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



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6.

SCIENTIFIC EVALUATION OF REGULATED PRODUCTS DEPARTMENT

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

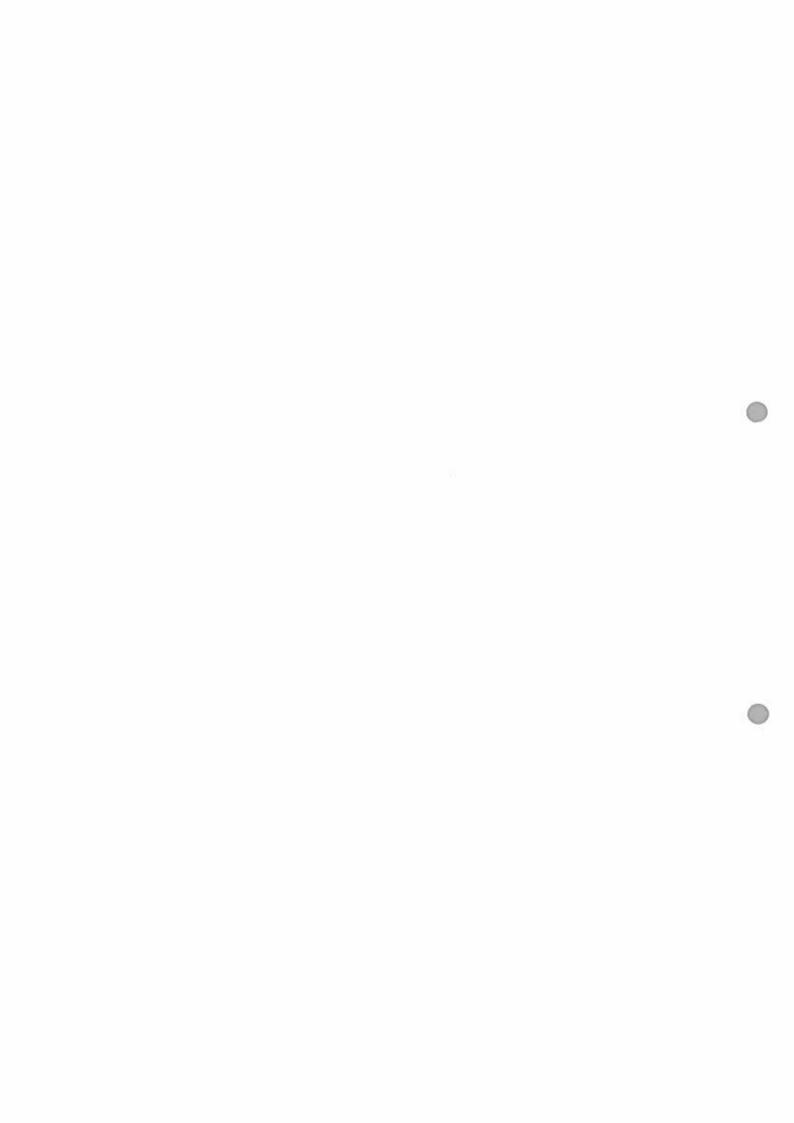
11 DECEMBER 2015, 10:00-11:00 OFFICE (SEAT 06/B12)

DRAFT AGENDA

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

	a) draft agendab) participantsc) meeting location			
2.	1			
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3.	t			

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





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: - (EFSA)(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:

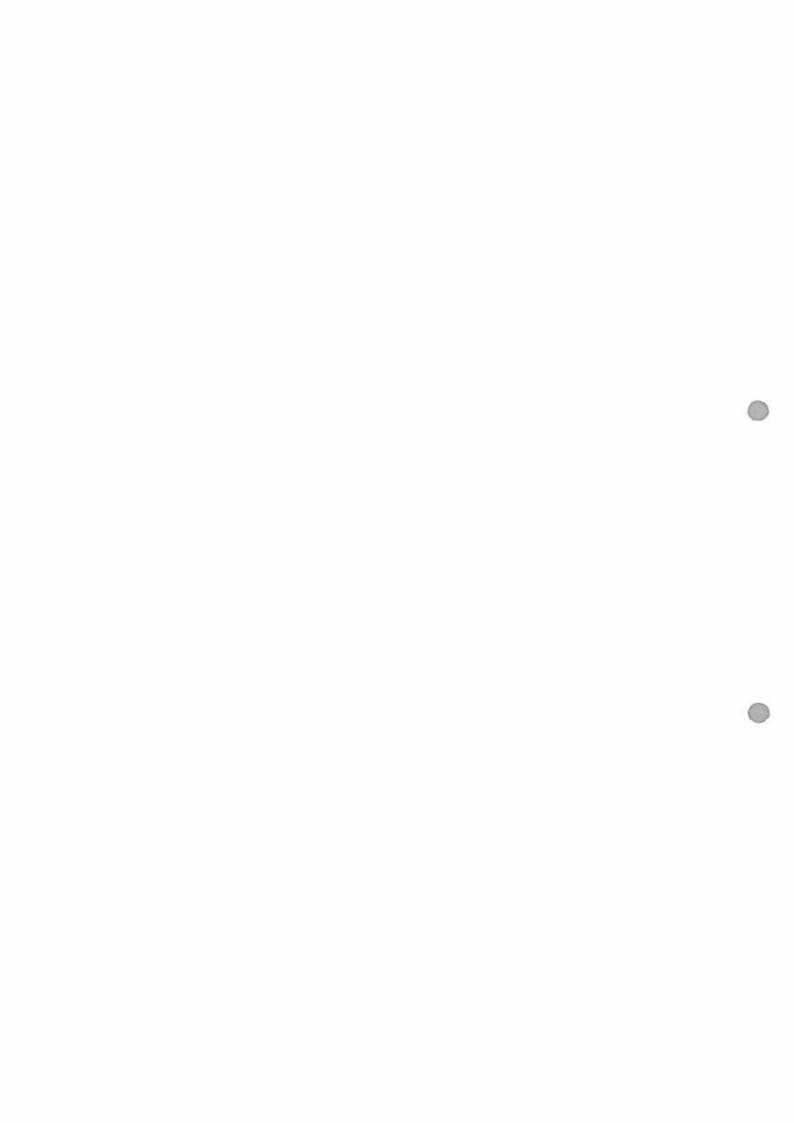
BfR: 1 expert covering all aspects of DAR and addendum

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.





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

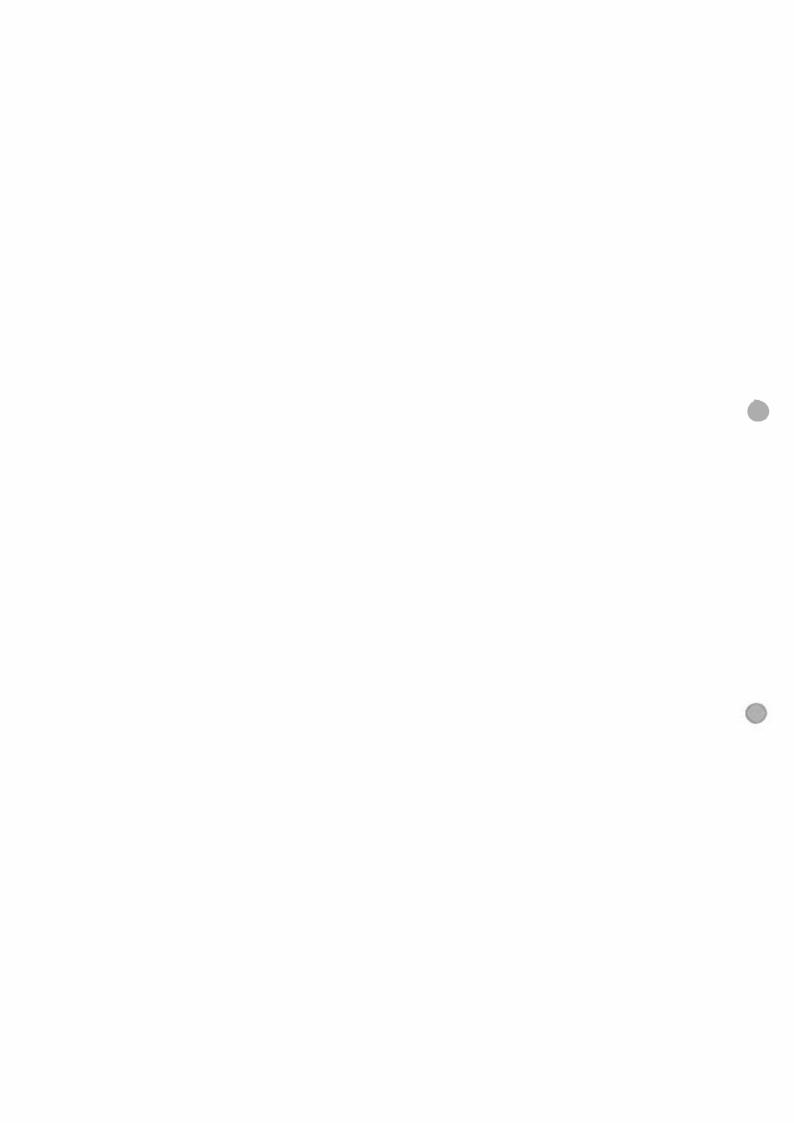
Participants

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

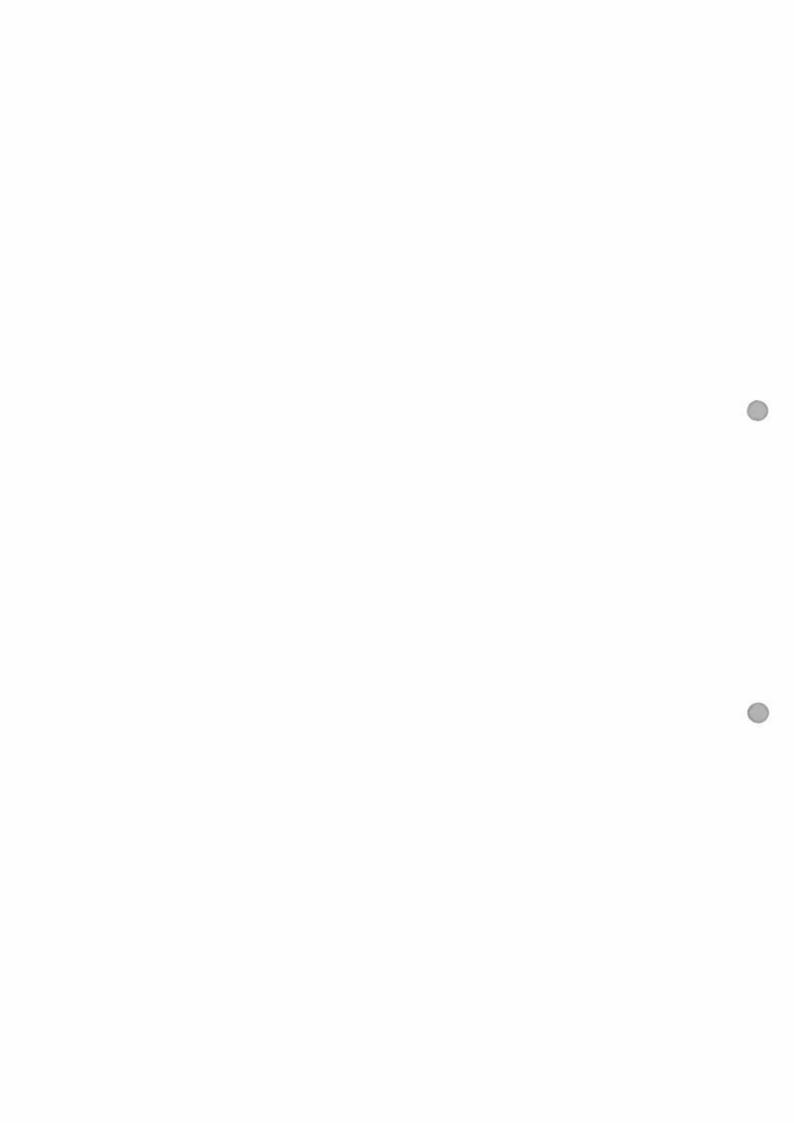
COMMS: Communications PRAS: Pesticides Unit

ADOI: Annual Declaration of Interest US EPA: United States Environmental Protection Agency



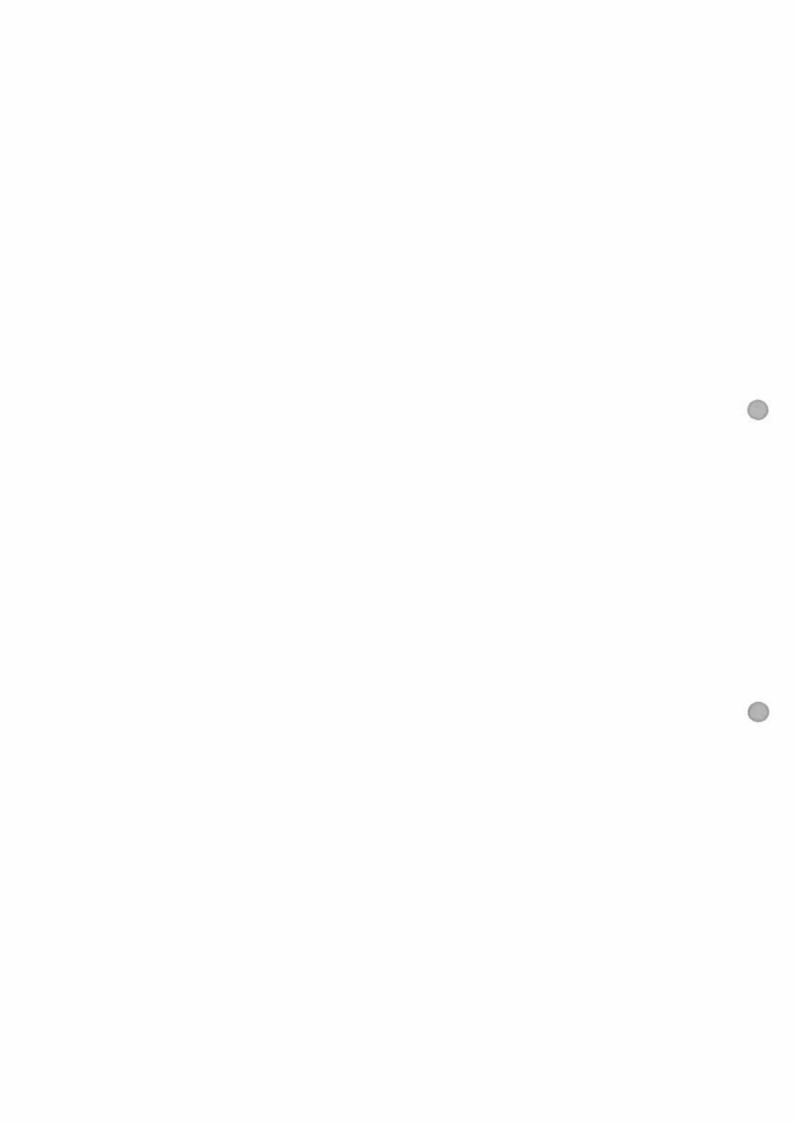
Invitation letters were sent to IARC and BfR on 8th Dec. So far no reply from IARC (reply received after the meeting). BfR will nominate one staff member after Christmas for a visit at EFSA and propose a later date for the meeting. BfR is also proposing to invite WHO as observer and intends to bring 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. (EFSA/IARC/BfR) in Brussels in the 3td level. 2016 a) draft agenda b) participants c) meeting location c) meeting location EFSA: (nverall process and genotoxicity), (epidemiology), c) (carcino), ; 1 staff taking minutes. No presence of the colleagues from COMMS is foreseen. However the agenda has to		ACTIONS
	Invitation letters were sent to IARC and BfR on 8 th Dec. So far no reply from IARC (reply received after the meeting). BfR will nominate one staff member after Christmas for a visit at EFSA and propose a	Action 20151211-01: PSC: to decide on the chairmanship of the meeting.
	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 DC CANTE Discussion to the attention of COM.	
· · · · · · · · · · · · · · · · · · ·	i scilleduled for coday.	
Details of the meeting: To be co-chaired by EFSA-IARC. discussed but not felt appropriate. Max 3-4 people should attend from FFSA: (nverall process and form (carcino), is staff No presence of the colleagues from	ntion to keep the discussion on a scientific	communication of the event. By today 11 Dec.
	External chairmanship (e.g. EChA, or JMPR) was	
No presence of the colleagues from COM	ide. kicity), ` (epidemiology), minutes.	
be reviewed considering a slot of 15 mins to decide and agree with the house of the event.	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.	





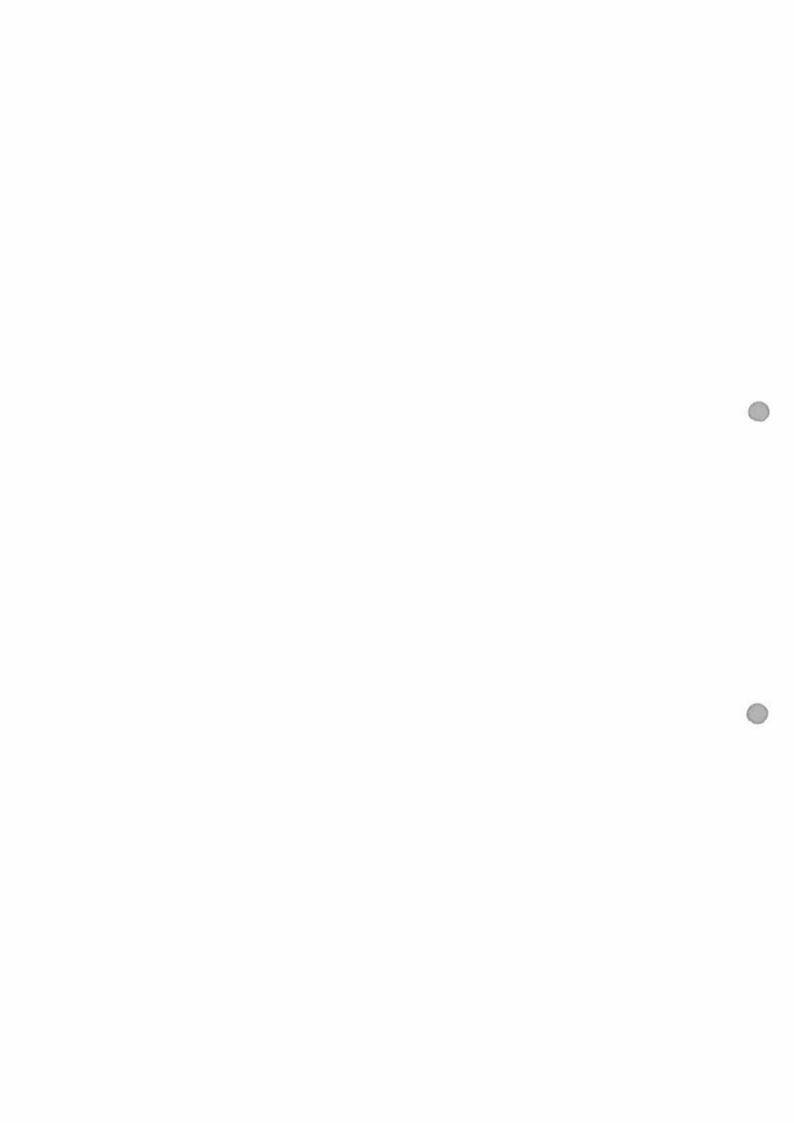
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Scientific publication explaining divergence between EFSA and IRAC opinion on glyphosate			
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Scientific publication explaining divergence between EFSA and IRAC opinion on glyphosate			
Scientific publication explaining divergence between EFSA and IRAC opinion on glyphosate			
3. 4. 5. Scientific publication explaining divergence between EFSA and IRAC opinion on alyphosate			Not discussed.
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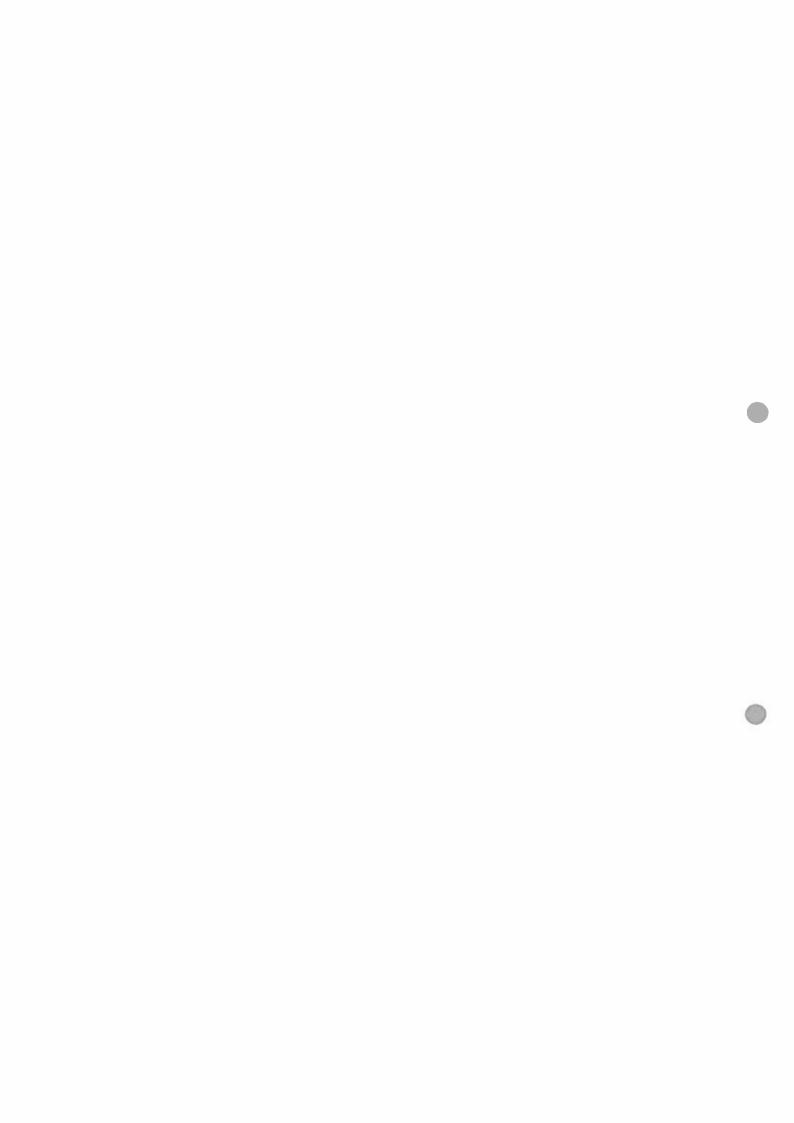
PROJECT STEERING COMMITTEE (PSC) (FOLLOW-UP WORK ON GLYPHOSATE) 11 DECEMBER 2015 10:00-11:00 MEETING MINUTES

Parma, 17 December 2015

Participants

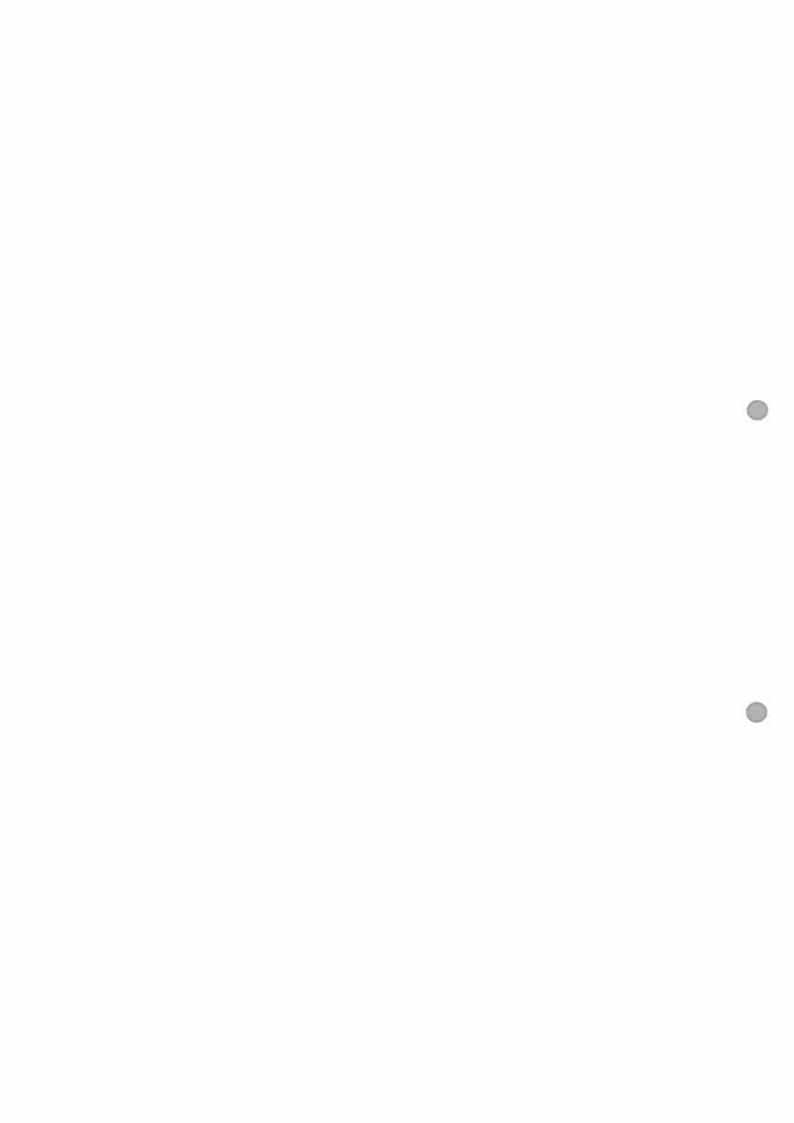
Acronyms

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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



efsa	European Food Safety Authority

ACTIONS	Action 20151211-01: PSC: to decide on the chairmanship of the meeting. Action 20151211-02: MT: Review the agenda: include 15	minutes on how to proceed with the communication of the event. By today 11 Dec.			
DISCUSSION AND DECISIONS	Invitation letters were sent to IARC and BfR on 8th Dec. So far no reply from IARC (reply received after the meeting). 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.	The PSC reiterated the need and the intention to keep the discussion on a scientific level.	Details of the meeting: To be co-chaired by EFSA-IARC. External chairmanship (e.g. EChA, or JMPR) was discussed but not felt appropriate. Max 3-4 people should attend from each side. EFSA: (overall process and genotoxicity), (epidemiology), (carcino), 1 staff taking minutes. No presence of the colleagues from COMMS is foreseen. However the agenda has to he reviewed concidering a slot of 15 minutes.		
AGENDA	Trilateral meeting	(EFSA/IARC/BfR) in Brussels in the 3 rd week of January 2016	a) draft agenda b) participants c) meeting location	1	

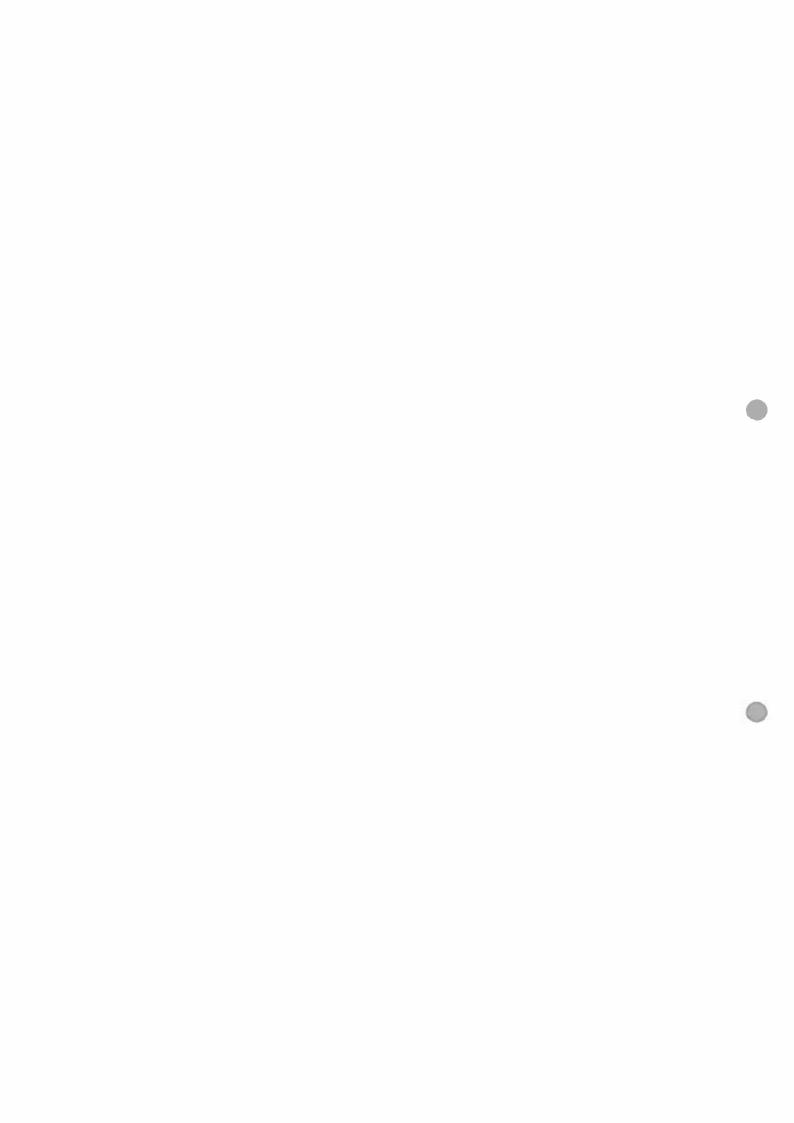


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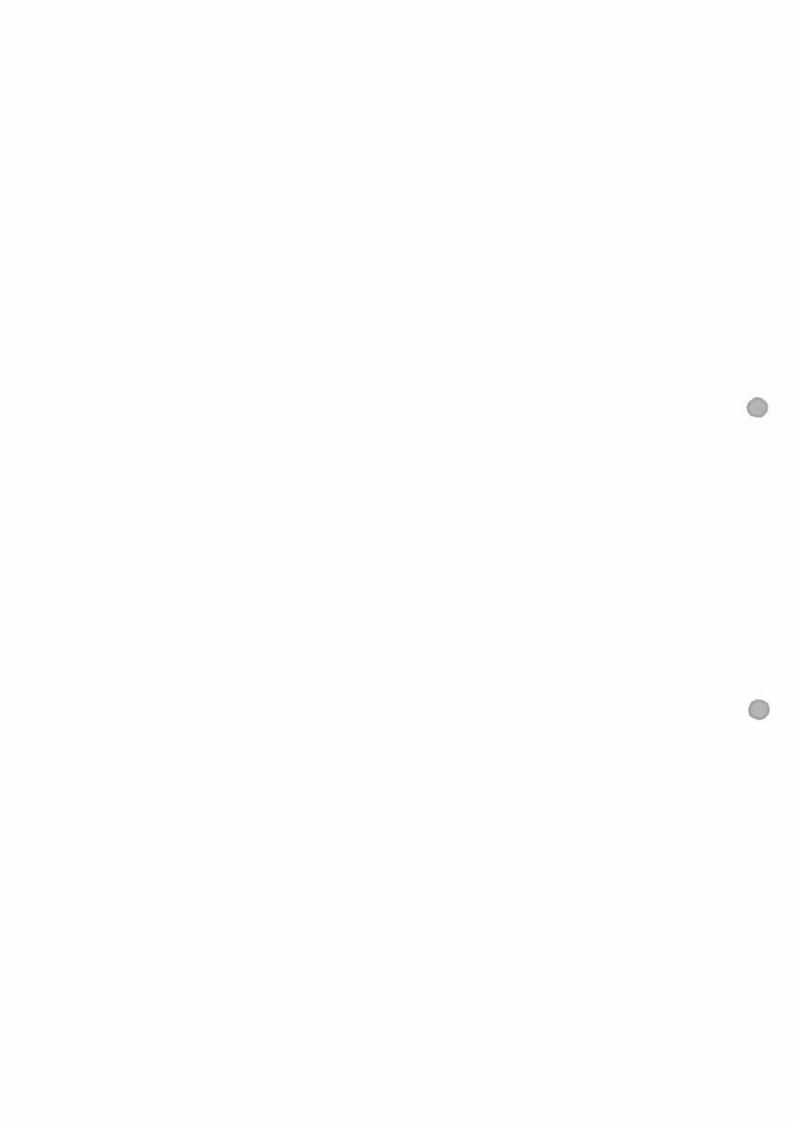
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Scientific publication Not discussed. explaining divergence between EFSA and IRAC opinion on glyphosate rų.



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SCIENTIFIC EVALUATION OF REGULATED PRODUCTS DEPARTMENT

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

18 DECEMBER 2015, 10:30-12:00

OFFICE (SEAT 08/B10)

DRAFT AGENDA

2.	Feedback from the teleconferences between EFSA/US-EPA and EFSA/IARC
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6.	Scientific publication explaining divergence between EFSA and IARC opinion on glyphosate
7.	
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PROJECT STEERING COMMITTEE (PSC) (FOLLOW-UP WORK ON GLYPHOSATE) 18 DECEMBER 2015 10:30-12:00 MEETING MINUTES

Parma, 7 January 2016

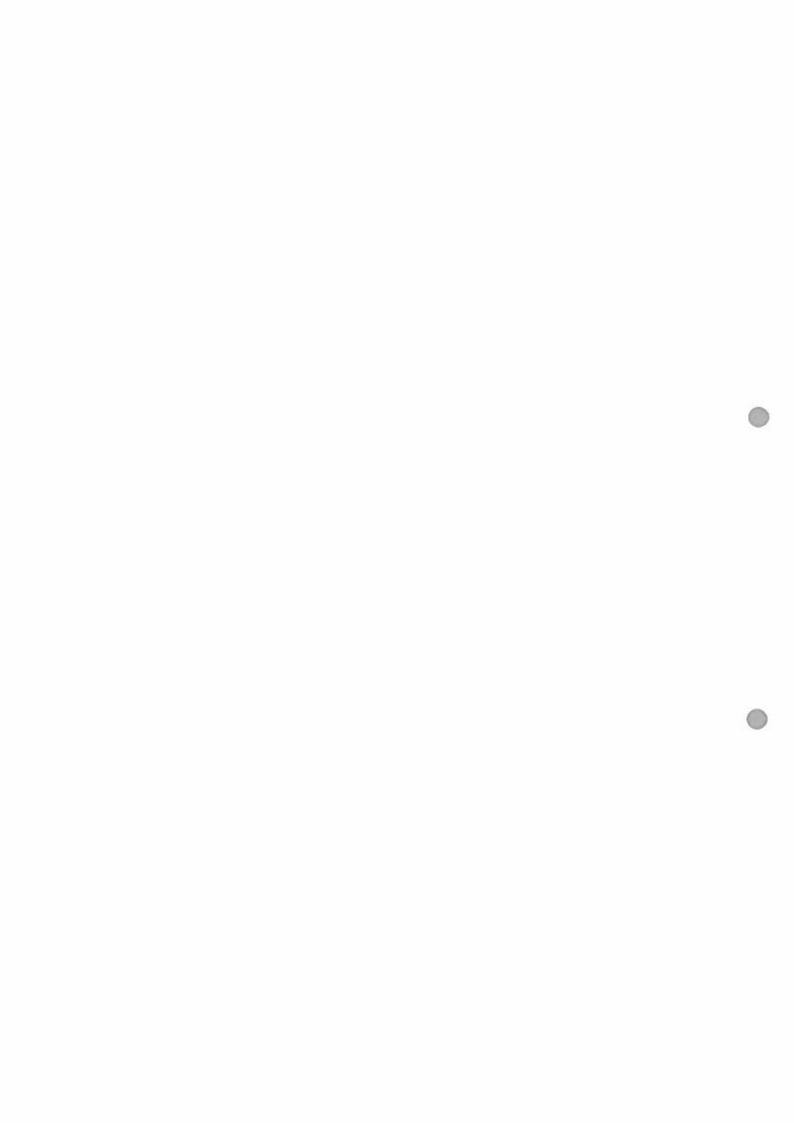
Participants

BfR: the German Federal Institute for Risk Assessment IARC: International Agency for Research on Cancer COMMS: Communications PRAS: Pesticides Unit

PSC: Project Steering Committee

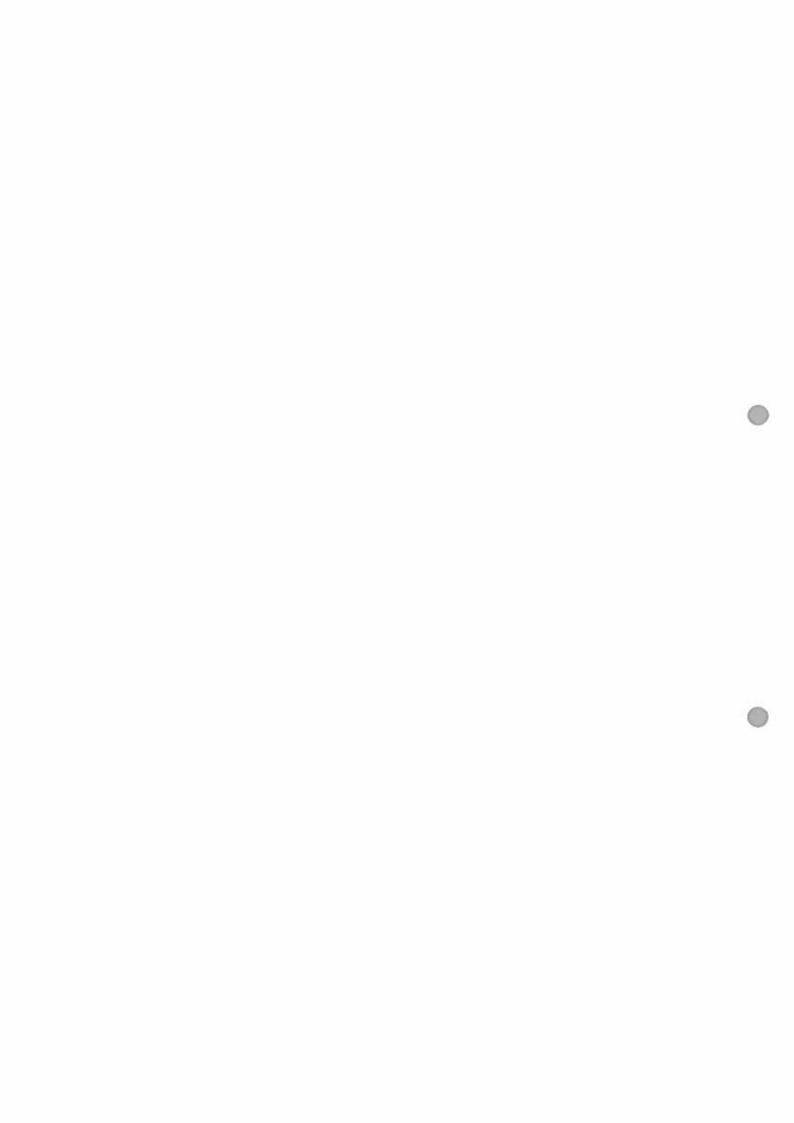
Acronyms

ADOI: Annual Declaration of Interest US EPA: United States Environmental Protection Agency ED: Executive Director



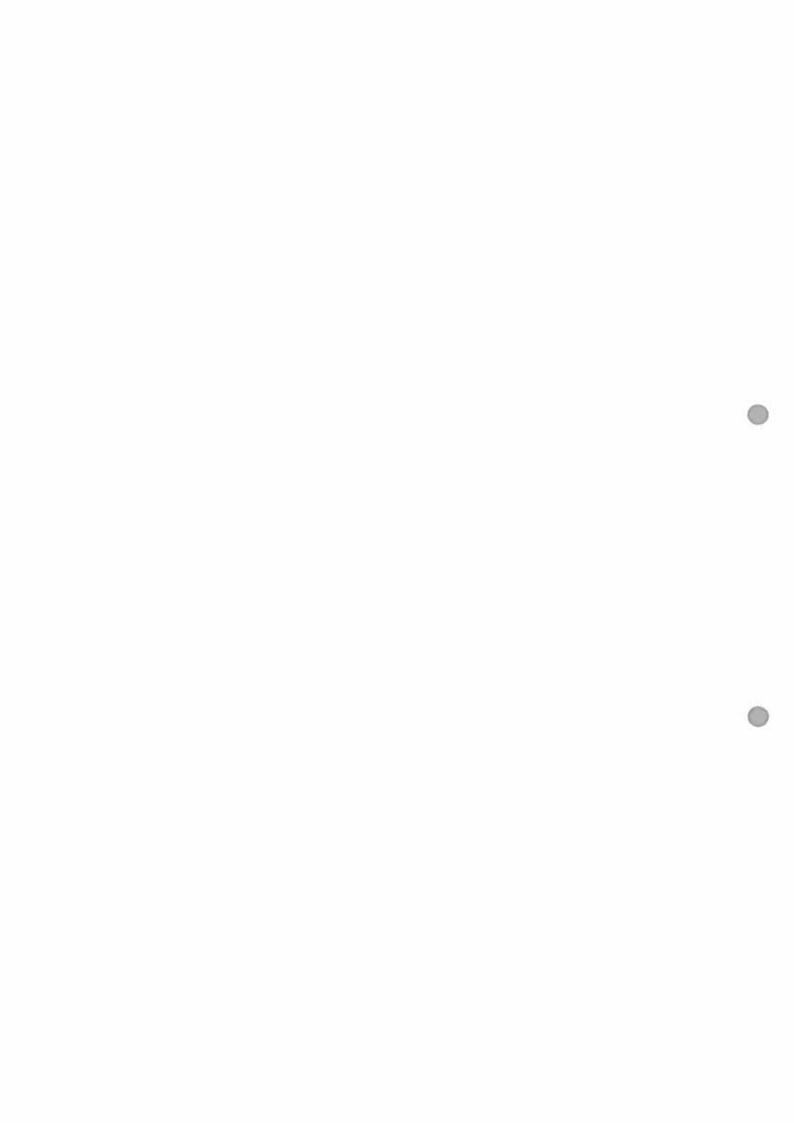
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Teleconference US EPA-EFSA drafted a document containing explana Portier's comment and to be used for the meet US EPA. The doc is aimed at further clarifying th EFSA conclusion; the document is not a comme the regulatory process. Teleconferences between EFSA/US- FPSA will reply to IARC including the following: The organisation of the meeting was discussed. EFSA will reply to IARC including the following: The meeting will take place in February S people max from each side CO-chairmanship EFSA-IARC BR and a IARC WG member could atten As soon as the meeting is confirmed, EFSA C discuss the communication issues before the me As soon as there's an agreement on the date I start the preparation of each scientific session.	ND DECISIONS	explanations/complementary information to address he meeting with IARC comments raised after the publication of the comments raised after the publication of the commentary of the EFSA conclusion and is not part of commentary of the EFSA conclusion and is not part of commentary of the EFSA conclusion and is not part of Action 20151218-03: MT to revise the agenda (increasing duration of the communication session). Action 20151218-03: MT to revise the agenda (increasing duration of the Communication session). EFSA COMMs should liaise with IARC COMM dept. to a the meeting. The date people have to be identified from each side to ession.	
AGENDA Feedback from the teleconferences between EFSA/US-EPA and EFSA/IARC	DISCUSSION AND DECISIONS	Teleconference US EPA-EFSA drafted a document containing explanations/complementary information to address drafted a document containing explanations/complementary information 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. Teleconference IARC-EFSA The organisation of the meeting was discussed. EFSA will reply to IARC including the following: The organisation of the meeting will take place in February Speople max from each side Co-chairmanship EFSA-IARC BR and a IARC WG member could attend As soon as the meeting is confirmed, EFSA COMMs should liaise with IARC COMM dept. to discuss the communication issues before the meeting. 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.	
	AGENDA	Feedback from the teleconferences between EFSA/US-EPA and EFSA/IARC	



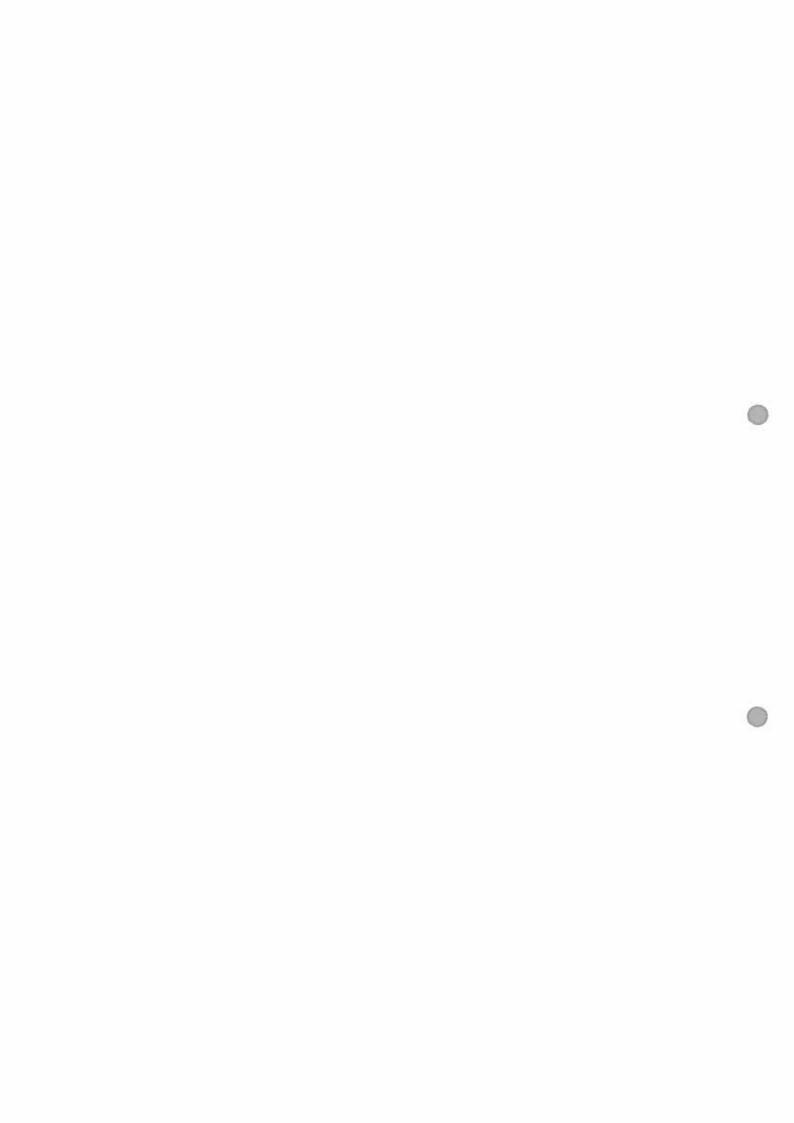


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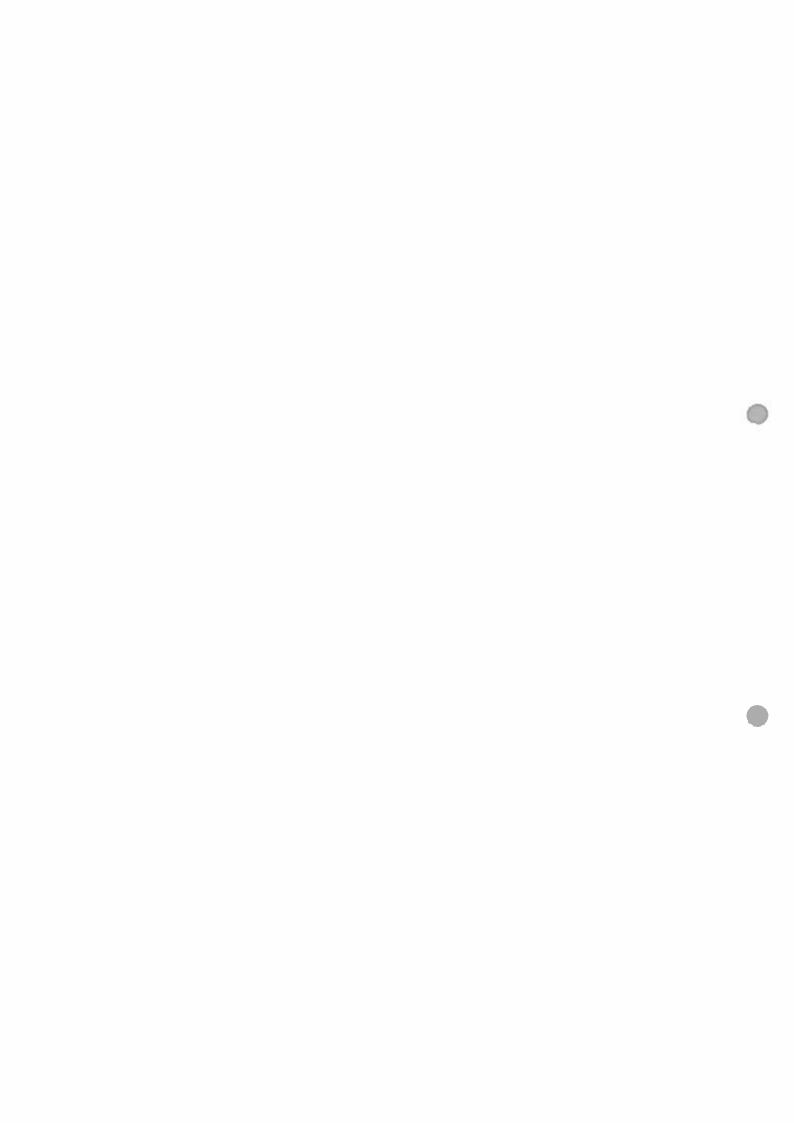


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Not discussed. Scientific publication explaining divergence between EFSA and IARC opinion on glyphosate 6.

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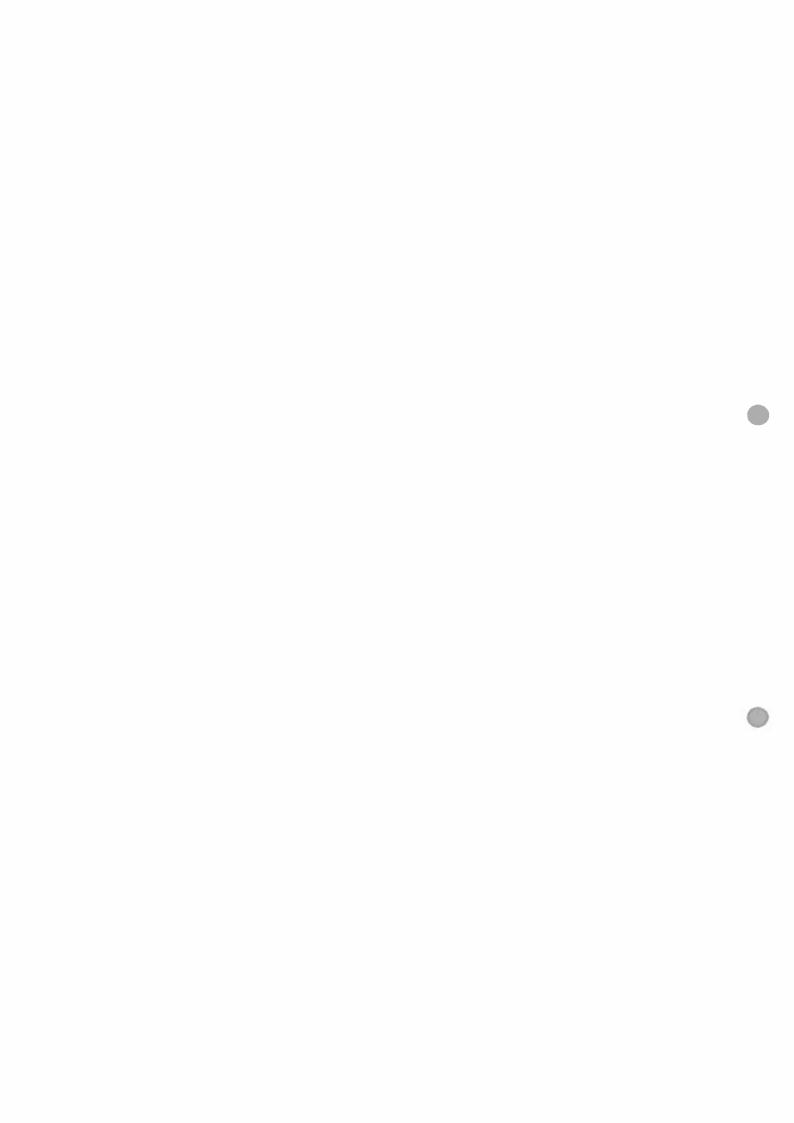
PROJECT STEERING COMMITTEE MEETING (FOLLOW-UP WORK ON GLYPHOSATE)

8 JANUARY 2016, 10:00-11:30

OFFICE (SEAT 08/B10)

DRAFT AGENDA

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2.	
3.	Bilateral meeting (EFSA/IARC) in Brussels in February 2016
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8.	Scientific publication explaining divergence between EFSA and IARC opinion on glyphosate
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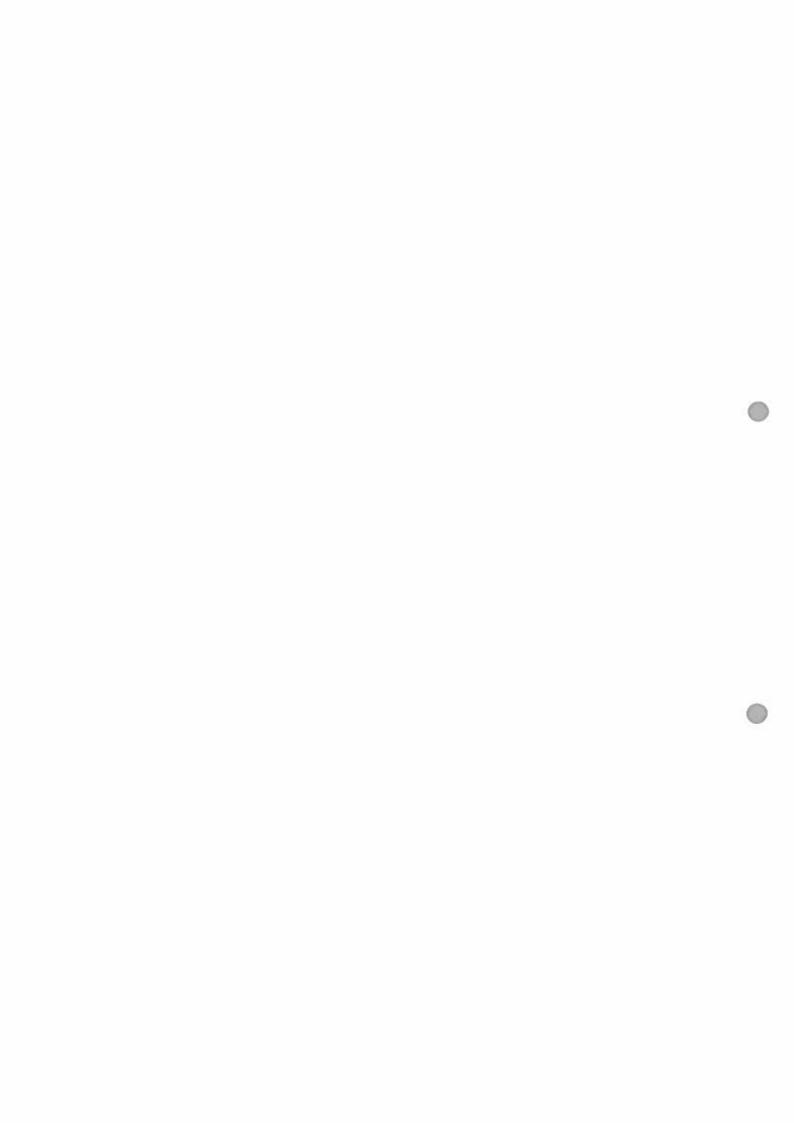
(FOLLOW-UP WORK ON GLYPHOSATE) 18 DECEMBER 2015 10:30-12:00 MEETING MINUTES

Participants

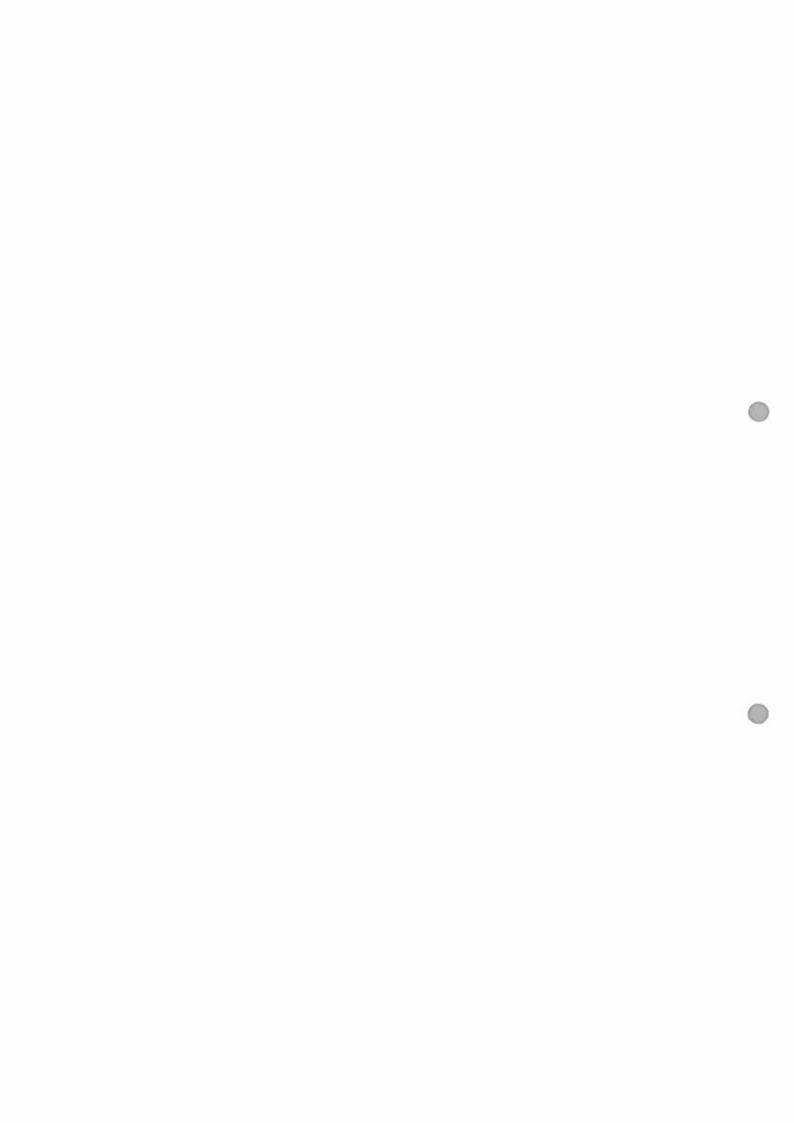
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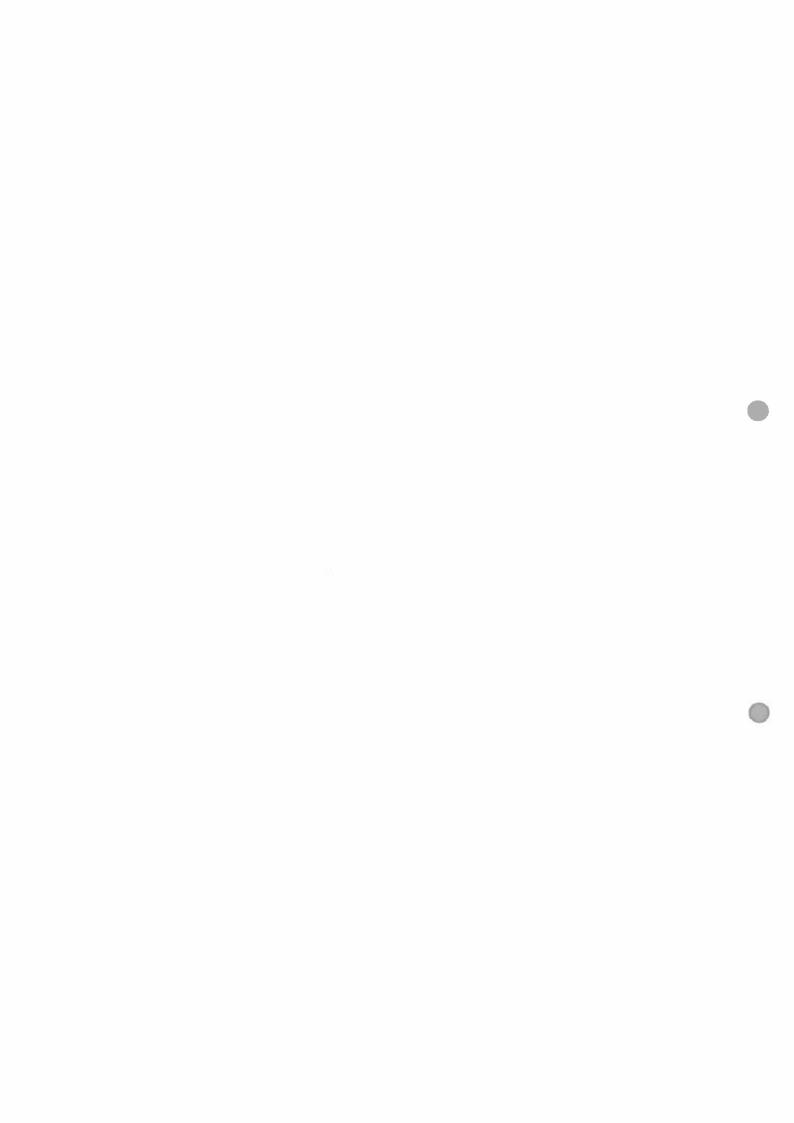
European Food Safety Authority • Via Carlo Magno 1A • 43126 Parma • ITALY Tel. +39 0521 036 111 • Fax +39 0521 036 110 • www.efsa.europa.eu



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AGENDA	DISCUSSION AND DECISIONS	ACTIONS
1.		•
	<u>Teleconference US EPA-EFSA</u> 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.	Action 20151218-03: If there are comments to the doc prepared by : to be done by Mo 21 Dec lunch time. Action 20151218-03:
2. Feedback from the teleconferences	<u>Teleconference IARC-EFSA</u> The organisation of the meeting was discussed. EFSA will reply to IARC including the following:	nevise une and duration from as the duration ication session).
EPA and EFSA/IARC	 The first max from each side Co-chairmanship EFSA-IARC BfR and a IARC WG member could attend 	Action 20151218-04: EFSA ED to send the reply letter to C. Wild with the proposals discussed by Tue 22 Dec
	As soon as the meeting is confirmed, EFSA COMMs should liaise with IARC COMM dept. to discuss the communication issues before the meeting.	
	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.	
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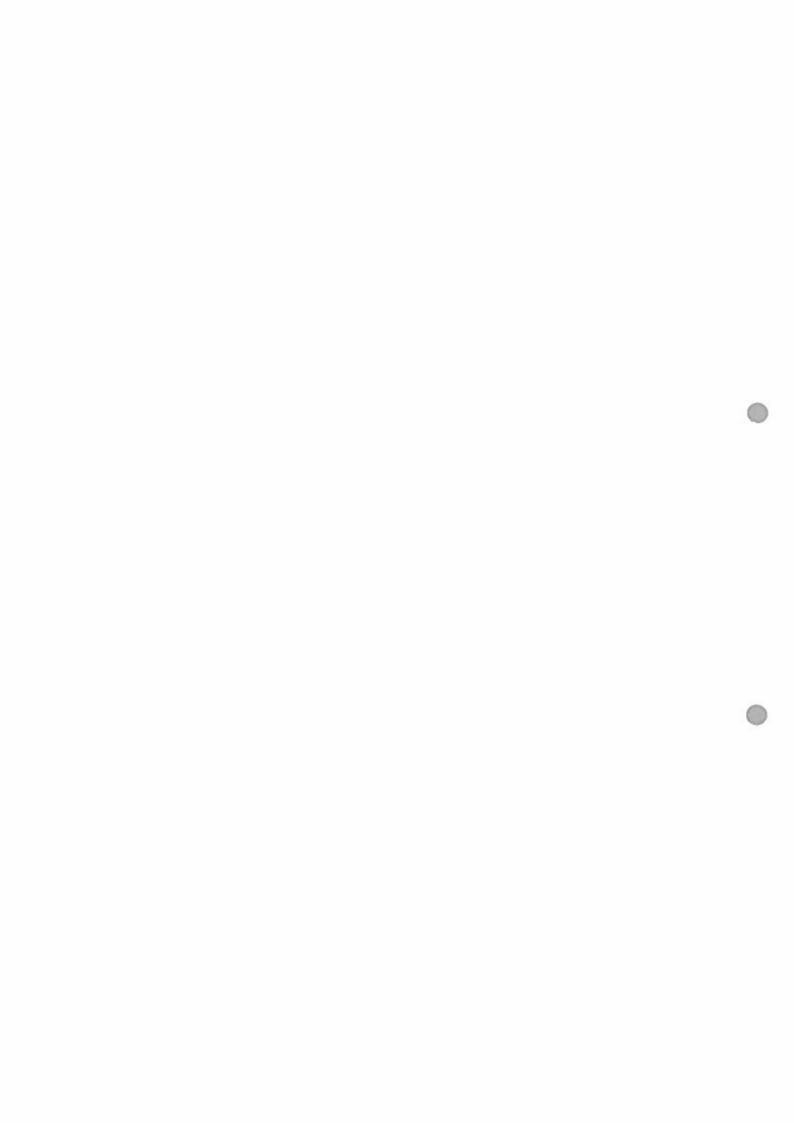






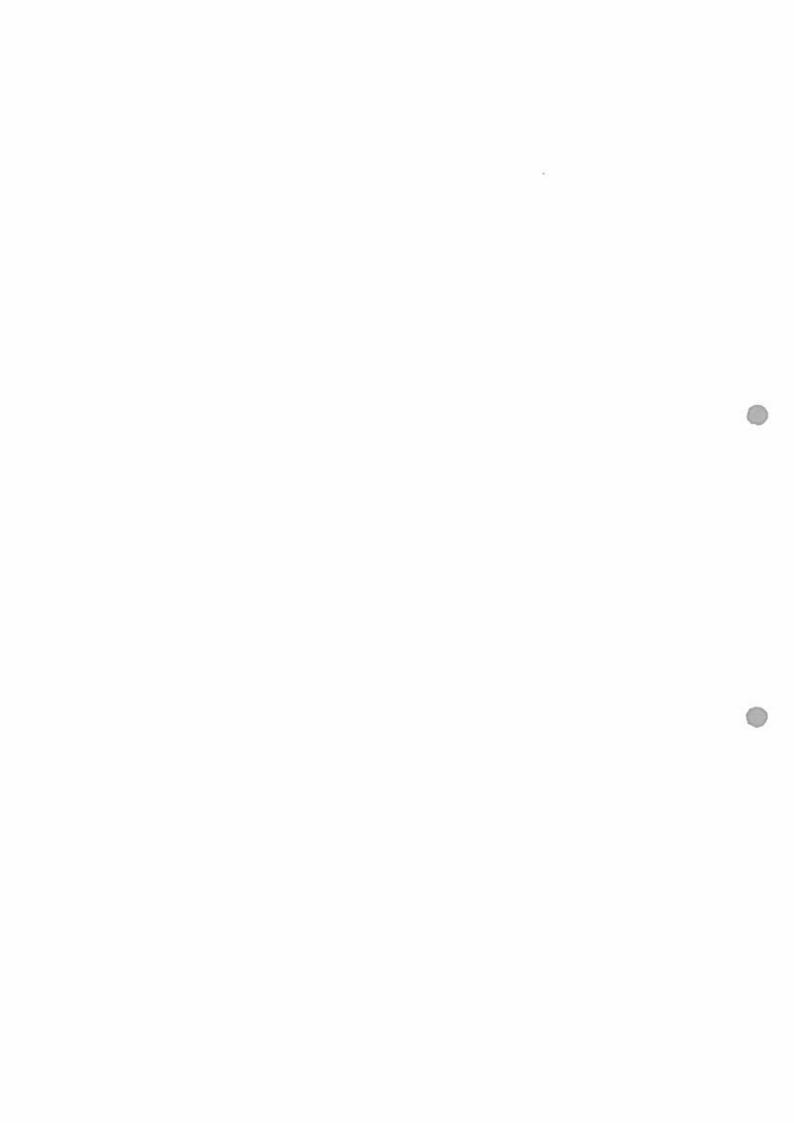


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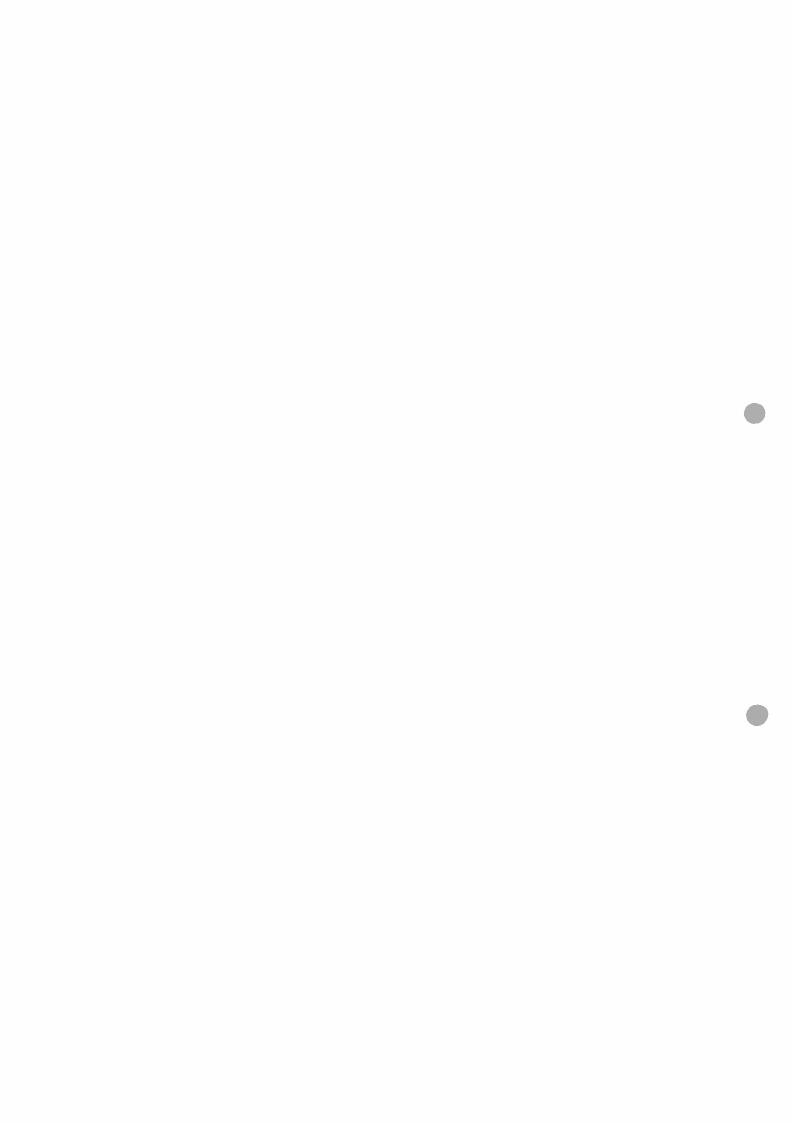


EXECUTIVE DIRECTOR

DRAFT AGENDA

IARC/EFSA Meeting on the scientific assessment of the carcinogenicity of the active pesticide substance glyphosate XX February 2016 09h00-17h00 - Brussels

	1	
Time	Торіс	Presenter
09.00-09.10	Opening remarks	Co-chair: (EFSA)(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 IARC
16.15-16.50	Communication to stakeholders on the outcome of the joint meeting	tbd
16.50-17.00	Next steps	EFSA-IARC



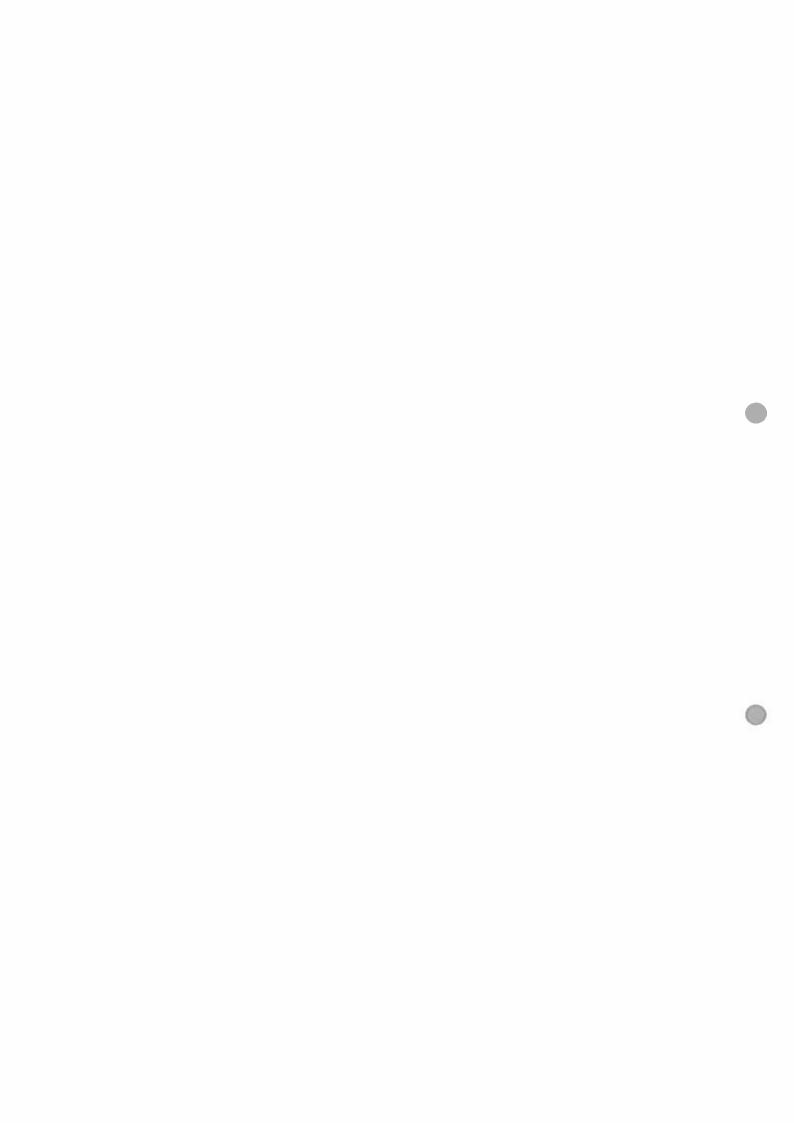


PROJECT STEERING COMMITTEE (PSC) (FOLLOW-UP WORK ON GLYPHOSATE) 8 JANUARY 2016 10:00-11:30 MEETING MINUTES

Participants

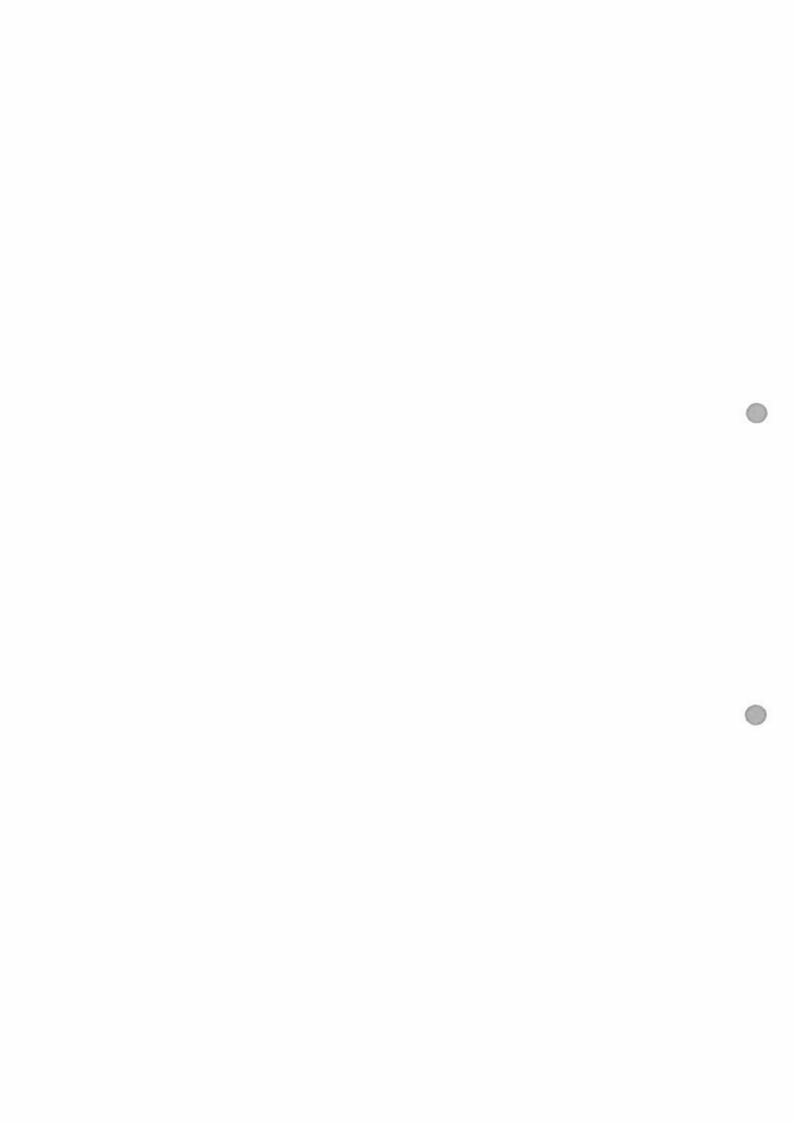
Acronyms

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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



ACTIONS	Action 20160108-03:	. to draft reply to IARC. Action 20160108-04:	to draft revised agenda.
DISCUSSION AND DECISIONS	IARC replied to the proposal of a joint meeting EFSA-IARC; the agenda will be slightly modified.		The meeting could have a positive outcome in terms of proposing future steps (e.g. interagency work on methodology in risk assessment?)
AGENDA		Bilateral meeting (EFSA/IARC) in	Brussels in February 2016

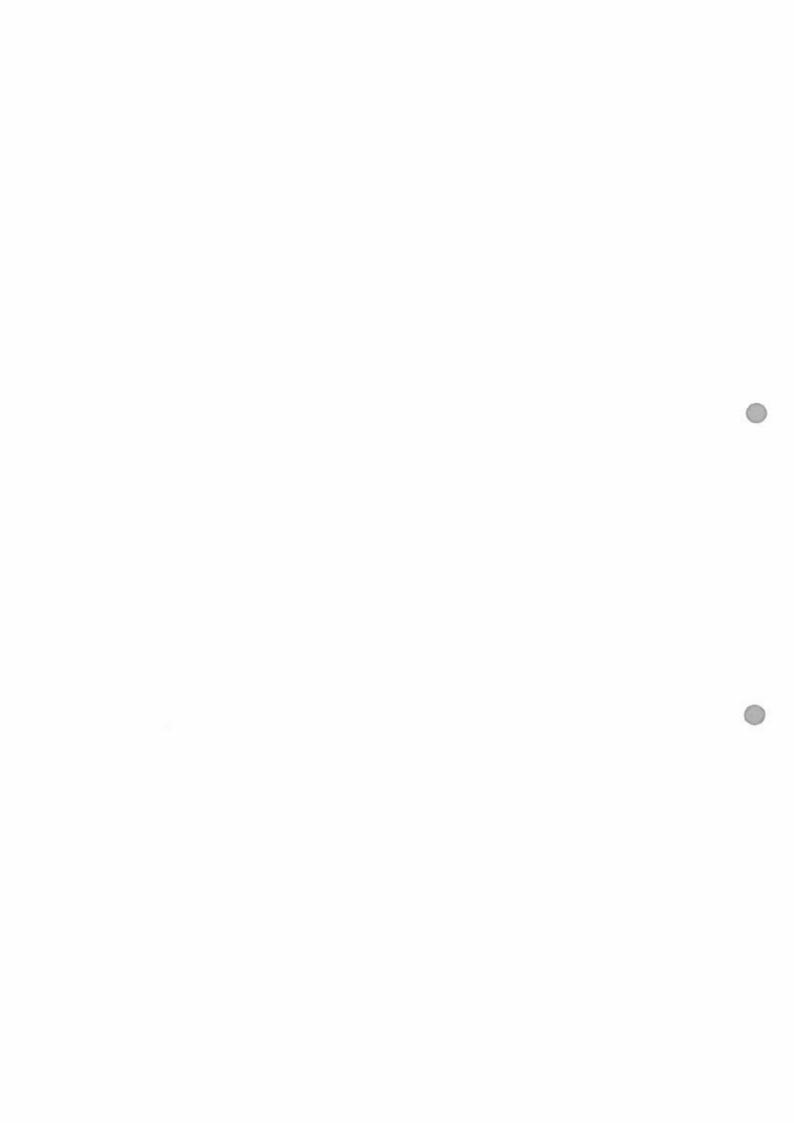




	Action 20160108-12: PRAS to invole to the	epidemiology WG of the PPR Panel.	Action 20160108-13:	Rediscuss with the sc publ.	
	Need to re-discuss the issue with PRAS.				
		Scientific publication	divergence EFSA and	pinion on	
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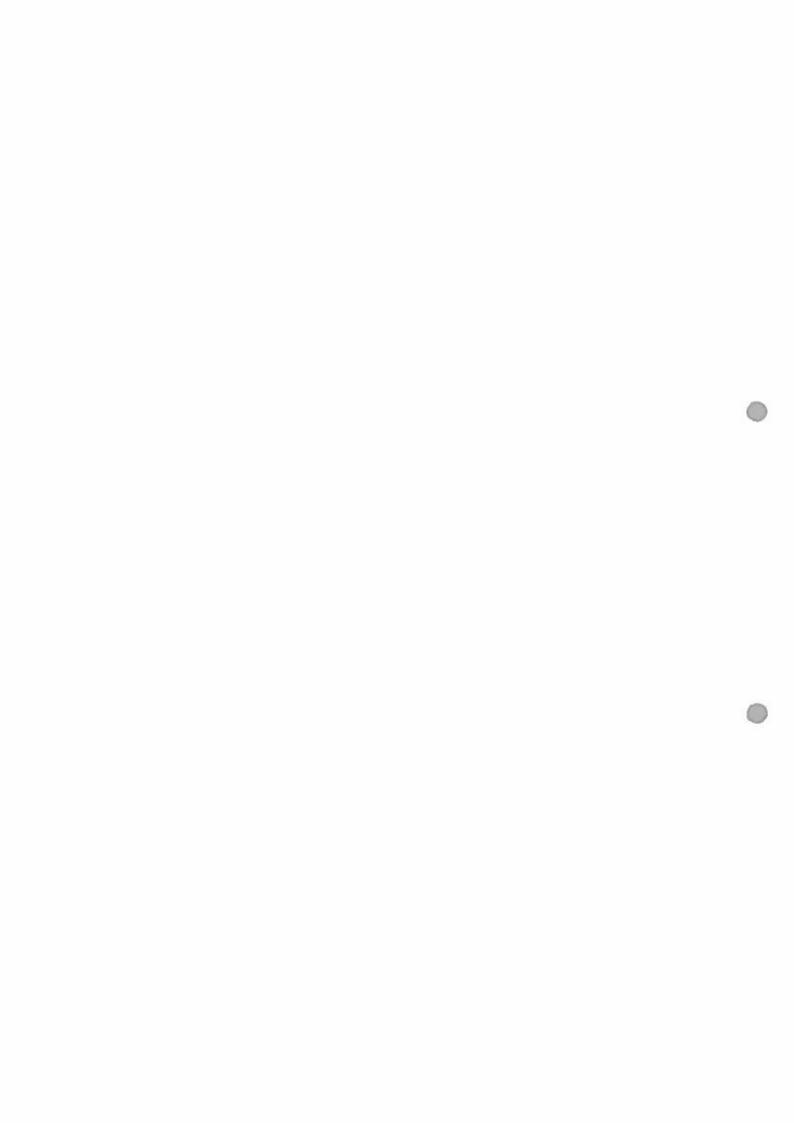
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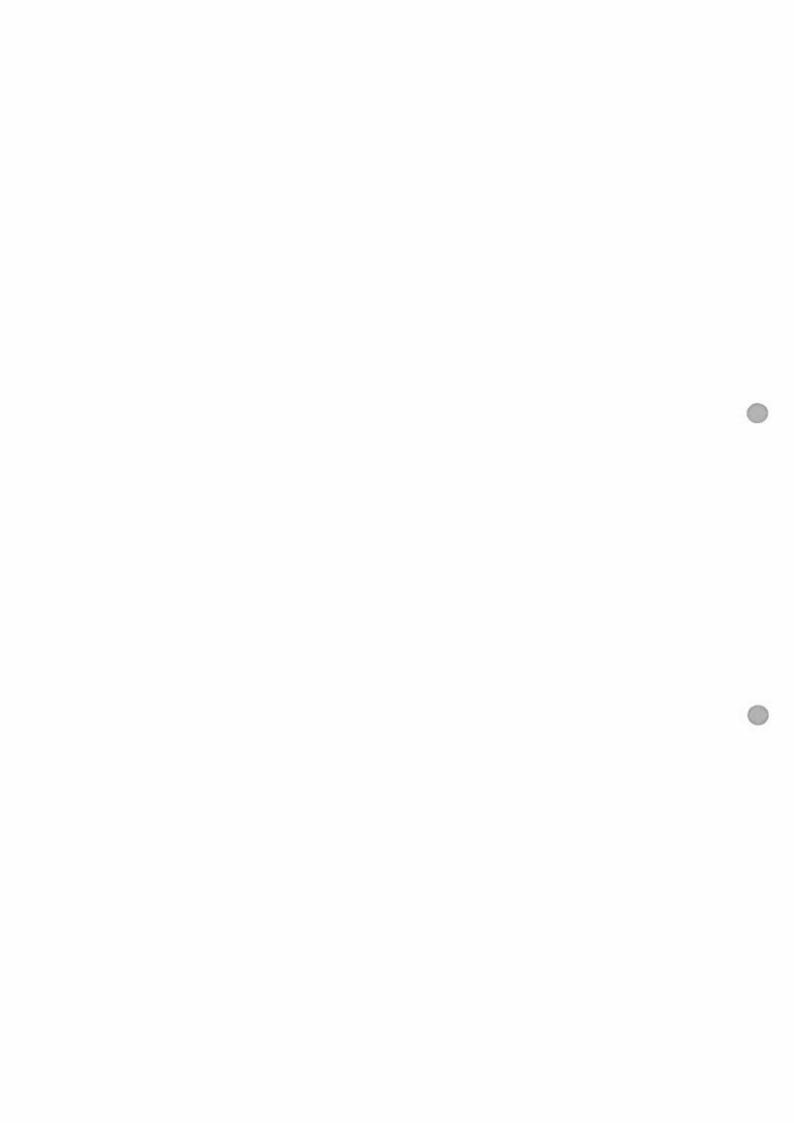


PROJECT STEERING COMMITTEE MEETING (FOLLOW-UP WORK ON GLYPHOSATE)

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.	The second secon
7.	



Parma, 13 January 2016

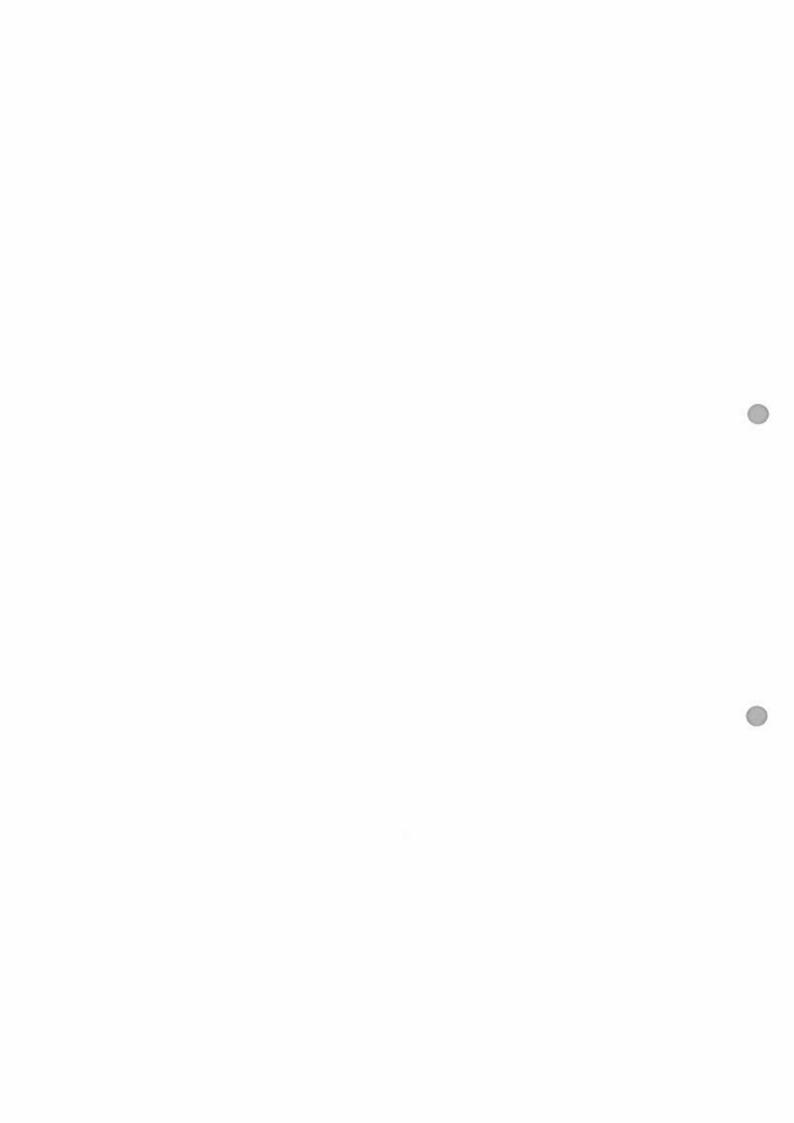
SCIENTIFIC EVALUATION OF REGULATED PRODUCTS DEPARTMENT

(FOLLOW-UP WORK ON GLYPHOSATE) 8 JANUARY 2016 10:00-11:30 MEETING MINUTES

Participants

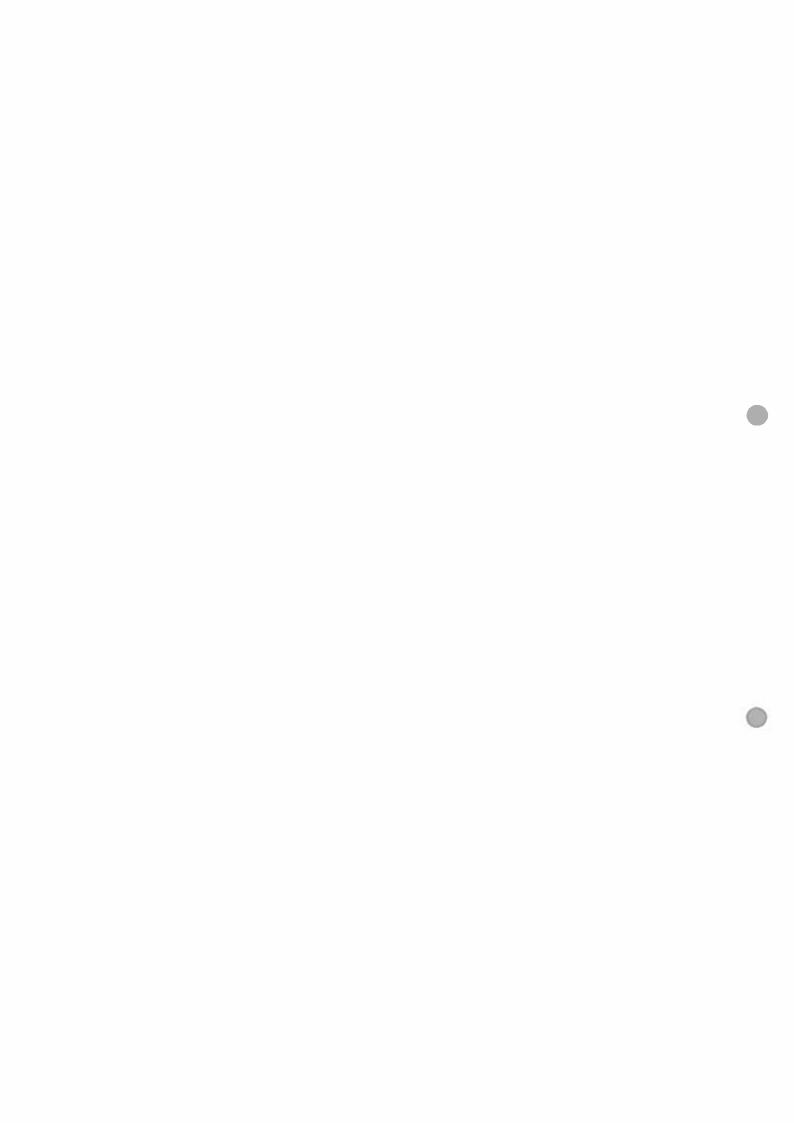
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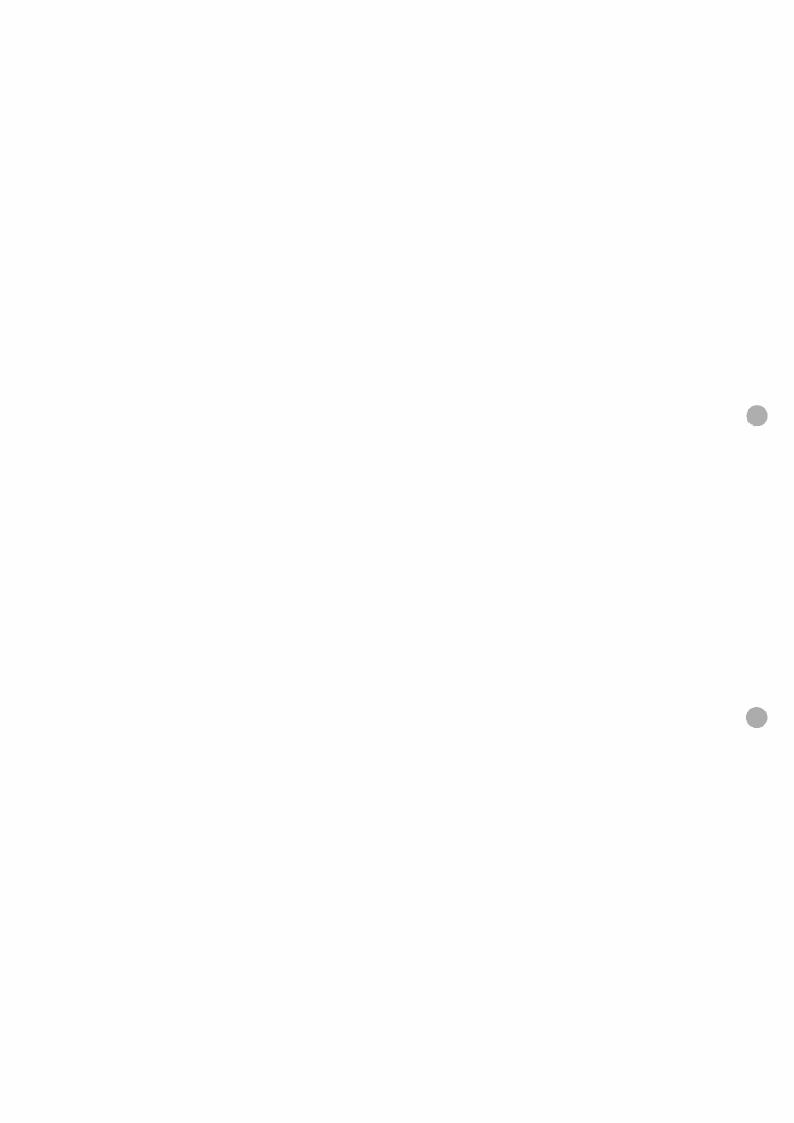


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ACTIONS			Action 20160108-03: to draft reply to IARC.	Action 20160108-04: to draft revised agenda.	
DISCUSSION AND DECISIONS			IARC replied to the proposal of a joint meeting EFSA-IARC; the agenda will be slightly modified.	The PSC considered helpful to propose a preparatory meeting with IARC. Tattending plus secretariat	The meeting could have a positive outcome in terms of proposing future steps (e.g. interagency work on methodology in risk assessment?)
AGENDA					2016
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Action 20160108-05: and to check cases of different classification IARC-EFSA.	Action 20160108-06: to propose preparatory meeting with IARC to coordinate.	Action 20160108-07: COMMS to liaise with IARC COMMS.			Action 20160108-12: PRAS to invole to the epidemiology WG of the PPR Panel. Action 20160108-13: Rediscuss with the sc publ.
					Need to re-discuss the issue with PRAS.
			, v.	7.	8. Scientific publication explaining divergence between EFSA and IARC opinion on glyphosate



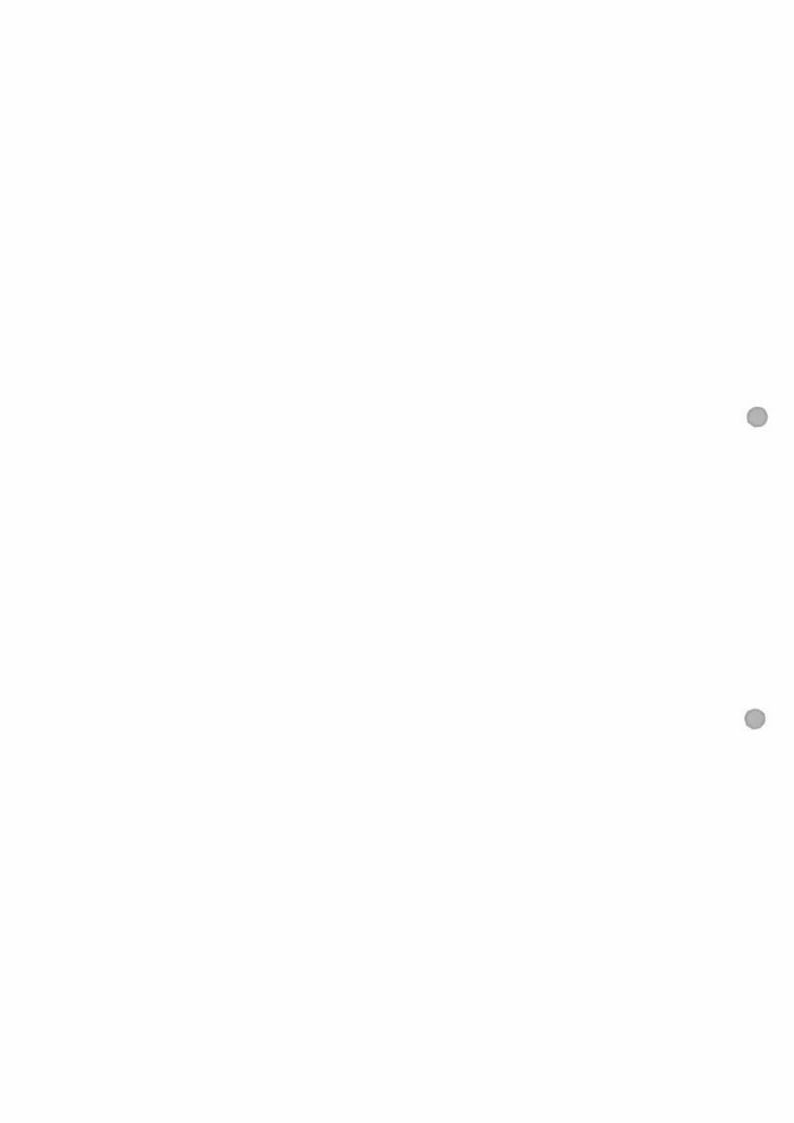


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DRAFT AGENDA

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: (EFSA) (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: (EFSA) (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 (the scientific secretariat will collect the point raised during the discussion)
10.00-11.00	Glyphosate: focus on experimental data on carcinogenicity	(EFSA)
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	(IARC)
15.15-16.15	Overall conclusion on divergent views and agreement of content of minutes of the meeting	EFSA-IARC (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 (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

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Version 3
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20 January 2016
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(FOLLOW-UP WORK ON GLYPHOSATE) PROJECT STEERING COMMITTEE (PSC) 21 JANUARY 2016 11:30-13:00 MEETING MINUTES

Parma, 25 January 2016

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

ACTIONS	1		
DISCUSSION AND DECISIONS			
AGENDA	1.	2.	

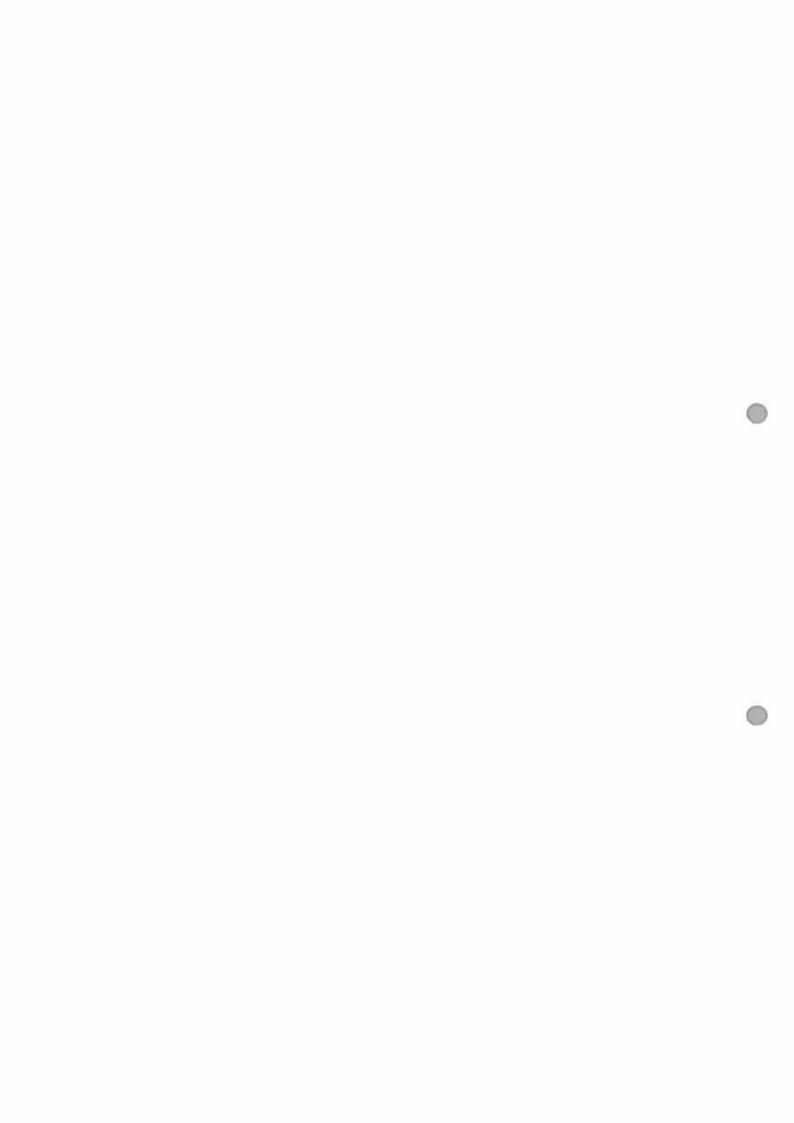
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Action 20160121-01: Communication in collaboration	with PRAS to review the letter to	incorrect or inappropriate towards IARC was reported		Action 20160121-02: EXREL to liaise with	(IARC, HoU		Action 20160121-03:	to organise a phone	(TABC) to discuss the principles	of the upcoming meeting.		Action 20160121-04: to prepare a list of key points	for the phone call between BU and C. Wild.	Action 20160121-05:	meeting. Liaise with CORSER		
The meeting will be held in Brussels on 17 Feb 2016 (from 9.30-17.00), and will be co-haired IARC-EFSA.	The participants could have a joint dinner the day before: for this IARC will inform us about their travel plans.	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 FFSA	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.	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.	Proposal of preliminary contacts with EFSA and IARC Communication Units: the contact point in	JARC	Proposal or Javing the 2 Communication Units connected via teleconference for the last session of the meeting was acreed	Participants from TARC:	An additional teleconference EFSA-1AKL LOUIN DE NEIO DEFORE the meeting in Feb		need to check previous cases where take was directly attacking EFSA. Communication to review the letter to Portier to see whether anything clearly against IARC.	Direct communication BU-C. Wild would be extremely helpful.	to provide with a few bullets points on what we need to achieve for the meeting.	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).	As for the meeting, DCM should present both carcino and epi.	PRAS to organise practically the meeting. Liaise with
							Feedback from the	EFSA/IARC	teleconference on the	rormat and agenda of the joint meeting in	February 2016						

efsam European Food Safety Authority

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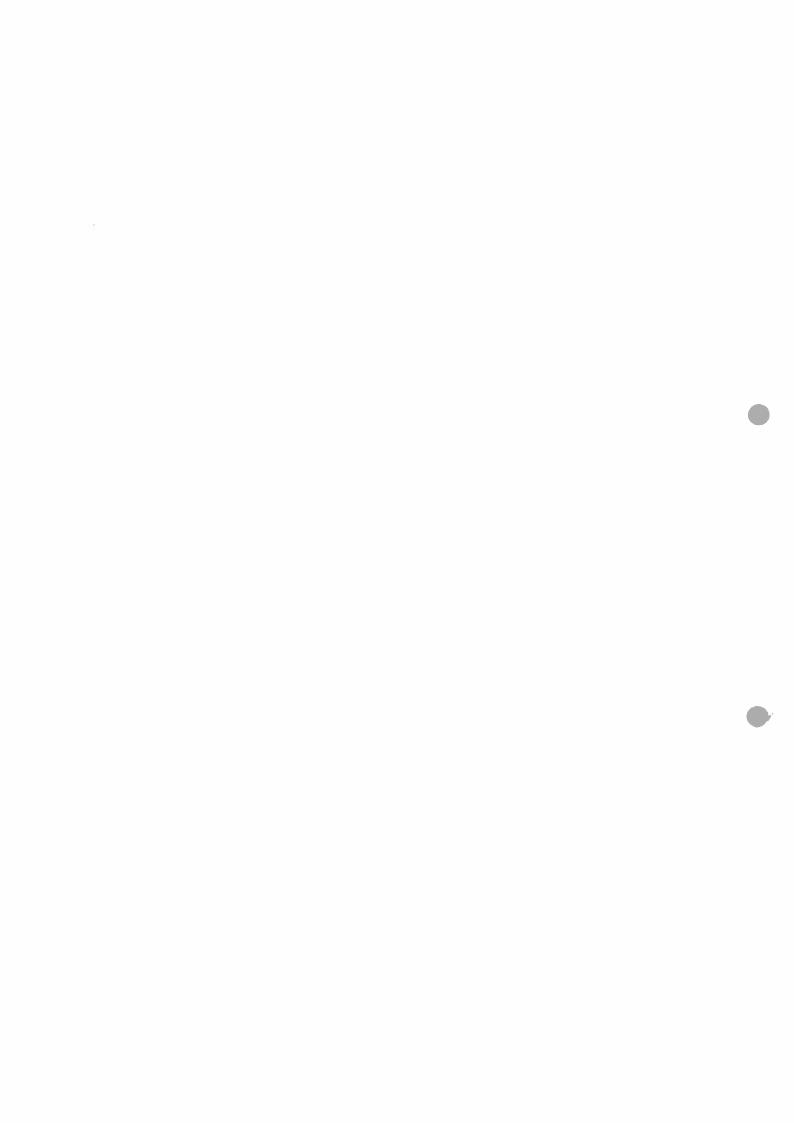




PROJECT STEERING COMMITTEE MEETING (FOLLOW-UP WORK ON GLYPHOSATE)

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

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

12 JANUARY 2016, 9:30-10:30
OFFICE (SEAT 06/B12)

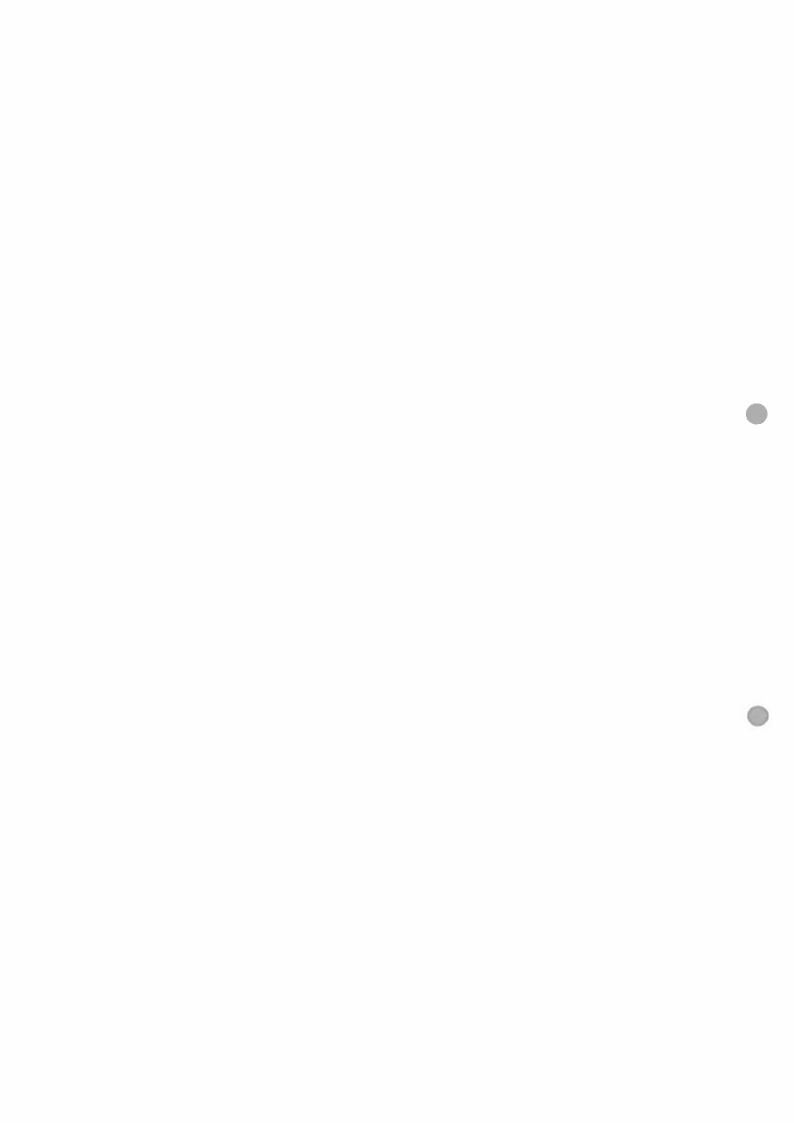
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5.	Bilateral meeting (EFSA/IARC) in Brussels in February 2016
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JOINT MEETING OF THE PROJECT TEAMS (FOLLOW-UP WORK ON GLYPHOSATE)

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4.	Bilateral meeting (EFSA/IAF	RC) in Brussels in February 2016 (incl. meeting venue)
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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:
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



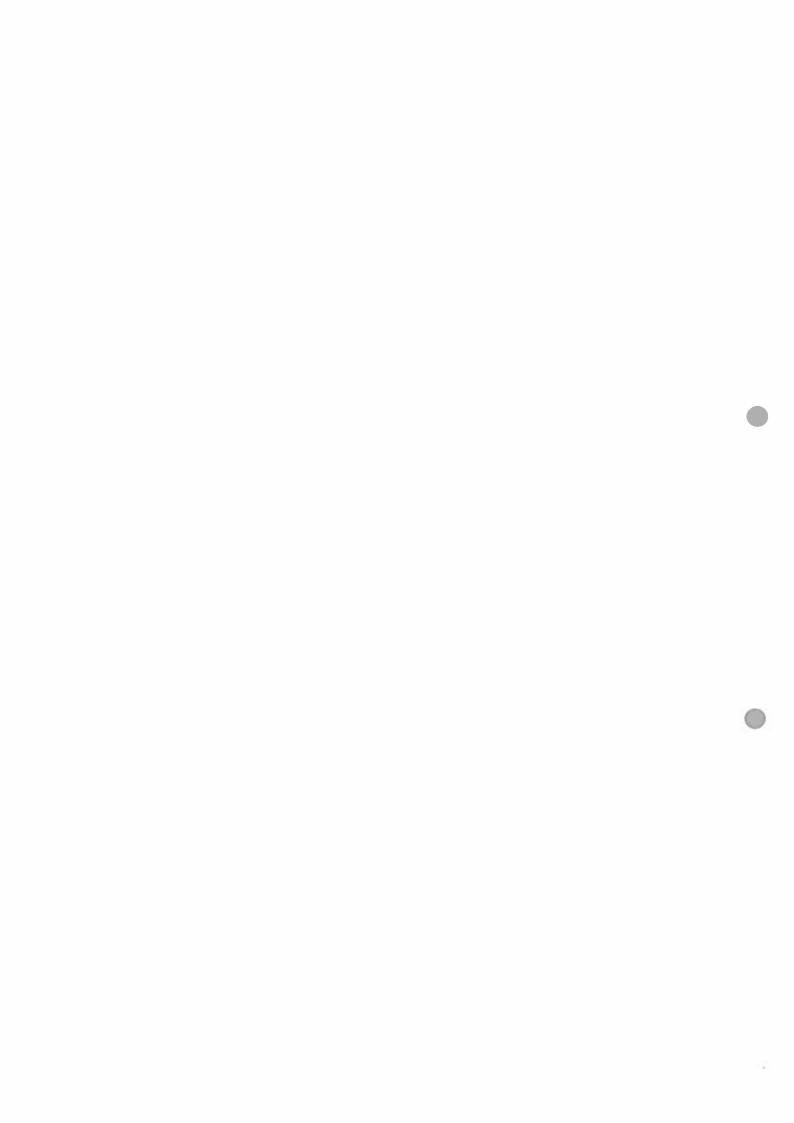
16.50-17.00	Next steps	EFSA-IARC



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

27 JANUARY 2016, 16:30-17:30 OFFICE (SEAT 06/B12)

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4.	Bilateral meeting	g (E	EFSA/IA	RC) in	Brus	sels in	Februa	ry 2016	5 – state	e of play
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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: EFSA) 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 (the scientific secretariat will collect the point raised during the discussion)
10.00-11.00	Glyphosate: focus on experimental data on carcinogenicity	(IARC)
11.00-11.15	Coffee/Tea break	
11.15-12.45	Glyphosate: focus on human and epidemiological data on carcinogenicity	(FFSA)
12.45-13.45	LUNCH	
13.45-15.15	Glyphosate: focus on the genotoxicity and mechanistic data on carcinogenicity	i (EFSA)
15.15-16.15	Overall conclusion on divergent views and agreement of content of minutes of the meeting	EFSA-IARC (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 (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	t history
Document reference	Version 3
Prepared by	44444_A-A-4-4-2014_A-4-4-4-2014_A-4-4-4-2-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4-
Reviewed by	
Last date modified	20 January 2016

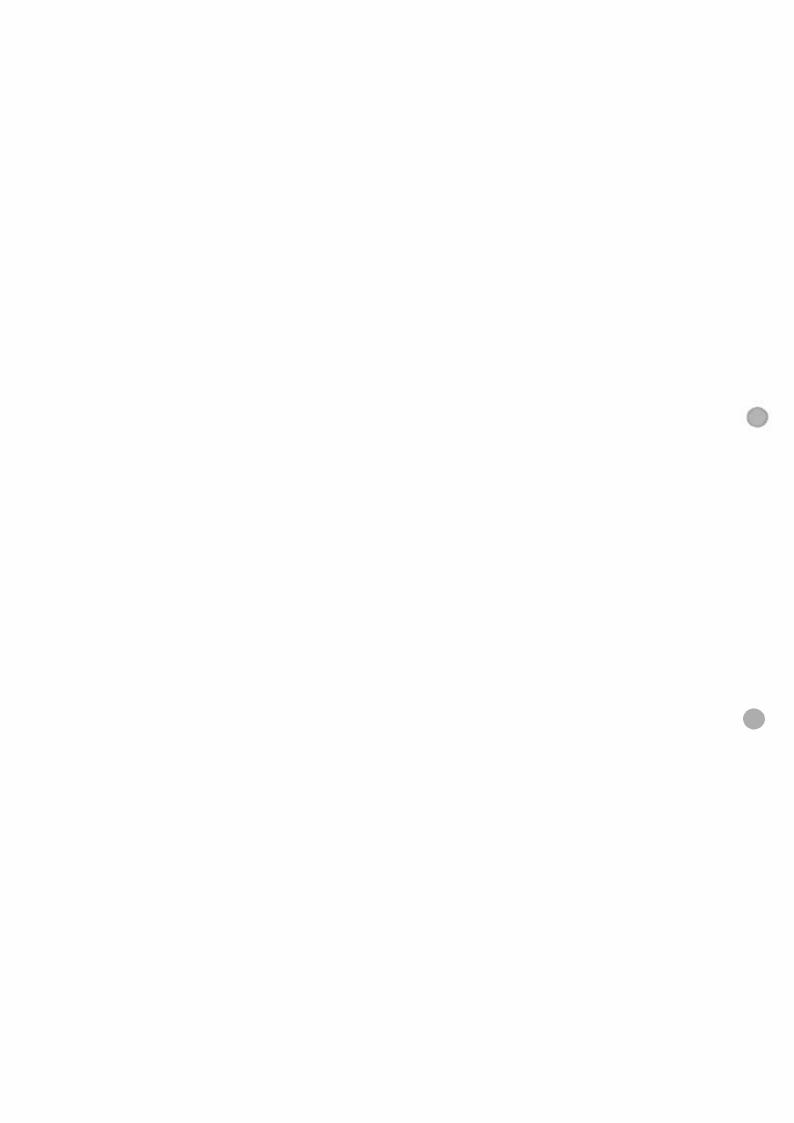


JOINT MEETING OF THE PROJECT TEAMS (FOLLOW-UP WORK ON GLYPHOSATE)

08 FEBRUARY 2016, 09:00-10:00

AGENDA

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4.	Bilateral meeting (EFSA/IARC) in Brussels in February 2016 – state of play and rev presentations a) Final agenda b) presentations	view
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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: (EFSA) 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 (the scientific secretariat will collect the point raised during the discussion)
10.00-11.00	Glyphosate: focus on experimental data on carcinogenicity	(EFSA)
11.00-11.15	Coffee/Tea break	
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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 (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 (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	and the analysis and the state of the analysis and the an		
Reviewed by	**************************************		
Last date modified	29 January 2016		

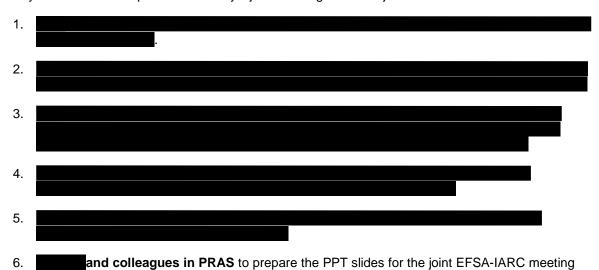
List of participants:

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(IARC)
(IARC)
(IARC)
(EFSA)
(EFSA)
(EFSA)
(EFSA)
(EFSA)
i (EFSA) - Scientific Secretariat
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2_PAD 2016/027 Internal discussions IARC findings_Vincent Harmsen EFSA internal emails

Dear Colleagues,

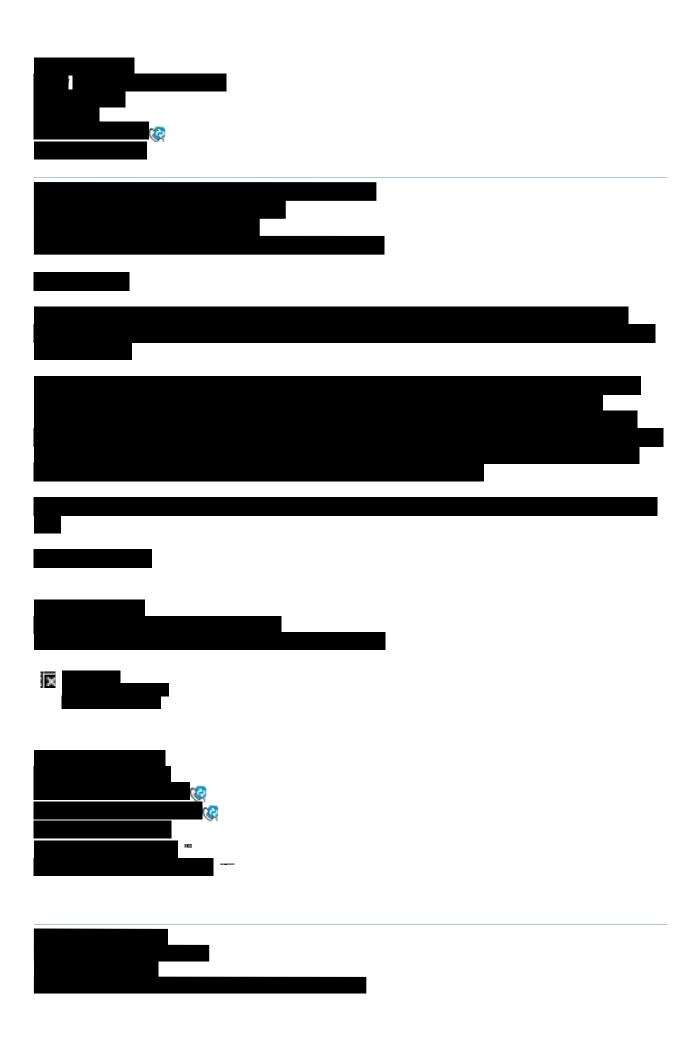
Below you find the action points from today's joint meeting of the Project Teams:

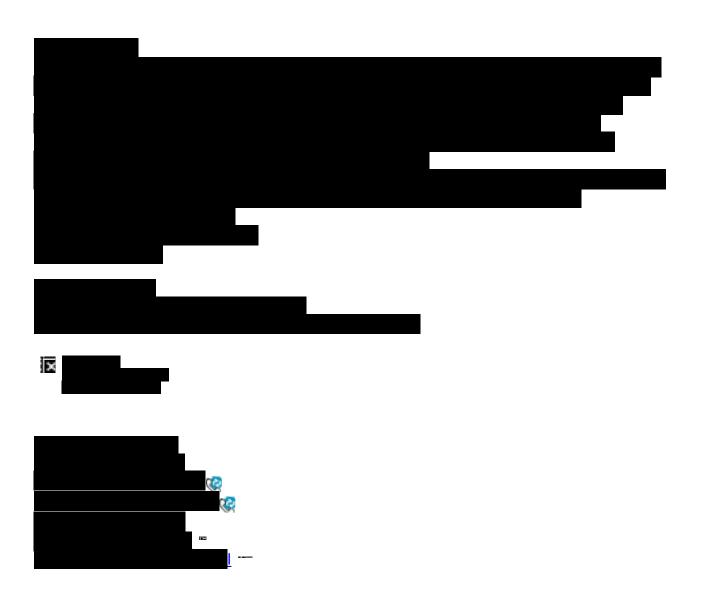


Kind regards,

(deadline: 5 February 2016).

Archived: 07 June 2016 14:22:30
From: Sent: 05 February 2016 16:17:01
To:
Cc: PMO.glyphosate;;;;; Subject: FW: EFSA / IARC meeting in Feb - communications
Response requested: No
Importance: Normal
Hi Hi
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 also if he's able to via phone or Facetime). It seems to me that we should be escalating this to seems to ensure at least the minimum level of alignment with IARC before the meeting.
Best,





Archived: 07 June 2016 14:24:51

From:

Sent: 09 February 2016 08:51:43

To: ;

Cc: PMO.glyphosate Subject: IARC Letter Importance: Normal

Attachments:

Draft response to version 3_ 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,

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 – It strongly believe that there is value in going ahead with the planned meeting

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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 <u>32</u>
Prepared by	
Reviewed by	
Last date modified	08/02/2016

Dear ,

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,

From:

Sent: 09 February 2016 08:52

To: ______; _____;

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). Besides that fine with me.

Best regards,

20001050

Sent from Outlook Mobile

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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.

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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 ofin 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

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

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Yours sincerely,

Bernhard Url

Document history	
Document reference	Version <u>3</u> 2 <u>comments</u>
Prepared by	
Reviewed by	
Last date modified	08 09/02/2016

Archived: 07 June 2016 14:29:59

From:

Sent: 09 February 2016 10:05:17

To: e;

Cc: PMO.glyphosate Subject: RE: IARC Letter Importance: Normal

Attachments:

Draft response to Chris Wild version 4.docx;

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,

From:

Sent: 09 February 2016 09:26

To: _____; ____; _____;

Cc: PMO.glyphosate **Subject:** RE: IARC Letter

Dear

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To: ______; _____;

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Yours sincerely,

Bernhard Url

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Document history	
Document reference	Version <u>3</u>2 <u>comments4</u>
Prepared by	,
Reviewed by	r
Last date modified	08 <u>09</u> /02/2016

Archived: 07 June 2016 14:36:58

From:

Sent: 12 February 2016 13:55:55

Cc: PMO.glyphosate;

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. could you please double check those highlighted in yellow? I will try to produce an equivalent one for the in vivo mammalian genotox. Thanks,

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	Study type	Dose levels	critical effect at the LOAEL	
Purity (%)	descriptions by notifier	(NOAEL/LOAEL)		
(IARC reference)	(SD) and RMS (RAR)	mg/kg bw per day		
Mice lo	ng-term chronic toxicity	and carcinogenicity	studies used in the EU evaluation	
TOX9552381,	2 yr, CD-1 carcino/	0, 157, 814, 4841	Males: Body weight reduction, hepatocellular	
1983, 99.7%	chron	(157/814)	centrilobular hypertrophy and bladder	
(IARC: EPA	Described in the		epithelial hyperplasia	
1985a,b, 1986,	previous EU evaluation			
1991a)	USEPA and IARC			
TOX9552382,	2 yr, CD-1, carcino	0, 100, 300, 1000	Equivocal enlarged/firm thymus, not	
1993, 98.6%	Described in the	(1000/>1000)	associated with histopathological findings	
(IARC: JMPR	previous EU evaluation		(considered not biologically relevant)	
2006)	JMPR and IARC	0 450 707 4446	Deduccient rain reduction food core 9 office	
IIA, 5.5.3/03 ASB2012-11493,	18 mo , CD-1 (ICR), OECD 451	0, 153, 787, 4116 (153/787)	Body weight gain, reduction food cons & effic, loose stool, caecum distended and increased	
1997,	SD pp 516-525	(153/767)	weight, prolapse and anus ulceration	
97.56/94.61%	RAR pp 1030-1040		weight, prolapse and ands diceration	
IIA, 5.5.3/02	18 mo, CD-1 (ICR),	0, 71, 234, 810	No effect observed	
ASB2012-11492,	OECD 451	(810/>810)	TWO CHOOL OBSERVED	
2009, 95.7%	SD pp 511-516	(0.10)		
	RAR pp 1023-1030			
Rat Ior	Rat long-term chronic toxicity and carcinogenicity studies used in the EU evaluation			
IIA, 5.5.2/05	26mo, SD rat,	0, 3, 10.3, 31.5	No effects observed*	
TOX2000-595,	combined	(31.5/>31.5)		
1981, 98.7%	No GLP			
(IARC: EPA	SD pp 479-485			
1991a,b.c.d)	RAR pp 987-993			
IIA, 5.5.2/06	2yr, SD rat, combined	0, 89, 362, 940	Reduction body weight and gain, increase	
TOX9300244,	USEPA F 83-5	(89/362)	liver weight, stomach mucosal inflammation,	
1990, 96.5%	SD pp 485-491		cataracts, decrease urine pH, survival <50%	
(IARC: EPA 1991a,b.c.d)	RAR pp 993-999		in all groups incl. controls	
IIA, 5.5.2/04	2yr, SD rat, combined	0, 10, 100, 300,	Pronounced salivary gland findings, increase	
TOX9750499,	USEPA F 83-5	1000	AP and liver weight	
1993, 98.9% &	SD pp 471-478	(100/300)	7. G.I.G. II VOI WOIGHT	
98.7%	RAR pp 999-1007	(.55/555)		
(IARC:JMPR,2006)				
IIA, 5.5.2/01	2yr, Wistar rat,	0, 6.3, 59.4, 595.2	Cataracts, increase AP	
TOX9651587,	combined	(60/595.2)		
1996, 96.8/96.0%	OECD GD 453			
	SD pp 451-456			
	RAR 1007-1013			
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 SD pp 447- 451 RAR pp 955-960	(141/560)	utilization, increase AP, focal basophilia of acinar cells of parotid salivary gland (not weighed)
IIA, 5.5.2/02 ASB2012-11484, 1997, 97.56/ 94.61%	2yr, SD rat, combined OECD GD 453 SD pp 457-463 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, 5.5.2/03 ASB2012-11488, 2001, 97.6% (IARC: JMPR,2006)	2yr, Wistar rat, combined OECD GD 453 SD pp 463-471 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, 5.5.2/08 ASB2012-11490, 2009, 95,7%	2yr, Wistar rat, combined OECD GD 453 SD pp 496-502 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)
	ustry sponsored studies		d during the EU assessments
IIA, 5.5.3/01 ASB2012-11491*, 2001, >95.14%	18 mo, Swiss albino, OECD 451 SD pp 504-511 RAR pp 1013-1023	Title: Carcinogenicity Albino Mice	y Study with Glyphosate Technical in Swiss
IIA, 5.5.2/07 ASB2012-11489 1997	2yr SD rat, combined OECD GD 453 SD pp 491-496 RAR pp 967-972	Title: Combined Chronic Toxicity/Carcinogenicity Study of Glyphosate Technical in Sprague Dawley Rat	