

# A TOXIC AFFAIR

HOW THE CHEMICAL LOBBY  
BLOCKED ACTION ON  
HORMONE DISRUPTING CHEMICALS



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# EXECUTIVE SUMMARY

Endocrine disruptors are chemicals that are present in everyday products – from plastics and cosmetics to pesticides. Because of their ability to interact with the hormonal (endocrine) systems of living organisms, they are suspected of having severe health and environmental impacts.

EU law demands action be taken on endocrine disruptors, with clear deadlines set. According to these rules, if a chemical is identified as an endocrine disruptor, a ban follows. The current approach is that chemicals are assessed following risk assessment procedures and safe levels of exposure are set accordingly. However, for endocrine disruptors it might be impossible to set such 'safe' levels.

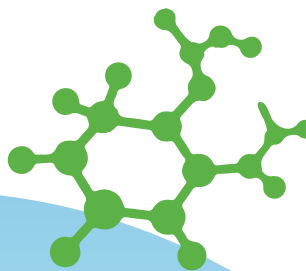
The Directorate-General (DG) for the Environment of the European Commission was put in charge of establishing a set of scientific criteria for 'what is an endocrine disruptor'. The chemical industry lobby was up in arms at the potential banning of some EDCs. The main lobby groups involved were the chemical and pesticide lobbies (CEFIC and ECPA), and the corporations at the forefront were BASF and Bayer. But they found allies in various member states, actors within the European Commission, and in the European Parliament.

The main lobbying tactics used included attempts to undermine and discredit the independent science on EDCs, while promoting industry's own studies as the only 'sound science'; to pressure other Directorates-General in the Commission to go against DG Environment; scaremongering about economic damage industry would suffer; creating delays in the policy process; and using the EU-US trade negotiations (TTIP) as a leverage to prevent any new 'trade barrier'.

By early Spring 2013, since DG Environment did not bend under the pressure, the corporate lobby focused on demanding an impact assessment as a delaying tactic. In a culmination of fierce lobbying pressure, DG Environment's proposal for scientific criteria to identify EDCs was finally rejected by the other DGs in the Commission. Moreover, in July 2013 the Secretary-General, Catherine Day, ordered the impact assessment the industry wanted so much.

This move meant that the Commission failed to meet the December 2013 deadline to come up with the scientific criteria, as demanded by EU law. As the decision process is still ongoing, with the impact assessment on its way, the best-case scenario foresees the final criteria to identify EDCs in 2017.

This report tells the story of how a major EU public health initiative was effectively obstructed by corporate lobby groups in tandem with actors within the European Commission. It shows how industry has successfully used some classic tactics of corporate lobbying. This report shows that some civil servants, even though employed in the services in charge of public health in the European Union, seem to have served corporate interests over public ones.



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### Endocrine Disrupting Chemicals



# Introduction

Endocrine disruptors are chemicals that are present in everyday products – from plastics and cosmetics to pesticides. Because of their ability to interact with the hormonal (endocrine) systems of living organisms, they are suspected of having severe health and environmental impacts. Human exposure to endocrine disrupting chemicals (EDCs) has been linked to diseases such as infertility, cancer and obesity. The medical cost of this serious public health issue has been recently estimated at €157 billion a year in the EU alone.<sup>1</sup> As legislators began to take action, industry has been mobilised for one of EU's biggest lobbying battles.

No less than three pieces of EU legislation demand action be taken on endocrine disruptors, with clear deadlines set: the 2006 regulation on chemicals (REACH), the 2009 pesticide regulation (1107/2009), and the 2012 regulation on biocides (528/2012). Within the European Commission, the Directorate-General (DG) for the Environment was mandated to take the lead. In line with the legislative requirements, DG Environment commissioned a study by independent experts, which was published in 2012. A proposal setting up scientific criteria to define endocrine disruptors, the necessary first step before any legislative action, was set to follow. So far so good? If only.

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## HOW THE CHEMICAL LOBBY BLOCKED ACTION ON HORMONE DISRUPTING CHEMICALS

Any potential action taken on endocrine disruptors is a thorn in the side of many industry sectors who see their profits jeopardised. Their efforts to counter any efforts at regulation have mobilised individual companies, lobby federations, and consultancies, both EU- and US-based. These lobbies represent both the chemical industry at large, as well as more specific sectors such as pesticides or plastics producers, that are heavily implicated in the use or manufacture of chemicals suspected to be endocrine disruptors.

In this corporate campaign, multiple lobbying tactics have been used. They include classics such as scaremongering about economic losses, discrediting scientific evidence pointing at the harmful effects of EDCs, and finding reasons to push for delays.

Delaying at all costs any regulations that could possibly deal with EDCs is of crucial importance to the industry because of another (industry-friendly) project the EU has embarked upon: negotiating a free trade deal with the US, the Transatlantic Trade and Investment Partnership (TTIP) – also known as Transatlantic Free Trade Agreement (TAFTA). One of the main goals of this deal is to flatten out the differences between EU and US regulations to facilitate trade. EU action on endocrine disruptors therefore has become a major leverage argument in the negotiations.

This report explores how chemical corporations and their lobby groups – but also actors within the EU institutions – have been working to stop the EU taking action on EDCs, directly endangering public health and the environment.

## The decision-maker and the scientist

In 2009, DG Environment was designated *chef de file* in charge of regulating endocrine disrupting chemicals, or EDCs (see box on EDCs next page and box on the regulation below). Its first initiative was to commission a report on the state of science of endocrine disruptors after a call for tender. Prepared by a consortium of experts led by Professor Andreas Kortenkamp of Brunel University, London, the 'State of the art assessment of endocrine disruptors' (from now onwards the Kortenkamp report) was published in January 2012.<sup>2</sup>

The Kortenkamp report is a detailed review of the science on EDCs and several hundred pages long, analysing the most recent body of literature of toxicological and epidemiological studies, and going through the evidence of the effects of EDCs on nature and humans. The authors concluded that any attempt to regulate EDCs would face one major challenge: there is no such thing as a universal, ready-to-use detection kit for EDCs. The reason is that the hormonal system is extremely complex and EDCs can hijack it in many different – and largely unknown – ways.

Indeed, the report identified a wide gap between the increasing knowledge about EDCs, and the way the EU regulates chemicals. They argued that the EU was simply not equipped with the right kind of tests to identify EDCs and pick up their effects. The report therefore recommended some measures to identify and regulate EDCs, in order to address this major threat to public health.

As summarised by Professor Kortenkamp, three elements are needed in order to regulate EDCs:

- 1- Definition (what is it you want to deal with?)
- 2- Tests (do you have the tools to identify an EDC?)
- 3- Criteria (how to translate test outcomes into regulatory decisions?)".<sup>3</sup>

To these ends, DG Environment started a broad-based policy development initiative. In 2010, it set up an Ad hoc working group involving more than 40 experts from Member States, national regulatory agencies, public research centres, and also representatives of other concerned DGs (Health and Consumers, Research, Enterprise, Employment), of the European Food Safety Authority (EFSA), and other EU bodies. Five 'observer' seats were allocated to industry and NGOs. In addition, DG Environment created an 'Expert Advisory Group' the following year, to provide technical advice on the development of the criteria.<sup>4</sup>

Within both working groups, a consensus quickly emerged accepting the World Health Organisation / International Programme on Chemical Safety (WHO/ IPCS) definition of EDCs: "An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations".<sup>5</sup> With this definition in place, attention shifted to the identification criteria of endocrine disruptors, which turned into a battleground.

### Box I

## The legal provisions

The 2009 pesticide regulation established "hazard-based cut-off criteria" for EDCs. As the law considers EDCs hazardous, pesticides with endocrine disrupting properties will no longer be authorised on the EU market. This 'hazard-based approach' replaces traditional risk assessment that – as described in Box 2 – aims to define a 'safe' level of exposure. The EU Commission had to develop a scientific definition and criteria to identify EDCs before 14 December 2013.<sup>6</sup>

As also required in a provision of the 2006 REACH chemical regulation, the EU Commission had to decide

on whether thresholds can be set for EDCs or not. If there are no safe thresholds and EDCs are dangerous whatever the concentrations, then these chemicals would eventually have to be substituted or simply banned. If alternatively, thresholds do exist and EDCs are considered safe under a certain concentration, they would be left on the market. This decision was to be taken before 1st June 2013.<sup>7</sup>

The chemical industry lobby groups strongly oppose the hazard-based approach of the pesticide regulation. They argue that EDCs can be regulated like any other chemical through the current system of risk assessment.<sup>8</sup>

## Box 2

## Endo-what?



Endocrine disrupting chemicals (EDCs) can interfere with the hormonal systems of mammals, fish, frogs, and other types of living organisms. Their toxicity only started to be fully acknowledged by scientists in the early 1990s. EDCs have the ability to mimic, block, or alter the levels of hormones such as oestrogens, testosterone, or thyroid hormones whose actions affect many functions of the body. Exposure to these chemicals in the early developmental stages of an organism can cause irreversible effects that will only become evident later in life.<sup>9</sup> There is a high probability that EDCs play a role in the genesis of many 'modern' diseases such as prostate, breast, and testicular cancers, infertility, genital abnormalities, brain development, diabetes, and obesity. Nearly 1000 substances have been identified so far as potential endocrine disruptors,<sup>10</sup> but it could be double that amount.<sup>11</sup> EDCs are found in widely used products such as pesticides, plastics, cosmetics, carpets, computers, and construction materials. They end up in food, air, dust, rivers, oceans, wild animals and... our bodies. One example of an EDC, bisphenol A (BPA), has already been banned from baby bottles in the EU over health concerns.

In 2013, a major report underlined the urgency of taking action on EDCs. The 'State of the Science on Endocrine Disrupting Chemicals' was published jointly by the World Health Organisation (WHO) and the United Nations Environmental Programme (UNEP), and highlighted that the vast majority of chemicals already on the market have never been tested for potential

endocrine disrupting effects, while international test methods capture only some of the known endocrine disrupting effects. EDCs represent a "global threat that needs to be resolved", the WHO/UNEP report concluded.<sup>12</sup>

The report also stated that the exposure of both humans and wildlife to such chemicals comes from an increasing number of sources, and that the risk from mixtures of these substances – the so-called 'cocktail effect' – is severely underestimated. The report underlined that these effects may occur below established safety levels for individual chemicals.

When chemicals are regulated (but many of them are not), they are assessed on the assumption that there is a 'safe level of use'. Thresholds are set below the "no observed adverse effect level" (NOAEL). It is however accepted that some chemicals do not have a 'safe level' or threshold that people can be exposed to. It is the case with some carcinogenic, mutagenic and reprotoxic chemicals (CMR) and also with persistent, bioaccumulative and toxic substances (PBTs). The question of a 'safe' threshold is at the core of the debate on EDCs. Yet according to one of the most detailed reviews of the science on EDCs to date, an authoritative report by a team led by Professor Kortenkamp for the European Commission (see next section), the current tools we have are not adequate to detect thresholds for these chemicals.<sup>13</sup> This would imply that EDCs should be regulated as "non-threshold" chemicals.

The Kortenkamp report recommended a list of criteria that would complement each other, such as adversity, mode of action, potency, lead toxicity, specificity, severity, irreversibility, and relevance. No criterion, the report stated, should be used in isolation as a cut-off filter.<sup>14</sup>

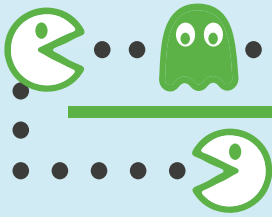
But in May 2011, the British and German authorities published a joint position on the EDC criteria.<sup>15</sup> Making no secret of their concern for the "great commercial impact" of the EDC regulation, the two Member States defended a cut-off criterion that would filter out only the most "potent" EDCs. The idea behind this proposal, explained Professor Kortenkamp, "would be to use the criterion of potency as a tool to cream off from the top the 'worst offenders' and leave the rest of EDCs totally

unregulated."<sup>16</sup> The Kortenkamp report clearly stated that such potency values were "largely arbitrary and not scientifically justifiable". Yet this was not a problem for the two Member States.

The inclusion of potency as a cut-off criterion could indeed spare a significant number of pesticide products from a ban. So it became a key lobbying demand of the chemical and pesticide industries. This idea was subsequently developed in a scientific article published in October 2012 in an industry-owned journal.<sup>17</sup> The article was sponsored by ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals), an industry-science organisation, whose members include BASF, Bayer, Dow, and Syngenta.<sup>18</sup>

## Corporate lobbyists tricks and ploys

The corporate lobby against the EDC regulation employs numerous tools from the lobbyists' toolbox. These include:



### Isolating the 'good guy'

Mobilise actors in the European Commission, such as DG Trade, DG Enterprise and the Secretariat General, against DG Environment.



### Scaremongering with economic losses

Lobby groups produce dramatic figures to tell the EU institutions how bad the economic impact on their sector will be.



### Hired-gun lobbyists

Specialised lobby consultancy firms (also called public relations / public affairs companies) and law firms are hired by corporations or sectoral lobby associations to develop strategies, broker meetings with officials or decision makers, etc.

### Undermine the science

Orchestrate and fund 'critiques' of the Kortenkamp report.

### Delay and derail

By asking for an impact assessment, industry aims to buy time hoping to get EDC regulation off the table for good later.

### Using 'free trade' agreement to undermine EU regulation

TTIP negotiations are aiming to align food and environmental safety rules with the US, which would in many instances lead to a downgrading of EU rules.

### Mobilising 'other voices' to repeat the message

Fund or otherwise support scientists, farmers organisations or other to join the chorus in attacking EDC criteria.

## Who are the lobbyists?

Brussels nowadays is the second capital of corporate lobbying in the world – after Washington DC. An estimated 20-30.000 lobbyists populate the EU quarter, the large majority of whom represents corporations.<sup>19</sup> All big corporations have their own lobby offices and in-house lobbyists.

But orchestrated campaigns such as the one about the endocrine disruptor criteria often happen through industry associations representing different sectors: in this case CEFIC (European Chemical Industry Council) and two of its spin-offs ECPA (European Crop Protection Association), and PlasticsEurope; and also Cosmetics Europe. ECPA's president is Martin Dawkins of Bayer. CEFIC's leadership team is dominated by (current and former) BASF people. PlasticEurope's president Patrick Thomas is the CEO of Bayer MaterialScience AG – one of the main world producers of bisphenol A.

The interests of US industry are well represented in Brussels. Most pesticide corporations are members of Croplife America, ECPA's sister organisation. Their interests are also defended by the American Chamber of Commerce (AmCham EU) that closely works with Brussels-based PR firm EPPA. Specialised 'hired-gun' lobby consultancy firms (also called 'public relations' (PR) or 'public affairs' (PA) companies) are contracted for particular jobs to support these corporations' interests.

Then there are those industry lobby platforms that aim to get business interests promoted in scientific debates and fora, such as ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals). ECETOC is described on its website as an "industry-funded expert not-for-profit think tank" whose purpose is "to enhance the quality of chemicals risk assessment".<sup>20</sup> Bayer, BASF, Dow, DuPont and Syngenta are among the many corporations member of ECETOC.<sup>21</sup>

## Box 5

# Big budgets

Access to reliable, high-quality information on lobbying in the EU is sparse. The European Transparency Register is voluntary, and information is not checked. According to the register, the CEFIC alone reported a total budget of 40 million euros in 2012, of which they reported to have spent 'only' 6 million on lobbying.<sup>22</sup> But defending their corporate members' interests in Brussels is their sole *raison d'être*. ECPA claims to spend merely between €50,000-100,000 per year on lobbying.<sup>23</sup> They only count the gross salary costs of the number of hours their lobbyists spend being present at the Commission, the Parliament or an agency like EFSA, plus some overhead costs. These self-reported figures do not represent the true lobbying costs.

## Box 6

# Revolving doors

Lobby groups often employ the classic tactic of the 'revolving door': in other words, to hire people who come straight from a job in government. Many lobbyists are former Commission officials or Members of the European Parliament, or Parliament or Council staff. They are therefore in a good position to then lobby their former colleagues, and they know how the system works from the inside. The revolving doors can also spin in the other direction, that is, when someone from within the industry moves to a key position in a public authority.

The pesticide lobby has many examples. Looking at ECPA's current staff: Stuart Rutherford used to work for DG Environment and Agatha Pietrasiuk at DG SANCO on pesticides, while Jess O'Flynn, Michal Kicinsky and Anna Gatt Seretny are all former MEP assistants.<sup>24</sup>

O'Flynn worked for British conservative MEP Julie Girling until the last European elections in 2014.<sup>25</sup> CEFIC lobbyist Lena Perenius previously worked in DG Enterprise on the chemical package REACH.<sup>26</sup> As for Ralf Burgstahler, he started at BASF, moved on to work in the European Commission on REACH (which BASF aimed to undermine), then took a position in a German ministry, and is now back at BASF as a lobbyist where he works on plasticisers (such as phthalates, known to be endocrine disruptors).<sup>27 28</sup>

In the US, the use of the revolving door is even more common. According to the Centre for Responsive Politics, more than half of CropLife America's lobbyists in the period 2013-2014 previously held government jobs.<sup>29</sup>

## Box 7

# The controversial case of bisphenol A



The chemical bisphenol A (BPA) is the most well-known example of an endocrine disrupting chemical.<sup>30</sup> It is primarily used to make shatter-proof polycarbonate plastics, and has been found to leach from these materials. It has been banned from baby bottles in the EU since 2011.<sup>31</sup> But BPA is still widely used in consumer products such as the inside of food and beverage cans, dental fillings and thermal paper for tickets. The French food safety authority ANSES concluded in 2011 that health effects from BPA had been proven in animals and suspected in humans, even at lower levels of exposure than the 'safe' dose allowed by EFSA.<sup>32</sup> Yet EFSA comes to different conclusions, including in its last review and opinion on BPA from January 2015, which provoked renewed criticism. In a response, French Environment Minister Ségolène Royal openly wondered what weight the industry had had over EFSA in this case.<sup>33</sup>



## Attacks on the Kortenkamp report

The main conclusions of the Kortenkamp report annoyed industry. Attacks soon followed. The first was a “critique” published in May 2012 in a peer-reviewed scientific journal.<sup>34</sup> It was sponsored by the American Chemistry Council, the lobbying organisation for the US chemical industry. All five authors worked as consultants for industry, two of them being employed by Gradient Corp, a product-defence company which performed studies on a known endocrine disrupting chemical (bisphenol A) on behalf of industry,<sup>35</sup> and has had Bayer amongst its clients.<sup>36</sup> Another industry critique was commissioned by ECETOC to Exponent, also a US-based product-defence company.<sup>37,38</sup> The third attack came from... the UK Government. In July 2012, the UK Department for Environment, Food and Rural Affairs (Defra) released an unsigned, 3-page long “comment” from its Hazardous Substances Advisory Committee (HSAC) criticising the Kortenkamp report’s methodology.<sup>39</sup>

As early as mid-2012, DG Environment’s reluctance to take the wishes of industry on board had become quite evident. DG Environment was however facing mounting pressure. From the British and German governments, from industry, but also from inside the Commission itself.

## The EFSA plot

On 1st October 2012, in a surprise move that undermined DG Environment’s position, EFSA announced that it had been tasked by the European Commission with forming a scientific opinion on “the human health and environmental risks associated with the possible

presence of endocrine disruptors in the food chain”.<sup>40</sup> This meant an opportunity to give their view on the issue of scientific criteria for endocrine disruptors as a whole.

The official mandate to EFSA was signed on 1st August 2012 by the Director General of DG SANCO Paola Testori Coggi.<sup>41</sup> DG Environment was not copied in on the official mandate and was only informed a few days later.<sup>42</sup> With this hostile gesture, DG SANCO sidelined DG Environment in an attempt to take some control over the development of the EDC criteria. Professor Kortenkamp confided that some of his colleagues expected EFSA to “come out in favour of potency based cut-off values, as proposed by industry and some Member States”.<sup>43</sup>

Was EFSA even the most adequate body to give a thorough scientific judgement on EDCs? EFSA’s previous work on bisphenol A had been controversial and criticised for instance by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES).<sup>44</sup>

EFSA went to work and formed a working group on EDCs. Soon after, a media report showed that 8 out of 18 members of the EFSA working group on endocrine disruptors had conflicts of interest. Three of them had ties with industry lobby group the International Life Sciences Institute (ILSI), one with CEFIC, another with Syngenta.<sup>45</sup>

Moreover, the EFSA group included three experts employed by the British and German administrations – which had already taken (pro-industry) sides in the potency criteria debate. Finally, only 4 out of 18 experts had done actual scientific research on endocrine disruptors. None was a specialist in human endocrinology.

So what did this EFSA working group come up with?

### Box 8

## What is a product-defence company?

Product defence companies are in the (big) business of shaping and skewing science to the liking of their clients. These companies employ scientists to perform studies, to produce data that suit the client’s interest, or to criticise studies that don’t. David Michaels, author of the reference book “Doubt is their Product”<sup>46</sup>, said about product defense firms: “I have yet to see a study published by a product defense firm that conflicts with the needs of the study’s sponsors. The intent is to cast doubt on real science.”<sup>47</sup>

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Two emails have surfaced, obtained through an access to documents request, that strongly suggest that at least one member of the EFSA working group had doubts about EFSA's opinion on EDCs shortly before it was published. The email relates to the fact that on 19 February 2013, an authoritative report on EDCs was published by the World Health Organisation and the United Nations Environment Programme (UNEP).

In an email sent on the following day, this working group member expressed grave concern to his (or her) colleagues and to EFSA staff supervising their work, about the quality of the group's own work:<sup>48</sup>

"Dear colleagues,

Life is complicated...

It is almost embarrassing to compare our current draft report with the WHO-UNEP report. The issues the WHO-UNEP report highlight and takes out as being specific for [endocrine disruptors], we in our report are trying to down-play or even avoid, when WHO-UNEP comes to the conclusion that traditional risk assessment of chemicals is not fit for purpose to assess [endocrine disruptors] (p 17), we are exactly coming to the opposite conclusion.... [T]hey discuss elegantly why "thresholds" could not be applied to [endocrine disruptors]. We stay at the best "luke-warm" to these issues.... I am happy I don't need to be at the press conference and stakeholder meeting (as planned the 20 March) and present and defend the current EFSA [Scientific Committee] report knowing that the audience have read the WHO-UNEP report. A straightforward killer situation!...

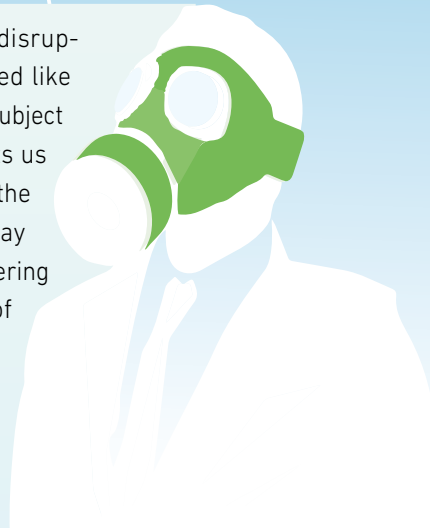
I cannot see any other way out of this than we have to re-do our report or at least significantly modify it...

We could wonderfully have used the WHO-UNEP report as a next step way forward in identifying for [endocrine disruptors], with all the precautions and restrictions it takes. Unfortunately we did not do this and now we are in a mess!"

Here is what Bernard Bottex, the EFSA staff member supervising the EDC working group, replied:

"[We need to] reconsider our conclusions: options 2 and 3 of the current conclusions where we

explain that [endocrine disruptors] should be considered like most other chemicals, ie subject to a risk assessment, puts us in isolation compared to the rest of the world, and may be hard to defend considering the uncertainties, lack of data and methods identified. Any suggestion for rewording based on these new parameters will be welcomed."<sup>49</sup>



When asked for a comment, EFSA replied that these emails took place within a wider scientific discussion and therefore "should not be seen in isolation". Other experts expressed contradicting views, EFSA said. EFSA added that the scope of the WHO/UNEP report "allowed for a deeper discussion" on issues like the low-dose effects, and that EFSA has now commissioned a new study into those effects.<sup>50</sup>

EFSA's opinion was finally published on 20 March 2013.<sup>51</sup> Despite the misgivings the above email expresses, the concluding sentence of EFSA's opinion that Bottex proposed to modify finally remained unchanged. EDCs "can therefore be treated like most other substances of concern for human health and the environment, i.e. be subject to risk assessment and not only to hazard assessment", said the conclusion. As explained earlier in this report, a hazard assessment of a chemical identifies its potential hazards such as endocrine disrupting properties. Risk assessment can then follow, establishing a 'safe level of use', but it is questioned whether this is at all possible for endocrine disruptors.

Yet EFSA had managed to somehow dodge the issue: the sentence does not *request* that EDCs should be subjected to risk assessment. And there's a good reason for this. The EU pesticide regulation prescribes a hazard-based approach for EDCs – so not a risk assessment approach. An EU agency, EFSA would probably not want to be seen to contradict the European law.

Although EFSA's opinion contained such inconsistencies and other problematic aspects, it nonetheless did not propose or advocate the industry's desired potency cut-off criterion. If it had been DG SANCO's intention to force DG Environment to include the latter by having EFSA legitimising it, then this attempt had ultimately failed.

## Meanwhile in the Parliament

Endocrine disruptors had become a topic of debate in the European Parliament too. In April 2012, an own-initiative report had been started, led by Swedish Socialist

MEP Åsa Westlund. This report supported the precautionary approach already taken by DG Environment. Westlund confirms that, especially in the beginning, she received numerous phone calls and emails from chemical industry lobbyists: "Industry tried to confuse the debate and shift the attention to phasing out only the most dangerous chemicals. But first you have to know what the most dangerous endocrine disruptors are!" she said.<sup>52</sup>

Westlund's work was directly challenged by British Conservative MEP Julie Girling (European Conservatives and Reformists Group). Girling is the agriculture spokesperson for the Conservative Party in the UK. She makes no secret of her views favourable to industry interests when it comes to issues like pesticides and GMOs.<sup>53,54</sup>

In September 2012, Girling set up an 'Informal Working Group on risk-based policy making'. On her website, she is said to be concerned that too many decisions are based on "ultra-cautious responses to perceived hazards rather than a rational and science-led examination and measurement of real risk".<sup>55</sup>

On behalf of this informal working group (which is unknown to have other members), she organised a closed event entitled "Risk versus Hazard – with reference to the Westlund report on Endocrine disruptors" scheduled for 22 January 2013. Girling wrote to the Chief Scientific Adviser of the President of the EU Commission Anne Glover to invite her as a guest speaker. In her letter, Girling called Westlund's report a "good example of how risk is being neglected when it comes to making policy decisions in the area of chemicals legislation". She promoted the event as a "chance to meet some of those supportive of risk-based policy-making".<sup>56</sup> Again, "risk-based policy

making" here refers to the approach that a 'safe level of use' can be established for any chemical.

Glover accepted the invitation to be a guest speaker, along with others such as EFSA Director of Science Strategy and Coordination Hubert Deluyker, and Rémi Bars, a toxicologist for Bayer and also chair of ECETOC. The "confirmed guest list" forwarded to Glover gives a clear picture of who was seen by Girling as "supportive of risk-based policy-making". The list included representatives of numerous chemical lobby outfits in Brussels: CEFIC, ECPA, PlasticsEurope, Toy Industries of Europe, someone representing Bayer and ECETOC, BASF, ExxonMobil, the American Chamber of Commerce (AmCham EU), and PR firm Burson Marsteller; but not a single environmental or public health NGO. And what's more, not even Westlund herself, who – despite the fact that her name was in the title of the event – was invited.<sup>57</sup>

In the run up to a vote in the Environment Committee on Westlund's report, MEPs Julie Girling and Miroslav Ouzky (both from the European Conservatives and Reformists Group - ECR) jointly tabled 22 amendments to the Westlund report. Their changes for instance aimed to get the precautionary principle out of the text, and replace it with promotion for classic risk assessment.<sup>58</sup> MEPs who tabled similar amendments in order to weaken Westlund's text included Oreste Rossi (from the right-wing and Eurosceptic Europe of Freedom and Democracy Group - EFD), Pilar Ayuso (from the also Conservative Group of the European People's Party - EPP), Cristina Gutierrez-Cortines (EPP) and Andres Perello Rodriguez (from the Socialists and Democrats Group - S&D).

Nonetheless, Westlund managed to secure a large majority of support for her resolution in the Parliament and it was adopted on 14 March 2013, just a few days before EFSA's opinion was published. It unambiguously stated that the precautionary principle "require[d] the Commission and the legislators to take adequate measures to reduce short- and long-term exposure of humans to endocrine disruptors". In opposition to what industry, the UK and Germany had been saying, the resolution also stressed that "no single criterion should be seen as cut-off or decisive for the identification of an endocrine disruptor". In short, it meant that the potency criterion should be discarded.

## Lobbying offensive, first round: the impact assessment

Early spring 2013 was a turning point. The WHO/UNEP report on endocrine disruptors had been published in February, stating that EDCs were a “global threat that needs to be resolved”. There was the Parliament report led by Westlund supporting the work accomplished by DG Environment. Then, relying on the Kortenkamp report and on EFSA’s opinion, DG Environment’s expert group published their own final report.<sup>59</sup> DG Environment’s services began finalising a proposal for the identification criteria of EDCs.

The chemical industry realised they did not hold a winning hand. Their strategy to have only a ban on the most potent endocrine disruptors seemed doomed to fail. They now became seriously alarmed and were looking for a way to throw a spanner in the works: in this case, to create a delay. An ideal tool for this is to request an impact assessment. This administrative procedure, which takes minimum 12 months, aims at evaluating the positive and negative impacts of a Commission policy proposal. History has shown that the outcome is more susceptible to favour economic interests than anything else (see Box Assessing What impacts, exactly?). This is what the toxic lobby decided to go for.

In Spring 2013, the industry lobbying campaign for an impact assessment took off in full force (See Annex I for examples). Special targets in the Commission were the Directorates-General SANCO, Enterprise and Trade, and also the Secretary General. The aim: to secure their support and to isolate DG Environment’s pocket of resistance. Of course, they would be quick to present their

own, alarmist figures on what the EDC criteria would mean for their industry. It is indeed a known classic strategy for industry to ‘cry wolf’ and overestimate the costs of new forthcoming environmental or public health legislations, never taking into account the (financial and non-financial) benefits that it produces.<sup>60</sup>

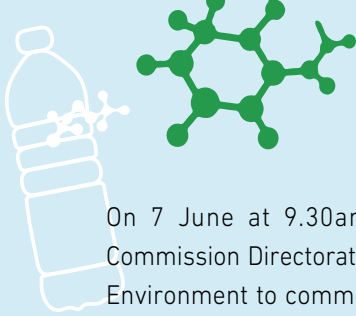
In March 2013, the pesticide industry lobbying organisation ECPA produced a document assessing the economic impact of the draft criteria for endocrine disruptors.<sup>61</sup> It relied mostly on an impact assessment performed in 2009 by the UK government and contained some alarmist claims. The criteria would “severely reduce the availability of crop protection products in Europe”, it said. The market value of products that could be affected by the EDC criteria was “calculated at between €3-4 billion”. The yield loss of key crops such as wheat, potatoes, oilseed rape and vines would be “between 10-20% in an average year – with losses of up to 50% being possible in years of high disease pressure”. In addition the criteria would of course severely hamper “global commerce”. This key lobbying document was subsequently spread widely among Commission officials.

Early June 2013, DG Environment’s proposal went into the final phase before being published. Up until the very last moment, industry tried every possible opening to apply pressure. Illustrative of this is an almost desperate attempt at the end of May 2013, by AmChamEU and EPPA (the lobby firm they hired) to get to see the Chief Scientific Adviser, Anne Glover, even though she had no immediate say in the matter. EPPA’s Miglena Mihova, chair of AmChamEU’s Environment Committee asked her for “even just 15 minutes”, “to share some of industry’s concerns”.<sup>62</sup>

### Box 9

## Assessing what impacts, exactly?

Even if impact assessments are supposed to evaluate “the potential economic, social and environmental consequences” of a Commission initiative,<sup>63</sup> the outcomes are more likely to be in favour of the economic aspects rather than the public health or environment aspects, for the simple reason that the latter are much more difficult to evaluate. “We know from the history of previous efforts to do cost-benefit analyses, impact assessments, that they’re deeply flawed generally speaking because it is much easier to put numbers on costs of regulation than it is to put numbers on what are the benefits to society over the next four or five decades of not having reproductive problems,” said David Gee, former Senior Advisor on science, policy and emerging issues at the European Environment Agency (EEA).<sup>64</sup> Conveniently for industry, an impact assessment takes on average 12 to 15 months and so can also work as a handy delaying tactic.



## How the chemical lobby blocked action on hormone disrupting chemicals

On 7 June at 9.30am sharp, all the concerned Commission Directorates-General were invited by DG Environment to comment on their draft criteria proposal.<sup>65</sup> The meeting, called 'interservice meeting', was a make or break moment. But by lunchtime, the draft was refused as it stood, and the rupture was effective.

From what happened thereafter, one can safely assume that DG Environment's proposal had already been leaked to the outside world previous to that meeting. That very same day of 7 June, at 2.04pm precisely, chemical giant Bayer sent a well-targeted email to the highest level in the Commission, the Secretariat General. The recipients were Marianne Klingbeil and Stefan Moser. Marianne Klingbeil is Deputy Secretary

General, and responsible for the EU impact assessments. Bayer, writing in German to a fellow countrywoman, put forward both the UK impact assessment and a similar report by Teagasc, the Irish Agriculture and Food Development Authority, about the impact of "an inappropriate endocrine disruption definition upon wheat disease control programmes and production in Ireland". "Despite the massive impacts on the combined industry and agriculture sector", Bayer complained, "the Commission has so far refused to undertake an impact assessment. We therefore ask you to stand up for the implementation of an impact assessment".<sup>66</sup>

In the weeks to come, the lobbying supporting the impact assessment only intensified further.

## Examples of lobbying emails sent by industry to various targets in the European Commission.

From: [redacted]@basf.com  
 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"**

... that my colleague Tobias sent out earlier today to your Cabinet Colleague Massimo proposed 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. Please let me know if you find this helpful and if we should forward the impact colleagues.

From: [redacted]@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"**

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

From: [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

**"impact assessment"**

From: FLUEH Michael (SANCO)  
 Sent: 07 October 2013 14:35  
 To: [redacted]  
 Subject: 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

Emails are available from Corporate Europe Observatory and Stéphane Horel.

As we mentioned, there is a particular concern about the impact on agriculture and crop production. There is also a substantial impact on research; please find enclosed an overview of a report that is under preparation which suggests that European focused R&D has actually decreased since the 1990s even though the overall R&D spend

From: [redacted]@ecpa.eu>  
 08 March 2013 17:37  
 HANSEN Bjorn (ENV); KORRYTAR 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-ISPR); EMBERGER Geraldine (TRADE); [redacted]@cefic.be;  
 RE: ECPA comments on document "Revised version of possible elements for criteria for identification of endocrine disruptors" - 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."**

... recognise the calls for further information on the possible impacts of the final criteria. This has not forward 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

From: [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"**

Dear Ms. Giral-Roebling,  
 ... 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 sc of many scientific debates, might be taken on political grounds, without first assessing what its impacts will be on t European Market.

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

**"impact assessment"**

Dear Ms. Dudzinska,  
 The AmCham EU Environment Committee has just 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

From: [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

**"substantial impact on research"**

Would the Commission bow to the demands for an impact assessment? First, we need to take a look at the chemical industry's parallel lobbying route against any EDC regulation: the EU-US trade negotiations.

### Lobbying offensive, 2nd round: the TTIP

Industry was in the meantime presented with a second, unique opportunity for a fruitful lobby against EDC regulation: the upcoming negotiation of a free trade deal between the EU and the US, known by its acronyms TTIP (Transatlantic Trade and Investment Partnership) or TAFTA (Trans-Atlantic Free Trade Agreement). One of the main goals of the TTIP is precisely to iron away the differences between EU and US regulations in order to facilitate trade flows. A regulation of EDCs would present a major new difference in rules between the two blocks. These negotiations were therefore latched on by industry as the perfect opportunity to get rid of the EDC issue altogether.

On the US side, the American Chemistry Council (ACC) and CropLife America (CLA) wrote to the US Office of Chemical Safety and Pollution Prevention (OCSPP) at the end of 2012, saying they have "serious concerns" that the EU EDC criteria will "would trigger negative and far reaching impacts on global commerce."<sup>67</sup> They warned that the adoption of an approach in the EU that differs so substantially from the US approach would "likely put in place precisely the kind of regulatory barriers that a potential US-EU Free Trade Agreement would be designed to address".

In March 2013, an unnamed consultant organised several meetings in Brussels for a delegation of the US pesticide lobby group CropLife America. According to an email he sent to Jean Ferriere of the Secretariat General of the European Commission, their main concern was the forthcoming regulation of EDCs which did not "appear to be consistent with the objectives of the US-EU negotiations for a TTIP".<sup>68</sup> The CropLife America delegation was invited to join a meeting already planned with ECPA on 20 March at the Secretary General.

Their demands were clearly formulated in a CropLife America position paper:<sup>69</sup>

- The hazard based cut-off criteria in EU Regulation 1107/2009 should not impact U.S.-EU trade;
- The EU's use of suspension or bans of products to control product uses while avoiding risk assessments should not impact U.S.-EU trade;
- The U.S. Government should defend itself using authority of the [Sanitary and Phytosanitary Measures] Agreement under [World Trade Organisation], if the EU pursues its proposed new regulatory regime for endocrine disruptors without an approach based on risk assessment."

Another key industry demand for TTIP is 'regulatory cooperation' (see Box 10). In June 2013, a delegation of the American Chamber of Commerce (AmCham EU) met with officials from DG Enterprise and DG Trade to discuss what regulatory cooperation could look like.<sup>70</sup> DG Trade imagined a mechanism that would make it obligatory to provide a justification, in the event that either the EU or US wished to create a new regulation that the other party disagreed with.

### Commission-industry symbiosis – push for 'regulatory cooperation'

Evidence shows that if industry does not do a good enough job at lobbying by itself, DG Trade will help them with a gentle nudge. In autumn 2012, DG Trade chased pesticide lobby group ECPA to participate in the then-ongoing public consultation on TTIP. As the European pesticide industry is "one of the key sectors we would be looking at in terms of improving the framework for business," DG Trade emailed ECPA, "your contribution, ideally sponsored by your US partner, would be most welcome".<sup>71</sup> ECPA responded a few weeks later, together with its US sister organisation CropLife America, demanding for instance the harmonisation for pesticide residues in food, and pushing for 'regulatory cooperation'.<sup>72</sup>

Regulatory cooperation is a tool that would prevent differences in standards in the future. This could represent a major new threat to any legislation aiming at protecting health and the environment.

#### Box 10

Shortly after, the chemical lobby (CEFIC and American Chemistry Council) proposed a very similar idea of a “Joint Scientific Advisory Council” to deal with “emerging” issues such as EDCs”.<sup>73</sup>

On 17 June 2013, José Manuel Barroso and Barack Obama announced the official launch of the negotiations over the EU-US trade agreement<sup>74</sup>.

Since summer 2013, lobbying has gone on unabated to use TTIP against any regulatory action on EDCs. But DG Trade has an increasingly hard time in selling TTIP to the European public. DG Trade official Jean-Luc Demarty pleaded to CEFIC that more vocal industry support was needed “in passing the message that TTIP is not about dismantling existing EU chemicals legislation.”<sup>75</sup> The US Government has been more straightforward about its role as industry agent; its trade department explicitly singled out the regulation of endocrine disruptors as a ‘trade barrier’ that should be removed through TTIP.<sup>76</sup> Industry also often requests that EU regulations should be based on “sound science”. This flagged expression was coined by the tobacco industry (see Box 11).

## Concerned scientists or industry front group?

While the industry lobbying offensive peaked this month of June 2013, another voice joined their chorus.

On 17 June 2013, a group of 56 scientists led by German toxicologist Wolfgang Dekant sent a letter to Barroso’s Chief Scientific Adviser Anne Glover, attacking the work done by DG Environment on EDCs.<sup>77</sup> “The currently drafted framework is based on virtually complete ignorance of all well-established and taught principles of pharmacology and toxicology”, they asserted, yet without referring to any precise document. The letter remained unknown to the public until 5 July 2013, when it was published online in a toxicology journal together with an editorial nailing their point. Entitled ‘Scientifically Unfounded Precaution Drives European Commission’s Recommendations on EDC Regulation, While Defying Common Sense, Well-Established Science and Risk Assessment Principles’, the editorial was signed by a further 18 editors and

## The rhetoric of ‘sound science’

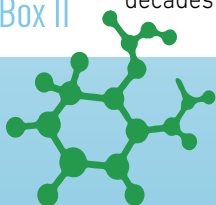
From tobacco in the 1950s to climate change today, there is now a long history of industry attempts to “manufacture doubt”<sup>78</sup> over scientific evidence that shows harmful effects of their products. One way to do this is for instance to fund studies that point at other possible causes for these harmful effects. Industry would then claim their studies to be ‘sound science’, while the inconvenient studies are labelled ‘junk science’ (other variations used are ‘not science-based’ or ‘not evidence-based’).

With the arrival of TTIP, industry is recycling this Orwellian notion of ‘sound science’ to stage an ongoing attack on the EU food safety system, including the precautionary principle. For instance, ECPA and CropLife demand “the inclusion of science-based risk assessment as the unified basis for pesticide regulation”,<sup>79</sup> implying that the EU pesticide regulation is not science-based.

One example of a political figure buying into industry’s framing is the British Conservative MEP Julie Girling. In an opinion piece in the *Wall Street Journal* titled “The Junk Science Threat to Free Trade”, she wrote that the biggest threats to TTIP’s success were the endocrine disruptors issue and the use of the precautionary principle in the EU. She described the evidence of harm of EDCs (and other classes of chemicals) for human health as “hypothetical at best, possibly illusory, and certainly never scientifically established.” Endocrine disruptors are now “stigmatized by anti-chemical activists”, she continued. She ended by saying that Europe needs to move to “a system that assesses real, known impacts based on sound science”.<sup>80</sup>

However, there is overwhelming evidence showing that government action against harmful substances – from asbestos to lead, and from tobacco to some pesticides, has been delayed for years, sometimes entire decades because of industry lobbying undermining the science.

### Box 11



associate editors of scientific journals led by Daniel Dietrich, a toxicologist at the University of Konstanz.<sup>81</sup> The editorial would thereafter be published in no less than 14 journals in the course of the following months. This *modus operandi* was unseen before in the history of scientific literature.

Considering the timing of this very unusual letter and editorial, coming in the heat of the fight of industry against action on EDCs, many eyebrows were raised. Its content did not go unanswered either. At the end of August 2013, the first rebuttal was published in the journal *Environmental Health* by 41 leading experts in endocrine disruption, four of whom had participated in the landmark WHO/UNEP 2013 report, and two in the Kortenkamp report. "We are concerned that the Dietrich editorial appears to be intended as an intervention designed to impact imminent decisions by the European Commission concerning endocrine disrupting chemicals", they wrote.<sup>82</sup> The second rebuttal was published a couple of weeks later in the journal of the Endocrine Society, this time signed by 104 scientists and editors of journals. The editorial, they concluded, "does the European Commission, science, including the field of toxicology, and most importantly, public health, a profound disservice".<sup>83</sup>

Shortly after, an investigation by *Environmental Health News* reported that out of the 18 editors who signed the Dietrich editorial, 17 had ties with the chemical, pesticide, cosmetics, pharmaceutical, biotechnology, or even tobacco industries. As far as the chemical industry is concerned, links could be identified with the American Chemistry Council, CEFIC, ECETOC and ILSI.<sup>84</sup> Furthermore, among the 56 original signatories of the letter to Anne Glover, at least 33 also had industry ties.<sup>85</sup> Some had received research funds from industry associations, while some had served as industry consultants or advisors.

Remarkably, the letter to Chief Scientific Adviser Anne Glover was signed by three scientists – namely Diane Benford, Gisela Degen, and Josef Schlatter – who also happened to be members of the 2012–2013 EFSA working group on EDCs. Benford, Degen and Schlatter were all three among those found to have conflicts of interest with the commercial sector.<sup>86</sup>

The letter undermining DG Environment's work seemed to hit home. Only three days after she received the

letter criticising the EDC criteria, Anne Glover sent a note to Karl Falkenberg, the Director General of DG Environment. She had received a letter from "a large number of very eminent experts in the field of toxicology", she wrote, presenting them as authoritative on the EDC issue. Then she demanded explanations on the process: how the "evidence was reviewed"? Why was EFSA's opinion "ignored"? Was it true that the EDC regulation "would be based solely on the base of *in vitro* tests"? The tone was not very amiable.<sup>87</sup>

But most importantly, Anne Glover copied her note to the cabinet of Barroso and to the Secretary General Catherine Day. Passing on the impression that there were legitimate reasons to question the scientific work performed by DG Environment, she rang the alarm bell at the upper floors of the Commission at a crucial moment.

### The decisive blow

On 2 July 2013, the decision process on the EDC criteria was finally derailed. The Commission Secretary General Catherine Day wrote a note to both Karl Falkenberg and Paola Testori Coggi, the Directors-General of DG Environment and SANCO respectively, ordering them to work together on the EDC criteria, demanding that the proposal "should be supported by an impact assessment including a public consultation on the various options for the criteria and their impact".<sup>88</sup>

The issue, further argued Catherine Day, 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". As various services of the Commission had been methodically fed with industry-commissioned and UK impact assessments, and warnings over the TTIP, the concern over "the potential impacts on parts of the chemical industry and international trade" can be easily explained. But what about the "diverging views held by the stakeholder community"? Which diverging view could that be except for the motley crowd of scientists, whose critique had been given weight and credit just a couple of weeks earlier by Anne Glover's intervention?

As acknowledged later by the Commission, industry lobbying and the letter by the scientists had indeed been the decisive factors for this outcome.<sup>89</sup>



With this decision to launch an impact assessment, the Secretary General had single-handedly thrown a monkey wrench in DG Environment's work on EDCs. Not to mention that the process would *de facto* be delayed for an undefined period of time regardless of the legal deadline – December 2013 – set by the Parliament. Industry had managed to buy the time they needed to try to weaken the criteria, and to benefit from the deregulatory, 'free trade' dynamic offered by the EU-US trade talks. The businesses with most to lose from regulation of EDCs could celebrate.

In early September 2013, the decision to make an impact assessment on the EDC criteria was finally made public. A group of eight MEPs following the issue closely responded with a letter to the then-President of the European Commission Barroso: "This decision is surprising, as one would expect scientific criteria to be based on objective scientific studies and not on an impact assessment, which is rather a tool to inform political decisions." In other words: if the aim is to develop a scientific definition of what an EDC is, then the potential economic (or other) impacts are completely irrelevant. The MEPs commented: "Doing an impact assessment from the outset seems to confuse science with policy-making and hazard with risk."<sup>90</sup>

## The surprise consensus package

On 24 October 2013 nonetheless, Chief Scientific Adviser Anne Glover convened a meeting in her office with representatives of the two scientific 'camps'. The camp who had criticised DG Environment's work with the letter to Glover, featured Alan Boobis, Wolfgang Dekant and Helmut Greim. The 'EDC scientists camp' – Anna Maria Andersson, Ulla Haas, and Andreas Kortenkamp. Nobody expected the confrontation would have such a surprising outcome: the critics' group radically changed their position. They agreed to sign a consensus statement, which contradicted their initial declarations, notably on the issue of whether there were safe thresholds for EDCs. "It is possible that thresholds do not exist", and "it is not possible to define thresholds only by experiments in whole organisms due to lack of sensitivity", stated the document.<sup>91</sup>

On 20 November, Anne Glover did inform DG Environment, DG SANCO and the Secretariat General about the

outcome of the scientific meeting. One might think that such a spectacular U-turn, putting an end to the 'controversy', would shatter the Commission and annihilate its convenient excuse to make an impact assessment. But it didn't.

By December 2013, the Commission had missed the deadline officially set by the 2009 pesticide regulation, nor did it schedule a new one.

MEPs of the Socialist Group (S&D) reminded the Commission that it had missed the legal deadline and should have already published the scientific criteria for EDCs.<sup>92</sup>

On 25 March 2014, the group of eight MEPs finally received a reply to their October 2013 letter to Barroso. Signed by Karl Falkenberg (DG Environment) and Paola Testori Coggi (DG SANCO), it justified the impact assessment not only for "concerns about the possible potential significant impacts on some sectors" associated with any set of EDC criteria, but also "the vigorous debate in the scientific community on endocrine disruptors that escalated over last summer".<sup>93</sup> Again, the Commission chose to ignore the fact that this debate had been extinguished in Anne Glover's office months earlier.

And it was not only in the Parliament that people were very upset. In March 2014, Sweden decided to bring the Commission to court for "failure to act".

## A Roadmap to nowhere

Now industry's attention shifted to the terms of the impact assessment. DG Environment and SANCO were charged with designing a 'Roadmap' that would set out the scope of the impact assessment, and that would present the policy options to be assessed within it. They convened a first meeting of the Impact Assessment Steering Group on 20 January 2014, inviting participants from across the Commission, including Research, Climate, Agriculture, Enterprise, and Trade.<sup>94</sup>

The pesticide lobby ECPA was clearly aware of this meeting, as well as who would be there. One week before, on 13 January, they sent their "suggestions" on the impact assessment to DG SANCO.<sup>95</sup> A few days later, CEFIC did the same.<sup>96</sup>

ECPA and CEFIC obviously made almost identical points. Among other things, they demanded that in order to arrive at a "meaningful assessment" of the impacts of EDC criteria, the impact assessment should be "sufficiently

detailed”, ie spelling out the expected impacts separately for each pesticide or group of pesticides, and for their specific uses. But since this would give a clear indication to the outside world which pesticides the Commission suspected to be endocrine disruptors, they “strongly recommended” to leave the public in the dark. In their own words: “this should not be published in a way that creates a public list of suspected endocrine disruptors: past experience has shown that some stakeholders may use such a list as a ‘black list’ thereby introducing the potential for unfair competition”.

On 20 June 2014, after months of tough negotiations between DG Environment and DG SANCO, the Roadmap was finally published.<sup>97</sup> Surprise! The potency criterion was back on the table, despite the fact that it had been ruled out by DG Environment’s expert group in March 2013.<sup>98</sup> The next step was a public consultation on this flawed Roadmap, launched on 29 September 2014.<sup>99</sup>

**Box 12** The US government submission to the public consultation steps up the level of bluntness by dismissing DG Environment’s proposal as “a failure to adopt a scientific approach”, that could impact – quoting corporate estimates – €65.3 billion worth of imports into the EU (of which over €4 billion worth would be US exports).<sup>100</sup>

## Juncker’s removal company

Meanwhile, the European elections of May 2014 had led to a new Parliament and a new team of Commissioners. On 10 September 2014, the new President of the European Commission Jean-Claude Juncker announced the names of the new Commissioners and his priorities for the next five years. At the bottom of the press release, there was a long table detailing the changes of tasks within the Commission.<sup>101</sup> DG Environment was being officially removed from their leading role on the EDC criteria which would now become the responsibility of... DG SANCO.

The impact assessment on the EDC criteria will still take a long time to be completed. Even in the best-case scenario, the EDC criteria will not be ready before the second half of 2016. The chemical and pesticide industry lobbying will continue unabated along the two parallel tracks: the obstructed EU process (see Box 13), and the TTIP negotiations.

## Adding more voices to the chorus

Box 13

### SCIENCE POLICY BREAKFAST

Series hosted by Jan Huitema MEP

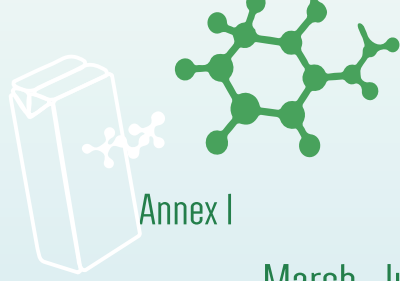
Sponsored by BASF

Richard Sharpe is a professor at the University of Edinburgh where he leads a research team and is one of Europe’s most prominent voices in the field of Endocrine Disruption. His research shows that diet, lifestyle and exposures in utero affects later reproductive health and offspring.

### Endocrine Disruption Who is regulating our hormones? Professor Richard M. Sharpe

More examples of the industry lobbying trick to mobilise ‘third voices’ were seen in Brussels. In January 2015 BASF sponsored a ‘Science Policy Breakfast meeting’ on EDCs<sup>102</sup> with a presentation by Richard Sharpe, a professor of Reproductive health at the University of Edinburgh and one of the signatories to the letter to Anne Glover. The event was hosted by MEP Jan Huitema (Dutch Liberals). Richard Sharpe said that unlike Kortenkamp he was not a “believer” in EDCs having no safe threshold. In February the British National Farmers Union (NFU, member of COPA-COGECA), in tandem with the British pesticide industry brought their “Healthy Harvest campaign” to Brussels.<sup>103</sup> The core of this campaign “for sound, science-based regulation” of pesticides was a report commissioned from a UK consultancy Andersons, concluding that the impact on UK agriculture would be “severe”, if pesticides would be removed from the market as a result of “overly precautionary definitions of endocrine disruptors”. In Brussels, ECPA and COPA-COGECA have joint events in the European Parliament. Two ECPA lobbyists were recruited from the NFU and a Polish member organisation of COPA-COGECA.

But there are also glimmers of hope in both tracks. In an unprecedented move, in January 2015, both the European Parliament and the Council (all Member States together) decided to officially support Sweden’s court case against the Commission over its failure to establish criteria for EDCs.<sup>104</sup> An overwhelming 21 Member States voted in favour, while only a few abstained, such as the UK. The TTIP negotiations are troubled by increasing critical public debate and resistance. The battle around this key public health and environment policy in the EU is far from over.



Annex I

## 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 Furing 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 Furing in the Secretariat General
11 July	Email including ECPA's own impact assessment	Bayer	SANCO

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