

# A TOXIC AFFAIR SEASON FINALE

## COMMISSION TO PUBLISH CRUCIAL DECISION ON ENDOCRINE DISRUPTORS

This story began in 2009 in the depths of EU bureaucracy and could have merely been the most boring bedtime story of all time. Yet a succession of unexpected developments over the course of several years turned it into a political thriller with cliffhangers worthy of a TV series.

Endocrine disrupting chemicals (EDCs) 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 serious health and environmental impacts.

The EU is supposed to regulate EDCs, but the first step - establishing scientific criteria to identify them - has not even been taken due to a massive industry lobbying campaign.

In May 2015, Corporate Europe Observatory and freelance journalist Stéphane Horel published *A Toxic Affair*, a detailed account of this story<sup>1</sup>. In October 2015, Horel also published a book (*Intoxication*, in French)<sup>2</sup>. The report ended with those words: “the battle around this key public health and environment policy in the EU is far from over”. This proved to be true.

On 15 June 2016, the Commission will finally announce the long-awaited scientific criteria. Time to do a recap of this last season's main episodes.





# Toxic Summary

In 2010, the European Commission's Directorate-General (DG) for the Environment was put in charge of establishing a set of scientific criteria for 'what is an endocrine disruptor'. The EU law demanded action be taken on endocrine disruptors. Clear deadlines were set: December 2013. According to these rules, if a chemical is identified as an endocrine disruptor, a ban or restrictions follow.

The chemical industry lobby was up in arms and struggled against any strict regulation of EDCs. The main lobby groups involved were the chemical and pesticide lobbies (CEFIC - European Chemical Industry Council & ECPA - European Crop Protection Association). Some corporations came also at the forefront, especially BASF and Bayer.

In Spring 2013, despite huge pressure and attacks on EDC science, DG Environment had finalised a draft proposal. But a lobbying Blitzkrieg left no means unused to derail the process: emails and meetings pushed for an impact assessment of the EDC criteria. To succeed, industry lobbies had found allies in various Member States (the UK and Germany in particular), in the European Parliament, and mostly within the European Commission itself (DG Health & Consumers, DG Enterprise, DG Trade).

Then on 2 July 2013, the Secretary-General of the European Commission decided a impact assessment would be carried out. The process, since, has been in a deadlock, and the legal deadline of December of 2013 passed without scientific criteria for EDCs being in place.

## Groundhog day

2015

1st  
June

That day, the alarm clock sounded a little like in that famous movie where Bill Murray wakes up every day on the same day in the wild borough of Punxsutawney<sup>3</sup>. The sound of *déjà heard*: another European Commission conference on endocrine disruptors.

The Commission's Directorate-General (DG) for the Environment had already organised a high-level conference on the regulation of EDCs in June 2012<sup>4</sup>. But in the meantime, DG Environment had been relieved of the file in favour of the very same Directorate-General whose officials had consistently sought to prevent their own colleagues from working: DG SANTE (Health and Food Safety) (*more details on this episode on page 18 of A Toxic Affair*). Three years later, the rival DG was now directing the shoot. Both the script and casting reflected a radical change of heart<sup>5</sup>.

As a symbolic summary of the entire day, the Commission had staged a scientific controversy for the first session. The "scientific debate on criteria to identify endocrine disruptors" pitted Daniel Dietrich

(University of Konstanz, Germany) against Tomas Zoeller (University of Massachusetts Amherst, USA). In one corner: one of the scientists tied to industry whose intervention at the upper levels of the Commission in June 2013 had contributed to the derailing of the regulation by creating the illusion of a controversy (*p. 16*). In the other corner: a world-renowned thyroid specialist, member of the respected Endocrine Society and of its EU EDC Task Force.

Three sessions were dedicated to the "potential impacts" of the criteria for the identification of EDCs. The only one focussing on the impacts on health and environment was moderated by British Conservative MEP Julie Girling (European Conservatives and Reformists Group - ECR), who had repeatedly voiced her doubts about the "causal link between exposure to [endocrine disruptors] and adverse health effects"<sup>6</sup> (*p. 11*).

It is in this state of mind that the Commission's impact assessment had been put on track. On the wrong track, maybe?

## Impact factor



The decision to carry out an impact assessment instead of adhering to the legal deadline set by MEPs in the Pesticides and Biocides regulations was taken by Commission Secretary General Catherine Day on 2 July 2013 (p. 16) after an intense industry lobbying Blitzkrieg (p.12). It took another year and a bit to actually launch the procedure with a so-called “public consultation”. So-called because, for the ordinary mortal, the abstruse questionnaire was utterly unanswerable without the help of a PhD graduate. “The objective of this consultation was to gather information for the impact assessment”<sup>7</sup>, stated DG SANTE (then DG SANCO) quite bluntly. Nowhere did the presentation text mention that the idea was to probe public opinion in order to take it into account.

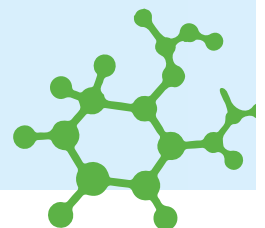
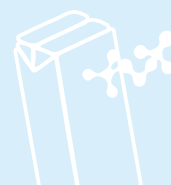
The consultation lasted from 29 September 2014 to 16 January 2015, and unexpectedly got “the highest number of responses among the public consultations launched so far by the European Commission”: 27,087<sup>8</sup>. This was mostly due to a web-based platform set up in seven languages by EDC-Free Europe, a coalition of health and environment NGOs<sup>9</sup>. Over 25,000 responses were received via this human-friendly website.

Interestingly, the Commission analysis report published in July 2015, gave just half a page to the arguments offered in this massive popular mobilisation. The 56 other contributions from various NGOs filled four pages. On the other hand, the contributions from industry and their allies were reported with the greatest care (and space). Three pages for “private companies” including Bayer, BASF, Dow, Dupont and Syngenta (136 responses). Seven pages for “industrial or trade associations” including the major ones in the EDC criteria debate:

ECPA (European Crop Protection Association), CropLife America, CEFIC (European Chemical Industry Council) and the American Chamber of Commerce; but also less prominent stakeholders such as the Ghana Agri-Input Dealers Association or the US Cranberry Institute (137 responses). The 521 contributions made by agricultural producers and farmers got three pages<sup>10</sup>.

As expected, all parties representing commercial interests went for option 4 of the Commission’s roadmap. This option contained one specific criterion that industry had been lobbying for because it could spare a great number of pesticide products from any restriction or ban: the ‘potency criterion’. In early 2013, when they were still in charge, DG Environment had rejected it<sup>11</sup> (p. 6). But that was before their staff were stripped of the file and replaced by DG SANCO.

In addition to potency, many industries were now asking for the inclusion of even more discriminating criteria such as the severity and the irreversibility of the effects. This is also what the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung - BfR) proposed in its own contribution to the consultation<sup>12</sup>, and that’s not a simple coincidence. Already in 2011, the BfR (together with the UK) was the first organisation to introduce the concept of a potency criterion in the regulatory discussion. Research has since shown that this position in fact had its origins in the chemical industry’s scientific think tank ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals), more precisely from a special task force composed of employees of companies such as BASF, Bayer, Syngenta, Total Petrochemicals, ExxonMobil and Johnson. Their proposals were barely altered by the German and UK authorities<sup>13</sup>.



2015

16  
December

## Failure to act

Exasperated to see the « Guardian of the treaties » driving on Procrastination highway, in 2014 Sweden decided to bring the Commission to court for “failure to act” (p. 18). In early 2015, four Member States (Denmark, Finland, France, Netherlands) together with the European Parliament and the Council also agreed that the Commission had knowingly missed the legal deadline in 2013. All of them decided to support the complaint.

The hearing took place on 17 November 2015 and the exceptionally swift ruling came just in time for Christmas, on 16 December. It was extremely severe. “By failing to adopt measures concerning the specification of scientific criteria for the determination of endocrine-disrupting properties, the Commission has breached EU law”, the General Court of the European Union announced unequivocally in a press release<sup>14</sup>. Whereas the Commission justified the delay by the lack of scientific consensus and industry concerns over the potential impact on the economy, the Court replied that “the existence of that criticism [was] irrelevant to the fact that the Commission had an obligation to act before 13 December 2013

by adopting the delegated acts referred to in the regulation”. As for the impact assessment itself, the ruling recalled that not a single provision in the regulation required anything of that sort<sup>15</sup>. The criteria, the Court insisted, shall therefore be “based on science”, “independently of any other considerations, especially economic ones” (our translation)<sup>16</sup>.

The Commission’s initial reaction just a few hours later left everyone dumbfounded. During the ‘Midday press briefing’, a daily event in the Subterranean world of Berlaymont building, Italian journalist Lorenzo Consoli thought it pertinent to ask for a comment on the ruling. The spokesman for the Commission trod the mauve carpeting up to the stage with a green file in his hands. The Commission “[took] note” of the judgement, Enrico Brivio said. “The impact assessment is now on track. The first phase of the assessment is ongoing and others will start in early 2016”. DG SANTE’s objective, he added, was “to conclude the impact assessment in 2016” so that the decision on the criteria would “follow thereafter”<sup>17</sup>.

Perhaps being two years late was not shocking enough - why not three?

2016

Spring

## Democracy strikes back

“Unacceptable”. Those were the words of the President of the European Parliament. On 13 January 2016, Martin Schulz himself decided to call on the President of the Commission Jean-Claude Juncker. It was “unacceptable”, he wrote, “that the Commission, the guardian of the Treaties, not only fail[ed] to act according to its obligations but also [did] not draw the consequences from its breach of EU law in stating that it plan[ned] to continue with business as usual (i.e. to continue with its impact assessment according to the already established timetable), thus completely disregarding the Court judgment”. The final sentence was unambiguous: “I ask you to take the necessary actions for the Commission to comply without delay with the Court’s judgement by adopting the delegated acts in question”<sup>18</sup>.

On 2 February 2016, Schulz’s letter was still left unanswered. No less than twenty-five MEPs from all political groups were scheduled to question the Commissioner for Health at the Plenary sitting in Strasbourg. Most of them to express their dissatisfaction. Didn’t the Court say the Guardian of the Treaties had breached the law?, ahumed the MEPs<sup>19</sup>. Under fire, Commissioner Vytenis Andriukaitis promised the Commission “ha[d] every intention to comply with the judgment”, yet with a personal interpretation of the terms “without delay”.

The EDC criteria would be ready “before Summer 2016”, he announced. Meanwhile and nonetheless, the impact assessment would be maintained, and the “evidence gathered” during the process used “to take a duly informed decision”<sup>20</sup>. One good reason for this: “science [was] not unanimous”, he argued. “Diverging views still exist[ed] within the scientific community on critical points on how endocrine disruptors should be identified”. The Commissioner’s second point was offbeat: “some Member States support a hazard-based approach, and others - a risk-based approach”. At that point, some wondered whether the Commissioner was even aware that the Pesticides and Biocides regulations required a hazard-based approach<sup>21</sup>.

One month later, Commissioners Vytenis Andriukaitis and Karmenu Vella (Environment, Maritime Affairs and Fisheries) held a press conference following the Environment Council of March 4<sup>th</sup>. Seizing the opportunity to say something on the EDC criteria, a topic he had never been questioned about in public before, Karmenu Vella jumped in: “yes”, he said, “potency will be taken into account”<sup>22</sup>. Slip of the tongue? Or, as Politico’s Carmen Paun nicely put it, did the Commissioner “let the cat out of the bag”<sup>23</sup>?

2016

11-12  
April

## So long, potency criterion!

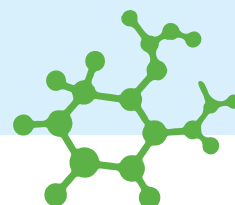
Since June 2013, the alleged lack of scientific consensus on EDCs had been pivotal in the Commission's arguments to justify the delay. So a group of scientists decided to initiate a discussion<sup>24</sup>: Åke Bergman (lead author of the landmark 2013 report 'State of the Science on Endocrine Disrupting Chemicals', p. 6), Susan Jobling (Director of the Institute for the Environment, Health and Societies at Brunel University, London), Andreas Kortenkamp (lead author of the 2012 'State of the art assessment of endocrine disruptors' commissioned by DG Environment, p.5), Tom Zoeller (member of the Endocrine Society EU EDC Task Force). Their idea was to try to reach an agreement on the crucial scientific points with the other 'camp' – mainly scientists who had participated in the June 2013 manoeuvres at the higher levels of the Commission (p. 15-16-17). Among these were Daniel Dietrich (Konstanz University, Germany - mentioned above), Alan Boobis (Imperial College, London) and Helmut Greim (retired, Technical University of Munich, Germany).

The meeting took place in April 2016 in Berlin under the auspices of the German Federal Institute for Risk Assessment, the BfR<sup>25</sup>. Those two intense days were moderated by the former Chief Scientific Adviser to the President of the Commission, Anne Glover, (who had somehow followed an intensive training for this role three years before, see p. 15 and 17 of *A Toxic Affair*).

The consensus document contained 31 bullet points and underlined that the scientific knowledge was "sufficiently advanced to warrant regulatory action". Point No 22 resolved the issue of potency for good: "We agree that a chemical's potency to induce an adverse effect is an important factor for consideration during the characterization of the hazards of endocrine disruptors. However, potency is not relevant for identification of a compound as an endocrine disruptor"<sup>26</sup>.

### End of the (potency) story?

While the text was still being finalized via email exchanges, seven prominent specialists including Andreas Kortenkamp and Tomas Zoeller discussed the scientific issues raised by the Commission's four regulatory options in an article published on 25 April in the international peer-reviewed scientific journal *Environmental Health Perspectives* ("The potency concept is not relevant to identification of hazards such as [endocrine disruptors]", they repeated). The text ended with these words: "As scientists, we consider that impact assessment studies should not be used to guide scientific criteria, nor as an argument to postpone the publication of a scientific definition". And with even more powerful words: "We are concerned that distorting scientific definitions can be used as a way to modify the spirit of a law (i.e., to move from a hazard-based to a risk-based management) thereby muddling science and policy; that one argues that consensus is lacking among scientists to define [endocrine disruptors] while [the World Health Organisation] has published an extensive and clear report defining [endocrine disruptors], leading in postponement of application of several laws voted up to 10 years earlier to protect public health"<sup>27</sup>.





2016

11  
May

## “Well-known Scientists Ready to Stem the Onslaught of Pseudoscience in the EU”

What a bizarre, pompous sentence. It was the title of a press release issued on 11 May 2016 by Daniel Dietrich's Konstanz University<sup>28</sup>. Attached was also a picture which could be downloaded in several resolutions. It showed Commissioner Vytenis Andriukaitis surrounded by seven grizzled seniors grinning in dark suits. Those self-described “respected scientists” came to see the Commissioner to warn him against the “deliberately selective” presentation of the EDC issue “to the public and to the Commission by some scientists”. “The concern was raised that public perceptions about EDCs are currently dominated by certain scientists, NGOs and well-funded pressure groups, who categorically assert that EDCs contribute to human cancer, reproductive disorders, obesity and type 2 diabetes”, they wrote. “The reality is that there is no robust, consistent scientific evidence to support such a dogmatic stance, and indeed most of the robust evidence points in the opposite direction”.

On top of that most peculiar account of the state of the science, the clique of seniors were also here to home deliver the outcome of the Berlin meeting to the

decision-maker: “potency and consideration of likely human exposure are necessary for any adequate evaluation of the human or environmental effects of EDCs”. Wow, wait! This was not what the consensus statement said, was it? Of course not. Could it be an unfortunate misunderstanding? Hardly. Three of the seven gentlemen were physically present in Berlin (Alan Boobis, Daniel Dietrich and Helmut Greim), and one was consulted on the text (Wolfgang Dekant). Furthermore, although the press release was only published on 11 May 2016, their interview with the Commissioner itself took place on 3 May. That is: one day before the consensus statement was even finalised, made public and put online. So whose opinion were the seven scientists sharing with the Commissioner? Who were they representing in his office? Who were they representing in Berlin? Their respective universities or institutes? Helmut Greim and Colin Berry are both retired. Themselves? Unfortunately, the competing financial interest section of the Berlin statement was left blank by the German Federal Institute for Risk Assessment (BfR).

2016

20  
May

## Ségolène and the secret room

A few days later, *Le Monde* reported that the BfR had refused to release the declarations of interests filled in by all participants at the Berlin meeting. Yet, according to the French newspaper's investigation, six out of the seven “Well-known Scientists Ready to Stem the Onslaught of Pseudoscience in the EU” were tied to industry – from chemicals giants such as BASF, Monsanto (directly concerned by the EDC regulation) or asbestos and tobacco companies<sup>29</sup>. Alan Boobis, a professor at Imperial College, London, was very well-known to Corporate Europe Observatory (CEO). His involvement with International Life Sciences Institute (ILSI) – a major lobbying organisation promoting the agenda and interests of the food industry – had caused problems when he was member of one of the scientific panels of the European Food Safety Authority (EFSA)<sup>30</sup>. CEO had also highlighted the conflicted situation of Alan Boobis during the saga surrounding Monsanto's herbicide, glyphosate<sup>31</sup>.

*Le Monde* reported that the seven scientists' Brussels expenses were covered by the European Risk Forum (ERF)<sup>32</sup>, a think tank created by the tobacco industry

in the 1990s<sup>33</sup>. In March 2016, ERF had eighteen members-funders from the chemical and pesticide sectors: BASF, Bayer, Dow, Syngenta, CEFIC, IFAH-Europe (veterinary pharmaceuticals), PlasticsEurope; the tobacco industry: British American Tobacco, Philip Morris International; metals: Nickel Institute, Norilsk Nickel Europe; and the toy lobby (TIE)<sup>34</sup>. The article series also revealed that the impact assessment existed in the form of a 250-page document, printed and locked in a room with security measures more severe than those established for the reading room containing official documents related to the EU-US trade negotiations (TTIP). Such exceptional measures seemed to upset the French Environment minister, Ségolène Royal. In an interview with *Le Monde*, she asked the Commission to immediately release the impact assessment. She also made a clear promise: “If these criteria are not consistent with the scientific consensus, and especially if they incorporate the concept of «potency», Sweden intends to continue the litigation against the Commission. And France will join it.” Clear? Clear.

# The Season Finale

It's now 25 May 2016. "Once again we have the sensitive issue of endocrine disruptors criteria on our plate", said Vytenis Andriukaitis in a sigh to an audience of dissatisfied MEPs. A motion of censure drafted by Piernicola Pedicini, from the eurosceptic Europe of Freedom and Direct Democracy group (EFDD), finally lapsed after 16 MEPs from the European United Left-Nordic Green Left group (GUE/NGL) withdrew their signature<sup>35</sup>. So the plenary sitting began with a vote for a motion for a resolution. Show of hands. Adopted.

A dozen MEPs were scheduled to speak. Gerben-Jan Gerbrandy (Alliance of Liberals and Democrats for Europe - ALDE) somehow managed to capture the feeling of many of his colleagues in his very first sentence: "When I was elected in this Parliament in 2009, I never would have thought we would end up in that debate that we're having tonight, where I have to call on the Commission, the Guardian of the treaties, (...) to respect a ruling of the EU Court and to comply". At the request of the Chair of the Committee on the Environment, Public Health and Food Safety (ENVI), the EU Court ruling was submitted to the Parliament Legal Service. "Legal services are the most cautious people on planet earth so when they are crystal clear, there is something", Gerbrandy warned. And what did these cautious people say: that the impact assessment "was not required". Period. "Let me be clear with Commissioner, you're not going to get away with it": that's Anja Hazekamp (GUE/NGL) reading from a notebook with the drawing of a

skull on it. "You said 'we are here again' as if WE like to be here again!", moaned Bas Eickhout (The Greens/European Free Alliance). "You are late and still using the impact assessment as an excuse". Then, saying out loud what many had been whispering lately, he added: "We think you are ill-advised by your advisors". The livestream video showed Vytenis Andriukaitis laughing heartily. "Why ignore the Court's ruling? Who is responsible? The College? You personally? Your predecessor? Juncker? Timmermans? Specifically, who is responsible?", asked Pavel Poc (Progressive Alliance of Socialists and Democrats - S&D).

Then it was Andriukaitis' turn. Standing theatrical with a hand on his heart, the Commissioner for Health who likes to remind his audiences that he is a medical doctor declaimed twice: "I am responsible, I am responsible!".

On Wednesday 8 June, the Parliament adopted to a very large majority (593 votes to 57, and 19 abstentions) a resolution condemning the Commission "for its failure to comply with its obligation", and "for failing to comply with its institutional obligations as laid down in the Treaties themselves". Hazard-based scientific criteria should be adopted "immediately", the MEPS required.

The responsible Commissioner will present his proposal for EDC criteria to the College of Commissioners on Wednesday 15 June 2016.

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- 2 Stéphane Horel. *Intoxication. Perturbateurs endocriniens, lobbyistes et eurocrates : une bataille d'influence contre la santé*. La Découverte, Paris, 2015.
- 3 *Ibid.*
- 4 European Commission. Endocrine Disruptors. [http://ec.europa.eu/environment/chemicals/endocrine/index\\_en.htm](http://ec.europa.eu/environment/chemicals/endocrine/index_en.htm)
- 5 European Commission. Conference "Endocrine disruptors: criteria for identification and related impacts". [http://ec.europa.eu/health/endocrine\\_disruptors/events/ev\\_20150416\\_en.htm](http://ec.europa.eu/health/endocrine_disruptors/events/ev_20150416_en.htm)
- 6 European Parliament. Debates. Strasbourg, 9 March 2015. <http://www.europarl.europa.eu/sides/getDoc.do?>

- 7 European Commission. "Public Consultation on defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection product regulation and the biocidal products regulation". [http://ec.europa.eu/dgs/health\\_food-safety/dgs\\_consultations/food\\_consultation\\_20150116\\_endocrine-disruptors\\_en.htm](http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/food_consultation_20150116_endocrine-disruptors_en.htm)
- 8 European Commission. *Report on Public consultation on defining criteria for identifying endocrine disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation*. 22 July 2015. [http://ec.europa.eu/health/endocrine\\_disruptors/docs/2015\\_public\\_consultation\\_report\\_en.pdf](http://ec.europa.eu/health/endocrine_disruptors/docs/2015_public_consultation_report_en.pdf)
- 9 EDC-Free Europe. "Say NO to hormone disrupting chemicals". <http://www.no2hormonedisruptingchemicals.org/>

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- 11 Stéphane Horel. *Intoxication. Perturbateurs endocriniens, lobbyistes et eurocrates : une bataille d'influence contre la santé*. P. 116. La Découverte, Paris, 2015.
- 12 Bundesinstitut für Risikobewertung. "BfR proposes further EU criteria to identify endocrine disruptors". 17/2015. 3 July 2015. [http://www.bfr.bund.de/en/press\\_information/2015/17/bfr\\_proposes\\_further\\_eu\\_criteria\\_to\\_identify\\_endocrine\\_disruptors-194580.html](http://www.bfr.bund.de/en/press_information/2015/17/bfr_proposes_further_eu_criteria_to_identify_endocrine_disruptors-194580.html)  
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- 15 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products Text with EEA relevance. <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32012R0528>
- 16 General Court of the European Union. Judgment in Case T-521/14. Sweden v Commission. <http://curia.europa.eu/juris/document/document.jsf?jsessionid=9ea7d2dc30d5ab14d308fb7c44e587a5e81fb4826ecbe34KaxiLc3qMb40Rch0SaxuTa3r0?text=&docid=173067&pageIndex=0&doclang=fr&mode=lst&dir=&occ=first&part=1&cid=526809>
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- 19 European Parliament. Debates. Strasbourg, Tuesday 2 February 2016. 12. Commission action to comply with judgment in Case T-521/14 Sweden vs. Commission (obligation to establish criteria for endocrine disruptors) (debate). <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+CRE+20160202+ITEM-012+DOC+XML+V0//EN&language=IT>
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- 23 Carmen Paun. "Disrupting hormones: the cat may be out of the bag". *Politico pro*, 7 March 2016.
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