIGHLIGHTS 12 November 2015

Glyphosate toxicological profile updated



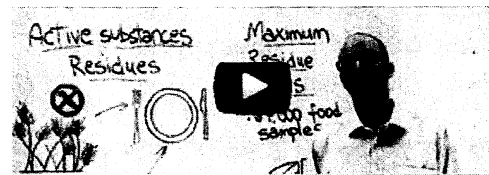
EFSA and the EU Member States have finalised the re-assessment of glyphosate, a chemical that is used widely in pesticides. The report concludes that glyphosate is unlikely to pose a carcinogenic hazard to humans and proposes a new safety measure that will tighten the control of glyphosate residues in food.

Non-specialist summary



EFSA explains risk assessment:
Glyphosate

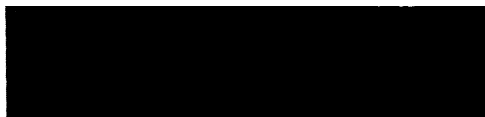
Understanding Science



What are pesticides and how
do they get into our food?

1 News

Xylella: workshop focuses on research



More than 100 experts from around the world are meeting this week to propose and discuss research initiatives on the *Xylella fastidiosa* bacterium. Follow the meeting live via the EFSA website.

10 November 2015

European Antibiotic Awareness Day 2015: join the Twitter chat

#EAAD
Twitter
chat

EUROPEAN
ANTIB(OTIC
AWARENESS
DAY



European Antibiotic Awareness Day is an annual initiative that takes place on 18 November to raise awareness about the threat to public health of antibiotic resistance and the importance of prudent antibiotic use.

18 November 2015

EFSA and Food Safety Commission of Japan strengthen cooperation



EFSA and the Food Safety Commission of Japan have renewed their memorandum of cooperation, based on their fruitful working relations over recent years. The two food safety bodies agreed to build upon the previous memorandum of cooperation, signed in 2009.

0 10 November 2015

Upcoming Events

25th meeting of the Foca! Point Network

Parma, 18 November 2015

eg Focal Points

75th plenary meeting of the Scientific Panel on Contaminants in the food chain

Parma, 18 November 2015

0 CONTAM

60th plenary meeting of the ANS Panel

Parma, 17 November 2015

0 ANS

Latest Publications

Assessment of new scientific studies on human in vitro dermal absorption

• 12 November 2015

0 Scientific Report of EFSA

Axtra@PHY for poultry and pigs

• 12 November 2015

0 Scientific Opinion

Peer review of the pesticide risk assessment of the active substance dithianon

0 12 November 2015

0 Conclusion on Pesticides

Peer review of the pesticide risk assessment of the active substance glyphosate

0 12 November 2015

0 Conclusion on Pesticides

Statement of EFSA on the co-formulant POE-tallowamine

0 12 November 2015

C Statement of EFSA

EFSA explains risk assessment: Glyphosate

0 12 November 2015

0 Corporate Publication

Safety and efficacy of Liderfeed0 (eugenol) for chickens for fattening

0 11 November 2015

0 Scientific Opinion

Calsporin® for ornamental fish

0 11 November 2015

C Scientific Opinion

Clarification on Scientific Opinions on transport of meat

• 11 November 2015

C Scientific Report of EFSA

Safety of Allura Red AC in feed for cats and dogs

0 10 November 2015

0 Scientific Opinion

Sodium selenite for all animal species

0 10 November 2015

0 Scientific Opinion

Additive 036 10 for piglets and minor species

0 10 November 2015 Scientific Opinion

Chernical Group 5 for all animal species

• 10 November 2015 0 Scientific Opinion

Aminotrace zinc bislysinate for all animal species

0 10 November 2015 Scientific Opinion

Review of the existing MRLs for suicotrione

0 10 November 2015 0 Reasoned Opinion

GIVEFSA/DCM/2013/01 .GA01 Final report

• 9 November 2015 0 External Scientific Report

Project Code : GP/EFSA/DCM/2013/01

0 9 November 2015 4 External Scientific Report

Implementation of Electronic Transmission of Chemical Occurrence Data (GP/EFSA/DCM/2013/01/03)

• 9 November 2015 0 External Scientific Report

Workshop on allergenicity assessment of GM plants

0 9 November 2015 Event Report

Modification of the existing MRLs for propamocarb in various crops

• 6 November 2015 Reasoned Opinion

Animal-based measures' gap analysis

0 6 November 2015 0 Technical report

Modification of the existing MRL for fluopicolide in blackberries, spinaches and purslanes

• 6 November 2015 Reasoned Opinion

Peer review of the pesticide risk assessment of the active substance picolinafen

0 4 November 2015 C Conclusion on Pesticides

Outcome of the consultation on the basic substance application for sweet whey

0 4 November 2015 0 Technical report

Modification of existing MRLs for proguinazid in currants and gooseberries

0 3 November 2015 C Reasoned Opinion

EFSA scientific advice to EC on accumulating formaldehyde in GM soybeans

0 3 November 2015 0 Technical report

Peer review of the pesticide risk assessment of the active substance Beauveria bassiana NPP111BO05

0 29 October 2015 C Conclusion on Pesticides

Review of the existing MRLs for methomyl

0 29 October 2015 0 Reasoned Opinion

Peer review of the pesticide risk assessment of the active substance Beauveria bassiana 147

0 28 October 2015 Conclusion on Pesticides

57

Relevance of a new scientific publication on previous RA conclusions on CryIAb-expressing maize

28 October 2015

0 Technical report

R Jobs

**Head of Scientific Evaluation of Regulated Products Department - REPRO
Department - Temporary Agent AD12 - EFSA/X/AD/2015/010**

Extended deadline: 16 November
2015

0 Jobs

Calls and consultations

Call for proposals GP/EFSA/SCER/ 2015/01 - "Modelling human variability in toxicokinetic and toxicodynamic processes using Bayesian meta-analysis, physiologically-based modelling and in vitro systems"

4 Deadline: 4 December 2015

C Article 36 grant

Call for tender Literature review of baseline information on RNAi that could support the food/feed and environmental risk assessment of RNAi-based GM plants (OC/EFSA/GMO/2015/02)

A Deadline: 14 December 2015

Procurement

Public consultation on the active substance mesosulfuron

Deadline: 9 January 2016 •

Public consultation

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- EFSA IEP daily summary notification

Von: <noreply@efsa.europa.eu >
An: <Susanne.Kaus@bfr.bund.de >
Datum: 13.11.2015 17:01
Betreff: EFSA IEP daily summary notification

Dear subscriber,

The following documents have been uploaded to the IEP:

1 - Glyphosate - EFSA and Experts from EU Member States Confirm Scientific Assessment of German Authorities STA DE en 12-11-2015.html

Located in: **14.Plant protection products and their residues (PPR & PRAPeR)/**

« This is an automated email sent by EFSA. If you have any problems, please contact servicedeskeefsa.ettropa.eu, >>

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An:

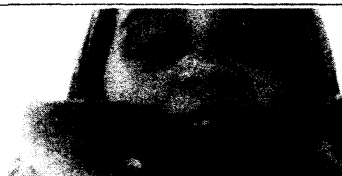
s@bfr.bund.de >

Datum: 15.11.2015 18:48

Betreff: Updates for your subscriptions

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EFSA email Alerts



15 November 2015

Subscription to Publications

Publications

Peer review of the pesticide risk assessment of the active substance glyphosate

15 November 2015

Statement of EFSA on the co-formulant POE-tallowamine

15 November 2015

Peer review of the pesticide risk assessment of the active substance dithianon

15 November 2015

New sequencing data on GM maize GA21

15 November 2015

Assessment of new scientific studies on human in vitro dermal absorption

15 November 2015'

Axtra@PHY for poultry and pigs

15 November 2015

Thaumatococcus (E 957): extension of use

15 November 2015

Efficacy of Sulfactin TM as a zootechnical additive for suckling piglets

15 November 2015

Assessment of the use of Animal Based Measures. Preparatory work.

15 November 2015

Peer review of the pesticide risk assessment of the active substance isofetamid

15 November 2015

Flavouring Group Evaluation 99, Revision 1

15 November 2015

Safety of LNnT and 2'-FL in food supplements for children

15 November 2015

Vitamin C and contribution to the normal function of the immune system

15 November 2015

Meal replacements for weight control

15 November 2015

Risk of using dead-in-shell chicks for the production of biogas or compost

15 November 2015

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- EFSA@EXPO: conference material now online; EFSA strategy 2020; Xylella

Von: EFSA Highlights <highlights@efsa.europa.eu >

An: @bfr.bund.de>

Datum: 19.11.2015 17:59

Betreff: EFSA@EXPO: conference material now online; EFSA strategy 2020; Xylella



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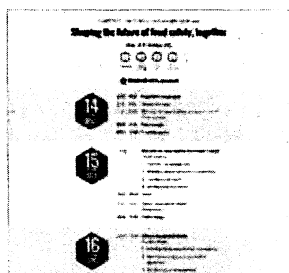
EFSA HIGHLIGHTS 19 November 2015

EFSA@EXPO: conference material now online



Do you want to watch the video coverage of the sessions you missed? Have you been waiting to browse through the presentations from the two plenary and nine break-out sessions? All this material is now available on the conference website.

Videos on demand

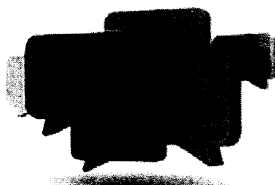


Wrap-up video report



if,11 News

EFSA Strategy 2020: consultation closes on 20 November



EFSA is asking all interested parties to help shape the Authority's strategic direction for the next five years. The draft EFSA Strategy 2020 is open for comment until 20 November.

0 17 November 2015

Xylella: more work needed on role of grapevine



Grapevine cannot be ruled out as a potential host plant for the strain of *Xylella fastidiosa* that is attacking olive trees in southern Italy, EFSA's plant health specialists have concluded.

0 19 November 2015

EU to fund new research on Xylella



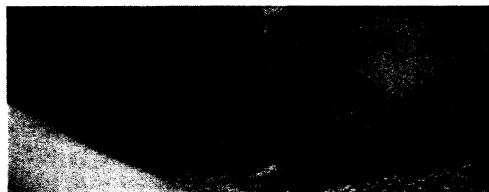
The European Commission is making funds available to boost research into *Xylella*



fastidiosa, a pathogenic bacterium that has been found on olive trees and other plants in southern Italy and on ornamental plants in southern France and Corsica.

O 18 November 2015

Ethoxyquin: safety assessment inconclusive



EFSA cannot conclude on the safety of ethoxyquin as a feed additive for any target animals, its safety for consumers or the environment. This is due to an overall lack of data to assess the safety of the substance, including its metabolites, and the presence of an impurity (p-phenetidine) which is a possible mutagen.

O 18 November 2015

Veterinary drug residue data for 2013 stable



With over one million samples from the 28 EU Member States, the latest EFSA report in an ongoing series summarises compliance rates with EU residue limits or targets for a range of veterinary medicines and contaminants.

O 18 November 2015

EFSA announces open plenary meetings for 2016



EFSA has set dates for the open plenary meetings of its scientific panels and Scientific Committee in 2016. All plenaries are expected to take place in Brussels to make it easier for observers to participate.

O 16 November 2015

Glyphosate: background documents published



EFSA has published the background documents relating to its peer review of glyphosate. These include the peer review report, and the final Renewal Assessment Report prepared by the German authorities.

• 19 November 2015

Upcoming Events

10th Meeting of the Network on Food Consumption Data

- Parma, 24 November 2015 O DATA

Info Session on Applications — Food Enzymes — Technical meeting with stakeholders on refinement of exposure estimates

- in Brussels, 24 November 2015 O FIP

African swine fever: harmonisation of data collection

- Parma, 23 November 2015 O AHAW

Latest Publications

Vitis sp. response to Xylella fastidiosa strain CoDiRO

- 0 19 November 2015 Scientific Opinion
- Residues in live animals and animal products – Results 2013**
- 0 18 November 2015 Technical report
- Re-evaluation of ascorbyl palmitate (E 304(i)) and ascorbyl stearate (E 304(ii))**
- 0 18 November 2015 Scientific Opinion
- Re-evaluation of cochineal, carminic acid, carmines (E 120) as a food additive**
- 0 18 November 2015 C Scientific Opinion
- Montmorillonite clay modified with dimethyldialkyl(C16 -C18)ammonium chloride**
- 0 18 November 2015 Scientific Opinion
- 4-Acrylamido-4-methyl-2-pentanone**
- 0 18 November 2015 Scientific Opinion
- Ethoxyquin for all animal species**
- 0 18 November 2015 0 Scientific Opinion
- Report from public consultation on small scale dairy farms**
- 0 17 November 2015 Technical report
- Revised annual 2013 PMEM report on maize MON 810**
- 0 17 November 2015 0 Scientific Opinion
- Assessment of E. multilocularis surveillance reports 2015**
- 0 16 November 2015 Scientific Report of EFSA
- Review of the existing MRLs for deltamethrin**
- 0 16 November 2015 Reasoned Opinion
- Risk of using deal-in-shell chicks for the production of biogas or compost**
- 0 13 November 2015 0 Scientific Opinion
- Catalytic hydro-treatment for Category 1 animal fat**
- 13 November 2015 Scientific Opinion
- Vitamin C and contribution to the normal function of the immune system**
- 0 13 November 2015 Scientific Opinion
- Meal replacements for weight control**
- 0 13 November 2015 Scientific Opinion
- Peer review of the pesticide risk assessment of the active substance isofetamid**
- 0 13 November 2015 Conclusion on Pesticides
- Flavouring Group Evaluation 99, Revision 1**
- 0 13 November 2015 Scientific Opinion
- Safety of LNnT and 2'-FL in food supplements for children**
- 0 13 November 2015 Scientific Opinion
- Assessment of the use of Animal Based Measures. Preparatory work.**
- 0 13 November 2015 0 External Scientific Report
- Efficacy of Suilectin TM as a zootechnical additive for suckling piglets**

13 November 2015

0 Scientific Opinion

Thaumatococcus (E 957): extension of use

0 12 November 2015

0 Scientific Opinion

Jobs

Junior Scientific Officer - REPRO Department - GMO Unit - Contract Agent FG IV

- **Deadline: 17 December 2015** 0 Jobs

Calls and consultations

"Crowdsourcing: engaging communities effectively in food and feed risk assessment" OC/EFSAJAMU/2015/03

- **Extended deadline: 15 January 2016** 0 Procurement

Multimedia and online communications related services: videos and animations (OC/EFSA/COMMS/2015/02)

Deadline: 18 January 2016 0 Procurement

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Von: efsa.europa.eu
An: EFSA-Focal-Point <efsa-focal-point@bfr.bund.de >
CC: Wittkowski Reiner <Reiner.Wittkowski@bfr.bund.de >, afsecretariat
<afsecretariat@efsa.europa.eu>
Datum: 04.12.2015 15:48
Betreff: RE: Antw: RE: 58th Advisory Forum Meeting, 8-9 December - Presentation

Dear

Many thanks.
Also now another question

The issue of Glyphosate is continuing to be of interest - is Professor Wittkowski wanting to say something on this at the meeting?
If necessary we can allocate some time to this under AoB.

Thanks again!

Regards,

From: EFSA-Focal-Point [mailto:efsa-focal-point@bfr.bund.de]
Sent: 04 December 2015 15:05
To:
Cc: Wittkowski Reiner; afsecretariat
Subject: Antw: RE: 58th Advisory Forum Meeting, 8-9 December - Presentation

Dear

Professor Wittkowski will introduce the topic regarding population subgroups with a verbal comment, no slides.
Kind regards,
on behalf

>>> @efsa.europa.eu <mailto: @efsa.europa.eu >>
04.12.2015 14:41 >>
Dear

Many thanks for sharing this information which we will upload and share with the other members for the meeting.

One question for you - The issue of Population Sub groups is on the Agenda and it was suggested that Germany would introduce this topic based on discussions between BfR, Anses and DTU. Will there be a presentation on this topic or will it be a verbal introduction?

Many thanks in advance for your help!

6s)

Kind regards,

- - Original Message - -

From: EFSA-Focal-Point

[<mailto:efsa-focal-point@bfr.bund.de>] <<mailto:efsa-focal-point@bfr.bund.de>>

Sent: 04 December 2015 14:33

To: afsecretariat

Cc:

Subject: 58th Advisory Forum Meeting, 8-9 December - Presentation

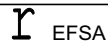
Dear Team, dear

Please find attached the presentation for the upcoming AF meeting (Top 9.2) "Approaches to tackle antimicrobial resistance in Germany: Data collection and risk assessment". Additionally, the German AF member will inform on the new BfR "Opinion-App" with the document attached.

With kind regards
on behalf

Susanne Kaus - Updates for your subscriptions**Von:** <alertsePk9.europa.eu >**An:** @bfr.bund.de"

@bfr.bund.de >

Datum: 08.12.2015 20:25**Betreff:** Updates for your subscriptions

8 December 2015

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Sodium selenite for all animal species**8 December 2015**Statement of EFSA on the co-formulant POE.tallowamine**8 December 2015**Calsporine for ornamental fish**8 December 2015**Negligible risk of classical scrapie in Denmark**8 December 2015**Negligible risk of classical scrapie in Finland**8 December 2015**Negligible risk of classical scrapie in Sweden**8 December 2015**Peer review of the pesticide risk assessment of the active substance allyphosate**8 December 2015**Montmorillonite clay modified with dimethyldialkyl(C16_C18)ammonium chloride**8 December 2015**Ethoxyquin for all animal species**8 December 2015**Re-evaluation of ascorbyl palmitate (E 304(i)) and ascorbyl stearate (E 304(ii))**8 December 2015**Report from public consultation on small scale dairy farms**8 December 2015**Revised annual 2013 PMEM report on maize MON 810

8 December 2015

Axtra®PHY for poultry and pigs

8 December 2015

New sequencing data on GM maize GA21

8 December 2015

Thaumatococcus (E 957): extension of use

8 December 2015

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psm - Wtrlt: Glyphosate draft report of the PPR meeting 125

Von:

An: psm

Datum: 23.12.2015 12:45

Betreff: Wtrlt: Glyphosate draft report of the PPR meeting 125

>>>

@efsa.europa.eu > 02.03.2015 10:39 > »

Dear colleagues,

We hope you had a safe trip home. Thank you for your contributions for the discussion on glyphosate.

I am now providing you with the draft report as discussed during the meeting. The File ('Report Pesticides Peer Review 125_01 Glyphosate 2015-02-27.docx') is available in the meeting folder:

[https://dms.efsa.europa.eu/otcs/cs.exe?](https://dms.efsa.europa.eu/otcs/cs.exe?func=118LobjId=137970768(objAction=browse&viewType=1)

[func=118LobjId=137970768\(objAction=browse&viewType=1](https://dms.efsa.europa.eu/otcs/cs.exe?func=118LobjId=137970768(objAction=browse&viewType=1)

Could you please provide us with your feedback by Wednesday, 4 March 2015, eob by e-mail?

Thanks already in advance.

Kind regards

Pesticides / Regulated Products

BfR Berlin Verfahren Pflanzenschutzmittel		Präs
29. DEZ. 2015		
Az.:	6774	3_0 1

e sann

European Food Safety Authority

Via Carlo Magno 1A

43126 Parma (Italy)

Tel. +39 0521 036

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Von: @efsa.europa.eu>
 An:
 CC: @efsa.europa.eu>
 Datum: 03.03.2015 15:47
 Betreff: Glyphosate (AIR II) - additional information - call for comments

PESTICIDE RISK ASSESSMENT PEER REVIEW
 ADDITIONAL INFORMATION - CALL FOR COMMENTS

Dear colleagues,

Following the peer review of the renewal assessment report of Glyphosate (AIR II) provided by the RMS (Germany) and according to the procedure laid down in Commission Regulation (EU) No 1141/2010, EFSA identified data requirements in relation to the physical and chemical properties, mammalian toxicology, residues, fate and behaviour and ecotoxicological section risk assessment.

EFSA is now circulating the following documents for comments via a written procedure on Chose points of data requirements which are not subject to an expert consultation in a Pesticides Peer Review experts' meeting:

Glyphosate_evaluationtable_AIRILsection_1_2015-01-29.doc

Glyphosate_evaluation_table_AIRII_section_2_2015-01-29.doc

Glyphosate_evaluationtable_AIRILsection_3_2015-03-02.doc

Glyphosate_evaluationtable_AIRIIsection_4_2015-03-02.doc

Glyphosate_evaluation_table_AIRILsection_5_2015-01-29.doc

Glyphosate reporting tablepublic consultation.doc

Glyphosate RAR 12_LoEP_CA-CP_rev 2015-01_29.docx

Glyphosate_reporting table_rev 0 2014-07-14.doc

Glyphosate reporting tables Vol. 4

Glyphosate Report Pesticides Peer Review Written Procedure on Additional Information.doc<<https://dms.efsa.europa.eu/otcs/cs.exe?func=11&objaction=overview&objid=13926323> >

Vol 1-3

vol 4-confidential

Please find the documents available in the EFSA Document Management System (A.s. assessments (external)/glyphosate/Q-2014-00546_PR_AIRII/Member State Consultation/02 Comments on additional information) by following the link given below:

<https://dms.efsa.europa.eu/otcs/cs.exe?func=11&objId=9693658&objAction=browse&viewType=1>

The confidential Volume 4 can be found in the EFSA Document Management System in the folder: 'Assessment report and addenda' (A.s. assessments (external)/Glyphosate/Q-2014-00546_PR_AIRII/ Assessment report and addenda/02_Addenda/Vol 4_CONFIDENTIAL), on the following link below:

<https://dms.efsa.europa.eu/otcs/cs.exe?func=11&objId=9693663&objAction=browse&viewType=1>

Please provide your comments in column 2 of the document titled 'Discussion Written Procedure' of Appendix 1 of the report 'Glyphosate._Report Pesticides Peer Review Written Procedure on Additional Information.doc.

Please upload your comments to the EFSA Document Management System, in the same folder indicated above (A.s. assessments (external)/glyphosate/Q-2014-00546_PR_AIRII/Member State Consultation/02 Comments on additional information), at the latest by 17 March 2015.

Kind regards,
 The Coordination Team

Pesticides Unit
 European Food Safety Authority - EFSA
 Via Carlo Magno 1/A
 1-43126 Parma
 Italy
 Email : pesticides.peerreview@efsa.europa.eu <<mailto:pesticides.peerreview@efsa.europa.eu> >

psm - Wtrlt: RE: Antw: Glyphosate - draft report of the PPR meeting 125

Von:

An: psm

Datum: 23.12.2015 12:46

Betreff: Wtrlt: RE: Antw: Glyphosate - draft report of the PPR meeting 125

>>>

@efsa.europa.eu > 04.03.2015 16:05 > »

Liebe

Nun, das ist ja im Grunde genommen klar, weil es im Verfahren nur ein Zeitfenster für neue Daten gibt, aber evtl. sollte man das dem breiten Publikum doch nochmal mitteilen

Vielen Dank für den Vorschlag und herzliche Grüße in die Hauptstadt

Pesticides Regulated Products

BiR Berlin Verfahren Pflanzenschutzmittel	Präs
29. BEZ. 2015	
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Tel. +39 0521 036

www.efsa.europa.eu

[twitter.com/EFSA EU](https://twitter.com/EFSA_EU) lir

youtube.com/EFSAchannel egal

From:

, bfr.bund.de]

Sent: 04 March 2015 15:44

To:

Cc:

Subject: RE: Antw: Glyphosate - draft report of the PPR meeting 125

Lieber

danke für die rasche Antwort!

Noch eine Idee: wir haben heute schon wieder von neuen Glyphosat-Papers erfahren. Die die Bewertung zwar nicht ändern werden, aber nun mal da sind. Sollte die EFSA nicht so eine Art "Redaktionsschluss" für die Bewertung mitteilen? Vielleicht so:

"The expert meeting was held in February, 2015. Discussions and conclusions were based on the most recent version of the RAR as released by the RMS by the end of January. Information that was published thereafter, could not be taken into consideration for this review."

Was hältst Du davon?

Herzlichst,

Bundesinstitut für Risikobewertung
Fachgruppe Toxikologie der Pestizide und Biozide
Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Unit Toxicology of Pesticides and Biocides
Department of Chemical Safety

Max-Dohrn-Straße 8-10,
10589 Berlin, Germany
Tel. +49 30 18412-
Fax +49 30 18412-
www.bfr.bund.de
ebfr.bund.de

>>>

@efsa.europa.eu ≥ 04.03.2015 15:33 > »

Dear

Thank you and very much for your comments and proposals.

Have a nice evening and best regards

Pesticides J Regulated Products

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European Food Safety Authority
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43126 Parma (Italy)
Tel. +39 0521 036 655
www.efsa.europa.eu
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youtube.com/EFSAchannel

From: @bfr.bund.de
Sent: 04 March 2015 15:26
To:
Cc:
Subject: Antw: Glyphosate - draft report of the PPR meeting 125

Dear

and I have just tried to check and, where necessary, to amend the minutes. Attached you may find our proposals taking into account also the comments provided by

Kind regards,

Bundesinstitut für Risikobewertung
Fachgruppe Toxikologie der Pestizide und Biozide
Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Und Toxicology of Pesticides and Biocides
Department of Chemical Safety

Max-Dohrn-Straße 8-10,
10589 Berlin, Germany
Tel. +49 30 18412-
Fax +49 30 18412-,
www.bfr.bund.de
bfr.bund.de

» »

@efsa.europa.eu ≥ 02.03.2015 10:39 > »

Dear colleagues,

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[https://dms.efsa.europa.eu/otcsics.exe?
func=118\(objId=137970768\(objAction=browse&viewType=1](https://dms.efsa.europa.eu/otcsics.exe?func=118(objId=137970768(objAction=browse&viewType=1)

Could you please provide us with your feedback by Wednesday, 4 March 2015, eob by e-mail?

Thanks already in advance.

Kind regards

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European Food Safety Authority
Via Carlo Magno 1A

43126 Parma (Italy)

Tel. +39 0521 036 [REDACTED]

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psm - Wtrlt: RE: Antw: Glyphosate - draft report of the PPR meeting 125

Von:

An: psm

Datum: 23.12.2015 12:45

Betreff: Wtrlt: RE: Antw: Glyphosate - draft report of the PPR meeting 125

>>>

@efsa.europa.eu > 04.03.2015 15:33 > »

Deal

Thank you and very much for your comments and proposals.

Have a nice evening and best regards

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29. DEZ, 2015		III
Az.: 24/I, 5		
Doc.-Nr.: 22 ss		

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From:

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Sent: 04 March 2015 15:26

To:

Cc:

Subject: Antw: Glyphosate - draft report of the PPR meeting 125

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Kind regards,

Bundesinstitut für Risikobewertung
Fachgruppe Toxikologie der Pestizide und Biozide
Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Unit Toxicology of Pesticides and Biocides
Department of Chemical Safety

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Fax +49 30 18412-
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3fsa.europa.eu ≥ 02.032015 10:39 > »

Dear colleagues,

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func=118&objId=137970768&objAction=browse&viewType=1](https://dms.efsa.europa.eu/iotcsics.exe?func=118&objId=137970768&objAction=browse&viewType=1)

Could you please provide us with your feedback by Wednesday, 4 March 2015, eob by e-mail?

Thanks already in advance.

Kind regards

Pesticides Regulated Products

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e sag.

European Food Safety Authority

Via Carlo Magno 1A
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Tel. +39 0521 036

www.efsa.europa.eu

[twitter.com/EFSA EU](https://twitter.com/EFSA_EU) 

youtube.com/EFSAchannel 

psm - Wtrlt: FW: A question regarding the glyphosate RAR

Von:

An: psm

Datum: 23.12.2015 12:47

Betreff: Wtrlt: FW: A question regarding the glyphosate RAR

>>

Aefsa.europa.eu > 04.05.2015 12:08 > >

Dea.

Please find here the citation for the RAR on glyphosate:

Germany, 2013. Renewal assessment report (DAR) on the active substance glyphosate prepared by the rapporteur Member State Germany in the framework of Regulation (EC) No 1107/2009, December 2013. Available of www.efsa.europa.eu

Best regards

BfR. Berlin Verfahren Pflanzenschutzmittel	Präs
29. DEZ. 2015	fri
Az.: 1,2 AA Doc.-Nr.: 107/1,1	

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youtube.com/EFSAchannel Yogira

From:

Sent: 04 May 2015 10:05

To:

Subject: FW: A question regarding the glyphosate RAR

Ciao

Can you please answer to the question from

Thanks a tot

From:

Sent: Monday, May 04, 2015 09:20

To:

Subject: RE: A question regarding the glyphosate RAR

Good morning , and was good to meet you in Brussels.
Sorry for my late reply but I have been to the JRC for 2 days last week. I will collect the information and will reply to yourself today
Talk soon

From: rmailtc bfr.bund.de
Sent: Wednesday, April 29, 2015 11:09
To: .
Subject: A question regarding the glyphosate RAR

Dear

I hope you have returned safely to Parma on Friday and had some time for recreation on the week-end.
Today, I have a question that you, perhaps, might answer.

We are just preparing a manuscript dealing with potential effects of a glyphosate-containing herbicide on rumen metabolism and microbial communities in cattle rumen. It will be based on a preliminary report that we had briefly mentioned in the RAR on glyphosate yet and we have been asked sometimes since then when the results will become published.

Not for this report but for some other purposes, I would like to refer to the RAR in this paper but I am not sure if I am allowed to do that and how to do it best. To my understanding, the version of the RAR for the 2014 "Public consultation" (as prepared and edited by EFSA) is no longer available since it has never been on the Internet but was submitted only on request. Is it possible at the moment to ask EFSA for this report? If so, I could cite it with the remark "available on request from EFSA". Or is it still somewhere "hidden" on the EFSA website?

On one hand, I don't want to include references that are not readily accessible. On the other hand, we have emphasised, e.g. on the meeting in Brussels last week, that the scientific community should make more use of such comprehensive documents like a DAR or RAR as credible sources of information.

I would be glad to receive your thoughts on that.
The best that I might expect would be a clear advice in which way to cite the RAR.

Kind regards,

Bundesinstitut für Risikobewertung
Fachgruppe Toxikologie der Pestizide und Biozide
Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Unit Toxicology of Pesticides and Biocides
Department of Chemical Safety

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10589 Berlin, Germany
Tel. +49 30 18412-
Fax +49 30 18412-3260
www.bfr.bund.de
ebfr.bund.de

psm - Wtrlt: RE: Request for clarification on certain studies on glyphosate

Von:

An: psm

Datum: 23.12.2015 12:48

Betreff: Wtrlt: RE: Request for clarification on certain studies on glyphosate

>>

@efsa.europa.eu > 07.05.2015 17:00 > »

Dear

Thanks a lot for your detailed answer and your support. After a first quick read, I think it will help a lot.

will put you both on the "to-be-paid-a-coffee" list.

Best regards

Pesticides Regulated Products

efsa

Eutopean Food Safety Authority

Via Carlo Magno-1A

43126 Parma (Italy)

Tel. +39 0521 036

www.efsa.europa.eu

[twitter.com/EFSA EU](https://twitter.com/EFSA_EU)

youtube.com/EFSAchannel

BfR. Berlin Verfahren Pflanzenschutzmittel	Präs
29. DEZ. 2015	
Doc.-Nr.: "i;	

[Handwritten signature]
2016

From:

bbfr.bund.dei

Sent: 07 May 2015 16:30

To:

Cc:

Subject: Request for clarification on certain studies on glyphosate

Dear

and I spent some time on this search but it was quite interesting.

What we found out, is the following:

We don't have any study I* on file in the BfR. However, the document number 77-2061A is clearly related to study 77-2061 which is a long-term study in mice that was completed in 1983 and provided by eing the principal authors. This study has got the BfR file number . It was reported in detail in the old DAR and is now considered still acceptable. Therefore, it was also mentioned in the RAR. was apparently the study pathologist.

In 1985, a re-review of histological slides of the kidneys was performed on request of U.S. EPA but not ... This time, the pathologist was . The result of this re-evaluation was recently reported by BfR in our preliminary response to the IARC assessment of glyphosate as carcinogenic and can be easily found there. I think that the question to EFSA might point into that direction.

is on file in the BfR and has got the number . It is not an addendum to the pathology report but, instead, contains the complete three-generation study on rats by . Apparently, it was provided in to support registration of glyphosate in West-Germany. At least, this purpose is indicated on the document. Therefore, it was not taken into account of previous EU evaluation. The pathology parts of MSL-1724 and of the original study are identical. The difference seems to be that additional analytical data on the diet is given in but not in the original study report. Therefore, the number of pages is higher. Anyway, the three-generation study by must be considered not acceptable from a today's point of view and was not used for re-evaluation of glyphosate. This opinion of the RMS has not been questioned by any party during the commenting period. Thus, there is no need to go deeper into the details.

I hope this will answer your questions.

Kind regards,

Bundesinstitut für Risikobewertung
Fachgruppe Toxikologie der Pestizide und Biozide
Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Unit Toxicology of Pesticides and Biocides
Department of Chemical Safety

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10589 Berlin, Germany
Tel. +49 30 18412-
Fax +49 30 18412-
www.bfr.bund.de
ebfr.bund.de

psm - Wtrt: PEO tallowamine

Von:

An: psm

Datum: 23.12.2015 12:48

Betreff: Welt: PEO tallowamine

>>>

Pefsa.europa.eu > 10.06.2015 18:08 > »

Dear

Sorry to come back to our favourite issue. We are now preparing our statement on the POE tallowamines. Just a simple question to avoid digging into the dossier. Were there any supporting studies on the part on the PEO tallowamines you presented in the RAR?

Thanks already in advance

Best regards

Pesticides , Regulated Products

e sag»

European Food Safety Authority

Via Carlo Magno 1A
43126 Parma (Italy)

Tel. +39 0521 036

www.efsa.europaseu

[twitter.com/EFSA EU te](https://twitter.com/EFSA_EU)

youtube.com/EFSAchannel Yes it is

BfR Berlin
Verfahren Phanzenschutemittel

Präs

29. DEZ. 2015

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rL Prie

psm - Wtrlt: RE: Antw: PEO tallowamine

Von:

An: psm

Datum: 23.12.2015 12:49

Betreff: Wtrlt: RE: Antw: PEO tallowamine

BfR Berlin Verfahren Pflanzenschutzmittel	Präs
29. DEZ. 2015 Azi	618 Jan. 2
Doc.-Nr.:	

> >>

@efsa.europa.eu > 11.06.2015 10:24 > »

Dea

Thanks a lot for your quick answer.

Hope you are well and not too much occupied answering the journalist's questions for glyphosate . We have a lot going on these days, as you may imagine.

Best regards as well to . ,nd 1

Pesticides , Regulated Products



European Food Safety Authority

Via Carlo Magno 1A

43126 Parma (Italy)

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www.efsa.europa.eu

twitter.com/EFSA_EU

youtube.com/EFSAchannel

From:

: bfr.bund.de

Sent: 11 June 2015 08:26

To:

Subject: Antw: PEO tallowamine

Dear

the major part of the toxicological information on POE tallowamines that is available to the RMS to can be found in Vol. 3 in Chapter B.6.13.3.(1). The studies adressed there were not part of the original GTF dossier but had been compiled in Germany before already and for other purposes. However, we feit it necessary to include this data in the RAR.

Furthermore, a number of in vitro studies have been performed (mainly by the proving a higher toxicity of PPP with POE talowamines as compared to the a.s. which were either part of the original dossier or were amended at later stages. They are reported on different sites of the RAR but

cannot recall at the moment the precise allocation. Of importance are, e.g., two studies of Mesnage et al. (2012 and 2013) that are cited under 8.6.8.4 (at least in the version that has been prepared in advance of the PRAS meeting in February).

Kind regards,

Bundesinstitut für Risikobewertung
Fachgruppe Toxikologie der Pestizide und Biozide
Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Unit Toxicology of Pesticides and Biocides
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Tel. +49 30 18412- -
Fax +49 30 18412-'

www.bfr.bund.de

bfr.bund.de

@efsa.europa.eu ≥ 10.06.2015 18:08 > »

Dear

Sorry to come back to our favourite issue. We are now preparing our statement on the POE tallowamines. Just a simple question to avoid digging into the dossier. Were there any supporting studies on the part on the PEO taliowamines you presented in the RAR?

Thanks already in advance

Best regards

Pesticides / Regulated Products

***--efsaudi**

EtKopeart Food Safety Authority

Via Carlo Magno 1A

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Tel. +39 0521 036

www.efsa.europa.eu

twitter.com/EFSA_EU

youtube.com/EFSAchannel To 

psm - Wtrlt: RE: Antw: Glyphosate - was sonst

BfR. Berlin Verfahren Pflanzenschutzmittel	Präs
Az.: 6 ? , --vi --dz,	
Doc.-Nr.: 2_4 W	

Von:

An: psm

Datum: 23.12.2015 12:50

Betreff: Wtrlt: RE: Antw: Glyphosate - was sonst

>>>

@efsa.europa.eu > 24.06.2015 12:04 > »

Dea

Thanks a lot for your explanation and the clarification of the situation. That helps a lot.

Have a nice day and best regards as well to

Pesticides / Regulated Products



European Food Safety Authority

Via Carlo Magnö 1A

43126 Parma (Italy)

Tel. +39 0521 036

www.efsa.europa.eu

twitter.com/EFSA_EU eir

youtube.com/EFSAchannel Ye 17/12/15

From: pbfr.bund.de

Sent: 24 June 2015 10:14

To:

Cc:

Subject: Antw: Glyphosate - was sonst

Dear

think I can explain:

You can't find the studies (industry studies and published papers) in the dossier of the Glyphosate Task Force because they were simply not part of it. As we tried to make clear in the RAR, Germany as the RMS (here: the BfR) has included in the RAR a tallowamine assessment that had been compiled in, think, 2010 for national purposes. (Subsequent to this assessment, certain talowamines in many glyphosate-containing herbicides have been in fact replaced by other surfactants, at least on the German market. I have no idea if companies did the same abroad.)

1 can tell you that it was quite difficult to get access to the industry studies at that time. We felt it important to make this information publically available even though it was not relevant for the representative formulation that does not contain tallowamines.

To my understanding, a MS is free to introduce into the RAR additional information that was not part of the dossier. For the glyphosate RAR, we did the same with many papers that we had been aware of before or that were mentioned during the public consultation. They are reported now but were not submitted in the original dossier.

The "green" studies had been allocated by _____ to the dossier for other reasons and are referred to in other parts of the RAR, too.

Kind regards and enjoy the coffee,

Bundesinstitut für Risikobewertung
Fachgruppe Toxikologie der Pestizide und Biozide
Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Unit Toxicology of Pesticides and Biocides
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Tel. +49 30 18412-
Fax +49 30 18412-

www.bfr.bund.de

[Abfr.bund.de](http://abfr.bund.de)

>>>

@efsa.europa.eu > 23.06.2015 14:09 > »

Dear colleagues,

Sorry to come back again to glyphosate.

On page 884 of the rev. RAR B.6, several studies are mentioned in table B.6.13-1:

The "green" ones we found in the dossier, but for the other ones, we don't have evidence that they have ever been included into an EU dossier.

The problem is, that we have or have not to confirm the access to these studies. Therefore I would like to crosscheck with you, whether these studies have or have not been in any of the EZ dossiers (the original one, the supplementary one and the updated one after the additional data request). I assume that these studies have been submitted under a national procedure?

Thanks already in advance and best regards

P.S.: I will now have a nice Italian coffee, which I would have liked to share with you

Pesticides / Regulated Products



e.sag.

European Food Safety Authority

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psm - Wtrlt: IRAC monograph

Von:

An: **psm**

Datum: 23.12.2015 13:02

Betreff: Wtrlt: IRAC monograph

> >>

2efsa.europa.eu > 26.06.2015 14:56 > »

Dear colleagues,

May 1 quickly check with you whether you intend to prepare a statement on the IARC monograph on glyphosate, once It will be available?

Thanks in advance.

Best regards and a nice weekend.

Pesticides / Regulated Products

jor:44, AK

sann

European Food Safety Authority

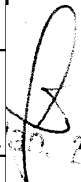
Via Carlo Magno 1A
43126 Parma (Italy)
Tel. +39 0521 036

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[youtubescom/EFSAchannel](https://www.youtube.com/EFSAchannel) **Yos** 

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psm - Wtrlt: FW: Consultation Access to documents ref. PAD 2015/54 Re-a
glyphosate

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Von: v
An: psm
Datum: 23.12.2015 13:02

Betreff: Wtrlt: FW: Consultation Access to documents ref. PAD 2015/54 Re-assessment of glyphosate
Anlagen: [Untitled].pdf, [Untitled] new32A2.pdf; 1 BFR emails.pdf

> > "EFSA.public.access.to .documents" <EFSA.public.access.to.documents@efsa.europa.eu > 06.07.2015 12:03
> >>

Dear

EFSA has received a request for public access to documents made by a non-governmental organisation submitted in accordance with Regulation (EC) No 1049/2001 (hereafter referred to as 'PAD Regulation') . This public access request concerns any letters, documentation of meetings and email correspondence (including attachments) in relation to the on-going re-assessment of glyphosate. Under the terms of Article 4(4) of the PAD Regulation, EFSA shall consult the third-party from which documents originate with a view of assessing whether an exception to disclosure foreseen by Article 4(1 or 2) of the PAD Regulation applies.

Hence EFSA is hereby consulting you to ascertain whether any exception to disclosure in the sense of Article 4(1 or 2) of the PAD Regulation may apply to the emails attached originating from you. Please note that we are also consulting you in relation to documents which were attached in correspondence between EFSA and BVL of which you are the originator.

We would appreciate to receive your reply with the following information:

an indication of any specific parts of the attached documents which in your view should not be released because of their confidential nature, as it would for instance undermine a commercial interest or an intellectual property right;

a thorough justification of the reasons for non-disclosure, 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.

All personal data (names, email addresses, signatures, comments of personal nature, etc) present in the documents will be masked by EFSA in case of disclosure in accordance with the exception relating to the protection of privacy and integrity of the individual, foreseen under Article 4(1) (b) of the PAD Regulation.

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 9 July 2015 at the latest. If we have not received a reply by this date or in case of an insufficiently substantiated negative answer, EFSA will decide on the access request in accordance with the information at its disposal.

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

Yours sincerely,

The EFSA public access
Legal and Regulatory Affairs Unit - EFSA

efSa

European Food Safety Authority

Via Carlo Magno 1A
43126 Parma (Italy)

www.efsa.europa.eu

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psm Wtrlt: FW: Consultation Access to documents ref. PAD 2015/54 Re-assessment of glyphosate

Von:

An: psm

Datum: 23.12.2015 13:02

Betreff: Wtrlt: FW: Consultation Access to documents ref. PAD 2015/54 Re-assessment of glyphosate

Anlagen: [Untitled].pdf; [Untitled]_new32A2.pdf; 1 BFR emails.pdf

> » "EFSA.public.access.to .documents" <EFSA.public.access.to.documents@efsa.europa.eu > 08.07.2015 16:29

> >>

Dear dear Mr

A gentle reminder an the below e-mail.

Many thanks.

Yours sincerely,

BfA. Berlin Verfahren Pflanzenschutzmittel	Präs
29. DEZ. 2052	· \
Az.: , ,A Doc.-Nr.:	

**EFSA Public Access to documents
Legal and Regulatory Affairs Unit**

From: On Behalf Of EFSA.public.access.to .documents

Sent: 06 July 2015 12:04

To:)@bfr.bund.de;

@bfr.bund.de

Cc: EFSA.public.access.to .documents;

Subject: FW: Consultation Access to documents ref. PAD 2015/54 Re-assessment of glyphosate

Dear dear Mr

EFSA has received a request for public access to documents made by a non-governmental organisation submitted in accordance with Regulation (EC) No 1049/2001 (hereafter referred to as 'PAD Regulation'). This public access request concerns any letters, documentation of meetings and email correspondence (including attachments) in relation to the on-going re-assessment of glyphosate. Under the terms of Article 4(4) of the PAD Regulation, EFSA shall consult the third-party from which documents originate with a view of assessing whether an exception to disclosure foreseen by Article 4(1 or 2) of the PAD Regulation applies.

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We would appreciate to receive your reply with the following information:

an indication of any specific Parts of the attached documents which in your view should not be released because of their confidential nature, as it would for instance undermine a commercial interest or an intellectual property right;

a thorough justification of the reasons for non-disclosure, 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.

All personal data (names, email addresses, signatures, comments of personal nature, etc) present in the documents will be masked by EFSA in case of disclosure in accordance with the exception relating to the protection of privacy and integrity of the individual, foreseen under Article 4(1) (b) of the PAD Regulation.

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 9 July 2015 at the latest. If we have not received a reply by this date or in case of an insufficiently substantiated negative answer, EFSA will decide on the access request in accordance with the information at its disposal.

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

Yours sincerely,

**The EFSA public access
Legal and Regulatory Affairs Unit - EFSA**

e sann

European Food Safety Authority

**Via Carlo Magno 1A
43126 Parma (Italy)**

www.efsa.europa.eu

[twitter.com/EFSA EU](https://twitter.com/EFSA_EU)

youtube.com/EFSAchannel Yee

Von: "PRAS.secretariat" <PRAS.secretariat@efsa.europa.eu >
An: @bfr.bund.de>
Datum: 08.09.2015 17:55
Betreff: Decision of the ED on Declarations of Interest - Pesticides Peer Review TC 117 Mammalian Toxicology

Dear

Following your nomination as participant in the Pesticides Peer Review TC 117 Mammalian Toxicology (29 September 2015), we would like to inform you that you are invited to submit your Annual Declaration of Interest (ADoI) for the Mammalian Toxicology group according to the revised Decision of the ED on Declaration of Interest<<http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf> >.

Article 10 of the implementing rules is of particular interest to you: The responsibility for the appointment or nomination of representatives of the Member State(s) or of its authorities rests exclusively at all times with their respective Member State(s). EFSA invites members of networks to complete and submit an ADoI for transparency reasons, without screening. EFSA shall publish the submitted ADols in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. No Specific Declaration of Interest (SDoI) or Oral Declaration of Interest (ODoI) are requested.

Please click on the following link to login with your EFSA Extranet username and password and submit your ADoI accordingly:

<https://ess.efsa.europa.eu/ess/doi>

Please use this username:

To get a password, please use the link below:

<https://sciencenet.efsa.europa.eu/sumt/pageLostPassword.jsp>

Please read carefully the following information and instructions:

The definitions of all interests are given in Article 2.2. of the Decision of the Executive Director (ED). It is important to bear these definitions in mind when completing the ADoI;

The concept of Food Safety Organisation (FSO) is described in Article 2.2.f. of the Decision of the ED). It is important that you Insert under "subject matter" sufficient information to justify whether the organisation where you are employed is an FSO or not. You are kindly requested to declare :

- o The legal remit of the entity or organisation;
- o Your role in the Organisation and your main tasks;
- o Whether the organisation has an official responsibility to carry out risk management or not. In case of employment by an organisation with an official capacity in risk management (for instance decision making on the authorisation of plant protection products), please indicate whether you are personally empowered to validate/take management action/decisions or not;

Interests should also be declared when finalised less than 5 years ago. On the other hand, it is recommended to delete activities that have been finalised more than 5 years ago ;

All acronyms and abbreviations should be clarified. These may be obvious to EFSA, but they are not necessarily so to all those consulting the ADols;

In the section "research funding", please indicate any funding received; so it is not the intention that you declare here research funded by your Organisation;

- If you declare in section III. membership of a scientific advisory body, you should mention as organisation not only the advisory body, but also the organisation where the advisory body is situated (for instance, you are member of a committee in an institute, then you also have to mention the institute under "organisation" and not just the advisory body). Under subject matter the following elements should be mentioned:
 - o the remit of the advisory body, including information on how and by whom the advices are taken into consideration;
 - o the nature of the advices delivered;
 - o your role (chair, member, alternate member,...);
 - o whether you have a right to vote or not and/or a right to veto.

Should you need any technical assistance, please contact servicedesk@efsa.europa.eu <<mailto:servicedesk@efsa.europa.eu>>

Thank you in advance for your kind cooperation.

Kind regards,

PESTICIDES
REPRO Department

[cid: image001.jpg@OIDOEAC.61E25D70]

Via Carlo Magno 1A
43126 Parma (Italy)
Tel : +39. 0521. 036

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youtube.com/EFSAchannel <[http://youtube.com/EFSAchannel](https://youtube.com/EFSAchannel)> [cid: image003.jpg@OIDOEAC.61E25D70]

Von: "PRAS.secretariat" <PRAS.secretariat@efsa.europa.eu >
An:

Datum: 16.09.2015 11:45
Betreff: *Invitation letter* Pesticides Peer review 117 Mammalian Toxicology (29 September 2015)
Anlagen: Invitation letter Pesticides Peer Review TC 117 MammalianToxicology.pdf

Dear Experts,

Please find attached the invitation letter for the forthcoming Pesticides Peer Review TC 117 Mammalian Toxicology which will take place on 29 September 2015 from 09:00 to 12:30 (GMT+2 Rome).

In the following days you will receive a meeting request containing the instructions and a web-link to join the audio-web conference.

Due to the high number of participants, we invite you to carefully read the instructions that will be distributed together with the web-link. In case you are not familiar with the audio conference system, we kindly invite you to test the audio conference system well in advance of the meeting and to contact EFSA's Servicedesk in case further support is needed.

As mentioned in the invitation letter, the teleconference will start at 09:00 but, in order to avoid possible delays and ensure that all participants will be connected at the scheduled time, you may be contacted already from 08:30.

Availability of documents for expert discussions:

We would like to inform you that the meeting documents will be available on the OpenText platform on Wednesday 23 September 2015. Please select the relevant a.s. folder. In this folder the meeting documents can be downloaded from 'Member State Consultation\06_Expert consultation mamtox September 2015' (<https://dms.efsa.europa.eu/otcsilivelink.exe?func=11&objId=14622742&objAction=browse&viewType=1>)

Should you have any question or need any clarification, please do not hesitate to contact me.

Kind regards

PESTICIDES
REPRO Department

[cid:image001.jpg@OID0F06E.77F8FEAO]

Via Carlo Magno 1A
43126 Parma (Italy)
Tel: +39. 0521. 036

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youtube.com/EFSAchannel <<http://youtube.com/EFSAchannel>> [cid: image003jpg@OID0F06E.77F8FEAO]

Von: @efsa.europa.eu
An: Solecki Roland <Roland.Solecki@bfr.bund.de >
CC: @bfr.bund.de>, psm <psm@bfr.bund.de>, @bfr.bund.de>
Datum: 18.09.2015 14:11
Betreff: RE: Antw: Participants invited for the TC on glyphosate

Dear Roland,
 Thanks ⁴ for information. We will send the invitation ASAP.
 Will you participate in person or by phone?
 Thanks,

- - Original Message - -

From: Solecki Roland [mailto:Roland.Solecki@bfr.bund.de]
 Sent: 18 September 2015 14:03
 To: @efsa.europa.eu
 Cc: psm;
 Subject: Antw: Participants invited for the TC on glyphosate
 Importance: High

** High Priority **

Dear ,
 we agreed that you would participate the Pesticides Peer Review TC 117 Mammalian Toxicology on: Glyphosate — AIR II (DE) — Discussion on classification following IARC monograph in Parma as representative of the Rapporteur, if you could sent an invitation via Email as soon as possible.
 He would appreciate, if you could have a short discussion before the telecon.
 would organised hotel and travel arrangements.
 I would participate via telecon from Berlin.
 Kind Regards
 Roland

Dr. Roland Solecki

Bundesinstitut für Risikobewertung
 Leitung der Abteilung Sicherheit von Pestiziden

Federal Institute for Risk Assessment
 Head of Department Pesticide Safety

Max-Dohm-Straße 8-10,
 10589 Berlin, Germany
 Tel.: +49 30 18412 3232
 Fax: +49 30 18412 3894
www.bfr.bund.de

>>> @efsa.europa.eu> 16.09.2015 18:46 >>>

Dear Roland,
 Following your request please find attached the list of experts invited to the teleconference on glyphosate.
 Kind regards,

[cid:image001.gif@01D0F0B0.1080C810]

Via Carlo Magno 1/A
 1-43126 Parma

Italy

Tel: +39 0521 036

www.efsa.europa.eu <http://www.efsa.europa.eu/>

twitter.com/EFSA_EU <http://twitter.com/EFSA_EU >

[cid:image002.png@01D0F0B0.1080C810] <https://twitter.com/efsa_eu >

youtube.com/EFSAchannel <http://youtube.com/EFSAchannel >

[cid:image003.png@01D0F0B0.1080C810] <http://youtube.com/EFSAchannel >

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authorised by a recipient), access to this e-mail message or any disclosure or copying of its content, or any action taken in reliance on it is unauthorised and may be unlawful. If you are not the intended recipient, please let the sender know immediately.

Von: @efsa.europa.eu >
 An: roland.solecki@bfr.bund.de

CC: @efsa.europa.eu >

Betreff: Teleconference documents for Pesticides Peer Review TC 117/Mammalian Toxicology (29 September 2015)
 Anlagen: DRAFT Report Pesticides Peer Review TC 117 Glyphosate 2015-09-29.docx

Dear all,

In order to help the discussions in the upcoming Pesticides Peer Review Teleconference 117, please find attached the discussion table containing some background information for the points under discussion.

The final version of the discussion including the outcomes of the scientific consultation will be finalized during the meeting.

Looking forward to meeting next week,

Best regards,

Pesticides Unit - Toxicology
 Scientific Evaluation of Regulated Products Directorate

[cid:image004.jpg@01D0F6AA.DD10BFC0]

European Food Safety Authority
 Via Carlo Magno 1/A 1-43126 Parma
 Tel : +39 0521 036
 Fax : +39 0521 036

<http://www.efsa.europa.eu> <<http://www.efsa.europa.eu/>>
twitter.com/EFSA_EU <[http://twitter.com/EFSA_EU](https://twitter.com/EFSA_EU)> [cid:image005.jpg@01D0F6AA.DD10BFC0]
[youtube.com/EFSAchannel](https://www.youtube.com/EFSAchannel) <[http://youtube.com/EFSAchannel](https://www.youtube.com/EFSAchannel)> [cid:image006.jpg@01D0F6AA.DD10BFC0]

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Von: PRAS.secretariat<PRAS.secretariat@efsa.europa.eu>
An: 'Roland SOLECKI(roland.solecki@bfr.bund.de)'<roland.solecki@bfr.bund.de>

CC: @efsa.europa.eu>
Betreff: Technical information teleweb connection TC 117 Mammalian Toxicology - Glyphosate (29 September 2015)

Dear Experts,

With regard to the teleconference mentioned in subject, I would like to give you further technical information to connect to the teleweb conference.

[cid:image004.png@OID0F7A1.6E0808C0]

In case the link you already received shouldn't work, please try with the following one

<https://meet.efsa.europa.eu/j/6W6C95N9D?sl=1>

[cid:image005.png@OID0F7A1.DD1FD2B0]

Due to the high number of participants and in order to avoid possible delays when connecting the attendees, you are kindly invited to insert your phone number according to the instructions below

[cid:image006.png@OID0F7A2.0E1DC8E0]

[cid:image007.png@OID0F7A2.0E1DC8E0]

Should you need further technical information, please do not hesitate to contact servicedesk@efsa.europa.eu <mailto:servicedesk@efsa.europa.eu>

Kind regards

PESTICIDES
REPRO Department

[cid:image001.jpg@OID0F79F.AAE1F460]

Via Carlo Magno 1A
43126 Parma (Italy)
Tel: +39. 0521. 036

www.efsa.europa.eu <http://www.efsa.europa.eu>

twitter.com/EFSA_EU <http://twitter.com/EFSA_EU> [cid:image002.jpg@OID0F79F.AAE1F460]

[youtube.com/EFSAchannel](https://www.youtube.com/EFSAchannel) <http://youtube.com/EFSAchannel> [cid:image003.jpg@OID0F79F.AAE1F460]

Von: @efsa.europa.eu>
An:

Roland [SOLECKI\(roland.solecki@bfr.bund.de \)<roland.solecki@bfr.bund.de](mailto:roland.solecki@bfr.bund.de)

CC: @efsa.europa.eu>; @efsa.europa.eu>; @ext.efsa.europa.eu>; EFSA
PESTICIDES PEER REVIEW<pesticides.peerreview@efsa.europa.eu

Datum: 29.09.2015 18:32
Betreff: Teleconference documents for Pesticides Peer Review TC 117Mammalian Toxicology (29 September 2015)
Anlagen: DRAFT ECHA Glyphosate.docx

Dear all,

We just received comments from ECHA colleagues that may be helpful to the discussion tomorrow and therefore I attached these for your information.

With kind regards,

From: @efsa.europa.eu>
Sent: 24 September 2015 09:39
To: Roland SOLECKI (roland.solecki@bfr.bund.de
EFSA PESTICIDES PEER REVIEW

Subject: Teleconference documents for Pesticides Peer Review TC 117 Mammalian Toxicology (29 September 2015)

Dear all,

In order to help the discussions in the upcoming Pesticides Peer Review Teleconference 117, please find attached the discussion table containing some background information for the points under discussion.

The final version of the discussion including the outcomes of the scientific consultation will be finalized during the meeting.

Looking forward to meeting next week,

Best regards,

Pesticides Unit - Toxicology
Scientific Evaluation of Regulated Products Directorate

[cid:image001.jpg@01D0FA0E.89770830]

European Food Safety Authority
Via Carlo Magno 1/A 1-43126 Parma
Tel : +39 0521 036
Fax : +39 0521 036 0

<http://www.efsa.europa.eu><<http://www.efsa.europa.eu>>
twitter.com/EFSA_EU<[http://twitter.com/EFSA_EU](https://twitter.com/EFSA_EU)> [cid:image002.jpg@01D0FA0E.89770830]
[youtube.com/EFSAchannel](https://www.youtube.com/EFSAchannel)<[http://youtube.com/EFSAchannel](https://www.youtube.com/EFSAchannel)> [cid:image003.jpg@01D0FA0E.89770830]

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Von: [@efsa.europa.eu](mailto:efsa.europa.eu)>
An:
CC: @bfr.bund.de>; Roland Soleck
@efsa.europa.eu
Betreff: Glyphosate - TC 117 meeting report
Anlagen: Report Pesticides Peer Review TC 117 Glyphosate 2015-09-29(final).docx

Dear,

Please find the final report of the Pesticides Peer Review TC 117 attached. There is no homework for the RMS.

The file is as well available on EFSA's DMS:

<https://dms.efsa.europa.eu/otcs/cs.exe?func=11&objId=14622742&objAction=browse&viewType=1>

Best regards

Pesticides / Regulated Products

[Description: EFSA Logo_EN_CMYK]

Via Carlo Magno 1A

43126 Poma (Italy)

Tel. +39 0521 036

www.efsa.europa.eu <<http://www.efsa.europa.eu/>>

twitter.com/EFSA_EU <http://twitter.com/EFSA_EU> [Description: Twitterlogo_blue] <https://twitter.com/efsa_eu>

youtube.com/EFSAchannel <<http://youtube.com/EFSAchannel>> [Description: YouTube-logo-full_color] <<http://youtube.com/EFSAchannel>>

Von: @efsa.europa.eu>
An:
CC: @bfr.bund.de>; Roland Solecki
@efsa.europa.eu @efsa.europa.eu>
Betreff: Glyphosate - TC 117 meeting report
Anlagen: Report Pesticides Peer Review TC 117 Glyphosate 2015-09-29(final).docx

Dear,

Please find the final report of the Pesticides Peer Review TC 117 attached. There is no homework for the RMS.

The file is as well available an EFSA's DMS:

<https://dms.efsa.europa.eu/otcs/cs.exe?func=11&objId=14622742&objAction=browse&viewType=1>

Best regards

Pesticides / Regulated Products

[Description: EFSA logo_EN_CMYK]

Via Carlo Magno 1A

43126 Parma (Italy)

Tel. +39 0521 036

www.efsa.europa.eu <<http://www.efsa.europa.eu>>

twitter.com/EFSA_EU <[http://twitter.com/EFSA_EU](https://twitter.com/EFSA_EU)> [Description: Twitter_logo_blue] <https://twitter.com/efsa_eu>

youtube.com/EFSAchannel <<http://youtube.com/EFSAchannel>> [Description: YouTube-logo-full_color] <<http://youtube.com/EFSAchannel>>

Von: @efsa.europa.eu>
An: @bfr.bund.de>
CC: @efsa.europa.eu >; Solecki Roland<Roland.Solecki@bfr.bund.de >; @bfr.bund.de >
Betreff: RE: Teleconference on Friday 27. November at 14.30

Dear

Thank you for your email.

I would like to inform you that as we are connecting via teleconference other participants, it would be easier for us to call all the attendees.

We will ensure to contact , and _ " " at the number you indicated below.

Best regards,

Head of Scientific Evaluation of Regulated Products Department (a.i.)

Via Carlo Magno 1A
43126 Parma (Italy)
Tel. +39 0521 036
www.efsa.europa.eu
twitter.com/EFSA_EU
youtube.com/EFSAchannel

Original Message

From: [mailto: @bfr.bund.de]
Sent: 25 November 2015 14:50
To: @efsa.europa.eu
Cc: Solecki Roland;
Subject: Teleconference on Friday 27. November at 14.30

Dear

on behalf of Dr. Solecki and I share the telephone number of the BfR for the teleconference on Friday.
The number is: +49 30 18412

Participants directly from the BfR. are:

Off course we can also call you, if you prefer.

Best regards
on behalf

Bundesinstitut für Risikobewertung
Abteilung Sicherheit von Pestiziden

Federal Institute for Risk Assessment
Department Pesticide Safety
Max-Dohrn-Str. 8-10, 10589 Berlin, Germany
Tel: + 49 30 18412-
www.bfr.bund.de
@bfr.bund.de

Von: @bfr.bund.de
An: @efsa.europa.eu
CC: Solecki, Roland;
Datum: 27.11.2015 11:49
Betreff: Glyphosat - CLH-Dossier
Anlagen: CLH_Glyphosat_BfR_2015-11-24.doc

Liebe

wie mit Hr. Dr. Solecki am Dienstag den 24.11.2015 besprochen, zur Information in Anlage beigefügt das CLH-Dossier zu Glyphosat.

Viele Grüße,

Bundesinstitut für Risikobewertung
Abteilung Sicherheit von Pestiziden

Federal Institute for Risk Assessment
Unit Steering and Overall Assessment - Plant Protection
Department Safety of Pesticides

Max-Dohrn-Straße 8-10, 10589 Berlin, Germany
Tel. +49 30 18412-
Fax +49 30 18412-
www.bfr.bund.de
@bfr.bund.de

Von: @efsa.europa.eu >
An: Roland Solecki (Roland.Solecki@bfr.bund.de)<Roland.Solecki@bfr.bund.de >;
Betreff: FW: EFSA Glyphosate Recommendations
Anlagen: EFSA-Glyphosate-Letter.pdf; ATT000öl.htm

Dear both

Thanks for the very good conversation. As promised here is the open letter by C. Portier on Glyphosate sent today to the Commissioner
Best wishes

European Food Safety Authority

Tel: +39 0521 036
@efsa.europa.eu <mailto: @efsa.europa.eu >

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From: On Behalf Of
Sent: 27 November 2015 10:08
To: @efsa.europa.eu <mailto: @efsa.europa.eu >
Subject: FW: EFSA Glyphosate Recommendations

For your consideration

From: Chris Portier [mailto:cportier@me.com] <mailto:mailto:cportier@me.comi >
Sent: 27 November 2015 09:57
To: CAB ANDRIUK AMS WEBPAGE; ANDRIUKAITIS Vyterii
Cc: URL Bernhard, ; @europarl.europa.eu <mailto: @europarl.europa.eu >, geuroparl.europa.eu,
leitung@bfr.bund.de <mailto:leitung@bfr.bund.de >, Director@iarc.fr <mailto:Directoraiarc.fr>;
Jones.jim@Epa.gov <mailto:Jones.jim@Epa.gov>; EFSA PESTICIDES PPR
poststelle@bmel.bund.de <mailto:poststelle@bmel.bund.de >; poststelle@bvl.bund.de <mailto:poststelle@bvl.bund.de >;
helmut.tschiersky@bvl.bund.de <mailto:helmut.tschiersky@bvl.bund.de >
Subject: EFSA Glyphosate Recommendations

Dear Commissioner Andriukaitis,

Attached to this email is a letter from 96 prominent epidemiologists, toxicologists, statisticians and molecular biologists from 25 countries. We have banded together and write to you at this time to express our deep concern over the recent European Food Safety Agency (EFSA) decision that the widely used herbicide, glyphosate "is unlikely to pose a carcinogenic hazard to humans." We ask that you read our letter and share it with those who will be advising you on accepting or rejecting EFSA's decision. We would greatly appreciate your sharing this with the members of the Standing Committee on Plants, Animals, Food and Feed before their next meeting on December 10, 2015. I will be in Brussels from November 30 to December 3. It would be helpful for me to discuss these concerns with you or your staff in person, please send email to this address or call

Thank you for your attention to this important issue.

Sincerely,

Prof. Christopher J. Portier

cc: Mr. Phil Hogan, European Commissioner for Agriculture and Human Development
Dr. Ladislav Miko, Deputy Director-General, DG Health & Food Safety
Dr. Bernhard Uri, Executive Director, EFSA
Dr. Giovanni La Via, Chair, ENVI Committee
EFSA Panel on Plant Protection Products and their Residues
Mr. Christian Schmidt, Minister of Food and Agriculture<https://en.wikipedia.org/wiki/Federal_Ministry_of_Food_and_Agriculture>
Dr. Helmut Tschiersky, President of the Federal Office of Consumer Protection and Food Safety (BVL)
Professor Dr. Dr. Andreas Hensel, President, BFR
Dr. Christopher Wild, Director, IARC
Mr. Jim Jones, Assistant Administrator, USEPA

Von: @efsa.europa.eu >
An: Solecki Roland <Roland.Solecki@bfr.bund.de >
CC: @bfr.bund.de>; @bfr.bund.de>; @efsa.europa.eu>, @efsa.europa.eu>;
@efsa.europa.eu>
Betreff: Teleconference on Friday 27. November at 14.30
Anlagen: ENVI Notes ldec15.docx

Dear Roland, dear all,
Please find attached the draft speaking notes for Bernhard Url and Jose Tarazona for the ENVI Committee meeting -exchange of views on glyphosate-, 1 December 2015

We are looking forward to our tele conference this afternoon
With my best wishes

European Food Safety Authority

Tel: +39 0521 036

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- - Original Message - -

From: Solecki Roland [mailto:Roland.Solecki@bfr.bund.de]

Sent: 25 November 2015 17:25

To: @efsa.europa.eu <mailto: @efsa.europa.eu>

[Cc:@bfr.bund.de](mailto:Roland.Solecki@bfr.bund.de), @efsa.europa.eu <mailto: @efsa.europa.eu>

Subject: Re: Teleconference on Friday 27. November at 14.30

I will participate on the phone Number 4
Kind regards from Brasilia
Roland

Von meinem iPad gesendet

Am 25.11.2015 um 12:27 schrieb
@efsa.europa.eu>:

Dear

Thank you for your email.

I would like to inform you that as we are connecting via teleconference other participants, it would be easier for us to call all the attendees.
We will ensure to contact at the number you indicated below.

Best regards,

Scientific Evaluation of Regulated Products Department (a.i.)

Via Carlo Magno 1A
43126 Parma (Italy)
Tel. +39 0521 036 698

www.efsa.europa.eu
twitter.com/EFSA_EU
youtube.com/EFSAchannel

- - -Original Message - - -

From: [mailto: @bfr.bund.de]
Sent: 25 November 2015 14:50
To: @efsa.europa.eu <mailto: @efsa.europa.eu >
Cc: Solecki Roland Subject: Teleconference on Friday 27. November of 14.30

Dear

on behalf of Dr. Solecki and I share the telephone number of
the BfR for the teleconference on Friday.
The number is: +49 30 18412

Participants directly from the BfR are:

Off course we can also call you, if you prefer.

Best regards
on behalf

Bundesinstitut für Risikobewertung

Abteilung Sicherheit von Pestiziden

Federal Institute for Risk Assessment

Department Pesticide Safety
Max-Dohrn-Str. 8-10, 10589 Berlin, Germany
Tel: + 49 30 18412-
www.bfr.bund.de
@bfr.bund.de

Von: @efsa.europa.eu>
An: @bfr.bund.de>
CC: Solecki Roland<Roland.Solecki@bfr.bund.de>
Betreff: RE: Antw: Teleconference on Friday 27. November at 14.30

Vielen herzlichen Dank . Sehr nützlich
Ihre

European Food Safety Authority
Scientific Evaluation of Regulated Products Department (a.i.)
Tel: +39 0521
@efsa.europa.eu

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- - Original Message - -

From: [mailto: @bfr.bund.de]
Sent: 27 November 2015 10:32
To: @efsa.europa.eu <mailto: @efsa.europa.eu>
Cc: Solecki Roland
Subject: Antw: Teleconference on Friday 27. November at 14.30

Dear

Please find attached our comment on the assessment of the epi studies on glyphosate which might be helpful for the tele-conference this afternoon.

Best regards,

>>> @efsa.europa.eu> 27.11.2015 10:11
>>>

Dear Roland, dear all,
Please find attached the draft speaking notes for Bernhard Url and Jose Tarazona for the ENVI Committee meeting -exchange of views on glyphosate-, 1 December 2015

We are looking forward to our tele conference this afternoon With my best wishes

European Food Safety Authority
Evaluation of Regulated Products Department (a.i.)
Tel: +39 0521
@efsa.europa.eu

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- - Original Message - -

From: Solecki Roland [mailto:Roland.Solecki@bfr.bund.de]
Sent: 25 November 2015 17:25

To: <mailto: @efsa.europa.eu >
Cc: @bfr.bund.de, @efsa.europa.eu
Subject: Re: Teleconference on Friday 27. November at 14.30

I will participate on the phone Number +49 .
Kind regards from Brasilia
Roland

Von meinem iPad gesendet

Am 25.11.2015 um 12:27 schrieb
@efsa.europa.eu>:

Dear
Thank you for your email.
I would like to inform you that as we are connecting via teleconference other participants, it would be easier for us to call all the attendees.
We will ensure to contact at the number you indicated below.

Best regards,

Scientific Evaluation of Regulated Products Department (a.i.)

Via Carlo Magno 1A
43126 Parma (Italy)
Tel. +39 0521 036
www.efsa.europa.eu
twitter.com/EFSA_EU
youtube.com/EFSAchannel

- - -Original Message - - -

From: [mailto: @bfr.bund.de]
Sent: 25 November 2015 14:50
To: @efsa.europa.eu <mailto: @efsa.europa.eu >
Cc: Solecki Roland;
Subject: Teleconference on Friday 27. November at 14.30

Dear

on behalf of Dr. Solecki and I share the telephone number of
the BfR for the teleconference on Friday.
The number is: +49 30 18412

Participants directly from the BfR are:

Off course we can also call you, if you prefer.

Best regards
on behalf

Bundesinstitut für Risikobewertung

Abteilung Sicherheit von Pestiziden

Federal Institute for Risk Assessment
Department Pesticide Safety
Max-Dohrn-Str. 8-10, 10589 Berlin, Germany
Tel: + 49 30 18412-
www.bfr.bund.de
@bfr.bund.de

Dear Member State Representative,

As you are aware, EFSA is subject to progressive standards requiring it to be open and transparent, and communicate both with the general public and interested parties.

This is to ask your individual authorisation as data subject under Regulation (EC) No 45/2001 to share with the concerned interested parties and with the public the information that you represented your administration in the context of the experts meetings organised by EFSA in the context of the peer review of the assessment of Glyphosate.

I would be most grateful if you could let me have your agreement on the above not later than 14 December 2015.

Please note that in the absence of an explicit and positive reply from your side EFSA will not be in a position to make this information public.

Yours sincerely,

**Legal and Regulatory Affairs Unit
Resources & Support Department**

[illegible]

**Via Carlo Magno 1A
43126 Parma (Italy)
Tel. +39 0521 036**

www.efsa.europa.eu <http://www.efsa.europa.eu>
twitter.com/EFSA_EU <http://twitter.com/EFSA_EU> [Description: Description: Description: Description: Description: Description: Description:
cid:image002.jpg@01D03EF5.E2296E20]
youtube.com/EFSAchannel <http://youtube.com/EFSAchannel> [Description: Description: Description: Description: Description: Description: Description:
Description: cid :image003.jpg@01D03EF5.E2296E20]

From: @bvl.bund.de>
Sent: 05 May 2015 17:38
To:
Subject: AW: Glyphosate - Comment RMS DE on the issue of indirect effects via tropic interactions

Hallo

nur eine kurze Rückmeldung zum Sachstand.

UBA hat sich noch nicht gemeldet, wie kurzfristig sie die benötigte Info ergänzen können.

Meine Holde weilt derzeit in Barcelona und besucht die SETAC Conference und kann nichts dazu beitragen.

Ich halte dich auf dem Laufenden.

Gruß

-----Ursprüngliche Nachricht-----

Von: [mailto:] @efsa.europa.eu]

Gesendet: Freitag, 30. Januar 2015 13:38

An:

Cc: V. [mailto:]

Betreff: RE: Glyphosate - Comment RMS DE on the issue of indirect effects via tropic interactions

Dea and [mailto:]

Sorry for the delayed answer. We have discussed your proposal internally and agreed to take the issue on indirect effects on biodiversity into consideration under the general discussion points for the Pesticides Peer Review Meeting 128.

I hope this addresses your concerns.

Have a nice and relaxing weekend.

Best regards

Pesticides Unit
European Food Safety Authority - EFSA

Via Carlo Magno 1/a
I-43126 Parma
Tel: +39 0521 036
Fax: +39 0521 036
Email: [@efsa.europa.eu](mailto:)
Website: <http://www.efsa.europa.eu>

-----Original Message-----

From: [mailto:] @bvl.bund.de]
Sent: 22 December 2014 08:23

To: EFSA PESTICIDES PEER REVIEW

Cc:

Subject: Glyphosate - Comment RMS DE on the issue of indirect effects via trophic interactions

Dear colleagues,

please find attached a comment from Germany as RMS for glyphosate suggesting to discuss the issue of indirect effects on non-target organisms at higher trophic level in a Pesticides Peer Review Experts' meeting.

I would appreciate if EFSA could reconsider the decision taken in the reporting table not to discuss this issue.

Finally I would like to wish you all a Merry Christmas and a Happy New Year!

Best regards

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
- Abteilung Pflanzenschutzmittel -
Messeweg 11/12
D-38104 Braunschweig

eMail: vl.bund.de
Fon: ++49-(0)531-299
Fax: ++49-(0)531-299
<http://www.bvl.bund.de>

Löst Glyphosat Krebs aus?

Mitteilung 007/2015 des BfR vom 23. März 2015

Der Pflanzenschutzmittelwirkstoff Glyphosat ist von den für die gesundheitliche Bewertung zuständigen nationalen, europäischen und anderen internationalen Institutionen einschließlich des WHO/FAO Joint Meeting on Pesticide Residues (JMPR) nach Prüfung aller vorliegenden Studien als nicht krebserzeugend bewertet worden.

Auf einer Sitzung der Internationalen Agentur für Krebsforschung (IARC) der Weltgesundheitsorganisation WHO im März 2015 in Lyon haben nun dort versammelte Experten Glyphosat auf Basis der ihnen zur Verfügung stehenden Studien andersartig eingestuft, nämlich als Kanzerogen Gruppe 2A, also wahrscheinlich krebserzeugend für den Menschen. Diese Einstufung wurde in einem kurzen Bericht in der Zeitschrift „Lancet“ am 20. März 2015 veröffentlicht. Das Bundesinstitut für Risikobewertung (BfR) kommentiert als Berichterstatter für den Wirkstoff Glyphosat im Zuge der EU-Neuevaluation diese Einstufung durch die IARC auf Basis des veröffentlichten Kurzberichts.

17 Experten aus 11 Ländern haben sich im März 2015 in der „International Agency for Research on Cancer“ (IARC; Lyon, France) getroffen, um die krebserzeugende bzw. potentiell krebserzeugende Wirkung von 4 Organophosphaten und Glyphosat zu bewerten, die alle von den zuständigen Europäischen Institutionen weder als kanzerogen noch als mutagen eingestuft sind.

In der Publikation vom 20. März 2015 in der Zeitschrift „Lancet“ ist die Einstufung von Glyphosat als Kanzerogen Gruppe 2A (probably carcinogenic to humans, wahrscheinlich krebserzeugend für den Menschen) für das BfR auf Basis der vorliegenden Informationen wissenschaftlich schlecht nachvollziehbar und offenbar nur mit wenigen Studien belegt. Die Entscheidung der IARC kann jedoch nicht abschließend beurteilt werden, da die finale IARC-Monographie, in der die Entscheidung ausführlicher begründet werden wird, noch nicht vorliegt.

Die jetzt publizierte IARC-Einstufung basiert zum einen auf Anhaltspunkten für kanzerogene Wirkung in Studien am Menschen, d.h. einem statistischen Zusammenhang zwischen Glyphosatexposition und einem erhöhten Risiko für Non-Hodgkin Lymphome. Dieses Risiko wird aus drei epidemiologischen Studien aus den USA, Kanada und Schweden abgeleitet. Allerdings wurde diese Einschätzung in einer sehr großen Kohorte der ebenfalls zitierten „Agricultural Health Study“ sowie weiteren Studien nicht bestätigt. Im aktuellen Bericht des BfR an die EU wurden jedoch über 30 epidemiologische Studien ausgewertet. In der Gesamteinschätzung ergab sich kein gesicherter Zusammenhang zwischen Glyphosatexposition und einem erhöhten Risiko für Non-Hodgkin Lymphome oder andere Krebsarten.

Zum anderen führt die IARC Befunde aus tierexperimentellen Studien als Beleg für eine kanzerogene Wirkung von Glyphosat auf. Alle diese Befunde wurden ebenfalls in den Glyphosat-Bewertungen des BfR, der EU-Institutionen und dem für die Bewertung von Pestizidwirkstoffen zuständigen Joint Meeting on Pesticide Residues (JMPR) der FAO/WHO berücksichtigt. Diese Gremien sind zur Gesamtschlussfolgerung gekommen, dass Glyphosat nicht kanzerogen ist. Dem BfR ist nicht bekannt, wie viele der 11 vom BfR als valide eingeschätzten Langzeitstudien an Ratten und Mäusen dem IARC vorgelegen haben.

Auch die in einer Studie postulierte Förderung von Hauttumoren durch eine hochkonzentrierte, hautreizende Formulierung mit dem Wirkstoff wurde von den Institutionen in der EU nicht als Beleg für kanzerogene Eigenschaften von Glyphosat betrachtet.

Die Anhaltspunkte für ein genotoxisches Potential von Glyphosat können aus dem von der IARC veröffentlichten Kurzbericht nicht nachvollzogen werden, zumal auch hier Studien mit nicht näher spezifizierten Formulierungen in die Bewertung einbezogen wurden.

Dass verschiedene Gremien aufgrund unterschiedlicher Informationen und Einschätzungen von experimentellen Daten Sachverhalte unterschiedlich bewerten, gehört zum Alltag in der Risikobewertung. Das BfR wird die von der IARC vorgenommene Einstufung nach dem Vorliegen der Monografie gründlich prüfen.

From: (
Sent: 26 March 2015 17:24
To:
Cc:
Subject: Glyphosat - BfR to publish English news story
Attachments: eng-20150323 Glyphosat und Krebs-final_2.docx

Dears,

Please find in attachment the English news story regarding glyphosate and the IARC classification as it will be published on the BfR's website.

Best,

,

-----Original Message-----

From: [mailto: info@bfr.bund.de]
Sent: 26 March 2015 16:36
To:
Cc:
Subject: Glyphosat

Hallo

wir werden der EFSA ein Addendum zum DAR senden, in dem die IARC Einstufung kommentiert wird. Wir warten aber auf die Monografie, denn aus dem zweiseitigen Lancet-Bericht lässt sich nichts entnehmen. Das haben wir in unserem Text auf der BfR Homepage am Montag auch so gesagt.
Ich schicke noch eine Text , der auf unserer englischen Homepage veröffentlicht wird.

Mit freundlichen Grüßen

1000



Does glyphosate cause cancer?

BfR Communication, 23 March 2015

In its recent evaluation from March 2015, the International Agency for Cancer Research (IARC), as the specialized cancer agency of the World Health Organization (WHO), came to the conclusion that glyphosate should now be classified as a carcinogenic substance in Group 2A (probably carcinogenic to humans), based on "limited evidence" in human-experiments and "sufficient evidence" in animal-experiments. This classification was published in a short report in the "Lancet" journal on 20 March 2015.

As the "Rapporteur Member State" for the active substance glyphosate within the framework of EU re-evaluation, the Federal Institute for Risk Assessment (BfR) was responsible for the human health risk assessment and has assessed glyphosate as non-carcinogenic. This was supported by competent national, European and other international institutions for health assessment including the WHO/FAO Joint Meeting on Pesticide Residues (JMPR). BfR is therefore issuing its comments on this classification by IARC based on the published short report.

The International Agency for Research on Cancer (IARC) is the specialized cancer agency of the World Health Organization. The main objective of the IARC is to promote international collaboration in cancer research. The evaluations of carcinogenic risk are made by international working groups of independent scientists and are qualitative in nature. No recommendation is given for regulation or legislation. For this reason, 17 experts from 11 countries met at the International Agency for Research on Cancer (IARC; Lyon, France) in March 2015 in order to assess the carcinogenic or potentially carcinogenic effects of 4 organophosphates and glyphosate. The working group classified glyphosate as "probably carcinogenic to humans". This assessments will be published as volume 112 of the IARC Monographs.

In the opinion of BfR, the classification of glyphosate as "carcinogenic in Group 2A" (probably carcinogenic to humans) as published in the 20 March 2015 issue of the "Lancet" journal comes as a surprise, since other evaluations performed by supranational bodies such as the EFSA (2014, confirmed in an expert meeting in February, 2015), and the JMPR of WHO and FAO (JMPR, 2004), and also by national regulatory agencies such as the U.S.EPA had concluded the contrary, i.e., that glyphosate was not carcinogenic. Unfortunately, the database on which the IARC evaluation is based is not known, since a background monograph that is usually produced by IARC following the evaluation meetings has not yet been released. Therefore, a comprehensive and scientifically sound consideration of the data and arguments that led to the IARC- conclusion is simply not possible at the moment.

In addition, Germany is the "Rapporteur Member State" in the ongoing re-evaluation process of glyphosate in the EU. For this purpose, an extensive "Renewal Assessment Report" (RAR) was provided in 2013 and has been revised in 2014 and again in 2015. The 2013 report was circulated by EFSA to the EU Member States and was made available for public consultation in 2014. Revisions were made to take into account the several hundred comments and remarks. The toxicological and residue chapters of the report have been prepared by the Federal Institute for Risk Assessment (BfR). For this purpose, we have compiled the most comprehensive toxicological database, presumably worldwide, for glyphosate. This database comprises hundreds of studies that were performed by or on behalf of the many manufacturers of glyphosate and thousands of references from the open literature. This huge amount of data makes glyphosate nearly unique among the active substances in plant protection products. We think that the entire database must be taken into account for toxicological evalua-

tion and risk assessment of a substance and not merely a more or less arbitrary selection of studies.

In the absence of more reliable information from IARC, BfR has tried to allocate the findings that are mentioned in the brief "Lancet" publication to certain studies in our database and, by doing that, to put them into perspective.

The new IARC classification for glyphosate as a carcinogenic substance is based firstly on "limited evidence" in humans. This risk is derived from three epidemiological studies in the USA, Canada and Sweden based on a statistical correlation between exposure to glyphosate and an increased risk of non-Hodgkin lymphoma. However, this assessment was not confirmed in a very large cohort of the also cited "Agricultural Health Study" or in other studies. A recent publication from 2012 has reviewed the epidemiologic literature to evaluate whether exposure to glyphosate is associated causally with cancer risk in humans and the relevant methodological and biomonitoring studies of glyphosate. The review found non-consistent patterns of positive associations indicating a causal relationship between total cancer or any site-specific cancer and exposure to glyphosate. The current report of the BfR to the EU based on the evaluation of over 30 epidemiological studies came to the overall assessment that there is no validated or significant relationship between exposure to glyphosate and an increased risk of non-Hodgkin lymphoma or other types of cancer.

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Secondly, IARC points to findings of studies based on animal experiments submitted by the producers of glyphosate as evidence for the carcinogenic effect of glyphosate. All these findings were also considered in the glyphosate assessments of the BfR, which did support the conclusion of the Joint Meeting on Pesticide Residues (JMPR) of the FAO/WHO responsible for the assessment of active substances in pesticides: "In view of the absence of a carcinogenic potential in animals and the lack of genotoxicity in standard tests, the Meeting concluded that glyphosate is unlikely to pose a carcinogenic risk to humans". The BfR does not have any information as to how many of the 11 long-term studies on rats and mice that were assessed as valid were available to IARC.

Moreover, IARC concluded that a glyphosate formulation promoted skin tumours. In general, testing of formulations should not be used for toxicological evaluation of active substances because co-formulants may alter the outcome to a large extent. Therefore, the claim, based on this 2-stage cancer model in mice, that a highly concentrated, skin-irritating formulation containing the active substance promotes skin tumours is not considered by the institutions in the EU to be evidence for the carcinogenic properties of glyphosate.

It is not possible to fully examine the indications for the genotoxic potential of glyphosate based on the short report published by IARC, in particular due to the fact that the assessment included studies using formulations that are not specified in any detail.

The fact that different bodies assess issues differently due to differing information and assessments of experimental data is part and parcel of the risk assessment process. The BfR will therefore perform a thorough review of the classification issued by IARC once the monograph becomes available.

From: bs@bvl.bund.de
Sent: 25 March 2015 14:01
To:
Subject: Glyphosat - IARC-Einstufung - Erste BfR-Stellungnahme

Hallo

mehr zu deiner Information, da leider nur in Deutsch, hier ein Link auf die BfR-Homepage in besagter Sache.

<http://www.bfr.bund.de/cm/343/loest-glyphosat-krebs-aus.pdf>

Gruß aus dem frühlingshaften BS



Löst Glyphosat Krebs aus?

Mitteilung 007/2015 des BfR vom 23. März 2015

Der Pflanzenschutzmittelwirkstoff Glyphosat ist von den für die gesundheitliche Bewertung zuständigen nationalen, europäischen und anderen internationalen Institutionen einschließlich des WHO/FAO Joint Meeting on Pesticide Residues (JMPR) nach Prüfung aller vorliegenden Studien als nicht krebserzeugend bewertet worden.

Auf einer Sitzung der Internationalen Agentur für Krebsforschung (IARC) der Weltgesundheitsorganisation WHO im März 2015 in Lyon haben nun dort versammelte Experten Glyphosat auf Basis der ihnen zur Verfügung stehenden Studien andersartig eingestuft, nämlich als Kanzerogen Gruppe 2A, also wahrscheinlich krebserzeugend für den Menschen. Diese Einstufung wurde in einem kurzen Bericht in der Zeitschrift „Lancet“ am 20. März 2015 veröffentlicht. Das Bundesinstitut für Risikobewertung (BfR) kommentiert als Berichterstatter für den Wirkstoff Glyphosat im Zuge der EU-Neuevaluation diese Einstufung durch die IARC auf Basis des veröffentlichten Kurzberichts.

17 Experten aus 11 Ländern haben sich im März 2015 in der „International Agency for Research on Cancer“ (IARC; Lyon, France) getroffen, um die krebserzeugende bzw. potentiell krebserzeugende Wirkung von 4 Organophosphaten und Glyphosat zu bewerten, die alle von den zuständigen Europäischen Institutionen weder als kanzerogen noch als mutagen eingestuft sind.

In der Publikation vom 20. März 2015 in der Zeitschrift „Lancet“ ist die Einstufung von Glyphosat als Kanzerogen Gruppe 2A (probably carcinogenic to humans, wahrscheinlich krebserzeugend für den Menschen) für das BfR auf Basis der vorliegenden Informationen wissenschaftlich schlecht nachvollziehbar und offenbar nur mit wenigen Studien belegt. Die Entscheidung der IARC kann jedoch nicht abschließend beurteilt werden, da die finale IARC-Monographie, in der die Entscheidung ausführlicher begründet werden wird, noch nicht vorliegt.

Die jetzt publizierte IARC-Einstufung basiert zum einen auf Anhaltspunkten für kanzerogene Wirkung in Studien am Menschen, d.h. einem statistischen Zusammenhang zwischen Glyphosatexposition und einem erhöhten Risiko für Non-Hodgkin Lymphome. Dieses Risiko wird aus drei epidemiologischen Studien aus den USA, Kanada und Schweden abgeleitet. Allerdings wurde diese Einschätzung in einer sehr großen Kohorte der ebenfalls zitierten „Agricultural Health Study“ sowie weiteren Studien nicht bestätigt. Im aktuellen Bericht des BfR an die EU wurden jedoch über 30 epidemiologische Studien ausgewertet. In der Gesamteinschätzung ergab sich kein gesicherter Zusammenhang zwischen Glyphosatexposition und einem erhöhten Risiko für Non-Hodgkin Lymphome oder andere Krebsarten.

Zum anderen führt die IARC Befunde aus tierexperimentellen Studien als Beleg für eine kanzerogene Wirkung von Glyphosat auf. Alle diese Befunde wurden ebenfalls in den Glyphosat-Bewertungen des BfR, der EU-Institutionen und dem für die Bewertung von Pestizidwirkstoffen zuständigen Joint Meeting on Pesticide Residues (JMPR) der FAO/WHO berücksichtigt. Diese Gremien sind zur Gesamtschlussfolgerung gekommen, dass Glyphosat nicht kanzerogen ist. Dem BfR ist nicht bekannt, wie viele der 11 vom BfR als valide eingeschätzten Langzeitstudien an Ratten und Mäusen dem IARC vorgelegen haben.

Auch die in einer Studie postulierte Förderung von Hauttumoren durch eine hochkonzentrierte, hautreizende Formulierung mit dem Wirkstoff wurde von den Institutionen in der EU nicht als Beleg für kanzerogene Eigenschaften von Glyphosat betrachtet.

Die Anhaltspunkte für ein genotoxisches Potential von Glyphosat können aus dem von der IARC veröffentlichten Kurzbericht nicht nachvollzogen werden, zumal auch hier Studien mit nicht näher spezifizierten Formulierungen in die Bewertung einbezogen wurden.

Dass verschiedene Gremien aufgrund unterschiedlicher Informationen und Einschätzungen von experimentellen Daten Sachverhalte unterschiedlich bewerten, gehört zum Alltag in der Risikobewertung. Das BfR wird die von der IARC vorgenommene Einstufung nach dem Vorliegen der Monografie gründlich prüfen.

From: info@bvl.bund.de
Sent: 02 April 2015 10:25
To:
Cc:
Subject: Glyphosate - RMS homework after the PPR expert meetings and preliminary statement on IARC classification
Attachments: Preliminary assessment of the carcinogenic risk of glyphosate with regard to the recent IARC evaluation_BfR.docx

Dear colleagues,

with this E-Mail I would like to inform you that we have now uploaded our RMS homework from the Pesticides Peer Review experts' meetings for glyphosate to the confidential dropbox on the EFSA DMS.

Volume 1 and Volume 3, Sections B.6, B.7, B.8 and B.9 of the RAR have been revised as well as the LoEP.

The evaluation tables for the respective sections 2, 3, 4 and 5 have been amended accordingly.

In addition, for your information, please find attached to this E-Mail a preliminary assessment from our BfR colleagues concerning the on-going discussion on the carcinogenic risk of glyphosate with regard to the recent IARC evaluation.

Finally, I would like to wish everyone a recreative easter break.

Best regards

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
- Abteilung Pflanzenschutzmittel -
Messeweg 11/12
D-38104 Braunschweig

eMail: info@bvl.bund.de
Fon: ++49-(0)531-299
Fax: ++49-(0)531-299
<http://www.bvl.bund.de>

-----Ursprüngliche Nachricht-----

Von: [\[mailto:info@bvl.bund.de\]](mailto:info@bvl.bund.de)
Gesendet: Dienstag, 10. März 2015 14:27
An:
Cc:
Betreff: Glyphosate- evaluation tables updated after the PPR expert meetings

Dear

Please find enclosed the evaluation tables (sections 2-5) for the AIR II substance glyphosate for which Germany is the RMS. The evaluation tables have been updated following the discussion of the active substance at the Pesticides Peer Review experts' meetings 125 (mammalian toxicology), 126 (fate), 127 (residues) and 128 (ecotoxicology). The relevant meeting reports are also attached for easier reference.

As RMS 'homework', you are now kindly requested to fulfil the remaining open points and prepare updated documentation as appropriate and to revise the list of end points where necessary. Please kindly consider the change in the toxicological reference values also in section 3 where relevant.

In order to make any new changes in the list of end points distinguishable from previous modifications they should be highlighted with a different colour than used before.

In order for EFSA to prepare the draft conclusion, please upload the revised documents (revised evaluation tables, list of endpoints and revised DAR if applicable) by the deadline of 24 March 2015 at the latest in the RMS dropbox (add link to the DMS folder). Considering the tight timelines in the upcoming steps of the procedure we would appreciate if the updated documents could be submitted on time.

Thank you in advance for your cooperation and support.

Kind regards,

European Food Safety Authority
Pesticide Risk Assessment Peer Review (PRAPeR)

Via Carlo Magno 1A
I-43126 Parma
Tel: +39 0521 036
Fax: +39 0521 036
Email: efsa.europa.eu
Website: <http://www.efsa.europa.eu>

Does glyphosate cause cancer?

Preliminary assessment of the carcinogenic risk of glyphosate with regard to the recent IARC evaluation

BfR Communication, 1st April 2015

As "Rapporteur Member State", Germany is responsible for the scientific assessment of the active substance glyphosate in the framework of EU re-evaluation. Within Germany the Federal Institute for Risk Assessment (BfR) is the competent authority for the human health risk assessment and is therefore issuing comments on the classification of glyphosate by IARC as "probably carcinogenic to humans" (Group 2A) based on the short report as published in the 20 March 2015 issue of the "Lancet" journal. [1,2]

Preface

The International Agency for Research on Cancer (IARC) is the specialized cancer agency of the World Health Organization (WHO). The main objective of the IARC is to promote international collaboration in cancer research. The evaluations of carcinogenic risk are made by international Working Groups of independent scientists and are qualitative in nature. The *Monographs* Programme provides scientific evaluations based on a comprehensive review of the scientific literature, but it remains the responsibility of individual governments and other international organizations to recommend regulations, legislation, or public health intervention. [1] IARC communications are not understood as basis for regulatory purposes [3].

The established procedure for *Monographs* evaluations is described in the Programme's Preamble. The *Monographs* represent the first step in carcinogen risk assessment, which involves examination of all relevant information in order to assess the strength of the available evidence that an agent could alter the age-specific incidence of cancer in humans. The *Monographs* may also indicate where additional research efforts are needed, specifically when data immediately relevant to an evaluation are not available. Evaluations are performed by panels of international experts, selected on the basis of their expertise. [1]

For Volume 112, a Working Group of 17 experts from 11 countries met at IARC on 3–10 March 2015 to assess the carcinogenicity of **tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate**. The in-person meeting followed nearly a year of review and preparation by the IARC secretariat and the Working Group, including a comprehensive review of the latest available scientific evidence. [1]

The Working Group classified the herbicide **glyphosate** as "probably carcinogenic to humans" (Group 2A). This category is used when there is *limited evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals. *Limited evidence of carcinogenicity* means that a positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence. *Sufficient evidence of carcinogenicity* means, that the Working Group considers that a causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (a) two or more species of animals or (b) two or more independent studies in one species carried out at different times or in different laboratories or under different protocols. [1]

The classification of glyphosate as "probably carcinogenic to humans" (Group 2A) was published in the 20 March 2015 issue of the "Lancet" journal [2] and is in contrast to other evaluations performed by supranational bodies such as the WHO/FAO-Panel of the Joint Meeting of Pesticide Residues (JMPR, 2004, [4]), or by national regulatory agencies such as the United States Environmental Protection Agency (U.S. EPA, 2012, [5]) that had concluded that glyphosate was not carcinogenic. The database on which the IARC evaluation is based is at present not known, since a background monograph (Volume 112) that is usually produced by IARC following the evaluation meetings has not

yet been released. Therefore, a comprehensive and scientifically sound consideration of the data and arguments that led to the IARC - conclusion is not possible at the moment. However, the aim is to publish the monograph within six months of the Working Group meeting, including concise statements of the principal line(s) of arguments that emerged, the conclusions of the Working Group on the strength of the evidence for each group of studies, citations to indicate which studies were pivotal to these conclusions, and an explanation of the reasoning of the Working Group in weighing data and making evaluations. When there are significant differences of scientific interpretation among Working Group Members, a brief summary of the alternative interpretations is provided, together with their scientific rationale and an indication of the relative degree of support for each alternative.

In the absence of more reliable information from IARC, BfR has tried to allocate the findings that are mentioned in the brief "Lancet" publication [2] to certain studies in our database and, by doing so, to put them into perspective.

- (1) First, the new IARC classification for glyphosate as a carcinogenic substance is based on *limited evidence* in humans (see above). This risk is derived from three epidemiological studies conducted in the USA, Canada and Sweden and based on a statistical correlation between the exposure to glyphosate and an increased risk of non-Hodgkin lymphoma (NHL) [2]. These three mentioned studies are not new studies and have been evaluated before. However, in other studies based on data of the very large cohort study, the also cited "Agricultural Health Study" (AHS), no correlation between glyphosate exposure and an increased risk of NHL was observed. The current assessment report (RAR) of the BfR to the EU based on the evaluation of over 30 epidemiological studies and came to the overall conclusion that there is no validated relationship between the exposure to glyphosate and an increased risk of NHL or other types of cancer.
- (2) Second, IARC points to findings of studies based on animal experiments submitted by the producers of glyphosate as evidence for the carcinogenic effect of glyphosate. All these studies were also considered in the above mentioned assessment report (RAR) of the BfR, and thus support the conclusion of the Joint Meeting on Pesticide Residues (JMPR) of the WHO/FAO responsible for the assessment of active substances in pesticides: "*In view of the absence of a carcinogenic potential in animals and the lack of genotoxicity in standard tests, the Meeting concluded that glyphosate is unlikely to pose a carcinogenic risk to humans*" [4]. The BfR does not have any information as to how many of the 11 long-term studies on rats and mice that were assessed as valid were available to the IARC.
- (3) Third, IARC concluded that a glyphosate formulation promoted skin tumours [2]. In general, testing of formulations should not be used for toxicological evaluation of active substances because co-formulants may alter the outcome to a large extent. This principle is especially important in the case of the assessment of glyphosate because a high number of studies demonstrated a clearly higher toxicity including genotoxicity of glyphosate formulations in comparison with the active substance glyphosate. Therefore, the claim, based on this 2-stage cancer model in mice, that a highly concentrated, skin-irritating formulation containing the active substance promotes skin tumours is not considered by the institutions in the EU to be evidence for the carcinogenic properties of glyphosate.

It is not possible to fully examine the postulated indications for the genotoxic potential of the active substance glyphosate based on the brief report published by IARC [2], in particular due to the fact that the assessment included studies using formulations that are not specified in any detail.

From: [REDACTED]
To: [REDACTED]
Subject: WG: Seralini - a new piece
Date: 08 July 2015 09:33:40
Attachments: [REDACTED]

Und die neue Publikation aus der Seralini-AG.

Gruß
[REDACTED]

-----Ursprüngliche Nachricht-----

Von: Ref. 203
Gesendet: Dienstag, 7. Juli 2015 12:41
An: [REDACTED]
Betreff: WG: Seralini - a new piece

-----Ursprüngliche Nachricht-----

Von: Ref. 201
Gesendet: Dienstag, 30. Juni 2015 09:21
An: Ref. 202; Ref. 203; Ref. 204; Ref. 205; Ref. 206; Ref. 207
Cc: [REDACTED]; [REDACTED]
Betreff: WG: Seralini - a new piece

z. K.

Gruß
[REDACTED]

[REDACTED]
Referentin
Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) Abteilung Pflanzenschutzmittel
Messeweg 11-12
38104 Braunschweig

Telefon: [REDACTED]
FAX: [REDACTED]
E-Mail: [REDACTED]@bvl.bund.de
Internet: bvl.bund.de

-----Ursprüngliche Nachricht-----

Von: Abt. 2
Gesendet: Dienstag, 30. Juni 2015 09:11
An: Ref. 201
Betreff: WG: Seralini - a new piece

Bitte verteilen an Interessenten.
[REDACTED]

-----Ursprüngliche Nachricht-----

Von: Bartsch, Detlef
Gesendet: Montag, 29. Juni 2015 15:50
An: Ref. 403
Cc: Ref. 405; Abt. 2

Betreff: Seralini - a new piece

Zur info.

Der pdf des Artikels war zwischendurch mal online, aber ist inzwischen wieder weg... Es wird also noch ein wenig bis zur offiziellen Veröffentlichung dauern.

Gruß

■

From: [REDACTED]
To: EFSA PESTICIDES PEER REVIEW; [REDACTED]
Cc: [REDACTED]; [REDACTED]; BfR; Ref. 203; Ref. 202; [REDACTED]
Subject: Glyphosate - Registry of CLH intentions
Date: 23 July 2015 10:19:18
Attachments: [REDACTED]

Dear colleagues,

I would like to inform you, that the German Member State Competent Authority BAuA (Federal Institute for Occupational Safety and Health) submitted a new intention to the registry of harmonised classification and labelling intentions for the substance glyphosate (CAS No. 1071 83 6).

Please find attached a copy of the completed ROI-form as well as an accompanying E-Mail.

Best regards

[REDACTED]

[REDACTED]

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
- Abteilung Pflanzenschutzmittel -
Messeweg 11/12
D-38104 Braunschweig

eMail: [REDACTED]@bvl.bund.de

Fon: [REDACTED]

Fax: [REDACTED]

<http://www.bvl.bund.de>

From: [REDACTED]
To: [REDACTED]
Cc: BfR; UBA; [REDACTED]; [REDACTED]
Subject: Glyphosate - Draft EFSA Conclusion - Comments DE
Date: 29 July 2015 13:37:14
Attachments: [REDACTED]

Dear [REDACTED],

for your information.

I have just uploaded our RMS comments to the draft EFSA Conclusion for glyphosate.

The List of end points was updated too. I uploaded a revised version (see pages 20 and 79) in the same folder.

Thank you very much again for extending the deadline for comments by one day.

Best regards

[REDACTED]

[REDACTED]
Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
- Abteilung Pflanzenschutzmittel -
Messeweg 11/12
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Fax: [REDACTED]

<http://www.bvl.bund.de>

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]; [REDACTED]
Subject: Glyphosate (AIR 2) - Data requirements set by RMS in RAR
Date: 06 August 2014 13:40:35
Attachments: [REDACTED]

Dear [REDACTED],

please find attached an extract of Vol. 1 of the Renewal Assessment Report for glyphosate.

This chapter of Level 3 lists the data requirements already proposed in the Renewal Assessment Report by the RMS after the initial evaluation.

As just discussed on the phone, the applicant (i.e. the Glyphosate Task Force) should be given the possibility to address also these data gaps with additional information in the framework of the stop the clock mechanism.

Some of them are already listed in the Reporting table.

However, for those marked in yellow no further comments were received during the peer review, in consequence these points do not appear in the Reporting table.

May I ask you kindly to consider these data requirements too and to add them to the official EFSA letter to the applicant with the request for additional information.

Best regards

[REDACTED]

[REDACTED]

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
- Abteilung Pflanzenschutzmittel -
Messeweg 11/12
D-38104 Braunschweig

eMail: hartmut.kula@bvl.bund.de
Fon: [REDACTED]
Fax: [REDACTED]
<http://www.bvl.bund.de>

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]
Subject: Glyphosate Reporting table (public consultation)
Date: 08 August 2014 14:12:49
Attachments: [REDACTED]

Hallo [REDACTED],

Kannst du bitte wie telefonisch besprochen in der Glyphosate reporting table (public consultation) auf der der ersten Seite von Appendix I folgende (s. Anhang) im Text türkis markierte Ergänzung vornehmen ?

Merci vielmals und schönes Wochenende
[REDACTED]

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]
Subject: AW: Chrono-in 97631_Complete edition of EFSA about "Glyphosate"_Risk assessment of glyphosate regarding health
Date: 19 August 2014 11:09:48

Dear [REDACTED],

according to my understanding the requester asked BfR for the human health report of glyphosate.

BfR correctly referred the requester to the sanitized version of the complete RAR (comprising also the tox. section), which is to be made available to the public by EFSA.

I would propose to inform the requester about the EFSA website, where this information can be downloaded by interested parties.

Regulation (EC) No 1107/2009 contains no legal provision to provide the public with the unsanitized version, which is only for COM, EFSA, MS and the applicant.

Best regards

[REDACTED]

[REDACTED]

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
- Abteilung Pflanzenschutzmittel -
Messeweg 11/12
D-38104 Braunschweig

eMail: [REDACTED]@bvl.bund.de
Fon: [REDACTED]
Fax: [REDACTED]
<http://www.bvl.bund.de>

-----Ursprüngliche Nachricht-----

Von: [REDACTED] [mailto:[REDACTED]@efsa.europa.eu]

Gesendet: Montag, 18. August 2014 11:49

An: [REDACTED]

Betreff: FW: Chrono-in 97631_Complete edition of EFSA about "Glyphosate"_Risk assessment of glyphosate regarding health

Dear [REDACTED],

We received the attached letter requesting access to glyphosate human health report. As the requester refers to previous contacts with the BfR, I kindly ask you to forward me a copy of the relevant correspondences and some further clarifications on what the BfR meant with the 'complete edition of EFSA regarding glyphosate'?

Many thanks for your kind cooperation.

Best regards,

A small, dark, rectangular redacted area, likely covering a signature or name.

From: [REDACTED]
To: EFSA PESTICIDES PEER REVIEW
Cc: [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]@bmel.bund.de; BfR; UBA;
Subject: Glyphosate - RAR Addendum 1 (Evaluation of IARC monograph)
Date: 01 September 2015 14:07:35
Attachments: [REDACTED]

Dear colleagues,

I would like to inform you, that Germany as RMS for the active substance glyphosate has evaluated the IARC Monograph 112 on glyphosate in an addendum to the Renewal Assessment Report.

This addendum has just been uploaded to the EFSA DMS in the RMS Dropbox in a separate folder "Addendum 1 (Evaluation IARC Monograph)".

Copies are attached for your convenience.

During the evaluation we realized that the IARC Monograph also referred to results of non-mammalian systems in vivo (e. g. fish, tadpoles, earthworms etc.), which might have further implications for the environmental risk assessment. Due to time constraints no full evaluation was possible, however, we will present these findings in a separate report in due time for further consideration at expert level.

For further discussion in the Pesticides Peer Review TC 117 (Mammalian toxicology) we would appreciate if EFSA could distribute the document to all experts participating in the teleconference including the observers of IARC, JMPR, US EPA and also to ECHA.

Do not hesitate to contact me in case of any further questions arising.

Best regards

[REDACTED]

[REDACTED]

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
- Abteilung Pflanzenschutzmittel -
Messeweg 11/12
D-38104 Braunschweig

eMail: [REDACTED]@bvl.bund.de
Fon: [REDACTED]
Fax: [REDACTED]
<http://www.bvl.bund.de>

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]
Subject: WG: Glyphosate - RAR Addendum 1 (Evaluation of IARC monograph)
Date: 02 September 2015 08:18:58
Attachments: [REDACTED]

Hallo [REDACTED],

kannst du mich bezüglich des weiteren Procederes zu diesem Addendum bitte mal anrufen?

Merci
[REDACTED]

-----Ursprüngliche Nachricht-----

Von: [REDACTED]
Gesendet: Dienstag, 1. September 2015 14:06
An: EFSA
Cc: COM [REDACTED]; COM [REDACTED]; [REDACTED]@efsa.europa.eu;
[REDACTED]@bmel.bund.de; BfR; UBA; [REDACTED]; [REDACTED]; [REDACTED]
Betreff: Glyphosate - RAR Addendum 1 (Evaluation of IARC monograph)

Dear colleagues,

I would like to inform you, that Germany as RMS for the active substance glyphosate has evaluated the IARC Monograph 112 on glyphosate in an addendum to the Renewal Assessment Report.

This addendum has just been uploaded to the EFSA DMS in the RMS Dropbox in a separate folder "Addendum 1 (Evaluation IARC Monograph)".

Copies are attached for your convenience.

During the evaluation we realized that the IARC Monograph also referred to results of non-mammalian systems in vivo (e. g. fish, tadpoles, earthworms etc.), which might have further implications for the environmental risk assessment. Due to time constraints no full evaluation was possible, however, we will present these findings in a separate report in due time for further consideration at expert level.

For further discussion in the Pesticides Peer Review TC 117 (Mammalian toxicology) we would appreciate if EFSA could distribute the document to all experts participating in the teleconference including the observers of IARC, JMPR, US EPA and also to ECHA.

Do not hesitate to contact me in case of any further questions arising.

Best regards
[REDACTED]

[REDACTED]
Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
- Abteilung Pflanzenschutzmittel -
Messeweg 11/12
D-38104 Braunschweig

eMail: [REDACTED]@bvl.bund.de
Fon: [REDACTED]
Fax: [REDACTED]
<http://www.bvl.bund.de>

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]; [REDACTED]
Subject: AW: Glyphosate - expert consultations
Date: 04 September 2014 15:31:49

Dear [REDACTED],

sorry for answering so late, but due to the holiday season I currently have to replace most of my colleagues.

Generally speaking, I could agree to your proposal. However, the necessary revision of the glyphosate RAR will be a huge task again.

Besides information for those data gaps already identified in the RAR also a lot of scientific publications (relevant new ones from 2013/2014 and those additionally identified during the Peer Review/public consultation) will have to be addressed in the revised RAR. It is currently not foreseeable, whether 2 months really will be sufficient to assess all these documents in depth.

Taking into account the workload with AIR 3 active substances (DE is currently evaluating 4 dossiers, i.e. dimethenamid-P, beta-cyfluthrin, fosthiazate and pyraclostrobin) we might also run into resource problems.

I will come back to you once the GTF has submitted the additional information. We will then have a clearer picture about the real amount of work.

Best regards
[REDACTED]

-----Ursprüngliche Nachricht-----

Von: [REDACTED] [mailto:[REDACTED]@efsa.europa.eu]
Gesendet: Dienstag, 2. September 2014 12:13
An: [REDACTED]
Cc: [REDACTED]; [REDACTED]
Betreff: RE: Glyphosate - expert consultations

Dear colleagues,

Could you be so kind to give me some feedback on the below proposed timelines for glyphosate?

Many thanks,
[REDACTED]

From: [REDACTED]
Sent: 27 August 2014 09:47
To: DE [REDACTED]
Subject: Glyphosate - expert consultations

Dear [REDACTED],

I am contacting you regarding the next steps in the peer review of glyphosate.

The applicants are currently working on the data requirements. They will submit the additional information by 08/09/2014. According to the legislation, the RMS DE has 2 months to submit the assessment of the additional information, so with a DL on 08/11/2014.

We are in the process of scheduling the next round of expert meetings in which also glyphosate will be discussed. Expert meetings are needed in all sections, except for section 1. These expert meetings will most likely take place in the second part of November – first part of December 2014, provided that the documents are submitted by the 08/11/2014.

Could you be so kind to confirm your agreement with the above proposed timelines?

I would like to thank you for your kind cooperation.

Best regards,



From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]@bfr.bund.de; [REDACTED]; [REDACTED]; [REDACTED]
Subject: AW: Glyphosate - TC 117 meeting report
Date: 01 October 2015 11:16:30

Dear [REDACTED],

thank you. Very much appreciated!!

Best regards
[REDACTED]

-----Ursprüngliche Nachricht-----

Von: [REDACTED] [mailto:[REDACTED]@efsa.europa.eu]

Gesendet: Donnerstag, 1. Oktober 2015 11:13

An: [REDACTED]

Cc: [REDACTED]@bfr.bund.de; [REDACTED] ([REDACTED]@me.com); [REDACTED]; [REDACTED]

Betreff: Glyphosate - TC 117 meeting report

Dear [REDACTED],

Please find the final report of the Pesticides Peer Review TC 117 attached. There is no homework for the RMS.

The file is as well available on EFSA's DMS:

<https://dms.efsa.europa.eu/otcs/cs.exe?func=ll&objId=14622742&objAction=browse&viewType=1>

Best regards

[REDACTED]

[REDACTED]

Scientific Officer

Pesticides / Regulated Products

Via Carlo Magno 1A

43126 Parma (Italy)

Tel. [REDACTED]

www.efsa.europa.eu <<http://www.efsa.europa.eu/>>

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youtube.com/EFSAchannel <<http://youtube.com/EFSAchannel>>
<<http://youtube.com/EFSAchannel>>

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]; [REDACTED]
Subject: Glyphosat - Übermittlung der revidierten Vol. 4 an GTF
Date: 20 October 2015 12:49:03
Attachments: [REDACTED]

Hallo [REDACTED],

kurz zu deiner Frage:

Die revidierten firmenspezifischen Vol. 4 (Fassungen vom 29.01.2015) wurden mit beigefügtem Schreiben am 02.02.2015 an Dr. Knoell Consult geschickt.

Bitte denkt daran, dass alles, was Vol. 4 angeht wegen der Vertraulichkeit über diesen Consultant laufen sollte.

Schönen Gruß
[REDACTED]

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED]
Subject: Glyphosate - updated Draft EFSA Conclusion and Draft EFSA Statement on POE tallowamine
Date: 20 October 2015 15:20:12
Attachments: [REDACTED]

Dear [REDACTED],

please find attached our comments on the updated Draft EFSA Conclusion for Glyphosat as well as on the Draft EFSA Statement on POE tallowamine.

These documents will also be uploaded to the EFSA DMS as usual.

In addition, attached to this E-Mail please find a version of the Draft EFSA conclusion in tc-mode, which was prepared by BfR. The required text changes as proposed in the commenting table are already inserted in this version for transparency reasons. This document is for your convenience only and will not be uploaded to the EFSA DMS.

Best regards

[REDACTED]

[REDACTED]

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
- Abteilung Pflanzenschutzmittel -
Messeweg 11/12
D-38104 Braunschweig

eMail: [REDACTED]@bvl.bund.de
Fon: [REDACTED]
Fax: [REDACTED]
<http://www.bvl.bund.de>

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]; [REDACTED]
Subject: Glyphosat - Addendum B.9 Appendix
Date: 21 October 2015 10:38:42

Hallo [REDACTED]

habe das gewünschte Dokument (word und pdf) in die RMS Drop box bei Glyphosat geladen (im Ordner Addendum B.9 Appendix_21-10-2015).

[REDACTED]

Gruß

[REDACTED]

5_PAD 2017/036 Glyphosate CEO

Correspondence with the German Federal Food Safety and Veterinary Office (BLV)

From: [REDACTED] on behalf of [PRAS.secretariat](#)
To: [REDACTED] [@blv.admin.ch](#)
Cc: [REDACTED] [@blv.admin.ch](#); [EFSA PESTICIDES PEER REVIEW](#)
Subject: RE: Nomination Form TC 117
Date: 07 August 2015 13:36:31

Dear [REDACTED],
Thank you for the nomination sent.
With regard to your request, at the moment the RAR for Glyphosate is not available yet.
You will be informed as soon as it is available.
Kind regards
[REDACTED]

[REDACTED]
Administrative assistant
PESTICIDES
REPRO Department



Via Carlo Magno 1A
43126 Parma (Italy)
Tel: [REDACTED]
www.efsa.europa.eu
twitter.com/EFSA_EU 
youtube.com/EFSAchannel 

From: [REDACTED] [@blv.admin.ch](#) [mailto:[REDACTED] [@blv.admin.ch](#)]
Sent: 07 August 2015 12:08
To: PRAS.secretariat
Cc: [REDACTED] [@blv.admin.ch](#)
Subject: Nomination Form TC 117

Dear [REDACTED]

Please find attached my nomination form for the Pesticides Peer Review Expert teleconference on Glyphosate (Mammalian Toxicology section) to be held on 29 September 2015. May I kindly ask you to provide me with the corresponding addendum to the RAR as soon as possible?

Thank you very much and kind regards,
[REDACTED]

[REDACTED]
Wissenschaftlicher Mitarbeiter

Eidgenössisches Departement des Innern EDI
Bundesamt für Lebensmittelsicherheit und Veterinärwesen BLV
Risikobewertung

Stauffacherstrasse 101
8004 Zürich
Tel. [REDACTED]

@blv.admin.ch
www.blv.admin.ch

Die Bundesverwaltung hat ab sofort neue Telefonnummern mit der einheitlichen Vorwahl 058.

6_PAD 2017/036 Glyphosate CEO

Correspondence with US Environmental Protection Agency (EPA)

From: epa.gov>
Sent: 19 May 2015 18:59
To:
Subject: Re: Bilateral EPA EFSA cooperation on pesticides

That sounds fine.

From:
Sent: Tuesday, May 19, 2015 5:36:47 PM
To:
Subject: RE: Bilateral EPA EFSA cooperation on pesticides

Dear

Can be meet at the OECD entry? I can check my email account, just in case my mobile phone number is +39

KR

From:
Sent: 10 May 2015 16:23
To:
Cc:
Subject: RE: Bilateral EPA EFSA cooperation on pesticides

That sounds fine.. Let's plan to meet at 8:30 on the 20th for now as you suggest. I will stay in touch too and we can work out the details then. Regards.

Sent from my Windows Phone

From
Sent: 5/10/2015 4:55 AM
To:
Cc
Subject: Re: Bilateral EPA EFSA cooperation on pesticides

Dear , thanks for your response, I will travel on the 19th May, arriving too late in Paris for a meeting. I am available at any time on the 20th morning. Maybe we can meet shortly before your meeting, e.g. at 8:30.
Please, let me know if this is feasible.
Kind regards,

Sent from my iPhone

On 09 May 2015, at 21:52, '@epa.gov<mailto: '@epa.gov>> wrote:

Hello

I am agreeable to meet with you; however, I will be attending an extended WGP Bureau meeting that was recently scheduled for the morning of 20 May (9:30-13). Likewise I will be at the GJR meeting the previous afternoon, so my availability is limited. How long do you think we will need to meet? I am not sure of your travel plans and availability but will try and accommodate if I can.

Pesticide Re-evaluation Division (7508P)
Office of Pesticide Programs
US Environmental Protection Agency
Phone

From: [REDACTED]
Sent: Friday, May 08, 2015 2:25 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: Bilateral EPA EFSA cooperation on pesticides

Dear [REDACTED]
Following the email from [REDACTED] please let me know if you see the option for a bilateral meeting in Paris on 20 May morning before the OECD Pesticides WG. I would like to have a general informal bilateral discussion on several issues related to the cooperation between our agencies, including [REDACTED] but also [REDACTED] (we will launch soon a public call for data), and the IARC classification of glyphosate [REDACTED]
Looking forward to hearing from you.
Best regards,

<image001.gif.secure>

Via Carlo Magno 1/A
I-43126 Parma
Italy

Tel: + [REDACTED] Fax: + [REDACTED]

E-mail: [REDACTED]

www.efsa.europa.eu<<http://www.efsa.europa.eu/>>

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From:
Sent: 23 March 2015 21:04
To: A
Cc:
Subject: RE: Additional info on EPA and chlorpyrifos epi
Attachments: Lancet Onco. Carcinogenicity of tetrachlorvinphos, parathion, malathion....pdf

Thanks. Lots of issues to think about and consider !

I've attached the IARC-authored *Lancet Oncology* article which goes into some additional detail while the actual Monograph is being prepared. It came out at 1300h on the web last Friday.

From: [mailto:]
Sent: Monday, March 23, 2015 3:55 PM
To:
Cc:
Subject: RE: Additional info on EPA and chlorpyrifos epi

Dear dear all,

Sorry for this late response, but I consider your email of interest for the WG as it highlights the impact of epi studies on stakeholders and forthcoming regulatory decisions. In particular, I would like to draw your attention on the sentence "*Dow criticizes EPA's use of the Columbia University epidemiological study, arguing the study offers no plausible mode of action to explain its results, which have not been replicated*". Of course epi studies cannot provide mechanistic data; for this reason there is a need to develop quantitative or qualitative adverse outcome pathways (AOP) to fill this gap. In fact, the WG Epi on Parkinson's diseases and Childhood Leukemia is already working on that matter and an AOP is expected to be developed. Data from in vivo animal testing, in vitro studies and computational toxicology are useful tools to achieve this goal.

On the other hand, IARC has recently classified glyphosate, malathion and diazinon as *probably carcinogenic to humans* (Group 2A) and tetrachlorvinphos and parathion as *possibly carcinogenic to humans* (Group 2B), based on human epidemiological studies. All the three substances classified as 2B might induce non-Hodgkin lymphomas in humans. In the following link you can find the two-pages report <http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf> (it is also enclosed in the attached file).

Best regards,

De: [mailto:]@epa.gov]
Enviado el: miércoles, 18 de marzo de 2015 23:49
Para:
CC:
Asunto: Additional info on EPA and chlorpyrifos epi

Dear all,

I spoke briefly during our WG meeting in Paris on EPA's approach to epidemiology in the Office of Pesticide Programs, covering some of the chlorpyrifos (CPY) epi work we are doing and its ramifications. I also provided in an earlier email that was sent by [REDACTED] hyperlink to the publically available draft which discussed our treatment of some of the available epidemiological studies (see <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0195>)

I've attached a recent news story from *Risk Policy Report* on our CPY assessment and our recent extension of the public comment period. Since it deals with some of issues with respect to our treatment/consideration of epidemiology data, I thought it would be good to forward on if there was interest. Note that our consideration of epidemiology here is just putting on a Food Quality Protection Act (FQPA)-required factor to account for our professed uncertainty regarding developmental neurotox based on the Columbia, CHAMACOS, and Mt. Sinai epidemiological studies, among others.

Anyway, I thought I'd forward this short news item to keep you informed about how some epi issues are developing (and continuing to develop) here.

Health Effects Division
Office of Pediatric Programs
703-305- (voice)
703-305- (fax)

Visit www.epa.gov/pesticides

From: EFSA [mailto:efsa@efsa.europa.eu]

Sent: Wednesday, March 04, 2015 5:05 AM

To: A 17

Cc: ↑

Subject: agreed minutes of the WG meeting in Paris

Dear all,

please find in attachment the agreed version of the minutes of the Working Group meeting we had on February 19 in Paris. Thank you all for your input. Please, consider I'll upload the current version of the minutes in DMS and that the "short version" of the minutes will be published soon in the EFSA website.

Thanks,

Regards



Pesticides Unit
European Food Safety Authority
Via Carlo Magno 1A
I-43126 Parma
Italy
Tel: (+39) 0521 431261 Fax: (+39) 0521 431262
pesticides@efsa.europa.eu
Website: efsa.europa.eu

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PRINT LESS. TURN DOWN. SWITCH OFF. RECYCLE. WALK. CHANGE.

Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate

In March, 2015, 17 experts from 11 countries met at the International Agency for Research on Cancer (IARC; Lyon, France) to assess the carcinogenicity of the organophosphate pesticides tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate (table). These assessments will be published as volume 112 of the IARC Monographs.¹

The insecticides tetrachlorvinphos and parathion were classified as "possibly carcinogenic to humans" (Group 2B). The evidence from human studies was scarce and considered inadequate. Tetrachlorvinphos induced hepatocellular tumours (benign or malignant) in mice, renal tubule tumours (benign or malignant) in male mice,² and spleen haemangioma in male rats. Tetrachlorvinphos is a reactive oxon with affinity for esterases. In experimental animals, tetrachlorvinphos is systemically distributed, metabolised, and eliminated in urine. Although bacterial mutagenesis tests were negative, tetrachlorvinphos induced genotoxicity in some assays (chromosomal damage in rats and in vitro) and increased cell proliferation (hyperplasia in rodents). Tetrachlorvinphos is banned in the European Union. In the USA, it continues to be used on animals, including in pet flea collars.

For parathion, associations with cancers in several tissues were observed in occupational studies, but the evidence in humans remains sparse. In mice, parathion increased bronchiolo-alveolar adenoma and/or carcinoma in males, and lymphoma in females. In rats, parathion induced adrenal cortical adenoma or carcinoma (combined),³ malignant pancreatic tumours, and thyroid follicular cell adenoma in males, and mammary gland adenocarcinoma (after subcutaneous injection in females).⁴ Parathion is rapidly absorbed and distributed. Parathion metabolism

to the bioactive metabolite, paraoxon, is similar across species. Although bacterial mutagenesis tests were negative, parathion induced DNA and chromosomal damage in human cells in vitro. Parathion markedly increased rat mammary gland terminal end bud density.⁴ Parathion use has been severely restricted since the 1980s.

The insecticides malathion and diazinon were classified as "probably carcinogenic to humans" (Group 2A). Malathion is used in agriculture, public health, and residential insect control. It continues to be produced in substantial volumes throughout the world. There is limited evidence in humans for the carcinogenicity of malathion. Case-control analyses of occupational exposures reported positive associations with non-Hodgkin lymphoma in the USA,⁵ Canada,⁶ and Sweden,⁷ although no increased risk of non-Hodgkin lymphoma was observed in the large Agricultural Health Study cohort (AHS). Occupational use was associated with an increased risk of prostate cancer in a Canadian case-control study⁸ and in the AHS, which reported a significant trend for

aggressive cancers after adjustment for other pesticides.⁹ In mice, malathion increased hepatocellular adenoma or carcinoma (combined).¹⁰ In rats, it increased thyroid carcinoma in males, hepatocellular adenoma or carcinoma (combined) in females, and mammary gland adenocarcinoma after subcutaneous injection in females.⁴ Malathion is rapidly absorbed and distributed. Metabolism to the bioactive metabolite, malaoxon, is similar across species. Malaoxon strongly inhibits esterases; atropine reduced carcinogenesis-related effects in one study.⁴ Malathion induced DNA and chromosomal damage in humans, corroborated by studies in animals and in vitro. Bacterial mutagenesis tests were negative. Compelling evidence supported disruption of hormone pathways. Hormonal effects probably mediate rodent thyroid and mammary gland proliferation.

Diazinon has been applied in agriculture and for control of home and garden insects. There was limited evidence for diazinon carcinogenicity in humans. Positive associations for non-Hodgkin lymphoma, with



Lancet Oncol 2015

Published Online
March 20, 2015
[http://dx.doi.org/10.1016/S1470-2045\(15\)70134-8](http://dx.doi.org/10.1016/S1470-2045(15)70134-8)

For more on the IARC Monographs see <http://monographs.iarc.fr>

Upcoming meetings
June 2–9, 2015, Volume 113:
Some organochlorine insecticides and some chlorophenox herbicides
Oct 6–13, 2015, Volume 114:
Red meat and processed meat

Monograph Working Group Members
A Blair (USA)—Meeting Chair,
L Fritschi (Australia);
J McLaughlin, C M Sergi (Canada),
G M Calaf (Chile); F Le Couteur
(Finland); I Baldi (France);
F Forastiere (Italy); H Kromhout
(Netherlands); A t Marnett
(New Zealand); T Rodriguez
(unable to attend) (Nicaragua),
P Egghy (unable to attend).

	Activity (current status)	Evidence in humans (cancer sites)	Evidence in animals	Mechanistic evidence	Classification*
Tetrachlorvinphos	Insecticide (restricted in the EU and for most uses in the USA)	Inadequate	Sufficient	..	2B
Parathion	Insecticide (restricted in the USA and EU)	Inadequate	Sufficient	..	2B
Malathion	Insecticide (currently used; high production volume chemical)	Limited (non-Hodgkin lymphoma, prostate)	Sufficient	Genotoxicity, oxidative stress, inflammation, receptor-mediated effects, and cell proliferation or death	2A†
Diazinon	Insecticide (restricted in the USA and EU)	Limited (non-Hodgkin lymphoma, leukaemia, lung)	Limited	Genotoxicity and oxidative stress	2A†
Glyphosate	Herbicide (currently used; highest global production volume herbicide)	Limited (non-Hodgkin lymphoma)	Sufficient	Genotoxicity and oxidative stress	2A†

EU=European Union. *See the International Agency for Research on Cancer (IARC) preamble for explanation of classification system (amended January, 2006). †The 2A classification of diazinon was based on limited evidence of carcinogenicity in humans and experimental animals, and strong mechanistic evidence; for malathion and glyphosate, the mechanistic evidence provided independent support of the 2A classification based on evidence of carcinogenicity in humans and experimental animals.

Table: IARC classification of some organophosphate pesticides

G D Jahnke, C W Jameson;
M T Martin, M K Ross, I Rusyn;
L Zeise (USA)

Invited Specialists
C Portier (Switzerland)

Representatives
M E Gouze, for the French
Agency for Food, Environment
and Occupational Health and
Safety (France); J Rowland, for
the US Environmental Protection
Agency (USA)

Observers
M K Boye Jensen, for Cheminova
(Denmark); B Fervers, for the
Léon Bérard Centre (France);
E Giroux, for University
Jean-Moulin Lyon 3 (France);
T Sorahan, for Monsanto
Company (USA); C Strupp, for
the European Crop Protection
Association (Belgium); P Sutton,
for the University of California,
San Francisco (USA)

IARC/WHO Secretariat
L Benbrahim-Tallaa, R Carel;
F El Ghissassi, Sonia El-Zaerney;
Y Grosse; N Guha; K Z Guyton;
C Le Cornet; M Leon, D Loomis;
H Mattock; C Scoccianti;
A Shapiro, K Straif; J Zavadil
For the Preamble to the IARC
Monographs see <http://monographs.iarc.fr/ENG/Preamble/index.php>

For declarations of interests see
<http://monographs.iarc.fr/ENG/Meetings/vol112-participants.pdf>

indications of exposure-response trends, were reported by two large multicentre case-control studies of occupational exposures.^{5,6} The AHS reported positive associations with specific subtypes, which persisted after adjustment for other pesticides, but no overall increased risk of non-Hodgkin lymphoma.¹¹ Support for an increased risk of leukaemia in the AHS was strengthened by a monotonic increase in risk with cumulative diazinon exposure after adjustment for other pesticides. Multiple updates from the AHS consistently showed an increased risk of lung cancer with an exposure-response association that was not explained by confounding by other pesticides, smoking, or other established lung cancer risk factors.¹² Nonetheless, this finding was not replicated in other populations. In rodents, diazinon increased hepatocellular carcinoma in mice and leukaemia or lymphoma (combined) in rats, but only in males receiving the low dose in each study. Diazinon induced DNA or chromosomal damage in rodents and in human and mammalian cells in vitro. Some additional support for human relevance was provided by a positive study of a small number of volunteers exposed to a diazinon formulation.¹³

Glyphosate is a broad-spectrum herbicide, currently with the highest production volumes of all herbicides. It is used in more than 750 different products for agriculture, forestry, urban, and home applications. Its use has increased sharply with the development of genetically modified glyphosate-resistant crop varieties. Glyphosate has been detected in air during spraying, in water, and in food. There was limited evidence in humans for the carcinogenicity of glyphosate. Case-control studies of occupational exposure in the USA,¹⁴ Canada,⁵ and Sweden⁷ reported increased risks for non-Hodgkin lymphoma that persisted after adjustment for other pesticides. The AHS cohort did not show a significantly increased risk

of non-Hodgkin lymphoma. In male CD-1 mice, glyphosate induced a positive trend in the incidence of a rare tumour, renal tubule carcinoma. A second study reported a positive trend for haemangiosarcoma in male mice.¹⁵ Glyphosate increased pancreatic islet-cell adenoma in male rats in two studies. A glyphosate formulation promoted skin tumours in an initiation-promotion study in mice.

Glyphosate has been detected in the blood and urine of agricultural workers, indicating absorption. Soil microbes degrade glyphosate to aminomethylphosphoric acid (AMPA). Blood AMPA detection after poisonings suggests intestinal microbial metabolism in humans. Glyphosate and glyphosate formulations induced DNA and chromosomal damage in mammals, and in human and animal cells in vitro. One study reported increases in blood markers of chromosomal damage (micronuclei) in residents of several communities after spraying of glyphosate formulations.¹⁶ Bacterial mutagenesis tests were negative. Glyphosate, glyphosate formulations, and AMPA induced oxidative stress in rodents and in vitro. The Working Group classified glyphosate as "probably carcinogenic to humans" (Group 2A).

We declare no competing interests.

Kathryn Z Guyton, Dana Loomis,
Yann Grosse, Fatiha El Ghissassi,
Lamia Benbrahim-Tallaa, Neela Guha,
Chiara Scoccianti, Heidi Mattock,
Kurt Straif, on behalf of the
International Agency for Research on
Cancer Monograph Working Group,
IARC, Lyon, France

International Agency for Research on Cancer, Lyon,
France

- 1 International Agency for Research on Cancer Volume 112: Some organophosphate insecticides and herbicides: tetrachlorvinphos, parathion, malathion, diazinon and glyphosate. IARC Working Group. Lyon; 3-10 March 2015. IARC Monogr Eval Carcinog Risk Chem Hum (in press).
- 2 Parker CM, Van Gelder GA, Chai EY, et al. Oncogenic evaluation of tetrachlorvinphos in the B6C3F1 mouse. *Fundam Appl Toxicol* 1985; 5: 840-54.

- 3 National Toxicology Program. Bioassay of parathion for possible carcinogenicity. *Natl Cancer Inst Carcinog Tech Rep Ser* 1979; 70: 1-123.
- 4 Cabello G, Valenzuela M, Vilaxa A, et al. A rat mammary tumor model induced by the organophosphorus pesticides parathion and malathion, possibly through acetylcholinesterase inhibition. *Environ Health Perspect* 2001; 109: 471-79.
- 5 Waddell BL, Zahm SH, Baris D, et al. Agricultural use of organophosphate pesticides and the risk of non-Hodgkin's lymphoma among male farmers (United States). *Cancer Causes Control* 2001; 12: 509-17.
- 6 McDuffie HH, Pahwa P, McLaughlin JR, et al. Non-Hodgkin's lymphoma and specific pesticide exposures in men: cross-Canada study of pesticides and health. *Cancer Epidemiol Biomarkers Prev* 2001; 10: 1155-63.
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- 8 Band PR, Abanto Z, Bert J, et al. Prostate cancer risk and exposure to pesticides in British Columbia farmers. *Prostate* 2011; 71: 168-83.
- 9 Koutros S, Beane, Freeman LE, et al. Risk of total and aggressive prostate cancer and pesticide use in the Agricultural Health Study. *Am J Epidemiol* 2013; 177: 59-74.
- 10 US Environmental Protection Agency. Peer review of malathion: 18-month carcinogenicity study in mice. http://www.epa.gov/opp00001/chem_search/cleared_reviews/csr_PC-057701_undated_004.pdf (accessed March 6, 2015).
- 11 Alavanja MC, Hofmann JM, Lynch CF, et al. Non-Hodgkin lymphoma risk and insecticide, fungicide and fumigant use in the agricultural health study. *PLoS ONE* 2014; 9: e109332.
- 12 Jones RR, Barone-Adesi F, Koutros S, et al. Incidence of solid tumors among pesticide applicators exposed to the organophosphate insecticide diazinon in the Agricultural Health Study: an updated analysis. *Occup Environ Med* 2015 (in press).
- 13 Hatjian BA, Mutch E, Williams FM, Blain PG, Edwards JW. Cytogenetic response without changes in peripheral cholinesterase enzymes following exposure to a sheep dip containing diazinon in vivo and in vitro. *Mutat Res* 2000; 472: 85-92.
- 14 De Roos AJ, Zahm SH, Cantor KP, et al. Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men. *Occup Environ Med* 2003; 60: E11.
- 15 WHO/FAO. Glyphosate. Pesticides residues in food 2004 Joint FAO/WHO Meeting on Pesticides Residues. Part II Toxicological. IPCS/WHO 2004, 95-162. http://www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en/ (accessed March 6, 2015).
- 16 Bolognesi C, Carrasquilla G, Volpi S, Solomon KR, Marshall EJ. Biomonitoring of genotoxic risk in agricultural workers from five Colombian regions: association to occupational exposure to glyphosate. *J Toxicol Environ Health A* 2009; 72: 985-97.

From: [REDACTED] on behalf of [EFSA PESTICIDES PEER REVIEW](#)
To: [REDACTED]
Cc: [EFSA PESTICIDES PEER REVIEW](#)
Subject: RE: Glyphosate Renewal Assessment Report
Date: 10 September 2015 08:13:03
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)

Dear [REDACTED],

Thank you for your message.

As there is no Memorandum of Understanding in place between EFSA and USEPA I kindly inform you that your request will be treated as a Public Access to Documents request and you will get a formal response from the EFSA Legal Services.

As you will be attending the Peer Review Teleconference on 29 September 2015 as an observer, you will receive the requested documents on confidential basis after signing a declaration of confidentiality. You will be contacted by our secretariat directly.

Please do not hesitate to contact me in case you have further questions.

Kind regards,

[REDACTED]

[REDACTED]
Senior Scientific Officer
Pesticides Unit / Scientific Evaluation of Regulated Products



Via Carlo Magno 1A
43126 Parma (Italy)

Tel. [REDACTED]

www.efsa.europa.eu

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youtube.com/EFSAchannel 

From: [REDACTED] [mailto:[REDACTED]@epa.gov]
Sent: 08 September 2015 14:35
To: EFSA PESTICIDES PEER REVIEW
Subject: Glyphosate Renewal Assessment Report
Importance: High

Greetings

The Office of Pesticide Programs is currently reviewing the toxicity and carcinogenicity data on

glyphosate, In that regard, is it possible for you send me the following reports which will be of valuable use in our assessment

Germany Rapporteur Member State. (2015a). Glyphosate Renewal Assessment Report, Volume 1. Report and Proposed Decision. Revised 29th, January 2015.

Germany Rapporteur Member State. (2015b). Glyphosate Renewal Assessment Report, Volume 3, Annex B.6.1 Toxicology and Metabolism . Revised 29th, January 2015.

Thank you for your assistance

Regards

[REDACTED]

Deputy Director

Health Effects Division

Office of Pesticide Programs

U.S. Environmental Protection Agency

[REDACTED]

From: [REDACTED]
To: [REDACTED]
Cc: [EFSA PESTICIDES PEER REVIEW](#); [REDACTED]
Subject: RE: GLyphosate
Date: 02 October 2015 16:23:02
Attachments: [REDACTED]

Dear [REDACTED],

Please find enclosed the report of the Pesticides Peer Review TC 117, as mentioned earlier, under embargo.

I hope that you recovered well from the missed-night-sleep!

Kind regards,

[REDACTED]

From: [REDACTED] [mailto:[REDACTED]@epa.gov]
Sent: 02 October 2015 15:33
To: [REDACTED]
Subject: RE: GLyphosate

Dear [REDACTED]

Thank you for the note. I would like to have the meeting minutes with the understanding of the embargo.

Regards

[REDACTED]

Sent from my Windows Phone

From: [REDACTED]
Sent: 10/2/2015 3:32 AM
To: [REDACTED]
Cc: [EFSA PESTICIDES PEER REVIEW](#); [REDACTED]; [PRAS.secretariat](#)
Subject: RE: GLyphosate

Dear [REDACTED],

Indeed your participation was very helpful, and we were glad to have you on board, thank you!

The report of the meeting will be published together with the EFSA conclusion (as background documents in the peer review report) that is expected to be in November.

However if you need to receive the minutes earlier, I can send them to you under embargo; kindly let me know.

Kind regards,

Danièle

[REDACTED]

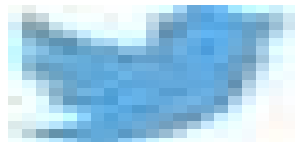
Pesticides Unit - Toxicology
Scientific Evaluation of Regulated Products Directorate
European Food Safety Authority

Via Carlo Magno 1/A I-43126 Parma
Tel : [REDACTED]
Fax : [REDACTED] [\[REDACTED\]@efsa.europa.eu](mailto:[REDACTED]@efsa.europa.eu)
<http://www.efsa.europa.eu>

From: [REDACTED] **On Behalf Of** PRAS.secretariat
Sent: 02 October 2015 09:05
To: [REDACTED]
Cc: [REDACTED]; EFSA PESTICIDES PEER REVIEW
Subject: RE: GLyphosate

Dear [REDACTED],
Thank you very much for your message, I'm really happy about your feedback.
With regard to your question, I'm copying my colleague [REDACTED] and the Peer Review scientific coordination team who will be able to answer you.
Kind regards
[REDACTED]

[REDACTED]
Administrative assistant
PESTICIDES
REPRO Department



Via Carlo Magno 1A
43126 Parma (Italy)
Tel: [REDACTED]
www.efsa.europa.eu
twitter.com/EFSA_EU 
youtube.com/EFSAchannel 

From: [REDACTED] [\[mailto:\[REDACTED\]@epa.gov\]](mailto:[REDACTED]@epa.gov)
Sent: 01 October 2015 18:19
To: PRAS.secretariat
Subject: GLyphosate

[REDACTED]

Thank you for the opportunity to participate in the EFSA meeting. I hope I was helpful.
That was very interesting and I learned a lot on the review and evaluation of the studies by the different countries.
What will be next step? If there is a report, can you tell me when that would be coming out?

Regards

[REDACTED]

Deputy Director
Health Effects Division



From: [REDACTED]
To: [REDACTED]
Subject: RE: Glyphosate
Date: 08 October 2015 12:55:03
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)

Dear [REDACTED]

Thank you so much for the information.

Regards

[REDACTED]

[REDACTED]

[REDACTED]

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
[REDACTED]

From: [REDACTED] [mailto:[REDACTED]@efsa.europa.eu]
Sent: Thursday, October 08, 2015 1:54 AM
To: [REDACTED]
Cc: EFSA PESTICIDES PEER REVIEW; [REDACTED]
Subject: RE: Glyphosate

Dear [REDACTED]

After the adoption of our conclusion, we have to undergo the step of sanitisation before we can publish the documents on our website. For the conclusion, I guess, this might not take much longer than 2 weeks. So, we expect the conclusion to be available to the public by mid-November. I am sorry, but for the time being, I cannot be more precise.

Let me know, if additional information on the process is needed.

Best regards

[REDACTED]

[REDACTED]

Scientific Officer
Pesticides / Regulated Products



European Food Safety Authority

Via Carlo Magno 1A

43126 Parma (Italy)

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www.efsa.europa.eu

twitter.com/EFSA_EU 

youtube.com/EFSAchannel 

From: [REDACTED]

Sent: 07 October 2015 21:26

To: [REDACTED]

Cc: EFSA PESTICIDES PEER REVIEW; [REDACTED]

Subject: Re: Glyphosate

Dear [REDACTED],

Thank you for the information, I include in cc [REDACTED] who is coordinating the peer review. He will be able to give you more precise information regarding the publication.

Kind regards,

[REDACTED]

Enviado do meu iPhone

No dia 7 de out de 2015, às 20:48, [REDACTED] <[REDACTED]@epa.gov> escreveu:

Dear [REDACTED]

OPP is in the process of conducting risk assessment on glyphosate, which will include the re-evaluation of carcinogenicity. We would like to release our risk assessment at the same time when EFSA conclusion is published. I see you plan to release your report in November; can you give some approximate date of the release so we can make our plans.

Thank you and kind regards

[REDACTED]

[REDACTED]

Health Effects Division

Office of Pesticide Programs

U.S. Environmental Protection Agency

[REDACTED]

From: [REDACTED]

[mailto:[REDACTED]@efsa.europa.eu]

Sent: Friday, October 02, 2015 3:32 AM

To: [REDACTED]

Cc: EFSA PESTICIDES PEER REVIEW; [REDACTED]; PRAS.secretariat

Subject: RE: Glyphosate

Dear [REDACTED],

Indeed your participation was very helpful, and we were glad to have you on board, thank you!

The report of the meeting will be published together with the EFSA conclusion (as background documents in the peer review report) that is expected to be in November.

However if you need to receive the minutes earlier, I can send them to you under embargo; kindly let me know.

Kind regards,

[REDACTED]

[REDACTED]

Pesticides Unit - Toxicology
Scientific Evaluation of Regulated Products Directorate
European Food Safety Authority

Via Carlo Magno 1/A I-43126 Parma

Tel : [REDACTED]

Fax : [REDACTED]

[REDACTED]@efsa.europa.eu

<http://www.efsa.europa.eu>

From: [REDACTED] **On Behalf Of** PRAS.secretariat

Sent: 02 October 2015 09:05

To: [REDACTED]

Cc: [REDACTED]; EFSA PESTICIDES PEER REVIEW

Subject: RE: GLyphosate

Dear [REDACTED],

Thank you very much for your message, I'm really happy about your feedback.

With regard to your question, I'm copying my colleague [REDACTED] and the Peer Review scientific coordination team who will be able to answer you.

Kind regards

[REDACTED]

[REDACTED]

Administrative assistant
PESTICIDES
REPRO Department



Via Carlo Magno 1A
43126 Parma (Italy)

Tel: [REDACTED]

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twitter.com/EFSA_EU <image001.jpg.secure>

[youtube.com/EFSAchannel](https://www.youtube.com/EFSAchannel) <image002.jpg.secure>

From: [REDACTED] [[mailto:\[REDACTED\]@epa.gov](mailto:[REDACTED]@epa.gov)]

Sent: 01 October 2015 18:19

To: PRAS.secretariat

Subject: GLyphosate

Hi [REDACTED]

Thank you for the opportunity to participate in the EFSA meeting. I hope I was helpful.

That was very interesting and I learned a lot on the review and evaluation of the studies by the different countries.

What will be next step? If there is a report, can you tell me when that would be coming out?

Regards

[REDACTED]

Deputy Director

Health Effects Division

[REDACTED]