Overal 10.2.e

Doc. 1

From: omics_workshop
To: [redacted]@rivm.nl
Cc: [redacted]
Subject: 3rd ECETOC Workshop on 'Omics and Risk Assessment Science
Date: 01-02-2013 18:31
Attachments: Hotel AC Palacio Booking Form.docx
Draft Programme 1-Feb-13.docx

ECETOC

EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS AISBL

1st February 2013

3rd ECETOC Workshop on 'Omics and Risk Assessment Science
25-26 February 2013, Málaga (Spain)

Dear [redacted],

Thank you for agreeing to present at the third ECETOC workshop on 'Omics and Risk Assessment Science to be held at Hotel AC Málaga Palacio, Málaga, Spain on 25 and 26 February 2013. The workshop will start at 12:00 on day 1 and finish at 14:00 on day 2.

I would also like to invite you to chair the ***plenary session – Syndicate reports and discussion*** at the end of day 2 (see attached the latest draft of the programme) and would be grateful if you could give me your answer by next Wednesday.

Regarding your presentation in *section 3: Dose response characterization with the 'OMICS technologies:* with the title ***Dose and time genomic responses to reproductive toxicants,*** could you please structure your talk in such a way that it introduces the participants to the relevant issues that should be discussed by the groups in the syndicate sessions.

Would you please be so kind as to send the following:

- An abstract of your presentation for the workshop booklet, by 13th February.
- A short resume, or your CV, also for the booklet, by 13th February.
- An electronic copy of your presentation by 18th February.

(A PC linked to an LCD projector will be available to support your presentation.)

By the way, you are most welcome to download the reports from the first two workshops without charge from the following links:
Workshop Report No. 11: The Application of 'Omics in Toxicology and Ecotoxicology: Case Studies and Risk Assessment 6-7 December 2007, Malaga (Published July 2008)
Workshop Report No. 19: 'Omics in (Eco)toxicology: Case Studies and Risk Assessment 22-23 February 2010, Málaga (Published June 2010)

If there are any questions, please contact myself or [redacted] (omics_workshop@ecetoc.org).

Overal
10.2.e

Doc. 2

From:
To: @imperial.ac.uk; @toxi.uni-wuerzburg.de; @basf.com; p@pharmacy.ac.uk; @biobase.dk; @syngenta.com; @rivm.nl; @hrsu.mrc.ac.uk; @niehs.nih.gov; @epa.gov; @bayer.com
Cc:
Subject: Expert panel to better understand ED low doses - April 22nd and 23rd, 2013
Date: 12-02-2013 18:21
For Follow Up: Normal Priority.
Attachments: image001.png

Dear Colleague,

Many thanks for providing your availabilities for the planned ECETOC workshop organised at the Condes Hotel, Paseo de Gracia, in Barcelona. The common date that suited nearly everybody **is 22nd/23rd April** and we have thus decided to hold the meeting then.

Dear Dear

We did our utmost to find a suitable date to enable everyone to attend in person. As this will unfortunately not be possible for you, we would like to suggest (if at all possible) that you participate at least to part of the meeting by video link (Skype). We hope that you will be able to participate in person to future face to face meetings of this panel.

We will send more details on how to book your accommodation in the next few days.

Thank you again and I am looking forwards to meeting you in Barcelona.

Best wishes,

[redacted]

[redacted]

ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals)
Avenue E. Van Nieuwenhuyse Building 2, 3rd Floor, Bte 8
B-1160 Brussels
Tel +32 2 - [redacted]

Fax +32 2 - [redacted]

E-mail: [redacted]@ecetoc.org

www.ecetoc.org

[IMAGE]

EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS AISBL

As you are aware, there is currently much debate, uncertainty and concern around endocrine active chemicals in the environment and effects that may be seen at low doses

and the potential for non-monotonic dose responses. We would like to invite you as an acknowledged expert in the field to be part of an Independent Scientific Advisory Board. The group will comprise up to 19 members with representation from academia, regulatory authorities and industry. The purpose of this group would be to design and oversee the conduct and interpretation of a definitive programme of experimental work to address the hypotheses that:

ü Endocrine active chemicals do not have a threshold below which adverse effects are seen and should be regarded and tested in a different way to chemicals acting through other modes of action.

ü At low dose/exposure levels, endocrine active chemicals exhibit non monotonic dose responses.

ü When mixed at low doses, endocrine active chemicals produce effects greater than those which may be predicted from simple dose addition.

As an initial step, we would like to hold a meeting/workshop to agree on the concepts of the programme of work and how it could be best designed, conducted and managed to ensure that the outcome is both scientifically valid, and would be accepted as unbiased and as a significant scientific contribution to the field. The date and venue of the proposed meeting is 13th-15th February 2013 at Hotel Condes de Barcelona, Barcelona, Spain. The intention of this meeting is to share some initial thoughts in order to start the process. Funding options will also be explored.

We would be grateful if you would consider this request and would ask you respond indicating if you would be able to participate; if not, please could you indicate who from your organisation or sector might be a suitable alternative participant. Should you require it, ECETOC is able to cover the costs of travel and accommodation for this first meeting.

Yours sincerely

ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals)

Avenue E. Van Nieuwenhuyse Building 2, 3rd Floor, Bte 8

B - 1160 Brussels

Tel: +32 2 -

Fax: +32 2 -

E-mail: @ecetoc.org

www.ecetoc.org

Overal 10.2.e

Doc. 3

From: [redacted]
To: [redacted]@bayer.com; [redacted]@imperial.ac.uk; [redacted]@toxi.uni-wuerzburg.de; [redacted]@basf.com; [redacted]@brunel.ac.uk; [redacted]@biobase.dk; [redacted]@syngenta.com; [redacted]@[redacted].freeserve.co.uk; [redacted]@rivm.nl; [redacted]@hrsu.mrc.ac.uk
Cc: [redacted]@niehs.nih.gov; [redacted]@epa.gov; [redacted]
Subject: Expert panel to better understand ED low doses - Barcelona, April 22nd and 23rd, 2013
Date: 01-03-2013 11:41
For Follow Up: Normal Priority.
Attachments: image001.png

Dear Colleague,

Thank you for accepting to be part of the above mentioned 2-day workshop to be held at Hotel Condes, Barcelona (Spain) on the 22nd and 23rd April 2013. The workshop will start at 12:30 on day 1 to allow for you to travel comfortably.

You are kindly invited to book your accommodation directly with the workshop hotel at: https://booking.ihotelier.com/istay/istay.jsp?hotelid=4791#CORP. To make your booking please select CORPORATE RATES and enter the code 'ECETOC'. The deadline for booking the rooms at the ECETOC corporate rate is 2nd of April.

A provisional programme will be forwarded to you shortly.

A video link will be set up for [redacted] and [redacted]. More details on this will be sent to both of you nearer to the date.

Kind regards,

[redacted]

Assistant to [redacted]

[redacted]

ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals)
2 avenue E. Van Nieuwenhuyse
B-1160 Brussels

Doc. 3

Tel +32 2 -

Fax +32 2 -

E-mail: @ecetoc.org

www.ecetoc.org

From: [mailto: @ecetoc.org]
Sent: 18 February 2013 18:24
To:
Cc:
Subject: Fxpert panel to better understand ED low doses -Barcelona, April 22nd and 23rd, 2013
Importance: High

cid:image001.png@01CE1056.04141560

EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS AISBL

Dear Colleague,

As you are aware, there is currently much debate, uncertainty and concern around endocrine active chemicals in the environment and effects that may be seen at low doses and the potential for non-monotonic dose responses. We would like to invite you as an acknowledged expert in the field to be part of an Independent Scientific Advisory Board with the role of moderator/ facilitator in these discussions. The group will comprise up to 19 members with representation from academia, regulatory authorities and industry, from Europe and the US. The purpose of this group would be to design and oversee the conduct and interpretation of a definitive programme of experimental work to address the hypotheses that:

ü Endocrine active chemicals do not have a threshold below which adverse effects are seen and should be regarded and tested in a different way to chemicals acting through other modes of action.

ü At low dose/exposure levels, endocrine active chemicals exhibit non monotonic dose responses.

ü When mixed at low doses, endocrine active chemicals produce effects greater than those which may be predicted from simple dose addition.

As an initial step, we would like to hold a meeting/workshop to agree on the concepts of the programme of work and how it could be best designed, conducted and managed to ensure that the outcome is both scientifically valid, and would be accepted as unbiased and as a significant scientific contribution to the field. The date and venue of the proposed meeting is 22nd/23rd April 2013 at Hotel Condes de Barcelona, Barcelona, Spain. The intention of this meeting is to share some initial thoughts in order to start the process. Funding options will also be explored.

We would be grateful if you would consider this request and would ask you respond indicating if you would be able to take the role as a moderator/ facilitator in this meeting. Should you require it, ECETOC is able to cover the costs of travel and accommodation.

I will be happy to discuss this further in a telephone call and provide you with some more details. Please let me know. I will be available to call you on Wednesday 20th Feb.

Yours sincerely,

[redacted]

[redacted]

[redacted]

ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals)

Avenue E. Van Nieuwenhuyse Building 2, 3rd Floor, Bte 8

B - 1160 Brussels

Tel: +32 2 - [redacted]

Fax: +32 2 - [redacted]

E-mail: [redacted]@ecetoc.org

www.ecetoc.org

Doc. 4

Overal 10.2.e

From: [redacted]
To: [redacted]@epa.gov); [redacted]@epa.gov); [redacted]@mcmaster.ca); [redacted]s@creighton.edu; [redacted]@exponent.com); [redacted]@rivm.nl); [redacted]@sciences.com)
Subject: Attending Teratology Society Annual Meeting?
Date: 17-04-2013 16:06

HESI DART Scientific Advisors –

It was a pleasure meeting those of you who could make it to the Spring meeting in DC. The DART leadership and I have been discussing ways to better engage you in your "formal" roles as scientific advisors to help shape the growth and development of the committee in a strategic and impactful way to the field. To that end, we would like to hold an informal dinner at the Teratology Society Annual Meeting in June for those of you who will be in attendance.

Please respond to this email and let me know:

1. Will you be attending the TS meeting?
2. Preferred/available date for dinner : *Saturday, Monday, and/or Tuesday*

Thank you again for your contributions to this committee.

Kind regards,

[redacted]

[redacted]

[redacted]

ILSI Health and Environmental Sciences Institute (HESI)
1156 15th St NW, Suite 200
Washington, DC 20005
Office: 202-659-3306 x131
Mobile: 2[redacted]
[redacted]@hesiglobal.org
www.hesiglobal.org

Doc. 5

Overal 10.2.e

From: [redacted]
To: [redacted]@bayer.com; [redacted]; [redacted]@imperial.ac.uk; [redacted]@toxi.uni-wuerzburg.de; [redacted]@basf.com; [redacted]@niehs.nih.gov; [redacted]@epa.gov; [redacted]@nihs.go.jp; [redacted]@brunel.ac.uk; [redacted]@gmail.com; [redacted]@syngenta.com; [redacted]r@[redacted].freeserve.co.uk; [redacted]@ivz-rs.si; [redacted]@yahoo.co.uk; [redacted]@rivm.nl; [redacted]@ed.ac.uk
Cc: [redacted]
Subject: Expert panel to better understand Endocrine Disruptor Low Doses Effects - Barcelona 22-23rd April 2013
Date: 18-04-2013 14:48
Attachments: DIRECTIONS TO HOTEL CONDES.docx
Reimbursement Form.docx
Reimbursement procedure.docx
Draft Programme Low Doses (6).docx

Dear workshop Participant,

Thank you for taking part in the 'Expert panel to better understand Endocrine Disrupter Low Doses Effects'. We would like to take this opportunity to give you some additional information about the arrangements for the meeting.

Attached please find:

- Directions to Hotel Condes
- Reimbursement Form & Procedures
- The Draft Programme

The meeting will be held at Hotel Condes, Passeig de Gràcia, 73-75, 08008 Barcelona and will start with a tapas lunch on the terrace of the 'PICASSO' meeting room at 12:15 hours. The meeting will end at around 17:00 hours on the 23rd of April. If you need to leave earlier please let us know.

Your presentations will be uploaded to the main PC during lunchtime, so please have your USB sticks handy.

The dinner will take place the evening of the 22nd of April at 20:00 hours, at Restaurant 'El Cangrejo Loco', Moll de Gregal 29-30 (Port Olimpic), 08005 Barcelona. Your choice of the main course has already been forwarded to the restaurant. [redacted] has the instructions on how to get there, so don't lose her out of your sight!
www.elcangrejoloco.com/

If you have any further questions, please do not hesitate to contact me.

Warm regards,

[redacted]
Assistant to [redacted]

[redacted]
ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals)
2 avenue E. Van Nieuwenhuyse
B-1160 Brussels
Tel +32 2 - [redacted]
Fax +32 2 - [redacted]
E-mail: [redacted]@ecetoc.org
www.ecetoc.org

REIMBURSEMENT PROCEDURE

For **non-industry** participants, the following procedure will apply for all your expenses:

- The cost of the hotel room and meals will be covered by ECETOC.
- Travel costs (if not already paid for by ECETOC) will be transferred to your bank account after the meeting. Please complete the enclosed Request for Reimbursement form, attach all receipts for expenses and travel tickets and send to Geneviève Gérits, Av. E. Van Nieuwenhuyse, bldg. 2, Box 8, B-1160 Brussels, Belgium.
- The following charges will not be covered: double room supplement, bar, minibar, laundry services, telephone calls and faxes, supplementary nights not requested for your participation in the meeting.

We wish you a very pleasant stay in Málaga and a most productive meeting.

Doc. 5.3

REQUEST FOR REIMBURSEMENT

Workshop on 'Expert panel to better understand ED low doses'

Barcelona 22nd–23rd April 2013

Please complete in block letters and return by mail to:
ECETOC
Geneviève Gérits
2 avenue E. Van Nieuwenhuyse
1160 Brussels
Belgium

EXPENSES

Name of claimant: _____

Address of claimant: _____

_____

Total amount to be reimbursed: _____

Please attach original invoices and/or receipts

BANK COORDINATES

Name of bank: _____

Name of account holder: _____

Bank Address: _____

_____

Account No: _____

IBAN No: _____

BIC (Swift) No: _____

Date: _____ Signature: _____

Doc. 6

Overal 10.2.e

From:
To:
Subject: Re: Betr: ED paper
Date: 08-05-2013 12:23

Dear all, turned into a very nice piece of work. What are now the next steps ?

Best regards.

Am 07.05.13 11:41, schrieb :

,

Very nice work, my compliments, we are close to final as far as I am concerned. I have scrutinized the paper in detail and edited text without affecting the main line, and added some additional suggestions in various places. Please see attached for details.

Kind regards to all,

National Institute for Public Health and the Environment RIVM
Antonie van Leeuwenhoeklaan 9
P.O.Box 1
3720 BA Bilthoven
The Netherlands
phone +31 30
fax +31 30 274 4446
email @rivm.nl

----- @iss.it> schreef: -----
Aan: @unimi.it>, @toxi.uni-wuerzburg.de>, @rivm.nl>, @unimi.it" @unimi.it>, @ed.ac.uk>
Van: @iss.it>
Datum: 6-5-2013 09:48
Onderwerp: ED paper

Dear all,

Thanks for sending me your comments and proposed for changes. I have tried to do my best to address all the comments I have received in the version of the ED paper you can find attached. There are still few comments from my side, specifically directed to some of you asking for clarification and/or references (if needed). Can you please have a look to this 'almost final' version and give me a feedback ASAP?

I have given to the document the format of a paper by proposing a title (please feel free to change it), indicating the Authors' names (please complete your affiliation) and inserting a list of references, in view of the publication on Toxicology Research, as proposed by . On this respect, we have received no negative comment on this. Do you all agree to go ahead with this proposal? If

yes, I do not know the editorial requests of the journal, that would imply some editorial changes. Can you check? An additional point : the figure it is in now is directly taken from the UK-DE position paper, without modification. I guess we cannot use It , unless we ask for permission. It is not strictly necessary, so we can also decide to delete it. What is your idea?

Thanks a lot for your cooperation and see you soon

Istituto Superiore di Sanità
Environment & Primary Prevention Dept.
Mechanisms of Toxicity Unit
Viale Regina Elena, 299
00161 Roma (Italy)
Tel. +39 06
Fax +39 06
E-mail: @iss.it

Da: @me.com]
Inviato: venerdì 22 marzo 2013 17:44
A:
Cc:
Oggetto: Fwd: SOT San Antonio - thank you! Greetings from Cambridge, and follow-up on the regulatory review

FYI

--

European Registered Toxicologist (ERT)
Lab. Toxicology
Department of Pharmacological and Biotechnological Sciences
Via Balzaretti, 9 20133
University of Milan
Milan Italy

Doc. 6

tel +39 (0)

@unimi.it
@me.com

Inizio messaggio inoltrato:

Da: "TOXRES-RSC (Shared): Journal Toxicology Research" <toxres-rsc@rsc.org>

Oggetto: RE: SOT San Antonio - thank you! Greetings from Cambridge, and follow-up on the regulatory review

Data: 22 marzo 2013 14:49:27 CET

A: 'Laboratorio Tossicologia' <trisk@unimi.it>

Cc: @unimi.it>

Dear

Thank you very much for these news ☺ ☺ yes, that will be perfect if you're able to send a draft of the position paper to when ready.

We will be starting an internal news bulletin for the Advisory Board, so that everyone is kept up-to-date with the latest development on *Toxicology Research*.

In the meantime, do not hesitate to:

Sign-up for the journal☺ ☺s e-alert

Register to receive the Newsletter

Follow us on Twitter (@ToxRes)

Doc. 6

We'll be in touch shortly in any case.

With best wishes,

[redacted]

[redacted]

Deputy Editor

Organic & Biomolecular Chemistry, MedChemComm, Natural Product Reports and Toxicology Research

Royal Society of Chemistry, Thomas Graham House,
Science Park, Cambridge, CB4 0WF, UK

Tel: +44 ([redacted] Fax: +44 (0)[redacted]

Toxicology Research: A new, multi-disciplinary journal covering the best research in both fundamental and applied aspects of toxicology

From: Laboratorio Tossicologia [mailto:trisk@unimi.it]
Sent: 21 March 2013 13:33
To: TOXRES-RSC (Shared): Journal Toxicology Research; [redacted]
Cc: [redacted]
Subject: R: SOT San Antonio - thank you! Greetings from Cambridge, and follow-up on the regulatory review

Dear [redacted]

I was very pleased about the outcome of our meeting last week and thank you for taking the time to share with me more in detail the journal's vision and key features. I look forward to receiving a sample copy of the journal in the upcoming weeks. Just today I spoke with several of the authors of the position paper on endocrine disrupting chemicals and was about to send [redacted] a note asking him if our paper could be of interest to your readers. I hope to get their approval to publish the paper Toxicology Research next week.

Unfortunately I don't have an abstract at the time, but as I told you the Italian Toxicology Society (SITOX) specifically commissioned the paper to help clarify the difference between the endocrine disruptors and endocrine active substances. The authors of the paper are [redacted] to be confirmed) and myself. The final draft is should be ready in early April

and if you agree, I could send it to [redacted] to get his thoughts and opinion about its publication in the next issue of Toxicology Research.

Thanks again and I'll be in touch.

Cordially

[redacted]

--

[redacted]
European Registered Toxicologist (ERT)
Lab. Toxicology
Department of Pharmacological and Biotechnological Sciences
Via Balzaretti, 9 20133
University of Milan
Milan Italy

tel +39 (0)[redacted]

[redacted]@unimi.it
[redacted]@me.com

Inizio messaggio inoltrato:

Da: "TOXRES-RSC (Shared): Journal Toxicology Research" <toxres-rsc@rsc.org>

Oggetto: SOT San Antonio - thank you! Greetings from Cambridge, and follow-up on the regulatory review

Data: 21 marzo 2013 11:43:11 CET

Doc. 6

A: [redacted]@me.com>

Dear [redacted]

It was a pleasure to meet you at SOT last week, and I hope that all is well back in Italy.

This is just a quick note to say that a print copy of the journal has just been sent via the post for you – you should receive it shortly, but please do let me know if this wasn't the case.

I chatted to [redacted] about the Viewpoint style review article you mentioned, covering regulatory issues, he felt that would make a very worthwhile addition to the journal, for the benefit be of the readership – we should take this further – please let me know your thoughts! I can circulate a short abstract to the Editorial Board if you have one at hand at all?

With very best wishes,

[redacted]

[redacted]

Deputy Editor, *Toxicology Research*

Royal Society of Chemistry, Thomas Graham House,
Science Park, Cambridge, CB4 0WF, UK

Tel: +44 ([redacted] Fax: +44 ([redacted]

DISCLAIMER:

This communication (including any attachments) is intended for the use of the addressee only and may contain confidential, privileged or copyright material. It may not be relied upon or disclosed to any other person without the consent of the RSC. If you have received it in error, please contact us immediately. Any advice given by the RSC has been carefully formulated but is necessarily based on the information available, and the RSC cannot be held responsible for accuracy or completeness. In this respect, the RSC owes no duty of care and shall not be liable for any resulting damage or loss. The RSC acknowledges that a

Overal 10.2.e

Doc. 7

From: [redacted]
To: [redacted]@unimi.it
Cc: [redacted]
Subject: Re: ED paper
Date: 13-05-2013 12:59
For Follow Up: Normal Priority.
Attachments: image001.gif
ED Sitox Document 13-05-RMS.doc

Dear All

Please find my further suggested changes/additions to the revised document. In my opinion, it is now a reasonably cohesive and sensibly argued position paper, that does not come across as being selective or unduly biased. Indeed, it is brimming with common sense! I also added in a few head ins within the text to break it up a bit into sections, but feel free to amend or add further. I also suggested another title.

Best wishes

[redacted]

From: [redacted]
Date: [redacted]
[redacted]
Cc: [redacted]
Subject: ED paper

Dear [redacted],
I hav[redacted]tion from [redacted]. Since we are quite close to an end, I hope you will be [redacted]mments in the next few days.
Just in case we will see no answer, [redacted] will try to contact you during next week, since I will be in Kosovo.
[redacted]ce week end

[redacted]

[redacted]

Istituto Superiore di Sanità
Environment & Primary Prevention Dept.
Mechanisms of Toxicity Unit
Viale Regina Elena, 299
00161 Roma (I
Tel. +39 06 4[redacted]
Fax +39
E-mail: [redacted]@iss.it<mailto:[redacted]@iss.it>

[cid:image001.gif@01CE4DAC.F1326B10]Rispetta l'ambiente. Non stampare questa mail se non è necessario
PPlease consider your environmental responsibility before printing this e-mail

Da: [redacted]
Inviato: martedì 7 maggio 2013 11:41

Dubbel met doc. 6

[redacted]

Doc. 8

Overal 10.2.e

From: [redacted]
To: [redacted]@hrsu.mrc.ac.uk; [redacted]@unimi.it; [redacted]i
Subject: Fw: [Spam] Position paper on endocrine disrupters by the Italian Society of Toxicology Task Force
Date: 14-06-2013 16:39
Attachments: ED-PositionPaper-SITOX.pdf

Dear collegues,

I think the point made by [redacted] needs to be checked. I cannot remember there was a sentence to this effect in our report, if this is correct, then the line quoted by [redacted], mentioned in the SITOX news item should be deleted. [redacted], could one of you take this on?

Best,
[redacted]

[redacted]
Laboratory for Health Protection Research
National Institute for Public Health and the Environment RIVM
Antonie van Leeuwenhoeklaan 9
P.O.Box 1
3720 BA Bilthoven
The Netherlands
phone +31 30 [redacted]
fax +31 30 274 4446
email [redacted]@rivm.nl

-----Doorgestuurd door [redacted]/RIVM/NL op 14-6-2013 16:32 -----
Aan: [redacted]@rivm.nl>, [redacted]@toxi.uni-wuerzburg.de" [redacted]t@toxi.uni-wuerzburg.de>, [redacted]@hrsu.mrc.ac.uk" <[redacted]@hrsu.mrc.ac.uk>
Van: [redacted]@brunel.ac.uk>
Datum: 14-6-2013 13:33
cc: [redacted]
Onderwerp: [Spam] Position paper on endocrine disrupters by the Italian Society of Toxicology Task Force

(Zie bijlage: ED-PositionPaper-SITOX.pdf)

Dear [redacted],

It was good to interact with you on the occasion of the recent ECETOC workshop in Barcelona.

It has come to my attention that you authored a position paper on endocrine disrupters by the Italian Society of Toxicology. This is published on their website (see attachment).

With reference to the State of the Art Assessment on Endocrine Disrupters which we prepared for the European Commission, the material published on the website reads:

"The document has aroused more than a concern in the scientific community both for the scientific and methodological aspects, also in anticipation of an application in the regulatory field. For example, previous documents generated by regulatory bodies such as WHO of some

significance have not been taken into due consideration in the document [redacted]."

I am surprised that such a statement is attributed to you. Even after a cursory reading of our report it should have become clear the we used the WHO 2002 document as the starting point for our effort (this was stipulated by the Europ Commission). Our report made explicit reference to the WHO 2002 report, followed their general lay-out and even contained sections detailing the scientific progress made since the WHO 2002 report.

I do realise that the topic of endocrine disruption currently gives rises to many misunderstandings and controversies (although I find that your position, as detailed on the SITOX website is not miles away from ours). As you know, I am always eager to deal with differences in opinion by open debate. However, that debate has to be conducted fairly and on the basis of material that is factually correct.

I would be grateful if you could comment on the criticism of our report that is attributed to you.

It may be that someone has summarised your report, and that you indeed have not written the above paragraph. In that case, would you be so kind as to impress on the Italian Society of Toxicology to remove this factually incorrect material?

Kind regards

[redacted]

[redacted]

Institute for the Environment

Brunel University

Kingston Lane

Uxbridge UB8 3PH

Tel 0044 [redacted]

Email [redacted]@brunel.ac.uk

Overal
10.2.e

Doc. 9

From:
To: @sanofi-aventis.com); @cbg-meb.nl; @exxonmobil.com); @bms.com); @abbott.com); [PRDBE]; @pfizer.com); @gsk.com; @crl.com); @Merck.com); @gsk.com; @astrazeneca.com);
Cc:
Subject: DART Second Species - Rescheduled TC & Side F2F Meeting
Date: 22-07-2013 20:18

To the DART Second Species workstream,

By now you should have received an invite from , rescheduling tomorrow's teleconference for next week. Hopefully most of you will be able to call-in next **Tuesday 31 July from 10-11:30 (Eastern)**. will be presenting some in depth case studies. Slides will be forwarded in advance of the call.

Also, you should have received a second invite regarding a **½ day side meeting**. Please tentatively hold **Wed 25 September** afternoon prior the DART Fall F2F meeting. The date/time of the side meeting will be finalized on next week's call (Fri 27 September morning is also an option).

Don't hesitate to contact me or if you have any questions or concerns.

Many thanks,

202-659-3306 x131
@hesiglobal.org

-----Original Appointment-----
From:
Sent: Friday, June 28, 2013 1:02 PM
To: @sanofi-aventis.com); @cbg-meb.nl; @exxonmobil.com); @bms.com); @abbott.com); [PRDBE]; @pfizer.com); @gsk.com; @crl.com); @Merck.com); @gsk.com; @astrazeneca.com);
Cc:
Subject: DART Second Species TC
When: Wednesday, July 31, 2013 10:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where:

Doc. 9

Dear DART Second Species workstream,

This teleconference **has been rescheduled** for Wednesday, August 31 at 10 am Eastern US time. Connection details are below.

Best,
[redacted]

DIAL-IN INFORMATION
Access code: 2000523

Country	Dial-In #
US	888-706-6468
Belgium	0800-7-6926
Australia	1-800-21-2361
Canada	888-706-6468
Denmark	80-885302
France	0800-91-3424
Germany	0800-182-9571
Italy	800-789555
Japan	0-3-32984452
Netherlands	0800-022-7141
Norway	800-14350
Spain	900-98-1198
Sweden	020-79-1395
Switzerland	0800-83-6214
United Kingdom	0808-234-3676

If you have problems dialing-in or need additional country dial-in numbers, please visit:
https://www.teleconference.att.com/servlet/glbAccess?process=1&accessCode=5654699&accessNumber=8887066468

Overal 10.2.e

Doc. 10

From:
To:

@fda.hhs.gov); @crl.com);
@rivm.nl); @sciences.com);
@covance.com); @uwo.ca; @abbvie.com);
r@fda.hhs.gov); @abbvie.com);
@sanofi.com); s@astrazeneca.com);
@altamira-llc.com); @pfizer.com);
@fda.hhs.gov); @sanofi.com;
@novartis.com); lilly.com);
@lilly.com); @scj.com);
@gsk.com); @dow.com);
@u.washington.edu); @crl.com);
i@covance.com); @pg.com);
@covance.com); @amgen.com);
@pfizer.com); novartis.com);
@nuhs.edu.sg); @interchange.ubc.ca);
@astrazeneca.com); @creighton.edu;
@astrazeneca.com); @boehringer-ingelheim.com);
@exxonmobil.com);
@mhra.gsi.gov.uk); @bms.com);
@its.jnj.com); @epa.gov); @celgene.com);
@gsk.com); @cbg-meb.nl;
@fagg.be); @mpa.se);
@bms.com); @abbott.com);
r@rti.org); lilly.com);
@crl.com); @fda.hhs.gov);
@tgrd.com); @bms.com);
@exponent.com); @davidson2.plus.com);
@abbott.com); @merck.com);
@its.jnj.com); @fda.hhs.gov); @its.jnj.com);
@pfizer.com); @uga.edu);
s@abbott.com); @gsk.com); @bms.com;
@epamail.epa.gov); @pfizer.com);
@astrazeneca.com);
@abbvie.com); @its.jnj.com);
@niehs.nih.gov); @rivm.nl);
@its.jnj.com); @dow.com);
@pfizer.com); @merck.com);
@pfizer.com); @bayer.com);
@fagg.be); @fda.hhs.gov);
@astrazeneca.com); @epa.gov);
@gsk.com); @epamail.epa.gov);
@beckman.com); @jhsph.edu); @epa.gov);
@mpa.se); @bms.com);
@fda.hhs.gov); @mcmaster.ca);
@lilly.com); @live.com); @sanofi.com

Cc:
Subject: Response requested: Sept 26 DART meeting
Date: 24-07-2013 17:28

Dear DART Technical Committee,

As the summer goes on, we are continuing to plan for the fall face-to-face committee meeting on September 26. You should all have this invite on your calendars already. To plan the logistics, and I need to know whether you are planning to be in attendance at the meeting. A teleconference option will be available to those unable to travel.

If you are planning to attend in person, please reply to me to confirm by Friday, August 2.

Please also include any dietary restrictions. Thank you! And let me know if you have any questions or concerns.

Best regards,

Scientific Program Associate
ILSI Health and Environmental Sciences Institute
1156 15th Street, NW
Suite 200
Washington, DC 20005

[redacted]@hesiglobal.org

Follow HESI:

Doc. 11

Overal 10.2.e

From:
To: @abbvie.com); @abbvie.com; @astrazeneca.com); @bayer.com); @boehringer-ingelheim.com; @bms.com); @bms.com); @celgene.com); @crl.com); @crl.com); @crl.com); @covance.com); @covance.com); @dow.com); @dow.com); @dupont.com); @lilly.com); @exxonmobil.com); @gsk.com); @gsk.com); @its.jnj.com); @merck.com); @pfizer.com); @pfizer.com); @pg.com); @sanofi.com); @sanofi.com); @tgrd.com); @creighton.edu); @mcmaster.ca); @rivm.nl); @exponent.com); @exponent.com); @sciences.com); @abbvie.com); @abbvie.com)
Cc: @epa.gov); @epa.gov); @fda.hhs.gov);
Subject: RE: DART Comments on FDA Guidance on Endocrine Disruption
Date: 17-10-2013 15:21

All,

Thank you to everyone who responded to my previous email. Based on the responses received thus far, there will be **no coordinated effort** to submit comments on behalf of this committee given that several of the DART sponsor companies will be sending comments to the FDA independently.

For those individuals ( ) who volunteered to be on a scoping team to further develop a potential workstream related to endocrine toxicants, we will aim to hold the first teleconference in early November. If anyone else is interested in participating in this scoping team, please let me or know.

Best regards,

202-
@hesiglobal.org

From:
Sent: Tuesday, October 01, 2013 4:34 AM
To: @abbvie.com); @abbvie.com; @astrazeneca.com); @bayer.com); @boehringer-ingelheim.com); @bms.com); @bms.com); @celgene.com); @crl.com); @crl.com); @crl.com); @covance.com); @covance.com); @dow.com); @dow.com); @dupont.com); lilly.com); @exxonmobil.com); @gsk.com); @gsk.com); @its.jnj.com); @merck.com); pfizer.com); @pfizer.com); G @pg.com); @sanofi.com); @sanofi.com); @tgrd.com);

Doc. 11

[redacted]@creighton.edu); [redacted]@mcmaster.ca); [redacted]@rivm.nl); [redacted]@exponent.com); [redacted]@exponent.com); [redacted]@sciences.com); [redacted]@abbvie.com); [redacted]@abbvie.com)
Cc: [redacted]@epa.gov); [redacted]@epa.gov); [redacted]@fda.hhs.gov); [redacted]@fda.hhs.gov); [redacted]
Subject: DART Comments on FDA Guidance on Endocrine Disruption

To the DART Steering Committee –

Per the discussions from last week's meeting, attached is the recent FDA Guidance for Industry on the Endocrine Disruption Potential of Drugs which was released on September 20th.

Given the short 60 day comment window, please respond to this email by next **Friday October 11th** and let me know if you/your company will be submitting comments independently or if you would like to submit comments via this committee.

Many thanks,
[redacted]

[redacted]
[redacted]
202-[redacted]
[redacted]@hesiglobal.org

Overal 10.2.e

Doc. 12

From:
To: @bayer.com; @wiv-isp.be; @imperial.ac.uk; @toxi.uni-wuerzburg.de; t@basf.com; @nihs.go.jp; @brunel.ac.uk; @leffers.co.dk; @syngenta.com; @ .freeserve.co.uk; @ivz-rs.si; @rivm.nl; @hrsu.mrc.ac.uk; @niehs.nih.gov; @epa.gov
Cc:
Subject: ECETOC Workshop Report no.27: Expert Panel to Better Understand Endocrine Disrupter Low Doses Effects, 22-23 April 2013, Barcelona
Date: 24-10-2013 12:57

Dear Expert Panel Participants,

We are pleased to announce the publication of ECETOC Workshop Report no.27 on the *Expert Panel to Better Understand Endocrine Disrupter Low Doses Effects, 22-23 April 2013, Barcelona.*

Please note that, as part of our continuing drive for efficiency and environmental care, all ECETOC publications are now distributed exclusively in electronic format. To this end, we have prepared the following direct link for your use to download the report whenever required:
WR27: http://bit.ly/ecetoc-wr27-pdf

We take this opportunity to thank you for the time and effort that you have put into this report.

Best wishes,

Environmental Sciences Manager
ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals)
Avenue E. Van Nieuwenhuyse Building 2, 3rd Floor, Bte 8
B-1160 Brussels
Tel +32 2 -
Fax +32 2 -
E-mail: @ecetoc.org
www.ecetoc.org

Sent on behalf of by , ECETOC Communications, Media and Web Manager

Doc. 13

From: [redacted]@dupont.com
To: t[redacted]@rivm.nl
Subject: RE: Betr: Protected Cropping Model
Date: 25-03-2015 19:51

Overal 10.2.e

Hi [redacted]

Another month has passed and I thought I'd quickly check in ahead of Easter to see if there are any further developments?

[redacted]

From: [redacted] [mailto:[redacted]@rivm.nl]
Sent: 20 February 2015 12:03
To: [redacted]
Subject: RE: Betr: Protected Cropping Model

Hi [redacted],
People at the ministries in The Hague have asked me some additional information, which I provided more than a week ago. I did not yet receive permission to release GEM. It is ready for that. (A manual is available and the report for soil bound is finished. I will try to finish the report for soilless next week)
This week and next week are school vacations in part of the Netherlands, So that may be a cause for delay.
[redacted]

From: <[redacted]@dupont.com>
To: [redacted]@rivm.nl>,
Date: 19-02-2015 17:31
Subject: RE: Betr: Protected Cropping Model

zie ook doc.18

Hi [redacted],

I'm attending a meeting next week where developments with protected cropping will be discussed...I thought I would drop you a very quick note to see if there are any updates on the likely timetable for release of GEM.

[redacted]

From: [redacted]
Sent: 20 January 2015 08:23
To: '[redacted]'
Subject: RE: Betr: Protected Cropping Model

Thanks [redacted] I look forward to further developments...!

From: [redacted] [mailto:t[redacted]@rivm.nl]
Sent: 19 January 2015 15:34
To: [redacted]
Subject: RE: Betr: Protected Cropping Model

Dear [redacted]
The EFSA GD gave three example scenarios, one for soilless and two for soil-bound.

There were insufficient data (available) to establish representative scenarios for greenhouses (to cover Europe). The data in the GEM package will include several soil-less and several soil-bound scenarios for the Netherlands. We cannot claim that these scenarios are representative for Europe.
Kind regards,

[redacted]

-----<[redacted]@dupont.com> schreef: -----
Aan: <[redacted]@rivm.nl>
Van: <[redacted]@dupont.com>
Datum: 01/19/2015 03:51PM
Onderwerp: RE: Betr: Protected Cropping Model

[redacted]

Thank you..do you have a rough estimate of when the software will be available for public release testing? As I recall the EFSA GD was very careful not to present a definitive standard glasshouse soil-less scenario. Will this still be the case or will example files be provided that could be used to support submissions with amendment as needed?

[redacted]

From: [redacted] [mailto:[redacted]@rivm.nl]
Sent: 19 January 2015 13:07
To: [redacted]
Subject: Betr: Protected Cropping Model

Dear [redacted]
You are correct, we promised that it would be available soon. The good thing is that it is ready for distribution. The bad thing is that we did not get a response from our ministries on our question whether it can be released. As I am in Italy now, I only can promise that I will try to contact the ministries and ask them to decide quickly.

Some documentation is ready as well, but it will take a few weeks to finish the scenario report for the Netherlands.
Kind regards,

[redacted]

-----<[redacted]@dupont.com> schreef: -----
Aan: <[redacted]@rivm.nl>
Van: <[redacted]@dupont.com>
Datum: 01/19/2015 11:09AM
Onderwerp: Protected Cropping Model
Dear [redacted]

I am preparing some protected cropping submissions and would like to try to run through the GEM package. As I recall from the stakeholders meeting in EFSA last summer this modelling framework was in beta-testing at the time and would be made publicly available sometime soon. Can you provide me with a quick update about release plans?

Thanks

[redacted]

Du Pont (U.K.) Limited
Wedgwood Way, Stevenage
Hertfordshire, SG1 4QN, England
Place of Registration: Companies House London
Company Registration No.: 4556216

Overal
10.2.e

Doc. 14

From:
To: - Istituto di Ricerche Farmacologiche; Uppsala University; - University of Amsterdam; - University of Newcastle; - IUF (Institut für umweltmedizinische Forschung an der Heinrich-Heine-Universität Düsseldorf gGmbH); - Università degli studi di Milano; - Rijksuniversiteit van Gent; - University of Manchester; - RIVM (National Institute for Public Health and the Environment); - VITO; - ETH (Swiss Federal Institute of Technology);
Cc: - Solvay SA; - Unilever Research; - BASF SE;
Subject: FYI EFSA 2nd Scientific Conference "Shaping the Future of Food Safety, Together" 14-16 October @ World EXPO 2015 - Milan, IT
Date: 16-04-2015 15:59

Dear ESAP members,

The European Foods Safety Agency (EFSA) 2nd Scientific Conference will take place next 14-16 October in the World EXPO 2015 site (Milan, Italy).
Registration to attend the conference is open until 15 May 2015.

On the occasion of the World EXPO 2015 exhibition in Milan, which will have food as its central theme, representatives from the scientific and risk assessment community as well as risk managers from in and outside Europe are invited to contribute to a major scientific conference EFSA is organising on 14-16 October 2015 in the EXPO site. The conference will take stock of the challenges and opportunities ahead in the domain of EFSA's activities with a focus on two major themes: Assessment Science; and Science, Innovation and Society. It will be organised in plenary and breakout sessions; thematic poster sessions will be held for scientists to showcase their work in areas of relevance for the conference. This event follows EFSA's first successful Scientific Conference "Challenging boundaries in risk assessment – sharing experiences", organised to mark its 10th year anniversary in November 2012, and is part of the broader EU scientific programme for EXPO 2015.

EFSA's 2nd Scientific Conference - Shaping the Future of Food Safety, Together

Objectives of the conference

Assessment science is the main theme of the conference, with EFSA aiming to attract an audience of 800 participants. Hence, scientists working in risk assessment organisations are invited to attend. As the purpose of assessment is policy development and evaluation, risk managers and risk communicators are invited as well. Another objective of the conference is to broaden the debate beyond food safety risk assessment per se. Therefore scientists working in a domain or having an interest in the field of science-based assessment are invited to participate. Young scientists are particularly encouraged to join.

Yours,

Science Policy Interface
Cefic AISBL (European Chemical Industry Council)
Avenue E. van Nieuwenhuyse 4
B-1160 Brussels
Phone +32 (0)2
Fax +32 (0)2
Email @cefic.be
www.cefic.org
www.cefic-lri.org

Doc. 14

SusChem Strategic Innovation and Research Agenda (SIRA)
http://www.suschem.org/

The new SIRA sets out SusChem's research and innovation priorities for the short and medium term.
The next steps and implementation for this ambitious agenda will be a major theme of the SusChem Stakeholder event next 8 and 9 of June 2015, in Brussels.

Cefic, the European Chemical Industry Council, is the Brussels-based organisation representing the European chemical industry. Created in 1972, it represents 29,000 companies that produce nearly a fifth of the world's chemicals and employ 1.2 million people.

LRI, the Long-Range Research Initiative (LRI), is one of the major voluntary initiatives of the European chemical industry to support its competitiveness and innovation potential. Launched in 1999, it aims to identify and fill gaps in our understanding of the hazards posed by chemicals and to improve the methods available for assessing the associated risks.
LRI sponsors high-quality research, published in peer-reviewed journals, and seeks to provide sound scientific advice on which industry and regulatory bodies will draw to respond more quickly and accurately to the public's concerns.

Doc. 15

Overal 10.2.e

From: [redacted]@basf.com
To: [redacted]@rivm.nl
Cc: [redacted]
Subject: TELCON - Final selection oral paper
Date: 22-05-2015 13:11

Hi [redacted]

ok, looks like **10 am Tuesday 22nd May** works for everyone then let's do that (1 hour or more is fine for me). I can host the call, no problem. Dial in details as follows:

The list of dial-in numbers by country is here:

https://www.intercallonline.com/listNumbersByCode.action?confCode=8470207652#S

The conference code:

8470207652

look forward to talking to you then

Regards,

[redacted]

Mit freundlichen Grüßen / Best Regards
[redacted]
Crop Protection - Environmental Fate Modelling

Phone: +49 [redacted] Mobile: +49 [redacted] Fax: +49 [redacted] E-Mail: [redacted]@basf.com
Postal Address: BASF SE, APD/EF - LI444, 67117 Limburgerhof, Germany

150 years
BASF - We create chemistry

Von: [redacted]@rivm.nl>
An: [redacted]@slu.se>
Kopie: [redacted]s@basf.com" <[redacted]@basf.com>
Datum: 22.05.2015 12:46
Betreff: Re: Final selection oral paper (Plain)

No problem to start at 10.00.

From: @slu.se>
To: @rivm.nl>,
Cc: @basf.com" @basf.com>
Date: 22-05-2015 11:45
Subject: Re: Final selection oral paper

I could start earlier on Tuesday, it's on Wednesday morning I have a meeting until 11.
So, if OK with both of you maybe we could start at 10 am on Tuesday?
, is it easy for you to organize a tele-con? If not I will check our possibilities here at SLU!
/

22 maj 2015 kl. 11:38 skrev @rivm.nl>:

Hi and ,
, thank you for contacting and starting things.
I am available for a telecon Tuesday next week until 15.00 (starttime of another telecon after which I will leave for Parma). So, given the timeconstraint of , a telecon 11.00 - 12.00 (or maybe a bit longer) seems OK to me. I will do my best to go through the abstracts.
For me it is not possible to organise the telecon at such short notice (may remember that). So if one of you could call me, that would be great.
Kind regards,

From: @slu.se>
To: @basf.com" < @basf.com>,
Cc: @rivm.nl" < @rivm.nl>, < r@slu.se>
Date: 22-05-2015 10:50
Subject: Re: Final selection oral paper

Hi,

Glad to see that we finally received the abstracts yesterday!

I'm available for a tele meeting on Tuesday until 14:00 (or after 16:30). On Wednesday I'm available after 11:00.

Please note that my e-mail address has changed, it is now a bit shorter, i.e. @slu.se

Looking forward talking to you next week,

22 maj 2015 kl. 08:13 skrev @basf.com:

Doc. 15

Hi [redacted]

I will be on vacation next week Wednesday until mid of June, which makes things a bit difficult with Ettore's 10-day timeline. Monday is also a public holiday here in Germany.

Would you be available on Tuesday for a telephone call to discuss the focus of the session and choices for platform and poster? I can do any time on Tuesday. Otherwise Wednesday would also be possible for me if necessary (I will be at home).

Regards

[redacted]

Mit freundlichen Grüßen / Best Regards
[redacted]
Crop Protection - Environmental Fate Modelling

Phone: +49 [redacted] Mobile: +49 [redacted] Fax: +49 [redacted] E-Mail: [redacted]@basf.com
Postal Address: BASF SE, APD/EF - LI444, 67117 Limburgerhof, Germany

150 years
BASF - We create chemistry

----- Weitergeleitet von [redacted] /EU/BASF am 22.05.2015 08:03 -----

Von: [redacted]@unicatt.it>
An: [redacted]@rivm.nl", [redacted]@rivm.nl>, [redacted]@waterborne-env.com>, [redacted]@ARS.USDA.GOV", [redacted]@ARS.USDA.GOV>, [redacted]@basf.com" <[redacted]@basf.com>, [redacted]@dupont.com", [redacted]@dupont.com>, [redacted]@bpi.gr>, [redacted]@efsa.europa.eu" <[redacted]@efsa.europa.eu>, "[redacted]@bayer.com" [redacted]@bayer.com>, [redacted]@slu.se", [redacted]@slu.se>, "[redacted]@agroscope.admin.ch" <[redacted]@agroscope.admin.ch>, "[redacted]@basf.com" <[redacted]@basf.com>, [redacted]@basf.com>, [redacted]@gmail.com>, [redacted]@anses.fr", [redacted]@anses.fr>, "[redacted]@wur.nl" [redacted]@wur.nl>, [redacted]@fera.gsi.gov.uk", [redacted]@fera.gsi.gov.uk>, [redacted]@dow.com>, [redacted]@cranfield.ac.uk>, "[redacted]@bayer.com" [redacted]@bayer.com>, "[redacted]@ec.europa.eu" [redacted]@ec.europa.eu>, "[redacted]@ARS.USDA.GOV" [redacted]@ARS.USDA.GOV>, [redacted]@efsa.europa.eu" <[redacted]@efsa.europa.eu>, [redacted]@idaea.csic.es" [redacted]@idaea.csic.es>
Kopie: [redacted]@unicatt.it>, [redacted]@unicatt.it>, [redacted]@unicatt.it>, [redacted]@unicatt.it>, [redacted]@unicatt.it>
Datum: 21.05.2015 15:33
Betreff: Final selection oral paper (Plain)

Dear Chairs
Herewith attached you find the list of the abstracts received for the symposium that were previously checked and approved by the organizing committee (OC).
Your action now is the following

- Selection of the oral presentation (see below the number expected)
- Set the final list of the paper (oral and poster) in each session

A brief summary – one page - of the session (including main message) is responsibility of the chair and it will be published in the proceedings. This is due by the end of June.
We invite you as chairs of each session to meet (as you wish by email or teconf) and take a final decision for each of the above bullet points. In case you consider more appropriate allocate papers in other session please let us know.
What we have planned is a conference proceedings as folder of the different paper (1 page each) that will be distributed during the conference. In addition the author could upload supporting documentation in the website before the symposium
The program is organized as in the previous edition (see the link in the website) with the following schedule based on the number of paper submitted and oral presentation requested. The oral presentation last 20 ' (15 plus 5 for questions)
The conference start at 13.30 September, 2 with WELCOME
First session:
Laboratory studies (September, 2 – provisional 14.00 to 18.30)
Select 11 oral
Field study (September, 3 – provisional 8.50 to 9.50)
Select 7 oral
Landscape (September, 3 – provisional 11.20 to 15.30)
Select 9 oral
Monitoring (September, 3 – provisional 15.30 to 18.00; the session can proceed the following day)
Select 9 oral
Risk mitigation
Sustainable Use Directive (September, 4 – provisional 11.30 to 13.30)
Select 4 oral

As you see above the time set is provisional. However we intend to have a range of 40-44 oral presentations. Let's working with 18 for Lab+Field, 18 for Lan+Monit and 4 for RM +SUD: then we have 4 papers as reserve
We are looking forward to have your feedback possibly in 10 day time to allow the author to submit the final abstract.
We thank you very much for the cooperation. Do not hesitate in contacting us for clarification.

(on behalf of the OC)

ricerca scientifica, progetti medico-assistenziali e sociali dell'Ateneo e del Policlinico "A. Gemelli".
Info: ***www.unicatt.it/5permille***

<Abstracts Final.doc><Abstracts List Final.xlsx>

Proclaimer RIVM http://www.rivm.nl/Proclaimer

Overal 10.2.e

Doc. 16

From: [redacted]
To: [redacted] - Istituto di Ricerche Farmacologiche [redacted]"; [redacted] - University of Amsterdam; [redacted] - University of Newcastle; [redacted] - University of Manchester; [redacted] - RIVM (National Institute for Public Health and the Environment); [redacted] - ETH (Swiss Federal Institute of Technology)
Cc: [redacted]
Subject: RE: Cefic ESAP meeting 02 June 2015 - 09h00 to 15h30 @ Cefic - Templates for your honorarium invoice and expense claims
Date: 29-05-2015 10:23
Attachments: 20150602 ESAP template for Invoice Honorarium.doc
20150602 Expense claim ESAP meeting.xls

Dear ESAP members,

Please find attached the templates for your honorarium invoice and expense claims.

Yours sincerely,
[redacted]

From: [redacted]
Sent: Wednesday, 27 May 2015 5:09 PM
To: [redacted] Rijksuniversiteit van Gent'; ' University Manchester'; ' [redacted] '
Cc: ' [redacted]
Subject: RE: Cefic ESAP meeting 02 June 2015 - 09h00 to 15h30 @ Cefic

Dear ESAP members,

For our meeting next June 02nd, Tuesday, at 09h00 at Cefic, you will find attached to this message:

1) ESAP draft agenda
2) Draft LRI Manuscript version 13.5.2015

Our informal dinner June 1st, Monday, at 19h00 will take place at the

Café Métropole
31, place de Brouckère
B - 1000 Brussels | Belgium
T +32-2-217 23 00 | F +32-2-218 02 20
www.metropolehotel.com

Lastly, for your information, please find attached the European Commission Science Advice Mechanism.

Wishing you all a pleasant trip and greetings from Brussels.

[redacted]

[redacted]
Science Policy Interface

Cefic AISBL (European Chemical Industry Council)
Avenue E. van Nieuwenhuyse 4
B-1160 Brussels
Phone +32 (
Fax +32 (0)2
Email csi@cefic.be
www.cefic.org
www.cefic-lri.org

SusChem Strategic Innovation and Research Agenda (SIRA)

http://www.suschem.org/

The new SIRA sets out SusChem's research and innovation priorities for the short and medium term.
The next steps and implementation for this ambitious agenda will be a major theme of the SusChem Stakeholder event next 8 and 9 of June 2015, in Brussels.

Cefic, the European Chemical Industry Council, is the Brussels-based organisation representing the European chemical industry. Created in 1972, it represents 29,000 companies that produce nearly a fifth of the world's chemicals and employ 1.2 million people.

LRI, the Long-Range Research Initiative (LRI), is one of the major voluntary initiatives of the European chemical industry to support its competitiveness and innovation potential. Launched in 1999, it aims to identify and fill gaps in our understanding of the hazards posed by chemicals and to improve the methods available for assessing the associated risks.
LRI sponsors high-quality research, published in peer-reviewed journals, and seeks to provide sound scientific advice on which industry and regulatory bodies will draw to respond more quickly and accurately to the public's concerns.

From:
Sent: Tuesday, 3 March 2015 5:05 PM
To:
Rijksuniversiteit van Gent';
University Manchester';
Cc:
Subject: Cefic ESAP meeting 02 June 2015 - 09h00 to 15h30 @ Cefic

Dear ESAP members,

The next ESAP meeting will take place on June 02nd , from 09h00 to 15h30 at Cefic.
We would like also to invite you also for an informal dinner on June 1st at 19h00, location to be defined.

Can you please confirm your attendance (or not) to the meeting and to the dinner by **return of this email**?

You will find attached to this message:

1) The ESAP draft agenda

2) The Cefic partner hotels' list – please feel free to book your stay at your best convenience

Below the link to Cefic contact information "how to reach us"
http://www.cefic.org/About-us/Contact-us/How-to-reach-us-/

Please do not hesitate to contact me if you have any additional questions.
Many thanks for your confirmation already and looking forward to welcome you at Cefic.

Yours sincerely,

Science Policy Interface
Cefic AISBL (European Chemical Industry Council)
Avenue E. van Nieuwenhuyse 4
B-1160 Brussels
Phone +32 (
Fax +32 (0)2
Email csi@cefic.be
www.cefic.org
www.cefic-lri.org

LRI Innovative Science Award 2015: Competition is open!

Apply before March 17th and you might win a 100.000€ award to support promising new research in the **field of novel use of surrogate data to assess apical endpoints in human health and/or environmental risk assessment.**

http://cefic-lri.org/funding-opportunities/apply-for-the-lri-award/

Cefic, the European Chemical Industry Council, is the Brussels-based organisation representing the European chemical industry. Created in 1972, it represents 29,000 companies that produce nearly a fifth of the world's chemicals and employ 1.2 million people.

LRI, the Long-Range Research Initiative (LRI), is one of the major voluntary initiatives of the European chemical industry to support its competitiveness and innovation potential. Launched in 1999, it aims to identify and fill gaps in our understanding of the hazards posed by chemicals and to improve the methods available for assessing the associated risks.
LRI sponsors high-quality research, published in peer-reviewed journals, and seeks to provide sound scientific advice on which industry and regulatory bodies will draw to respond more quickly and accurately to the public's concerns.

Doc. 16.1

Date: 02/06/2015

Name :
Address:
Postal code:
Country :
VAT Number :

CEFIC AISBL
Contact person: 10.2.e
Research & Innovation
Av Van Nieuwenhuyse 4
1160 - Brussels
Belgium

VAT Nr : BE 0412.849.915

Invoice

ESAP meeting 2015-06-02
- Consultancy fees 1,500€
- Total: 1,500€

Signature: _____

Complete Bank Details :
Account Beneficiary name:
Bank name :
Bank Address :
Account number :
Iban :
Bic Codes :

Doc. 16.2

cefic

EXTERNAL EXPENSES CLAIM
EUROPE

First name and Last name:

Phone (with country and area code):

e-mail:

Direct Superior

Date 10.2.e

EXPENSES INCURED AT (name of meeting/workshop) ESAP June meeting

place and date (ex.: LONDON 22/10/09) Brussels, Cefic, 02/06/2015

PROGR. NR XX	ISSUES/S. GROUP XXX	SPECIAL ACTIVITIES XXXX	TYPE OF EXPENSE XX	FREE SPACE XXXX
(*) A	B	C		
11	016	0002	08	0003

Attached # original invoices, tickets, bording pass and receipts for each amount :

A B C XX XXX XXXX(*) only if you want to split	D E XX XXXX	ITEM	Currency	Amount	CONVERSION IN € OR €	Receipt N°
COST CENTER		TRAVEL subtotal		-	-	
COST CENTER		HOTEL subtotal		-	-	
COST CENTER		MEETING subtotal		-	-	
COST CENTER		MISCELLANEOUS subtotal		-	-	
		SUBTOTAL (automatic)		-	-	
		ADVANCE				
		AMOUNT RETURNED				
		TO PAY		-	-	

Please pay to **Complete in CAPITAL LETTERS :**

Beneficiary Account name (it's not the bank name)

Address

Post code /town & country

*IBAN (1) Code (22 digits):

*SWIFT or BIC (2) code (8 to 11 digits):

*SWIFT code (8 to 11 digits):

Banker name

Address

Post code /town & country

* Cefic cannot pay without these codes. They are on your bank statement or please ask your bank

(1) International Bank Account Number (2) Account Holder Institution

SIGNATURE EXPENSE GENERATOR	SIGNATURE PROGRAMME HEAD

Overal 10.2.e

Doc. 17

From: [redacted]
To: [redacted] - Istituto di Ricerche Farmacologiche [redacted] - Uppsala University; [redacted] - University of Amsterdam; [redacted] University of Newcastle; [redacted] IUF (Institut für umweltmedizinische Forschung an der Heinrich-Heine-Universität Düsseldorf gGmbH); [redacted] - Rijksuniversiteit van Gent; [redacted] University of Manchester; [redacted] - RIVM (National Institute for Public Health and the Environment); [redacted] - VITO; [redacted] - ETH (Swiss Federal Institute of Technology)
Cc: [redacted] Solvay SA; [redacted] - Unilever Research; [redacted] - BASF SE
Subject: RE: Cefic ESAP meeting 02 June 2015 - 09h00 to 15h30 @ Cefic
Date: 03-06-2015 16:19
Attachments: LRI impact stories - skin + B.docx
HelsinkiBWorkshop_Cefic-LRI_FinalReport_update.pdf
Joint WS Skin Sensitization Alternatives 2015 - Flash report.pdf

Hello ESAP,

as there was interest in a write-up of recent LRI policy impact stories, I attach a story document on the skin and bioaccumulation efforts paying off

I attach also the B WS summary and the skin WS flash report for those interested
Cheers.

[redacted]
http://www.youtube.com/watch?v=7bV0yP5dBq8

LRI
The Long-range Research Initiative
[redacted]
Research & Innovation
Long Range Research Initiative (LRI) Programme Manager
CEFIC - The European Chemical Industry Council
4 Avenue E. Van Nieuwenhuyse
B-1160 Brussels
Tel +32 2 [redacted]
Fax +32 2 [redacted]

www.cefic.be www.cefic-lri.org **Visit our new LRI website!**

About LRI
Launched 15 years ago, the Long-Range Research Initiative (LRI) is one of the major voluntary initiatives of the European chemical industry to support its competitiveness and innovation potential. LRI aims to identify and fill gaps in our understanding of the hazards posed by chemicals and to improve the methods available for assessing the associated risks.
LRI sponsors high-quality research, published in peer-reviewed journals, and seeks to provide sound scientific advice on which industry and regulatory bodies will draw to respond more quickly and accurately to the public's concerns.

From: [redacted]
Sent: Wednesday, 27 May 2015 17:09
To: [redacted] - Istituto di Ricerche Farmacologiche [redacted] - Uppsala University; [redacted] - University of Amsterdam; [redacted] - University of Newcastle; [redacted] - IUF (Institut für umweltmedizinische Forschung an der Heinrich-Heine-Universität Düsseldorf gGmbH); [redacted] - Rijksuniversiteit van Gent; [redacted] - University of Manchester; [redacted] - RIVM (National Institute for Public Health and the Environment); [redacted] ; [redacted] - VITO; [redacted] - ETH (Swiss Federal Institute of Technology)
Cc: [redacted] - Solvay SA; [redacted] - Unilever Research; [redacted] - BASF SE
Subject: RE: Cefic ESAP meeting 02 June 2015 - 09h00 to 15h30 @ Cefic

Dear ESAP members,

Doc. 17

For our meeting next June 02nd, Tuesday, at 09h00 at Cefic, you will find attached to this message:

1) ESAP draft agenda
2) Draft LRI Manuscript version 13.5.2015

Our informal dinner June 1st, Monday, at 19h00 will take place at the

Café Métropole
31, place de Brouckère
B - 1000 Brussels | Belgium
T +32-2-217 23 00 | F +32-2-218 02 20
www.metropolehotel.com

Lastly, for your information, please find attached the European Commission Science Advice Mechanism.

Wishing you all a pleasant trip and greetings from Brussels.

[redacted]

[redacted]
Science Policy Interface
Cefic AISBL (European Chemical Industry Council)
Avenue E. van Nieuwenhuyse 4
B-1160 Brussels
Phone +32 (0)[redacted]
Fax +32 (0)2[redacted]
Email csi@cefic.be
www.cefic.org
www.cefic-lri.org

SusChem Strategic Innovation and Research Agenda (SIRA)
http://www.suschem.org/

The new SIRA sets out SusChem's research and innovation priorities for the short and medium term.
The next steps and implementation for this ambitious agenda will be a major theme of the SusChem Stakeholder event next 8 and 9 of June 2015, in Brussels.

Cefic, the European Chemical Industry Council, is the Brussels-based organisation representing the European chemical industry. Created in 1972, it represents 29,000 companies that produce nearly a fifth of the world's chemicals and employ 1.2 million people.

LRI, the Long-Range Research Initiative (LRI), is one of the major voluntary initiatives of the European chemical industry to support its competitiveness and innovation potential. Launched in 1999, it aims to identify and fill gaps in our understanding of the hazards posed by chemicals and to improve the methods available for assessing the associated risks.
LRI sponsors high-quality research, published in peer-reviewed journals, and seeks to provide sound scientific advice on which industry and regulatory bodies will draw to respond more quickly and accurately to the public's concerns.

Doc. 17

Respect the environment. Turn down. Switch off. Recycle. Walk. Do you really need to print this message?

From: [redacted]
Sent: Tuesday, 3 March 2015 5:05 PM
To: [redacted] Rijksuniversiteit van Gent'; University Manchester'; [redacted]
Cc: [redacted]
Subject: Cefic ESAP meeting 02 June 2015 - 09h00 to 15h30 @ Cefic

Dear ESAP members,

The next ESAP meeting will take place on June 02nd , from 09h00 to 15h30 at Cefic.
We would like also to invite you also for an informal dinner on June 1st at 19h00, location to be defined.

Can you please confirm your attendance (or not) to the meeting and to the dinner by **return of this email**?

You will find attached to this message:

1) The ESAP draft agenda
2) The Cefic partner hotels' list – please feel free to book your stay at your best convenience

Below the link to Cefic contact information "how to reach us"
http://www.cefic.org/About-us/Contact-us/How-to-reach-us-/

Please do not hesitate to contact me if you have any additional questions.
Many thanks for your confirmation already and looking forward to welcome you at Cefic.

Yours sincerely,
[redacted]

[redacted]
Science Policy Interface
Cefic AISBL (European Chemical Industry Council)
Avenue E. van Nieuwenhuyse 4
B-1160 Brussels
Phone +32 (0)2 [redacted]
Fax +32 (0)2 [redacted]
Email csi@cefic.be
www.cefic.org
www.cefic-lri.org

LRI Innovative Science Award 2015: Competition is open!

Doc. 17

Apply before March 17th and you might win a 100.000€ award to support promising new research in the **field of novel use of surrogate data to assess apical endpoints in human health and/or environmental risk assessment.**

http://cefic-lri.org/funding-opportunities/apply-for-the-lri-award/

Cefic, the European Chemical Industry Council, is the Brussels-based organisation representing the European chemical industry. Created in 1972, it represents 29,000 companies that produce nearly a fifth of the world's chemicals and employ 1.2 million people.

LRI, the Long-Range Research Initiative (LRI), is one of the major voluntary initiatives of the European chemical industry to support its competitiveness and innovation potential. Launched in 1999, it aims to identify and fill gaps in our understanding of the hazards posed by chemicals and to improve the methods available for assessing the associated risks.
LRI sponsors high-quality research, published in peer-reviewed journals, and seeks to provide sound scientific advice on which industry and regulatory bodies will draw to respond more quickly and accurately to the public's concerns.

LRI policy impact stories June 2015

Policy impact through REACH guidance revision: LRI geared up to deliver scientific input on bioaccumulation (PBT) and skin sensitisation testing

Chemical regulations, and the numerous technical guidances that accompany them, need to keep pace with scientific progress and developments, amongst others in the rapidly evolving field of animal testing alternatives. LRI has and continues to contribute to bring for instance to ECHA recent scientific developments it has sponsored. LRI also strives to align industry-agency views on the integrated strategies and their interpretations, a point of opportunity for the companies in making their filings more successful. This streamlines also member companies R&D operations through better, faster and cheaper predictions at early stages of product development ("better efficiency by failing early").

More particularly, LRI is actively engaged on bringing scientific input –quality stamped by peer-reviewed publications- from its research programme, which support the REACH guidance revision process (2015-2016) on skin sensitisation testing and on bioaccumulation (PBT). This will be in due time for companies to perform better risk assessment based on these endpoints for REACH 2018 (low tonnage registrations).

On skin sensitization, since 2010, LRI organized three workshops, the last one hosted by ECHA, and organized with the European Partnership for Alternative Approaches to Animal Testing (EPAA), gathering regulators and experts coming from industries, several EU Members States, ECHA, EURL-ECVAM and OECD. These workshops, which included the 2010 and 2011 and 2013 joint meetings on Local Lymph Node Assay and alternative skin sensitization testing, were an overwhelming success. Recently, last April, an LRI-ECHA workshop (in collaboration with EPAA and Cosmetics Europe) has further paved the way for future collaboration between industry and ECHA and the national authorities in charge of implementing alternative approaches to animal testing. It is the expectation that these type of testing strategies, which are based on *in-vitro* only methods, could replace animal testing for skin sensitization within a few years, and in due time for REACH 2018 for which several members would be planning in-vitro only for skin sensitisation. Several of these non-animal *in-vitro* methods test methods have been formally validated by EC JRC EURL-ECVAM (validation center) and now appear as OECD Test Guidelines. It is important for industry to receive input from the regulators as to which prerequisites they deem necessary for such strategies to be accepted for registration of chemicals. There was broad consensus –also from ECHA- last April that a simple and transparent stepwise process involving a specific combination of assays was an opportunity now waiting to be seized. There was strong feeling also that the approach should be used within the adequate applicability domains. Knowing the very large fraction of chemicals that need to be tested for skin sensitisation, the related animal and cost saving potential for our members is a golden opportunity.

On bioaccumulation, current guidance is scientifically outdated (20 y.o.). In LRI-ECHA workshop held at ECHA offices in September 2014, LRI has provided new evidence on the latest key developments of bioaccumulation science (ca. last 6 years), including, but not limited to, ongoing and finalized Cefic-LRI projects. The evaluation of current bioaccumulation assessment practices for discrete organic chemicals and the identification of optimal assessment approaches based on the 'State of the Science' is based on new concepts quantified by coefficients of bio-concentration, bio-transformation, bio-magnification, trophic magnification and half-lifes. This creates a new framework on the subject, overtaking the current and overly conservative one, and thereby removing innovation obstacles and potential existing market issues .

SKIN SENSITIZATION ALTERNATIVES flash

EPAA-Cefic LRI-Cosmetics Europe Joint Workshop

Helsinki, Finland, April 23-24th 2015

Joint cross-sector workshop on Alternatives for Skin sensitization testing and assessment

The next in a series of CEFIC-LRI/EPAA/Cosmetics Europe workshops on skin sensitization was again hosted in Helsinki by the European Chemicals Agency (ECHA) on April 23rd/24th 2015. Approximately 60 participants, of whom the majority were from ECHA and EU member state regulatory agencies, considered the issues associated with the use of non-animal test data in hazard identification and classification, including for potency sub-categorisation. The overall objectives of the event were to undertake a critical assessment of how in vitro skin sensitisation data can be used in a weight of evidence approach to enable a defensible classification decision on a substance. In addition, key strengths and limitations, plus future needs were actively addressed.

At the last workshop, just 2 years ago it was noted that in "this area of toxicology, it is very likely that integrated testing strategies (ITS) which are based on in vitro methods will at least partially replace in vivo methods for skin sensitization within just 2-3 years". That probability is now a reality. The formal validation of two in vitro methods which address two key events in the adverse outcome pathway (AOP) for skin sensitization, i.e. protein reactivity and, keratinocyte activation have been translated into OECD Guidelines; a further method, addressing the third key event of the AOP, dendritic cell activation, the human cell line activation test (h-CLAT) has been validated by EURL-ECVAM and has a draft guideline under awaiting OECD approval. Accordingly, it is essential for industry and the regulatory community to co-operate so that the progress from validation, through acceptance to practical use can be expedited.

"It is very likely that in-vitro-based Integrated Testing Strategies will at least partially replace in vivo methods for skin sensitization within just 2-3 years"

On April 23rd, the workshop heard platform presentations from industry and regulators detailing current status of in vitro methods regarding the prediction of skin sensitization hazard, the potential for sensitisation potency assessment and approaches to the integrated assessment of data from multiple methods. This material was given a practical spin by the presentation of 6 individual case studies. These explored individual substances, specific ITS/IATA (integrated approaches to testing and assessment) strategies and the challenges faced by those undertaking and/or reviewing the data.

On April 24th, the second part of the workshop, three break-out groups addressed key questions, these being followed by an open workshop discussion. One focus

PTO>

The Workshop, hosted by ECHA, in Helsinki

was on the question of how to integrate data from multiple assays, balancing harmonisation of approach for regulatory use with a need for some flexibility. The second group considered questions on the use of the methods for hazard identification, asking what level of uncertainty of prediction was acceptable. It was then noted that on current evidence, the prediction of skin sensitisation potential in humans appears to be more accurate from in vitro tests than from existing animal tests.

However, it was recognised/concluded that, given the limitations and availability of the data, all of the information, including animal tests and studies of humans would need considered to establish the best predictor for humans. The third group extended this challenge to reflect on whether and to what extent the potency of an identified sensitiser could be predicted by in vitro methods. A key discussion point asked whether a sufficient body of human evidence exists to give reassurance that the predictions have merit?

"None of the existing assays are perfect; the in vitro methods should not be expected to be so either, but by the use of these methods, we have the opportunity to improve"

The overall output from the break out groups coalesced into a few key points and recommendations. These can be summarised best by reflecting that we now have non-animal testing tools that represent the first three Key Events (KE) of the AOP. With two already having become official OECD Test Guidelines and a third enticingly close to that position (the Direct Peptide Reactivity Assay for KE1, Keratinosens for KE2 and h-CLAT for KE3), the switch from a primary requirement for LLNA data to a requirement for in vitro evidence is an imminent reality for those substances which fit within their applicability domain. ECHA is in the process of updating its guidance documents to reflect what registrants need to provide if data from combinations of these tests are to be used to meet regulatory requirements of the REACH Regulation.

So what is still needed? First and foremost perhaps is that submissions must be adequately argued in the sense of providing a solid scientific foundation for decisions based on the outputs of these methods, taking into account any other contributions to the weight of evidence (the most obvious being knowledge from chemical structure). Particularly, where data is discordant, an adequate rationale to explain this must form part of the dossier. Helping to provide confidence for all will be clarity in the matters of applicability domains and any uncertainties associated with the assays and gathering and sharing experience of their use. It has to be recognised that IATAs are not yet in a mature phase, such that the workshop contained much active debate on several aspects.

Nevertheless, there was broad consensus that a simple and transparent stepwise process involving the validated methods was an opportunity now waiting to be seized. There was also strong feeling that the approach should not be so rigidly defined that assay variations and alternative tests for the KEs were locked out, nor that it should preclude more complex IATAs being used within industries for their own purposes.

Perhaps on a final note, all were reminded that the ultimate goal is a high level of protection of human health, and thus it will be the experience of people that will ultimately be the final arbiter of whether toxicological predictions are, or are not, correct. None of the existing assays are perfect; the in vitro methods should not be expected to be so either, but by use of these methods and all other relevant information, including clinical feedback, we have the opportunity to continue to improve.

Participating Organisations

AirLiquide/SEPPIC
BASF
Beiersdorf
British Health & Safety Executive
BUAV/ECEAE
CAAT EU
Cefic LRI
Chemical Watch
Clariant
Danish MSC member
ECHA
EPAA
European Commission DG JRC/EURL ECVAM
European Commission, DG ENV
European Commission, DG GROW
EVONIK/ CES
Henkel
HUMANE SOCIETY INTERNATIONAL
KAO Corp.
L'Oréal
Merck group (MSD)
OECD
Polish Bureau for Chemical Substances - Department for Risk Assessment
Procter & Gamble
Rhodia / Solvay
RIVM
Romanian Chemical Department - National Environmental Protection Agency,
Shiseido
Symrise


Panel Discussion

About EPAA

EPAA is a Public-Private Partnership across seven industry sectors and between European Commission and Industry stakeholders. Launched in 2005, it gathers 36 companies, 7 European trade federations and 5 Directorates-General of the European Commission.

About LRI

Launched 15 years ago, the Long-Range Research Initiative (LRI) is one of the major voluntary initiatives of the European chemical industry to support its competitiveness and innovation potential. LRI aims to identify and fill gaps in our understanding of the hazards posed by chemicals and to improve the methods available for assessing the associated risks.

LRI sponsors high quality research, published in peer-reviewed journals, and seeks to provide sound scientific advice on which industry and regulatory bodies will draw to respond more quickly and accurately to the public's concerns.

About Cosmetics Europe

Cosmetics Europe is the European trade association representing the interests of the cosmetics industry. Its membership consists of 27 national associations of the EU Member States and beyond, 16 major international companies, four supporting association members, four supporting corporate members and four correspondent members associated members. Cosmetics Europe represents more than 4,000 companies throughout the EU via the active representation of its member national associations.

CONTACT

epaa The European Partnership for Alternative Approaches to Animal Testing

entr-epaa@ec.europa.eu
www.epaa.eu.com
+32 (0)2 29 52 014

CONTACT

LRI Long-Range Research Initiative

man@cefic.be
www.cefic-lri.org
+32 (0)2 676 73 68

CONTACT

Cosmetics Europe the personal care association

KCondon@cosmeticseurope.eu
www.cosmeticseurope.eu
+32 2 227 6610

Doc. 18

Overal 10.2.e

From: [redacted]@dupont.com
To: [redacted]@rivm.nl
Subject: RE: Betr: Protected Cropping Model
Date: 18-06-2015 16:53

[redacted]

Thank you for your very helpful and comprehensive response!

[redacted]

From: [redacted] [mailto:[redacted]@rivm.nl]
Sent: 18 June 2015 15:46
To: [redacted]
Subject: RE: Betr: Protected Cropping Model

Hi [redacted],
You are just in time. After today I will not be in the office until July 14. First EFSA and then vacation (with probably little access to internet).

To update you:
Package is ready, which means that a GEM installation package is ready (soil-bound and soilless scenario's, PEARL, TOXSWA, models for substrate, database SPIN for substance properties) and also user manual, and three reports (derivation soil-bound scenarios, derivation soilless scenarios, impactanalysis substrate).
The ministries have been informed on that. They now have to approve the release. We earlier got the message that they wanted to have the package complete (i.e. no draft report)
Procedures for printing the reports have been started (procedures at Alterra and RIVM are slightly different). As soon as I have an approved pdf of the scenario report , ministries must react within one month. Without reaction RIVM will (and has to) publish the report.
Kind regards,
[redacted]

From: [redacted]@dupont.com>
To: [redacted]@rivm.nl>,
Date: 18-06-2015 16:21
Subject: RE: Betr: Protected Cropping Model

Hi [redacted]

As the summer vacation period looms ahead I thought I'd quickly drop you a note to check in with you for an update as I might not catch you later...are there any updates on release/availability of GEM?

[redacted]

From: [redacted] [mailto:[redacted]@rivm.nl]
Sent: 20 February 2015 12:03
To: [redacted]
Subject: RE: Betr: Protected Cropping Model

Hi Neal,

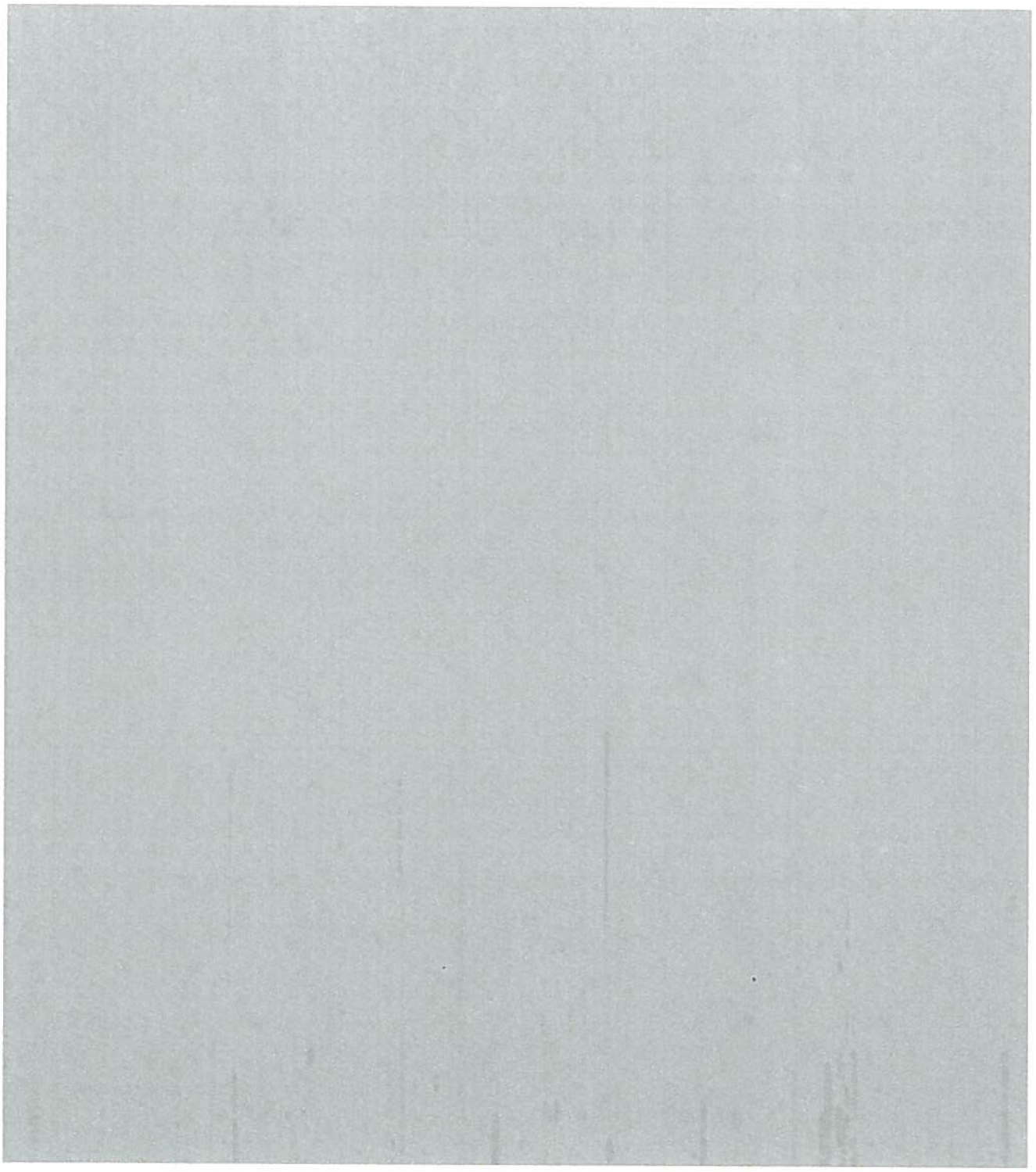
Doc. 18

People at the ministries in The Hague have asked me some additional information, which I provided more than a week ago. I did not yet receive permission to release GEM. It is ready for that. (A manual is available and the report for soil bound is finished. I will try to finish the report for soilless next week)
This week and next week are school vacations in part of the Netherlands, So that may be a cause for delay.

[redacted]

From: <[redacted]@dupont.com>
To: <[redacted]@rivm.nl>,
Date: 19-02-2015 17:31
Subject: RE: Betr: Protected Cropping Model

Dubbel met doc. 13



Doc. 19

Overal 10.2.e

From: [redacted]
To: [redacted]
Subject: RE: Betr: Invitation to present at symposium at Rothamsted in March 2016
Date: 22-06-2015 09:45

Thanks [redacted]
We will be in touch with further information.
Have a good vacation.

Best regards

[redacted]

From: [redacted] [mailto:[redacted]@rivm.nl]
Sent: 22 June 2015 08:42
To: [redacted]
Subject: RE: Betr: Invitation to present at symposium at Rothamsted in March 2016

Dear [redacted]
Sorry for not getting back to you earlier. Last weeks were quite busy due to finalising EFSA output.

In principle, my boss agrees to contributing.

This week I will be at EFSA in Parma, thereafter I have a vacation break. I will be back in office on July 14th. Probably best to arrange then further.
Kind regards,
[redacted]

From: [redacted]@exponent.com>
To: [redacted]@rivm.nl>,
Date: 22-06-2015 09:26
Subject: RE: Betr: Invitation to present at symposium at Rothamsted in March 2016

H[redacted]
Have you had the opportunity to discuss this with your boss?

Best regards

[redacted]

From: [redacted] [mailto:[redacted]@rivm.nl]
Sent: 26 May 2015 18:55
To: [redacted]
Subject: Betr: Invitation to present at symposium at Rothamsted in March 2016

Dear [redacted]
I will consult my boss on this. I will be back in office next week.
Kind regards,
[redacted]

Doc. 19

----- [redacted] < [redacted]@exponent.com> schreef: -----
Aan: "[redacted]@rivm.nl" <[redacted]@rivm.nl>
Van: [redacted]@exponent.com>
Datum: 05/26/2015 05:39PM
Onderwerp: Invitation to present at symposium at Rothamsted in March 2016

Dear [redacted]

As one of the organisers of a new event to be held at The Rothamsted Centre for Research and Enterprise, I would like to invite you to deliver a presentation on what constitutes a protected crop and what should the risk assessment look like.

This new event will be titled 'Environmental Risk Assessment for Plant Protection Products 2016. The 2016 theme is '*The Future for Higher-Tier Assessments*'.

From speaking to various stakeholders we have received positive feedback that there is an appetite for this type of event and that an emphasis on environmental exposure and risk, in a regulatory context, is welcome. In addition, the current uncertain regulatory environment in which we all have to work deserves some open discussion and exchange of views to the benefit of both industry and those who regulate plant protection products. You have been involved with the development of risk assessment methodologies for protected crops and I am certain that your thoughts would be of interest.

The event will be held on one day (with a reception the evening before) based on platform presentations and plenty of time for discussion and networking. We expect delegates from across Europe.

The topics covered will include protection aims, recent approaches (and their success) in environmental exposure assessments, the future of ecological modelling, some recent highlights on risk assessment (e.g. field testing for bees) and a comparison of refinements and higher-tier approaches in the USA with Europe. All presentations will be delivered by well-recognised experts selected by the programme committee (who are Exponent International, JSCi and TSGE Consulting). We have confirmations from three speakers to date (Syngenta, Eurofins and FMC).

As with all speakers, we will support reasonable travel expenses and accommodation.

I hope you can join us in this new and, hopefully, productive venture. I will send you a draft programme soon.

I look forward to hearing from you soon and please do not hesitate to contact me should you have any questions.

Best regards

[redacted]

[redacted]
Senior Managing Scientist - Environmental Fate
Exponent International Limited
The Lenz, Hornbeam Business Park, Harrogate, North Yorkshire, HG2 8RE, UK
Tel: +44 (0) [redacted]
Mobile: + 44 (0) [redacted]
Skype: [redacted]_exponent

Website: www.exponent.com

Meet Exponent at ChemCon Asia 2015 in Hong Kong, 15th - 19th June. Visit us at booth 15 or contact [redacted] ([redacted]@exponent.com) or [redacted] ([redacted]@exponent.com) to arrange a meeting.

Proclaimer RIVM http://www.rivm.nl/Proclaimer

Overal 10.2.e

Doc. 20

From: [redacted]
To: [redacted]@rivm.nl
Cc: [redacted]
Subject: Invitation to an ECETOC Workshop: Defining the role of chemical activity in environmental risk assessment within the context of mode of action: Practical guidance and advice - Please reply by July 10th
Date: 25-06-2015 13:10
Importance: High
Attachments: Workshop programme - Defining the role of chemical activity in environmental risk assessment.pdf
Workshop programme - Defining the role of chemical activity in environmental risk assessment.pdf

---

Dear [redacted]

I would like to remind you of our invitation to participate in the workshop on '***Defining the role of chemical activity in environmental risk assessment within the context of mode of action: Practical guidance and advice'***, to be held **29-30 October 2015** at the Snowbird Resort, Cliff Lodge, Utah, USA.

I am pleased to announce that the deadline for registration to the workshop has been extended to **Wednesday, July 10th**.

Could you please let us know whether you will attend the workshop, and if so, please complete the online form at http://www.ecetoc.org/v7ntbnzb9kyxumxk . Note that the form also gives you the option to be kept informed of the outcome of the workshop if unable to attend.

If you cannot attend please *let us know as soon as possible*.

Thank you very much in advance.

I look forward to hearing from you soon.

Best regards,

[redacted]

[redacted] Administrative Assistant
European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)
Avenue E. Van Nieuwenhuyse 2, (box 8) | B-1160 Brussels | Belgium
VAT BE 0418 344 469 | Tel: +32 2 [redacted] | Fax: +32 2 [redacted] 5
E-mail: [redacted]@ecetoc org | Website: www.ecetoc.org

ecetoc

EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS

Invitation to an ECETOC Workshop on
Defining the role of chemical activity in environmental risk assessment within the context of mode of action: Practical guidance and advice

29-30 October 2015
Snowbird Resort, Cliff Lodge, Utah, USA

17 June 2015

Dear Colleague,

In collaboration with RIFM (Research Institute for Fragrance Materials), ECETOC is in the process of organising a workshop to discuss and report current thinking on the practical guidance and advice regarding the role of chemical activity in environmental risk assessment. The event will be held 29-30 October 2015 at the Snowbird Resort in Utah, prior to the SETAC North America meeting in neighbouring Salt Lake City.

The workshop will focus on three key aspects:
1) Full utilisation of the chemical activity concept for non-polar organic chemicals (Log Kow = 2),
2) Classification of chemicals according to MOA and chemical activity or other dose metrics for chemicals with specific mode of action,
3) Challenges and potential limitations to the application of the chemical activity concept for ecological risk assessment – Physicochemical properties & partitioning.

More details can be found in the attached draft programme.

Recognising your expertise in this field, I would like to formally invite you to attend and contribute to the discussions. In order for us to reserve a place for you and to finalise the programme, please could you let us know as soon as possible whether you can accept our invitation by completing the online registration form which is available at:

http://www.ecetoc.org/v7ntbnzb9kyxumxk

The registration deadline is **June the 28th** at the latest.

Should you accept, please see the following logistics:

A block-booking has been made at the workshop venue at a discounted rate. Participants should book their accommodation as a part of the ECETOC group, directly with the hotel via the following options: to Snowbird's Central Reservation Office by calling 1-800-453-3000, by emailing lodging@snowbird.com or via the web link

https://reservations.snowbird.com/default.aspx?p=&group=2bZ3BS&bookingstep=1

Please also pass your travel information to the hotel.

This block-booking is kept until June 28th. If you need an extension to this deadline please let us know (Cliff Lodge – Canyon or Mountain View Bedroom).

The resort is located near to Salt Lake City, and will provide transport from Salt Lake City International Airport. Upon arrival at the Salt Lake International Airport, attendees should check-in at the Canyon Transportation airport shuttle desk. The Canyon Transportation can also take participants after the workshop to a designated location near the SETAC venue.

Additional details regarding the facilities provided at the Snowbird Resort can be found at: http://www.snowbirdmeetings.com

Your economy travel costs (which should not exceed EUR 1300 without prior approval from ECETOC office) and accommodation at the workshop hotel will be reimbursed by the organisers.

I do hope that you will be able to accept this invitation, but if unable to attend you may also use the online form to opt to be kept informed of the outcome of the workshop.

We look forward to hearing from you soon.

Best regards,

[redacted]

[redacted]
ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals)
2 avenue E. Van Nieuwenhuyse

B-1160 Brussels

Tel +32 2 [redacted]

E-mail [redacted]@ecetoc.org

www.ecetoc.org

Sent on behalf of [redacted] by

[redacted] | Administrative Assistant
European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)
Avenue E. Van Nieuwenhuyse 2, (box 8) | B-1160 Brussels | Belgium
Tel: +32 2 [redacted] | Fax: +32 [redacted] 5
E-mail: [redacted]@ecetoc.org | Website: www.ecetoc.org

Overal 10.2.e

Doc. 21

From: [redacted]@basf.com
To: [redacted]@efsa.europa.eu; [redacted]@rivm.nl; [redacted]@ime.fraunhofer.de
Cc: [redacted]@battelleuk.com
Subject: ECPA TDS data sets for EFSA opinion on TDS guidance
Date: 29-06-2015 16:40

Dear all,

I write this email on behalf of the ECPA TDS working group that commissioned the testing of real TDS data sets for guideline testing to Battelle where Ian Hardy prepared a report which was also submitted to EFSA.

During the Fresenius conference it was mentioned that a final evaluation of the procedure how to include TDS as higher tier for leaching calculations was not possible since the EFSA working group on this topic did not receive the necessary data from industry. However, the request was never directed to the data owner which would have to compile and make available the needed data. Ian Hardy forwarded the request to us and we responded that we would be willing to provide the data sets if possible but we would need to know what data and how many of the data are needed. Although Ian tried several times to find out we did not get a list of what exactly is required by EFSA.

Since this seems to be a crucial point for the further process and finally for a successful implementation of TDS in the exposure assessment I hope that this Email will improve the communication and I propose the following steps:

1. The EFSA working group compiles a list of which data are needed for further evaluation of the guidance: Please specify how many data sets are needed, what a data set is (one soil, all soils with one substance, ???) what additional data not included in the Battelle evaluation are necessary.
2. [redacted] selects the most appropriate data sets for the EFSA evaluation due to his experience with the test of the guidance
3. ECPA checks whether the requested data (TDS + other data) can be made available.
4. ECPA provides the necessary data
5.

ECPA can do the data checking, compiling and making available of the data at relatively short notice. However, as mentioned, we need to know what is required. The data used for the ECPA evaluations of Battelle are readily available and already provided to FERA for their evaluations. These data would have been directly available to EFSA but it was indicated that additional data were required.

I hope that this Email will help to finally come to a recommendation how TDS can be used in leaching modelling as well as in other areas. It was a tremendous effort for all FERA, Battelle and ECPA to reach the current status on knowledge about TDS. It would be a huge waste of resources if the use of TDS would be further delayed to an unknown time frame.

Best regards, [redacted] on behalf of the ECPA TDS working group

Mit freundlichen Grüßen - Best regards
[redacted]

Phone: +49 [redacted] Mobile: +49 [redacted] Fax: +49 [redacted] E-Mail: [redacted]@basf.com
Postal Address: BASF SE, APD/EF - LI444, 67117 Limburgerhof, Germany

Overal 10.2.e

Doc. 22

From: [redacted]
To: [redacted]
Cc: [redacted]
Subject: visit to BfR and summer academy
Date: 21-08-2015 14:24

Dag allen,

Ik ben deze week op bezoek geweest bij de BfR, deels op hun verzoek om een training te geven tijdens de zogenaamde BfR summer school.
In het kader van EuroMix werkzaamheden heb ik een aantal mensen op gezocht.

Tijdens de meeting met [redacted], centrumhood voedselveiligheid, kwamen daarbij een aantal algmene onderwerpen van samenwerking tussen BfR en RIVM ter sprake, die op julie terrein liggen.

[redacted] en ik hebben al eerder met BfR gesproken over het samen op trekken aangaande het verzamelen en intepreteren van processing factoren voor het verfijnen van dietary risk assessment. @[redacted] leek het een goed idee om daar voor rekening mee te houden in de kennisvragen. Ik stuur je nog een vergaderverzoek om daarover bij te praten, indien nodig.

Daarnaast is deze afdeling ook geinteresseerd in het gebruik van ConsEXPO voor de beoordeling van Biociden. Ik heb aan gegeven dat ik niet over ConsEXPO ga, maar het aan [redacted] en [redacted] zou doorgeven. Voor zover ik weet heeft BfR in de persoon van [redacted] gebruik gemaakt van ConsEXPO in het kader van non-dietary exposure voor contaminanten. [redacted] zijn vraag gaat over Biociden en [redacted] werkt in hij werkt in een andere centrum/department. Zie hieronder zijn verzoek voor gebruik ConsExpo2015.0 as a tool developed within RIVM for exposure assessment,
standard tool for refinement within the tiered approach used for biocide exposure.

@[redacted] en [redacted], ik laat het aan jullie om daar wel/niet iets mee te doen. Volgens mij zit [redacted] te ver weg van [redacted] en kun je overwegen om hem algemene informatie over ConsEXPO en gesprekken met BfR, en een voorbeeld berekening aangaande biocide toe te sturen.

Groet,

[redacted]
National Institute for Public Health and the Environment (RIVM)
P.O. Box 1 3720 BA, Bilthoven
The Netherlands
tel: + 31 - (0)30 - [redacted]
mobile + 31 - (0)6 - [redacted]
E-mail: [redacted]@rivm.nl
----- Forwarded by [redacted]/RIVM/NL on 08/21/2015 02:06 PM -----

From: [redacted]@bfr.bund.de>
To: [redacted]@rivm.nl>,
Cc: [redacted]@bfr.bund.de>, "[redacted]@bfr.bund.de>, [redacted]@bfr.bund.de>, [redacted]@bfr.bund.de>, "[redacted]@bfr.bund.de>, [redacted]@bfr.bund.de>
Date: 08/06/2015 01:14 PM
Subject: Antw: visit to BfR and summer academy

Doc. 22

Dear [redacted]
I would very much appreciate, if you could visit my departement on Wednesday 19th.
Please give me a replay, what is you time window, I will have a meeting with my ministry from 15:00 h.

Because BfR is preparing a plan for Co-operation with RIVM if would be very helpful, if we could discuss some issues with regard to this working programme as well as the EUROMIX project.

I am interested to discuss the following issues as you proposed:

Issues for cooperation BfR - RIVM
review of dermal adsorption factors provided by industry to EFSA (and BfR)
BfR plans to finalize and validate work on processing factors
(BfR is currently compiling the outcome of all of the processing studies (processing factors) which have been submitted in the framework of applications for authorization of plant protection products; supplemented by further data e.g. processing data from industry (peel/pulp). A joint effort including validation of the data and particularly feeding the data into other projects like ACROPOLIS would be a promising project between BfR and RIVM.)
BfR is interested to join the Acropolis working group as an active member.
(For the next ACROPOLIS step the BfR is interested in joining the project to provide useful support with data (consumption data, recipes data, non-dietary exposure data) and by participating in specific work packages especially for consumer or operator exposure. Details should be set up when the next ACROPOLIS step is in preparation.)
RIVM for DG SANTE to implement the ACROPOLIS achievement
training for specific issues (e.g. an AOP training course at RIVM which is planned).
Further cooperation in practical examples using MCRA, especially for an assessment of German Monitoring data from 2009-2014 and for non-dietary exposure.
ConsExpo2015.0 as a tool developed within RIVM for exposure assessment, standard tool for refinement within the tiered approach used for biocide exposure.

EUROMIX
integration of BfR into WP4 for non-dietary exposure assessment procedures and working groups of OECD, ECHA, EFSA and DG SANTE in WP9.

relevance of the Adverse Outcome Pathway work (wiki) - how we should apply it to
EuroMix achievements

[redacted]

Bundesinstitut für Risikobewertung
Leitung der Abteilung Chemikaliensicherheit

Federal Institute for Risk Assessment
Head of Department Chemical Safety

Max-Dohrn-Straße 8-10,
10589 Berlin,
Tel.: +49 30 [redacted]
Fax: +49 30
www.bfr.bund

>

Doc. 23

Overal 10.2.e

From: [redacted]
To: [redacted]@rivm.nl)
Cc: [redacted]
Subject: AW: Format of Session - AgChem Forum
Date: 24-08-2015 12:04

Dear all,

would it be possible about equal time for the 3 talks? I don´t know whether [redacted] can squeeze the Dutch developments into 10 min – but for me it would certainly be a bit challenging, since I intend not only to cover the Dutch situation but also to address a little bit the situation in other member states and EU.
Regarding the "dialog" I would prefer sequential presentations by [redacted] and me. Doing this as a true dialog would only make sense if could focus on 1 specific topic (e.g. the GEM model) and as explained above I would like to give the presentation a broader scope.

I have no problem to exchange with [redacted] presentations before the meeting, so we can avoid duplications.

Freundliche Grüße / Best regards,
[redacted]
Head of Environmental Modelling

Bayer CropScience

Science For A Better Life
Bayer CropScience Aktiengesellschaft
BCS AG-R&D-D-EnSa-EMod
Monheim, 6690
Tel: +49 [redacted]
Mobil: +49 [redacted]

E-mail: [redacted]@bayer.com
Web: www.cropscience.bayer.com
Vorstand: Liam Condon, Vorsitzender | Bernd Naaf, Michael A. Schulz
Vorsitzender des Aufsichtsrats: Werner Baumann
Sitz der Gesellschaft: Monheim am Rhein | Eintragung: Amtsgericht Düsseldorf, HRB 46985

Von: [redacted] [mailto:[redacted]@informa.com]
Gesendet: Montag, 24. August 2015 10:26
An: [redacted]@rivm.nl)
Cc: [redacted]
Betreff: RE: Format of Session - AgChem Forum

Dear [redacted]

Many thanks for your email. Here is the outline you all submitted for each of your talks, so in terms content that is as much as I know for each talk.

09.35 **EFSA Working Group: New EFSA Scientific Guidance Document on Protected Crops (Greenhouses and Crops Grown Under Cover) to Relevant Environmental Compartments**

- Protected crops: The science behind the guidance
- Emissions from green house to surface water, ground water and air: Risk assessment
- What tools should industry be using to implement this?

Ton van der Linden, Senior Scientist Pesticide Research, **RIVM,** The Netherlands

10.10 Morning Coffee & Exhibition Viewing

DUAL DIALOGUE

10.40 **Implementation of the EFSA Guidance on Covered Crops at Member State Level: Developments in The Netherlands**

- The Greenhouse Emission Model (GEM): Substrate cultivation and soil-bound cultivation
- Background of the scenarios in GEM
- Results of calculations with model substances

[redacted], Environmental Fate Scientist, **Alterra (Wageningen UR)**, The Netherlands

An Industry View on the Implementation of the New EFSA Scientific Guidance Document on Emissions from Protected Crops (Greenhouses)

- How to address requirements from EFSA and MS
- How should the risk assessment be carried out?
- Tools used to implement the guidance

[redacted], Head of Environmental Modelling, **Bayer CropScience AG**, Germany

We do need to keep the times as they are but apart from that we are flexible with the format of this session so I am happy to structure in anyway which you all think is best. My original plan was for [redacted] to present first from 09:35 – 11:10 to give EFSAs perspective and then [redacted] and [redacted] to present either together or one after each other from 10:40-11:15 but I can change this if you wish?

Best wishes

[redacted]

From: [redacted] [mailto:[redacted]@wur.nl]
Sent: 21 August 2015 16:52
To: [redacted]@bayer.com; [redacted]@rivm.nl)
Cc: [redacted]
Subject: RE: Format of Session - AgChem Forum

Dear [redacted]

Thank you for sending the information and guidelines. I am kind of puzzled though. The presentation of [redacted], planned before the dual dialogue session seems to be one of three presentations on Covered Crops. Wouldn't it be more effective to put the three presentations together in one dialogue session? What is it that the organisation would like to achieve with the dual dialogue session related to this particular topic?

Or is it that the session of [redacted] is about all covered crops (also plastic tunnels etc.) and that the dialogue session should focus on protected crops, such as greenhouse crops?

[redacted] and [redacted], I would be pleased if you could give also your view on this.

Kind regards, [redacted]

From: [redacted] [mailto:[redacted]@informa.com]
Sent: maandag 13 juli 2015 17:16
To: [redacted]@bayer.com
Cc: [redacted]
Subject: Format of Session - AgChem Forum

Dear [redacted] and [redacted]

I hope you are well. I wanted to put you in contact with each other so that you can discuss your

session at AgChem Forum as outlined below.

The session will last for 35mins, including Q&A. With regards to the format, we are flexible with this and happy for you to divide in any way that you think best suits the topic. I suggest you each present for 15 minutes each leaving 5 minutes at the end for Q&A.

DUAL DIALOGUE
10.40 **Implementation of the EFSA Guidance on Covered Crops at Member State Level: Developments in The Netherlands**
- The Greenhouse Emission Model (GEM): Substrate cultivation and soil-bound cultivation
- Background of the scenarios in GEM
- Results of calculations with model substances

[redacted], Environmental Fate Scientist, **Alterra (Wageningen UR),** The Netherlands

An Industry View on the Implementation of the New EFSA Scientific Guidance Document on Emissions from Protected Crops (Greenhouses)
- How to address requirements from EFSA and MS
- How should the risk assessment be carried out?
- Tools used to implement the guidance

[redacted], Head of Environmental Modelling, **Bayer CropScience AG,** Germany

Please let me know if you have any questions. I look forward to seeing you at the event.

Best wishes

[redacted]

[redacted]
Conference Director
informa
life sciences
an **Informa** business

Maple House | 149 Tottenham Court Road | London | W1T 7AD
Direct line: +44 (0) 20 [redacted]
Switchboard: +44 (0) 20 [redacted]
Fax: +44 (0) 20 [redacted]
[redacted]@informa.com
www.informa-ls.com

Upcoming Events:

Crops and Chemicals USA
July 21-24, 2015, Raleigh, North Carolina, USA
www.cropsandchemicalsusa.com

AgChem Fourm
23-24 September 2015, Barcelona, Spain

www.agchemforum.com

Overal 10.2.e

Doc. 24

From: [redacted]
To: [redacted]@rivm.nl
Cc: [redacted]
Subject: LRI-ECO31: Develop testing approaches / strategies to provide relevant abiotic and biotic half-lives and confidence around those rates
Date: 26-08-2015 15:35

Dear [redacted],

I would like to kindly ask you to confirm your availability on **October 14th,** to participate in the Selection Team meeting (from 10:30 until 16:30, location to be confirm) for the ***LRI-ECO31: Develop testing approaches / strategies to provide relevant abiotic and biotic half-lives and confidence around those rates.***

Thank you in advance.

Best regards,

[redacted]

[redacted] | Administrative Assistant
European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)
Avenue E. Van Nieuwenhuyse 2, (box 8) | B-1160 Brussels | Belgium
VAT BE 0418 344 469 | Tel: +32 [redacted] | Fax: +32 2 [redacted]
E-mail: [redacted]@ecetoc.org | Website: www.ecetoc.org

From: [redacted]
Sent: 18 August 2015 13:44
To: [redacted]'
Cc: [redacted]
Subject: LRI-ECO31: Develop testing approaches / strategies to provide relevant abiotic and biotic half-lives and confidence around those rates
Importance: High

Dear [redacted],

Thank you for the positive response.

At this stage, we would like to ask you to be part of the selection team only.

The selection procedure, in general terms, is as follows:

- We receive from the LRi the submitted proposals for review, some days after the deadline which this year is September 6th.
- We in turn, send the proposals to the selection team members for reviewing.
- Reviewers need to send us their assessments (we provide a form with a series of criteria to be followed) prior to the face to face meeting.
- At the face to face meeting, all the projects are discussed in detail and a decision is made on the best one. The length of this meeting would depend among other things, on the numbers of proposals submitted. We have been very fortunate to receive very good proposals and sometimes the decision is not easy.
- The face to face meeting for this Selection Team is **October 14th**. Details of the location will be sent shortly.

I hope this email answers you questions and please feel free to contact me for any further inquiries.

Best regards,

[redacted] | Administrative Assistant
European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)
Avenue E. Van Nieuwenhuyse 2, (box 8) | B-1160 Brussels | Belgium
VAT BE 0418 344 469 | Tel: +32 [redacted] | Fax: +32 [redacted]
E-mail: [redacted]@ecetoc.org | Website: www.ecetoc.org

From: [redacted] [mailto:[redacted]@rivm.nl]
Sent: 17 August 2015 13:46

Doc. 24

To: [redacted]
Cc: [redacted]
Subject: Re: Reminder - LRI-ECO31: Develop testing approaches / strategies to provide relevant abiotic and biotic half-lives and confidence around those rates

Dear [redacted],

Sorry for the delay in response. This was mainly due to non-simultaneous absence of myself and other people because of summer vacation. If still relevant, I'm interested in taking part in the review team of LRI-ECO31 on the same terms as I did before for LRI-ECO012 (advisory role, non-funded). Could you please give some more information what is expected from me: is it to take part in a review team (as in LRI-ECO012) to advise upon the work being carried out or has it not yet been decided who is the contractor and is the invitation meant as a selection team for that purpose only? Do you have an idea of the time it will take (e.g. how many meeting, place of the meetings etc.)?
Looking forward to hear from you.

Best regards, [redacted]

From: [redacted]@ecetoc.org>
To: [redacted]@rivm.nl" <[redacted]@rivm.nl>,
Cc: [redacted]@ecetoc.org>, [redacted]@ecetoc.org>
Date: 08/13/2015 05:36 PM
Subject: Reminder - LRI-ECO31: Develop testing approaches / strategies to provide relevant abiotic and biotic half-lives and confidence around those rates

---

Dear [redacted],
I would like to remind you of the invitation to be considered as part of the team reviewing **LRI-ECO31: Develop testing approaches / strategies to provide relevant abiotic and biotic half-lives and confidence around those rates. Deadline: 6 September 2015** (see http://www.cefic-lri.org/request-for-proposals)

All the details can be found in the original email below.

Can you kindly let us know, by tomorrow **August 14th**, whether you would be able to be part of this selection team?

Please if you cannot manage, kindly let us know.

Best regards,

[redacted]

[redacted] | Administrative Assistant
European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)
Avenue E. Van Nieuwenhuyse 2, (box 8) | B-1160 Brussels | Belgium
Tel: +32 2 [redacted] | Fax: +32 2 [redacted]

Doc. 24

E-mail: [redacted]@ecetoc.org| Website: www.ecetoc.org

From: [redacted]
Sent: 29 June 2015 17:31
Cc: [redacted]
Subject: FW: LRI-ECO31: Develop testing approaches / strategies to provide relevant abiotic and biotic half-lives and confidence around those rates
Importance: High

Dear Colleague,

As you probably know, the 2015 LRI Requests for Proposals are now advertised on the Cefic LRI website and the Selection Teams are being set up.
I would like to invite you to provide your availability to be considered as part of the team reviewing **LRI-ECO31: Develop testing approaches / strategies to provide relevant abiotic and biotic half-lives and confidence around those rates. Deadline: 6 September 2015** (see http://www.cefic-lri.org/request-for-proposals)

Please note this invitation does not constitute an unconditional offer to be part of the reviewing team. ECETOC must complete its internal procedures prior to confirming the appointment. Please also note that if you or a member of your company / institution has submitted an application for this project, you will not be able to participate in the selection team.
The Selection Team will meet during September/October.

Could you provide your availabilities by ***Friday July 31st*** for the following dates:

- September 30th
- October 1st
- October 2nd
- October 14th
- October 15th
- October 16th

Thank you in advance and I look forward to hearing from you.

Best regards,

[redacted]

[redacted]

Environmental Science Manager
ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals)

4 avenue E. Van Nieuwenhuyse
B-1160 Brussels
Tel +32 2 - [redacted]
Fax +32 2 - [redacted]
E-mail: [redacted]@ecetoc.org
www.ecetoc.org

Doc. 25

Overal 10.2.e

From: [redacted]
To: [redacted]
Cc: [redacted]
Subject: RE: Cefic ESAP meeting 20 November 2015 - 09h00 to 15h30 at Le Plaza Hotel Brussels
Date: 29-09-2015 15:06

[redacted]

select the dates first on the bottom left window "your selection", then only go click on "book room" and it should work...
Cheers,

[redacted]
http://www.youtube.com/watch?v=7bV0yP5dBq8

LRI The Long-range Research Initiative

[redacted]
Research & Innovation
Long Range Research Initiative (LRI) Programme Manager
CEFIC - The European Chemical Industry Council
4 Avenue E. Van Nieuwenhuyse
B-1160 Brussels
Tel +32 2 [redacted]
Fax +32 2 [redacted]

www.cefic.be www.cefic-lri.org **Visit our new LRI website!**

About LRI
Launched 17 years ago, the Long-Range Research Initiative (LRI) is one of the major voluntary initiatives of the European chemical industry to support its competitiveness and innovation potential. LRI aims to identify and fill gaps in our understanding of the hazards posed by chemicals and to improve the methods available for assessing the associated risks.
LRI sponsors high-quality research, published in peer-reviewed journals, and seeks to provide sound scientific advice on which industry and regulatory bodies will draw to respond more quickly and accurately to the public's concerns.

From: [redacted] [mailto:[redacted]@rivm.nl]
Sent: Monday, 28 September 2015 15:29
To: [redacted]
Subject: Re: Cefic ESAP meeting 20 November 2015 - 09h00 to 15h30 at Le Plaza Hotel Brussels

Dear [redacted], I'm happy to attend the diner and meeting. I cannot use the reservation link; it only allows arrival on the 17th and departure on the 18th..... [redacted]

From: [redacted]@cefic.be>
To: [redacted]@cefic.be>, '[redacted] - Istituto di Ricerche Farmacologiche \"Mario Negri\"" [redacted]@marionegri.it>, [redacted] - Uppsala University" <[redacted]@stanford.edu>, '[redacted] - University of Amsterdam" [redacted]@rivm.vu.nl>, [redacted] - University of Newcastle" [redacted]@newcastle.ac.uk>, [redacted] - IUF (Institut für umweltmedizinische Forschung an der Heinrich-Heine-Universität Düsseldorf gGmbH) [redacted]@uni-duesseldorf.de>, [redacted] - Università degli studi di Milano <[redacted]@unimi.it>, [redacted]@ineris.fr>, [redacted] - University of Manchester [redacted]@manchester.ac.uk>, '[redacted] - RIVM (National Institute for Public Health and the Environment)" [redacted]@uu.nl>, '[redacted]@rivm.nl>, [redacted] - VITO [redacted]@vito.be>, '[redacted] - ETH (Swiss Federal Institute of Technology)" [redacted]@ethz.ch>,
Cc: [redacted]@cefic.be>, [redacted]@cefic.be>, [redacted]@cefic.be>, [redacted] - Unilever Research <[redacted]@unilever.com>, [redacted]@cefic.be>
Date: 24-09-2015 14:52
Subject: Cefic ESAP meeting 20 November 2015 - 09h00 to 15h30 at Le Plaza Hotel Brussels

---

Doc. 25

Dear ESAP members,

As mentioned earlier, this confirms that our next ESAP meeting will take place on **Nov 20, from 09h00 to 15h30 at Le Plaza Hotel Brussels**.

Le Plaza Hotel Brussels
Blvd Adolphe Max 118-126
1000 Brussels, Belgium
Tel. +32 2 278 01 00
reservations@leplaza.be

We have a block booking at discounted rate. This is the link to « Le Plaza » Hotel in order to book the accommodations at the special Cefic rate :
www.leplaza-brussels.com/en/special/lriworkshop
This is by the way the same location as the LRI Workshop (Nov 18-19).

I would also like to invite you also to our usual **informal dinner on Nov 19 at 19h30, at the same Le Plaza Hotel Brussels**.

Can you please already confirm your attendance (or not) to the meeting and to the dinner?
You will find attached to this message:
1) Minutes. **Pl have a look at the action list on the top page and follow those with your name**.
2) The Cefic partner hotels' list – please feel free to book your stay at your best convenience

The **agenda is in preparation** and will be sent asap. Let me know if you have any particular request or items to cover. One item that I would like to cover is what your thoughts are on new/emerging scientific issues in your areas of expertise, that could be potentially relevant for LRI to look at for a future/hypothetical policy impact. Things that LRI doesn't really do already. For instance, one item I pick up a recent SOT's is the significance on non-coding RNA's for chemical risk assessment. How could this impact the way toxicogenomics are tested in interpreted? This as a way example. So if you could warp your thoughts about this new/emerging scientific issues in your areas of expertise and spend each 5 minutes giving your views in a tour the table. This fits with the discussion we had in June about Cefic's expectations on panel members. The outcome of this could then be spinned at the LRI SIG level for further discussion.

Many thanks for your confirmation already and looking forward to see you again.
Cheers,

[redacted]
http://www.youtube.com/watch?v=7bV0yP5dBq8

[redacted]
Research & Innovation
Long Range Research Initiative (LRI) Programme Manager
CEFIC - The European Chemical Industry Council
4 Avenue E. Van Nieuwenhuyse
B-1160 Brussels
Tel +32 2 [redacted]
Fax +32 2 [redacted]
www.cefic.be www.cefic-lri.org **Visit our new LRI website!**

About LRI

Launched 17 years ago, the Long-Range Research Initiative (LRI) is one of the major voluntary initiatives of the European chemical industry to support its competitiveness and innovation potential. LRI aims to identify and fill gaps in our understanding of the hazards posed by chemicals and to improve the methods available for assessing the associated risks.

LRI sponsors high-quality research, published in peer-reviewed journals, and seeks to provide sound scientific advice on which industry and regulatory bodies will draw to respond more quickly and accurately to the public's concerns.

Be green - keep it on screen[attachment "Cefic Partner_Hotels_in_Brussels-_2015.xls" deleted by Erik Lebret/RIVM/NL] [attachment "150602 ESAP Draft minutes.docx" deleted by Erik Lebret/RIVM/NL]

Overal 10.2.e

Doc. 26

From: [redacted]
Reply To:
To: [redacted]@rivm.nl
Cc: [redacted]/rivm/nl@rivm; [redacted]/rivm/nl@rivm; [redacted]s/rivm/nl@rivm; [redacted]/rivm/nl@rivm; [redacted]/rivm/nl@rivm; [redacted]/rivm/nl@rivm
Subject: Re: Fw: Expert Meeting to reach Scientific Consensus on Endocrine Disruptors
Date: 06-10-2015 22:29

Wil ik wel organiseren. Had het vandaag met [redacted] ook al erover dat we binnenkort een afstemming nodig hebben binnen rivm over te volgen algemene lijn op ED..

Delivered to you by RIVM Mobile environment.

--Original message---
Sender: [redacted]@rivm.nl
Time: Tue Oct 06 17:42:00 CEST 2015
Cc: [redacted]/rivm/nl@rivm, [redacted]/rivm/nl@rivm, [redacted]/rivm/nl@rivm, [redacted]/rivm/nl@rivm, [redacted]/rivm/nl@rivm, [redacted]/rivm/nl@rivm, [redacted]/rivm/nl@rivm,
Subject: Re: Fw: Expert Meeting to reach Scientific Consensus on Endocrine Disruptors

Ha [redacted]

Lijkt me heel belangrijk om aan mee te doen, fijn dat je hiervoor gevraagd bent. En met de personen in het organiserend committee heb je ook alle extremen in opvattingen wel afgedekt, dus het lijkt me dat de kans op een gebalanceerde uitkomst aanwezig is.

Interne afstemming voorafgaand aan de expert meeting is natuurlijk belangrijk, zoals je zelf ook aangeeft. De meeting is op 14/15 december zie ik dus dat is best kort dag. Lijkt me belangrijk om snel eind november of zo tijd te reserveren bij de leden van de ED groep. Wie regelt dit ook al weer op het moment?

Groet,
[redacted]

[redacted]
RIVM/Centre for Nutrition, Prevention and Health Services (VPZ)
PO Box 1, 3720 BA Bilthoven
The Netherlands
tel. +31 30 [redacted], fax +31 [redacted]
mobile +31 6 [redacted]
E-mail: [redacted]@rivm.nl

Not available on Wednesdays

[redacted]---06-10-2015 16:43:14---Beste allen, Bijgaand een uitnodiging aan mijn adres om een expert meeting bij te wonen om te komen

From: [redacted]/RIVM/NL
To: [redacted]@RIVM, [redacted]@RIVM, [redacted]@RIVM, [redacted]@RIVM, [redacted]@RIVM,
Cc: [redacted]/RIVM/NL@RIVM, [redacted]/RIVM/NL@RIVM
Date: 06-10-2015 16:43
Subject: Fw: Expert Meeting to reach Scientific Consensus on Endocrine Disruptors

---

Beste allen,

Bijgaand een uitnodiging aan mijn adres om een expert meeting bij te wonen om te komen tot "scientific consensus on endocrine disrupters". Er is een beperkte groep experts uitgenodigd, zie bijgaande email. Ik heb dit afgestemd met [redacted] en we stellen voor dat ik de uitnodiging accepteer. Het is belangrijk dat we hier dicht bij het vuur zitten en meedenken met de wetenschappelijke consensusvorming op dit gebied. Ik stel voor om vooraf aan de workshop nog eens samen te zitten met onze ED groep om mijn inbreng af te stemmen.

Groet,
[redacted]

[redacted]
Center for Health Protection
National Institute for Public Health and the Environment RIVM
Antonie van Leeuwenhoeklaan 9
P.O.Box 1
3720 BA Bilthoven
The Netherlands
phone +31 30 [redacted]
email [redacted]@rivm.nl

----- Forwarded by [redacted]/RIVM/NL on 06-10-2015 13:39 -----

From: "biozid" <biozid@bfr.bund.de>
To: [redacted]@abdn.ac.uk>, <[redacted]@anses.fr>, '[redacted]@bfr.bund.de>, [redacted]@bio.umass.edu>, <[redacted]@brunel.ac.uk>, [redacted]@brunel.ac.uk>, [redacted]@charite.de>, [redacted]@ec.europa.eu>, <[redacted]@ec.europa.eu>, [redacted]@ed.ac.uk>, <[redacted]@efsa.europa.eu>, [redacted]@epa.gov>, [redacted]@few.vu.nl>, <[redacted]@thi.no>, [redacted]@food.dtu.dk>, [redacted]@ifado.de>, [redacted]@imperial.ac.uk>, [redacted]@iss.it>, [redacted]@ki.se>, [redacted]@lrz.tu-muenchen.de>, [redacted]@ph.au.dk>, [redacted]@rh.regionh.dk>, [redacted]@rivm.nl>, [redacted]@swetox.se>, [redacted]@toxi.uni-wuerzburg.de>, [redacted]@ujf-grenoble.fr>, [redacted]@uni-konstanz.de>, [redacted]@utu.fi>, [redacted]@uu.nl>, [redacted]@uu.nl>,
Date: 02-10-2015 10:57
Subject: Expert Meeting to reach Scientific Consensus on Endocrine Disruptors

---

Dear Colleagues,

Please find attached the invitation to the Expert Meeting to reach Scientific Consensus on Endocrine Disruptors.

Best regards

[redacted]

Bundesinstitut für Risikobewertung
Fachgruppe Steuerung und Gesamtbewertung Biozide
Abteilung Sicherheit von Pestiziden

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

Doc. 27

Overal 10.2.e

From: [redacted]
To: [redacted]
Subject: RE: Betr: Availability on Thursday Afternoon
Date: 06-10-2015 18:23

Dear [redacted]

Thanks for the quick reply when you are so busy. I will suggest to [redacted] that we hold the meeting at the previous time to give you more time to give us written comments prior to the call. I am sorry that we were unable to find a time when everyone could join.

Regards,
[redacted]

From: [redacted] [mailto[redacted]@rivm.nl]
Sent: Tuesday, October 06, 2015 12:05 PM
To: [redacted]
Subject: Betr: Availability on Thursday Afternoon

Dear [redacted]
Sorry, but Thursday is not possible for me. There is an EFSA / ECHA meeting in Helsinki. I just arrived here. These two weeks are really busy. I will try to deliver remarks by mail.
Kind regards,
[redacted]

----- [redacted]@bayer.com> schreef: -----
Aan: "[redacted]@rivm.nl" [redacted]@rivm.nl>
Van: [redacted]@bayer.com>
Datum: 10/06/2015 12:50PM
Onderwerp: Availability on Thursday Afternoon

Dear [redacted]

As you probably saw, after I sent out the invitation for the conference call that you could not make, [redacted] indicated that this Thursday was also a possibility so we could include you. Are you available for a call this Thursday afternoon? If so I will change the call to Thursday. I sent out a new Doodle but since everyone else has replied all I need is your availability which you can provide by e-mail if this is more convenient.

Regards,
[redacted]

Doc. 28

Overal 10.2.e

From: [redacted]
To: [redacted]
Subject: Fw: ILSI North America Invitation to Risk-Based Assessment of Mycotoxins Mitigation Symposium at WMFmeetsIUPAC2016
Date: 28-10-2015 11:50
Attachments: image001.emz
image002.emz
image003.emz
image007.png
Draft Agenda ILSI North America Mycotoxin Symposium.pdf

Hoi [redacted]

Omdat ons PO niet doorging gisteren, hebben we het ook niet over dit verzoek van ILSI kunnen hebben. Men heeft mij weer benaderd om snel een beslissing te nemen. Het leek me wel een goede mogelijkheid om te laten zien dat je voor dit soort vragen APROBA zou moeten gebruiken, omdat de output daarvan veel meer/betere informatie geeft om beslissingen te nemen die gebaseerd zijn op de beschikbare kennis (en afwezigheid daarvan).
Maar ik vermoed dat mijn agenda volgend jaar weer vol zal zijn, dus ik wil eigenlijk bedanken.

Als je hier anders over denkt laat je me dan even weten?

[redacted]

----- Forwarded by [redacted] /RIVM/NL on 10/28/2015 11:09 AM -----

From: [redacted] /RIVM/NL
To: [redacted] /RIVM/NL@RIVM,
Date: 10/22/2015 12:00 PM
Subject: Fw: ILSI North America Invitation to Risk-Based Assessment of Mycotoxins Mitigation Symposium at WMFmeetsIUPAC2016

Hoi B[redacted]

ik kreeg pas dit verzoek, kunnen we misschien dinsdag (PO) even over hebben

[redacted]

----- Forwarded by [redacted] /RIVM/NL on 10/22/2015 11:59 AM -----

From: [redacted] @ilsi.org>
To: [redacted] @rivm.nl" [redacted] @rivm.nl>,
Cc: [redacted] @ilsi.org>, [redacted] @ilsi.org>, [redacted] @abbott.com>
Date: 10/20/2015 08:28 PM
Subject: [Spam] ILSI North America Invitation to Risk-Based Assessment of Mycotoxins Mitigation Symposium at WMFmeetsIUPAC2016

Doc. 28

20 October 2015

[redacted]
Centre for Nutrition, Prevention and Care
National Institute for Public Health and the Environment (RIVM)
3720 BA, Bilthoven
The Netherlands

Dear [redacted],

On behalf of the ILSI North America Technical Committee on Food and Chemical Safety, we would like to extend an invitation to participate in a symposium on "Risk-Based Assessment of Mycotoxins Mitigation". The symposium will be presented on Thursday 9 June 2016 at the Combined Conference of The World Mycotoxin Forum and IUPAC International Symposium on Mycotoxins (WMFmeetsIUPAC2016) in Winnipeg, Canada, June 6-9, 2016.

Throughout history, humans have been exposed to mycotoxins that are inherent in many of the foods that are consumed as part of standard diets. Globally, mycotoxins have significant human health, economic and international trade implications. Only relatively recently, regulatory agencies have implemented food safety measures to reduce consumer exposure to mycotoxins with the ultimate goal of reducing risk. While consumer risk is the product of the hazard of the mycotoxins and the extent of exposure, efforts to reduce risk are focused solely on reducing exposure. Several approaches have been used by regulatory agencies, including: establishing regulatory limits, creating action levels, and developing codes of practice. Evaluating the impact of these mitigation efforts on human health must focus on overall risk, which is the product of hazard and exposure. Therefore, determining the success of mitigation efforts by solely focusing on exposure reduction does not accurately reflect whether there was an actual reduction in risk.

This symposium on "Risk-Based Assessment of Mycotoxins Mitigation" will build on the concepts from recent scientific efforts by the ILSI North America Technical Committee on

Food and Chemical Safety which resulted in a foundational framework (decision tree) to proactively evaluate the risk of compounds as opposed to their hazards. In May 2015, the Committee hosted a workshop to gain consensus within the scientific community on a framework which utilizes risk based decision making approach for mitigation efforts rather than just focusing on the ability to reduce exposure, as not all reductions in exposure result in a correlated reduction in risk. While initially designed to address process-formed compounds, such as acrylamide, participants at the workshop agreed that the concepts would apply to other classes of "not readily avoidable" compounds, such as mycotoxins. The outcome of the workshop was a decision tree that can be used by the scientific community and has enormous potential of being adopted as a global regulatory tool for evaluating the impact on risk caused by "not readily avoidable" compounds such as process-formed compounds, mycotoxins, and heavy metals (*workshop proceedings manuscript in preparation*).

The WMFmeetsIUPAC2016 conference provides an excellent forum to discuss the application of the decision tree to mycotoxins and assess whether it could aid in creating risk-based decisions for effective mycotoxin mitigation to reduce consumer risk. This symposium on "Risk-Based Assessment of Mycotoxins Mitigation" will focus on: (i) evaluating the impact of current mitigation efforts on the risk posed by mycotoxins (ii) mitigation of mycotoxins in the context of a proactive, risk-based decision approach, and (iii) determining the potential for incorporation of risk-based decision making into future mycotoxin mitigation efforts. A draft agenda for the symposium is attached.

If you accept our invitation, your presentation at the symposium is tentatively titled, **"Refining Hazard Assessment to Better Inform Mycotoxin Mitigation Efforts".** Additional details regarding the symposium can be found in the attached draft agenda.

A conference dinner will be held the night before the symposium, Wednesday, 8 June 2016.

To the extent permitted by your institution, ILSI North America will pay roundtrip coach or economy class airline travel expenses and three nights lodging to present at this symposium.

ILSI North America is a public, nonprofit foundation that provides a forum to advance understanding scientific issues related to the nutritional quality and safety of the food supply by sponsoring research programs, educational seminars and workshops, and publications. ILSI North America's scientific programs are guided in significant part by the expert advice and intellectual contributions of more than 50 academic advisors and government liaisons. We value these collaborative relationships very highly, because they bring a wealth of knowledge and experience, and a diversity of viewpoints, that ensure the precision, balance, and integrity of our work. The ILSI North America Technical Committee on Food and Chemical Safety promotes a science-based determination of the chemical safety of foods to support the advancement of public health.

We hope that you will be able to participate in our symposium at WMFmeetsIUPAC2016

conference. **Please RSVP to** [redacted] **(at** [redacted] ilsi.org) **by Friday 23 October whether or not you plan to attend**. If you are able to accept, Mansi will work with you to make your travel and hotel arrangements.

Thank you in advance for your consideration.

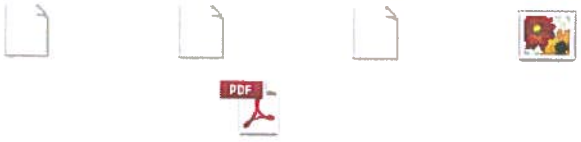
Kind regards,

[redacted]

Director, Science Programs, ILSI North America
1156 15th St. NW Suite 200
Washington, D.C. 20005

[redacted]

Science Program Manager, ILSI North America
1156 15th St. NW Suite 200
Washington, D.C. 20005



Doc. 29

Overal 10.2.e

From: [redacted]
To: [redacted]@rivm.nl
Cc: [redacted]@bastiaanse-communication.com; [redacted]
Subject: RE: REMINDER: ILSI North America Invitation to Risk-Based Assessment of Mycotoxins Mitigation Symposium at WMFmeetsIUPAC2016
Date: 29-10-2015 20:27

Dear [redacted]

We are disappointed that you will not be able to participate in the session. However, we would like to thank you for your valuable inputs on the case study to illustrate the applicability quantitative risk assessment tools that take uncertainties into account.

We look forward to future opportunities to discuss this important area of research.

Best Regards,
[redacted]

[redacted]
Science Program Manager
ILSI North America
1156 Fifteenth Street, NW
Suite 200
Washington, DC
20005-1743
[redacted]
[redacted]@ilsi.org

From: [redacted] [mailto[redacted]@rivm.nl]
Sent: Thursday, October 29, 2015 11:47 AM
To: [redacted]@ilsi.org>
Cc: [redacted]@bastiaanse-communication.com; [redacted]
[redacted]@rivm.nl>
Subject: Re: REMINDER: ILSI North America Invitation to Risk-Based Assessment of Mycotoxins Mitigation Symposium at WMFmeetsIUPAC2016

Dear [redacted]

I talked about this with [redacted] on the phone yesterday, and I explained here that I cannot really afford to spend a whole week or so to an unplanned activity. One reason is that I my agenda is very full (every year), the other is that normally my working hours need financial coverage, RIVM being a cost-based institute. By the way, RIVM is not able/willing to receive financial support from ILSI for reasons of conflict of interest.

[redacted] and I talked quite a while, and I told her that over the past years we have been developing tools for quantitative risk assessment that take uncertainties into account. These tools appear very suitable for answering questions that are relevant for unavoidable contaminants. These probabilistic approaches make clear what we know and what we do not know, in the quantitative sense, about the potential health effects in the population, and as such they could be very well applied to evaluate the possible impact of mitigation measures of mycotoxins (or other contaminants). My suggestion to [redacted] was that it would be more effective to first work out a short case study to illustrate how these tools could be usefully applied, and then present such a case study at the (next) mycotoxin

conference.

Right now we are finalizing a paper that describes the application of the probabilistic approach to some 25 compounds, and I promised [redacted] to send her a draft as soon as we submit. This might give her a better idea of what I have in mind, and this might serve as a stimulus to take initiatives int he direction just indicated.

I wish you a successful conference, and possibly we meet another time,

best wishes,
[redacted]

From: [redacted]@ilsi.org>
To: '[redacted]@rivm.nl" <[redacted]@rivm.nl>,
Date: 10/29/2015 03:11 PM
Subject: REMINDER: ILSI North America Invitation to Risk-Based Assessment of Mycotoxins Mitigation Symposium at WMFmeetsIUPAC2016

1156 Fifteenth Street, NW
Suite 200
Washington, DC 20005

1.202.[redacted] voice
1.202.659.3859 fax
www.ilsina.org

ILSI
North America

20 October 2015

[redacted]
Centre for Nutrition, Prevention and Care
National Institute for Public Health and the Environment (RIVM)
3720 BA, Bilthoven
The Netherlands

Dear [redacted],

On behalf of the ILSI North America Technical Committee on Food and Chemical Safety, we would like to extend an invitation to participate in a symposium on "Risk-Based Assessment of Mycotoxins Mitigation". The symposium will be presented on Thursday 9 June 2016 at the Combined Conference of The World Mycotoxin

Forum and IUPAC International Symposium on Mycotoxins (WMFmeetsIUPAC2016) in Winnipeg, Canada, June 6-9, 2016.

Throughout history, humans have been exposed to mycotoxins that are inherent in many of the foods that are consumed as part of standard diets. Globally, mycotoxins have significant human health, economic and international trade implications. Only relatively recently, regulatory agencies have implemented food safety measures to reduce consumer exposure to mycotoxins with the ultimate goal of reducing risk. While consumer risk is the product of the hazard of the mycotoxins and the extent of exposure, efforts to reduce risk are focused solely on reducing exposure. Several approaches have been used by regulatory agencies, including: establishing regulatory limits, creating action levels, and developing codes of practice. Evaluating the impact of these mitigation efforts on human health must focus on overall risk, which is the product of hazard and exposure. Therefore, determining the success of mitigation efforts by solely focusing on exposure reduction does not accurately reflect whether there was an actual reduction in risk.

This symposium on "Risk-Based Assessment of Mycotoxins Mitigation" will build on the concepts from recent scientific efforts by the ILSI North America Technical Committee on Food and Chemical Safety which resulted in a foundational framework (decision tree) to proactively evaluate the risk of compounds as opposed to their hazards. In May 2015, the Committee hosted a workshop to gain consensus within the scientific community on a framework which utilizes risk based decision making approach for mitigation efforts rather than just focusing on the ability to reduce exposure, as not all reductions in exposure result in a correlated reduction in risk. While initially designed to address process-formed compounds, such as acrylamide, participants at the workshop agreed that the concepts would apply to other classes of "not readily avoidable" compounds, such as mycotoxins. The outcome of the workshop was a decision tree that can be used by the scientific community and has enormous potential of being adopted as a global regulatory tool for evaluating the impact on risk caused by "not readily avoidable" compounds such as process-formed compounds, mycotoxins, and heavy metals (*workshop proceedings manuscript in preparation*).

The WMFmeetsIUPAC2016 conference provides an excellent forum to discuss the application of the decision tree to mycotoxins and assess whether it could aid in creating risk-based decisions for effective mycotoxin mitigation to reduce consumer risk. This symposium on "Risk-Based Assessment of Mycotoxins Mitigation" will focus on: (i) evaluating the impact of current mitigation efforts on the risk posed by mycotoxins (ii) mitigation of mycotoxins in the context of a proactive, risk-based decision approach, and (iii) determining the potential for incorporation of risk-based decision making into future mycotoxin mitigation efforts. A draft agenda for the symposium is attached.

If you accept our invitation, your presentation at the symposium is tentatively titled, **"Refining Hazard Assessment to Better Inform Mycotoxin Mitigation Efforts".** Additional details regarding the symposium can be found in the attached draft agenda.

A conference dinner will be held the night before the symposium, Wednesday, 8 June 2016.

To the extent permitted by your institution, ILSI North America will pay roundtrip coach or economy class airline travel expenses and three nights lodging to present at this symposium.

ILSI North America is a public, nonprofit foundation that provides a forum to advance understanding scientific issues related to the nutritional quality and safety of the food supply by sponsoring research programs, educational seminars and workshops, and publications. ILSI North America's scientific programs are guided in

significant part by the expert advice and intellectual contributions of more than 50 academic advisors and government liaisons. We value these collaborative relationships very highly, because they bring a wealth of knowledge and experience, and a diversity of viewpoints, that ensure the precision, balance, and integrity of our work. The ILSI North America Technical Committee on Food and Chemical Safety promotes a science-based determination of the chemical safety of foods to support the advancement of public health.

We hope that you will be able to participate in our symposium at WMFmeetsIUPAC2016 conference. **Please RSVP to** [redacted] **(at** [redacted]@ilsi.org) **by Friday 23 October whether or not you plan to attend.** If you are able to accept, [redacted] will work with you to make your travel and hotel arrangements.

Thank you in advance for your consideration.

Kind regards,

[redacted]
Director, Science Programs, ILSI North America
1156 15th St. NW Suite 200
Washington, D.C. 20005

[redacted]
Science Program Manager, ILSI North America
1156 15th St. NW Suite 200
Washington, D.C. 20005

Overal 10.2.e

Doc. 30

From: [redacted]
To: [redacted] - Istituto di Ricerche Farmacologiche \"Mario Negri\"; [redacted] Uppsala University; [redacted] - University of Amsterdam; [redacted] University of Newcastle; [redacted] - IUF (Institut für umweltmedizinische Forschung an der Heinrich-Heine-Universität Düsseldorf gGmbH); [redacted] - Università degli studi di Milano; [redacted] - University of Manchester; [redacted] - RIVM (National Institute for Public Health and the Environment); [redacted] ; [redacted] - VITO; [redacted] - ETH (Swiss Federal Institute of Technology)
Cc: [redacted] - Unilever Research; [redacted]
Subject: RE: Cefic ESAP meeting 20 November 2015 - 09h00 to 15h00 at Le Plaza Hotel Brussels
Date: 16-11-2015 15:55
Attachments: 151120 ESAP Draft Agenda NO DOCS.docx
20150602 ESAP template for Invoice Honorarium.doc
20150602 Expense claim ESAP meeting.xls

Dear ESAP,

pl see an update of our agenda for Nov 20 attached and via link for the fully document loaded version (16Mb)
http://sendit.cefic.org/DMZ/DownLoad.aspx?UID=b737bdb2-5d5f-46bd-9b32-5091a96a53cd

Please note
-The item "MoA EFSA, analyse the importance and applicability to mixtures" has been removed as [redacted] is not coming.
-Pl ensure you prepare for the tour de table "What are you aware of in terms of new research trends that could impact ongoing or lead to future policy discussions?" Five minutes each and a slide or two if needed can be shown (send to me preferably in advance)
-Areas of expertise will be covered. Still timely to fill the XL sheet in the agenda and send to me if not done yet (I have those of [redacted] (thx)). Feel free to add other entries in the areas if need be
-The meeting finishes at 3PM to allow better travel times

Attached invoice docs as well

See you later this week!
Cheers,

[redacted]
http://www.youtube.com/watch?v=7bV0yP5dBq8

LRI The Long-range Research Initiative
[redacted]
Research & Innovation
Long Range Research Initiative (LRI) Programme Manager
CEFIC - The European Chemical Industry Council
4 Avenue E. Van Nieuwenhuyse
B-1160 Brussels
Tel +32 2 [redacted]
Fax +32 2 [redacted]

www.cefic.be www.cefic-lri.org **Visit our new LRI website!**

About LRI
Launched 17 years ago, the Long-Range Research Initiative (LRI) is one of the major voluntary initiatives of the European chemical industry to support its competitiveness and innovation potential. LRI aims to identify and fill gaps in our understanding of the hazards posed by chemicals and to improve the methods available for assessing the associated risks.
LRI sponsors high-quality research, published in peer-reviewed journals, and seeks to provide sound scientific advice on which industry and regulatory bodies will draw to respond more quickly and accurately to the public's concerns.

From: [redacted]
Sent: Tuesday, 3 November 2015 13:08
To: [redacted] - Istituto di Ricerche Farmacologiche "Mario Negri"; [redacted] - Uppsala University; [redacted] - University of Amsterdam; [redacted] - University of Newcastle; [redacted] - IUF (Institut für umweltmedizinische Forschung an der Heinrich-Heine-Universität Düsseldorf gGmbH); [redacted] - Università degli studi di Milano'; [redacted] - University of Manchester; [redacted] - RIVM (National Institute for Public Health and the Environment); [redacted] '; [redacted] - VITO; [redacted] - ETH (Swiss Federal Institute of Technology)
Cc: [redacted] - Unilever Research; [redacted]
Subject: RE: Cefic ESAP meeting 20 November 2015 - 09h00 to 15h30 at Le Plaza Hotel Brussels

Dear ESAP,

pl see our agenda for Nov 20 attached and via link for the fully document loaded version (16Mb)
http://sendit.cefic.org/DMZ/DownLoad.aspx?UID=5b44b296-feec-4b7f-a1f5-6e6228818ec8

A number of items stem from the June discussion (specific items for [redacted], [redacted]: pl send me slides ahead of time as needed). Other points are new. Have a look, also on item 8 (tour de table) where some preparation is needed

We will all be present (a premiere!)

Many thanks already
Cheers.

[redacted]
http://www.youtube.com/watch?v=7bV0yP5dBq8

LRI
The Long-range Research Initiative
[redacted]
Research & Innovation
Long Range Research Initiative (LRI) Programme Manager
CEFIC - The European Chemical Industry Council
4 Avenue E. Van Nieuwenhuyse
B-1160 Brussels
Tel +32 2 6[redacted]
Fax +32 2[redacted]

www.cefic.be www.cefic-lri.org **Visit our new LRI website!**

About LRI
Launched 17 years ago, the Long-Range Research Initiative (LRI) is one of the major voluntary initiatives of the European chemical industry to support its competitiveness and innovation potential. LRI aims to identify and fill gaps in our understanding of the hazards posed by chemicals and to improve the methods available for assessing the associated risks.
LRI sponsors high-quality research, published in peer-reviewed journals, and seeks to provide sound scientific advice on which industry and regulatory bodies will draw to respond more quickly and accurately to the public's concerns.

From: [redacted]
Sent: Thursday, 24 September 2015 14:51
To: [redacted] - Istituto di Ricerche Farmacologiche "Mario Negri"; [redacted] - Uppsala University; [redacted] - University of Amsterdam; [redacted] - University of Newcastle; [redacted] - IUF (Institut für umweltmedizinische Forschung an der Heinrich-Heine-Universität Düsseldorf gGmbH); [redacted] - Università degli studi di Milano; [redacted];

[redacted] - University of Manchester; [redacted] - RIVM (National Institute for Public Health and the Environment); [redacted] - VITO; [redacted] - ETH (Swiss Federal Institute of Technology)
Cc: [redacted] - Unilever Research; [redacted]
Subject: Cefic ESAP meeting 20 November 2015 - 09h00 to 15h30 at Le Plaza Hotel Brussels

Dear ESAP members,

As mentioned earlier, this confirms that our next ESAP meeting will take place on **Nov 20, from 09h00 to 15h30 at Le Plaza Hotel Brussels**.

Le Plaza Hotel Brussels
Blvd Adolphe Max 118-126
1000 Brussels, Belgium
Tel. +32 2 278 01 00
reservations@leplaza.be

We have a block booking at discounted rate. This is the link to « Le Plaza » Hotel in order to book the accommodations at the special Cefic rate :
www.leplaza-brussels.com/en/special/lriworkshop
This is by the way the same location as the LRI Workshop (Nov 18-19).

I would also like to invite you also to our usual **informal dinner on Nov 19 at 19h30, at the same Le Plaza Hotel Brussels**.

Can you please already confirm your attendance (or not) to the meeting and to the dinner?
You will find attached to this message:

1) Minutes. **Pl have a look at the action list on the top page and follow those with your name**.
2) The Cefic partner hotels' list – please feel free to book your stay at your best convenience

The **agenda is in preparation** and will be sent asap. Let me know if you have any particular request or items to cover. One item that I would like to cover is what your thoughts are on new/emerging scientific issues in your areas of expertise, that could be potentially relevant for LRI to look at for a future/hypothetical policy impact. Things that LRI doesn't really do already. For instance, one item I pick up a recent SOT's is the significance on non-coding RNA's for chemical risk assessment. How could this impact the way toxicogenomics are tested in interpreted? This as a way example. So if you could warp your thoughts about this new/emerging scientific issues in your areas of expertise and spend each 5 minutes giving your views in a tour the table. This fits with the discussion we had in June about Cefic's expectations on panel members. The outcome of this could then be spinned at the LRI SIG level for further discussion.

Many thanks for your confirmation already and looking forward to see you again.
Cheers,

[redacted]
http://www.youtube.com/watch?v=7bV0yP5dBq8

LRI
The Long-range Research Initiative

Doc. 30

[redacted]
Research & Innovation
Long Range Research Initiative (LRI) Programme Manager
CEFIC - The European Chemical Industry Council
4 Avenue E. Van Nieuwenhuyse
B-1160 Brussels
Tel +32 2 [redacted]
Fax +32 2 [redacted]

www.cefic.be www.cefic-lri.org **Visit our new LRI website!**

About LRI

Launched 17 years ago, the Long-Range Research Initiative (LRI) is one of the major voluntary initiatives of the European chemical industry to support its competitiveness and innovation potential. LRI aims to identify and fill gaps in our understanding of the hazards posed by chemicals and to improve the methods available for assessing the associated risks.

LRI sponsors high-quality research, published in peer-reviewed journals, and seeks to provide sound scientific advice on which industry and regulatory bodies will draw to respond more quickly and accurately to the public's concerns.

Doc. 30.1

Date: 02/06/2015

Name :
Address:
Postal code:
Country :
VAT Number :

CEFIC AISBL
Contact person: 10.2.e
Research & Innovation
Av Van Nieuwenhuyse 4
1160 - Brussels
Belgium

VAT Nr : BE 0412.849.915

Invoice

ESAP meeting 2015-06-02
- Consultancy fees 1,500€
- Total: 1,500€

Signature: _____

Complete Bank Details :
Account Beneficiary name:
Bank name :
Bank Address :
Account number :
Iban :
Bic Codes :

Doc. 30.2

cefic

AGENDA DRAFT

Meeting: External Scientific Advisory Panel (ESAP)
Place: Le Plaza Brussels Hotel
Address: 4 Av E van Nieuwenhuyse, 1160 - Brussels
Date of meeting: 20 Nov 2015, 09:00 – 15:00

Time	Item	Presented by	Action required
9:00 – 9:45	1. Administration a) Welcome, apologies b) Approval of the minutes of the last meeting and actions c) Members to inform any conflicts of interest and confidentiality d) Approval of the agenda 2. ESAP membership / areas of expertise	[redacted] [redacted]	Approval Discussion
9:45 – 11:00	3. LRI update a) 2015 EoI's and earlier projects impacts (ECHA/OECD) b) EUROTOX 2015 feedback (Mixtures, NMDRC) c) LRI contributions' article d) ICCA-LRI workshop 2015 outcomeLRI award 2016	[redacted] c) [redacted]	a-d) Information
11:00 – 11:20	4. EC Committees: are you involved? -SCCS (Scientific Committee on Consumer Safety) -SCHER (Scientific Committee on Health, Environmental and Emerging Risk) -SCENHIR (Scientific Committee on Emerging and Newly Identified Health Risks -SAM (Scientific Advise Mechanism)	[redacted]	Presentation and Discussion
11:20 – 12:15	5. LRI-S-line -S3: talk in plenary at 2015 LRI WS -S4: do we have an initiative?	[redacted] [redacted]	Presentation and Discussion
12:15 – 13:45	Lunch		
13:45 – 14:00	6. Feedback on development of EFSA and VITO work on DNT.	[redacted]	Information
14:00 – 14:55	7. Tour de table (5min each): "What are you aware of in terms of new research trends that could impact ongoing or lead to future policy discussions?"	ALL	Discussion
14:55 – 15:00	8. a) AOB b) Meetings 2016: June 7,	[redacted]	

	November 18		

Distribution List

ESAP Members

[redacted]

Istituto Mario Negri
Uppsala University
VU University
Newcastle University
University of Düsseldorf
University of Milan
INERIS
University of Manchester
Utrecht University
VITO
ETHZ

Cefic R&I Executive Director
Cefic R&I Long-range Research Initiative Mgr
Cefic R&I ESPI, Communication Mgr

Permanent guest

[redacted]

Unilever, Chair LRI SIG

Action list		Who?	By when?	Status
ESAP Meeting 21 November 2014				
1.	Develop template for 1 page executive summary of LRI projects results	[redacted]	ASAP	Done
2.	Share the EEA and DG ENV roadmap on "late lessons from early warnings", when available.	[redacted]	Sept 2015	
3.	To circulate LRI RfP AIMT5 before publication for information.	[redacted]	June	Done
4.	Circulate the final document of the standard to certify the Risk Assessment Advanced Training Programmes.	[redacted]	By Nov 2015 meeting	Not before next RAATP meeting (when is that?)
5.	Revise and add suggestions to the ESAP areas of expertise' table.	ALL	By Nov 2015 meeting	Pending
6.	Feedback on development of EFSA and VITO work on DNT.	[redacted]	By Nov 2015 meeting	On agenda
7.	Draft report of the 2015 LRI workshop panel "What's needed to streamline the science argumentation and consensus process? Develop further thoughts about this exercise and what actions should be put forward.	[redacted]	By Nov 2015 meeting	
8.	Present a thought starter on impact of research.	[redacted]	ASAP	Done

	2014 EP STOA measuring scientific p			
9.	MoA EFSA, analyse the importance and applicability to mixtures.		November 2015	On agenda
10	Send to and suggestions of experts on ecosystem impact services to replace , by end of August.	All	ASAP	On agenda
11	Pull together a matrix of publications, citations, universities and research institutes to show the value of LRI programme and how much it contributed.		ASAP	
12	will join the LRI ECO35 monitoring team.		Feb-March 2016	Pending
13	and to present the LRI Awardees at the LRI WS 2015.		Nov 2015	Postponed
14	and to submit a revised S4 RfP proposal to be discussed at the 20 November meeting		Nov 2015	On agenda

cefic

EXTERNAL EXPENSES CLAIM
EUROPE

First name and Last name:	
Phone (with country and area code):	
e-mail:	

Direct Superior	
Date	10.2.8
EXPENSES INCURED AT (name of meeting/workshop)	ESAP June meeting
place and date (ex : LONDON 22/10/09)	Brussels, Cefic, 02/06/2015

PROGR. NR XX	ISSUES/S. GROUP XXX	SPECIAL ACTIVITIES XXXX	TYPE OF EXPENSE XX	FREE SPACE XXXX
(*) A	B	C		
11	016	0002	08	0003

Attached # original invoices, tickets, bording pass and receipts for each amount :

A B C XX XXX XXXX(*) only if you want to split	D E XX XXXX	ITEM		Currency	Amount	CONVERSION IN € OR €	Receipt N°
COST CENTER		TRAVEL	subtotal		-	-	
COST CENTER		HOTEL	subtotal		-	-	
COST CENTER		MEETING	subtotal		-	-	
COST CENTER		MISCELLANEOUS	subtotal		-	-	
		SUBTOTAL (automatic)			-	-	
		ADVANCE					
		AMOUNT RETURNED					
			TO PAY		-	-	

Please pay to

Complete in CAPITAL LETTERS :

Beneficiary Account name (it's not the bank name)
Address
Post code /town & country

*IBAN (1) Code (22 digits):
*SWIFT or BIC (2) code (8 to 11 digits):

*SWIFT code (8 to 11 digits):

Banker name
Address
Post code /town & country

* Cefic cannot pay without these codes. They are on your bank statement or please ask your bank
(1) International Bank Account Number (2) Account Holder Institution

SIGNATURE EXPENSE GENERATOR	SIGNATURE PROGRAMME HEAD

Doc. 31

Overal 10.2.e

From: [redacted]
To: [redacted] @rivm.nl
Cc: [redacted]
Subject: LRI ECO 31 project "Develop testing approaches / strategies to provide relevant abiotic and biotic half-lives and confidence around those rates"
Date: 15-12-2015 13:33
Importance: High

ecetoc

EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS AISBL

[redacted]
RIVM
Expert
Centre for
Substances
PO Box 1,
Bilthoven
Netherlands

Brussels, 15 December 2015

Dear [redacted],

I would like to invite you to be part of the Research Liaison Team for the LRI ECO 31 project *"Develop testing approaches / strategies to provide relevant abiotic and biotic half-lives and confidence around those rates"*. As you know, this project is led by [redacted] and colleague.

Please could you confirm your agreement by **December 23rd**. Should you need an extension of this deadline, please let us know.

The kick-off meeting will take place sometime in January/February. A Doodle poll will be sent to find a suitable date.

I am looking forward to hearing from you.

Best wishes,

[redacted]

Environmental Sciences Manager

[redacted]

Environmental Sciences Manager
ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals)
Avenue E. Van Nieuwenhuyse Building 2, 3rd Floor, Bte 8
B-1160 Brussels
Tel +32 2 [redacted]
Fax +32 2 [redacted]
E-mail [redacted] @ecetoc.org
www.ecetoc.org

Sent on behalf of [redacted]
[redacted] | Administrative Assistant
European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)
Avenue E. Van Nieuwenhuyse 2, (box 8) | B-1160 Brussels | Belgium
VAT BE 0418 344 469 | Tel: +32 2 [redacted] | Fax: +32 2 [redacted] 5
E-mail: [redacted] @ecetoc.org | Website: www.ecetoc.org

Overal 10.2.e

Doc. 32

From: [redacted]
To: [redacted]
Cc: [redacted]@rivm.nl'; [redacted]@rivm.nl'
Subject: RE: RE: partnership in EFSA call
Date: 22-12-2015 15:20

[redacted]

As far as I know it is up to each institution.

Best wishes,

[redacted]

From: [redacted] [mailto:[redacted]@rivm.nl]
Sent: 22 December 2015 13:40
To: [redacted]
Cc: [redacted]@rivm.nl; [redacted]@rivm.nl
Subject: RE: RE: partnership in EFSA call

Many thanks [redacted] for the fast response. We'll try to find another partner.

Just being curieus: how hard is it in the UK to become an art.36 organization? Is this a centralized procedure or can any University / Institute apply?

My best wishes for Xmas and the new year,
[redacted]

Delivered to you by RIVM Mobile environment.

From: [redacted]@imperial.ac.uk>
Sent: 22 dec. 2015 14:11
To: "[redacted]@rivm.nl>, "[redacted]@rivm.nl'"
[redacted]@rivm.nl>
Cc: "[redacted]@rivm.nl'" [redacted]@rivm.nl>
Subject: RE: RE: partnership in EFSA call

[redacted]

It does sound as if they are reluctant to commit to this. It might be better to look for another partner for this aspect of the work before submission.

Best wishes,

[redacted]

From: [redacted] [mailto:[redacted]@rivm.nl]
Sent: 22 December 2015 13:07
To: [redacted]@rivm.nl; [redacted]
Cc: [redacted]@rivm.nl
Subject: Fwd: RE: partnership in EFSA call

Dear [redacted],

Please see email exchange below, about potential involvement of Simcyp in the EFSA PBPK call. We could perhaps involve them by downgrading their contribution in the offer, which of course may not be very attractive to them. It could be possible though, if we get the project, to get them involved at the right level & give them the credits they deserve.
How do you read [redacted] response below, are they still interested or just trying to find a polite way to get out?
We need a quick decision here because we may need another partner.

Best,
[redacted]

Doc. 32

Delivered to you by RIVM Mobile environment.

From: [redacted]@certara.com>
Sent: 22 dec. 2015 13:41
To: [redacted]@rivm.nl>
Cc: '[redacted]@manchester.ac.uk>, [redacted]@rivm.nl>, [redacted]@rivm.nl>, [redacted]@certara.com>
Subject: RE: partnership in EFSA call

H[redacted]

Reading through the call proposal it says that only ancillary and assistance tasks can be sub-contracted – it seems it is more for things like development of an IT application rather than for scientific aspects. I think it would give you the best chance of success if we are not part of the project as I am not convinced that we would be eligible to sub-contract.

Kind regards

[redacted]

From: [redacted] [mailto[redacted]@rivm.nl]
Sent: 17 December 2015 14:48
To: [redacted]@certara.com>
Cc: [redacted]@manchester.ac.uk>; [redacted]@rivm.nl>; [redacted]@rivm.nl> [redacted]@certara.com>
Subject: RE: partnership in EFSA call

Dear [redacted]

In that case we would like to propose the following approach:

There's sufficient knowledge within our institute (and the entire consortium) on the topic of PBTK en PBTD modelling but the actual development/construction of these models would become a task (not a core task) that would be allocated to you. This means that Certara would become a subcontractor to us, RIVM.
This may sound as downgrading the work but in practice we will work together and more important, publish together, on an equal basis.

What do you think of this proposal?

Kind regards,

[redacted]

[redacted]
Senior Risk Assessor
Department of Food Safety
Centre for Nutrition, Prevention and Health Services
National Institute for Public Health and the Environment (RIVM)
Ant. van Leeuwenhoeklaan 9 | 3721 MA | Bilthoven | G22, 2nd floor
P.O. Box 1 | 3720 BA | Bilthoven | the Netherlands
T +31 (0)30 - [redacted]
M +31 (0)6 - [redacted]
F +31 (0)30 - [redacted]
[redacted]@rivm.nl
www.rivm.nl

From [redacted]@certara.com>
To [redacted]@rivm.nl>, '[redacted]@manchester.ac.uk>,
Cc [redacted]@certara.com>, [redacted]@rivm.nl>, [redacted]@rivm.nl>
Date 17-12-2015 12:44
Subject RE: partnership in EFSA call

Doc. 32

Hi [redacted]

From the Simcyp side we checked the eligibility when [redacted] approached us and we are not listed as part of article 36 and would not be eligible to be listed.

In terms of sub-contracting it says that core tasks can not be subcontracted so I am not sure how that would work if we were to be involved – it seems to me that unfortunately Simcyp would not be eligible to be involved in this initiative.

Kind regards

[redacted]

From: [redacted] [mailto:[redacted]@rivm.nl]
Sent: 17 December 2015 11:16
To: [redacted]@certara.com>; [redacted]@manchester.ac.uk>
Cc: [redacted]@certara.com>; [redacted]@rivm.nl>; [redacted]@rivm.nl>
Subject: partnership in EFSA call

Dear [redacted] and [redacted],

On behalf of my colleague [redacted] I would like to ask you if you could check if you are eligible to participate in the EFSA call, see call for proposals and guide for applicants that can be found at http://www.efsa.europa.eu/en/art36grants/article36/gpefsascer20101.

At section 1.4 on eligible organisations you will find a link that will direct you to the following link:
http://www.efsa.europa.eu/en/partnersnetworks/scorg
As you can see, some universities in the UK are mentioned on the list of competent organisations but the University of Manchester is not on this list.
Probably Simcyp/Certara could be involved as a subcontractor to us or to the University of Manchester. In the latter case, the University of Manchester needs to register as an Aticle 36 organisation so that the university can be a full partner in our offer and will be taken up in the consortium. All the other partners in our consortium are article 36 organisations.

Furthermore, we would like you to consider to participate (as UniMan/Simcyp/Certara) in the PBPK modelling as requested by EFSA in objectives 1 and 2 part iv (data collection will be done by others). The in vitro data obtained in objective 3 will also be included in the PBPK modelling. The final PBPK model must be implemented in a web-based tool as described in objective 4. This implementation will be carried out by another Dutch research institute.

In short, if we can come up with an eligible partnership construction we would like you to participate mainly in objective 4 and partly in objectives 1 and 2, part iv.

Therefore, could you please indicate at short notice if your are willing and able to participate in our offer. Thanks in advance.

Kind regards,

[redacted]

[redacted]

.....

Senior Risk Assessor
Department of Food Safety

Centre for Nutrition, Prevention and Health Services
National Institute for Public Health and the Environment (RIVM)
Ant. van Leeuwenhoeklaan 9 | 3721 MA | Bilthoven | G22, 2nd floor
P.O. Box 1 | 3720 BA | Bilthoven | the Netherlands
.....
T +31 (0)30 - [redacted]
M +31 (0)6 - [redacted]
F +31 (0)30 - 274 4475
[redacted]@rivm.nl
www.rivm.nl

Proclaimer RIVM http://www.rivm.nl/Proclaimer

Doc. 33

Overal 10.2.e, tenzij anders aangegeven

From: [redacted]
To: [redacted]
Cc: [redacted] @crl.com; [redacted] @rivm.nl'; [redacted]; @abbvie.com; @sanofi.com; @gsk.com; - Network; @covance.com; @apconix.com; @exxonmobil.com; @celgene.com; @bms.com; @epa.gov; [redacted]; @ts.jnj.com; @epa.gov; @epa.gov; @bms.com; [redacted]; @merck.com; @fagg.be; @gsk.com;
Subject: RE: Reminder: Edits/Comments on HESI DART 2nd species Opinion paper
Date: 25-03-2016 11:34

[redacted] and all,

First of all, again many many thanks to [redacted] for the hard work done to get this draft manuscript together. I do appreciate the difficulty of the subject and of putting such a manuscript together. I have been planning to work on it ever since it came available but could not make that work due to other ongoing issues. In addition, I found it difficult to suggest edits as I would probably have built the argumentation in a different way.

10.2.g

[redacted]

10.2.g

[redacted]

Perhaps this can serve as food for thought for the next telecon.

Kind regards to all,
[redacted]

[redacted]
Center for Health Protection
National Institute for Public Health and the Environment RIVM
Antonie van Leeuwenhoeklaan 9
P.O.Box 1
3720 BA Bilthoven
The Netherlands
phone +31 30 [redacted]
email [redacted] @rivm.nl

[redacted] ---25-03-2016 08:15:54---Dear all Thus far I had not to much time to read the 3rd paper. Several times I made a start, but co

From: [redacted] n@cbg-meb.nl>
To: [redacted]

Doc. 33

[redacted]

Cc: [redacted]
Date: 25-03-2016 08:15
Subject: RE: Reminder: Edits/Comments on HESI DART 2nd species Opinion paper

---

Dear all

Thus far I had not to much time to read the 3rd paper. Several times I made a start, but could not finish. I like [redacted]

10.2.g

Success with further writing the opinion paper.

[redacted]
Section on Pharmacology, Toxicology and Kinetics (FTK)
Medicines Evaluation Board
Graadt van Roggenweg 500, 3531 AH Utrecht, The Netherlands
[redacted]@cbg-meb.nl
+31 (0)88 [redacted]
Mobile: + 31 (0)6 [redacted]

Van: [redacted]@fda.hhs.gov]
Verzonden: vrijdag 25 maart 2016 2:25
Aan: [redacted]
CC: [redacted]
Onderwerp: Re: Reminder: Edits/Comments on HESI DART 2nd species Opinion paper

Thank you for those comments. I strongly agree.

From: [redacted]
Sent: Thursday, March 24, 2016 7:13 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Reminder: Edits/Comments on HESI DART 2nd species Opinion paper

Doc. 33

Dear All,

A big "Thank you" to those who prepared the Version 3.

10.2.g

[redacted]

10.2.g

[redacted]

10.2.g

[redacted]

Regards,

[redacted]

From: [redacted] [mailto[redacted]@hesiglobal.org]
Sent: Tuesday, March 22, 2016 9:08 AM
To: [redacted]
Cc: [redacted]
Subject: Reminder: Edits/Comments on HESI DART 2nd species Opinion paper

Dear all,

Thanks to everyone who has provided comments on the manuscript so far. This is a friendly reminder to **add your thoughts/comments/edits to the paper to do so by COB next Monday, March 28th**. This allows a 1-week buffer for all to review and prepare for the next teleconference, scheduled for Monday, April 4 at 10AM (Eastern).

The most recent draft (as of 10AM EDT), with formatting changes accepted, has been attached as a PDF for your convenience. Please add your edits and comments on the collaborative

document on the SharePoint site:

https://ilsiglobal.sharepoint.com/hesi/science/dart
➔ Working Groups
➔ Second Species
➔ Manuscripts

You can also find the previous two manuscripts (in case you need a refresher) on the SharePoint site, in case you need a refresher on ground that has already been covered.

Please let [redacted] or me know if you are having problems logging into the site, need a new invitation to the site, and/or don't know how to edit via SharePoint.

Best regards.
[redacted]

[redacted]
HESI, Scientific Program Manager
(202) 659-[redacted]
[redacted]@hesiglobal.org

[redacted]
HESI, Scientific Program Manager
(202) 659-[redacted]
[redacted]@hesiglobal.org

From: [redacted]@lilly.com]
Sent: Tuesday, March 15, 2016 12:32 PM
To: [redacted]@pfizer.com>; [redacted]@hesiglobal.org>; [redacted]@sanofi.com
Cc: [redacted]
Subject: RE: For review: HESI DART 2nd species Opinion paper

[redacted] et al.,

I'm sorry if I have dug up old issues; [redacted]

10.2.g

[redacted]

From: [mailto @pfizer.com]
Sent: Tuesday, March 15, 2016 12:17 PM
To: @sanofi.com
Cc:
Subject: RE: For review: HESI DART 2nd species Opinion paper

Thanks for the comments. In response to your questions

10.2.g

From: @lilly.com]
Sent: Tuesday, March 15, 2016 10:01 AM
To: @sanofi.com
Cc: @fagg.be; Network; @its.jnj.com; @abbvie.com; @exxonmobil.com; @fda.hhs.gov; @takeda.com; @crl.com; @celgene.com; @epa.gov; @gsk.com; @epa.gov; @epa.gov; @bms.com; @gsk.com; @apconix.com; @bms.com; @abbvie.com; @covance.com; cbg-meb.nl; @merck.com;
Subject: RE: For review: HESI DART 2nd species Opinion paper

et al,

Nice Job on the paper.

After my review of this manuscript and another draft manuscript I reviewed a few days ago, and thinking about our effort on

10.2.g

Doc. 33

10.2.g

[redacted]

From: [redacted] [mailto: [redacted] @hesiglobal.org]
Sent: Monday, March 14, 2016 4:23 PM
To: [redacted] @sanofi.com
Cc: [redacted] @fagg.be; [redacted] @pfizer.com; [redacted] - Network; [redacted] @its.jnj.com; [redacted] @abbvie.com; [redacted] @exxonmobil.com; [redacted] k@fda.hhs.gov; [redacted] @takeda.com; [redacted] @crl.com; [redacted] @celgene.com; [redacted] @epa.gov; [redacted] @gsk.com; [redacted] @epa.gov; [redacted] @epa.gov; [redacted] @bms.com; [redacted] s@gsk.com; [redacted] @apconix.com; [redacted] @bms.com; [redacted] @abbvie.com; [redacted] r@covance.com; [redacted] @cbg-meb.nl; [redacted] @merck.com; [redacted]
Subject: Re: For review: HESI DART 2nd species Opinion paper

Thanks for mentioning that [redacted]

There have only been a handful of edits so far, but one of the quirks with the new site is that in preview mode (and "Edit in Word Online" mode) you can see comments but not inline edits. The inline edits are only visible when you select "Edit" and then "Edit in Word".

If anyone is having problems accessing the file or editing/adding comments via the Sharepoint site, please don't hesitate to reach out.

If you need the invite to the Sharepoint site resent, [redacted] can help you with that while I'm out of the office.

On Mar 14, 2016, at 1:21 PM, "[redacted] @sanofi.com" [redacted] @sanofi.com> wrote:

H[redacted]

[redacted], and [redacted] did a nice job on this draft manuscript. I added a few comments, but noticed that it is not clear in the on-line editing where revisions have been made (I actually used the Word version since it had some features that were easier for me to use).

Best regards,
[redacted]

[redacted]
Sanofi U.S. Inc.
[redacted] @sanofi.com
TEL.: 908.[redacted]
55 CORPORATE DRIVE - BRIDGEWATER - New Jersey 08807
<image001.jpg>

Please consider the environment before printing this email!

From: [redacted] [mailto [redacted] @hesiglobal.org]
Sent: Monday, March 07, 2016 8:04 AM

Doc. 33

To: [redacted]@fagg.be; [redacted] R&D/US; [redacted]@pfizer.com)'; [redacted]@covance.com; [redacted]@its.jnj.com)'; [redacted]@abbvie.com)'; [redacted]@exxonmobil.com)'; [redacted]@takeda.com; [redacted]@crl.com)'; [redacted]@celgene.com)'; [redacted]@epa.gov)'; [redacted]@gsk.com)'; [redacted]@epa.gov); [redacted]@epa.gov; [redacted]@bms.com)'; [redacted]@gsk.com)'; [redacted]@bms.com)'; [redacted]@abbvie.com); [redacted]@covance.com)'; [redacted]@cbg-meb.nl)'; [redacted]@merck.com)'
Cc: [redacted]
Subject: For review: HESI DART 2nd species Opinion paper

Dear 2nd species group,

The next draft of the risk assessment paper is attached for your review. Please do not send edits back through the PDF. As noted in my previous email, edits should be made via HESI DART's new SharePoint site. (The edits will be automatically tracked and saved.)

Bookmark the HESI DART SharePoint site: https://ilsiglobal.sharepoint.com/hesi/science/dart

How to access:

You will receive an email invitation inviting you to the DART Extranet site. Please click the link to accept the invitation, and initiate the steps to set up your account to access the site.

Please accept this invite to access HESI's DART Extranet site. If you have any questions please email [redacted]@hesiglobal.org.

Go to DART Committee
Follow this site to get updates in your newsfeed.

When you have successfully set up your account, you can find the manuscript here:
→ Working Groups → Second Species → Manuscripts

A few things to note:

- Please check your junk/spam folder for the invitation. If you don't receive an email invitation within 24 hours, please let Oscar or me know.
- The email invitation will expire in 7 days. If the invitation expires, please let Oscar and me know.
- If you have already set up access to the DART page through another workgroup (i.e., Blank Page or DASTON), you can ignore this email. You already have access to the entire site and can go directly to the 2nd species workgroup page.
- If you have set up access to the Neonatal Peds site (only), you will need to click on the email invitation to the DART site to allow you access to the entire DART site.
- For those who are not familiar with SharePoint, attached is a simple how to guide with screenshots.

As always, let me or [redacted] know if you have any questions.

Best regards,

HESI, Scientific Program Manager
(202) 659-
@hesiglobal.org

From:
Sent: Thursday, March 3, 2016 12:27 PM
To: @fagg.be' < @fagg.be>; @sanofi.com)' @sanofi.com>; @lilly.com>; @pfizer.com)' @pfizer.com>; @covance.com' @covance.com>; @its.jnj.com)' its.jnj.com>; @abbvie.com)' @abbvie.com>; @exxonmobil.com)' @exxonmobil.com>; @fda.hhs.gov>; @takeda.com' < @takeda.com>; @crl.com)' @crl.com>; @celgene.com)' @celgene.com>; @epa.gov)' @epa.gov>; gsk.com)' @gsk.com>; @epa.gov) < n@epa.gov>; @epa.gov' < @epa.gov>; @bms.com)' @bms.com>; @gsk.com)' @gsk.com>; @apconix.com>; @bms.com)' @bms.com>; @abbvie.com) @abbvie.com>; @covance.com)' @covance.com>; @cbg-meb.nl)' cbg-meb.n @merck.com)' < @merck.com>
Cc: @hesiglobal.org) < @hesiglobal.org>
Subject: HESI DART 2nd species: Opinion paper next steps

Dear 2nd species group,

and are finalizing a new version of the opinion (risk assessment) manuscript which will be circulated to you for review/comment shortly.

Please note that rather than having multiple version circulating by email, you will be directed to make your edits and comments through DART's new SharePoint site. Although there may be an initial learning curve, editing via SharePoint will truly be a more efficient way to work collaboratively on the same document. The SharePoint site will automatically track your changes and versions (rather than wait for me to merge documents), and multiple users can be in the same document at one time.

Since it is now hosted through Microsoft Office 365, you will receive another email inviting you to set up an account. You only need to set up access to the DART SharePoint site once, so if you have already done so for another workgroup/project you can ignore this portion of the email and go directly to the 2nd species workgroup page.

Below are some key dates to mark in your calendar:

- **Mon March 7**: receive draft for review/comment; invite to new SharePoint site (and

how-to use SharePoint pointers)

- **Mon March 28**: deadline to provide comments
- **Early April**: telecon to discuss edits

Best regards,
[redacted]

[redacted]
HESI, Scientific Program Manager
(202) 659-[redacted]
[redacted]@hesiglobal.org

###

###

Overal 10.2.e

Doc. 34

From: [redacted]
To: [redacted]
Cc: [redacted]
Subject: Re: Second species paper(s)
Date: 18-05-2016 15:54

[redacted]

The current 2-species analysis is related to pharma compounds only. It follows up from a smilar earlier analysis in the chemicals arena, which was published as Janer et al (including me as a senior author) several years ago. At RIVM we are currently contemplating updating that analysis for chemicals and pesticides/herbicides.

I will not be able to attend TerSoc this year due to an overloaded agenda.

See you in France next month,

Best,
[redacted]

[redacted]
Center for Health Protection
National Institute for Public Health and the Environment RIVM
Antonie van Leeuwenhoeklaan 9
P.O.Box 1
3720 BA Bilthoven
The Netherlands
phone +31 [redacted]
email [redacted]@rivm.nl

▼ [redacted] ---18-05-2016 12:08:10---Dear [redacted], I will be very pleased to meet with you on June in our site of Sophia Antipolis where I

From: [redacted]@bayer.com>
To: [redacted]@rivm.nl>,
Cc: [redacted]@bayer.com>
Date: 18-05-2016 12:08
Subject: Second species paper(s)

Dear [redacted]

I will be very pleased to meet with you on June in our site of Sophia Antipolis where I am located now.

I am sure we will have interesting and fruitful exchanges about the Developmental Tox in vitro models...as we already had in the dinner of the previous ETS 2015 congress in Amsterdam.

About the working group on the second species from the DART Committee of HESI ILSI, I am wondering where you are for involving chemical and/or agro-chemical companies. I saw the 2 draft papers with the 309 pharmaceuticals only.

And, will you plan to go to the Teratology Society congress in San Antonio this year ?

Best regards,

Doc. 35

Overal 10.2.e

From: [redacted]
To: [redacted]
Subject: Re: Invitation: 'omics workshop Oct 10-12
Date: 23-05-2016 09:47

[redacted]

Thank you for this kind invitation. I am happy to join.

Best,
[redacted]

[redacted]
Center for Health Protection
National Institute for Public Health and the Environment RIVM
Antonie van Leeuwenhoeklaan 9
P.O.Box 1
3720 BA Bilthoven
The Netherlands
phone +31 30 [redacted]
email [redacted]@rivm.nl

▼ [redacted] ---21-05-2016 18:23:25---Dear [redacted], I writing to invite you to speak at ECETOC's upcoming workshop : "Applying 'Omics Techn

From: [redacted]@ecetoc.org>
To: [redacted]@rivm.nl>,
Date: 21-05-2016 18:23
Subject: Invitation: 'omics workshop Oct 10-12

Dear [redacted],

I writing to invite you to speak at ECETOC's upcoming workshop : "Applying 'Omics Technologies in Chemicals Risk Assessment" on 10-12 October 2016 in Madrid, Spain.

As you can see from the attached annotated agenda for day 1, we would like to hear the perspectives from regulators on the needs, challenges and opportunities for 'omics technologies in regulatory risk assessment. This would either be as part of a panel discussion or a keynote speech – depending on final confirmations.

The attached flyer summarises the reason and desired outcomes of the workshop. We hope you will be able to stay the full 3 days and actively participate in the breakout sessions as well. The attached slide summarises

how the 3 days will run.

I would be very grateful if you could let me know if you are interested and available?

I look forward to hearing from you.

With kind regards,
[redacted] [attachment "'omics WS flyer.pdf" deleted by [redacted] /RIVM/NL] [attachment "omics workshop agenda.pptx" deleted by [redacted] /RIVM/NL] [attachment "2016_May 21_ANNOTATED AGENDA.docx" deleted by [redacted] /RIVM/NL]

Overal 10.2.e

Doc. 36

From: [redacted]
To: [redacted]@rivm.nl; [redacted]@rivm.nl; [redacted]@rivm.nl; [redacted]@rivm.nl
Subject: 'Omics Technologies in Chemicals Risk Assessment workshop registration now open
Date: 31-05-2016 15:58
Attachments: 'omics WS_FL.pdf

Dear Colleague,

ECETOC is delighted to invite you to its three-day workshop:
Applying 'Omics Technologies in Chemicals Risk Assessment
10-12th October 2016, NH Eurobuilding Hotel, Madrid, Spain
The registration is now open and can be completed via the link in the attached leaflet. The agenda will be available shortly.

Thank you in advance for your consideration of this invitation,

With kind regards,

[redacted]
Human Health Scientist
European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)
Avenue E. Van Nieuwenhuyse 2, (box 8) | B-1160 Brussels | Belgium
VAT BE 0418 344 469 | Tel: +32 2[redacted] | Fax: +32 2[redacted]
E-mail: [redacted]@ecetoc.org | website: www.ecetoc.org

Doc. 36.1

ecetoc

ECETOC WORKSHOP

Applying 'Omics Technologies in Chemicals Risk Assessment

10-12 October, 2016
NH Eurobuilding Hotel, Madrid, Spain

Objectives:

1. With representatives from European Commission; the OECD; US-EPA; US-FDA - share and update frameworks developed by ECETOC multi-expert teams on how to aquire, analyse and apply 'omics data. Ensue fitness for purpose.

2. Generate consensus of opinion on the steps needed to achieve best practices for applying 'omics technologies in chemicals risk assessment.

Topics covered (Room Documents distributed prior to the workshop):

- ✓ Establishing GLP-like Context for Collecting, Storing and Curating 'Omics Data
- ✓ Best Practices for Analysisng 'Omics Data
- ✓ Best Practices for WoE Approaches for Integrating 'Omics Data
- ✓ Best Practices for Establishing Pathways to Connect Results of 'Omic Data to Phenotype

Context:

'Omics technologies hold the promise of generating detailed information faster, more accurately and easier than ever before. These emerging technologies could help:

- ✓ Reduce animal testing, with the ultimate goal of replacing animal testing altogether
- ✓ Increase the number of chemicals that can be accurately and efficiently tested in a given time
- ✓ Identify new and emerging risks through toxicological screening and reliable biomarkers

Yet current methodological and analytical uncertainties limit the application of 'omics technologies. Best practice for acquiring, analysing and applying 'omics data is needed so that information from 'omics can be reliably verified and confidently integrated into regulatory risk assessment.

FOR REGISTRATION PLEASE USE THE FOLLOWING LINK:
http://www.ecetoc.org/2016-2/9e45k1fx9h6bs35o/

The registration deadline for this event is: 1st September 2016

For further information, please contact Agnieszka Harris:
E-mail: 10.2.e [redacted] @ecetoc.org

hosted by

European Centre for Ecotoxicology and Toxicology of Chemicals

www.ecetoc.org

Doc. 37

Overal 10.2.e

From: [redacted]
To: [redacted]
Cc: [redacted]@rivm.nl)'; [redacted]
Subject: Re: 2nd species manuscript resubmission: due Sept 1
Date: 09-06-2016 17:38

[redacted]

thanks for your help, we appreciate the message!

Best,
[redacted]

[redacted]
Center for Health Protection
National Institute for Public Health and the Environment RIVM
Antonie van Leeuwenhoeklaan 9
P.O.Box 1
3720 BA Bilthoven
The Netherlands
phone +31 30 [redacted]
email [redacted]@rivm.nl

▼ [redacted] ---09-06-2016 17:35:27--- [redacted] and [redacted], Since the assistant's email cross with the editor's email, just wanted to confirm

From: [redacted]@hesiglobal.org>
To: "[redacted]@rivm.nl)'"
[redacted]@rivm.nl>, [redacted]@cbg-meb.nl>,
Date: 09-06-2016 17:35
Subject: 2nd species manuscript resubmission: due Sept 1

[redacted] and [redacted]

Since the assistant's email cross with the editor's email, just wanted to confirm that the resubmission due date is **SEPT 1**. If you could still aim for Aug 1, I'm sure the journal (, co-authors and your families) would appreciate it. ☺

[redacted]

-----Original Message-----
From: [redacted] [mailto[redacted]@att.net]
Sent: Thursday, June 9, 2016 11:22 AM

Doc. 37

To: [redacted]@hesiglobal.org>
Cc: [redacted]@att.net; [redacted]@hargray.com; [redacted]@rivm.nl)' [redacted]@rivm.nl>; [redacted]@cbg-meb.nl>
Subject: Re: Critical Reviews in Toxicology: Resubmission of Manuscript ID BTXC-2016-0009 BTXC-2016-0010

[redacted]

Thanks for your note. By copy of this e-mail I am asking my assistant, [redacted], to enter a target date of September 1, 2016 for submission of a revised manuscript. This should give you and your co-authors sufficient time to prepare a high quality revision of your review.

Best regards, [redacted]

On Thu, 6/9/16, [redacted]@hesiglobal.org> wrote:

Subject: Critical Reviews in Toxicology: Resubmission of Manuscript ID BTXC-2016-0009 BTXC-2016-0010
To: "[redacted]@att.net" <[redacted]@att.net>, "[redacted]@hargray.com" <[redacted]@hargray.com>
Cc: [redacted]@rivm.nl)'" [redacted]@rivm.nl>, "[redacted]@cbg-meb.nl>
Date: Thursday, June 9, 2016, 8:13 AM

Dear [redacted] and [redacted]

The primary and corresponding authors have been working diligently on the response to reviewer comments and will not be able to meet the June 14th deadline. Per your accompanying note with the response to reviewer comments, we understand that the resubmission date is somewhat arbitrary to help facilitate timely publication of manuscripts submitted to Critical Reviews in Toxicology.

We kindly request an extension to August 1 and that you not consider the papers a new submission. The additional time will enable all reviewer comments to be addressed sufficiently, and thus help improve the quality of revised paper.

Thank you for considering the request, and we look forward to hearing back from you soon.

Best regards,
[redacted]
(on behalf of [redacted], [redacted] and co-authors)

[redacted]
MPH
HESI, Scientific Program Manager
(202) 659[redacted]
x131
[redacted]@hesiglobal.org

-----Original Message-----
From: onbehalfof+r[redacted]t@manuscriptcentral.com [mailto:onbehalfof+[redacted]@manuscriptcentral.com]

On Behalf Of [redacted]@att.net
Sent: Tuesday, May 31, 2016 12:43 AM
To: [redacted]@hesiglobal.org>
Cc: [redacted]@hargray.com
Subject: Reminder: Critical Reviews in Toxicology

31-May-2016

[redacted]

Recently, you received a decision on Manuscript ID BTXC-2016-0009, entitled "Comparison of rat and rabbit embryo-fetal developmental toxicity data for 379 pharmaceuticals: on the nature and severity of developmental effects." The manuscript and decision letter are located in your Author Center at https://mc.manuscriptcentral.com/btxc.

This e-mail is simply a reminder that your revision is due in two weeks. If it is not possible for you to submit your revision within two weeks, we will consider your paper as a new submission.

Sincerely,

[redacted]
Editor-in-Chief,
Critical Reviews in Toxicology
[redacted]@att.net

31-May-2016

Dear [redacted]

Recently, you received a decision on Manuscript ID BTXC-2016-0010, entitled "Comparing rat and rabbit embryo-fetal developmental toxicity studies for 379 pharmaceuticals: On systemic dose and developmental effects." The manuscript and decision letter are located in your Author Center at https://mc.manuscriptcentral.com/btxc.

This e-mail is simply a reminder that your revision is due in two weeks. If it is not possible for you to submit your revision within two weeks, we will consider your paper as a new submission.

Sincerely,

[redacted]
Editor-in-Chief, Critical Reviews in Toxicology [redacted]@att.net

Overal 10.2.e

Doc. 38

From: [redacted]
To: [redacted]
Cc: [redacted]
Subject: Re: Will you Chair a brainstorm group during omics WS?
Date: 28-09-2016 14:15
Attachments: [redacted] Omic WS Madrid 2016.pptx

[redacted]

I'll be happy to chair one of the breakout groups.

My two slides requested earlier are attached.

Best,
[redacted]

[redacted]
Center for Health Protection
National Institute for Public Health and the Environment RIVM
Antonie van Leeuwenhoeklaan 9
P.O.Box 1
3720 BA Bilthoven
The Netherlands
phone +31 [redacted]
email [redacted]@rivm.nl

[redacted] ---26-09-2016 12:16:50---Dear [redacted], I am looking for Chairs for the brainstorm sessions during our Omics Workshop in Madrid

From: [redacted]@ecetoc.org>
To: [redacted]@rivm.nl>,
Cc: [redacted]@ecetoc.org>
Date: 26-09-2016 12:16
Subject: Will you Chair a brainstorm group during omics WS?

Dear [redacted]

I am looking for Chairs for the brainstorm sessions during our Omics Workshop in Madrid. I would like to invite you to be Chair for one of the brainstorm groups during Session 2: "Best Practices for WoE Approaches for Integrating 'Omics data".

What it entails:

(i) As Chair, you would ensure that the participants of your group

answer the pre-defined questions (will be written in the agenda and displayed on the screen in the breakout room) within the allotted time. This requires a pragmatic personality, as participants may need to be guidend into coming up with answers that are do-able, relevant and impactful.
(ii) You would be supported by a Rapporteur, who will capture the outcomes of the brainstorm discussion on a slide
(iii) During coffee break (immediately after the brainstorm session) you would work with the Rapporteur to finalise the slide(s) (so you miss some, if not all of the coffee break!)
(iv) Present the outcomes of your group during plenary

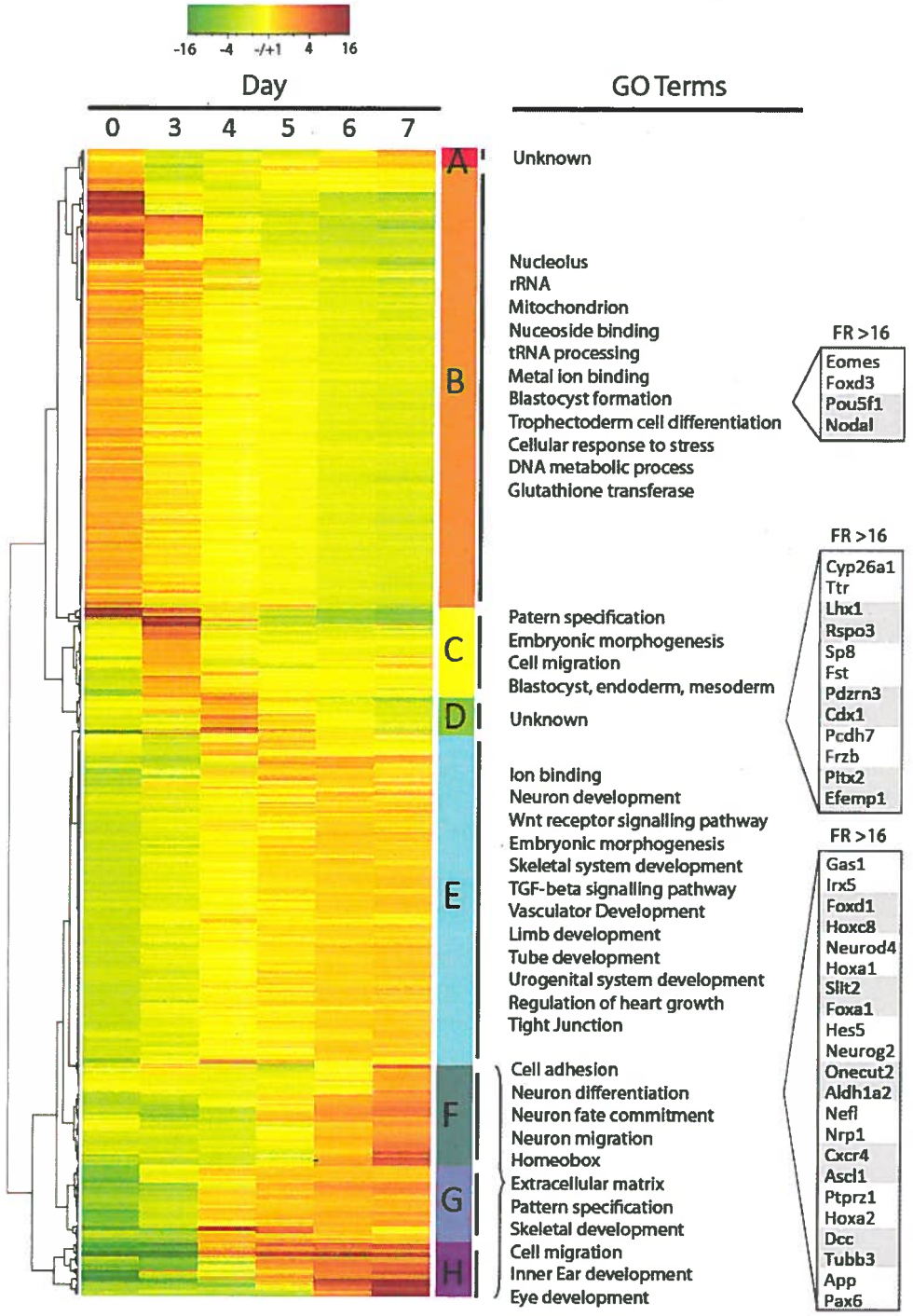
Please let me know if this is something you can help us with (no obligation!)

Many thanks in advance for considering the request.

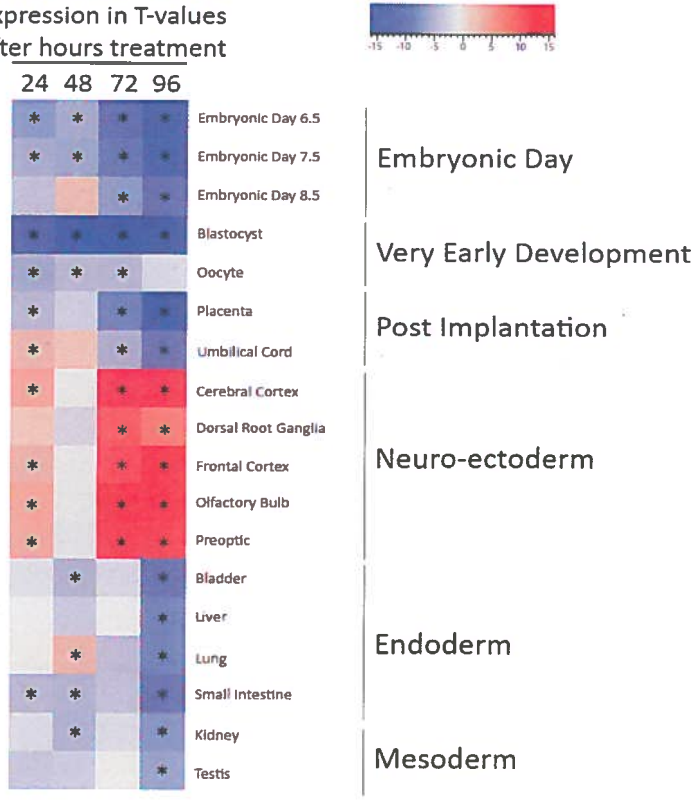
Best,
[redacted]

[redacted]
Human Health Scientist
ECETOC – European Centre for Ecotoxicology and Toxicology of Chemicals
Avenue E. Van Nieuwenhyse 2, Bte 8
1160 Brussels
Belgium
T: +32 2 [redacted]
E: [redacted]@ecetoc.org

EST Neural Differentiation



Effect of MeHg on BioGPS tissue gene set expression in T-values after hours treatment



Theunissen et al., 2011

Omics best practices notes

- Gene expression response magnitude (fold change) is not limiting biological relevance
- In mixed cell type tissues individual genes may show limited response that may be highly biologically significant if related e.g. to a single cell type
- Single gene expression changes gain weight in pathway analysis of related gene expression changes
- Time courses and dose-response are superior over single time points and doses
- Reproduction of gene expression changes in more than one biological system adds to weight of evidence
- Understanding the biology of the test system is important for omics results interpretation

Overal
10.2.e

Doc. 39

From: [redacted]
To: [redacted]
Subject: RE: ik wilde dit richting OECD sturen ivm het proces
Date: 03-10-2016 14:54

Hoi

Ok, zie hier en daar alleen wat typefouten.....
Gr. [redacted]

From: [redacted] [mailto:[redacted]@rivm.nl]
Sent: maandag 3 oktober 2016 14:45
To: [redacted]
Subject: ik wilde dit richting OECD sturen ivm het proces

Zijn jullie het hier mee eens. Ik wilde het om circa 15:00 sturen

Dear [redacted] and [redacted]

In preparation of the teleconference of today NL would like to give an update on their perception of the OECD discussion regarding the SPSF on the inhalation TGs for nanomaterials. The NL is of the opinion that it is important that the history and decisions are clear to all of us in order to move further with this work.

1 In 2014 (of was het 2013) US has prepared a SPSF for the update of the OECD TGs for nanomaterials.
It was agree upon by the WNT that the decision on the lung burden (LB) was dependent on a feasibility study that had to address
- how lung burden is to be used
- how it can be measured (in the same animal as originally proposed

2. A feasibility study was prepared and discussed in the Washington meeting in 2014.
3 The Washington meeting could not be attended by all experts . Unfortunately, the organising country was not able to facilitate a webex or other connection for those who were not in the position to travel
4 The Wasgington meeting was not able to reach agreement on the document on the feasibility study
5 In 2015 US provided a draft update of the TG 413 which included about 80 additional animals for LB. This resulted in many questions from several Member Countries and stakeholders regarding the rationale for the additional animals.
6 In order to provide some constructive input for the huge number of animals, and still the lack of clear rationale why the information from LB is requested, the NL tried to be constructive in the WNT to provide some pragmatic suggestion. As as consequence the NL was requested by the WNT to become the co-lead.
7 NL has tried to accommodate the pragmatic proposal as agreed upon in the WNT, but from the comments it is clear that there are too many questions regarding the LB, that can not be answered by NL. It is US who has proposed the LB and it was NL and other countries who questioned the use of the LB.
8 In order to move further at this moment and stage it is essential that US provides a clear rationale and examples on how to use the LB. From all comments we have noted this is essential to move further with this part of the update of the TG
9 As regards to the other issues of the SPSF (BAL, size, and recovery) NL is willing (already busy) with to accomodate those issues.

For the teleconference of today it is important

1 to go through the RCOM. discuss which issue are topic for the discussion in Washinton
2 to have a agreement on how to deal with LB
3 to distribute the work

[redacted]
Department for Industrial Chemicals
Centre for Safety of Substances and Products (VSP)
P.O. Box 1, 3720 BA Bilthoven, The Netherlands

RIVM (http://www.rivm.nl)
T: + 31 [redacted]
Email: [redacted]@rivm.nl

Overal 10.2.e

Doc. 40

From: [redacted]
To: [redacted]@oecd.org
Cc: [redacted]@iss.it; [redacted]@oecd.org; [redacted]@nihs.go.jp; [redacted]@biology.sdu.dk; [redacted]@regulatoryscience.com; [redacted]; [redacted]@humanesociety.org; [redacted]2@nih.gov; [redacted]@phe.gov.uk; [redacted]@oecd.org; [redacted]@[redacted].freeserve.co.uk; [redacted]@food.dtu.dk; [redacted]@hotmail.co.jp; [redacted]@nih.gov; [redacted]@rivm.nl
Subject: RE: HT_DK on GD 150 TC
Date: 10-11-2016 00:26

Dear all,

I agree with the sentiment of not changing the headers, echoing [redacted]s points as to why the changes are confusing, with the previous headers being more neutral; and the fact that the vast majority of the standard mammalian studies (even TG 443 as [redacted] points out) were not designed with the primary aim of identifying endocrine disruption.

Regarding TG 416, I would suggest it remains in level 5 as it always will be an "*In Vivo* Assay Providing More Comprehensive Data on Adverse Effects on Endocrine-Relevant Endpoints Over More Extensive Parts of the Life Cycle of the Organism" (the title of level 5). I would also suggest the note 'most recent update' is removed from this study. This has always caused confusion with respect to where older TG 416 studies are placed in the CF. My perspective on this is that all TG 416 studies (regardless of whether or not they have the 'extra ED endpoints') fit into level 5 (for the reason descried above) and that the presence/absence of the 'extra endocrine endpoints' is simply something to consider when evaluating the weight/strength of the evidence, alongside additional factors such as study quality and effects seen in other studies. A well conducted older TG 416 study gives a lot of powerful information when determining if a compound has endocrine-disrupting potential, or not.

Lastly, TG 409 (90 day study in non-rodents) has never been in the CF, has any consideration been given to adding it? This study type is commonly available for plant protection product active ingredients for example and should form part of a weight of evidence evaluation.

Best regards,

[redacted]

[redacted]
Toxicologist and Risk Assessor – Human Health Assessment
Dow AgroSciences Ltd.
Tel: +44(0)[redacted]
e-mail: [redacted]@dow.com

From: [redacted] [mailto:[redacted]@MST.DK]
Sent: 09 November 2016 18:40
To: [redacted]@echa.europa.eu>; [redacted]@rivm.nl>; [redacted]@oecd.org
Cc: [redacted]@iss.it; [redacted]oecd.org; [redacted]@rivm.nl>; [redacted]@nihs.go.jp; [redacted]@biology.sdu.dk; [redacted]@regulatoryscience.com; [redacted]@dow.com>; [redacted]@ec.europa.eu>; [redacted]

[redacted]@echa.europa.eu>; [redacted]@humanesociety.org; [redacted]@nih.gov; [redacted]@phe.gov.uk; [redacted]@oecd.org; [redacted]@[redacted].freeserve.co.uk; [redacted]@dow.com>; [redacted]@ec.europa.eu>; [redacted]@food.dtu.dk; [redacted]@hotmail.co.jp; [redacted]@nih.gov; [redacted]t@rivm.nl
Subject: SV: HT_DK on GD 150 TC

Dear [redacted]

Regarding section A, B & C of the table: Thanks for your input. I can see your points. Based on your arguments and the difficulty I have with the proposed reference to as to whether the TGs were *"primarily" developed for identification of EDs* I now think that it may well be that we instead should simply refer to two sets of methods depending on whether guidance has been provided or not - i.e. a section A (Guidance provided) section B (Guidance not provided). It could be explained that those methods in such a section B does not contain information making it possible to conclude on whether the effects are attributable to an ED MoA or not.

If this is done I think it would be relevant to either move TG 416 to level 4 of the ED CF or if left together with TG 443 at level 5 to keep the current footnote of the ED CF explaining that the latter contains more comprehensive information relative to identification of EDs that the former .

Best regards

[redacted]

Fra: [redacted] [mailto[redacted]@echa.europa.eu]
Sendt: 9. november 2016 17:53
Til: [redacted]@oecd.org
Cc: [redacted]@iss.it; [redacted]@oecd.org; [redacted]@nihs.go.jp; [redacted]@biology.sdu.dk; j[redacted]@regulatoryscience.com; [redacted]@dow.com; [redacted]; [redacted]@humanesociety.org; [redacted]@nih.gov; [redacted]@phe.gov.uk; [redacted]@oecd.org; [redacted]@[redacted].freeserve.co.uk; [redacted]@dow.com; [redacted]@food.dtu.dk; [redacted]@hotmail.co.jp; [redacted]@nih.gov; [redacted]@rivm.nl
Emne: RE: HT_DK on GD 150 TC

Dear all,

I think the previous wording in the categorisation was more appropriate and less debatable.

As ED is a mode of action, one cannot say that the 90 day or the generations studies were not designed to evaluate also ED like effects. They are designed to understand systemic toxicity and the fact they do not have in the title something on ED, does not mean they do not address it since it is part of the systemic toxicity. The studies placed now under the header "designed primarily to identify interaction with ED pathways" can also be misleading. They are just receptor assays that also address only some part of the pathway, the same way the 90 day findings for example on thyroid or reproductive organs would do.

Therefore I would propose no changes in the headers as it can cause confusion, whereas the previous titles were more neutral and referred to what guidance is provided. If the titles change as per proposal it might give the message that the receptor assays are better as they were "designed for ED" compared to higher tier ones.

Happy to discuss

Kind regards

[redacted]

[redacted]
Senior Scientific Officer
Evaluation Unit E1
European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel. +358 [redacted]

[redacted]@echa.europa.eu
http://echa.europa.eu/

From: [redacted]@MST.DK]
Sent: 09 November 2016 16:03
To: [redacted]@rivm.nl>; [redacted]@oecd.org
Cc: [redacted]@iss.it; [redacted]@oecd.org; [redacted]@rivm.nl>; [redacted]@echa.europa.eu>; [redacted]@nihs.go.jp; [redacted]@biology.sdu.dk; j[redacted]@regulatoryscience.com; [redacted]@dow.com; [redacted]@ec.europa.eu>; [redacted]@echa.europa.eu>; [redacted]@humanesociety.org; [redacted]@nih.gov; [redacted]@phe.gov.uk; [redacted]@oecd.org; [redacted]@[redacted].freeserve.co.uk; [redacted]@dow.com; [redacted]@ec.europa.eu>; [redacted]@food.dtu.dk; [redacted]@hotmail.co.jp; [redacted]@nih.gov; [redacted]@rivm.nl
Subject: HT_DK on GD 150 TC

Dear all.

I have a few additional considerations as regards the proposal from [redacted] And also an input concerning the remarks from [redacted].

Comments to [redacted] proposal for re-arranging the table regarding standard test methods in respect to section A or B.

I support some of these ideas but have also some concerns:

The **title of column A** should in my view be reworded, but perhaps we should modify the wording a bit more from "A. Assays primarily designed to identify

interaction with endocrine pathways, for which guidance is provided in the main Guidance Document" to "**A. Assays primarily or also designed to identify interaction with endocrine pathways, for which guidance is provided in the main Guidance Document.**" And then it would not be needed to replace TG 407, 421/422 or TG 414* to section B - if the latter is also being revised before completion of the rev. ED GD (see footnote below) .

* Footnote: Please Note that there is currently an OECD TG project for a small revision of TG 414 to include a few ED related endpoints (which might be especially relevant for substances with no TG 421/422 and no TG 443 data) - depending of its finalization we may add a foot note referring to this

REASON for the proposed addition of "or also" in the title of section A: I don´t think that TG 443 was primarily designed to identify interaction with endocrine pathways but has a boarder scope even though this test guideline was also developed to constitute the most comprehensive test guideline for identifying a range of ED MoAs concerning the EATS pathways and their adverse reproductive toxicity effects. The same goes with MEOGRTS and ZEOGTS.

Also note that both **TG 407 and TG 421/422** has in the past been revised to include also some ED relevant biomarker endpoints .

In relation to **TG 415** I think we may skip this not really used test guideline from the list (it is also very old, contains virtually no endocrine specific endpoints and it is also likely that this TG will be proposed for deletion at WNT 2017, which seems to be acceptable to all consulted so far).

As for the best placing of **TG 426 (DNT study)** in either section A or B: I´m unsure but perhaps the proposal to place it is section B is in fact the most appropriate (?)

I wonder furthermore whether it furthermore should be considered whether we should consider in section A at level 5 to also place the new **NIH MOG test guideline** ??? ... - just a thought for check up / consideration by more informed people of the group than me regarding particular guideline....

Comments to [redacted] **intervention on adding FELS.** Fine to include this FELS test guideline in section C - placing at level 4 - see comments below, which also apply here:

Final **general remark:**
I understand the idea /coverage of the **ED CF levels 1-5** - where actually level 1 is in my view somewhat confusing because it refers to existing data (which could be data from all ED CF levels) - but **does the application of test methods to each ED CF level apply to methods in section C at all ?** : How can it, when the experience with them in respect to ED identification is so low that currently no guidance can be provided at all here in this guidance document?

Best regards

[redacted]
Danish EPA

Fra: [redacted]@rivm.nl]
Sendt: 8. november 2016 23:18
Til: [redacted]@oecd.org
Cc: [redacted]@iss.it; [redacted]@oecd.org; [redacted]; [redacted]@echa.europa.eu; [redacted]@nihs.go.jp; [redacted]@biology.sdu.dk; [redacted]@regulatoryscience.com; [redacted]@dow.com; [redacted]@ec.europa.eu; [redacted]@echa.europa.eu; [redacted]@humanesociety.org; [redacted]@nih.gov; [redacted]@phe.gov.uk; [redacted]@oecd.org; [redacted]@[redacted].freeserve.co.uk; [redacted]@dow.com; [redacted]@ec.europa.eu; [redacted]@food.dtu.dk; [redacted]@hotmail.co.jp; [redacted]@nih.gov
Emne: Betr: GD 150 TC

Dear [redacted]
We support the proposal of DK to use the word non-mammalian and mammalian. In addition, TG210 (fish early life stage test) has not yet been included in the attached table. As this TG is the standard information requirements for REACH, pesticides, biocides, pharmaceuticals, etc, it is important to include this TG in the guidance e.g. as a test of level 4 in category C.

Best regards
[redacted]

-----<[redacted]@oecd.org> schreef: -----
Aan: <[redacted]@oecd.org>, [redacted]@nih.gov>, [redacted]@food.dtu.dk>, [redacted]@rivm.nl>, <[redacted]@oecd.org>, [redacted]@dow.com>, <[redacted]@rivm.nl>, <[redacted]@nihs.go.jp>, [redacted]biology.sdu.dk>, <[redacted]@hotmail.co.jp>, [redacted]@phe.gov.uk>, <[redacted]@echa.europa.eu>, [redacted]@iss.it>, <[redacted]@[redacted].freeserve.co.uk>, <[redacted]@nih.gov>, [redacted]ec.europa.eu>, [redacted]@regulatoryscience.com>, <[redacted]@ec.europa.eu>, <[redacted]@echa.europa.eu>, <[redacted]@mst.dk>, [redacted]@dow.com>, [redacted]@humanesociety.org>
Van: <[redacted]@oecd.org>
Datum: 7-11-2016 14:58
cc: [redacted]@oecd.org>
Onderwerp: GD 150 TC

Dear colleagues,

Please find below a draft agenda for Thursday's conference call as well as a revised draft of Table A.1 (attached) prepared by [redacted] and [redacted] for discussion. In addition, we will use the conference call to address questions from [redacted] and [redacted] as the begin revisions of GD 150.

Proposed draft agenda:

- Review of draft Table A.1 (Consultants)

- Questions regarding proposed re-categorisation of assays (Consultants)

GD 150 2012	Proposed update GD 150
A. Validated assays for which guidance is	A. Assays designed primarily to identify

provided in the main GD	interaction with endocrine pathways, for which guidance is provided in the main GD
B. Assays that have not yet completed validation, or not primarily designed for detection of endocrine disruption, for which limited guidance is given in Annex 2.	B. Assays not primarily designed for detection of interaction with endocrine pathways but which have some endpoints sensitive to endocrine activity, for which guidance is given in Annex 2.
C. Assays corresponding to those in the CF (original or revised) for which no guidance has been written at present.	C. Assays corresponding to those in the CF (original or revised) for which no guidance has been written at present.

. Timing of EDTA meeting(s): May 2017, second meeting in Fall 2017? (Secretariat)

All the best,
[redacted]

[bijlage "Table A1 revision v2jo.docx" verwijderd door [redacted]/RIVM/NL]

Doc. 41

Overal 10.2.e

From: [redacted]
To: [redacted]
Subject: RE: AW: Collaboration opportunity?
Date: 22-11-2016 13:48

Hi [redacted],

This is a shame. We were hoping for a quick turnaround to deliver a publication and position in parallel with the ED technical guidance development. I know we would work well together. But would worry if we involve others it might take too long.

I discussed with [redacted] and we do intend to ask [redacted] and probably another academic to be involved. If this does not provide the sort of 'balance' RIVM needs we should probably pass on this one. But perhaps look for another project with a larger group so that we do something together in the future. Any ideas?

Best wishes,

[redacted]

From: [redacted] [mailto:[redacted]@rivm.nl]
Sent: 20 November 2016 08:52
To: [redacted]@basf.com>
Cc: [redacted]@dow.com>
Subject: RE: AW: Collaboration opportunity?

Hi [redacted]
The first choice would be [redacted], who was also in the Pellston workshop and who understands well fish issues. The second choice would be [redacted] or [redacted]. I talked with [redacted] in October and understand that she is involved in RMO now. In the past, she was in the JRC ED EAG group in which [redacted] and I were involved. According to [redacted] is the main person from UBA for the ECHA ED group. During the ECHA ED meeting in November, I talked with [redacted] too over SSC and noticed that their objectives are similar to those described in the email of [redacted] Therefore, I suggest that we can try to contact them to explore the possibility.
best regards
[redacted]

From: [redacted]@basf.com>
To: [redacted]@rivm.nl>,
Cc: [redacted]@dow.com>
Date: 11/19/2016 10:48 PM
Subject: RE: AW: Collaboration opportunity?

Hi [redacted], who is the expert from UBA you're referring to?

Doc. 41

Cheers [redacted]

Sent from my Windows Phone

From: [redacted]
Sent: 19/11/2016 11:14
To: [redacted]
Cc: [redacted]
Subject: AW: AW: Collaboration opportunity?

Hi [redacted]
1. I forwarded your email over [redacted] to my boss and got the negative answer as expected.
2. I have a different opinion over the expert from UBA. I suggest that we make a try. UBA have experts from different sectors (e.g.REACH, and pharmaceuticals). Another person would be [redacted] from CRD of UK.
best regards
[redacted]

[redacted]@basf.com> schreef: -----
Aan: [redacted]@rivm.nl>
Van: [redacted]@basf.com>
Datum: 18-11-2016 21:37
cc: '[redacted]@dow.com>
Onderwerp: AW: AW: Collaboration opportunity?

Hi [redacted],

I will meet [redacted] on Monday and we'll discuss the topic including ideas for EU regulators that could contribute. I don't think a co-author could come from UBA, given that UBA put forward the slides at the ECHA ED EG meeting.

More next week!

best wishes / freundliche Grüße

[redacted]
Senior Regulatory Scientist

Phone: +49 621[redacted], Mobile: +49 174 [redacted], Fax: +49 621 60-2[redacted], Email: [redacted]@basf.com

Postal Address: BASF SE, Crop Protection - Ecotoxicology, Speyerer Strasse 2, 67117 Limburgerhof, Germany

BASF
We create chemistry

Doc. 41

Von: [mailto: @rivm.nl]
Gesendet: Freitag, 18. November 2016 16:50
An: @basf.com>
Cc: @dow.com>
Betreff: Re: AW: Collaboration opportunity?

Hi
When I talked with our staff this morning, I have mentioned the name of . But the boss said is from the university but not from the government organisation. I tried several arguments like the paper will be based on science and only dealt with science etc, Till the end, I noticed that the argument of experts from other government organisation joining the activity would be the good reason.
At this stage, I do not have other solutions. If you have any suggestions, please let me know.
nice weekend

From: @basf.com>
To: @rivm.nl>, ' @dow.com>,
Date: 11/18/2016 04:17 PM
Subject: AW: Collaboration opportunity?

Hi

It occurred to me that (if he would accept our invitation) is member of the Advisory Committee on Pesticides that advises the UK authority CRD on scientific issues around pesticide dossiers. Would that satisfy your management?

best wishes,

Senior Regulatory Scientist

Phone: +49 , Mobile: +49 174 , Fax: +49 621 60- , Email: @basf.com
Postal Address: BASF SE, Crop Protection - Ecotoxicology, Speyerer Strasse 2, 67117 Limburgerhof, Germany

BASF
We create chemistry

BASF SE, Registered Office: 67056 Ludwigshafen, Germany
Registration Court: Amtsgericht Ludwigshafen, Registration No.: HRB 6000

Doc. 41

Von: [mailto @rivm.nl]
Gesendet: Freitag, 18. November 2016 14:11
An: @dow.com>
Cc: @basf.com>
Betreff: Re: Collaboration opportunity?

Hi
Many thanks for your kind invitation. I appreciate your effort and would like to join you. When I asked for permission, I got a negative response because we are a government institute. After further discussion, my boss agrees that I can join you on the condition that one extra expert who works in the EU government organisation can join this activity. I wonder whether you would like to include such an expert from the government organisation? If yes, we can find somebody from e.g. UBA or other organisation. If needed and if you like, we can discuss the possible candidates. If you do not like this idea, I have to stop according to the instruction of RIVM.
By the way, I was in the ECHA ED meeting last week. During the discussion on SSC, I suggested that all biomarkers in fish should be considered. I think your initiative would be important.

best regards

Centre for Safety of Substances and Products
RIVM - National Institute for Public Health and the Environment
PO Box 1, 3720 BA, Bilthoven, the Netherlands
Tel: +31-30- , m: 06-4
Fax: + 31-30 274 4401
E-mail: @rivm.nl

From: @dow.com>
To: @rivm.nl" < @rivm.nl>,
Cc: @basf.com" @basf.com>
Date: 11/18/2016 11:00 AM
Subject: Collaboration opportunity?

Hi ,

I was thinking about our recent discussions for some sort of collaboration... and I were together this week and got discussing one of the topics raised at the last ECHA ED expert group – on the potential adversity of secondary sexual characteristics in fish.

We were thinking it would be useful to write a commentary/short communication piece on the issue and its implications. Therefore were wondering if you would be interested to collaborate?

Our thoughts were along the following lines:-

- Essentially biomarker at screening tier so should be interpreted as not-adverse (much like VTG) but used to trigger higher tier testing where appropriate
  - Tie in technical issues with determination, variability, lack of quantitative link to adverse outcomes and susceptibility to being secondary responses from non-endocrine modes of action
- At higher tier should be interpreted in a weight of evidence manner with all the endpoints – in this regard to those that we know are adverse and population relevant.
- Similar framework and points to the signposts not traffic lights paper from [redacted], [redacted] et al ...

If you would be interested please let me know and I will set up a brief call to discuss (I will also flesh out and outline to assist in the call). I was thinking we may also ask [redacted] to participate as it links so nicely to his previous work.

Best wishes,

[redacted]

[redacted] Regulatory Ecotoxicologist

Direct dial: +44 (0)1235 [redacted] @dow.com

Dow AgroSciences
3B Park Square, Milton Park, Abingdon, Oxfordshire, OX14 4RN, UK

www.dowagro.com

DOW Dow AgroSciences | *Solutions for the Growing World*

DENK AAN HET MILIEU VOORDAT U DIT BERICHT PRINT
Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.
www.rivm.nl *De zorg voor morgen* begint vandaag

PLEASE CONSIDER THE ENVIRONMENT BEFORE PRINTING
This message may contain information that is not intended for you. If you are not the addressee or if this message was sent to you by mistake, you are requested to inform the sender and delete the message. RIVM accepts no liability for damage of any kind resulting from the risks inherent in the electronic transmission of messages.
www.rivm.nl/en Committed to *health and sustainability*

DENK AAN HET MILIEU VOORDAT U DIT BERICHT PRINT
Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. Het