

## A Trojan horse in the identification of endocrine disruptors

### Call on the European Parliament to veto the Commission's attempt to add an illegal derogation to the Pesticides Regulation

Endocrine disruptors are chemicals that can disrupt the hormonal system of humans and animals. They may have very serious effects, even at low dose, ranging from cancer to the deterioration of male fertility, the increase of obesity and the disruption of human brain development.<sup>1</sup>

In 2009, aware of the rising health and environmental concerns that endocrine disruptors pose, the European Parliament and the Council decided to ban these chemicals from being used as pesticides (with two narrow derogations).<sup>2</sup> However, unlike carcinogens for example, no criteria existed at the time (and today still), under any international convention or EU laws, to *identify* endocrine disruptors. In this context, the European Parliament and the Council, within the Pesticides Regulation, gave the mandate to the Commission to adopt such scientific criteria.<sup>3</sup>

The process has suffered from a systematic disregard for the principles of good governance that the Commission pledged to respect,<sup>4</sup> from transparency,<sup>5</sup> to respect of deadlines and appropriate use of impact assessment.<sup>6</sup> On the 4<sup>th</sup> of July 2017, after a 4 years delay, the final draft of the criteria was finally adopted (the "Proposal").<sup>7</sup> The Proposal reveals yet another maladministration: **the Commission has clearly exceeded the mandate granted by the European Parliament and Council by coming back on the co-legislators' decision to strictly ban endocrine disruptors from pesticides.**

It is now for the European Parliament to review the Proposal to which it has the power to object under the pre-Lisbon comitology procedure.<sup>8</sup> **ClientEarth is calling the European Parliament to prevent the Commission from using the Proposal as a Trojan horse to force a new derogation into the Regulation**, a.k.a illegally disregarding what was decided in 2009 following a democratic debate.

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<sup>1</sup> See case study on Bisphenol A in the European Environment Agency's publication 'Late lessons from early warnings', 2013, Chapter 10 available at: <https://www.eea.europa.eu/publications/late-lessons-2>.

<sup>2</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 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, 24.11.2009, p. 1–50, ("**Pesticides Regulation**"), Article 4.7, Annex II, Point 3.6.5 and Point 3.8.2.

<sup>3</sup> Pesticides Regulation, op.cit. note 2, Annex II, Point 3.6.5.

<sup>4</sup> Commission, Good Governance White Paper, COM(2001) 428, available at: [http://europa.eu/rapid/press-release\\_DOC-01-10\\_en.htm](http://europa.eu/rapid/press-release_DOC-01-10_en.htm).

<sup>5</sup> Le Monde, *Perturbateurs endocriniens: la fabrique d'un mensonge*, S. Horel, 29 November 2016, translation available here : <http://www.env-health.org/news/latest-news/article/endocrine-disrupters-the>

<sup>6</sup> Judgment of the General Court of 16 December 2015, *Kingdom of Sweden v European Commission*, Case T-521/14, ECLI:EU:T:2015:976, para.

<sup>7</sup> Commission, Draft Regulation amending Annex II to Regulation (EC) 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties, available at: <http://data.consilium.europa.eu/doc/document/ST-11470-2017-INIT/en/pdf>.

<sup>8</sup> "regulatory procedure with scrutiny" according to Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

## 1 The Commission's proposal: a breach in the ban set by the co-legislators

When the European Parliament and the Council adopted the Pesticides Regulation, they decided that endocrine disruptors that may cause adverse effects on humans<sup>9</sup> or on non-target organisms<sup>10</sup> ought to be banned from being used as pesticides. The co-legislators created only two narrow derogations to the ban:

- using the substance can be allowed when the exposure to humans, and to non-target organisms, is “negligible”.<sup>11</sup>
- a *temporary use* can be allowed when a *serious* danger to plant health arise which cannot be contained by *any* other available means *and if* mitigation measures minimise the risk.<sup>12</sup>

In this context, the European Parliament and the Council delegated to the Commission a power narrowly defined:

*“By 14 December 2013, the Commission shall present to the Standing Committee on [Plants, Animals, Food and Feed] a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4)”<sup>13</sup>.*

In its Proposal, the Commission started by setting out criteria to identify endocrine disruptors,<sup>14</sup> but then added the following clause:

*“If the intended plant protection mode of action of the active substance being assessed, consists of controlling target organisms other than vertebrates via their endocrine systems, the effects on organisms of the same taxonomic phylum as the targeted one, shall not be considered for the identification of the substance as having endocrine disrupting properties with respect to non-target organisms.”<sup>15</sup>*

Put simply, this means that, if a chemical is ‘intended’ to be an endocrine disruptor it will not be “considered as” an endocrine disruptor, even if it is an endocrine disruptor according to the criteria set out in the Proposal itself. As a result, whilst being, by definition, an endocrine disruptor, the chemical will, ultimately, escape the ban. The clause is presented as dealing with the *identification* of endocrine disruptors, but in effect it creates, in all but in name, a **new derogation to the ban** explicitly intended by the co-legislators.

<sup>9</sup> Pesticides Regulation, Article 23 and Annex II 3.6.5.

<sup>10</sup> Pesticides Regulation, Annex II 3.8.2.

<sup>11</sup> Pesticides Regulation, Annex II 3.6.5 and 3.8.2, more precisely “under realistic proposed conditions of use” for example when the pesticide is used in closed system.

<sup>12</sup> Pesticides Regulation, Article 4.7.

<sup>13</sup> Pesticides Regulation, Annex II, Point 3.6.5 para. 2 (emphasis added).

<sup>14</sup> First the criteria for endocrine disruptors that may cause adverse effect in humans (Annex of the Proposal, Point 1), and then criteria for those that may cause adverse effects on animals or organisms other than the pest targeted (Annex of the Proposal, Point 2).

<sup>15</sup> Proposal, Annex, last para. (emphasis added).

This new derogation is redacted to *appear* in compliance with the Commission’s mandate, but is, in fact, a textbook example of the Commission exceeding its powers.

## 2 A textbook example of exceeding implementing powers

### 2.1 A mandate limited to amend non-essential elements of the Pesticides Regulation

Under the European Treaties, the Commission can complement or modify existing environmental laws only if the co-legislators give it the power to do so. The Commission’s mandate is defined in the basic act – in this case the Pesticides Regulation – and the Commission cannot act beyond without violating the Treaty as well as the balance of power between the European institutions.

The Pesticides Regulation contains two legal basis for the Commission to adopt implementing acts. The first legal basis is Annex 3.6.5 of the Pesticides Regulation, which gives to the Commission the mandate to adopt scientific criteria to identify endocrine disruptors. The new derogation clearly goes beyond this mandate from which the Commission received only the power to define *scientific* criteria for the *identification* of endocrine disruptors, *not* to decide *which* should be authorized or banned.

The second legal basis is Article 78(1) of the Pesticides Regulation, which grants to the Commission the power to adopt a list of “*measures designed to amend non-essential elements of (the Pesticides) regulation*”, which includes “(a) *Amendments to the annexes taking into account current scientific and technical knowledge*”. The Commission seems to think that Article 78(1) of the Pesticides Regulation suffices to ground the adoption of the new exemption.<sup>16</sup> This is however not the case, as the new exemption alters *existing essential elements* of the basic instrument, aka the Pesticides Regulation.

### 2.2 A new derogation altering essential elements of the Pesticides Regulations

Under EU law, the “essential elements” of a legislative act are strictly reserved to the legislator – so much so that even the co-legislators do not have the power to delegate their adoption to the Commission.<sup>17</sup> While it can be difficult to define whether an amendment touches upon an “essential” element of a legislative act, this case provides a textbook example of what an essential element looks like.

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<sup>16</sup> The preamble of the Proposal refers to both Article 78 (1)(a) and to the specific mandate to adopt scientific criteria for identification. The Commission therefore implicitly considers that these legal bases cover the scope of its proposal.

<sup>17</sup> See Article 290 TFEU and for the situation pre-Lisbon see C-355/10 Judgment of the Court of 5 September 2012, *European Parliament v Council of the European Union*, Case C-355/10, ECLI:EU:C:2012:516, para. 63 and 76 to 78).

According to settled case-law, “*Identifying the elements of a matter which must be categorised as essential (...) requires account to be taken of the characteristics and particular features of the field concerned*”.<sup>18</sup> Because the identification of essential elements requires a case-by-case approach, there is no ‘list’ to which one could just refer. However, the Court isolated a few actions which, by their nature, touch upon the essential elements of a basic act, including:

- Decisions which require a “*political choice*” “*falling within the responsibilities of the European legislature, in that it requires the conflicting interests at issue to be weighed up on the basis of a number of assessments*”;<sup>19</sup>
- When the contested decision deals and **tempers with the very core** of the basic instrument.<sup>20</sup>

The core of the Pesticides Regulation has to be identified in relations to its dual objective. The Regulation aims both at improving the functioning of the internal market *and* at protecting health and the environment. The balance between these two imperatives is achieved by the political determination of what is an acceptable risk for society. The ‘acceptable risk’ is itself defined by the particular system of bans and derogations set by the Pesticides Regulation, which includes the ban of endocrine disruptors except in two limited cases, a.k.a use with negligible exposure and use when only solution to tackle a serious risk to plant health. **The ban and the choice to have only two derogations are the core of the Pesticides Regulation and its most politically sensitive parts – they are therefore essential elements amendable only by the EU legislature.**

The Court confirmed that the scope of the ban was an essential element in a case brought by Sweden against the Commission judged in 2015.<sup>21</sup> The case was decided under the Biocides Regulation<sup>22</sup>, but is directly relevant for assessing the scope of the Commission’s delegated power under the Pesticides Regulation. Indeed, the Biocides Regulation contains a similar ban of endocrine disruptors with limited exemptions, and the Court was asked in that case to examine the Commission’s failure to adopt the scientific criteria to identify endocrine disruptors, a mandate that the co-legislators copied from the Pesticides Regulation.

In this case, even though the Commission had a clear mandate (adopt scientific criteria by December 13, 2013), it argued that the deadline should be flexibly applied considering both the vocal opposition of the industry and the potential economic implications of the ban.<sup>23</sup>

The Court answered that none of these considerations were relevant. It concluded from the existence of the ban of endocrine disruptors, completed by a restricted list of exceptions, that the co-legislators took a final decision about the adequate balance between the market and health/

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<sup>18</sup> Judgment of the Court of 10 September 2015, *European Parliament v Council of the European Union*, Case C-363/14, ECLI:EU:C:2015:579, para. 47.

<sup>19</sup> Judgment of the Court of 5 September 2012, *European Parliament v Council of the European Union*, Case C-355/10, ECLI:EU:C:2012:516, para.76.

<sup>20</sup> *Ibid.* para. 71-75 and 79.

<sup>21</sup> Judgment of the General Court of 16 December 2015, *Kingdom of Sweden v European Commission*, Case T-521/14, ECLI:EU:T:2015:976.

<sup>22</sup> 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, OJ L 167, 27.6.2012, p. 1–123.

<sup>23</sup> *Ibid.* para 69-71.

environmental protection. The Court stated twice that the Commission “*ne saurait remettre en cause*” (“**shall not meddle in any way with**”) the legislator’s choice of adequate balance when using its delegated power.

### 2.3 The Commission knowingly exceeded its mandate for economic reasons

The Commission has recognized that the scope of the ban of endocrine disruptors is an essential element reserved to the co-legislators at several occasions. It did so during the audience of the case brought by Sweden under the Biocides Regulation<sup>24</sup>, but not only. Similarly, the Commission itself affirmed in a communication: “*the issue faced by the Commission in this exercise is to establish criteria to determine what is an endocrine disruptor for the purposes of plant protection products and biocidal products - not to decide how to regulate these substances*”.<sup>25</sup> In its Impact Assessment, the Commission also acknowledged the boundaries of its legal mandate. When it considered the inclusion of socio-economic considerations to broaden the derogation to the ban, the Impact Assessment concluded, “[t]his option would request a modification via ordinary legislative procedure of the current PPP Regulation.”<sup>26</sup>

The purpose of this new derogation - to avoid the ban provided under the Pesticides Regulation - is recognized without ambiguity in the summary report of the Standing Committee on Plants, Animals, Food and Feed from 28 February 2017:

*“Furthermore, the rationale behind the provision on active substances with an intended endocrine mode of action (below called growth regulators (GR)) was explained. [...] The provision on GR allows that the cut-off criteria [=the ban] will not be applied to substances with an intended endocrine mode of action [...].”<sup>27</sup>*

The Commission’s motivation to limit the number of pesticides banned despite the co-legislators’ clear intention does not come as a surprise. This was already the purpose of the Impact

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<sup>24</sup> Ibid. 70 and 72.

<sup>25</sup> Commission, Press Release, Fact Sheet, 15 June 2016, available at: [http://europa.eu/rapid/press-release MEMO-16-2151\\_en.pdf](http://europa.eu/rapid/press-release_MEMO-16-2151_en.pdf)

<sup>26</sup> Commission, Staff Working Document, Impact Assessment, Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation, SWD(2016) 211 final, available at: [https://ec.europa.eu/health/sites/health/files/endocrine\\_disruptors/docs/2016\\_impact\\_assessment\\_en.pdf](https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_en.pdf), see p. 240 and 277 (“**Impact Assessment**”).

<sup>27</sup> Summary Report of the Standing Committee on Plants, Animals, Food and Feed, held in Brussels on 28 February 2017, (sante.ddg2.g.5(2017)1691319), available at: [https://ec.europa.eu/health/sites/health/files/endocrine\\_disruptors/docs/ev\\_20170228\\_sum\\_en.pdf](https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/ev_20170228_sum_en.pdf) (emphasis added).



Assessment,<sup>28</sup> which, according to the Commission's Regulatory Scrutiny Board, was based on a "*methodological bias [...] favouring options banning fewer Substances*".<sup>29</sup>

The Commission openly relies on the "proportionality principle" to exclude from the ban "intended" endocrine disruptors.<sup>30</sup> If the Commission considers that banning endocrine disruptors is disproportionate for the pesticides industry, or trade, it is entitled to make a proposal to amend the Pesticides Regulation under the ordinary legislative procedure. **However, it does not have the power, via the comitology procedure, to decide to take a risk for the environment that the European Parliament and Council have decided not to take.**

### 3 Conclusion

The Commission was well aware of the boundaries of its implementing powers. Nevertheless, the Proposal confirms the Commission's intention to limit, on economic grounds, the number of pesticides that would be prohibited, in contradiction with the co-legislators' will.

In September 2016, the Chair of the ENVI committee of the European Parliament has reminded the Commission of the limits of its power in this case.<sup>31</sup> The message has not been heard.

**ClientEarth now calls on the European Parliament to veto the Commission's attempt to shrink the ban of endocrine disruptors, which scope was democratically decided.**

It is not only a question of protection of the environment. It is about the balance of powers between EU institutions, and making sure that EU citizens, represented directly in the European Parliament, have a say. In the Endocrine disruptors criteria case, the Commission has showed a systematic disregard for the co-legislator's will, the EU Treaties, and the principles of good administration. It will continue to do so until forced to respect its obligations.

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<sup>28</sup> Impact Assessment, p. 26, "Step 1: Number of substances identified as ED", p. 338 "*the best indicator for assessing the impact is the number of substances identified*", "*the more substances are identified as ED, the more likely that substances would be taken out of the market or approved only under restricted conditions, leading consequently to higher negative impacts on the single market*".

<sup>29</sup> Commission, Regulatory Scrutiny Board, Opinion, 3 June 2016, available at: [http://ec.europa.eu/smart-regulation/impact/ia\\_carried\\_out/docs/ia\\_2016/sec\\_2016\\_0305\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2016/sec_2016_0305_en.pdf)

<sup>30</sup> Proposal, Recital 7.

<sup>31</sup> Letter from G. La Via, dated 15 September 2016, available at: [http://www.stephanehorel.fr/wp-content/uploads/2016/11/1%E2%80%93Lettre\\_EP\\_Andriukaitis\\_2016.pdf](http://www.stephanehorel.fr/wp-content/uploads/2016/11/1%E2%80%93Lettre_EP_Andriukaitis_2016.pdf)

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ClientEarth is a non-profit environmental law organisation based in London, Brussels and Warsaw. We are activist lawyers working at the interface of law, science and policy. Using the power of the law, we develop legal strategies and tools to address major environmental issues.

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