From:
Sent: 23 March 2015 11:02
To:
Cc:
Subject: RE: glyphosate

Dear

Glyphosate is being considered under the AIR II procedure and was discussed at the PPR125 meeting end of February 2015.

We are aware of the IARC conclusions, the RMS will address it in an addendum to the RAR currently being drafted. I don't see a reason for the PPR to be involved.

Kind regards,

From:
Sent: 23 March 2015 10:48
To:
Subject: FW: unable to travel this week!

Dear colleagues,

There is a proposal of to put a point at the agenda of the plenary meeting of the panel this week about the recent IARC classification of Glyphosate. It is quite unusual to have a discussion about an AS without any mandate and I'm not sure that it makes sense.

Are you aware of this classification and is this something which is covered by the AIR II conclusions?

Kind regards,

From:
Sent: 23 March 2015 10:30
To:

Subject: unable to travel this week!

Dear

Ok fine with me.

I have a suggestion to the agenda. Could we on AOB put a point on the recent IARC classification of Glyphosate. The situation and how it is managed ?

KR

From:
Sent: maandag 23 maart 2015 6:22
To:

Cc
Subject: RE: unable to travel this week!

Dear

I am able to chair this week but would also be absolutely happy if . . does it.

With kind regards

18

From:
Sent: 27 March 2015 15:59
To:
Subject: Glyphosate (IARC press release)

Dear ,

In preparation to the meeting with please see below the key information.

The BfR press release is available at:

http://www.bfr.bund.de/cm/349/does-glyphosate-cause-cancer.pdf

The conducted and planned actions are:

-
- We have agreed with DE and they will include an assessment of the IARC statement in the addendum to the RAR
- We have contacted IARC, the full report (needed to understand the proposal) may take one year. Thus we have requested a list of the studies used by the WG, to check if there is new information
- We will consider the IARC statement in the EFSA conclusion

Note: MSs are getting pressure, but until now, the MSs have not submitted intentions for harmonised classification to ECHA

KR,

From:
Sent: 23 March 2015 12:03
To: C
Cc: KA
Subject: RE: Media Request from EU Food Policy on glyphosate (IARC press release)

Dear
It is BfR.
KR,

From
Sent: 23 March 2015 11:58
To: T
Cc: F
Subject: RE: Media Request from EU Food Policy on glyphosate (IARC press release)

Thanks ,

Is it the BfR or the BVL in Germany or both?

Best,

From:
Sent: 23 March 2015 11:53
To:
Cc:
Subject: RE: Media Request from EU Food Policy on glyphosate (IARC press release)

Dear

Your proposal is fine, this is an ongoing assessment. If useful, you can mention that the IARC assessment will be addressed by Germany as RMS and by EFSA. Maybe you could liaise with the Communication service of Germany as it seems that they are considering to prepare a press release on the issue.
KR

From:
Sent: 23 March
To:
Cc:
Subject: Media Request from EU Food Policy on glyphosate (IARC press release)
Importance: High

Dears,

the International Agency for Research on Cancer published a press release on Friday, saying that as a result of the IARC evaluations, the herbicide glyphosate and the insecticides malathion and diazinon were classified as probably carcinogenic to humans (Group 2A). http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf

/ is asking us, if we have a reaction to the IARC saying. will put a story out today.

course we cannot comment on an on-going assessment.

What we could say is that (as far as I know):

- Germany as RMS is currently preparing an update of the assessment following expert meeting discussions at EFSA
- Afterwards EFSA will draft its conclusion, followed by a MS consultations of 2 weeks on the draft conclusion.
- the legal deadline for the EFSA conclusion is on 13 August 2015

What are your views, anything to add or drop?

Best,

Communications & External Relations Department

efsa
European Food Safety Authority

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43126 Parma, Italy
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Does glyphosate cause cancer?

BfR Communication No 007/2015, 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 assessment 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 WHO-Panel of the Joint Meeting of Pesticide residues (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, BfR has 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. BfR thinks 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 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 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". 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. BfR will therefore perform a thorough review of the classification issued by IARC once the monograph becomes available.

From:
Sent: 24 March 2015 13:39
To:
Cc:
Subject: RE: New Article on roundup causing cancer

Maybe it was related to a co-formulant. There were some articles in different media, but it is not always very clear what journalists conclude from a scientific study.
Anyway, since we are finalising the glyphosate assessment, we should be aware of assessments of other bodies like IARC.
Best regards,

From:
Sent: 24 March 2015 11:13
To:
Cc:
Subject: RE: New Article on roundup causing cancer

Thanks

We are looking forward to see the full report of the IARC assessment to understand their rationale for this conclusion.

Kind regards,

From:
Sent: 24 March 2015 10:09
To:
Cc:
Subject: New Article on roundup causing cancer

http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(15)70134-8/fulltext

These assessments will be published as volume 112 of the IARC Monographs.

From:
Sent: 27 March 2015 09:51
To:
Cc:
Subject: RE: Carcinogenic assessment of glyphosate by IARC

Thanks, I do not have further comments.
KR,

From:
Sent: 27 March 2015 09:42
To:
Cc:
Subject: FW: Carcinogenic assessment of glyphosate by IARC

Dear

Thanks for the draft. I made some minor amendments. Please feel free to ignore. Probably we should ask his agreement as a matter of courtesy and to be on the safe side, although I believe it would not be needed.

Regards

Scientific Officer
Pesticides / Regulated Products

efsa
European Food Safety Authority

Via Carlo Magno 1A
43126 Parma (Italy)
Tel. +39 0521 036
www.efsa.europa.eu
twitter.com/EFSA_EU
youtube.com/EFSAchannel

From:
Sent: 27 March 2015 09:34
To:
Subject: FW: Carcinogenic assessment of glyphosate by IARC

Dear

Please see below my proposed answer to Dr hould we ask their agreement to share the list of reference with other MSs/Germany?
Your comments are welcome,
Thanks a lot

Dear

Thank you for your quick answer. Indeed the glyphosate assessment is of high importance to public health.

As we ~~should~~ will draft ~~ourselves a~~ the EFSA conclusion on glyphosate shortly, we would be grateful if you could provide us with your list of references to ensure that we do not miss relevant data. Kindly further inform us whether you would agree that we share this list with Member States participating to the peer review.

Best regards.

From:
Sent: 26 March 2015 16:48
To:
Cc: K
Subject: Re: Carcinogenic assessment of glyphosate by IARC

Dear

Thanks for your interest in the IARC assessment of of glyphosate. The full monograph with complete details of the evaluation will be published after fact checking and technical editing. This process typically takes about a year, but can be somewhat shorter or longer depending on the amount of material and the public health importance of the topic. However, if information about glyphosate is needed sooner, we would be glad to discuss providing Efsa with a reference list.

[redacted]st regards

IARC Monographs Section
IARC/WHO
150, cours Albert Thomas
69372 Lyon cedex 08, France
Tel: +33 (0)4 72 73
Mobile:
Email:

From:
Date: Wednesday, 25 March 2015 17:25
To
Subject: Carcinogenic assessment of glyphosate by IARC

Dear [redacted]

I'm working on the glyphosate peer review at the Pesticides Unit of EFSA.
I took the opportunity of your participation to EFSA projects to ask my colleague, [redacted] r your contact.
We are aware of the publication "Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate" by the IARC which is, of course, of great relevance to our assessment.
Would it be possible for you to give me an estimation of the date foreseen for the publication of the volume 112 of the IARC Monographs where details on the carcinogenic assessment of glyphosate will be available?
Or, if possible, to provide the list of studies available to the IARC assessment?

Thanking you in advance for your kind collaboration,
Best regards,

From:
Sent: 23 April 2015 17:16
To:
Subject: FW: Carcinogenic assessment of glyphosate by IARC
Attachments: Vol112.Glyphosate.All.docx

Importance: High

Dear all,

See below IARC response to our request: 34 pages of references that are all published literature, including government reports (many from the US EPA, JMPR, IPCS, FAO, EFSA annual report).

Please note that "The glyphosate Monograph is undergoing accelerated production and can be made available to national and international agencies in early July 2015, following fact- and reference-verification and editing processes. Publication of Volume 112 in final layout is expected in 2016"

Kind regards

From:
Sent: 23 April 2015 16:42
To:
Cc
Subject: Re: Carcinogenic assessment of glyphosate by IARC
Importance: High

Der

Per your recent request, please find appended a list of references on glyphosate considered by the Volume 112 Working Group. This reference list is provided to you in strict confidence, as the Monograph is not yet publicly available. We kindly ask that you do not share this email or the attachments outside of your organisation (EFSA).

Background information

The IARC Monographs are performed by panels of independent international experts, selected on the basis of their knowledge and experience as well as an absence of real or apparent conflicts of interest. IARC Working Groups follow established procedures and criteria for the selection, evaluation and integration of evidence. The identified epidemiology, bioassay and mechanistic data for the Monographs included peer-reviewed literature and government reports that were available in their final form. For exposure and other information (e.g., chemical and physical properties, production, use, and occurrence) published and unpublished sources of information may be included.

References considered by the Working Group

The appended references were identified from comprehensive electronic searches of peer-reviewed literature, screened for relevance to the topic and supplemented by manual searching (e.g. of other authoritative reviews). Government reports in their final form were also considered. When published, volume 112 of the IARC Monographs on Carcinogenic Risks to Humans may not necessarily cite all listed studies (see data for the Monographs).

Next steps

The glyphosate Monograph is undergoing accelerated production and can be made available to national and international agencies in early July 2015, following fact- and reference-verification and editing processes. Publication of Volume 112 in final layout is expected in 2016.

Thank you again for your interest in our work.

Kind regards,

Monographs Section

International Agency for Research on Cancer
150, cours Albert Thomas
69372 Lyon Cedex 08

France
Tel: [+33] (C

From: @iarc.fr>
Date: Monday 20 April 6:49
To
Cc:

Subject: Re: Carcinogenic assessment of glyphosate by IARC

Dear

We are working on the consolidated reference list for the glyphosate assessment and hope to send it to you this week.

Regards

IARC/WHO
150, cours Albert Thomas
69372 Lyon cedex 08, France
Tel: +33 (0)4 72

From:
Date: Monday, 20 April 2015 16:38
To
Cc

Subject: RE: Carcinogenic assessment of glyphosate by IARC

Dear I colleagues,

I would like to send you a kind reminder whether you would agree to provide to EFSA your list of references for glyphosate as we are now in the process of drafting the conclusion on the glyphosate peer review.

Thanking you in advance for your collaboration.

Best regards,

---

om
Sent: 27 March 2015 11:08
To:
Cc:
Subject: RE: Carcinogenic assessment of glyphosate by IARC

Dear

Thank you for your quick answer. Indeed the glyphosate assessment is of high importance to public health.
As we will draft the EFSA conclusion on glyphosate shortly, we would be grateful if you could provide us with your list of references to ensure that we do not miss relevant data. Kindly further inform us whether you would agree that we share this list with Member States participating to the peer review.

Best regards,

From:
Sent: 26 March 2015 16:48
To

Glyphosate references considered by the IARC Monographs Volume 112 Working Group

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From:
Sent: 27 March 2015 18:00
To:
Subject: RE: Glyphosate

Dear all,

FYI the link to the IARC classification list. Caffeine is Cat 3. Glyphosate, is already listed in Cat 2A and there are several well known carcinogens in the group.

http://monographs.iarc.fr/ENG/Classification/ClassificationsGroupOrder.pdf

KR,

-----Original Appointment-----
From:
Sent: 25 March 2015 18:01
To:
Subject: Glyphosate
When: 27 March 2015 16:30-17:00 (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna.
Where:

Following 's request and the IARC publication; we are calling for a short wrap up meeting.

Best regards,

To:
Subject: Fw: feedback from PPR plenary 25-26 March

Dear

With respect to the feedback to the SC this week, in addition to the discussion on the , I think I should inform the SC on the discussion on glyphosate (IARC vs peer-review), from the perspective of the use of epidemiological data in pesticide risk assessment, and link the media attention in several member states to the current PPR mandates on this.
I won't go into who is right or wrong but I would like to explain that there is an ongoing peer review in the Pesticide unit /DE and that there will be further follow-up when the IARC monograph becomes available, and that this is an example where epidemiological data do not match with the animal data.
Is this OK with you?

Kind regards,

Mobile
E-mail:

---- Forwarde 04-2015 14:54 ----

From:
To:
Cc:
Date: 13-04-2015 10:47
Subject: eedback from PPR plenary 25-26 March

Dear

From:
Sent: 22 April 2015 13:15
To:
Subject: Carcinogenic assessment of glyphosate by IARC

Sensitivity:

Dear

We have been informed by the EC colleagues that the Cabinet yesterday decided that the Commission will officially ask EFSA to check out the carcinogenicity assessment with IARC; a letter from is currently under preparation.

KR,

glyphosate raised by IARC and, where necessary, to liaise with that organisation, as to obtain the necessary elements. It is our understanding that, while the publication of the final IARC Monograph is only foreseen for 2016, on technical level IARC has agreed to make a reference list of the studies used by IARC in its assessment of glyphosate available to EFSA within the month of April 2015.

EFSA should examine whether any additional information was relied upon by IARC, as compared to the information available for the renewal procedure. Furthermore, EFSA should establish to which extent IARC's assessment was based on information on the active substance glyphosate vs. on formulated plant protection products containing glyphosate and co-formulants.

Thereafter, EFSA should consider whether an amendment of the original proposal as regards classification of glyphosate is necessary, and whether a firm causality can be established between the phenomena observed in IARC's assessment and the application of glyphosate containing plant protection products consistent with good plant protection practice and having regard to realistic conditions of use.

While the Commission requests EFSA to integrate the above considerations into the framework of the peer review of the active substance glyphosate, reference is also made to Article 30(1) and (2) of Regulation (EC) No 178/2002, which deals with diverging scientific opinions.

I would highly appreciate if EFSA could react to this request within the agreed timelines of the ongoing peer review.

My services remain at your disposal for further information. On this matter, you can contact [redacted] who is responsible for this dossier in the pesticide sector of Unit E3.

Yours sincerely,

[redacted]

Cc: [redacted]

From:
Sent: 20 May 2015 16:12
To:
Cc:
Subject: RE: Art.31 - glyphosate - acceptance of mandate
Attachments: Gliphosate - Acceptance letter for Mandate to consider findings by IARC .pdf

Categories:

Dear ,

Please find in attachment the ED acceptance letter for upload on the RAW.

Thank you.

Kind regards.

From:
Sent: 12 May 2015 11:19
To: PRAS.secretariat
Cc:
Subject: RE: Art.31 - glyphosate - acceptance of mandate

Dear

The Q number is EFSA-Q-2015-00279. Please fill in the missing fields including point H of your email. The draft output number should be linked by the Unit.

Thanks

From:
Sent: 12 May 2015 09:31
To:
Cc:
Subject: FW: Art.31 - glyphosate - acceptance of mandate

Ciao ,

Poichè non c'è ci puoi pensare tu?

Grazie mille.

From:
Sent: 11 May 2015 15:00
To:
Cc:
Subject: Art.31 - glyphosate - acceptance of mandate

Dear

Please find in attachment the letter from EC, could you please open a new question linked to the on-going mandate M-2014-0226:

1. Upload the EC letter at mandate level
2. Information for the question:
    a. Question type: Application
    b. Food sector area: Pesticides
    c. Subject/subarea: Request to consider the findings by IARC as regards the potential carcinogenicity of glyphosate or glyphosate containing plant protection products in the ongoing peer review of the active substance
    d. Visibility: visible
    e. Activity: Activity 2
    f. Type of deadline: Negotiated deadline
    g. Deadline: 13/08/2015
    h. Output type: Other Scientific Outputs – Conclusion on Pesticides Peer Review.

Thank you.

Kind regards,

efsa
European Food Safety Authority

EXECUTIVE DIRECTOR

19 MAY 2015

Ref. [redacted](2015) – out- 14186575

Mr [redacted]
[redacted]
Directorate General for Health and Food Safety
European Commission
200, rue de la Loi
B-1049 Brussels
Belgium

Re: Request to consider the findings by IARC as regards the potential carcinogenicity of glyphosate or glyphosate containing plant protection products in the ongoing peer review of the active substance

Ref.: Ares(2015)1823991 – 29/04/2015

Dear Mr [redacted],

On 30 April 2015, the European Food Safety Authority (EFSA) received from the European Commission (EC) the mandate to take into account in its ongoing peer review of glyphosate the findings of IARC, to investigate the carcinogenic potential of glyphosate raised by IARC and where necessary to liaise with IARC as to obtain the necessary elements.

EFSA has already contacted IARC asking for additional information, but following this mandate, we will submit a formal request referring to Article 30(2) of Regulation (EC) No 178/2002. The monograph supporting the IARC findings is not available, this information is essential for a proper understanding of the scientific arguments supporting the IARC proposal.

EFSA accepts the mandate and has assigned EFSA Question Number EFSA-Q-2015-00279 to this task. EFSA will integrate its views on the proposed IARC classification into the conclusion on the peer review of the active substance glyphosate (deadline on 13 August 2015). After receiving the information from IARC, EFSA would require at least two months for conducting a proper evaluation of the IARC assessment. Therefore, this deadline may require an extension if IARC submits or publishes relevant information after 13 June 2015. If this is the case, EFSA will consult your services and request an extension of the deadline for the EFSA conclusion on glyphosate in order to cover properly this mandate.

Yours sincerely,

[redacted]

Cc:

From:
Sent: 20 May 2015 16:43
To: com@iarc fr
Cc:

Subject: Final monograph supporting IARC classification of glyphosate
Attachments: Glyphosate - Access request to final monograph supporting IARC classification.pdf

Dear

On behalf of , please find attached the letter regarding the access request to final monograph supporting the IARC classification of glyphosate as "probably carcinogenic to humans".
The original document will be sent by post.

Yours sincerely,

PESTICIDES Unit
REPRO Department

efsa
European Food Safety Authority

Via Carlo Magno 1A
43126 Parma (Italy)
Tel: +39. 0521. 036
www.efsa.europa.eu
twitter.com/EFSA_EU
youtube.com/EFSAchannel

From:
Sent: 23 March 2015 18:08
To:
Cc:

Subject: RE: unable to travel this week!

Dear
It is fine with me. Maybe will bring it up and now we would be prepared in case.

The situation is a bit awkward because the same data is being assessed by different experts and the conclusions don't seem in line.
I am also thinking about the upcoming event of the commission that many of us will be involved in (the 24th of April). So if it is raised we could complement each other.
Kind regards

Sendt fra Samsung mobil

-------- Oprindelig meddelelse --------
Fra:
Dato: 23/03/2015 16:38 (GMT+01:00)
Til:
Cc:

Emne: RE: unable to travel this week!

Dear

Thank you for the information regarding the IARC classification of glyphosate. I check the state of play with my colleagues involved in the peer-review. Glyphosate is being considered under the AIR II procedure and was discussed in expert meeting end of February 2015. EFSA is aware of the IARC conclusions and the RMS will address this in an addendum to the RAR currently being drafted.

Probably this is addressing your point and to my opinion, there is no need to have a formal point raised in the plenary. Can you confirm?

Kind regards,

From:
Sent: 23 March 2015 10:30
To:

Subject: SV: unable to travel this week!

Dear

Ok fine with me.

I have a suggestion to the agenda. Could we on AOB put a point on the recent IARC classification of Glyphosate. The situation and how it is managed ?

KR

From:
Sent: maandag 23 maart 2015 6:22
To:
Cc:
Subject: RE: unable to travel this week!

Dear

I am able to chair this week but would also be absolutely happy if [redacted] does it.

[redacted] If.

With kind regards

Sendt fra Samsung mobil

-------- Oprindelig meddelelse --------

Fra: [redacted]

Dato: 23/03/2015 00:12 (GMT+01:00)

Til:

P[redacted]

Cc. [redacted]

Emne: unable to travel this week!

Dear all,

To my regret I am unable to travel this week to attend the WG on residue definition and the PPR Plenary meeting.

[redacted] research. My [redacted] s tomorrow but it is already clear that it is impossible for me to travel to Parma on Tuesday morning. I am very sorry to let you down, please give my apologies to the PPR Panel.

I am sorry for forcing you to take over chairing the meeting on very short notice.

Kind regards,

Delivered to you by [redacted] environment.

From:
Sent: 21 April 2015 20:29
To:
Cc:
Subject: RE: SV: feedback from PPR plenary 25-26 March

OK, sounds reasonable.

Kind regards,

Delivered to you by environment.

From:)efsa.europa.eu>
Sent: 21 apr. 2015 18:52
To:
Cc:

Subject: RE: SV: feedback from PPR plenary 25-26 March

Dear

It is fine if you inform the SC about the procedural status of glyphosate under Regulation 1107/2009.

However, it's better not to make any qualitative appreciation of the EU and IARC assessments. Although it is true that we still have little experience with epidemiological studies, we are not sure that the divergence of opinion between the RMS and IARC regarding glyphosate carcinogenicity is based on divergent results, but rather a different interpretation of the results (according to a preliminary assessment done by the RMS as the IARC monograph is not yet available). Furthermore the summary of the IARC evaluation states that their classification is based mainly on animal data, supported by epidemiological data.

In addition, it hasn't been discussed whether a follow up would be needed when the IARC monograph becomes available. Note that other pesticides referred by the IARC publication (malathion and diazinon) are also reported as genotoxic carcinogen.

Kind regards,

From:)@
Sent: 21 April 2015 15:01
To: M
Subject: Fw: SV: feedback from PPR plenary 25-26 March

Dear

With respect to the feedback to the SC this week, in addition to the discussion on the ERA opinions I think I should inform the SC on the discussion on glyphosate (IARC vs peer-review), from the perspective of the use of epidemiological data in pesticide risk assessment, and link the media attention in several member states to the current PPR mandates on this.
I won't go into who is right or wrong but I would like to explain that there is an ongoing peer review in the Pesticide unit /DE and that there will be further follow-up when the IARC monograph becomes available, and that this is an example where epidemiological data do not match with the animal data.
Is this OK with you?

From:
Sent: 19 May 2015 19:10
To:
Subject: RE: Glyphosate

Dear , in that case it might not be interesting enough. I hope you do not mind.
With kind regards,

-----Original Message-----
From: [mailto: a.europa.eu]
Sent: dinsdag 19 mei 2015 19:06
To:
Cc:
Subject: Re: Glyphosate

Dea we can present the EFSA process, which includes both hazard and risk assessment elements but not in the context of IARC. We can explain how EFSA considers other assessments and address divergences. My concern is that for glyphosate we are still in the evaluation phase, thus there are not two assessments and we cannot anticipate the EFSA view. I assume that a technical comparison of the classification criteria is not relevant for your audience, thus, please consider if our presence can be of interest when the only message we can provide now is that we will publish our conclusion after the summer. KR

Sent from my iPhone

> On 19 May 2015, at 13:24, > wrote:
>
> Dear
>
> This sounds good. We would in particular be interested in a presentation that discusses EFSA's pesticide risk assessment process (hazard and exposure) in the context of the IARC process (hazard only and how the two different approaches should be regarded for human health risk. We expect this would help a lot to understand the differences in assessments by different agencies with the resulting confusions and misunderstandings. Will this be possible to include in the presentation?
>
> The date for the round table is June 18 in the morning.
>
> Looking forward to hearing from you.
>
> With kind regards,
>
>
>
>
> -----Original Message-----
> From: [mailto: efsa.europa.eu]
> Sent: maandag 18 mei 2015 9:56
> To:
> Cc:
> Subject: RE: Glyphosate
>
> Dear
> As already indicated, according to the EFSA policy we do not comment/anticipate ongoing risk assessments. Thus, specifically on glyphosate, the only information we are able to provide is that we are finalising the peer-review and that the EFSA conclusion will be available during the summer. As already mentioned to we can provide a generic overview on EFSA role and activities on pesticides. The current assessment on glyphosate is part of the standard regular renewal process for pesticides in the EU, and we can present the procedural issues, but the EFSA view will not be ready by June. Please let me know if this general presentation could be of interest for you and the exact date.

> Best regards,
>
>
>
>
>
>
> Via Carlo Magno 1/A
> I-43126 Parma
> Italy
> Tel: +39 0521 036 Fax: +39 0521 036
> E-mail: @efsa.europa.eu
> www.efsa.europa.eu
> twitter.com/EFSA_EU
> youtube.com/EFSAchannel
>
> 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. If you are not the intended recipient, please let the sender know immediately.
>
>
>
>
> -----Original Message-----
> From: [mailto: wur.nl]
> Sent: 16 May 2015 17:04
> To:
> Cc:
> Subject: FW: Glyphosate
>
> Dear
>
> was so kind to provide me with your contact details.
>
> I like to inquire if you or a member of your unit could give a presentation on EFSA's activities on human and environmental risk assessment. As I understood from you cannot talk about the ongoing glyphosate case, but we would be interested to learn how the activities relate to the current glyphosate case. I hope this will be possible. The presentation would be part of a plenary session of the 2015 ICABR conference in Ravello, Italy, June 16 to 20, 2015. The panel will include a representative of Monsanto, a representative from PRMA Canada, an environmental economist, and hopefully an EFSA representative.
>
> About 120 people attend the conference every year. Participants are mainly economists working in the field of bioeconomy economics and policy. You can find additional information about the ICABR and this year's conference at http://economia.uniroma2.it/icabr . The conference organisers would be happy to cover your travel and accommodation costs.
>
> Looking forward to hearing from you at your earliest convenience.
>
> With kind regards,
>
>
>
> _____
>
>
>
> e-mail: @ nl
>
>

From: [redacted]
To: [redacted]
Subject: FW: Anfrage ARD Report
Date: 04 June 2015 09:28:09

Hi [redacted],

[redacted] meint, dass der BFR draft assessment report unter dem untenstehenden Link verfügbar ist. Ich hatte ihm gesagt, nach Rücksprache mit der Unit (dir) dass der BfR Report nur auf der BfR Seite zu finden ist.

Unter dem Link http://dar.efsa.europa.eu/dar-web/provision finde ich aber nur Commission regulations in der Spalte "Glyphosate".

Was ist jetzt richtig?

Und: Gibt es Neuigkeiten bezgl. des IARC? Haben die geliefert und wir schaffen es in der Deadline für Glyphosate oder verschieben wir unsere Deadline?

Viele Grüße,

[redacted]

From: [redacted]
Sent: 03 June 2015 18:54
To: [redacted]; [redacted]
Subject: RE: Anfrage ARD Report

Hi [redacted] – I don't think this is correct…we publish the Draft Assessment Reports from the RMS. I found the link at last, it is here… http://dar.efsa.europa.eu/dar-web/provision
I also found a note I had made for myself on the whole process, best [redacted]

- EFSA receives the DAR from the Rapporteur Member State
- EFSA initiates the 2-month commenting period with Member States (they receive the full unredacted version of the application)
- In parallel, EFSA carries out a 'sanitisation' process with the applicant to determine which data/info in the application are to be deemed confidential for commercial reasons. EFSA allows 2 weeks for this process but in rare cases it can drag on, sometimes for a period of several weeks.
- Once EFSA and the applicant finalise the sanitisation process, the redacted version of the DAR is published on our website here: http://dar.efsa.europa.eu/dar-web/provision
- This signals the launch of the 2 month public consultation
- Once EFSA finalises the commenting period with MS, it begins the peer review incorporating comments from MS and the public consultation as and when it receives them during the process.
- Once the peer review is finalised (6 months after receiving the DAR unless EFSA makes additional requests for data to the applicant) it is published on our website.

From: [redacted]
To: [redacted]
Subject: FW: Glyphosate[redacted]
Date: 19 June 2015 13:00:21
Attachments: [redacted]

FYI as there are so many things on-going in parallel.

Best regards,
[redacted]

From: [redacted]
Sent: 19 June 2015 12:21
To: [redacted];
Cc: [redacted];
Subject: RE: Glyphosate[redacted]

Dear [redacted],

Following our phone call earlier this morning, I attach the updated internal note on glyphosate. Please let me know if you need further input from my side,

[redacted]

From: [redacted]
Sent: 19 June 2015 11:29
To: [redacted]
Cc: [redacted]; [redacted]; [redacted]
Subject: RE: Glyphosate/ update [redacted]

EU Food Policy refers to WHO has created an ah hoc expert task force on glyphosate to consider possible divergences between IARC and WHO/FAO joint mtg on pesticides residues
I tend to think that this is something different but not sure
[redacted]

From: [redacted]
Sent: 19 June 2015 11:22
To: [redacted]
Cc: [redacted]; [redacted]; [redacted]
Subject: Re: Glyphosate[redacted]

Dear [redacted], I assume your reference is to the ad hoc JMPR WG. We have also agreed to exchange the assessments and coordinate the publication. KR [redacted]

Sent from my iPhone

On 19 Jun 2015, at 10:29, [redacted] <[redacted]@efsa.europa.eu> wrote:

> Thanks [redacted] – just read in the EU Food Policy that WHO set up a task force on glyphosate and see some familiar names there: [redacted], [redacted], [redacted]…

Can you tell us something about this development, how it fits into the picture, if you allow the expression?
Thanks
[redacted]

From: [redacted]
Sent: 19 June 2015 05:47
To: [redacted]
Cc: [redacted]; [redacted]; [redacted]; [redacted]
Subject: Re: Glyphosate [redacted]

Thanks [redacted], the additional information on glyphosate is as follows:
IARC has confirmed the publication in July but the actual date is unknown, most likely our conclusion will be delayed for allowing a proper assessment
To minimize the delay we will launch a MS consultation on the Efsa draft now covering all other endpoints and a second on carcinogenicity later, after assessing the IARC monograph
USEPA has also postponed their assessment until the IARC publication, we are considering an exchange of views among the exerts of both agencies and coordination regarding the publication and dissemination of the outcomes.
Greenpeace has requested access to all documents and internal/external exchanges, this is creating a high additional workload, we are also checking with EC if they have a similar request
Please let me know if you need something else.
[redacted]

Sent from my iPhone

On 15 Jun 2015, at 12:03, [redacted]
<[redacted]@efsa.europa.eu> wrote:

> [redacted]!
> [redacted]
> I am writing to you as next week [redacted] meets the Commissioner (not on glyphosate) and in my view as this is taking a high and higher political profile, I think it would be helpful to have one page/brief note summarising where we are etc -- [redacted] prepared this updated already for the ANSES visit (3/06) and that information coupled by any new updates, i.e., IARC monograph etc, would be very helpful.
> Can you accommodate this? if so, can you share by Friday/end of this week?
> Thanks a lot
> [redacted]
>
> ---
>
> **From:** [redacted]
> **Sent:** Monday, June 15, 2015 11:43 AM
> **To:** [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; Management Team; [redacted]; Team COMMS; [redacted]
> **Cc:** EFSA Press

Subject: EFSA Daily Press Review 15 June 2015

From: [redacted]
To: [redacted]
Subject: RE: glyphosate ongoing activities
Date: 30 June 2015 11:06:06

Thank you [redacted]!

[redacted]

_____
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] and [redacted]), [redacted] will be in EFSA as a member of the [redacted] 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]'s 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]; [redacted]; Team External Relations; [redacted]; [redacted]; [redacted]
Subject: RE: Summary: Communications re IARC - Glyphosate / News in Brief for next week
Date: 17 July 2015 17:42:59
Attachments: image002.png
image004.png
image006.png

Dear [redacted],

See my comments below.

Regards

[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]
Sent: 17 July 2015 17:34
To: [redacted]; [redacted]; [redacted]; [redacted]
Cc: [redacted]; [redacted]; [redacted]; Team External Relations
Subject: Summary: Communications re IARC - Glyphosate / News in Brief for next week

Dear All,

As discussed yesterday among [redacted], [redacted], [redacted] and myself we think we should publish a NIB once we received the IARC monograph.

[redacted] and I had a quick chat today and he is available for drafting the NIB early next week.

According to the Unit, we should receive it next week Wednesday.

Aspects that should be mentioned in the NIB, which should be published on the day we receive the IARC doc:

- EFSA's two mandates (peer review of glyphopsate and IARC mandate)
- EFSA received the IARC and will assess it
- EFSA will merge BfR assessment of IARC and its own assessment and integrate **it in the peer review** of glyphosate. EFSA will integrate the assessment of the IARC monograph into the EFSA conclusion on the peer review as referred to in the mandate (link to the RAW: http://swansea-as1.efsa.eu.int:8080/raw-war/mandateLoader?2 ich hoffe der funktioniert
- Deadline for sending final conclusion to the EU Commission will be postponed until 30. October (as

agreed by the Commission) EFSA will ask for an extension of the legal deadline, which has to be agreed by COM. It is aimed to finalise the EFSA conclusion including the assessment of the IARC monograph by end of October 2015.

I will try to reach BfR's press office on Monday and find out what kind of communications they are planning. Will give an update. Great!

Please note:

- The Unit said: In case we DO NOT receive the IARC before the end of the month, we publish nothing and go ahead with deadline 13 August (sending to the commission).

We said: if the monograph is will not be available by the end of July, we will stick to the original DL of 13 August 2105 and publish the EFSA conclusion without an evaluation of the IARC monograph.

Have all a good weekend

From: [redacted]
To: [redacted]
Subject: FW: Glyphosate
Date: 29 July 2015 09:47:06
Attachments: [redacted]

Dear [redacted],

Can you please answer to [redacted]?

Thanks a lot,

[redacted]

From: [redacted]
Sent: 28 July 2015 17:26
To: [redacted]; [redacted]
Cc: [redacted]; [redacted]; [redacted]; [redacted]
Subject: RE: Glyphosate

Dear Both

Thanks for the updates. However, would I be correct in thinking it is practically certain that we will have to take the IARC paper into account – even if this means going back to the Commission at the end of this week/early next week to agree to extend the timeline?

Some other information that I have just learnt today (that you probably already know) that would support the re-scheduling of the deadline is that [redacted] recently wrote to MEPs declining an invitation to take part in a debate on glyphosate in September but confirming that EFSA would be happy to do this after the end of October when we had published our glyphosate assessment (see attached).

Best

[redacted]

From: [redacted]
Sent: 28 July 2015 12:25
To: [redacted]
Cc: [redacted]; [redacted]
Subject: Re: Glyphosate

Dear [redacted],

I copy [redacted] as he is in the office in case you need further info.
IARC announed they will publish by end of July so we are confident they will. However it is correct that in case they don't publish by end July, we'll have to liaise with EC and it might be

decided we go ahead with the finalisation of the conclusion without the IARC monograph. [redacted] explained correctly that DE will prepare an addendum to the RAR that will than be peer reviewed by EFSA and the other MS.
Best regards,
[redacted]

Verstuurd vanaf mijn iPhone

Op 28 jul. 2015 om 11:11 heeft [redacted] <[redacted]@efsa.europa.eu> het volgende geschreven:

> Dear [redacted],
>
> As far as I know, the IARC monograph is/will shortly be available and reviewed by the RMS Germany in an addendum to the RAR. This means that it will be covered by the PRAS conclusion.
>
> I cc [redacted] in case I'm wrong or for further details.
>
> Kind regards,
>
> [redacted]
>
> ---
>
> **From:** [redacted]
> **Sent:** 27 July 2015 17:49
> **To:** [redacted]
> **Subject:** Glyphosate
> **Importance:** High
>
> Hi [redacted]
>
> Hope you're well. I've just returned from my holidays and wondered if you could clarify an issue regarding the peer review of glyphosate.
>
> A couple of weeks ago I had a discussion with [redacted] who said that we would definitely wait until we had received the paper from IARC so that we could consider it as part of our assessment. This means we would not deliver the peer review until November / December. (A draft news in brief has already been written and approved by PRAS in anticipation of this).
>
> However, I have heard that there is now a possibility that if we don't receive the IARC paper soon (this week???) then we may go ahead and publish the peer review without it according to the original timeline of Sept.
>
> I'd be grateful if you could confirm so that we can plan communication activities.
>
> Best
>
> [redacted]

[redacted]
[redacted]
Risk Communication Unit
Communications and External Relations
European Food Safety Authority (EFSA)
Via Carlo Magno 1A
43126 Parma, Italy

Tel: [redacted]
Fax: [redacted]

Email: [redacted]@efsa.europa.eu
Website: http://www.efsa.europa.eu

Follow @efsa_eu

From: [redacted]
To: [redacted]
Subject: Re: Glyphosate
Date: 29 July 2015 15:02:33
Attachments: image007.png
image008.png
image009.png

[redacted]

[redacted]

Op 29 jul. 2015 om 10:23 heeft [redacted]
<[redacted]@efsa.europa.eu> het volgende geschreven:

Dear [redacted],

There are different scenarios possible regarding the EFSA conclusion on glyphosate:

1. The IARC monograph will be available – as indicated – by the end of this month
   a. In this case approx. 10 additional weeks are needed
   b. EFSA will ask for an extension of the legal deadline of 13 August 2015 and take the IARC findings into consideration
   c. The legal deadline will probably be moved to 30 October 2015.

2. The IARC monograph will not be available before the expiry of the legal deadline
   a. We have to re-consider the situation

I just know by accident that there was an invitation for [redacted] to attend the session on glyphosate, but I don't know any details about the letter you are referring to. The PRAS co-ordinators have not been informed.

Let me know, if further information is needed. I am available.

Best regards

[redacted]

[redacted]
Scientific Officer
Pesticides / Regulated Products

<image007.png.secure>

Via Carlo Magno 1A
43126 Parma (Italy)

Tel. [redacted]
www.efsa.europa.eu
twitter.com/EFSA_EU <image008.png.secure>
youtube.com/EFSAchannel <image009.png.secure>

From: [redacted]
Sent: 29 July 2015 09:47
To: [redacted]
Subject: FW: Glyphosate

Dear [redacted],

Can you please answer to [redacted]?

Thanks a lot,

[redacted]

From: [redacted]
Sent: 28 July 2015 17:26
To: [redacted]
Cc: [redacted]; [redacted]; [redacted]; [redacted]
Subject: RE: Glyphosate

Dear Both

Thanks for the updates. However, would I be correct in thinking it is practically certain that we will have to take the IARC paper into account – even if this means going back to the Commission at the end of this week/early next week to agree to extend the timeline?

Some other information that I have just learnt today (that you probably already know) that would support the re-scheduling of the deadline is that [redacted] recently wrote to MEPs declining an invitation to take part in a debate on glyphosate in September but confirming that EFSA would be happy to do this after the end of October when we had published our glyphosate assessment (see attached).

Best

[redacted]

From: [redacted]
Sent: 28 July 2015 12:25
To: [redacted]
Cc: [redacted]; [redacted]
Subject: Re: Glyphosate

Dear [redacted],

I copy [redacted] as he is in the office in case you need further info.
IARC announed they will publish by end of July so we are confident they will.
However it is correct that in case they don't publish by end July, we'll have to liaise with EC and it might be decided we go ahead with the finalisation of the conclusion without the IARC monograph. [redacted] explained correctly that DE will prepare an addendum to the RAR that will than be peer reviewed by EFSA and the other MS.
Best regards,
[redacted]

Verstuurd vanaf mijn iPhone

Op 28 jul. 2015 om 11:11 heeft [redacted]
<[redacted]@efsa.europa.eu> het volgende geschreven:

> Dear [redacted]
>
> As far as I know, the IARC monograph is/will shortly be available and reviewed by the RMS Germany in an addendum to the RAR. This means that it will be covered by the PRAS conclusion.
>
> I cc [redacted] in case I'm wrong or for further details.
>
> Kind regards,
>
> [redacted]
>
> ---
>
> **From:** [redacted]
> **Sent:** 27 July 2015 17:49
> **To:** [redacted]
> **Subject:** Glyphosate
> **Importance:** High
>
> Hi [redacted]
>
> Hope you're well. I've just returned from my holidays and wondered if you could clarify an issue regarding the peer review of glyphosate.
>
> A couple of weeks ago I had a discussion with [redacted] who said that we would definitely wait until we had received the paper from IARC so that we could consider it as part of our assessment. This means we would not deliver the peer review until November / December. (A draft news in brief has already been written and approved by PRAS in anticipation of this).
>
> However, I have heard that there is now a possibility that if we don't receive the IARC paper soon (this week???) then we may go ahead and publish the peer review without it according to the original timeline of Sept.

I'd be grateful if you could confirm so that we can plan communication activities.

Best

[redacted]

[redacted]
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Communications and External Relations
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