1_PAD 2016/027 Internal discussions IARC findings_Vincent Harmsen
Agenda and minutes of meetings internal steering committee glyphosate

# PROJECT STEERING COMMITTEE MEETING
# (FOLLOW-UP WORK ON GLYPHOSATE)

## 11 DECEMBER 2015, 10:00-11:00
## OFFICE (SEAT 06/B12)

## DRAFT AGENDA

1. Trilateral meeting (EFSA/IARC/BfR) in Brussels in the 3rd week of January 2016

   a) draft agenda
   b) participants
   c) meeting location

2. I

3.

4.

5. Scientific publication explaining divergence between EFSA and IRAC opinion on glyphosate

6.

# DRAFT AGENDA

## Trilateral meeting EFSA/BfR/IARC on the scientific assessment of the carcinogenicity of the active pesticide substance glyphosate

**19 (or 22) January 2016**
**10h00-16h00 – Brussels**

| Time | Topic | Presenter |
|---|---|---|
| 10.00-10.10 | Opening remarks | Co-chair:<br>(EFSA)<br>....(IARC) |
| 10.10-10.25 | The IARC process for the review and classification of chemicals: the IARC monographs | .....(IARC) |
| 10.25-10.40 | The peer review of carcinogenicity of plant protection products at EU level: the role of EFSA and MSs | (EFSA) |
| 10.40-11.00 | *Q&A session* | |
| 11.00-12.00 | Glyphosate: focus on the genotoxicity and mechanistic data on carcinogenicity | IARC/BfR/EFSA |
| 12.00-13.00 | Glyphosate: focus on experimental data on carcinogenicity | IARC/BfR/EFSA |
| 13.00-14.00 | LUNCH | |
| 14.00-15.00 | Glyphosate: focus on human and epidemiological data on carcinogenicity | IARC/BfR/EFSA |
| 15.00-15.50 | Overall conclusion on divergent views and agreement of content of minutes of the meeting | EFSA |
| 15.50-16.00 | ***Next steps*** | (EFSA) |

Participants:

BfR: 1 expert covering all aspects of DAR and addendum
IARC: 3-4 experts
EFSA: 3-4 people: (epi), (gentox overall process), (carcinogenicity); (Chair); 1 staff to take minutes. We could also consider asking ECHA to chair the meeting.

Parma, 17 December 2015

# PROJECT STEERING COMMITTEE (PSC) (FOLLOW-UP WORK ON GLYPHOSATE) 11 DECEMBER 2015 10:00-11:00 MEETING MINUTES

**Participants**

**Acronyms**

PSC: Project Steering Committee
BfR: the German Federal Institute for Risk Assessment
IARC: International Agency for Research on Cancer
EChA: European Chemical Agency
JMPR: Joint Meeting on Pesticide Residues
COMMS: Communications
PRAS: Pesticides Unit
ADoI: Annual Declaration of Interest
US EPA: United States Environmental Protection Agency

| AGENDA | DISCUSSION AND DECISIONS | ACTIONS |
|---|---|---|
| 1. Trilateral meeting (EFSA/IARC/BfR) in Brussels in the 3rd week of January 2016<br><br>a) draft agenda<br>b) participants<br>c) meeting location | Invitation letters were sent to IARC and BfR on 8th Dec.<br>So far no reply from IARC (reply received after the meeting).<br>BfR will nominate one staff member after Christmas for a visit at EFSA and propose a later date for the meeting. BfR is also proposing to invite WHO as observer and intends to bring the discussion to the attention of COM. This will be discussed by BU with the DG SANTE Director in a phone call scheduled for today.<br><br>The PSC reiterated the need and the intention to keep the discussion on a scientific level.<br><br>Details of the meeting:<br>To be co-chaired by EFSA-IARC. External chairmanship (e.g. EChA, or JMPR) was discussed but not felt appropriate.<br>Max 3-4 people should attend from each side.<br>EFSA: (overall proces[illegible] and genotoxicity), (epidemiology),<br>[illegible] (carcino), ; 1 staff taking minutes.<br>No presence of the colleagues from COMMS is foreseen. However the agenda has to be reviewed considering a slot of 15 mins to decide and agree with the participants on how to proceed with the communication of the outcomes of the event. | **Action 20151211-01**:<br>PSC: to decide on the chairmanship of the meeting.<br><br>**Action 20151211-02**:<br>MT: Review the agenda: include 15 minutes on how to proceed with the communication of the event. By today 11 Dec. |
| 2. | | |

| | | | |
|---|---|---|---|
| 3. | | | |
| 4. | | | |
| 5. | Scientific publication explaining divergence between EFSA and IRAC opinion on glyphosate | Not discussed. | |

6.

Parma, 17 December 2015

# PROJECT STEERING COMMITTEE (PSC) (FOLLOW-UP WORK ON GLYPHOSATE) 11 DECEMBER 2015 10:00-11:00 MEETING MINUTES

**Participants**

**Acronyms**

PSC: Project Steering Committee
BfR: the German Federal Institute for Risk Assessment
IARC: International Agency for Research on Cancer
EChA: European Chemical Agency
JMPR: Joint Meeting on Pesticide Residues
COMMS: Communications
PRAS: Pesticides Unit
ADoI: Annual Declaration of Interest
US EPA: United States Environmental Protection Agency

| AGENDA | DISCUSSION AND DECISIONS | ACTIONS |
|---|---|---|
| 1. Trilateral meeting (EFSA/IARC/BfR) in Brussels in the 3rd week of January 2016<br><br>a) draft agenda<br>b) participants<br>c) meeting location | Invitation letters were sent to IARC and BfR on 8th Dec.<br>So far no reply from IARC (reply received after the meeting).<br>BfR will nominate one staff member after Christmas for a visit at EFSA and propose a later date for the meeting. BfR is also proposing to invite WHO as observer and intends to bring the discussion to the attention of COM. This will be discussed by BU with the DG SANTE Director in a phone call scheduled for today.<br><br>The PSC reiterated the need and the intention to keep the discussion on a scientific level.<br><br>Details of the meeting:<br>To be co-chaired by EFSA-IARC. External chairmanship (e.g. EChA, or JMPR) was discussed but not felt appropriate.<br>Max 3-4 people should attend from each side.<br>EFSA: (overall process and genotoxicity), (epidemiology), (carcino), 1 staff taking minutes.<br>No presence of the colleagues from COMMS is foreseen. However the agenda has to be reviewed considering a slot of 15 mins to decide and agree with the participants on how to proceed with the communication of the outcomes of the event. | **Action 20151211-01**:<br>PSC: to decide on the chairmanship of the meeting.<br><br>**Action 20151211-02**:<br>MT: Review the agenda: include 15 minutes on how to proceed with the communication of the event. By today 11 Dec. |
| 2. | | |

| | | | |
|---|---|---|---|
| 3. | | | |
| 4. | | | |
| 5. | Scientific publication explaining divergence between EFSA and IRAC opinion on glyphosate | Not discussed. | |

6.

# PROJECT STEERING COMMITTEE MEETING
# (FOLLOW-UP WORK ON GLYPHOSATE)

## 18 DECEMBER 2015, 10:30-12:00

## OFFICE (SEAT 08/B10)

## DRAFT AGENDA

1.
2. Feedback from the teleconferences between EFSA/US-EPA and EFSA/IARC
3.
4.
5.
6. Scientific publication explaining divergence between EFSA and IARC opinion on glyphosate
7.
8.

Parma, 7 January 2016

# PROJECT STEERING COMMITTEE (PSC) (FOLLOW-UP WORK ON GLYPHOSATE) 18 DECEMBER 2015 10:30-12:00 MEETING MINUTES

**Participants**

**Acronyms**

PSC: Project Steering Committee
BfR: the German Federal Institute for Risk Assessment
IARC: International Agency for Research on Cancer
COMMS: Communications
PRAS: Pesticides Unit
ADoI: Annual Declaration of Interest
US EPA: United States Environmental Protection Agency
ED: Executive Director

| AGENDA | DISCUSSION AND DECISIONS | ACTIONS |
|---|---|---|
| 1. | | |
| 2. Feedback from the teleconferences between EFSA/US-EPA and EFSA/IARC | <u>Teleconference US EPA-EFSA</u><br>drafted a document containing explanations/complementary information to address Portier's comment and to be used for the meeting with IARC, with the intention to share with US EPA. The doc is aimed at further clarifying the comments raised after the publication of the EFSA conclusion; the document is not a commentary of the EFSA conclusion and is not part of the regulatory process.<br><br><u>Teleconference IARC-EFSA</u><br>The organisation of the meeting was discussed.<br>EFSA will reply to IARC including the following:<br>• The meeting will take place in February<br>• 5 people max from each side<br>• Co-chairmanship EFSA-IARC<br>• BfR and a IARC WG member could attend<br><br>As soon as the meeting is confirmed, EFSA COMMs should liaise with IARC COMM dept. to discuss the communication issues before the meeting.<br><br>As soon as there's an agreement on the date people have to be identified from each side to start the preparation of each scientific session. | **Action 20151218-03**:<br>If there are comments to the doc prepared by : to be done by Mo 21 Dec lunch time.<br><br>**Action 20151218-03**:<br>MT to revise the agenda (increasing duration from 9 to 17 as well as the duration of the Communication session).<br><br>**Action 20151218-04**:<br>EFSA ED to send the reply letter to C. Wild with the proposals discussed by Tue 22 Dec. |
| 3. | | |

efsa
European Food Safety Authority

4.

| | | | |
|---|---|---|---|
| 5. | | | |
| 6. | Scientific publication explaining divergence between EFSA and IARC opinion on glyphosate | Not discussed. | |
| 7. | | | |
| 8. | | | |

# PROJECT STEERING COMMITTEE MEETING
# (FOLLOW-UP WORK ON GLYPHOSATE)

## 8 JANUARY 2016, 10:00-11:30
## OFFICE (SEAT 08/B10)

## DRAFT AGENDA

1.
2.
3. Bilateral meeting (EFSA/IARC) in Brussels in February 2016
4.
5.
6.
7.
8. Scientific publication explaining divergence between EFSA and IARC opinion on glyphosate
9.
10.
11.
12.

Parma, 7 January 2016

# PROJECT STEERING COMMITTEE (PSC) (FOLLOW-UP WORK ON GLYPHOSATE) 18 DECEMBER 2015 10:30-12:00 MEETING MINUTES

**Participants**

**Acronyms**

PSC: Project Steering Committee
BfR: the German Federal Institute for Risk Assessment
IARC: International Agency for Research on Cancer
COMMS: Communications
PRAS: Pesticides Unit
ADoI: Annual Declaration of Interest
US EPA: United States Environmental Protection Agency
ED: Executive Director

| AGENDA | DISCUSSION AND DECISIONS | ACTIONS |
|---|---|---|
| 1. | | |
| 2. Feedback from the teleconferences between EFSA/US-EPA and EFSA/IARC | Teleconference US EPA-EFSA<br>drafted a document containing explanations/complementary information to address 's comment and to be used for the meeting with IARC, with the intention to share with US EPA. The doc is aimed at further clarifying the comments raised after the publication of the EFSA conclusion; the document is not a commentary of the EFSA conclusion and is not part of the regulatory process.<br><br>Teleconference IARC-EFSA<br>The organisation of the meeting was discussed.<br>EFSA will reply to IARC including the following:<br>• The meeting will take place in February<br>• 5 people max from each side<br>• Co-chairmanship EFSA-IARC<br>• BfR and a IARC WG member could attend<br><br>As soon as the meeting is confirmed, EFSA COMMs should liaise with IARC COMM dept. to discuss the communication issues before the meeting.<br><br>As soon as there's an agreement on the date people have to be identified from each side to start the preparation of each scientific session. | **Action 20151218-03**:<br>If there are comments to the doc prepared by : to be done by Mo 21 Dec lunch time.<br><br>**Action 20151218-03**:<br>to revise the agenda (increasing duration from 9 to 17 as well as the duration of the Communication session).<br><br>**Action 20151218-04**:<br>EFSA ED to send the reply letter to C. Wild with the proposals discussed by Tue 22 Dec. |
| 3. | | |

| | |
|---|---|
| 4. | |

| | | | |
|---|---|---|---|
| 5. | | | |
| 6. | Scientific publication explaining divergence between EFSA and IARC opinion on glyphosate | Not discussed. | |
| 7. | | | |
| 8. | | | |

efsa
European Food Safety Authority

EXECUTIVE DIRECTOR

# DRAFT AGENDA

## IARC/EFSA Meeting on the scientific assessment of the carcinogenicity of the active pesticide substance glyphosate

**Xx February 2016**
**09h00-17h00 – Brussels**

| Time | Topic | Presenter |
|---|---|---|
| 09.00-09.10 | Opening remarks | Co-chair:<br>(EFSA)<br>....(IARC) |
| 09.10-09.25 | The IARC process for the review and classification of chemicals: the IARC monographs | .....(IARC) |
| 09.25-09.40 | The peer review of carcinogenicity of plant protection products at EU level: the role of EFSA and MSs | (EFSA) |
| 09.40-10.00 | Summary of main differences between IARC process and EFSA peer review | |
| 10.00-11.00 | Glyphosate: focus on the genotoxicity and mechanistic data on carcinogenicity | IARC/EFSA/BfR |
| *11.00-11.15* | *Coffee/Tea break* | |
| 11.15-12.45 | Glyphosate: focus on experimental data on carcinogenicity | IARC/EFSA/BfR |
| *12.45-13.45* | *LUNCH* | |
| 13.45-15.15 | Glyphosate: focus on human and epidemiological data on carcinogenicity | IARC/EFSA/BfR |
| 15.15-16.15 | Overall conclusion on divergent views and agreement of content of minutes of the meeting | EFSA<br>IARC |
| 16.15-16.50 | Communication to stakeholders on the outcome of the joint meeting | tbd |
| 16.50-17.00 | Next steps | EFSA-IARC |

Parma, 13 January 2016

# PROJECT STEERING COMMITTEE (PSC) (FOLLOW-UP WORK ON GLYPHOSATE) 8 JANUARY 2016 10:00-11:30 MEETING MINUTES

**Participants**

**Acronyms**

PSC: Project Steering Committee
BfR: the German Federal Institute for Risk Assessment
IARC: International Agency for Research on Cancer
COMMS: Communications
PRAS: Pesticides Unit
ADoI: Annual Declaration of Interest
US EPA: United States Environmental Protection Agency
ED: Executive Director

| AGENDA | DISCUSSION AND DECISIONS | ACTIONS |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. Bilateral meeting (EFSA/IARC) in Brussels in February 2016 | IARC replied to the proposal of a joint meeting EFSA-IARC; the agenda will be slightly modified.<br><br>The PSC considered helpful to propose a preparatory meeting with IARC.<br>17 Feb; attending plus secretariat<br><br>The meeting could have a positive outcome in terms of proposing future steps (e.g. interagency work on methodology in risk assessment?) | **Action 20160108-03:** to draft reply to IARC.<br><br>**Action 20160108-04:** to draft revised agenda. |

| | | |
|---|---|---|
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. Scientific publication explaining divergence between EFSA and IARC opinion on glyphosate | Need to re-discuss the issue with PRAS. | **Action 20160108-12**: PRAS to invole to the epidemiology WG of the PPR Panel.<br><br>**Action 20160108-13**: Rediscuss witl the sc publ. |

9.

10.

11.

12.

# PROJECT STEERING COMMITTEE MEETING
# (FOLLOW-UP WORK ON GLYPHOSATE)

## 21 JANUARY 2016, 11:30-13:00
## OFFICE (SEAT 06/B12)

## DRAFT AGENDA

1.
2.
3. Feedback from the EFSA/IARC teleconference on the format and agenda of the joint meeting in February 2016
4.
5. Scientific publication explaining divergence between EFSA and IARC opinion on glyphosate
6.
7.

Parma, 13 January 2016

# PROJECT STEERING COMMITTEE (PSC) (FOLLOW-UP WORK ON GLYPHOSATE) 8 JANUARY 2016 10:00-11:30 MEETING MINUTES

**Participants**

**Acronyms**

PSC: Project Steering Committee
BfR: the German Federal Institute for Risk Assessment
IARC: International Agency for Research on Cancer
COMMS: Communications
PRAS: Pesticides Unit
ADoI: Annual Declaration of Interest
US EPA: United States Environmental Protection Agency
ED: Executive Director

| AGENDA | DISCUSSION AND DECISIONS | ACTIONS |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. Bilateral meeting (EFSA/IARC) in Brussels in February 2016 | IARC replied to the proposal of a joint meeting EFSA-IARC; the agenda will be slightly modified.<br><br>The PSC considered helpful to propose a preparatory meeting with IARC.<br>17 Feb; attending plus secretariat<br><br>The meeting could have a positive outcome in terms of proposing future steps (e.g. interagency work on methodology in risk assessment?) | **Action 20160108-03**:<br>to draft reply to IARC.<br><br>**Action 20160108-04**:<br>to draft revised agenda. |

| | | |
|---|---|---|
| | | **Action 20160108-05**: and to check cases of different classification IARC-EFSA.<br><br>**Action 20160108-06**: to propose preparatory meeting with IARC to coordinate.<br><br>**Action 20160108-07**: COMMS to liaise with IARC COMMS. |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. Scientific publication explaining divergence between EFSA and IARC opinion on glyphosate | Need to re-discuss the issue with PRAS. | **Action 20160108-12**: PRAS to invole to the epidemiology WG of the PPR Panel.<br><br>**Action 20160108-13**: Rediscuss with the sc publ. |

| |
|---|
| 9. |
| 10. |
| 11. |
| 12. |

# DRAFT AGENDA

## IARC/EFSA Meeting on the scientific assessment of the carcinogenicity of the active pesticide substance glyphosate

**17 February 2016**
**09h00-17h00 – Brussels**

| Time | Topic | Presenter |
|---|---|---|
| 09.00-09.10 | Opening remarks | Co-chairs:<br>(EFSA)<br>....(IARC) |
| 09.10-09.25 | The IARC process for the review and classification of chemicals: the IARC monographs | IARC |
| 09.25-09.40 | The peer review of carcinogenicity of plant protection products at EU level: the role of EFSA and MSs | EFSA |
| 09.40-10.00 | Summary of main differences between IARC process and EFSA peer review | EFSA-IARC |
| 10.00-11.00 | Glyphosate: focus on experimental data on carcinogenicity | EFSA-IARC |
| 11.00-11.15 | Coffee/Tea break | |
| 11.15-12.45 | Glyphosate: focus on human and epidemiological data on carcinogenicity | EFSA-IARC |
| 12.45-13.45 | LUNCH | |
| 13.45-15.15 | Glyphosate: focus on the genotoxicity and mechanistic data on carcinogenicity | EFSA-IARC |
| 15.15-16.15 | Overall conclusion on divergent views and agreement of content of minutes of the meeting | EFSA-IARC |
| 16.15-16.50 | Communication to stakeholders on the outcome of the joint meeting | EFSA-IARC |

| | | |
|---|---|---|
| 16.50-17.00 | ***Next steps*** | EFSA-IARC |

# DRAFT AGENDA

## IARC/EFSA Meeting on the scientific assessment of the carcinogenicity of the active pesticide substance glyphosate

**17 February 2016**
**09h30-17h00 – Brussels**

| Time | Topic | Presenter |
|---|---|---|
| 09.00-09.10 | Opening remarks | Co-chair:<br>(EFSA)<br>(IARC) |
| 09.10-09.25 | The IARC process for the review and classification of chemicals: the IARC monographs | (IARC) |
| 09.25-09.40 | The peer review of carcinogenicity of plant protection products at EU level: the role of EFSA and MSs | (EFSA) |
| 09.40-10.00 | Summary of main differences between IARC process and EFSA peer review | EFSA-IARC<br>***(the scientific secretariat will collect the point raised during the discussion)*** |
| 10.00-11.00 | Glyphosate: focus on experimental data on carcinogenicity | (EFSA)<br>(IARC) |
| 11.00-11.15 | Coffee/Tea break | |
| 11.15-12.45 | Glyphosate: focus on human and epidemiological data on carcinogenicity | (EFSA)<br>(IARC) |
| 12.45-13.45 | LUNCH | |
| 13.45-15.15 | Glyphosate: focus on the genotoxicity and mechanistic data on carcinogenicity | (EFSA)<br>(IARC) |
| 15.15-16.15 | Overall conclusion on divergent views and agreement of content of minutes of the meeting | EFSA-IARC<br>***(the scientific secretariat will collect the point raised during the discussion)*** |

| | | |
|---|---|---|
| 16.15-16.50 | Communication to stakeholders on the outcome of the joint meeting | EFSA-IARC<br>***(the scientific secretariat in collaboration with the Communication Units from both sides will collect and present the point raised during the discussion)*** |
| 16.50-17.00 | ***Next steps*** | EFSA-IARC |

| **Document history** | |
|---|---|
| **Document reference** | **Version 3** |
| **Prepared by** | |
| **Reviewed by** | |
| **Last date modified** | **20 January 2016** |

Parma, 25 January 2016

# PROJECT STEERING COMMITTEE (PSC)
# (FOLLOW-UP WORK ON GLYPHOSATE)
# 21 JANUARY 2016 11:30-13:00
# MEETING MINUTES

**Participants**

**Acronyms**

PSC: Project Steering Committee
BfR: the German Federal Institute for Risk Assessment
IARC: International Agency for Research on Cancer
COMMS: Communications
PRAS: Pesticides Unit
ADoI: Annual Declaration of Interest
US EPA: United States Environmental Protection Agency
ED: Executive Director

| AGENDA | DISCUSSION AND DECISIONS | ACTIONS |
|---|---|---|
| 1. | | - |
| 2. | | - |

| | | |
|---|---|---|
| 3. Feedback from the EFSA/IARC teleconference on the format and agenda of the joint meeting in February 2016 | The meeting will be held in Brussels on 17 Feb 2016 (from 9.30-17.00), and will be co-haired IARC-EFSA.<br>The participants could have a joint dinner the day before: for this IARC will inform us about their travel plans.<br>EFSA proposed to hold the meeting with the final purpose to prepare a joint position statement on different processes, roles, etc. in EFSA and IARC: the reply to prof. Portier's letter that EFSA recently published on the website was considered inaccurate by IARC therefore it is unclear at the moment if a common position will be found. IARC's Director C. Wild will send soon a letter of reply to EFSA.<br>EFSA proposal of having preparatory scientific meetings was not accepted because of current workload, as well as the possibility to share the slides of the presentations in advance.<br>Proposal of preliminary contacts with EFSA and IARC Communication Units: the contact point in IARC<br>Proposal of having the 2 Communication Units connected via teleconference for the last session of the meeting was agreed.<br>Participants from IARC: n<br>An additional teleconference EFSA-IARC could be held before the meeting in Feb<br><br>Need to check previous cases where IARC was directly attacking EFSA.<br>Communication to review the letter to Portier to see whether anything clearly against IARC.<br><br>Direct communication BU-C. Wild would be extremely helpful.<br><br>to provide with a few bullets points on what we need to achieve for the meeting.<br><br>The support of a BfR scientist is no longer needed; however can join EFSA the day before the Sc Committee (he can be here on 15 Feb 2016).<br><br>As for the meeting, DCM should present both carcino and epi.<br><br>PRAS to organise practically the meeting. Liaise with | **Action 20160121-01**: Communication in collaboration with PRAS to review the letter to Portier to see whether anything incorrect or inappropriate towards IARC was reported.<br><br>**Action 20160121-02**: EXREL to liaise with (IARC, HoU Communications).<br><br>**Action 20160121-03**: to organise a phone call between BU and C. Wild (IARC) to discuss the principles of the upcoming meeting.<br><br>**Action 20160121-04**: to prepare a list of key points for the phone call between BU and C. Wild.<br><br>**Action 20160121-05**: PRAS to organise practically the meeting. Liaise with CORSER |
| 4. | | |

5.

6.

7.

# PROJECT STEERING COMMITTEE MEETING
# (FOLLOW-UP WORK ON GLYPHOSATE)

## 10 FEBRUARY 2016, 15:00-17:00
## OFFICE (SEAT 06/B12)

## DRAFT AGENDA

1.
2.
3. EFSA/IARC meeting in February 2016:
   a) Current status
   b) Review presentations
4.
5.
6.
7.
8.

# JOINT MEETING OF THE PROJECT TEAMS (FOLLOW-UP WORK ON GLYPHOSATE)

## 12 JANUARY 2016, 9:30-10:30

OFFICE (SEAT 06/B12)

## DRAFT AGENDA

1.
2.
3.
4.
5. Bilateral meeting (EFSA/IARC) in Brussels in February 2016
6.
7

# JOINT MEETING OF THE PROJECT TEAMS (FOLLOW-UP WORK ON GLYPHOSATE)

## 19 JANUARY 2016, 14:30-15:30

OFFICE (SEAT 06/B12)

## DRAFT AGENDA

1. Agenda for adoption
2. 
3. 
4. Bilateral meeting (EFSA/IARC) in Brussels in February 2016 (incl. meeting venue)
5. 
6. 

# DRAFT AGENDA

## IARC/EFSA Meeting on the scientific assessment of the carcinogenicity of the active pesticide substance glyphosate

**17 February 2016**
**09h00-17h00 – Brussels**

| Time | Topic | Presenter |
|---|---|---|
| 09.00-09.10 | Opening remarks | Co-chairs:<br>· (EFSA)<br>....(IARC) |
| 09.10-09.25 | The IARC process for the review and classification of chemicals: the IARC monographs | IARC |
| 09.25-09.40 | The peer review of carcinogenicity of plant protection products at EU level: the role of EFSA and MSs | EFSA |
| 09.40-10.00 | Summary of main differences between IARC process and EFSA peer review | EFSA-IARC |
| 10.00-11.00 | Glyphosate: focus on experimental data on carcinogenicity | EFSA-IARC |
| 11.00-11.15 | Coffee/Tea break | |
| 11.15-12.45 | Glyphosate: focus on human and epidemiological data on carcinogenicity | EFSA-IARC |
| 12.45-13.45 | LUNCH | |
| 13.45-15.15 | Glyphosate: focus on the genotoxicity and mechanistic data on carcinogenicity | EFSA-IARC |
| 15.15-16.15 | Overall conclusion on divergent views and agreement of content of minutes of the meeting | EFSA-IARC |
| 16.15-16.50 | Communication to stakeholders on the outcome of the joint meeting | EFSA-IARC |

| | | |
|---|---|---|
| 16.50-17.00 | ***Next steps*** | EFSA-IARC |

# JOINT MEETING OF THE PROJECT TEAMS (FOLLOW-UP WORK ON GLYPHOSATE)

## 27 JANUARY 2016, 16:30-17:30

### OFFICE (SEAT 06/B12)

## DRAFT AGENDA

1. [illegible]
2. [illegible]
3. [illegible]
4. Bilateral meeting (EFSA/IARC) in Brussels in February 2016 – state of play
5. [illegible]
6. [illegible]

# DRAFT AGENDA

## IARC/EFSA Meeting on the scientific assessment of the carcinogenicity of the active pesticide substance glyphosate

**17 February 2016**
**09h30-17h00 – Brussels**

| Time | Topic | Presenter |
|---|---|---|
| 09.00-09.10 | Opening remarks | Co-chair:<br>, EFSA)<br>f (IARC) |
| 09.10-09.25 | The IARC process for the review and classification of chemicals: the IARC monographs | (IARC) |
| 09.25-09.40 | The peer review of carcinogenicity of plant protection products at EU level: the role of EFSA and MSs | (EFSA) |
| 09.40-10.00 | Summary of main differences between IARC process and EFSA peer review | EFSA-IARC<br>***(the scientific secretariat will collect the point raised during the discussion)*** |
| 10.00-11.00 | Glyphosate: focus on experimental data on carcinogenicity | (EFSA)<br>(IARC) |
| 11.00-11.15 | Coffee/Tea break | |
| 11.15-12.45 | Glyphosate: focus on human and epidemiological data on carcinogenicity | EFSA)<br>; (IARC) |
| 12.45-13.45 | LUNCH | |
| 13.45-15.15 | Glyphosate: focus on the genotoxicity and mechanistic data on carcinogenicity | ; (EFSA)<br>1 (IARC) |
| 15.15-16.15 | Overall conclusion on divergent views and agreement of content of minutes of the meeting | EFSA-IARC<br>***(the scientific secretariat will collect the point raised during the discussion)*** |

| | | |
|---|---|---|
| 16.15-16.50 | Communication to stakeholders on the outcome of the joint meeting | EFSA-IARC<br>***(the scientific secretariat in collaboration with the Communication Units from both sides will collect and present the point raised during the discussion)*** |
| 16.50-17.00 | ***Next steps*** | EFSA-IARC |

| **Document history** | |
|---|---|
| **Document reference** | **Version 3** |
| **Prepared by** | |
| **Reviewed by** | |
| **Last date modified** | **20 January 2016** |

# JOINT MEETING OF THE PROJECT TEAMS (FOLLOW-UP WORK ON GLYPHOSATE)

## 08 FEBRUARY 2016, 09:00-10:00

## [illegible]FICE (SEAT 06/B12)

## AGENDA

1. [illegible]
2. [illegible]ts
3. [illegible]
4. Bilateral meeting (EFSA/IARC) in Brussels in February 2016 – state of play and review presentations
   a) Final agenda
   b) presentations
5. [illegible]
6. [illegible]

# DRAFT AGENDA

## IARC/EFSA Meeting on the scientific assessment of the carcinogenicity of the active pesticide substance glyphosate

**17 February 2016, 09h30-17h00**
**Brussels, Sheraton Brussels Airport Hotel**

| Time | Topic | Presenter |
|---|---|---|
| 09.00-09.10 | Opening remarks | Co-chair:<br>(EFSA)<br>ARC) |
| 09.10-09.25 | The IARC process for the review and classification of chemicals: the IARC monographs | (IARC) |
| 09.25-09.40 | The peer review of carcinogenicity of plant protection products at EU level: the role of EFSA and MSs | EFSA) |
| 09.40-10.00 | Summary of main differences between IARC process and EFSA peer review | EFSA-IARC<br>***(the scientific secretariat will collect the point raised during the discussion)*** |
| 10.00-11.00 | Glyphosate: focus on experimental data on carcinogenicity | (EFSA)<br>(IARC) |
| 11.00-11.15 | Coffee/Tea break | |
| 11.15-12.45 | Glyphosate: focus on human and epidemiological data on carcinogenicity | , (EFSA)<br>(IARC) |
| 12.45-13.45 | LUNCH | |
| 13.45-15.15 | Glyphosate: focus on the genotoxicity and mechanistic data on carcinogenicity | (EFSA)<br>IARC) |
| 15.15-16.15 | Overall conclusion on divergent views and agreement of content of minutes of the meeting | EFSA-IARC<br>***(the scientific secretariat will collect the point raised during the discussion)*** |

| | | |
|---|---|---|
| 16.15-16.50 | Communication to stakeholders on the outcome of the joint meeting | EFSA-IARC<br>***(the scientific secretariat in collaboration with the Communication Units from both sides will collect and present the point raised during the discussion)*** |
| 16.50-17.00 | ***Next steps*** | EFSA-IARC |

| **Document history** | |
|---|---|
| **Document reference** | **Version 4** |
| **Prepared by** | |
| **Reviewed by** | |
| **Last date modified** | **29 January 2016** |

**List of participants:**

**(IARC)**
**· (IARC)**
**IARC)**
**· (EFSA)**
**r (EFSA)**
**(EFSA)**
**; (EFSA)**
**i (EFSA) - Scientific Secretariat**

2_PAD 2016/027 Internal discussions IARC findings_Vincent Harmsen
EFSA internal emails

**Archived:** 07 June 2016 14:10:07
**From:** [redacted]
**Sent:** 27 January 2016 18:46:08
**To:** [redacted]
**Cc:** PMO.glyphosate; [redacted]
**Subject:** joint meeting of the Project Teams (27 January) - action points
**Importance:** Normal

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Dear Colleagues,

Below you find the action points from today's joint meeting of the Project Teams:

1. [redacted].
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted] **and colleagues in PRAS** to prepare the PPT slides for the joint EFSA-IARC meeting (deadline: 5 February 2016).

Kind regards,
[redacted]

**Archived:** 07 June 2016 14:22:30
**From:** [redacted]
**Sent:** 05 February 2016 16:17:01
**To:** [redacted]
**Cc:** PMO.glyphosate; [redacted]; [redacted]; [redacted]
**Subject:** FW: EFSA / IARC meeting in Feb - communications
**Response requested:** No
**Importance:** Normal

---

Hi [redacted]

Pls see below the response from IARC regarding aligning comms expectations before the meeting … (!)

I'm not sure how things are progressing from the science side but this is clearly not a particularly helpful approach. My concern is that we are still not aligned on what the expected **outputs** (not necessarily outcomes) are for this meeting e.g. joint statement for media, minutes, etc.

Perhaps this point could be added to the project meeting on Monday which [redacted] or I will attend ([redacted] also if he's able to via phone or Facetime). It seems to me that we should be escalating this to [redacted]'s level to ensure at least the minimum level of alignment with IARC before the meeting.

Best, [redacted]

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[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

**Archived:** 07 June 2016 14:24:51
**From:** [redacted]
**Sent:** 09 February 2016 08:51:43
**To:** [redacted]; [redacted]; [redacted]
**Cc:** PMO.glyphosate
**Subject:** IARC Letter
**Importance:** Normal
**Attachments:**
Draft response to [redacted] version 3_[redacted]01.docx ;

---

Dear all,
thanks for the excellent letter.
Please look at one change I proposed regarding IARC's use of industry GLP studies. I brought in a note of caution just to avoid another potential source of misunderstanding. Does this reflect reality? (as they looked at some industry studies published by EPA, as far as I am aware).
Besides that fine with me.
Best regards,
[redacted]

Sent from Outlook Mobile

Dear Dr Wild,

I refer to your letter of 5 February 2016 in which you raise concerns about the way in which EFSA refers to the IARC Monographs on our website.

Firstly, please allow me to reassure you that EFSA recognises the important contribution IARC makes to the assessment of cancer hazards and to the high scientific standards set by the IARC Monograph programme. It is for precisely this reason that EFSA's evaluation of glyphosate was postponed as this enabled us to consider the findings of the IARC assessment in our own work. It is also why we invited IARC to take part as observers in EFSA's expert discussions prior to adopting our conclusions.

Please also allow me to reassure you that by referring to the IARC Monographs as a first step or "screening assessment" in our response letter to Dr Christopher Portier on 13 January 2016 we in no way meant to imply criticism or to characterise the Monographs as superficial. These references stem from IARC's own description of the Monographs that can be found on the IARC website: "The *Monographs* represent the first step in carcinogen risk assessment…" and "The *Monographs* are used by national and international authorities to make risk assessments" [original emphasis][1]. The purpose of these references was merely to draw attention to the fact that EFSA operates in a specific regulatory context and that the scope and objectives of the EFSA and IARC hazard assessments are different and not directly comparable.

This also explains why we state on our website the fact that EFSA assessed more evidence than IARC. Here we refer to the mandatory Good Laboratory Practice studies that applicants must submit according to EU pesticides legislation and that EFSA and EU Member States appraise, not all of which were ~~not~~ considered by IARC in its assessment of glyphosate.

Regarding your concern about the phrase "IARC assesses generic agents", this was inferred from the IARC Monograph Preamble which states that the term 'agent' "refers to any entity or circumstance that is subject to evaluation in a *Monograph*" and may include "specific chemicals, groups of related chemicals, complex mixtures, occupational or environmental exposure, cultural or behavioural practices, biological organisms and physical agents"[2].

Regarding the other specific statements by EFSA that you refer to in your letter, again these are not intended as criticisms of IARC but rather represent EFSA's scientific view based on our review of the evidence in the IARC Monograph on glyphosate. EFSA and IARC may have differences of opinion about these issues but it was my understanding that we had agreed to meet in February precisely in order that we could discuss these differences in more detail and, where possible, seek to explain them.

With this in mind – and given the high level of public concern about glyphosate – ~~I~~ I strongly believe that there is value in going ahead with the planned meeting

[1] http://monographs.iarc.fr/ENG/Preamble/currenta2objective0706.php
[2] Ibid

between EFSA and IARC. Not only ~~as it~~ will it allow for an in-depth scientific discussion among our experts, ~~on this topic of high public concern.~~ I also believe that a face-to-face meeting is the best way to address any remaining misunderstandings between our two organisations, which inevitably are difficult to avoid through written communication alone. I hope that you share this view in line with the spirit of openness and friendly co-operation that you refer to in your letter.

I am happy to publish this exchange of letters on our website and, should you agree, the minutes of the planned meeting next week which would provide space to set out any divergent views the two organisations may have about the science behind glyphosate. Following the meeting, I would of course also be willing to correct any factual mistakes about IARC on our website should these remain.

Yours sincerely,

Bernhard Url

| Document history | |
|---|---|
| Document reference | Version 3~~2~~ |
| Prepared by | [redacted] |
| Reviewed by | |
| Last date modified | 08/02/2016 |

**Archived:** 07 June 2016 14:27:37
**From:** [redacted]
**Sent:** 09 February 2016 09:25:51
**To:** [redacted]; [redacted]; [redacted]
**Cc:** PMO.glyphosate
**Subject:** RE: IARC Letter
**Importance:** Normal
**Attachments:**
Draft response to [redacted]version 3_[redacted]01_[redacted].docx ;

---

Dear [redacted],
See attached a proposal for the sentence, based on factual information. (IARC did not look at the GLP studies but to their evaluations by others).
KR, [redacted]

**From:** [redacted]
**Sent:** 09 February 2016 08:52
**To:** [redacted]; [redacted]; [redacted]
**Cc:** PMO.glyphosate
**Subject:** IARC Letter

Dear all,
thanks for the excellent letter.
Please look at one change I proposed regarding IARC's use of industry GLP studies. I brought in a note of caution just to avoid another potential source of misunderstanding. Does this reflect reality? (as they looked at some industry studies published by EPA, as far as I am aware).
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Sent from Outlook Mobile

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This also explains why we state on our website the fact that EFSA assessed more evidence than IARC. Here we refer to the mandatory Good Laboratory Practice studies that applicants must submit according to EU pesticides legislation and that EFSA and EU Member States appraise~~,~~; ~~not all of~~in particular, the new studied not included in the JMPR and USEPA evaluations ~~which were not~~ considered by IARC in its assessment of glyphosate.

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[1] http://monographs.iarc.fr/ENG/Preamble/currenta2objective0706.php
[2] Ibid

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Yours sincerely,

Bernhard Url

| Document history | |
|---|---|
| Document reference | Version 3~~2~~ [redacted] comments |
| Prepared by | [redacted] |
| Reviewed by | |
| Last date modified | ~~08~~09/02/2016 |

**Archived:** 07 June 2016 14:29:59
**From:** [redacted]
**Sent:** 09 February 2016 10:05:17
**To:** [redacted]e; [redacted]; [redacted]
**Cc:** PMO.glyphosate
**Subject:** RE: IARC Letter
**Importance:** Normal
**Attachments:**
Draft response to Chris Wild version 4.docx ;

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Dear all

I've tried to simplify /improve flow of this para –see below. Think it's ready now to format and sign

This also explains why we state on our website the fact that EFSA assessed more evidence than IARC. Here we refer to the mandatory Good Laboratory Practice studies (not described in the WHO-JMPR or US-EPA reports that IARC assessed) that applicants were required to submit according to EU pesticides legislation and that, unlike IARC, EFSA and EU Member States appraised.

Best, [redacted]

---

**From:** [redacted]
**Sent:** 09 February 2016 09:26
**To:** [redacted]; [redacted]; [redacted]
**Cc:** PMO.glyphosate
**Subject:** RE: IARC Letter

Dear [redacted],
See attached a proposal for the sentence, based on factual information. (IARC did not look at the GLP studies but to their evaluations by others).
KR, [redacted]

**From:** [redacted]
**Sent:** 09 February 2016 08:52
**To:** [redacted]; [redacted]; [redacted]
**Cc:** PMO.glyphosate
**Subject:** IARC Letter

Dear all,
thanks for the excellent letter.
Please look at one change I proposed regarding IARC's use of industry GLP studies. I brought in a note of caution just to avoid another potential source of misunderstanding. Does this reflect reality? (as they looked at some industry studies published by EPA, as far as I am aware).
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Sent from Outlook Mobile

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This also explains why we state on our website the fact that EFSA assessed more evidence than IARC. Here we refer to the mandatory Good Laboratory Practice studies (not described in the WHO-JMPR or US-EPA reports that IARC assessed) that applicants were required to submit ~~must submit~~ according to EU pesticides legislation and that, unlike IARC, EFSA and EU Member States appraised.; ~~not all of~~in particular, the new studied not included in the JMPR and USEPA evaluations ~~which were not considered by IARC in its assessment of glyphosate.~~

Regarding your concern about the phrase "IARC assesses generic agents", this was inferred from the IARC Monograph Preamble which states that the term 'agent' "refers to any entity or circumstance that is subject to evaluation in a *Monograph*" and may include "specific chemicals, groups of related chemicals, complex mixtures, occupational or environmental exposure, cultural or behavioural practices, biological organisms and physical agents"[2].

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[1] http://monographs.iarc.fr/ENG/Preamble/currenta2objective0706.php
[2] Ibid

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Yours sincerely,

Bernhard Url

| Document history | |
|---|---|
| Document reference | Version ~~32~~ [redacted] ~~comments4~~ |
| Prepared by | [redacted], [redacted] |
| Reviewed by | [redacted]r |
| Last date modified | ~~08~~09/02/2016 |

**Archived:** 07 June 2016 14:36:58
**From:** [redacted]
**Sent:** 12 February 2016 13:55:55
**To:** [redacted]; [redacted]; [redacted]
**Cc:** PMO.glyphosate; [redacted]
**Subject:** Table with the links to the study description for carcinogenicity
**Importance:** Normal
**Attachments:**
Evidence on glyphosate carcinogenicity.doc ;

---

Dear all,
This is the table I mentioned at the meeting, it contains all study codes and the page numbers in the public pdf files (summary dossier and final RAR) with the study description and German assessment. I added the reference used by IARC. [redacted] could you please double check those highlighted in yellow?
I will try to produce an equivalent one for the in vivo mammalian genotox.
Thanks,
[redacted]

**Available evidence on glyphosate carcinogenicity**

Table 1 summarises the industry sponsored studies used in the EU assessment described by the notifier in the summary dossier (SD) available at the EFSA web site http://registerofquestions.efsa.europa.eu and the Review Assessment Report (RAR) by the Rapporteur Member State (Germnay, 2015). Two mice studies were assessed in the previous EU assessment (EC, 2002) and are not described in detail in the information published by EFSA; however, these are the studies described by US EPA and JMPR and summarised in the IARC monograph.

Table1. Long-term chronic toxicity and carcinogenicity studies considered valid and used in the EU assessment.

| **Study Reference** Purity (%) (IARC reference) | **Study type** *descriptions by notifier (SD) and RMS (RAR)* | **Dose levels** (NOAEL/LOAEL) mg/kg bw per day | **critical effect at the LOAEL** |
|---|---|---|---|
| **Mice long-term chronic toxicity and carcinogenicity studies used in the EU evaluation** | | | |
| TOX9552381, 1983, 99.7% (IARC: EPA 1985a,b, 1986, 1991a) | **2 yr**, CD-1 carcino/ chron *Described in the previous EU evaluation USEPA and IARC* | 0, 157, 814, 4841 (157/814) | Males: Body weight reduction, hepatocellular centrilobular hypertrophy and bladder epithelial hyperplasia |
| TOX9552382, 1993, 98.6% (IARC: JMPR 2006) | **2 yr**, CD-1, carcino *Described in the previous EU evaluation JMPR and IARC* | 0, 100, 300, 1000 (1000/>1000) | Equivocal enlarged/firm thymus, not associated with histopathological findings (considered not biologically relevant) |
| **IIA, 5.5.3/03** ASB2012-11493, 1997, 97.56/94.61% | **18 mo**, CD-1 (ICR), OECD 451 *SD pp 516-525 RAR pp 1030-1040* | 0, 153, 787, 4116 (153/787) | Body weight gain, reduction food cons & effic, loose stool, caecum distended and increased weight, prolapse and anus ulceration |
| **IIA, 5.5.3/02** ASB2012-11492, 2009, 95.7% | 18 mo, CD-1 (ICR), OECD 451 *SD pp 511-516 RAR pp 1023-1030* | 0, 71, 234, 810 (810/>810) | No effect observed |
| **Rat long-term chronic toxicity and carcinogenicity studies used in the EU evaluation** | | | |
| **IIA, 5.5.2/05** TOX2000-595, 1981, 98.7% (IARC: EPA 1991a,b.c.d) | 26mo, SD rat, combined No GLP *SD pp 479-485 RAR pp 987-993* | 0, 3, 10.3, 31.5 (31.5/>31.5) | No effects observed* |
| **IIA, 5.5.2/06** TOX9300244, 1990, 96.5% (IARC: EPA 1991a,b.c.d) | 2yr, SD rat, combined USEPA F 83-5 *SD pp 485-491 RAR pp 993-999* | 0, 89, 362, 940 (89/362) | Reduction body weight and gain, increase liver weight, stomach mucosal inflammation, cataracts, decrease urine pH, survival <50% in all groups incl. controls |
| **IIA, 5.5.2/04** TOX9750499, 1993, 98.9% & 98.7% (IARC:JMPR,2006) | 2yr, SD rat, combined USEPA F 83-5 *SD pp 471-478 RAR pp 999-1007* | 0, 10, 100, 300, 1000 (100/300) | Pronounced salivary gland findings, increase AP and liver weight |
| **IIA, 5.5.2/01** TOX9651587, 1996, 96.8/96.0% | 2yr, Wistar rat, combined OECD GD 453 *SD pp 451-456 RAR 1007-1013* | 0, 6.3, 59.4, 595.2 (60/595.2) | Cataracts, increase AP |
| **IIA, 5.5.1/01** | 12mo, Wistar rat | 0, 141, 560, 1409 | Reduction in body weight, food cons and |

| | | | |
|---|---|---|---|
| TOX2000-1998, 1996, 95.6% (IARC:JMPR,2006) | OECD GD 452<br>*SD pp 447- 451*<br>*RAR pp 955-960* | (141/560) | utilization, increase AP, focal basophilia of acinar cells of parotid salivary gland (not weighed) |
| **IIA, 5.2/02**<br>ASB2012-11484, 1997, 97.56/ 94.61% | 2yr, SD rat, combined<br>OECD GD 453<br>*SD pp 457-463*<br>*RAR pp 960-966* | 0, 104, 354, 1127 (104/354) | Reduction body weight, gain, food cons (initially) and utilization, increase loose stool, increase tail masses due to follicular hyperkeratosis and abscesses, caecum: distention and increase weight, pH reduction and dark appearance of urine |
| **IIA, 5.2/03**<br>ASB2012-11488, 2001, 97.6% (IARC: JMPR,2006) | 2yr, Wistar rat, combined<br>OECD GD 453<br>*SD pp 463-471*<br>*RAR pp 972-980* | 0, 121, 361, 1214 (361/1214) | Reduction body weight, food cons and (initially) utilization, clinical chemistry findings (increase AP and ALAT activity and bilirubin, decrease urine pH), kidney papillary necrosis, prostatis and periodontal inflammation |
| **IIA, 5.2/08**<br>ASB2012-11490, 2009, 95,7% | 2yr, Wistar rat, combined<br>OECD GD 453<br>*SD pp 496-502*<br>*RAR pp 980-987* | 0, 86, 285, 1077 (285/1077) | Reduction body weight gain, transient increase AP, changes in distribution of renal mineralisation, increase adipose infiltration of bone marrow (indicative of hypoplasia) |
| **Industry sponsored studies considered non-valid during the EU assessments** | | | |
| IIA, 5.5.3/01<br>ASB2012-11491*, 2001, >95.14% | 18 mo, Swiss albino,<br>OECD 451<br>*SD pp 504-511*<br>*RAR pp 1013-1023* | Title: Carcinogenicity Study with Glyphosate Technical in Swiss Albino<br>Mice | |
| **IIA, 5.5.2/07**<br>ASB2012-11489<br>1997 | 2yr SD rat, combined<br>OECD GD 453<br>*SD pp 491-496*<br>*RAR pp 967-972* | Title: Combined Chronic Toxicity/Carcinogenicity Study of Glyphosate<br>Technical in Sprague Dawley Rat | |