



## *Hundreds of disclosed documents now reveal:*

**How EU Commission Health service DG SANTE joined forces with economic DG's on the criteria for endocrine disruption and crushed not only their enemy, lead DG Environment, but also the entire new EU policy on endocrine disruption.**

### **= Reconstruction of the timeline of events =**

*( the timeline links to the - by DG's- disclosed documents, we are happy to send you the full documents you need)*

**December 2008:**

**Compromise agreed on the hazard approach for endocrines**

1. In December 2008 EU Council, Commission and Parliament agreed on a compromise in the "trialogue" for the final text of the pesticide Regulation, declaring that "pesticides with endocrine disrupting (ED) properties that may cause adverse effects" cannot be approved; no exposure to humans is allowed (a "hazard" approach), comparable to pesticides with genotoxic effects and a policy in clear contrast to traditional risk assessment;

2. However, it was also agreed that Commission had to present "measures concerning specific scientific criteria for the determination of endocrine disrupting properties"; Commission agreed that DG Environment has the lead in developing such measures and criteria;

**2010: While DG Environment has the lead, industry, UK, Germany and EFSA already start their undermining activities**

3. After the adoption of the pesticide Regulation, industrial lobby groups like ECETOC, ECPA and CEFIC have immediately started lobbying to reverse the new policy on endocrine disrupting pesticides (ED-policy) EDs policy and criteria, and to maintain the standard risk assessment with 'safe levels' of exposure. Furthermore, they promoted numerous ways to disqualify observed adverse effects in animal studies, for example assuming that effects in rats are not relevant for humans;

4. UK and Germany tries to take the lead on criteria by putting their ideas forward and especially introducing the criterion "potency", meaning that adverse effects seen in test animals at high dose do not count, knowing very well that generally only high doses are tested in animal studies;

5. July 2010, EFSA asked to get a role on defining criteria for endocrines; Health DG SANCO keeps EFSA in check at that time still by saying not to overlap the work of DG ENV. SANCO promised EFSA that it will be consulted on the work of DG Env. during the development of criteria

6. EFSA in July 2011 adopts the typical industry view in an opinion on Threshold of Toxicological Concern (TTC) that endocrine effects are reversible and have safe levels.

**Spring 2012: the pressure is rising;  
DG Enterprise demands a peer-review**

7. Pressure increased at the time that Prof. Kortenkamp was hired by DG Environment to develop a 'state-of-the-art' document on endocrine disruptors. Kortenkamp develops draft criteria in February 2012; at the same time industry lobby group ECPA launches a personal attack on Kortenkamp;

8. April 2012, DG ENTR, DG EMPL and DG SANCO are joining forces to have a peer-review of the work of Kortenkamp (they call him "the guy"); May 2012, DG ENTR internally reports that DG ENV gets nowhere with their criteria-drafting ("no agreement on anything" between member states and industry, NGO's) and qualify them as arrogant; behind the back of DG ENV, they prepare a peer review

9. A scientific meeting organised by DG ENV on the state of the science on endocrine disruptors in June 2012 in Brussels with international top-level scientists was fiercely opposed by ECPA and industry; they lobbied at all levels to stop the meeting and also asked science advisor Glover to help including "regulatory scientists" in the meeting;

10. EFSA tries more and more to take a role; in June 2012 it organises a colloquium with numerous industry representatives casting doubt on new scientific insights such as low dose and non-monotonous effects that are observed in independent research on endocrine disruptors;

**June 29, 2012,  
Health DG SANCO puts the first knife in the back of DG Environment.**

11. Behind the back of DG Environment , but supported by DG Enterprise and others, DG SANCO decides to make a mandate for a peer-review, first for the three SANCO advisory committees, but later for EFSA, now not only on the report of Kortenkamp but on criteria for endocrines in general; DG Environment is not informed till the mandate is send off;

12. The first drafts of the mandate in July 2012 talk about risk assessment instead of the hazard in the Regulation and the work of DG Environment is completely ignored, allowing EFSA to start from scratch; in the final mandate of July 26, risk assessment is deleted but still regulatory irrelevant exposure-topics for EDs are mentioned such as safe thresholds;

13. November 2012, DG ENTR suggests to involve science advisor Glover on endocrines "to control DG Environment";

14. November 2012, EFSA starts the endocrine Working Group (wg); the first selection had no mammalian endocrinologist on board at all, 5 out of 9 had no endocrinology experience whatsoever, 4 out of 9 were civil servants from UK/IRL, countries known to oppose hazard criteria, and only 2 out of 9 were scientists;

15. December 2012, as a response to the protests, EFSA includes 3 endocrinologists (out of 18), while still 11 out of 18 have no experience whatsoever on endocrinology; the German and UK representatives are civil servants with double hats, having fiercely opposed the criteria proposed by DG ENV in the expert groups organised by DG ENV;

16. February 2013, DG Environment proposes draft criteria to the other DGs, but refuses to include the industry- and the UK-proposed risk assessment elements: potency, lead toxicity, reversibility and severity;

17. February 20, 2013, a discussion starts in the EFSA wg. Now it appears that the draft EFSA opinion on virtually all points contradicts the just released 2012 WHO-UNEP-report on endocrine disruptors; WHO-UNEP concludes that traditional risk assessment is not fit for the purpose to assess endocrines, whereas EFSA concludes that risk assessment is the best method. A big majority, with UK and German-representatives in the forefront in the wg. decides to ignore the WHO-UNEP-report;

18. February 21, 2013, EFSA's staff propose to delete the words "endocrine disrupting chemicals could be considered like most other chemicals" to avoid contradicting openly UNEP/WHO but at the end the working group didn't change anything to the EFSA-report;

19. February, 26, 2013, industry group CEFIC, DG ENTR and DG TRADE, behind closed doors, agree to prioritise endocrine disrupting chemicals for the trade talks with US; DG TRADE proposes "advanced talks" on this particular topic, before the official launch of the process;

**March 2013, industry in highest lobby gear to ask for an impact assessment and for inclusion of "potency" in the criteria.**

20. March 2013, industry starts a new lobby campaign to promote an impact assessment including the impact on international trade, alarmed by the draft criteria of DG ENV; ECPA, DOW, CEFIC, Croplife America, all focus their lobby on the Secr. Gen. (Duncan Johnston) in different meetings; CEFIC states that without "potency" the forthcoming EU-US trade talks could be impaired;

21. March 1, 2013, SANCO Director Testori gets impressed by the ECPA story that 20% of all pesticides (this is 100 of the current total of 500) could be banned by current criteria and 80% of the fungicides (azoles, dithiocarbamates) for cereals, and communicates this with SG (Michel Servoz), in a kind of panic mail;

22. March 12, 2013, next SG (William Sleath) wonders if intervention by SG in the interservice consultations is needed at this stage; SANCO (Eric Thevenard) thinks it is not needed at this stage; DG ENV seems unaware of all this communication;

23. March 2013, BASF states internally to DG ENTR that criteria could be acceptable by including "potency"; the company will contact DG TRADE to talk about the major market impact that the criteria will have; ENTR and TRADE actively lobby for inclusion of potency;

24. March 20, 2013, EFSA publishes an opinion fully supporting industry views such as including "lead effect", "reversibility" and "potency" and favouring traditional risk assessment over a hazard approach that is agreed in the Regulation;

25. April 2013, DG ENTR, on a BASF-meeting, reassures BASF-employees that they support a risk-based assessment of chemicals and invite industry to put forward proposals to include elements of risk assessment (e.g. potency) in the criteria, which then could be discussed with DG ENV, may-be not for the horizontal (criteria counting for all chemicals) but at least for the vertical legislations (criteria for specific chemicals such as pesticides);

26. May 2013, new wave of industry lobby (Amcham, DuPont, US industry) to DG ENTR (and AGRI) emerges asking for inclusion potency and for accepting safe thresholds;

27. June 2013, industrial lobby at maximum gear, Bayer to SG, ECPA and CEFIC to ENTR, ECPA to AGRI, COPA to AGRI, and even communication company Burston Marsteller lobbies DG ENTR; ECPA claims less R&D in Europe because of regulatory hurdles.

28. June 20, 2013, Barroso's science advisor Glover adds to the choir of lobbyist complaining about endocrine criteria with an alarming message to Catherine Day, the Commission's Secretary-General, and to Johannes Laitenberger, Barroso's head of cabinet, based on a letter of a group of toxicology and pharmacology experts, later all shown to have conflicts of interest with industry.

29. June 24, 2013, SANCO director Testori to Commissioner Borg in internal note states that an impact assessment could reasonably be expected for the decision on criteria; "US, Brazil and Canada voiced concerns, which might lead to important repercussions in trade";

30. June 26, 2013 Amcham again meeting ENTR and TRADE emphasizes need for impact assessment; TRADE says that while they want trade talks to be successful, "they would not like to be seen as lowering EU standards;

**July 2013, industry and UK get their way;  
ENTR, TRADE and SANCO put the second knife in the back of DG ENV**

31. June 2013, Interservice meeting. DG ENTR, AGRI, TRADE demand inclusion of "potency" in the criteria; DG ENV refuses to do so; at the very first Interservice meeting the criteria were already blocked by ENTR and SANCO at desk level;

32. July 2, 2013, SG-director Catherine Day intervenes and puts the Interservice talks to a halt and imposes an impact assessment on regulation of pesticides and biocides by the various options for criteria; the result of the exercise should be two legal proposals for implementation with the same content;

33. July 12, 2013, SANCO director Testori to Comm. Borg and Dir. Falkenburg of DG ENV: since both proposals need to be identical, the implementing act (SANCO/pesticides) should

precede the delegated act (ENV/biocides), meaning that the Standing Committee on pesticides with the 28 ministries of agriculture decides on both pesticides and biocides, effectively SANCO taking the lead from DG ENV;

34. July 16, 2013, DG SANCO drafts a roadmap for the impact assessment on the criteria; however the roadmap is delayed for months; SG (Duncan Johnston) in different messages throughout Nov and Dec pushes DG ENV to move on and not publish "only DG ENV views";

35. August 13, 2013, EFSA states to Ms. Glover that it is cooperating with DG SANCO to open a route so that endocrine disrupting pesticides can remain on the market; SANCO develops a general derogation option by widening the text on "negligible exposure";

36. August 16, 2013, Assistant Jan Mueller of Ms. Glover suggests to organise a consensus meeting between two groups of scientists fighting over thresholds, low-dose effects and non-monotonic effects; in the meeting on November 24 a consensus is achieved on thresholds ("it is uncertain that there are thresholds at all"), on non-monotonic dose-response curves "(they exist but have been observed only occasionally)", effects on foetuses ("windows of vulnerability exist", but rarely tested pointing at the only recent discovered effects of Paracetamol on foetuses), while disagreement remained on the use of "potency" and "safe levels of exposure" in the EU regulations.

37. October 13, 2013, Group of MEP's write to the EU President, asking to base the endocrine criteria on science and according to the rules and not on economic impacts as will be done in the impact assessment;

38. January 2014, industry lobby continues, Amcham meets SG again, US farmers complain about too strict food standards, ECPA provides for input on the impact assessment;

**The end of endocrine criteria,  
the economic impact assessment and the EU-US trade talks TTIP will give the endocrine policy  
the final blow.**

39. June 2014, DG SANCO and ENV present the roadmap for the "socio-economic" impact assessment; derogations for a ban of endocrines are already included as a reality; three of the options suggested are a complete violation of the Regulation: not present criteria at all, change the law from hazard to risk assessment, and allow derogations for socio-economic reasons;

40. August 2014, in the EU-US trade talks start a "pilot" on the EU-US "harmonisation" of endocrine criteria.

41. The topic "biocides" is moved from DG ENV to DG SANCO by new EU President Juncker, sidelining DG ENV even further. DG SANCO (now SANTE) on the steering wheel.