Endocrine Disrupting Chemical Wars: the Saga Continues

The Court Found the Commission in Failure to Act (and May Need to Strike Back Later)

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Case T-521/14, Kingdom of Sweden v European Commission, Judgment of the General Court (Third Chamber) of 16 December 2015, ECLI:EU:T:2015:976

Case T-521/14 is a new stop on the perilous journey towards the appropriate regulation of endocrine disrupting chemicals. The Biocidal Product Regulation required the Commission to adopt criteria defining endocrine disrupting properties by 13 December 2013; the deadline was not respected. Even though the failure to act was obvious, the Court's reasoning in T-521/14 matters greatly. It exposes a structural weakness in the EU's risk governance system by reminding the Commission that strong private opposition to regulatory action does not justify tampering with the level of environmental or health protection set by the legislator. The now adopted criteria indicate that this lesson was not taken to heart.

I. Facts

Regulation n°528/2012 on Biodical Products (BPR)[1] sets the conditions under which these substances can be allowed on the market (Article 4). In order to ensure a high level of health and environmental protection, some biocidal substances are banned in principle from the market (Article 5). The ban is however not absolute. Exceptions are authorised when it is shown that the dangerous substance is essential to prevent societal harm, if it presents negligible risks, or if the societal impact of the ban exceeds its societal benefits[2]. The legislator has therefore set the conditions under which competing societal interests should be balanced.

In the last 20 years, a growing scientific corpus has been blowing the whistle on the negative impacts of some chemicals on the endocrine system of humans and animals.[3] Mimicking or blocking hormones, endocrine disrupting chemicals (EDCs) raise risks including cancer, decreased fertility, behavioural disruption, cognitive impairment (etc.), in particular when the exposure happens *in utero*. Reacting to those concerns, the EU legislator decided to ban biocidal products with endocrine disrupting properties under the conditions set by Article 5 BPR.

However, at the time of adoption, more reflection was still needed on the proper way to define them, assess them, and, as a result, regulate them. The legislator therefore decided to charge the Commission with adopting, 'no later than 13 December 2013' 'scientific criteria for the determination of endocrine-disrupting properties'.[4] In the interim, the BPR provides for temporary criteria. Have to be considered as biocidal products having endocrine disrupting properties:[5]

- the substances identified under REACH as potentially of very high concern because of their endocrine disrupting properties 5 or
- the substances classified as or meeting the criteria to be classified as suspected carcinogens or as

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1 Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, OJ L 167.

2 See Article 5.2 a) to c) BPR.

3 These concerns have been publicised broadly by the publication of *Our Stolen Future : Are We Threatening Our Fertility, Intelligence and Survival ?* by Theo Colbron, Dianne Dumanoski and John Peterson Myers in 1997. But in 1962 already Rachel Carson observed the endocrine disrupting effects of some chemicals in her bestseller *Silent Spring*, the book which had a crucial impact on the improvement of chemical regulation.

4 Article 5.3 al.1 BPR see note 1.

5 Article 5.1 d) BPR substances 'which **are identified in** accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 REACH as having endocrine disrupting properties'.

suspected reproductive toxicants[6] under Regulation n°1272/2008 (CLP).[7]

The temporary criteria guaranteed that some EDCs would be caught in the regulatory net, but not necessarily all. According to increasing scientific evidence, EDCs should indeed be regulated as a specific category because of their very specific mode of action. The definitions used under the CLP regulation allow for the identification of some of the *effects* of EDCs but artificially mask the *specificity* of EDCs, potentially ignoring their peculiar effect at low dose, cumulative effect and the time sensitivity in the exposure.

This explains why the BPR charges the Commission with identifying criteria specific to EDCs. As the scope of the ban set by Article 5.1(d) depends on the criteria, their definition has been, from the beginning, highly contentious. Considering the importance and complexity of the task, the deadline given to the Commission may seem harsh – only one and a half years after the adoption of the BPR. In practice, however, the Commission had been working on the topic since 2009. The Plant Protection Products Regulation (PPPR) had indeed already ordered the Commission to elaborate 'specific scientific criteria for the determination of endocrine disrupting properties' by 14 December 2013.[8] The BPR simply aligned its schedule with the PPPR giving the Commission's Directorate General (DG) Environment, in charge of the case, the opportunity to kill two birds with one stone.

DG Environment was on track to meet the 2013 deadline. It prepared a draft with the support of an *ad hoc* working group, an expert advisory group[9] and a state of the art specifically prepared by commissioned independent experts.[10] However, as explained by the Commission itself,[11] strong mobilisation from industry lobbies put a halt to the process. The industry criticised the (leaked) draft for not being scientifically sound and for having a significant economic and trade impact with an efficient lobbying strategy analysed in detail by the journalist Stephane Horel.[12]

The criteria proposed by DG Environment to the College on 7 June 2013 were rejected. DG Sanco was made co-responsible for the file with DG Environment in July 2013 (it became solely responsible in September 2014 under the Junker Commission). In September 2013, at the explicit request of the industry, the Commission declared that an impact assessment of the different regulatory options was necessary. The decision was contentious as it was not clear whether the BPR authorised the Commission to appreciate the societal impact of the criteria it had to adopt.

On 3 March 2014, Sweden called upon the Commission to act under Article 265 TFEU. In June 2014, the roadmap for the impact assessment was published. On 4 July 2014 Sweden lodged an application to seek the recognition by the Court of the Commission's failure to act. The action was considerably reinforced when the Parliament and the Council, as well as the states active in the EDCs debate (France, Denmark, the Netherlands and Finland) decided to intervene in support of Sweden's application. On the 16th of December 2015, the Court affirmed that the Commission indeed failed to act, in violation of the BPR.

6 Which includes the substances suspected to have an adverse effect on sexual function, fertility, on development as well as the substances having an impact on or via lactation.

7 Article 5.3 BPR – 'Pending the adoption of those criteria, **active substances** that **are classified** in accordance with Regulation (EC) No 1272/2008 **CLP** (Classification, labeling and packaging of substances and mixtures) as, or **meet the criteria to be classified** as, carcinogen category 2
Substances such as those that **are classified** in accordance with Regulation (EC) No 1272/2008 as, or **that meet the criteria to be classified** as, toxic for reproduction category 2 and that have toxic effects on the endocrine organs, **may be** considered as having endocrine-disrupting properties.'

8 Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, Annex II 3.6.5 'shall present to the Standing Committee on the Food Chain and Animal Health a draft of the measures to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

9 Who issued a report in 2013 http://publications.jrc.ec.europa.eu/repository/bitstream/JRC79981/lbna25919enn.pdf.

10 Andreas Kortenkamp, Olwenn Martin, Michael Faust, Richard Evans, Rebecca McKinlay, Frances Orton and Erika Rosivatz, *Final Report State of the art assessment of endocrine disrupters*, 23.12.2011, available on the internet at http://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf (last accessed on 16.08.2016).

11 See the Parliament Magazine 'DG Environment explains delegated acts on biocides' 14 October 2014, available on the internet at https://www.theparliamentmagazine.eu/articles/eu-monitoring/dg-environment-explains-delegated-acts-biocides (last accessed on 16.08.2016).

12 See her thoroughly documented investigation *A toxic affair. How the chemical lobby blocked action on hormone disrupting chemicals*, May 2015, available on the internet at http://corporateeurope.org/sites/default/files/toxic_lobby_edc.pdf (last accessed on 16.08.2016). See also Bernardo Delogu, *Risk analysis and governance in EU policy making and regulations* (Springer International Publishing, 2016), Chapter 4 p. 98-109.

II. Judgment of the Court

When Sweden decided to bring the Commission to the Court, it was clear that the latter would need to be remarkably creative to win: set deadlines are the actions for failure to act's best friends. As confirmed by the Court, Article 5.3 Regulation n°520/2012 sets a clear, precise and unconditional mandate, from which there is no escape: 'No later than 13 December 2013' the Commission had to act.[13] Now, I hear you say: if it was so simple, why is the decision worth commenting on?

The interest lies in the argumentation of the Commission, or more precisely in the authoritative and articulated way the Court reacted to it. First, the Commission failed, without surprise, to convince the Court that the deadline was not an obligation of result, but a (more flexible) objective. The deadline was unambiguous and could not be changed by interpretation. [14] The really interesting bits relate to the second series of arguments, asking the Court to give the Commission some discretion because of the exceptional circumstances of the case, aka the scientific controversy and the claim by industry lobbies that the economic impact would be excessive.

There are three main issues with that claim. First, the situation described by the Commission is by no way exceptional. Risk regulation typically places the Commission in the difficult position. It has to act according to a tight mandate in highly contentious, lobby-active situations tainted by scientific controversy and conflicting values (think genetically modified organisms, nanotechnologies, etc.). Second, the scientific controversy was prompted by the industry, following the modus operandi of the tabacco industry. [15] Third, it was not clear whether the BPR actually gave the Commission the power to take into account the economic impact of the criteria at that stage, since the mandate pointed only towards taking stock of the scientific state of the art. Fourth, it would be perilous to grant the Commission extra discretion in the implementation of EU law because its task was difficult, when a similar request by the Member States was rejected.[16]

The Court did not need to address these arguments as it had already established that Article 5.3 sets a strict obligation. However, the Court decided to call for order by detailing its perception of how the Commission handled the industry pressure.

On the scientific controversy, the Court affirms that the Commission does not need to wait for a scientific consensus – the precautionary principle was not mentioned, but one recognises its spirit. The Commission is free to favour one scientific position over another as long as the BPR is respected. This argument would have been enough, but the decision interestingly assesses *whether* there was indeed scientific controversy. The details of the industry strategy are detailed and documented in Horel's report.[17] The Court exposes what was maybe the most shoking part of it.

On 18 June 2013, a letter was sent to the Chief Scientific Adviser, signed by 56 scientists - a majority of which were found later to have conflicts of interest[18], heavily criticising the (leaked) proposal of the DG Environment. The letter was used as support for a violent editorial which was published in July 2013 to influence EU policy,[19] with critiques expressed '*in very rude terms*'.[20] The Chief Scientific Adviser, Anne Glover, relayed these concerns to the highest level of the Commission mid-June 2013. Quickly, 41 leading experts in endocrine disruption and 104 scientists and editors[21] rebutted the editorial. The Commission therefore had evidence that the scientific brouhaha was at least partly orchestrated. The artificiality of the controversy - or at least the confusion on the real degree of controversy, intentionally spread - was made obvious in October 2013. The Chief Scientific Adviser organised a meeting with representatives of both

13 Case T-521/14, para. 53.

14 Case T-521/14, para. 62. For the full argument, see from para. 53-61.

15 The Tabacco industry strategy, and its impact on current lobbying practices, is brilliantly exposed by David Michaels, in *Doubt is their product* (Oxford: Oxford University Press, 2008).

16 See for example C-68/11, European Commission v Italian Republic, Judgment of the Court (First Chamber) of 19 December 2012, ECLI:EU:C:2012:815.

17 See Horel's report, note 12.

18 See Horel's report, note 12.

19 Dietrich et al. 'Scientifically unfounded precaution drives European Commission's recommendations on EDC regulation, while defying common sense, well- established science and risk assessment principles' 30(3) *ALTEX* (2013) 381-5. See for a detail examination of the mistakes in that editorial and for a condemnation of the practice altogether : Delogu note 12.

20 See Delogu, note 12, page 108-109.

21 See Horel, and Bergman *et al.* 'Commentary in Environmental Health. Science and policy on endocrine disrupters must not be mixed: a reply to a "common sense" intervention by toxicology journal editors' *Environmental Health Journal* 27 August 2013 and Gore AC *et al*. 'Policy Decisions on Endocrine Disrupters Should Be Based on Science Across Disciplines: A Response to Dietrich et al.' 154(11) *Endocrinology* (2013) 3957-60.

'sides'. At the meeting the opponents to the Commission's proposal 'agreed to sign a consensus statement which contradicted their initial declarations, notably on the issue of whether there were safe thresholds for EDCs'.[22] Unfortunately, this final act happened *after* the official decision to launch the impact assessment.

The science of EDCs assessment is complex, and still in development. It is however of the highest importance for the regulators to distinguish between what is real uncertainty and what is strategically and unduly spread doubt, as it is now a well-known lobby modus operandi. The Court seems to agree, noting that in this particular case the 2013 proposal of DG Environment reflected the scientific consensus – the controversy was not real.

The Commission then tried to justify the delay by affirming the necessity to conduct an impact assessment in light of the concerns, expressed by the industry, related to the consequences of the criteria for trade and the economy. The Court rejected the argument using compelling reasons. First, the criteria had to be determined objectively and with regard only to the scientific data related to these properties – the potential economic impacts of the criteria were irrelevant at this stage. Second, the assessment of the economic impact was not needed because the legislator already decided, in the BPR, the extent to which economic interests should be balanced with environmental and health protection. The legislator decided that EDCs with adverse health impact shall be banned, but authorised exceptions, indirectly covering the scenario of a ban causing an excessive economic impact.[23] By taking the industry's claims on board, the Commission was therefore meddling with an essential element of the legislation which falls under the exclusive power of the EU legislator: the choice of what is the acceptable level of risk.[24] The Court does not explicitly reject the decision to assess the impact, but reminds that in any case, if done, it had to respect the legislative timeline.

The remaining arguments of the Commission suffer from the same disregard towards the level of protection set by the legislator. First, the Commission considers that the temporary criteria are sufficiently protective. Second, that the objective to set horizontal (rather than sectoral) EDCs criteria in 2020, according to the 7th program, overrode the BPR mandate. The Court rejects both, considering this appreciation of the necessity to adopt criteria as an inacceptable intrusion into the legislator's competence.[25]

III. Comments

This case is a judicial confirmation of the mess which has characterised the management of risks related to EDCs. The story is not over, as even if the Commission did adopt the criteria required by the BPR[26] and the PPPR,[27] the drafts confirm that old habits die hard. This note is not the place for a detailed explanation of why the Commission seems to once again have the intention of modifying the balance of interests set by the legislator, in particular for the PPPR. Schenten and Führ's compelling analysis, commissioned by ClientEarth, should be referred to for further information.[28]

For risk governance more generally, two lessons should be learned from the case. First, the management of scientific controversy must be improved. Responsiveness to new scientific knowledge is a healthy feature for a risk governance system. However, it is imperative to handle direct opposition to regulatory action carefully, even by scientists. Industry lobbies have, for quite some time, established tight connections with the academic world which are not always tied to nor used in the public interest. Public authorities need to take stock of the situation.

Second, the Commission needs to reflect on the essence of its role in risk regulation. The power to adopt delegated or implementation acts makes the Commission assailable in highly contentious contexts. This vulnerability should make the Commission even more guarded in the use of its powers, but it results too often in a worrying disregard for their

22 See Horel page 17 and Case T-512/14 para. 73.

23 Regulation BPR Article 5.2.c).

24 See para. 72.

25 See para. 75-77.

26 Commission, Draft of Commission delegated regulation … setting out scientific criteria for the determination of endocrine disrupting properties pursuant to Regulation (EU) No 528/2012, C(2016) 3752 project.

27 Commission, Draft of Annex to the Regulation … setting out scientific criteria for the determination of endocrine disrupting properties and amending Annex II to Regulation (EC) 1107/2009, C(2016) 3751 project.

28 Julia Schenten and Martin Führ 'The European Commission proposals and legal requirements concerning the determination of scientific criteria to identify endocrine disruptive properties of active substances' 16-3 *Sofia-Studien* 2006 available on the internet at http://www.sofia-darmstadt.de/fileadmin/Dokumente/Studien/2016/Online_Schenten_and_Fuehr_Endocrine_disrupters_.pdf (last accessed on 16.08.2016).

limits in favour of economic interests. The recent decision of the European Ombudsman in case 12/2013/MDC is but another example also related to agro-chemicals.[29] The Commission autonomous regulatory powers are all linked to the preservation of free circulations. Does it have an influence on the way it exercises delegated powers? In any case, the Commission should keep this bad habit in check. The power to select the appropriate balance between economic freedoms, the environment and health belongs to the legislator. Certainly things are rarely that clear-cut, but as the General Court reiterated in T-521/14, the Commission should, at least, not change the level of protection when it was clearly set by the legislator in the basic act. What is at stake is no less than legal certainty and the reputation of the EU institutions, which, truly, could do with a little polishing these days.

29 European Ombudsman, Decision in case 12/2013/MDC on the practices of the European Commission regarding the authorisation and placing on the market of plant protection products (pesticides), 18.02.2016, available on the internet at http://www.ombudsman.europa.eu/en/cases/decision.faces/en/64069/html.bookmark (last accessed on 16.08.2016).