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EU Commission's new illegal attempt to weaken the control of endocrine disruptors used in Pesticides – call for action

Executive Summary

In July, at the request of a few Member States, the European Commission brought back an amendment of the Pesticides Regulation that was severely criticised in 2016 by the European Parliament and several other Member States. This amendment was put back on the table of the Member States in the context of the Standing Committee on Plans, Animals, Food and Feed (ScoPAFF). This Proposal attempts to **weaken significantly the level of protection against endocrine disruptors set in the Pesticides Regulation**.

In doing so, it forces Member States, the European Parliament and civil society to keep playing a resource intensive and dangerous whack-a-mole game which has been going on for years. If lost, this unfortunate 'game' will lead to the exposure of people and the environment to endocrine properties against the express intention of the co-legislators.

The Proposal to amend such an essential element of the Pesticides Regulation **goes beyond the Commission's delegated powers**. It touches the very core of the Pesticides Regulation: the determination of what risk 'acceptable' for society. It is also not motivated by any new scientific developments, contrary to the Commission's allegations. The decision, taken in 2009, to limit exposure to endocrine disruptors to a negligible level is based on scientific knowledge revealing that these chemicals have the potential to cause harm of equivalent seriousness as cancer. Since 2009, the scientific knowledge on endocrine disruptors has expanded in a way that supports stricter control of endocrine disruptors – and not a weaker one, which would be the result of the Commission's proposal.

That is why:

- **We call on the Member States to vote against the Proposal at ScoPAFF, and if it were to pass in ScoPAFF, to veto the Proposal during the scrutiny stage of the Council.**

If ScoPAFF nevertheless approves the Proposal, the European Parliament would have the same right as the Council to veto the Proposal by a majority vote.

- **We call on the MEPs to veto the Proposal, as it encroaches upon their reserved power, again.**

Introduction

Endocrine disruptors (EDCs) 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[1].

Taking into account their potential for serious adverse effects, the European Parliament and the Council decided to prohibit, in principle, the use of EDCs in pesticides. Outside situations of emergency[2], the EU legislators decided to allow exposure of people and the environment only if this exposure is "negligible"[3]. In doing so, they decided to align the management of the risks of EDCs in pesticides with the preventive approach chosen for chemicals classified as carcinogenic, mutagen or toxic for reproduction (CMR).

The Pesticides Regulation entrusted the Commission with adopting the scientific criteria to be used in the identification of EDCs, and with updating the non-essential elements of the annexes when new knowledge or techniques require it. The Commission has systematically misused these powers. It unduly delayed the adoption of the identification criteria[4]. When it did adopt a proposal, in June 2016, the text contained an amendment that authorised the use of EDCs in pesticides even in situations where the exposure to people and the environment is not negligible, in total contradiction with what the EU legislature decided initially.

Faced with the opposition of the European Parliament[5], civil society[6] and some Member States[7], the Commission proposed a new text without this amendment in 2016. The revised version of the criteria, however, still included a Trojan horse[8] meant to create an illegal additional derogation to the EDC ban – which led to a veto by the European Parliament, reminding the Commission that the determination of the scope of the ban is a power reserved to the EU legislature.[9]

But it was not the end of the track for the dropped amendment. To convince reluctant Member States to approve the criteria without the amendment, the Commission promised to propose it,

[1] See case study on Bisphenol A in the European Environment Agency's publication 'Late lessons from early warnings', 2013, Chapter 10 (https://www.eea.europa.eu/publications/late-lessons-2/late-lessons-chapters/late-lessons-ii-chapter-10/view); see the website of the World Health Organisation (http://www.who.int/ceh/publications/endocrine_disrupters_child/en/); and see the website of the Endocrine Society, a global group of 18 000 health practitioners specialised on endocrinology (https://www.endocrine.org/topics/edc)

[2] It is however still possible for Member States to allow the use of prohibited pesticides in case of "emergency" in very specific circumstances (Article 53 of the Pesticides Regulation). In practice, it is now very clear that this "emergency" mechanism is misused and abused. On that topic, see the "Bee Emergency Call" report available here: https://www.documents.clientearth.org/wp-content/uploads/library/2017-02-15-bee-emergency-call-coll-en.pdf. This emergency mechanism is however not the subject matter of the present analysis which sheds light on a new attempt of the Commission to weaken the Pesticides Regulation itself.

[3] 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"), Annex II, Point 3.6.5 and Point 3.8.2.

[4] Judgment of the General Court of 16 December 2015, *Kingdom of Sweden v European Commission*, Case T-521/14, ECLI:EU:T:2015:976.

[5] Letter from G. La Via, dated 15 September 2016, available at : https://tinyurl.com/yd228nsv

[6] See for example Chemtrust's blog: https://tinyurl.com/y7golluk and the legal opinion made on behalf of ClientEarth in 2016 already denouncing the illegality of the approach See https://tinyurl.com/y943vj9w

[7] See Summary reports of ScoPAFF September, November and December 2016 (available at: https://ec.europa.eu/food/plant/standing_committees/sc_phytopharmaceuticals_en) . It was also explicitly recognised in the summary report of the ScoPAFF meeting held in February.2017 see p. 1.

[8] See https://www.documents.clientearth.org/wp-content/uploads/library/2017-09-25-a-trojan-horse-in-the-identification-of-endocrine-disruptors-ce-en.pdf

[9] European Parliament Press Release, 4 October 2017, http://www.europarl.europa.eu/news/en/press-room/20171002IPR85122/identifying-endocrine-disruptors-meps-block-plans-exempting-some-pesticides

again, at a later stage[10]. Now that the criteria are adopted, the Commission has proposed the amendment as promised;[11] even though it is a manifestly illegal intrusion into a power strictly reserved to the EU legislature.

ClientEarth calls on the Commission to not push for a proposal that the European Parliament has publicly condemned, the last time on the 13th of September 2018, warning the Commission 'that any reinterpretation of the term 'negligible exposure' as 'negligible risk' would be against the letter and the spirit of the law'.[12]

ClientEarth calls on the Member States and the European Parliament to block these repeated attacks on the EDC ban. The Commission's multiple attacks on the risk management decision of the co-legislators show a trend of systemic maladministration and a worrying disdain towards the limits of its power. This requires a strong reaction, able to shine light on this Commission, on the next Commission and on the individual Member States that have pushed or supported these attacks behind the closed doors of the ScoPAFF.[13]

1 The Commission's repeated attacks on the EDC ban

In July 2018, the Commission re-proposed to the Standing Committee on Plans, Animals, Food and Feed (ScoPAFF) the amendment severely criticised in 2016 by the European Parliament and the Member States (the Proposal)[14]. In doing so, it forces Member States, the European Parliament and civil society to keep playing a resource intensive and dangerous whack-a-mole game. If lost, this 'game' will lead to the exposure of people and the environment to endocrine properties against the express intention of the co-legislators.

The current scope of the ban by the Pesticides Regulation – Annex II:

- **3.6.5.** "*An active substance, safener or synergist shall only be approved if, (…) it is not considered to have endocrine disrupting properties that may cause adverse effect in humans,* **unless the exposure** *of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use,* **is negligible***,* **that is,** *the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on*

[10] See Extract on the summary report of the ScoPAFF held in Brussels on 12 December 2017-13 December 2017 referring to the Commission 'commitment made in July 2017 to table the 2nd text with the amendment to the derogation possibilities (changes to points 3.6.5 and 3.8.2 of annex II to Regulation 1107/2009) once the criteria will be adopted. P 2.
[11] See agenda of ScoPAFF meeting of July 2018, point A.18(2) https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20180719_ppl_agenda.pdf ;The Commission had committed to the Member States to do so in July 2017 – see Summary report ScoPAFF December 2017, point B.14 available at: https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20171212_pppl_sum.pdf;
[12] European Parliament resolution of 13 September 2018 on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009 (2017/2128(INI)), paragraph 50.
[13] The summary records of the ScoPAFF reveal that certain Member States supported and even pushed the Commission to make this proposal. Four Member States abstained because the text did not include the negligible risk proposal, and one even opposed for that reason. (see for example summary record of July 2017: https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20170704_pppl_sum.pdf) ; Unfortunately, the names of these Member States are not published in these summary records, protecting them from public scrutiny
[14] Draft Commission Regulation amending points 3.6.5. and 3.8.2. of Annex II to Regulation (EC) 1107/2009 taking into account current scientific and technical knowledge SANTE-2016-12011-REV 2 C(2016) 3751 project (available at: https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/press-releases/Proposal%20to%20substitute%20to%20negligible%20risk%20-%20Dec%202016%20-%20July%202018.pdf#overlay-context=media/press-releases)

food and feed do not exceed the **default value set in accordance with point (b) of Article 18(1)** *of Regulation (EC) No 396/2005".*

- **3.8.2.** "*An active substance, safener or synergist shall only be approved if, (…) it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms* **unless the exposure** *of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use* **is negligible".**

The draft Commission Regulation (the Proposal) amending the conditions justifying a derogation from the ban*:*

- **3.6.5.** *"An active substance, safener or synergist shall only be approved if, (…) it is not considered, in accordance with the criteria specified in the fifth paragraph, to have endocrine disrupting properties that may cause adverse effect in humans,* **unless the risk** *to humans from exposure to that active substance, safener or synergist in a plant protection product, under realistic worst case proposed conditions of use***, is negligible***,* **in particular** *where the product is used in closed systems* **or in other conditions** *which aim at excluding contact with humans, and where maximum residue levels of the active substance, safener or synergist concerned in or on food and feed* **can***, taking account of the latest opinion of the Authority with respect to that active substance, synergist, safener,* **be set** *in accordance with Regulation (EC) No 396/2005, which ensure a high level of consumer protection".*

- **3.8.2.** *"An active substance, safener or synergist shall only be approved if it is not considered, (…) to have endocrine disrupting properties that may cause adverse effects on non-target organisms,* **unless the risk** *to the non-target organisms from exposure to that active substance, safener or synergist in a plant protection product under realistic worst case proposed conditions of use***, is negligible***".*

As is obvious from the current text of the Pesticides Regulation, the EU legislature decided that when it comes to EDCs in pesticides, exposing people and the environment entails an inacceptable risk. Considering that EDCs are identified by their adverse effects on the endocrine system, and considering the gravity of these effects, the EU legislature considered that exposure should be avoided. The 'ban' is a prohibition of exposure, acceptable only when it is 'negligible' – the same ban applies to CMRs.

As is similarly obvious from the amendment proposed, the Commission intends to reverse this decision by considering that it is acceptable to expose people and the environment to EDCs in pesticides, if a complex evaluation of the 'risk' involved (exposure x hazard) shows that it remains 'negligible'.

The Commission is trying to revoke the special treatment given to EDCs, which the EU legislature decided to identify as a regulatory category deserving the same preventative approach as carcinogens, mutagens and reprotoxics. Authorising EDCs when the risk is negligible indeed requires:

1. That EDCs are now submitted to the same conditions as all other substances, since the Pesticides Regulation already sets out that pesticides "shall not have any harmful effects

on human health or animal health"[15] (a requirement which seems to be already stronger than 'negligible' risk) and that they "shall not have any unacceptable effect on the environment" (which requires an assessment of the risk)[16].

2. To undertake the complex enterprise of characterising the risk of the substance, even though the substance is an EDC, identified as such because of its grave adverse effects.

The Commission also changes the level of acceptable residue of the pesticides containing ED substances in food. It is currently set at the default value of 0,01 mg/kg (Article 18.1.b Regulation 396/2005) and could be set lower if needed, in application of Article 18.1.b. In contrast, the Proposal merely requires that an Maximum Residue Level (MRL) 'can' be set, which offers a lower level of protection and requires a resource-consuming risk assessment[17]. **By no means does the Commission have the power to adopt such amendments via an implementing act. The fact that a few States pushed the Commission to do so does not change the fact that this action is illegal.**

2 An illegal grab of a power reserved to the EU legislature

2.1 An amendment altering essential elements of the Pesticides Regulations

Article 78(1) (a) of the Pesticides Regulation 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 give it power to adopt a modification of the ban, as the amendment is physically placed in the annex. This is however not the case, as the Proposal alters essential elements of the Pesticides Regulation, knowing that the essential elements of a legislative act are always reserved to the EU co-legislators under EU law. **The change relates to the annexes formally, but this is not enough to give to the Commission the right to encroach upon the power reserved to the EU co-legislators**.

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. 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 that, by their nature, touch upon the essential elements of a basic act, including: decisions that 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"[18]; or when the contested decision deals and **tempers with the very core** of the basic instrument.[19]

The core of the Pesticides Regulation has to be identified in relation 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

[15] Pesticides Regulation Article 4.2.a.
[16] Pesticides Regulation Article 4;2.b.
[17] Art. 10(1) and Art. 14(2) Regulation 396/2005.
[18] 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.
[19] Ibid. para. 71-75 and 79.

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 - use with negligible exposure or use when it is the only solution to tackling a serious risk to plant health. The ban and the choice of the conditions justifying a derogation are the core of the Pesticides Regulation and its most politically sensitive parts – **they are therefore essential elements amendable only by the EU legislature**. This is confirmed by the legislative history of the Pesticides Regulation. Indeed, it shows that when the EU legislature had to weigh up the conflicting interests at stake in the ban of EDCs in pesticides and its associated derogations, it purposefully chose 'negligible exposure' as offering the only politically acceptable level of protection[20].

In addition, the Court already confirmed[21] – in the context of the Biocide Regulation[22], similar to the Pesticide Regulation[23] - that the scope of the EDC ban was an essential element. The Court 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/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**.

Without any doubt, Article 78(1) of the Pesticides Regulation therefore does not give to the Commission the power to adopt an implementing Regulation changing the conditions of the derogations to the ban of the use of EDCs in pesticides.

2.2 The current scientific and technical knowledge does not justify lowering the protection against EDCs in pesticides

The Commission claims that the evolution of scientific and technical knowledge since the adoption of the Pesticides Regulation justifies the amendment it proposes[24]. This argument does not hold. First, even if there were such new knowledge, only the EU legislature would have the power to adopt the amendment proposed, as explained above. Second, the 'evidence' presented by the Commission does not support its claim.

What the Commission sees as 'new evidence' are an opinion of EFSA[25] and a Memorandum from the Scientific Committee on Consumer Safety (SCCS)[26] that both affirm that EDCs may be subject to risk assessment. However, if EFSA's opinion does make this affirmation, it also specifies that, "[w]hether hazard characterisation criteria alone, or risk assessment should be used for defining the level of concern for identified EDs for further regulatory measures is **beyond the scope** of this opinion and is a risk management decision"[27]. As for the SCCS memorandum, it merely expressed the SCCS position on the criteria that should be used to identify EDCs, the difficulty to identify substances with endocrine activity and endorsed EFSA's opinion. Neither of these

[20] See Parliament's position at first reading: legislative resolution of 23.10.2007 (P6_TA(2007)0445); the Council's common position: ST 11119/9/08 rev.8 of 15.9.2008 approved by the EP at second reading: legislative resolution of 13.01.2009 (P6_TA(2009)0011).
[21] Judgment of the General Court of 16 December 2015, *Kingdom of Sweden v European Commission*, Case T-521/14, ECLI:EU:T:2015:976.
[22] 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.
[23] 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.
[24] See Recital 5 of the Proposal.
[25] EFSA Scientific Committee, Scientific Opinion on the hazard assessment of endocrine disruptors, EFSA Journal 2013;11(3):3132.
[26] Scientific Committee on Consumer Safety (SCCS) Memorandum on Endocrine Disruptors. Retrieved from: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_009.pdf.
[27] EFSA Scientific Committee (fn. 17), p. 43.

documents brings new scientific knowledge that would justify a change of the EDC ban in pesticides. Indeed, carcinogenic, mutagenic and reprotoxic (CMRs) substances are submitted to the same regime under the Pesticides Regulation and it is well known that they may also be submitted to a risk assessment.

Since the adoption of the Pesticides Regulation, scientific knowledge has evolved but not in a direction that would justify weakening the prohibition of endocrine disruptors. It confirms, in fact, the wise decision of the co-legislators in 2009 to prevent exposure to endocrine disruptors, and would justify even more stringent rules to prevent exposure.[28] **They do not justify to make the used of endocrine disruptors in pesticides easier**.

In addition, as so clearly affirmed by EFSA itself, the fact that EDCs may be subject to a risk assessment does not change the fact that the EU legislature has the power to decide that the potential for adverse effects of EDCs politically justifies, as do CMRs, a regulatory constraint in the context of the Pesticides Regulation. As expressed by the Commission in its Communication on the Precautionary Principle the "appropriate response in a given situation [of concern] is thus the result of a political decision, a function of the risk level that is 'acceptable' to the society on which the risk is imposed"[29]. The acceptability of a risk is for the European Parliament and the Council to decide; not the European Commission and Member States' "experts" behind the closed doors of the Scopaff committee.

3 Call on the Member States and the European Parliament to block the Proposal

The Member States and the Members of the Parliament need to block the Commission's proposal for two reasons. First, the Commission **manifestly exceeds the limits of its power** and encroaches upon a matter reserved to the EU legislature. Second, because of their adverse effects, EDCs **need to be treated as a specific regulatory category**, and be submitted under the Pesticides Regulation to the same conditions as carcinogens, mutagens and reprotoxic substances, which are of equivalent level of concern.

No Member State should have pushed the Commission to re-propose an amendment so clearly illegal – it is both a waste of public money and an affront to the rule of law. The other Member States, that we hope reach a majority, are now in a privileged position to oppose this attempt to illegally modify the Pesticides Regulation. They can do it first through their representatives at ScoPAFF, considering that the Commission needs the Member State representatives in this committee to approve its Proposal with a qualified majority to be allowed to adopt the final act[30]. In addition, even if the Proposal were to reach a qualified majority in ScoPAFF, the Member States would have another opportunity to oppose the Proposal as the Council would have three months to veto the final act under the pre-Lisbon comitology procedure applicable here, with a qualified majority vote. The Council has the right to veto the Proposal if, as it the case here, it exceeds the

[28] See for example: EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals, Endocrine Reviews, Volume 36, Issue 6, 1 December 2015, Pages E1–E150, available at: https://academic.oup.com/edrv/article-lookup/doi/10.1210/er.2015-1010.
[29] COM(2000) 1 fin, 2.2.2000, p. 16, 13.
[30] Article 5a – if the Committee does not reach a qualified majority in favour or against, the Commission shall submit the proposal to the Council. See Council Decision of 28 June 1999 *laying down the procedures for the exercise of implementing powers conferred on the Commission* (1999/468/EC), (OJ L 184, 17.7.1999, p.23).

implementing powers provided for in the basic instrument or is not compatible with its aim or content.[31]

- **We call on the Member States to vote against the proposal at ScoPAFF, and to veto the proposal during the scrutiny stage if it were to pass in ScoPAFF.**

If the Regulation were nevertheless approved by ScoPAFF, the European Parliament would have the same right as the Council to veto the proposal by a majority vote[32].

- **We call on the MEPs to veto the proposal if it were to pass in ScoPAFF.**

The Commission's repeated attempts to weaken the level of health and environmental protection set by the co-legislators and that only the EU legislature has the right to set show a trend of worrying disdain towards the limits of its power and the rule of law. This requires a strong reaction, able to prevent this Commission from acting illegally and to dissuade the next Commission to repeat such maladministration.

[31] Article 5a3.(b) Council Decision 1999/468/EC.
[32] Article 5a.3.(b) Council Decision 1999/468/EC.

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