La vulnérabilité de la régulation :
le cas emblématique des perturbateurs endocrininens

Séminaire IDDRI
Paris, 14.06.2016
Stéphane Horel

TOP DÉPART

2009 Règlement pesticides
critères guillotine (Cut-off)
> Définition

2012 Règlement biocides
+ Provision REACH

DEADLINE déc. 2013

La MISSION

DAVID contre GOLIATH saison 275 episode 83

cefic

40 millions € / an
170 employés

European Crop Protection

BASF
The Chemical Company

BAYER

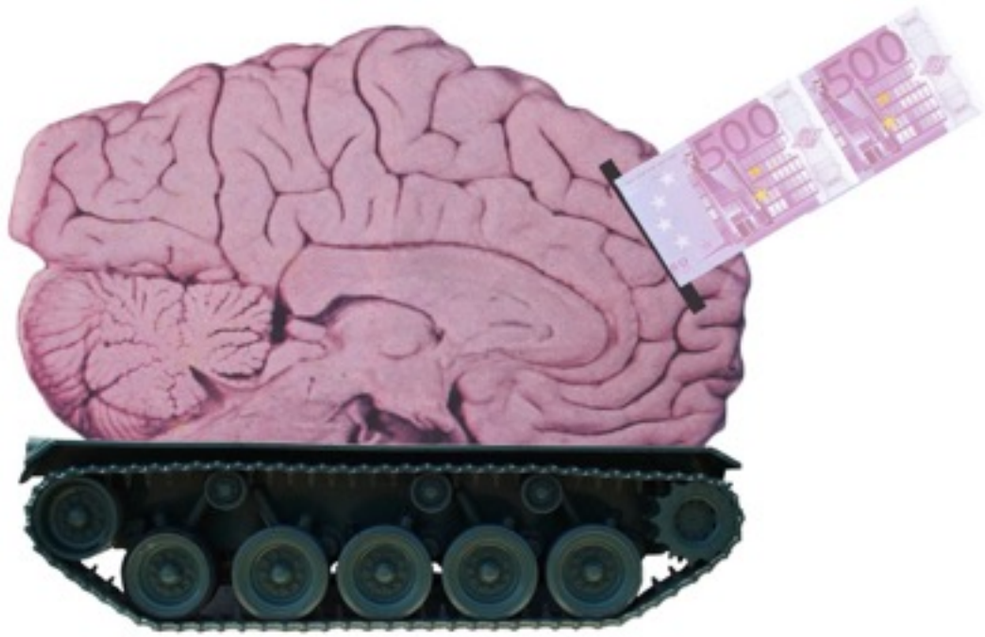
syngenta

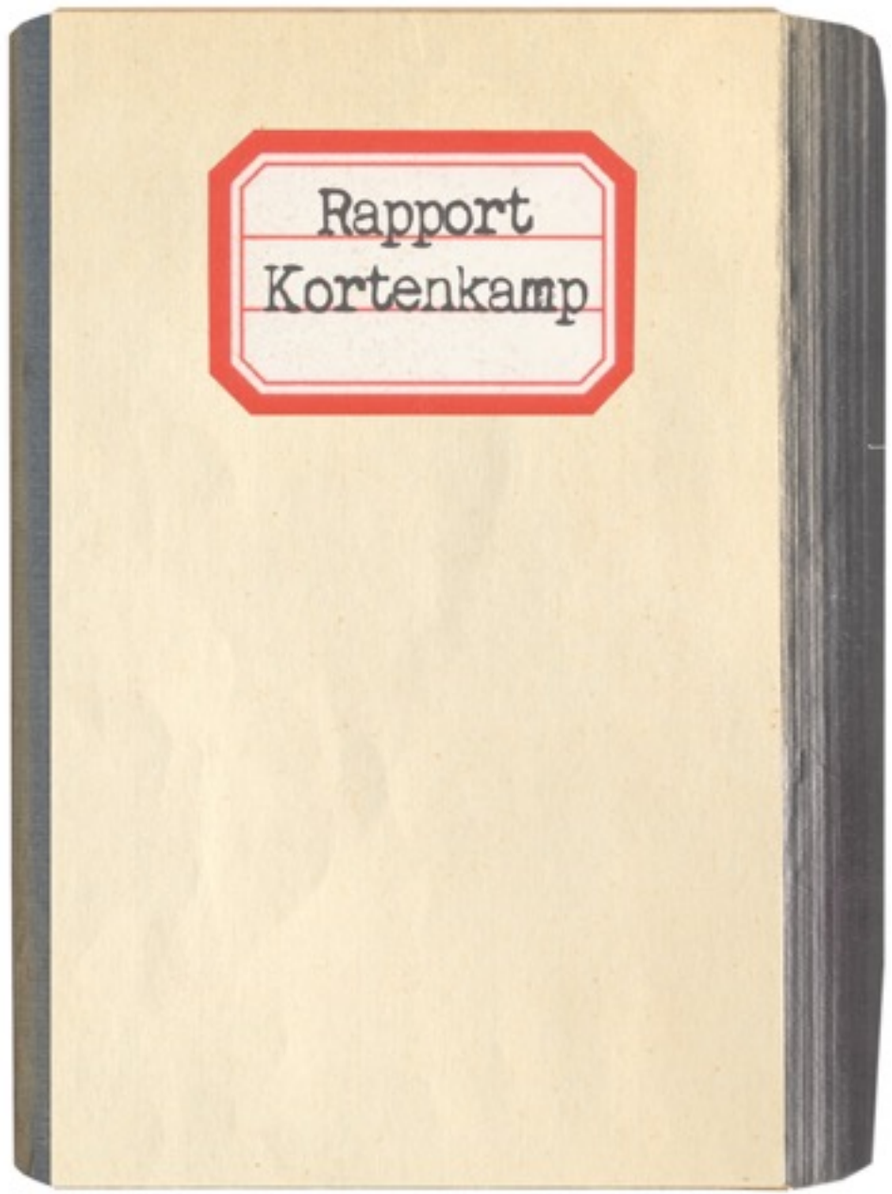
Health and Environment Alliance

680.260 € / an
8 employés

La SCIENCE est un SPORT DE COMBAT

2012 Rapport Kortenkamp sur l'État de la science sur les pertubateurs endocriniens





Critical Reviews in Toxicology, 2012; 42(10): 865–873
© 2012 Informa Healthcare USA, Inc.
ISSN 1040-8444 print/ISSN 1547-6898 online
DOI: 10.3109/10408444.2012.690940

REVIEW ARTICLE

A critique of the European Commission "State of the Art Assessment of End

Lorenz R. Rhomberg[1], Julie E. Goodman[1], Wa
Glen Van Der Kraak[5]

[1]Gradient, Cambridge, MA, USA, [2]Departm
[3]Applied Pharmacology and Toxi
Florida College of Veterin
Guelph, Ontari

Declaration of interest

The employment affiliations of the authors are as shown on the cover page. Lorenz Rhomberg and Julie Goodman are employees of Gradient, a private consulting firm that provides services to both private and public

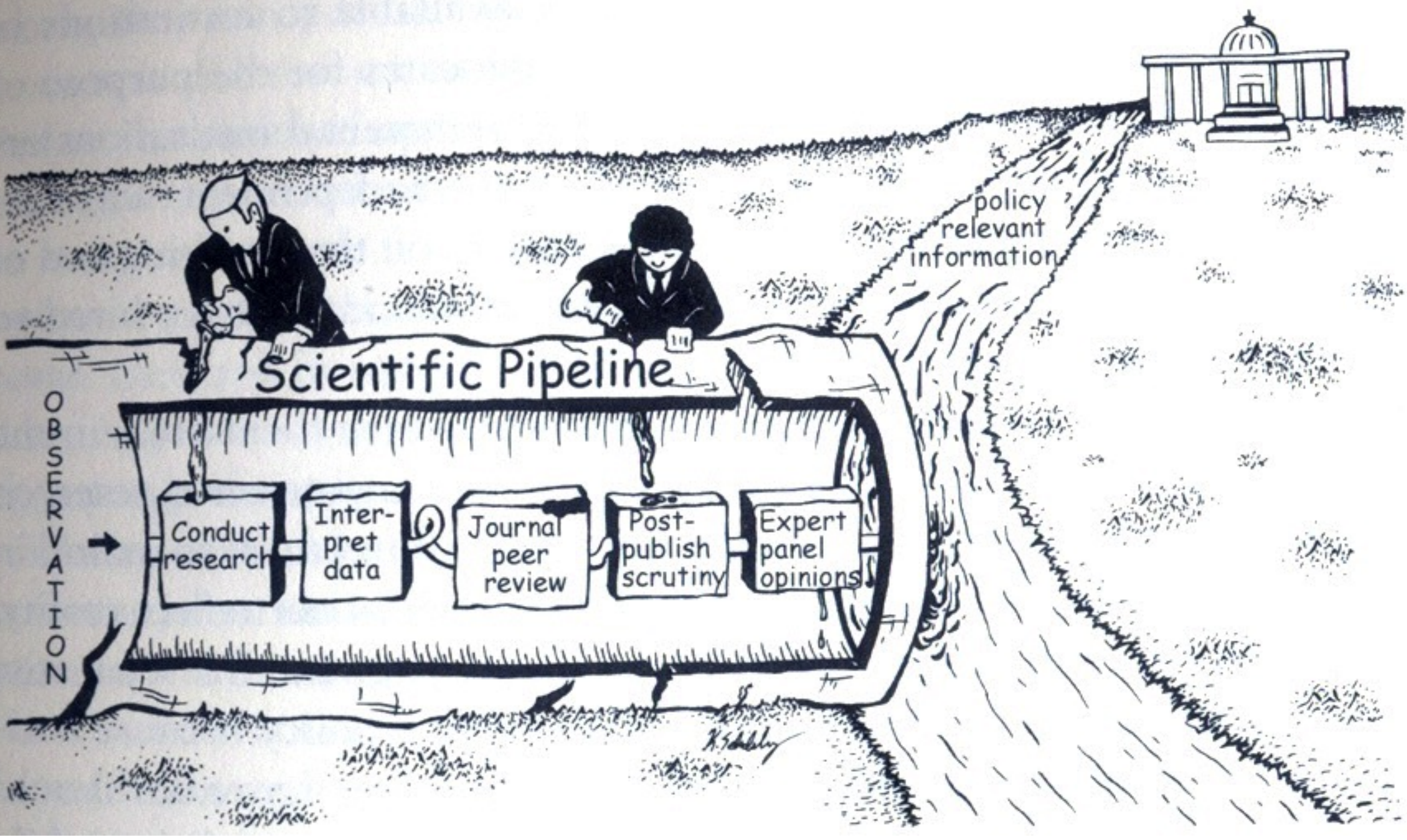
La MATRICE

Manufacture du doute

Incertitude –> doute
(Surtout dans l'esprit du décideur)

Moyen :
Création de pseudo-controverses

Exemples :
Amiante, pesticides, changement climatique



(Source : Mc Garity TD, Wagner WE. Bending Science. Harvard University Press 2008)

Droit d'ACCÈS à l'INFORMATION

REGULATION (EC) No 1049/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 30 May 2001
regarding public access to European Parliament, Council and Commission documents

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 Commission [1],

Acting in accordance with the procedure referred to in Article 251 of the Treaty [2],

Whereas:

(1) 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

this Regulation as regards documents concerning the activities covered by those two Treaties.

(6) Wider access should be granted to documents in cases where the institutions are acting in their legislative capacity, including under delegated powers, while at the same time preserving the effectiveness of the institutions' decision-making process. Such documents should be made directly accessible to the greatest possible extent.

(7) In accordance with Articles 28(1) and 41(1) of the EU Treaty, the right of access also applies to documents relating to the common foreign and security policy and to police and judicial cooperation in criminal matters. Each institution should respect its security rules.

(8) In order to ensure the full application of this Regulation

- A preliminary impact
current criteria. Most
80% of all fungicides in cereals would

Paola Testori Coggi
Envoyé de mon iphone

From [redacted]
Sent: Thursday, February
To: MIKO Ladislav (SAN
(SANCO);

TACTIQUES de LOBBYING

– Critère de puissance
ECETOC 01.2009

– Stratégie de l'encerclement

– Chiffre épouvantail
3-4 B € / 65 B €

– Chantage au TTIP

– Étude d'impact
Délai 12-18 mois

PP/13/AP/22658 - *Rev.3.*

European
Crop Protection

POTENTIAL IMPACT OF CURRENT DRAFT PROPOSAL FOR ENDOCRINE DISRUPTION CRITERIA

Executive summary

- ***The latest version of the endocrine disruption criteria prepared by DG Environment[1] is expected to severely reduce the availability of crop protection products in Europe, with a substantially greater impact than originally expected when Regulation 1107/2009 was adopted.***

- ***Based on an assessment made in 2009 by the UK government (PSD/CRD), the market value of products identified as being affected by the ED criteria has been calculated at between €3-4 billion. While the 37 active substances represent 10% of the number of approved active substances currently on the European market, they represent 35-45% of the current European market in terms of formulated plant protection product use.***

- ***Looking at the criteria as currently drafted, the number of substances likely to be affected is greater than the 37 active substances that were initially identified by PSD/CRD.***

- ***Fungicides in particular are most vulnerable. Applying the PSD/CRD criteria, the 10***

la BLITZKRIEG

Mai 2013 : Désaccord au sein de la Commission

Juin 2013 : harcèlement pour une étude d'impact

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

BAYER Bayer CropScience

Science For A Better Life

Bayer CropScience
Square de Meeus 40
Belgium – 1000 Brussels

14 March 2013 20:56
GIRAL-ROEBLING Anne (ENTR)
[redacted]@basf.com; [redacted]@basf.com
Endocrines
Proposal to amend ED criteria.doc: ECPA agri impact assessment of ED criteria - 8 March 2013.doc

"impact assessment"

HANSEN Bjorn (ENV); KORYTAR Peter (ENV)
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); [redacted]@cefic.be; [redacted]@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

"possible impacts of the final criteria."

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,
gou 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
colleagues.

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)
[redacted]@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"

[redacted]@amchameu.eu>
24 May 2013 09:58
GIRAL-ROEBLING Anne (ENTR)
[redacted]@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

"assessing what its impacts will be"

ear Ms. Giral-Roebling,

the key points for us is the lack of impact assessment to accompany the development of
dieves 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

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 s
of many scientific debates, might be taken on political grounds, without first assessing what its impacts will be on
European Market.

<[redacted].@bayer.com>
07 June 2013 14:04
KLINGBEIL Marianne (SG): MOSER Stefan (SG)
Notwendigkeit für Impact Assessment - Vorschlag der Kommission zu Endokrinen Disruptoren
Teagasc ED Impact Assessment.pdf; 22658_Agri impact of ED criteria - April 2013 (2).pdf

eehrte Frau Dr. Klingbeil, sehr geehrter Herr Moser,

"impact assessment"

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,

The AmCham EU Environment Committee [redacted] ed that any decision 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

om: FLUEH Michael (SANCO)
ent: 07 October 2013 14:35
o: [redacted]
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

[redacted]@ecpa.eu>
25 June 2013 07:11
Francesca.Benini@ec.europa.eu
GIRAL-ROEBLING Anne (ENTR); [redacted]@basf.com; [redacted]@basf.com
Follow-up: Meeting with ECPA and BASF regarding Endocrine Disruptors
W13-032 - RD spending.pdf

"substancial impact on research"

March-July 2013. Examples of industry lobby communications to the European Commission on EDC criteria, nearly all calling for impact assessment.

Date	What	Sender	Target
08 March	Email including ECPA's own impact assessment	ECPA	DG Environment, SANCO, Enterprise, Trade, and the Joint Research Center
11 March	Email including ECPA's own impact assessment	ECPA	Janez Potočnik, Environment Commissioner
14 March	Email including ECPA's own impact assessment	BASF	DG Enterprise
23 March	Email including ECPA's own impact assessment	ECPA	Secretariat General
16 April	Email including ECPA's own impact assessment	?	DG Enterprise
21 May	Letter	COPA-COGECA	DG Environment
29 May	Request meeting	AmCham and EPPA	Anne Glover
06 June *	Letter	CEFIC	Bjorn Hansen DG Environment
07 June	Email including ECPA's own impact assessment	Bayer	Marianne Klingbeil in the Secretariat General
07 June	Email	AmCham	DG Enterprise
13 June	Meeting	Bayer	DG SANCO
19 June *	Meeting and follow up mail	ECPA	DG Agriculture
20 June *	Meeting	ECPA	Duncan Johnstone and Stefan Fuering in the Secretariat General
21 June	Email including ECPA's own impact assessment (Three industry-commissioned impact assessments in attachment)	ECPA	DG Enterprise
21 June *	Meeting	ECPA and BASF	Fabrizia Benini, member of cabinet of Antonio TAJANI, Enterprise Commissioner
24 June	Letter	CEFIC Director General Hubert Mandery	Janez Potočnik, Environment Commissioner
25 June	Email	CEFIC	DG Enterprise
25 June	Follow-up email	ECPA	Fabrizia Benini, member of cabinet of Vice-President Antonio Tajani, Enterprise Commissioner
26 June	Meeting on TTIP	AmCham EU	DG Enterprise and Trade
?	Email including ECPA's own impact assessment	?	DG Trade
27 June	Email including ECPA's own impact assessment	ECPA	Duncan Johnstone and Stefan Fuering in the Secretariat General
11 July	Email including ECPA's own impact assessment	Bayer	SANCO

6 RDV
en 15 jours

la LETTRE à ANNE

Science and conflicts of interest: Ties to industry revealed

By Stéphane Horel
Environmental Health News

September 23, 2013

Seventeen of 18 scientists who wrote a controversial editorial critical of the European Commission's plan to regulate endocrine-disrupting chemicals have past or current ties to industries. *[Full story here.]*

Bas Blaauboer, Editor-Europe, *Toxicology in Vitro,* and professor of toxicology, Utrecht University, the Netherlands
Received $529,370 in research funding from the European Chemical Industry Council (CEFIC) between April, 2008 and March, 2010. A member of Risk 21, a risk assessment project at the Health and Environmental Science Institute, which is part of the International Life Sciences Institute (ILSI), funded by food, agricultural, chemical, pharmaceutical and biotechnology companies.

Abby C. Collier, Section Editor, *Chemico-Biological Interactions*, and associate professor, John A. Burns School of Medicine, University of Hawaii, United States
Published a study partly supported by the "Human Drug Conjugation Consortium" (AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, F. Hoffman-La Roche, Lilly, Novartis, Pfizer, and Wyeth-Ayerst) in 2012. Her lab is partly funded by private foundations.

Wolfgang Dekant, Editor-in-Chief, *Toxicology Letters,* and professor of toxicology, University of Würzburg, Germany
Received funding for a 2008 study on bisphenol A (BPA) from the American Chemistry Council. Signed 18 consultancy contracts with non-disclosed private companies between 2007 and 2012. Member of the scientific advisory panel of the Research Institute for Fragrance Material, an organization for the fragrance, detergents and cosmetics industry. Former member of an advisory group for the German Association of the Automotive Industry. Receives research funding from Honeywell, since 2006. Received funding for a 2013 study from the Tetrahydrofuran Task Force, a consortium of U.S. manufacturers of tetrahydrofuran, European Chemical Industry Council (CEFIC) and The Toxicology Forum. Collaborated with industry lobby group International Life Sciences Institute (ILSI) in 2005.

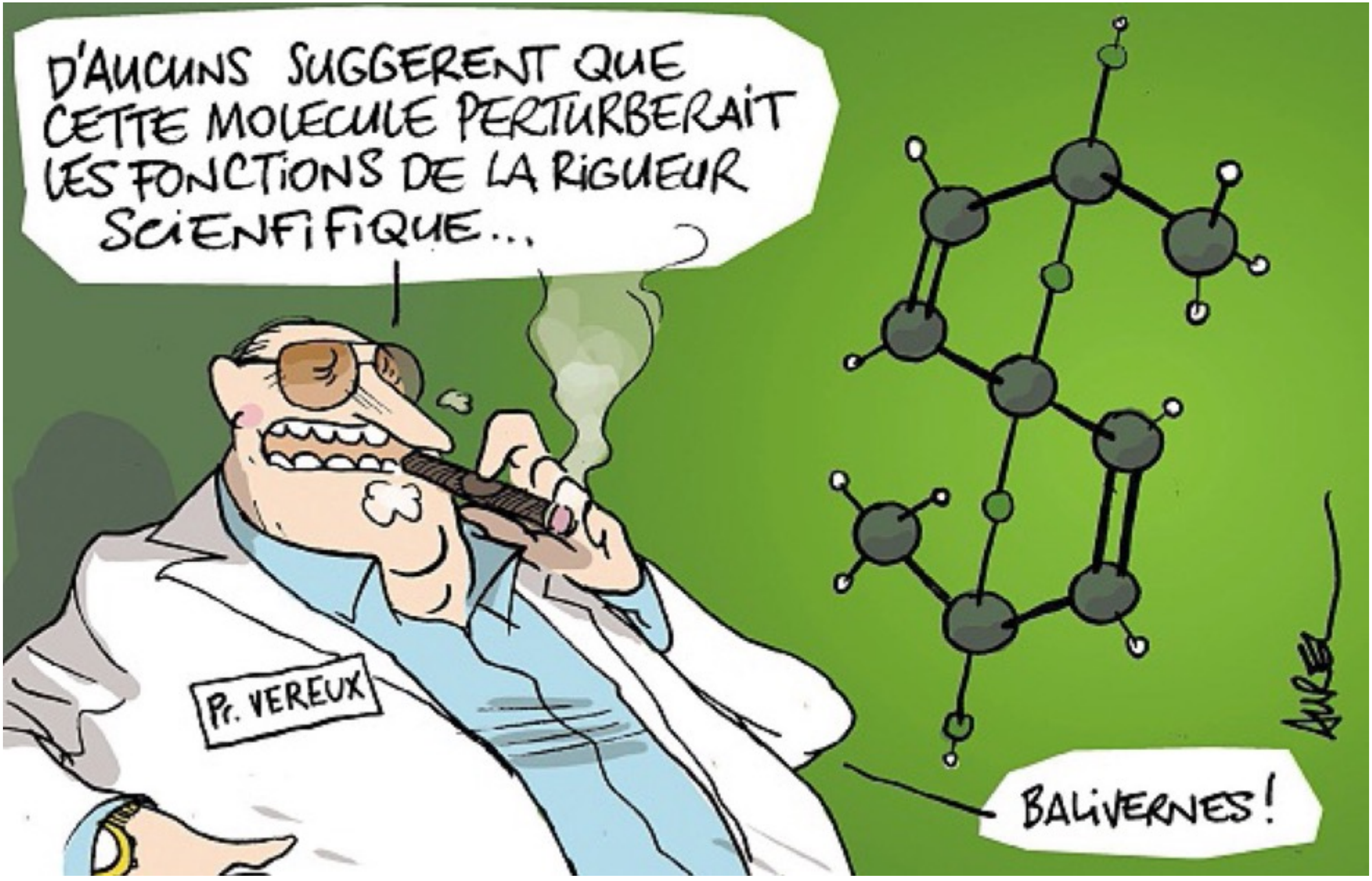
Daniel R. Dietrich, Editor-in-Chief, *Chemico-Biological Interactions*, and head of Environmental Toxicology Research Group, University of Konstanz, Germany
Former expert for the European Center for Ecotoxicology and Toxicology of Chemicals (ECETOC), funded by chemical, pesticide and oil companies. Has co-authored research with employees of Dow Europe and AstraZeneca and Bayer Healthcare.

Nigel Gooderham, Editor-in-Chief, *Toxicology Research,* and professor of molecular toxicology, Imperial College London, England
Member of the expert panel of the U.S. Flavor and Extract Manufacturers Association, the trade association of the flavor industry. Received research funds from GlaxoSmithKline and pesticide manufacturer Syngenta and collaborated with Nestlé. Former consultant for Procter & Gamble and shareholder of Banco Santander and Hargreaves Lansdown. Has co-authored studies with employees of GlaxoSmithKline, AstraZeneca and Syngenta.

Gio Batta Gori, Editor-in-chief, *Regulatory Toxicology and Pharmacology*
Tobacco industry consultant with a financial income of several million dollars from 1980 until 1999. "Regulatory Toxicology and Pharmacology" is owned by the

50 / 68 scientifiques liés à l'industrie

dont 25 ont des mandats dans des groupes d'experts
de la Commission européenne



Aurel, Le Monde 4.10.2013

Le B.A.-ba du LOBBYING

le bon message à
la bonne personne au
bon moment

EUROPEAN COMMISSION

Chief Scientific Adviser to the President

Brussels, 20 June 2013

NOTE TO KARL FALKENBERG, DIRECTOR-GENERAL ENV

Subject: Endocrine Disruptors

I have received the enclosed letter signed by a large number of very eminent experts in the field of toxicology, many of them serving or having served on Scientific Committees of the European Commission. The letter voices strong criticism of the approach taken by the Commission on endocrine disruptors.

In order to prepare my reply, I would appreciate if your service could answer the following questions:

- What scientific evidence has been used – or not used – in the current regulatory process on endocrine disruptors?
- How was this evidence procured and assessed?
- Is it correct that advice received from EFSA was ignored and if so, why?
- Why have the relevant Scientific Committees set up by the EC, such as the Scientific Committee on Health and Environmental Risks, not been consulted?
- Is it correct that a departure from existing principles – in particular the definition of safe thresholds for substances that are classified as endocrine disruptors, i.e. going from a risk to a hazard-based assessment – is intended and if so, why and on which scientific grounds?
- Is it correct that the intended legislation would allow classifying a substance as endocrine disruptor based on *in vitro* tests only?
- Has the impact of the foreseen legislation been assessed and what was the result?

I also would like to ask you to involve the Chief Scientific Adviser to the President already at an early stage in scientifically relevant files that are of such a sensitive and controversial nature. Thank you in advance for your cooperation and I am looking forward to working with you on this file.

Professor Anne Glover CBE

Cc: J. LAITENBERGER, K. VANDENBERGHE, J. BELL, C. DAY, P. TESTORI-COGGI, D. CALLEJA CRESPO, D. RISTORI

EUROPEAN COMMISSION
SECRETARIAT-GENERAL

The Secretary General

Brussels, 020713
SG.dsg1.d2. DJ/cv

NOTE FOR THE ATTENTION OF
MR K. FALKENBERG, DIRECTOR-GENERAL, DG ENV
MS P. TESTORI COGGI, DIRECTOR-GENERAL, DG SANCO

Subject: Endocrine disruptors – Next steps

By the end of 2013, the Commission has to establish criteria that will be used to identify substances with endocrine disrupting properties which will subsequently be largely phased out under the Plant Protection and Biocides Regulations. The elaboration of these criteria is sensitive because of the diverging views held by the stakeholder community and the potential impacts on parts of the chemical industry and international trade. It is important, therefore, that the Commission be able to demonstrate that it has followed a sound process in developing these legal acts and is able to defend robustly whatever decision it takes. With this in mind, we would like to make the following comments.

(1) DG ENV is developing a delegated act establishing criteria for identifying endocrine substances and envisages in addition a Commission Recommendation, a Communication with a revised endocrine strategy and a Commission staff working document assessing the current endocrine strategy. SANCO must also prepare an implementing act establishing criteria for identifying endocrine substances. There is substantial overlap between these tasks so it is important that

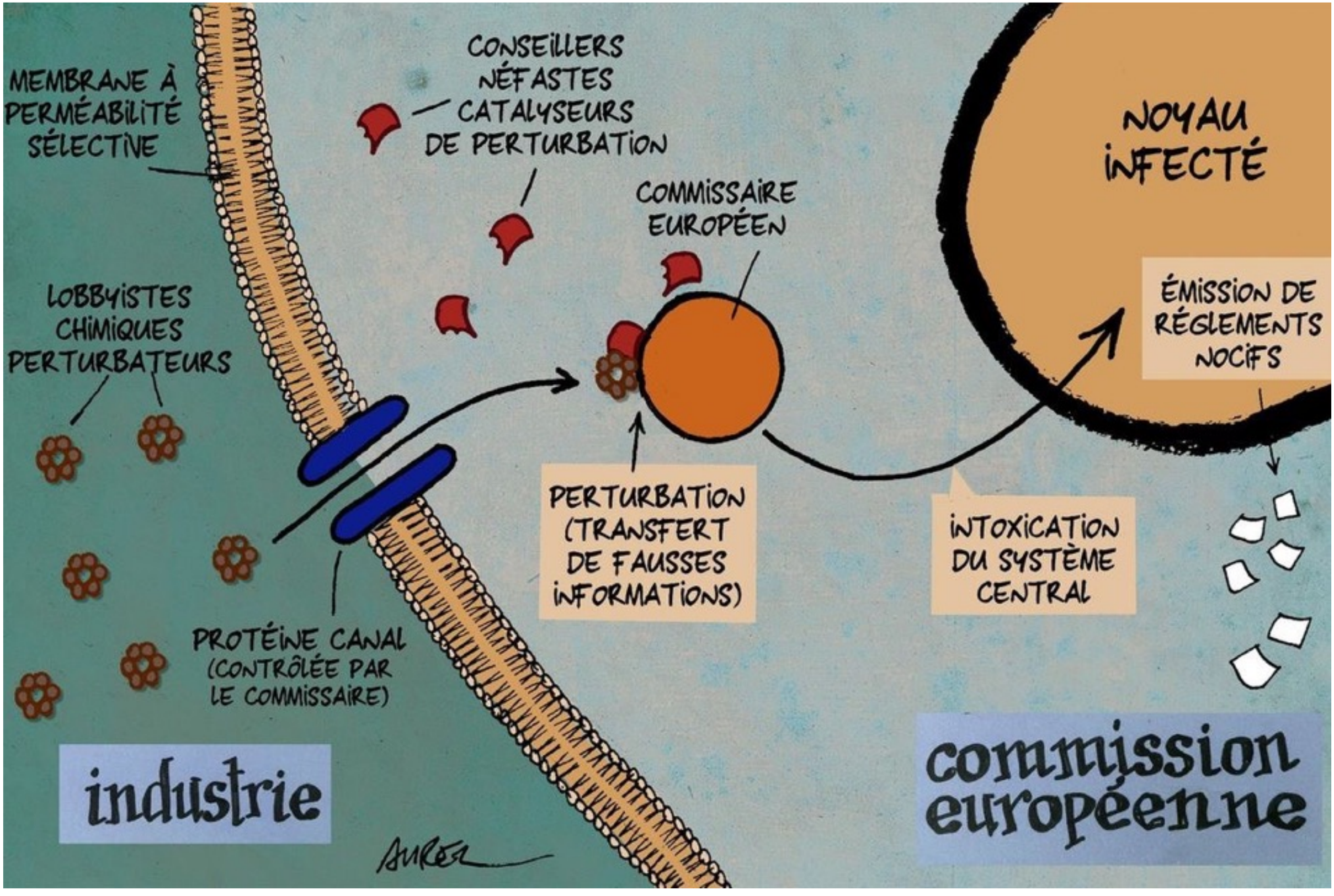
Le DÉRAILLEMENT

Déc. 2013
Deadline non respectée

Automne 2014
DG Environnement > DG SANCO//SANTE
Consultation publique et étude d'impact

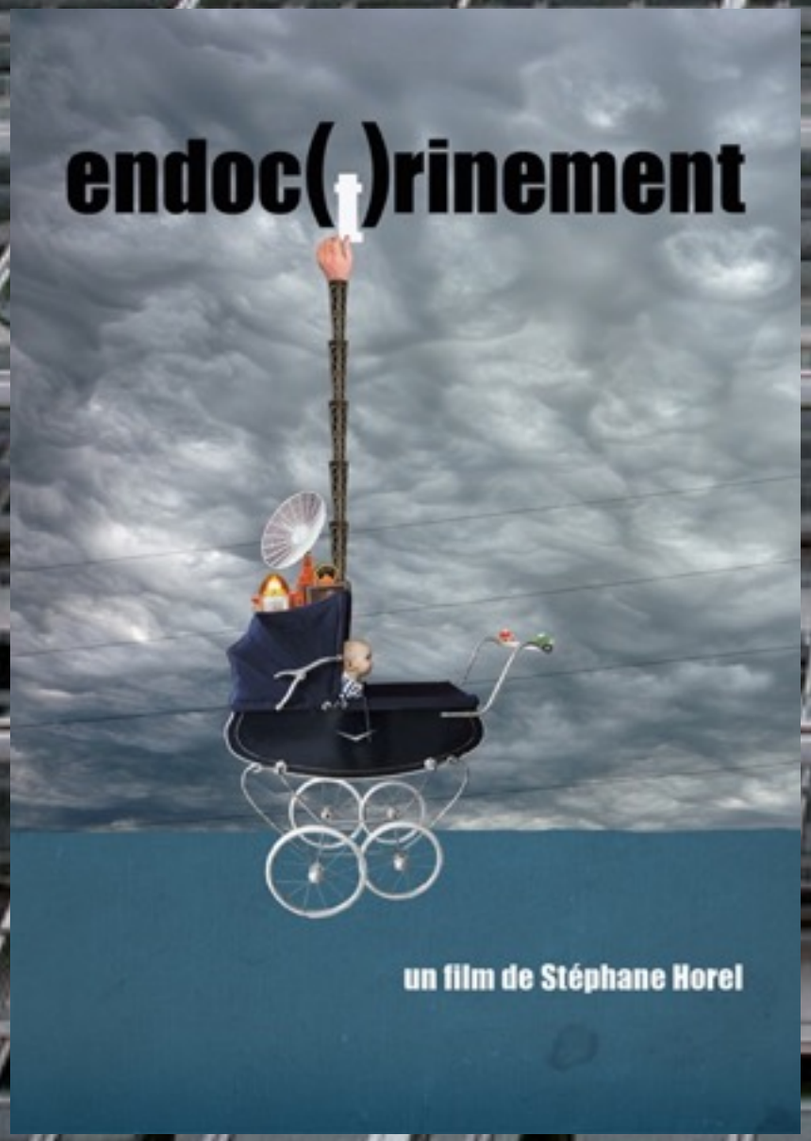
Décembre 2015
CJEU Recours en carence // Suède Vs Commission
(+ Parlement, Conseil, FR, DK, NL, FIN)

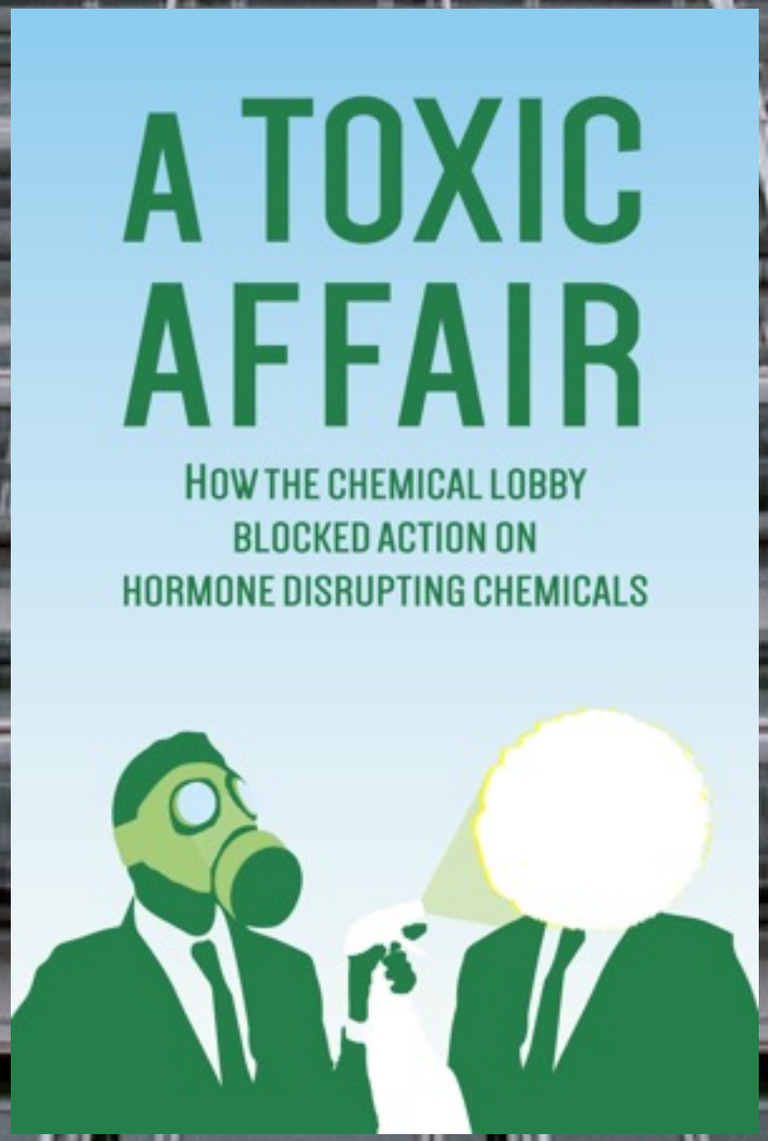
ULTIMES MANŒUVRES



Aurel, Le Monde 21.06.2013

Sources


endoc( )rinement
un film de Stéphane Horel


A TOXIC AFFAIR
How the chemical lobby blocked action on hormone disrupting chemicals


STÉPHANE HOREL
INTOXICATION
PERTURBATEURS ENDOCRINIENS,
LOBBYISTES ET EUROCRATES :
UNE BATAILLE D'INFLUENCE CONTRE LA SANTÉ
LA DÉCOUVERTE