## How to have FOlfun in the EU

Dataharvest — 23.09.2020 Stéphane Horel



## REGULATION (EC) No 1049/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

regarding public access to European Parliament, Council and Commission documents

(6)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 255(2) thereof,

Having regard to the proposal from the

Acting in accordance with the process 251 of the Treaty (2),

Vhereas:

The second subparagraph of Article 1 of the Treaty on European Union enshrines the concept of openness, stating that the Treaty marks a new stage in the process of creating an ever closer union among the peoples of Europe, in which decisions are taken as openly as possible and as closely as possible to the citizen.

this Regulation as regards documents coactivities covered by those two Treaties

Wider access should be granted to divide where the institutions are acting capacity, including under delegated same time preserving the effective decision-making process. Such made directly accessible to the

(7) In accordance with Articles
Treaty, the right of access
relating to the common for
to police and judicial of
Each institution should

(8) In order to ensure to all activities of the institutions states this Regulation

Openness enables citizens to participate more closely in the decision-making process and guarantees that the



## what LOBBYING is

Scrap

Water down

**Divert** 

**Delay** 

Write

the law



## who the "LOBBYS" are

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* Trade associations:
CEFIC, EFPIA, CosmeticsEurope...

* In-house lobbyists: Bayer, BASF, Microsoft...

* Lobbying and public relations firms:
APCO, Burson-Marsteller, Fleishman-Hillard...

* Think tanks: European Risk Forum...
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- \* Law firms
- \* Product-Defense firms (science & technical matters)
  The Weinberg Group, Exponent, Gradient...

## diy MAPPING

















5.5.2017

EN

Official Journal of the European Union

(Legislative acts)

#### **REGULATIONS**

#### REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION.

Having regard to the Treaty on Article 168(4)(c) thereof,

Having regard to the proposal from t

After transmission of the draft legisla

Having regard to the opinion of the I

After consulting the Committee of th

Acting in accordance with the ordina



## last night a DG didn't save my life

Ref. Ares(2018)4109709 - 03/08/2018



#### EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Director-General

0 3 AOUT 2018 Brussels, GROW/D4/AM/bl grow.ddg1.d.4(2018)4311095

Ms Stéphane Horel Le Monde 80, boulevard Auguste Blanqui F-75707 Paris Cedex 13

e-mail: s.horel@wanadoo.fr

Subject:

Your application for access to documents

- Ref. GestDem No 2018/2829

We refer to your request for access to documents, submitted by e-mail on 11/5/2018 and Dear Ms Horel,

registered on 24/5/2018 under the above mentioned reference number.

This re-----t results from your initial application on 26/3/2018, our fair solution proposa

officials of DG SANCO/Sante, DG Enterprise/GROW, the Secretary General, the European Medicine Agency (EMA), the EC President's Cabinet (including Commissioners and their Cabinet members)

AND

representatives of the following organisations:

- AESGP (Association of the European Self-Medication Industry)
- BVMed (German Medical Technology Association)
- COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry)
- EAMDR (European Association for Medical Device Reprocessing)
- EDMA (European Diagnostic Manufacturers Association)
- EFPIA (European Federation of Pharmaceutical Industries Associations) and
- Eucomed
- Irish MedTech (Irish Medical Devices Association)
- **Medical Mountains**
- MedtechEurope
- SNITEM (Syndicat national de l'industrie des technologies médicales)
- Johnson & Johnson
- Medical Device Manufacturers Association (MDMA)
- Medtronic
- Norgine
- Bill and Melinda Court

of 19/4 applica reason 11/5/2 No 20 under

1. "On the topic of medical devices, all correspondence (including emails), the list of meetings with detailed minutes and any other reports of such meetings between DG SANCO/Sante, DG Enterprise/GROW, the Secretary General, the European Medicine Agency (EMA), the EC President's Cabinet (including Commissioners and their Cabinet members) between January 2015 and 30 June 2017.

## **OUTSMART EU Commission's lawyers**

- \* What you can ask for (and get)
  - = Emails and letter
  - = Documents and draft versions
  - = Minutes of meetings

**Internal & external** 

- \* Be precise —> time frame
- \* Be reasonnable —> target
- \* Be patient
- \* Be ready to play with super qualified lawyers

## How to pretend you made a compromise

- all correspondence (including emails), the list of meetings with detailed minutes and any other reports of such meetings concerning the consultation on the 1999 chlorpyrifos DAR within the EU Commission, and also between the EU Commission and Member States or Member States competent authorities.
- all correspondence (including emails) to the EU Commission from Dow and other chlorpyrifos manufacturers from January 1993 to December 1995.
- all correspondence (including emails) concerning the designation by the EU Commission of Spain as the rapporteur Member State for chlorpyrifos between 1993 and 1995.
- 4) the minutes of the first tripartite meeting of 23 October 2000 on chlorpyrifos with the main data submitter and the rapporteur Member State, and also all correspondence (including emails) concerning this meeting.
- all correspondence (including emails), the list of meetings with detailed minutes and any other reports of such meetings concerning the consultation following the first tripartite meeting of 23 October 2000 on chlorpyrifos.
- 6) the minutes of the second tripartite meeting of 3 Februray 2004 on chlorpyrifos with the main data submitter and the rapporteur Member State, and also all correspondence (including emails) concerning this meeting.
- 7) all correspondence (including emails), the list of meetings with detailed minutes and any other reports of such meetings concerning the consultation following the second tripartite meeting of 3 February 2004 with the main data submitter and the rapporteur Member State.
- 8) all documents (correspondence, memos, etc.), and the list of meetings with detailed minutes and any other reports of such meetings concerning the final examination and review of chlorpyrifos for the meetings of the Standing Committee on the Food Chain and Animal Health (SCOPAFF) of 3 June 2005.
- the detailed minutes of the meeting of the SCOPAFF of 3 June 2005.
- the Review Report (SANCO/3059/99 rev. 1.5) for chlorpyrifos, finalised in the Standing Committee on the Food Chain and Animal Health (SCFCAH).
- all correspondence (including emails), the list of meetings with detailed minutes and any other reports of such meetings concerning the request by DG SANCO to the Chlorpyrifos Task Force to provide toxicological studies to the Commission, to EFSA and to Spain as rapporteur Member State (RMS) in 2012.

#### And on chlorpyrifos and/or other plant protection products:

- 14) the concise outline report of ECCO 131 peer review meeting (14464/ECCO/BVL/03, 12 February 2003), and all its annexes, including:
  - -Annex 5: thiamethoxam (Rep\_4(ECCO131)\_5thiamethoxam.doc)
  - -Annex 6: chlorpyrifos (Rep\_4(ECCO131)\_6chlorpyrifos.doc)
  - -Annex 7: chlorpyrifos-methyl (Rep\_4(ECCO131)\_7chlorpyrifos-methyl.doc)
- 15) the concise outline report of ECCO 132 peer review meeting (14691 /ECCO/BVL/03, 10 March 2003), and all its annexes, including:
  - -Annex 5:thiamethoxam (Rep\_1(ECCO132)\_5thiametoxam.doc)
  - -Annex 6: chlorpyrifos (Rep. 1(ECCO132) 6chlorpyrifos.doc)
  - -Annex 7: chlorpyrifos-methyl (Rep\_1(ECCO132)\_7chlorpyrifos-methyl.doc)
- 16) the concise outline report of ECCO 82 peer review meeting, and all its annexes (1999)
- 17) the concise outline report of ECCO 76 peer review meeting, and all its annexes (1999)
- 18) the concise outline report of ECCO 78 peer review meeting, and all its annexes (1999)

Initial FOI request (I exaggerated a bit) (I admit)

## (The EU Commission CLEARLY exaggerated too)



#### EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation Pesticides and biocides

> Brussels, SANTE.E.4/DI/mb(2020)470117

Sent by email only to: horel@lemonde.fr

Dear Ms Horel.

Subject: Your application for access to documents – Ref GestDem No 2020/0297

According to our first estimates, the handling of your request would take 63 working days, broken down as follows:

- identification of the documents falling under your request: 20 working days;
- retrieval and establishment of a complete list of the documents identified: 3 working days;
- scanning of the documents: 3 working days;
- assessment of the content of the documents in light of the exceptions of Article 4 of Regulation 1049/2001: 10 working days:
- third-party/Member State consultations under Article 4(4) and/or 4(5) of Regulation 1049/2001: 10 working days;
  - final assessment of the documents in light of the comments received: 5 working days;
  - drafting of the reply: 2 working days;
  - redaction of those parts of the documents to which one or several exceptions apply(ies): 3 working days;
  - internal approval of the draft decision on your request: 5 working days;
  - preparation of the reply and the documents for dispatch (scanning of the redacted versions, administrative treatment,...): 2 working days.

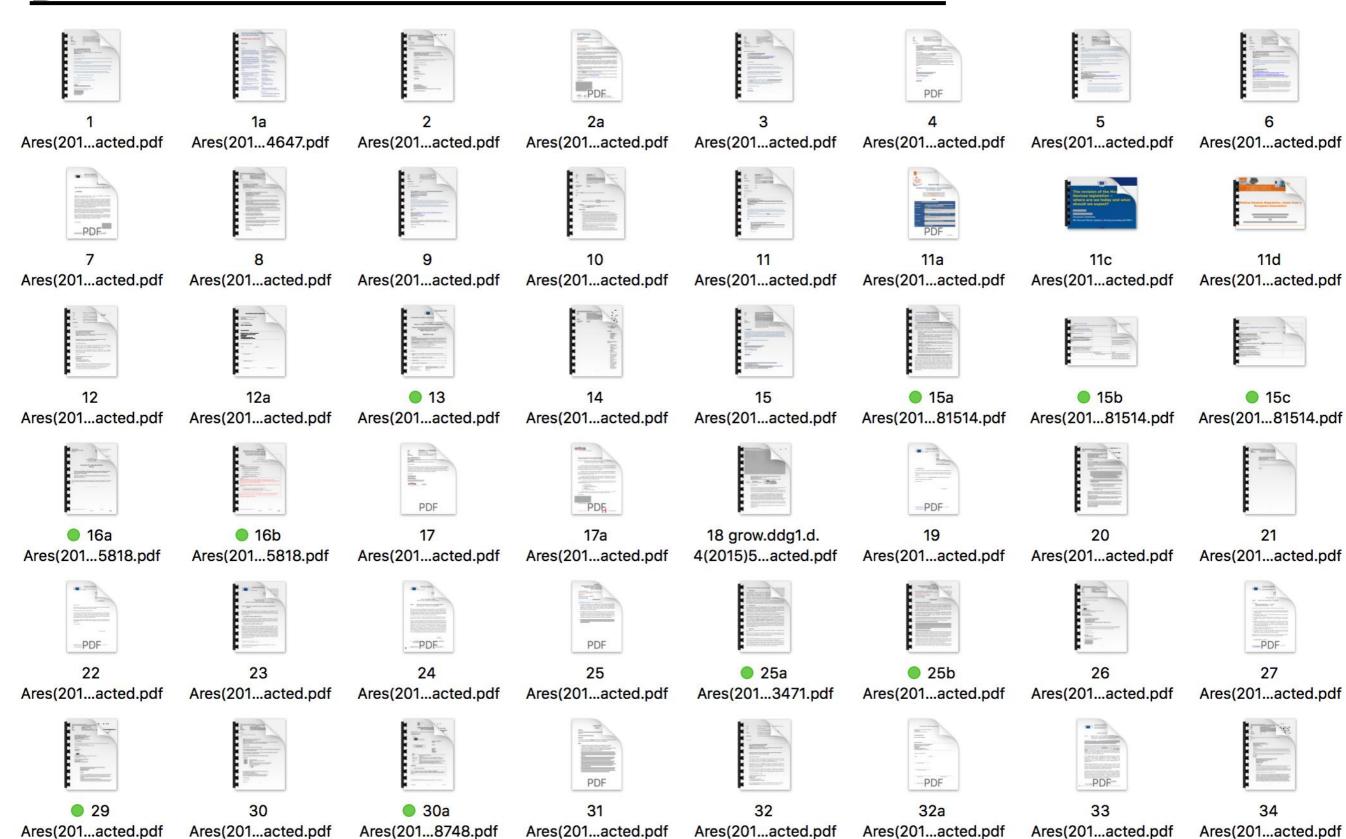
#### (pretending I became reasonable)

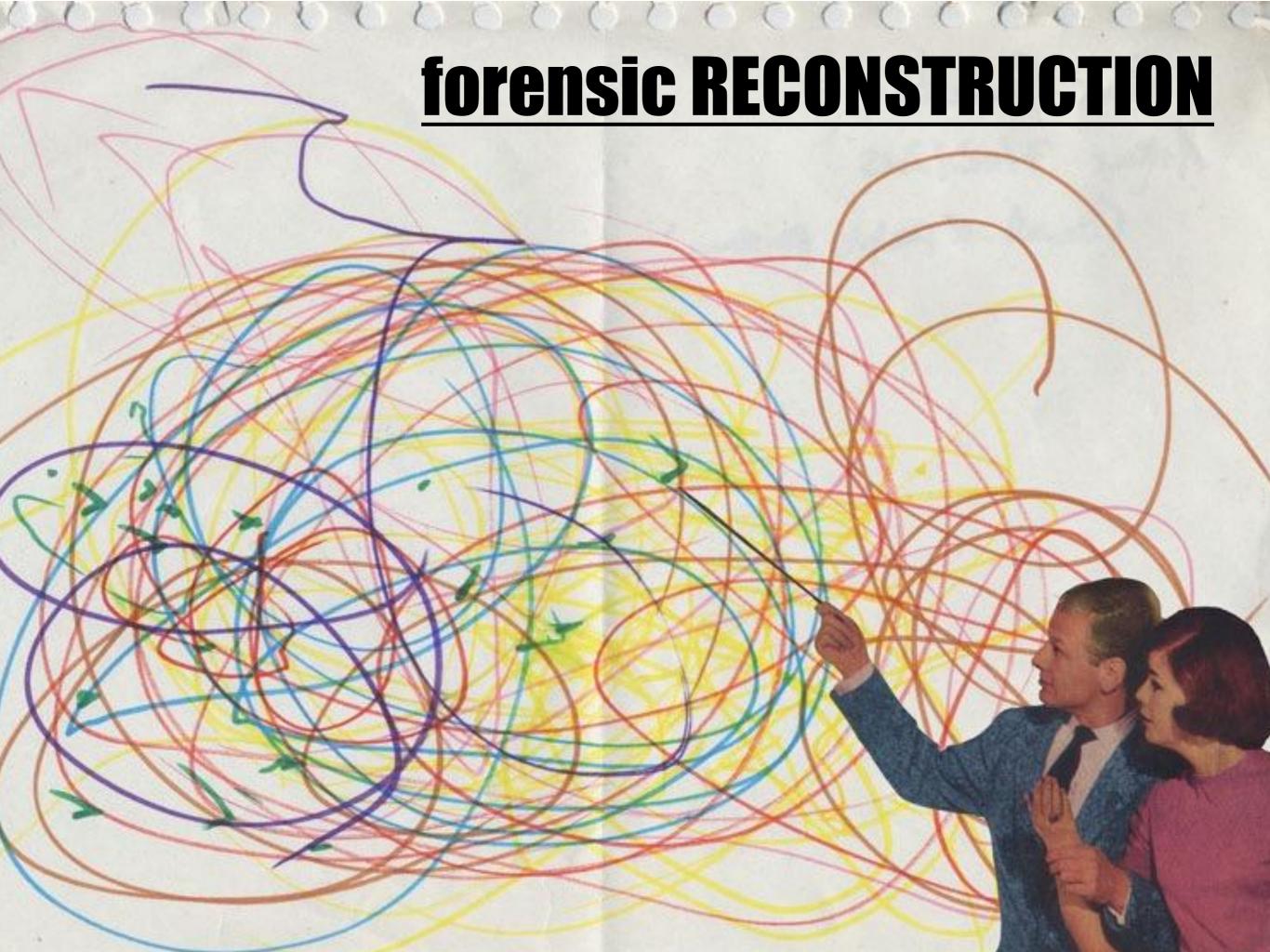
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## HARVEST time +õ

Nr.	Title of document	Type of document	Date of document	Associati on/Organi sation/Co mpany concerne d	Reference Number	Sender	Addressee	Attach ment(s	Discl osure ? (Y/N)	Exception under Regulation 1049/2001	Comments
1	N/A	letter	16/01/2012		Ares(2012)54128	MEP M.	Commission		Y	Article 4(1)(b)	redaction of content which is outside
						McGuinness MEP M.	Commission				redaction of content which is outside
2	N/A	letter	31/01/2012	i	Ares(2012)123821	McGuinness	Commission		Y	Article 4(1)(b)	the scope of the request
3	Poly Implants Prothese (PIP)	letter	23/02/2012		Ares(2012)208773	Commission	MEP M. McGuinness		Y	Article 4(1)(b)	redaction of content which is outside the scope of the request
4	Revision of the regulatory framework for medical devices	note+annex to the note	02/02/2012		Ares(2012)118034	Commission	N/A	1	partial	Articles 4(1)(b); 4(2)	
5	Commission letter	e-mail+letter	06/02/2012		Ares(2012)135080	Team-NB	Commission	1	Y	Article 4(1)(b)	
6	N/A	letter	01/03/2012		Ares(2012)240920	Commission	Team-NB		Υ	Article 4(1)(b)	redaction of content which is outside the scope of the request
7	MedTech Forum 2012	e-mail+letter	29/05/2012		Ares(2012)641783	Eucomed	Commission		Υ	Article 4(1)(b)	
8	COCIR concerns on Medical Devices legislation	e-mail	27/06/2012		Ares(2012)779037	COCIR	Commission		Υ		
9	Eucomed letter MDD revision	e- mail+letter+a nnex to the letter	17/07/2012		Ares(2012)873810	Eucomed	Commission	2	Υ	Article 4(1)(b)	
10	N/A	letter	02/08/2012		Ares(2012)935916	Commission	Eucomed		Υ	Article 4(1)(b)	
11	Medical devices briefing	e-mail+note	21/09/2012		Ares(2012)1098020	Commission	N/A	1	Υ	Article 4(1)(b)	redaction of content which is outside the scope of the request
12	Proposal for a regulation on medical devices	e-mail	21/09/2012		Ares(2012)1109499	AESGP	Commission		Υ	Article 4(1)(b)	
13	MDR	e-mail	16/01/2013		Ares(2013)55178	B∨Med	Commission		Υ	Article 4(1)(b)	
14	Your e-mail on medical devices regulation	letter	06/02/2013		Ares(2013)152895	Commission	B∨Med		Υ	Article 4(1)(b)	
15	IVD - legal advice	e-mail+note	21/01/2013		Ares(2013)69533	MEP Liese	Commission	1	Υ	Article 4(1)(b)	English language version of the note is provided
16	Invite to speak on changing medical Device regulations	e-mail	29/03/2013		Ares(2013)721200	BSI	Commission		Υ	Article 4(1)(b)	
17	Invite to speak on changing medical Device regulations	e-mail	15/04/2013		sanco.ddg1.b.dir(201 3)788816	Commission	BSI		Υ	Article 4(1)(b)	
18	Draft reports of the European Parliament on the Proposal for a Regulation on medical devices	note	22/04/2013		Ares(2013)735775	Commission	N/A		Y	Article 4(1)(b)	
19	re: Invitation to speak at European MedTech CEO RoundTable	e-mail+letter	18/06/2013		Ares(2013)2471851	MedTech Europe	Commission	1	Υ	Article 4(1)(b)	

## your HOME screen for weeks





## A timeline is a FOI $\square$ 's best friend

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## WHO's who



#### https://op.europa.eu/en/web/who-is-who

		CAB LAJANI	nttp://www.europari.europa.eu/tne-president/tr/ie-cabinet	
EVANS Lowri (mrs)	DG GROW	Director general	https://ec.europa.eu/info/persons/director-general-lowri-evans_en	09.2015 –
D'ACUNTO Salvatore	DG GROW	Head of unit Dir D — D/4 Health Technology and Cosmetics		
PETTINELLI Carlo	DG GROW	Director Dir D — Consumer, Environmental and Health Technologies	Led the negotiations in trilogue	(11.2015) =2018
HANSSON Erik	DG GROW	Deputy Head of Unit Dir D — Consumer, Environmental and Health Technologies Unit 4. Health technology and Cosmetics	Working on MDs since 2012, in charge of the implementation of the Commission's « PIP Action plan ».  EU rep at IMDRF <a href="http://www.imdrf.org/about/mcma.asp">http://www.imdrf.org/about/mcma.asp</a>	
ROCHE Jean-François	DG GROW	Policy Officer Dir D — Consumer, Environmental and Health Technologies Unit 4. Health technology and Cosmetics		
HOUDRY Vincent	DG GROW	Policy Officer Medical Devices Dir D — Consumer, Environmental and Health Technologies Unit 4. Health technology and Cosmetics	Formely at the Permanent representation of France in Brussels at the Council as Counsellor (health, medicines and medical devices) at the Employment, social policy and health department 2012-2016 <a href="https://www.linkedin.com/in/vincent-houdry-58403a32/">https://www.linkedin.com/in/vincent-houdry-58403a32/</a> Formerly French ministry/agency ANSM.  One bio says he worked for the industry but this is not mentioned on his linkedIn profile <a href="https://www.medpharmplasteurope.org/sites/default/files/articles/files/29-11-2016%20MPPE%20Conference%202016_speakers%27%20bios.pdf">https://www.medpharmplasteurope.org/sites/default/files/articles/files/29-11-2016%20MPPE%20Conference%202016_speakers%27%20bios.pdf</a> .	Since July 2016
SCALZO Salvatore	DG GROW	Policy and Legal Officer THEN Legal Assistant Dir D — Consumer, Environmental and Health Technologies Unit 4. Health technology and Cosmetics	Main tasks: Negotiation of the proposed new EU Regulations on medical devices; Coordinator of the the EU Work Groups on device identification and traceability (UDI) and medical software; Harmonised standards (evaluation and daily policy management); contribution to the coordination of IMDRF (International Medical Devices Regulators Forum)-related activities and representation of the EU in the Forum; Policy and legal support in the context of other international activities; EU member of the GMDN (Global Medical Device Nomenclature) Policy Advisory Group.	Nov. 2013

## Profession: reading other people's mail

From:

Sent: Tuesday, July 07, 2015 2:48 PM

To: BERMIG Carsten (CAB-BIENKOWSKA)

Subject: BVMed goes Brussels - Trilog zur Medical Device Regulation kann beginnen /

Einladung zum Arbeitsessen am 21. September 2015

Ende Juni hat der Europäische Rat eine Positionierung zur geplanten Medizinprodukteverordnung (Medical Device Regulation) gefunden. Im September könnte dann der Trilog beginnen.

Bei einem

Arbeitsessen im Restaurant "Amor Amor" Rue du Trône, 59 1050 Bruxelles am Montag, 21. September 2015 von (18.30 Empfang) 19.00 – 21.00 Uhr

#### FUEHRING Stefan (SG)

From:

<

.@bayer.com>

Sent:

07 June 2013 14:04

To:

KLINGBEIL Marianne (SG); MOSER Stefan (SG)

Cc:

Subject:

Notwendigkeit für Impact Assessment - Vorschlag der Kommission zu Endokrinen

Disruptoren

Attachments:

Teagasc ED Impact Assessment.pdf; 22658\_Agri impact of ED criteria - April 2013

(2).pdf

Categories:

Blue Category

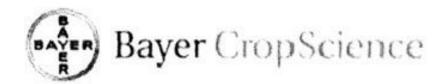
Sehr geehrte Frau Dr. Klingbeil, sehr geehrter Herr Moser,

Die Europäische Kommission bereitet zur Zeit unter Federführung von DG ENV eine "Empfehlung für eine Gemeinschaftsstrategie zu Endokrinen Disruptoren" vor. Hierbei wird die Kommission auch einen Vorschlag ("Recommendation") für die Definition, Identifizierung und Kategorisierung von Endokrinen Disruptoren vorlegen. Die Empfehlung ist engstens verknüpft mit den EU-Regulierungen zu Chemikalien, Pflanzenschutzmitteln, Bioziden und Kosmetika (Notwendigkeit der Umsetzung erfolgt in sektorale Gesetzgebung).

Wir bitten Sie deswegen, sich für die Durchführung eines Impact Assessments einzusetzen.

Sehr gerne würden wir weitere Argumente, die auf einer Analyse einer von uns beauftragten Internationalen Kanzlei beruhen, mit Ihnen in einem persönlichen Gespräch noch vor der Sommerpause austauschen.

Freundliche Grüße / Best regards



Science For A Better Life

Bayer CropScience Square de Meeus 40 Belgium – 1000 Brussels 14 March 2013 20:56 GIRAL-ROEBLING Anne (ENTR) @basf.com @basf.com; Proposal to amend ED criteria.doc; ECPA agri impact assessment of ED criteria - 8 Endocrines March 2013.doc

#### "impact assessment"

e that my colleague Tobias sent out earlier today to your Cabinet Colleague Massimo oposed wording about exactly your idea we discussed in our meeting with you, Eric, you about hazard characterization - and also a very recent impact assessment as we also ing our meeting. Plse let me know if you find this helpful and if we should forward the impact ect: :hments:

ARENA Francesca (SANCO); FLUEH Michael (SANCO); BEREND Klaus (ENTR); LIEGEOIS Eric (ENTR); Euros Jones; FABRIZI Laura (SANCO); GIRAL-ROEBLING Anne (ENTR); MUNN Sharon (JRC-ISPRA); EMBERGER Geraldine (TRADE); @cefic.be; @cefic.be; VAN DER JAGT Katinka (ENV) RE: ECPA comments on document "Revised version of possible elements for criteria for identification of endocrine disrupters" - February 2013 22661\_ECPA response to DG Env ED criteria questions - 8 March 2013.doc: ECPA agri impact assessment of ED criteria - 8 March 2013.doc

3jorn

#### 'possible impacts of the final criteria.'

HANSEN Bjorn (ENV); KORYTAR Peter (ENV)

cognise the calls for further information on the possible impacts of the final criteria. This has no ntforward task with several elements of the proposals being uncertain. But based on the second appears closer to the final criteria, we have undertaken an impact assessment for pesticides wh

@ecpa.eu> 23 March 2013 11:31 JOHNSTONE Duncan (SG)

# @dow.com

Follow-up: Meeting with Dow AgroSciences and the European Crop Protection Association: Wednesday 20 March at 10.00

3-US-EPA Comments - Commission ED Criteria.pdf; 22658 ECPA agri impact assessment of ED criteria - March 2013.pdf

"lack of impact assessment"

the key points for us is the lack of impact assessment to accompany the development of ·lieves will have deep impacts inter alia on manufacturing, trade, agricultural output and s to develop criteria to identify and rules to regulate endocrine disruption has been ongoing

om ent:

ubject:

@amchameu.eu> 24 May 2013 09:58 GIRAL-ROEBLING Anne (ENTR) @eppa.com

Request for a meeting with AmCham EU: lacking impact assessment on endocrine disruption draft criteria - 30 May meeting of the Commission's ad hoc working group on endocrine disruptors

ear Ms. Giral-Roebling,

"assessing what its impacts will be"

such a decision will have wide reaching implication for the REACH system and other EU environmental policy , as w for all industry actors who comply with this legislation, and we are worried to see that this decision, which is the si of many scientific debates, might be taken on political grounds, without first assessing what its impacts will be on European Market.

@bayer.com>

07 June 2013 14:04

KLINGBEIL Marianne (SG): MOSER Stefan (SG)

Notwendigkeit für Impact Assessment - Vorschlag der Kommission zu Endokrinen

Teagasc ED Impact Assessment.pdf; 22658\_Agri impact of ED criteria - April 2013

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eehrte Frau Dr. Klingbeil, sehr geehrter Herr Moser,

'impact assessment'

om:

FLUEH Michael (SANCO)

ent:

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07 October 2013 14:35

ubject:

FW: BTO of meeting Commissioner Borg/ECPA on 26 September 2013

On endocrine disruptor industry welcomes work of EFSA and on fact that impact assessment will now be carried out.

Dear Mrs Benini

From: Pierre Bouygues [mailto:PBO@amchameu.eu]

Sent: Wednesday, May 29, 2013 9:36 AM

To: DUDZINSKA Katarzyna (BEPA)

Cc: GLOVER Anne (BEPA); MUELLER Jan Marco (BEPA); meglena.mihova@eppa.com Subject: RE: Request for a meeting with AmCham EU: lacking impact assessment

on endocrine disruption draft criteria

Dear Ms. Dudzinska,

impact assessment

ed that any decision

The AmCham EU Environment Committee 100 years and on thresholds for endocrine disruptors would be adopted at the end of June. Therefore, we would like to kindly request a meeting with Professor Glover before the end of June to discuss with her the importance of an impact assessment before

@ecpa.eu>

25 June 2013 07:11

Francesca.Benini@ec.europa.eu

GIRAL-ROEBLING Anne (ENTR); @basf.com;

@basf.com

Follow-up: Meeting with ECPA and BASF regarding Endocrine Disruptors W13-032 - RD spending.pdf

"substancial impact on research"

# One FOI a day keeps the doctor away



### Thank you for your attention

# Think FOI

horel@lemonde.fr @stephanehorel Signal + 33 686 92 77 18

