

Message

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**From:** [Redacted]  
**Sent:** 3/22/2013 7:45:29 AM  
**To:** SALTMIRAS, DAVID A [Redacted]  
**Subject:** AW: Glyphosate carc review v6

Hi David,

I agree that Séralini has received more attention than he deserves and we should not contribute to this any further. If we had an idea about when we can expect Séralini's paper to disappear from the archives, we may decide to not even mention his name at all.

In any case, even if this means that I have worked through Séralini's "data" in vain, I also think we should remove any detailed discussion of this junk science from our MS.

We should rather include the Polish paper on the chronic rat study and potentially other publications fulfilling minimum validity criteria like number of rats per dose.

Best regards,

[Redacted]

**Von:** SALTMIRAS, DAVID A [Redacted]  
**Gesendet:** 18 March 2013 18:56  
**An:** [Redacted]  
**Cc:** [Redacted]  
**Betreff:** RE: Glyphosate carc review v6  
**Wichtigkeit:** Hoch

All,

Firstly, I agree with [Redacted] regarding order of studies reviewed. For the mouse studies, this will simple mean reversing order of the last two studies. More juggling of the order of the rat studies will be needed, so we will need to review changes carefully to ensure tables and text citations are correctly modified.

I agree with the bulk of [Redacted] comments/changes, but would like to reconsider whether or not to include the detail on NHL in the epidemiology section – I believe it is important to dispel the myth of NHL as a single disease, especially for a future IARC weight of evidence review.

I also like Chris's proposed rewritten section on exposure in the discussion; for clarity, I would like an example of a general public dietary exposure calculation.

Update on Seralini publication - A highly credible source informs me that the journal/publisher has asked Seralini to retract his paper from *Food and Chemical Toxicology*. I do not believe Seralini will voluntarily retract. However, there may now be sufficient grounds for the publisher to step in and remove/expunge the paper from their journal. Therefore, if we publish a review on the Seralini paper, we may further immortalize this poorly conducted research. I propose we cut Seralini from our review of industry sponsored chronic studies.

Furthermore, in five years time or so the Seralini paper may no longer be known of, but if published alongside our incredible regulatory data set, the Seralini research will always be revisited whenever someone cites our paper. If the Seralini paper is removed from the literature by the publisher, it should not be eligible for consideration if an IARC review of glyphosate takes place in the future. However, even if Seralini's paper is retracted in the future, if we publish our review of his research we open the gate for its consideration in an IARC glyphosate review.

Based on the sponsor's (Glyphosate Task Force) rationale for this paper, preparing for an IARC review to allow consideration of our regulatory data base (IARC will not consider unpublished studies) should such a review take place, I do not think we should include the Seralini paper. Given the extensive EFSA review and their outsourced reviews to MS experts in the attached, we simply do not have enough space to publish the justifiable criticisms of the Seralini paper.

Please let me know your thoughts. If you do not agree with cutting the Seralini paper, please explain your rationale and I will add this to the agenda for discussion at the GTF Toxicology Technical Working Group meeting on Friday this week.

Thank you all,

David Saltmiras, Ph.D., D.A.B.T.

Toxicology Manager

Regulatory Product Safety Center

Monsanto

**Redacted**

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

From: **Redacted**

Sent: Monday, March 18, 2013 7:59 AM

To: **Redacted**

Cc: SALTMIRAS, DAVID A **Redacted**

Subject: RE: Glyphosate carc review v6

**Redacted**

For sure - I guess we will not do mayor changes to the message itself or the presentation of the individual study summaries (which the companies have to agree to), but we can still do editorial changes/different presentations of the same message and work on the fine tuning of the introduction and discussion. I just fear that the companies may take up to 6 weeks for review until all are in, and this may hold us up if we don't get it initiated.

Best regards,

**Redacted**

**Redacted**

Corporate Toxicologist | MA Europe

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

From: [Redacted]

Sent: 18 March 2013 13:50

To: [Redacted]

Cc: SALTMIRAS, DAVID A ([Redacted])

Subject: RE: Glyphosate carc review v6

ok, I agree if we still have the possibiitiy of editorial changes.

[Redacted]

Am 2013-03-18 13:36, [Redacted]

> Dear colleagues,

>

> Here my latest comments (I used the version edited by David to make it

> a bit easier to implement without having too many versions to

> compare).

>

> I believe we are there - I propose that the last round of comments

> gets implemented and we circulate to the member companies for approval

- > right away, not to lose time on this end. In case we want to do some
- > polish meanwhile before submission, that should not have to go through
- > company review again.

>

> Best regards,

> **Redacted**

>

>

> **Redacted**

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>

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

> From: SALTMIRAS, DAVID A (AG/1000)

> **Redacted**

> Sent: 16 March 2013 00:43

> To: **Redacted**

> Subject: RE: Glyphosate carc review v6

>

> All,

>

> Thank you for the perseverance you have shown in reviewing multiple

> revisions of this important paper. I have thoroughly reviewed and

> have minor comments/suggestions, except for the added section on the

> Seralini paper, to which I have rearranged and consolidated to

> relevant data/discussion to carcinogenicity.

>

> I believe we are very close to having a final draft for company

> internal reviews. Please comment pack to Volker, especially on the

> Seralini section in the attached. If Volker would please try to

> address this ASAP, we may complete this before the anticipated BVL

> preliminary draft reevaluation assessment report.

>

> Regards,

>

> David Saltmiras, Ph.D., D.A.B.T.

> Toxicology Manager

> Regulatory Product Safety Center

> Monsanto

> ph: **Redacted**

>

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

> From: **Redacted**

> Sent: Thursday, March 14, 2013 11:26 AM

> To: **Redacted** SALTMIRAS, DAVID A **Redacted**

> Subject: Glyphosate carc review v6

>

> Gentlemen,

>

> attached you find the newest draft of the glyphosate cancer review.

>

> I have struggled hard, but I have summarised and discussed the

> Séralini paper. This was suggested by **Redacted** and I agree with him

> that we cannot simply say "this is junk science" and not mention it

> further. Seralini touches on carcinogenicity of glyphosate-based

> herbicides so we probably cannot ignore it. I know that Christian was

> strongly in favour of "less Séralini", but I guess the coverage is

> necessary to expose the subterranean quality of this study by

> "rounding it up" against the GLP studies.

>

> I have now created a separate MAK-style table for all studies.

> Publishers normally ask for the number of tables to be kept at a

> minimum and have thus deleted the summary tables listing all the

> studies and the tables with specific findings made in individual

> studies. We now have 16 tables in the MS and a total of 27 pages

> excluding Title page, References and Tables.

>

> As always, your comments are welcome!

>

> Kind regards,

> **Redacted**

>

>

>

>

> -----Ursprüngliche Nachricht-----

> **Redacted**

> Gesendet: 04 March 2013 07:41

> An: **Redacted** SALTMIRAS, DAVID A (AG/1000)

> Cc: **Redacted**

> Betreff: RE: Glyphosate carc review v5

>

> Dear colleagues,

>

> Here my comments as well.

>

> Best regards,

> **Redacted**

>

> **Redacted**

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>

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

> From: **Redacted**

> Sent: 02 March 2013 21:13

> To: SALTMIRAS, DAVID A **Redacted**

> Cc: **Redacted**

> Subject: RE: Glyphosate carc review v5

>

> Dear all,

> please find some comments on the most recent draft.

> Sincerely

> **Redacted**

>

> Comments to latest revision of the glyphosate draft

> General:

> The draft has been considerably improved, although it lacks essential

> data for evaluation of the different long term studies.

> Table 2:

- > The studies need to be identified (e.g. Monsanto 2010 or so) although
- > these are chronic, not lifetime studies, the number of animals per
- > group (under type of study) and the number of affected animals per
- > group should be provided under Targets/Main effects.

> Table 3:

- > The same applies to this Table: No of animals per group and the number
- > of affected animals per group for the different effects described.
- > Please always indicate the target organ, which e.g. is not given for
- > study No 6.
- > Delete Only in study 5 and 6.
- > Study 9, please check under dose levels and LOAEL 814 versus 841.
- > Tables 5, 6 etc. Whenever you provide details on studies listed in
- > Table 3 please include the number used in Table 3 as well.
- > Tables 6 etc. It is not clear what are the criteria for describing the
- > different details given in these tables. Something like “The prominent
- > effects in this studies are xyz. Further details are given in Table x.
- > That's it in Kürze
- > Best regards

> **Redacted**

>

>

> Am 2013-02-27 21:58, schrieb SALTMIRAS, DAVID A **Redacted**

>> **Redacted**

>>

>> I have thoroughly reviewed and commented in the latest revision of

>> the glyphosate carcinogenicity review manuscript, attached. More

>> specifically, I

>>

>> · refined the introduction and added citations;

>>

>> · asked Larry Kier to review the genotoxicity paragraph and

>> incorporated his suggestions in both this section and the conclusion;

>>

>> · thought it important in the epidemiology section to address the

>> very recent Alavanja et al. (2013) paper and his claim of a

>> glyphosate association with non-Hodgkin's lymphoma. I think this is

>> now thoroughly addressed in a reasonable manner, but please review

>> and let me know your thoughts (paper attached);

>>

>> · added some minor clarifying detail on two Monsanto studies;

>>

>> · made a couple of comments to be addressed on non-Monsanto studies;

>>

>> · provided an alternative to the risk assessment paragraphs in the

>> discussion, with justification in the comments;

>>

>> · added my declaration of interest;

>>

>> · included minor points of clarification to tables; and

>>

>> · asked for a couple clarifications on Table 14 (FSC mice data).

>>

>> NOTE: I would like all the data owners to review their data tables

>> 5-14 and confirm accuracy. **Redacted** can you please forward the

>> respective tables to the member company representatives to confirm

>> their data? No need for the Monsanto Tables 5 and 12.

>>

>> I also took the liberty to discuss the manuscript submission with

>> Roger McClellan, Editor in Chief of Critical Reviews in Toxicology.

>> Roger requested that we provide 7-8 suggestions of peer reviewers, so

>> please think about appropriate reviewers for this paper. Hopefully we

>> can finalize this manuscript soon and share with the Glyphosate Task

>> Force Toxicology Technical Working Group to start relevant company

>> internal approvals before submitting to Critical Reviews in

>> Toxicology.

>>

>> David Saltmiras, Ph.D., D.A.B.T.

>> Toxicology Manager

>> Regulatory Product Safety Center

>> Monsanto

>> **Redacted**

>>

>> FROM: **Redacted**

>> SENT: Tuesday, February 26, 2013 8:03 AM

>> TO: **Redacted**

>> **Redacted**

>> **Redacted** SALTMIRAS, DAVID A **Redacted**

>> SUBJECT: Glyphosate carc review v5

>>

>> Dear colleagues,

>>

>> I have worked through the various comments and suggestions from our

>> last telephone call. In addition, I have drafted a separate document

>> that summarises the studies in the MAK commission style (see

>> attachments).

>>

>> I hope that I implemented all of your suggestions. Let me know if you

>> are missing something.

>>

>> Kind regards,

>>

>> **Redacted**

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>> --

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>> **Redacted**

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>> European Registered Toxicologist (DGPT)

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>> Senior Expert Toxicology

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>> **Redacted**

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>> Links:

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>> **Redacted**

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