To: Mr Giovanni La Via, MEP
Chair of the Committee on the Environment,
Public Health and Food Safety
European Parliament
Rue Wiertz, 60
B-1047 Brussels

Rue du Trône 60
5ème étage
1050 Bruxelles
Belgique

+32 (0)2 808 34 65
info@clientearth.org
www.clientearth.org

4 November 2016

Subject: Draft Commission Regulation amending the approval rules for endocrine disruptors set out in Annex II to Regulation (EC) No 1107/2009

Dear Chairman,

On behalf of ClientEarth, we would like to make observations on the letter you received from the Commissioner for Health and Food Safety, Mr Andriukaitis, dated 18 October 2016 (Ares(2016)6019098) relating to the Commission's proposal to amend Regulation No 1107/2009 ("Pesticides Regulation") regarding endocrine disruptors. This letter, in our view, contains several inaccuracies and misrepresentations.

ClientEarth is a non-profit environmental law organisation committed to securing a healthy planet. As explained in the legal opinion that we commissioned and published in July this year, the Commission's draft proposal regarding endocrine disruptors in pesticides raises many legal issues. One of these issues relates to the proposed amendment to the derogation mechanism set out in the Pesticides Regulation and is the subject matter of Mr Andriukatis's letter.

According to this letter, DG Health considers that the Commission can lawfully modify the rules set out in the Pesticides Regulation that define under which circumstances endocrine disruptors are allowed in pesticides. This position is based on an erroneous interpretation of the Commission's delegated powers under Article 290 of the Treaty on the functioning of the EU ("TFEU") which only grants the Commission the power to amend "non-essential element" of a legislative act.

First, DG Health seems to consider that the derogation mechanism is not an essential element of the Pesticides Regulation for purely formalistic reasons: because it is set out in an "annex" of the legislative act. Neither the text of Article 290 TFEU nor the case-law of the CJEU supports this interpretation.

Second, affirming that "*neither the recital nor the basic act suggest that it was the intention of the legislator to maintain the derogation [...] unchanged*" reveals a misconception of the rules governing the balance of powers between the EU institutions. The co-legislators do not have to state explicitly which provisions of a legislative act they do not want the Commission to amend in the future. Quite the opposite, the co-legislators have to state explicitly, when delegating powers to the Commission, "[t]*he objectives, content, scope and duration of the delegation of power [...] in the legislative acts*".[1]

[1] Article 290(1) TFEU

The presumption that the Commission could legally amend any provision of a legislative act, unless provided otherwise, is thus in clear contradiction with Article 290 TFEU.

Third, DG Health affirms that if the Commission was not entitled to amend the derogation mechanism it would mean that it "*would be able to amend only the procedural elements in Annex II*". This statement is incorrect: the legal mandate granted to the Commission in the Pesticides Regulation clearly covers substantive elements, i.e. the "*criteria for the determination of endocrine disrupting properties".*[2]

Fourth, DG Health seems to confuse "*criteria for approval*"[3] of endocrine disruptors with "*criteria for the determination of endocrine disrupting properties*"[4]. These two sets of criteria serve different purposes: the "*criteria for the determination of endocrine disrupting properties*" are meant to define which chemicals are to be identified as endocrine disruptors, while the "*criteria for approval"* are meant to decide under which conditions endocrine disruptors should be allowed. Only the criteria for *identification* are within the scope of the Commission's mandate. The approval mechanism is no less than the "*subject matter*"[5] of the Pesticides Regulation. As such it is undoubtedly an essential element of this legislative act which the Commission cannot lawfully alter.[6]

Fifth, DG Health alleges that its proposal is lawful because it is meant to adapt the Pesticides Regulation to *"scientific progress*". However, simply reporting that it is possible to carry out a risk assessment for endocrine disruptors is not the result of any scientific progress. It has never been disputed that risk assessments, which are routinely carried out for carcinogens, mutagens and reprotoxicants, could also be carried for endocrine disruptors. In addition, the fact that the Commission has the power to amend some elements of the Pesticides Regulation in order to take scientific progress into account does not mean that it has the power to amend *any* element of this legislation. The Pesticides Regulation indeed specifies that it can only modify "non-essential" elements on that ground.[7]

Sixth, contrary to what DG Health seems to have understood, it is not because the derogation is of "hazard-based nature" that it qualifies as an essential element. What matters to determining if an element is "essential" is whether "*in order to be adopted, [it] require[d] political choices falling within the responsibilities of the European Union legislature*."[8] Deciding in which cases endocrine disruptors should be allowed in pesticides is clearly a political decision. According to the case-law cited above, only the co-legislators are therefore entitled to change this essential element.

Finally, DG Health alleges that the change in the derogation mechanism will improve protection of health and the environment. This is an empty statement based on a "belief" that is not supported by any explanation. As a matter of fact, allowing endocrine disruptors to be used depending on the result of a risk analysis (as proposed by the Commission) is less protective than automatically limiting

[2] point 3.6.5 of Annex II of the Pesticides Regulation
[3] See para. 1 of point 3.6.5 of Annex II of the Pesticides Regulation
[4] See para. 2 of point 3.6.5 of Annex II of the Pesticides Regulation
[5] Article 1(2) of the Pesticides Regulation indeed define its subject matter: "*This Regulation lays down both rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, and rules for adjuvants and co-formulants*".
[6] " *the adoption of rules essential to the subject-matter envisaged is reserved to the legislature of the European Union*" (Case C-355/10 para. 64)
[7] Article 78(1)(a) of the Pesticides Regulation allowing amendments "taking into account scientific and technical knowledge", limits these amendments to "non-essential elements of this Regulation".
[8] Case C-355/10 para. 65

exposure to negligible levels. More precisely, evaluating a "risk" consists in calculating the probabilities that human health and/or the environment will be harmed in various scenarios, based notably on different routes of exposure.[9] By contrast, limiting exposure to negligible levels (e.g. restricting their use to closed systems)[10] does not leave room for arguing that even if exposure was higher, the "risk" would be "negligible" due to other factors. This approach is therefore more protective of our health and the environment than the one proposed by the Commission.

Moreover, if the Commission really believes that a derogation based on a risk analysis is more protective, it seems surprising that it did not propose the same amendment to the approval mechanism of carcinogens and substances that are toxic for reproduction.[11]

In any event, DG Health's "belief" in that regard is irrelevant to the justification of its proposal: if the Commission was convinced that the current rules of approval of substances in pesticides - subject matter of the Pesticides Regulation - were not sufficiently protective of human health or the environment, it should have initiated the ordinary legislative procedure and proposed to the European Parliament and the Council to amend the Pesticides Regulation under Article 294 TFEU.

Our legal opinion therefore remains that the Commission would exceed its delegated powers if it was to amend the approval mechanism for endocrine disruptors in pesticides. We hope that you and the ENVI committee members will find these observations useful when assessing the Commission proposal.

Yours sincerely,

Vito A. Buonsante
Law & Policy Advisor, Chemicals & Biodiversity
+32 (0) 2 808 3472
vbuonsante@clientearth.org

Alice Bernard
Lawyer/Juriste, Chemicals
+32 (0) 28 08 8015
abernard@clientearth.org

[9] As explained already in 2000 by the Commission in its Communication on the precautionary principle (COM/2000/0001 final)
[10] "*closed systems or in other conditions excluding contact with humans and where residues of the active substance [...] on food and feed do not exceed*" a certain value (Pesticides Regulation - Annex II point 3.6.5.
[11] See point 3.6.3 and 3.6.4 of Annex II of the Pesticides Regulation