# Conflicts of interets at EFSA – season 10\*

Stéphane Horel 11 December 2012

(\*EFSA celebrates its 10th anniversary this autumn)

On October 1st 2012, the European Food Safety Agency (EFSA) announced the creation of a working group on endocrine disrupters – a question that has become highly political. Ten of its eighteen members have conflicts of interests. Josef Schlatter, a Swiss toxicologist, received fundings from the tobacco industry during twelve years. The scientific work of only four of these experts is directly related to the field of endocrine disrupters.

A first preliminary meeting took place in Brussels on 18<sup>th</sup>-19<sup>th</sup> October in order to determine the composition of this working group. EFSA published the <u>list of its members</u> on December 3<sup>rd</sup>. Still, the proceedings of the discussions are still not available online. A spectacular gesture of transparency. Especially as the very existence of this group is subject to controversy.

\*\*To understand the context of the group creation, see at the bottom of the article « The context »\*\*

The « Scientific Committee working group on endocrine active substances » comprises 18 experts.

#### A // Four members of EFSA's Scientific Committee

- Jan Alexander (chair)
- Anthony Hardy
- Robert Luttik
- Josef Schlatter

#### B // Three members of EFSA's Panel on « Plant Protection Products and their Residues » (with decoder :

the Pesticides panel)

- Karen Hirsch-Ernst
- Susanne Hougaard-Benekou
- Daniel Pickford

## C // Ten experts

-Jacques Auger - France

Reproductive biologist. <u>Assistance Publique – Hôpitaux de Paris</u>.

- Diane Benford - UK

Civil servant. Head of Chemical risk assessment unit at the Food standards agency.

- Susy Brescia - UK

Regulatory toxicologist, Health & Safety Executive.

- Gisela Degen - Germany

Toxicologist. Leibniz research Centre for working environment and human factors at Dortmund technical University (IfADo).

- Peter Hoet - Belgium

Researcher. Public health department Catholic university Leuven.

- Peter Matthiessen - UK

Ecotoxicologist. Consultant. Retired.

- Wim Mennes - Netherlands

Toxicologist. <u>Dutch National Institute for Public Health and the Environment</u> (RIVM).

- Thomas Platzek - Germany

Toxicologist. Head of toxicology of consumer products, German Federal Institute for Risk Assessment (BfR).

- Peter Pärt - Denmark

Doctor. Seconded expert. European Environment Agency (EEA).

- Emanuela Testai - Italy

Researcher at the Instituto Superiore di Sanità in Roma.

- Theo Vermeire - Netherlands

Doctor. <u>Dutch National Institute for Public Health and the Environment</u> (RIVM).

# Conflicts of interests in the working group

All EFSA's experts have to fill in a declaration of interests (DoI) – an administrative document where they record their collaborations – remunerated or not – with the private sector during the previous five years. The aim is to allow EFSA to prevent any conflict of interest. « Omissions » can lead to sanctions. (Decision implementing EFSA's Policy on Independence and Scientific Decision Making Processes regarding Declarations of interests 21.02.2012)

# 1 - Jan Alexander (Chair) - Norway

Medical doctor. Toxicologist. Deputy Director-General of the Norwegian Institute of public health.

Member of several working groups at EFSA since 2006.

Vice-chair of EFSA's Scientific Committee (2012-2015).

No conflicts of interests in his <u>5.04.2012 declaration of interests</u>.

# 2 - Jacques Auger - France

Reproductive biologist. <u>Assistance Publique – Hôpitaux de Paris</u>. No conflicts of interests in his 4.12.2012 declaration of interests.

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**3 – Diane Benford** – UK Civil servant. Head of Chemical risk assessment unit at the <u>Food standards agency</u>.

Member of several working groups at EFSA since 2006.

In her 5.11.2012 declaration of interests, she declared:

- = Member of expert group of the International Life Sciences Institute (<u>ILSI</u>) Europe on « Data Selection for BMD Modelling » on behalf of the Food Standards Agency (09/2009 04/2012).
- >> ILSI is an industry pressure group (see box 1 on ILSI below).
- = Member of ILSI Europe expert group on the « Margin of Exposure approach to substances that are genotoxic and carcinogenic » on behalf of the Food Standards Agency (07/2006 01/2010).
- >> A certain number of « omissions » in Diane Benford's Dol:
- = Co-author of an <u>ILSI publication</u>: Benford D, Bolger PM, Carthew P, Coulet M, DiNovi M, Leblanc JC, Renwick AG, Setzer W, Schlatter J, Smith B, Slob W, Williams G, Wildemann T. *Application of the Margin of Exposure (MOE) approach to substances in food that are genotoxic and carcinogenic. Food Chem Toxicol.* 2010 Jan;48 Suppl 1:S2-24. Review. One of the co-authors, Josef Schlatter, is also a member of EFSA's working group (see below: Josef Schlatter).
- = Member of the editorial board of the scientific journal « Regulatory Toxicology and Pharmacology. ».
- >> Regulatory Toxicology and Pharmacology is an industry-captured journal (see box 2 below).
- = Speaker on behalf of ILSI at EUROTOX 2008 congress. « Overview of the work of the export group on MoE and report back on the workshop ». (Eurotox 2008 Report)
- = Chair of the expert group on the « Application of the Margin of Exposure (MOE) Approach to Compounds in Food which are both Genotoxic and and Carcinogenic » at an ILSI workshop (1-3/10/2008, Rhodes, Greece).
- >> Before 2007:
- = Co-chair at the <u>FOSIE</u> third plenary meeting. FOSIE is an ILSI research project co-funded by the European Commission. Lisbon, Portugal, 23-25/10/2002 (<u>ILSI Europe-Newsletter49</u>. <u>Février 2003</u>).
- = Author of an <u>ILSI monography</u> « Principles of risk assessment of food and drinking water related to human health ». ILSI Europe concise monograph series, 2001.
- = Author of an <u>ILSI monography</u> « The acceptable daily intake : a tool for ensuring food safety ». ILSI Europe concise monograph series, 2000.

## Box 1 / International Life Sciences Institute (ILSI)

ILSI was created in 1978 by American giants of the food industry like Heinz, Procter & Gamble, General Foods and Kraft Foods. It was largely controlled by Coca-Cola at its beginnings. Until 1991, besides, ILSI was presided by Alex Malaspina, one of the Atlanta's multinational vice-presidents.

ILSI's sources of financing have since diversified: major corporations selling food (Coca-Cola, Danone, Kraft Foods, Ajinomoto – world leader for food additives), chemistry (BASF, Dow Chemicals, DuPont...), pesticides and GMOs (Monsanto, Bayer CropScience, Syngenta...), detergents (Procter & Gamble, Unilever), pharmaceuticals (Pfizer, Merck...), and even oil (Exxon Mobil) are ILSI members. (Source: ILSI annual report 2011).

With the notable exception of Antarctica, all continents host an ILSI branch. The headquarter is established in Washington DC. The European offices opened in Brussels in 1986.

ILSI describes itself as a « nonprofit, worldwide foundation » which « bring[s] together scientists from academia, government, industry, and the public sector » and « seeks a balanced approach to solving problems of common concern for the well being of the general public ». ILSI is in fact a lobby pressure group and has a sophisticated, efficient strategy. Many EFSA experts work for ILSI. Even the chair of EFSA's management board, Diana Banati. In a press conference in September 2010, European Green MEP José Bové revealed that she also was member of ILSI's Board of directors. Diana Banati resigned from EFSA in May 2012 after she was appointed ILSI executive and scientific director.

>> For a detailed account of the EFSA-ILSI connections, see the report by Corporate Europe Observatory and EarthOpenSource – <u>Conflicts on the menu.</u>)

# Box 2 / The International Society of Regulatory Toxicology & Pharmacology & Regulatory Toxicology and Pharmacology

« Regulatory Toxicology and Pharmacology » is an industry-captured journal. Its editor <u>Gio Gori</u> has worked many years for the tobacco industry (Source : <u>David Michaels</u>. <u>Doubt is their product</u>. <u>Oxford University Press</u>, 2008).

The journal's owner, the International Society of Regulatory Toxicology & Pharmacology (ISRTP) is an association dominated by industry scientists and consultants of regulatory firms who work for the industry. ISRTP has organised several <a href="workshops">workshops</a> on endocrine disrupters where presentations were made by representatives of firms like <a href="Monsanto">Monsanto</a> and <a href="Monsanto">Dow Chemicals</a> or regulatory consultancy firms like <a href="Exponent">Exponent</a>, <a href="Gradient Corp">Gradient Corp</a> and <a href="The Weinberg group">The Weinberg group</a>.

#### 4 - Susv Brescia - UK

Regulatory toxicologist, <u>Health & Safety Executive</u>.

No conflicts of interests in her 14.11.2012 declaration of interests.

#### >> She left out:

- = Speaker and session moderator at an <u>ECETOC</u> workshop on endocrine disrupters, « Risk assessment of endocrine disrupting chemicals » (Florence 9-10/05/2011 <u>Workshop report</u>). The European Centre for ecotoxicology and toxicology of chemicals (ECETOC) is a <u>lobby structure for the chemical industry</u>.
- >> Daniel Pickford also took part in the worskhop but only as an attendant. He nonetheless recorded that in his declaration of interests (see below: Daniel Pickford).
- >> As a Health & Safety Executive employee, Susy Brescia represents the position of her country. Now, the UK took an official stand on the endocrine disrupters criteria issue in May 2011 (>> to understand what this is all about, see below « The Context »). In a joint position paper with the German Federal Institute for Risk Assessment (BfR), the UK favoured the approach of potency threshold cut-off criteria. Because it would filter out certain chemicals from a stricter regulation, the industry have a preference for it. Potency-based cut-off criteria are severely criticised by NGOs and by a leading endocrine disrupter expert, Pr Andreas Kortenkamp, who considers that « such values are largely arbitrary and not scientifically justifiable ».

Susy Brescia is also member of the AdHoc group on the definition and criteria of endocrine disrupters at <u>DG Environment</u> – European Commission (idem: to understand what this is all about, see below « The Context »). Because she represents her country, one can hardly imagine she would adopt an independent position. Besides, she presented the UK proposition <u>in person</u> at a Food Standards Agency <u>workshop</u> on endocrine disrupters on October 19<sup>th</sup> 2010.

# 5 - Gisela Degen - Germany

Toxicologist. Leibniz research Centre for working environment and human factors at Dortmund technical University (IfADo).

Member of the Scientific Committee on Consumer safety – SCCS (European Commission).

In her 23.10.2012 declaration of interests, Gisela Degen declared:

= Research project on phytoestrogen exposure in children at and before puberty funded by <u>CEFIC</u> / Long-range research initiative (<u>LRI</u>) (07/2007 - 12/2009).

>> The European Chemical Industry Council (CEFIC) is the European organisation for the chemical industry. It employs 72 people for its lobbying activities in Brussels. CEFIC devotes 6 millions euros to these activities, according to the information it recorded on a voluntary basis on the <a href="mailto:transparency registry of the European Parliament">transparency registry of the European Parliament</a>.

# 6 - Anthony Hardy - UK

Honorary Professor. Worked at the UK Department for Environment, Health and Rural Affairs (DEFRA).

Member of several working groups at EFSA since 2006.

Chair of EFSA's Scientific Committee (2012-2015)

In his <u>9.08.2012 declaration of interests</u>, he declared :

- = Member of ILSI « Task Force on Evaluation of Agronomic Practices for Mitigation of Natural Toxins » (09/2008
- 10/2010). (Evaluation of Agronomic Practices for Mitigation of Natural Toxins)
- = Director of the <u>Centre for Low Carbon Futures</u>, a public structure at the University of York (04/2009 01/2010). >> In his declaration of interests, Anthony Hardy does not mention the fact that the Centre is supported by about <u>one hundred private partners</u>. Note: among the members of the Centre's <u>International advisory board</u> is Ian Johnson, operations director at Coca-Cola.
- = Unpaid chairman of Venturefest Yorkshire, a non-profit making organisation (since September 2009).
- >> In his declaration of interests, Anthony Hardy explains that Venturefest Yorkshire organises an annual « one-day exhibition and expo of entrepreneurial Technical, Digital and Creative businesses from around Yorkshire ». The 2013 sponsors are in majority investment societies and commercial organisations.

What's more, Venturefest Yorkshire is organised by York Professionals, whose goal is, according to its website, to « promot[e] business opportunities ». Anthony Hardy is one of the directors, which he omits to mention in is declaration of interests.

#### 7 - Karen Hirsch-Ernst - Germany

Toxicologist. Federal Institute for Risk Assessment (BfR).

Member of EFSA's Panel on Plant Protection Products and their Residues - PPR / Pesticides

Member of several EFSA working groups at EFSA since 2009.

No conflicts of interests in her 16.10.2012 declaration of interests.

Intellectual conflict of interests, though, like Susy Brescia (see hereabove: Susy Brescia): Mrs Hirsch-Ernest is employed by the Federal Institute for Risk Assessment (BfR) which took an official stand on the endocrine disrupters criteria in May 2011 (>> to understand what this is all about, see below « The Context »). In a joint position paper with the German Federal Institute for Risk Assessment (BfR), the UK favoured the approach of a potency threshold cut-off criteria. Because it would filter out certain chemicals from a stricter regulation, the industry have a preference for it. Potency-based cut-off criteria are severely criticised by NGOs and by a leading endocrine disrupter expert, Pr Andreas Kortenkamp, who considers that « such values are largely arbitrary and not scientifically justifiable ».

Mrs Hirsch-Ernst is also <u>co-author</u> of an article in the scientific literature exposing the cut-off criteria favoured by BfR. She was thus personally involved in the decision-process of the institute.

Besides, she is a member of the AdHoc group on the defintion and criteria of endocrine disrupters at <a href="DG">DG</a> <a href="Environment">Environment</a> – European Commission as a BfR representative (idem: to understand what this is all about, see below « The Context »). One can hardly imagine she would stand for a position that would different from her employer's.

#### 8 - Peter Hoet - Belgium

Researcher. Public health department Catholic university Leuven.

Member of the Scientific Committee on Emerging and Newly Identified Health Risks - <u>SCENIHR</u> (European Commission).

In his 28.11.2012 declaration of interests, Peter Hoet declares:

- = Board member of BelTox, the Belgian society of toxicology and Ecotoxicology.
- >> BelTox sponsors are the following firms: Janssen Pharmaceutica, Solvay (platina sponsors), Eusapharma,

<u>UCB</u>, <u>GlaxoSmithKline Vaccines</u> (gold sponsors), <u>Umicore</u>, <u>Total Petrochemicals</u>, <u>ECETOC</u> (silver sponsors). See the « bronze sponsors » on <u>BelTox website</u>.

## 9 – Susanne Hougaard-Benekou – Denmark

Toxicologist. Danish Environment Agency.

Member of several EFSA working group at EFSA since 2009.

Member of EFSA's Panel on Plant Protection Products and their Residues - PPR / Pesticides

No conflicts of interests in her 8.10.2012 declaration of interests.

#### 10 - Robert Luttik - Netherlands

Ecotoxicologist. <u>Dutch National Institute for Public health and the Environment</u>.

Member of several working groups at EFSA since 2009.

No conflicts of interests in his 15.11.2012 declaration of interests.

#### 11 - Peter Matthiessen - UK

Ecotoxicologist. Consultant. Retired.

In his 22.10.2012 declaration of interests, he mentioned:

= Consultant for Regulatory Science associates (RSA), a private consultancy firm (chemicals, pharmaceuticals) (05/2012 – 09/2012).

#### 12 - Wim Mennes - Netherlands

Toxicologist. Dutch National Institute for Public Health and the Environment (RIVM).

Member of several working groups at EFSA since 2008.

No conflicts of interests in his 30.10.2012 declaration of interests.

#### 13 - Daniel Pickford - UK

Ecotoxicologist. University lecturer at <u>Brunel University – Institute for the Environment</u>. Member of EFSA's <u>Panel on Plant Protection Products and their Residues – PPR</u> / Pesticides In his 16.10.2012 declaration of interests, Daniel Pickford declared:

- = Research supervision financed by  $\underline{\text{Syngenta}}$ . £35,000 over three years paid directly to Brunel University (05/2006 05/2009).
- = Invited attendance at <u>ECETOC</u> Workshop on endocrine disrupters « Risk assessment of endocrine disrupting chemicals » (Florence 9-10/05/2011 <u>Workshop report</u>). The European Centre for ecotoxicology and toxicology of chemicals (ECETOC) is a <u>lobby structure for the chemical industry</u>.
- >> Some of the collaborations he mentioned in his <u>2.05.2012 declaration of interests</u> no longer appear in his <u>16.10.2012 declaration</u>. (NB : According to <u>EFSA rules</u>, only collaborations during the previous five years have to be recorded).
- = Consultant for Syngenta (09/2003 05/2005).
- = Research scientist employed by AstraZeneca (02/1999 06/2003).
- >> During his time at AstraZeneca, Daniel Pickford carried out two studies on private funding :
- = Assessing chronic toxicity of Bisphenol A on frog for <u>CEFIC</u> (the European organisation for the chemical industry), the <u>Society of the Plastics Industry</u> Bisphenol A Environmental Working Group (£89,000 in 2000). (Source: tab « <u>research</u> »).
- = Conducting baseline studies on a marine snail for the Bisphenol A Environmental Research Task Group of the <u>American Plastics Council</u> (£174,000 in 2002). (Source : tab « <u>research</u> »).

#### 14 - Thomas Platzek - Germany

Toxicologist. Head of toxicology of consumer products, <u>German Federal Institute for Risk Assessment</u> (BfR). No conflicts of interests in his 16.10.2012 declaration of interests.

But Thomas Platzek, like Karen Hirsch-Ernst, is employed by the <u>German Federal Institute for Risk Assessment</u> (BfR) which took position for potency-based cut-off criteria for endocrine disrupters (>> see hereabove: Karen Hirsch-Ernst).

#### 15 - Peter Pärt - Denmark

Doctor. Seconded expert. <u>European Environment Agency</u> (EEA). No conflicts of interests in his <u>12.10.2012 declaration of interests</u>.

# 16 - Josef Schlatter - Switzerland

Toxicologist. Swiss federal office of public health.

Member of several working groups at EFSA since 2009.

In his <u>15.11.2012 declaration of interests</u>, he listed numerous conflicts of interests and a tight, decade-long collaboration with ILSI:

- = Member of ILSI EUROPE expert group on the « Application of the Thresholds of toxicological concern (or TTC) Approach to Cosmetic Ingredients » (11/2011 04/2012). This work was done within the frame of <u>COSMOS</u>, a research project jointly funded by the European Commission and <u>Cosmetics Europe</u> (European federation of the cosmetics industry).
- >> Josef Schlatter omits to mention that the project has the firms <u>Henkel</u> and <u>Merck</u> among its « partners » (Source : <u>Partners of the COSMOS project</u>).
- >> More important, ILSI is the inventor in the mid 1990s of the Thresholds of Toxicological Concern (TTC) concept and has been its main promoter since then. TTC aim to determine a threshold beneath which no toxicological test is required before marketing a chemical. This approach *de facto* eliminates the possibility of a substance to have effects at low doses.
- In 2008, curiously enough, EFSA deemed necessary to create a working group on TTC. A <u>detailed investigation by NGO PAN-Europe</u> revealed major conflicts of interests inside this group in 2011. Several members had been actively promoting TTC on the behalf of ILSI. Among them: Josef Schlatter, who was a co-author for several articles on TTC (<u>Kroes 2004</u>, <u>ILSI 2000</u>, <u>Dybing 2002</u> also co-authored by <u>Syngenta</u> employee <u>John Doe</u>). See also the <u>Le Monde article (in French)</u> where journalist Stéphane Foucart relates that the chair of the group, Susan Barlow, had been working for Philip Morris until the end of the 1990s.
- = Non-remunerated member of the Board of Trustees and member of the program strategy and stewardship committee of the Health and Environmental Sciences Institute (HESI), an ILSI structure. Scientific research on a « range of public health and environmental issues, for the most part on generic issues ». (01/2008 04/2012). (List of HESI Board of trustees members in 2011)
- = Member of ILSI Europe expert group <u>« Application of the Scientific Criteria to Food Allergens of Public Health Importance »</u> (07/2007 04/2012) and of expert committee <u>« Eliciting Dose of Allergens in Food (07/2003 7/2007).</u>
- = Member of ILSI Europe « <u>Risk Assessment of Genotoxic Carcinogens Task Force</u> » and some of its experts groups: « Margin of Exposure approach to substances that are genotoxic and carcinogenic », « Data Selection for BMD Modelling » (07/2002 04/2012). Diane Benford also participated in this work which lead to an <u>ILSI publication</u>: Benford D, Bolger PM, Carthew P, Coulet M, DiNovi M, Leblanc JC, Renwick AG, Setzer W, Schlatter J, Smith B, Slob W, Williams G, Wildemann T. *Application of the Margin of Exposure (MOE) approach to substances in food that are genotoxic and carcinogenic. Food Chem Toxicol.* 2010 Jan;48 Suppl 1:S2-24. Review. (See hereabove: Diane Benford).
- = Participant in workshops, annual meetings and congresses (co-)organized by ILSI and/or HESI (01/1999 06/2011).
- = Member of ILSI Europe « Process-related Compounds and Natural Toxins Task force » (01/1999 04/2012).
- = Member of ILSI Europe Scientific advisory committee « Nutrition, food safety, natural toxins in food » (01/1999 12/2010).
- = Member of the European food information council (EUFIC) scientific advisory board since March 2009.
  >> In his declaration of interests, Josef Schlatter presents EUFIC as a « non-profit organisation ». EUFIC is in fact a lobbying structure for the food industry financed by AB Sugar, Ajinomoto Sweeteners Europe, Bunge, Cargill, Cereal Partners, Coca-Cola, Danone, DSM Nutritional Products Europe Ltd., Ferrero, Kraft Foods, Mars, McDonald's, Nestlé, PepsiCo, Pfizer Animal Health, Südzucker and Unilever (List of members 2012).
- = Ad-Hoc Consultant to the Flavor and Extract Manufacturers Association of the U.S. (<u>FEMA</u>) expert panel (10/2009-09/2011).
- = Member of the International Society of Regulatory Toxicology & Pharmacology (<u>ISRTP</u>) since January 1998. >> Josef Schlatter presents it as a « scientific society » but ISRTP is an industry-captured journal (see hereabove box 2)
- = Finally, Josef Schlatter has worked a long time with the tobacco industry. All but madly elegant in a scientist's resume. As this collaboration took place at the beginning of his career, he had no obligation whatsoever to record

it in his EFSA declaration of interests. Nonetheless, here are a few details gathered during this investigation. Josef Schlatter benefited from fundings from the tobacco industry between 1972 and 1984. His thesis, in 1973, was about the effects of nicotine (Ref. A). Led under the direction of Pr Bättig at the Swiss Federal Institute of technology Zurich (ETH), his research was financed up to 237.500 US dollars between 1972 and 1974 (Ref. B). During the following years, Josef Schlatter obtained several research grants from the scientific commission of the Swiss association of cigarettes manufacturers in Friburg (Ref. C). In 1983, he wrote an article on second-hand smoke on the demand of the industry (Ref. D). A document dated 1984 explicitely says that the purpose of a study on second-hand smoke led by Josef Schlatter is to be « used as a souce of arguments for popularized press articles ». « The industry has to "get wet", because the general public is unilaterally informed at present. Mr Schlatter's work demonstrates once again that tobacco smoke can be a nuisance but that it is not harmful », says the document (Ref. E-F). The attendance of Josef Schlatter at the « Cigarettes working group » meetings of the Swiss industry is documented until November 1985 (Ref. G). In 1990, Mr Schlatter occupies a position at the Swiss federal office of public health... where he is an interlocutor for the tobacco industry regarding regulatory issues for additives in cigarettes (Ref. H).

(Download the documents in .zip)

## 17 - Emanuela Testai - Italy

Researcher at the Instituto Superiore di Sanità in Roma.

Expert for EFSA since 2010.

No conflicts of interests in her 13.11.2012 declaration of interests.

#### 18 - Theo Vermeire - Netherlands

Doctor. <u>Dutch National Institute for Public Health and the Environment</u> (RIVM).

Member of the Scientific Committee on Emerging and Newly Identified Health Risks - SCENIHR (European Commission).

No conflicts of interests in his 16.10.2012 declaration of interests.

# **Conclusion in figures**

On eighteen members, eight declared collaborations with the industry / the private sector:

- Diane Benford
- Susy Brescia
- Gisela Degen
- Anthony Hardy
- Peter Hoet
- Peter Matthiessen
- Daniel Pickford
- Josef Schlatter

Including three with ILSI.

Three experts have an intellectual conflict of interest because of the official position taken by their countries and/or their employer organisms:

- Susy Brescia, Health & Safety Executive, UK
- Karen Hirsch-Ernst, German Federal Institute for Risk Assessment (BfR), Germany
- Thomas Platzek, German Federal Institute for Risk Assessment (BfR), Germany

Apparently, EFSA did not see fit to include an expert in human endocrinology. A nothing less but surprising choice.

However, EFSA enrolled three ecotoxicologists – who study the impact of chemicals on the environment (Robert Luttik, Peter Matthiessen, Daniel Pickford).

The scientific work of only four of these experts is directly related to the field of endocrine disrupters (Jacques Auger, Peter Matthiessen, Daniel Pickford, Emanuela Testai).

Finally, one can wonder whether a countries count reflects a politically-oriented choice from EFSA.

The group is dominated by the UK (5) and Germany (3) – which positions on the criteria for endocrine disrupters are crystal clear.

Then, we have: Netherlands (3), Denmark (2), Norway (1), Belgium (1), Switzerland (1), Italy (1). In the first version of the list (3<sup>rd</sup> December), France was not represented in the group. The name of French scientist Jacques Auger – a specialist in male fertility issues – was added on Thursday 6th December. Why would the Dutch National Institute for Public Health and the Environment (RIVM) have three representatives, the German BfR – two, and the French National Agency for Food, Environmental and Occupational Health & Safety (ANSES) not a single one?

Note that ANSES acknowledges the low-dose effects of bisphenol-A since September 2011 (Collective expert report on health effects of bisphenol A). Which is not the case for EFSA.

In 2007, EFSA even increased the tolerable daily intake of bisphenol A from 10 to 50µg/d and reaffirmed its safety despite numerous studies showing its effects at low-doses (Scientific references on low-dose effects of bisphenol A gathered by Fred vom Saal in October 2006. For April 2012 update, see Fred Vom Saal's website).

The conclusions of EFSA's « Scientific Committee working group on endocrine active substances » will be published in March 2013.

# The context

The European Commision has one year left to attribute a definition and precise criteria to endocrine disrupters. You wouldn't think, but it is an arduous task. All the more that this decision will impact the regulation of all chemicals in the European Union.

Using simple words, let's say that endocrine disrupters are chemicals that have the ability to hijack the hormonal system and influence the levels of hormones secreted by the body. Hormones are estrogens, testosteron, insulin, steroids, thyroid hormones etc. There are about 50 of them. No need to have a triple Ph. D. to understand that non-programmed variations in hormone levels can have an impact. And especially during pregnancy: hormones play a crucial role during the fetus development. Endocrine disrupters are linked to numerous « modern » diseases like declining male fertility, abnormalities of the genital tract of baby boys, cancers (testis, breast, prostate, thyroid), obesity, diabetes, brain development. To date, scientists have identified around 870 endocrine disrupters.

(For further explanations on endocrine disrupters, see <u>Theo Colborn</u>'s <u>TEDX</u> or my documentary *The Great Invasion* – part 1, 2, 3, 4).

Using more scholarly terms, the Endocrine Society says: « An endocrine-disrupting chemical (EDC) is an exogenous chemical, or mixture of chemicals, that interferes with any aspect of hormone action ». (Endocrine-Disrupting Chemicals and Public Health Protection: A Statement of Principles from The Endocrine Society)

But not everyone agrees on the choice of words. A scientific definition is one thing. A definition meant to be used within a regulatory frame is another one.

From that choice will stem the regulation of hundreds of chemicals that we use every day. Phthalates and bisphenol A are well known by the general public. But the decision also implies pesticides and biocides – this sweet name covers pesticides intended to kill cockroaches, fleas and other little bugs inside our homes.

To wich extent, in this time of crisis, economic stakes will weigh in Brussels's choice of words? That is the question.

<u>Direction (or DG) Environment</u> started the decision process in 2011 by creating an AdHoc working group. DG Environment can rely on a report written by <u>Pr Andreas Kortenkamp</u> (<u>State of the Art of the Assessment of Endocrine Disruptors</u>). In June 2012, it organised an <u>important conference</u>. The whole work was supposed to end at the beginning of 2013.

Everything was on the right track until October 1<sup>st</sup> 2012. Then, to everyone's surprise, the European Food Safety Agency (EFSA) anounced that it would, too, set up a working group on endocrine disrupters. As its supervision authority, <u>DG SANCO</u> (Health and consumers) mandated EFSA.

This is not just about a bureaucratic squabble – DG SANCO stepping on DG Environment's toes. This is above all a proper by-pass of the process led by DG Environment that shocked all European NGOs (NGOS Letter to Commissioners Dalli and Potočnik).

This autumn 2012, EFSA celebrates its 10<sup>th</sup> anniversary in total denial of its more than questionable management of conflicts of interets. The European Parliament has expressed its concern about that precisely and <u>refused to vote EFSA's budget discharge in April 2012</u>. So has the European Court of auditors. On October 11<sup>th</sup>, it published a <u>special report on the « management of conflicts of interests in selected EU agencies »</u>, including EFSA, and judged that <u>« selected EU agencies did not adequately manage conflict of interest situations »</u>. NGOs, for their part, have continuously documented the conflicts of interests at EFSA and their potential consequences for the health of the European population (See the detailed report by Corporate Europe Observatory and EarthOpenSource – <u>Conflicts on the menu</u>). Around twenty NGOs have troubled the Agency's anniversary festivity last November in Parma and have called for <u>radical changes in EFSA's organisation</u>.

For the record, EFSA is in charge of the authorisation of thousands of chemicals and products that end up in our food: GMOs, pesticides, additives, nanotechnologies. EFSA is also in charge of the bisphenol A case file.

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