Strasbourg, 17 December 2015

EUROPEAN PARLIAMENT

President Jean-Claude Juncker
European Commission
Rue de la Loi 200
B - 1049 Brussels

Dear President,

We are writing to you following yesterday's judgement by the General Court in case T-521/14 Sweden vs. Commission declaring that the European Commission has breached EU law by failing to adopt measures concerning the specification of scientific criteria for the determination of endocrine-disrupting properties according to Regulation No 528/2012 concerning the making available on the market and use of biocidal products.

We are shocked by the first reaction of the Commission's spokesperson at the Midday briefing yesterday: while taking note of the judgement, the Commission intends to continue its work on the impact assessment, which is the root cause for its unlawful failure to act, as planned - as if nothing had happened. Moreover, the spokesperson continued to raise arguments for the impact assessment, even though the General Court explicitly found that "*there is no provision of the regulation which requires such an impact analysis. What is more, even if the Commission ought to have carried out such an impact analysis, that does not in any way exonerate it, in the absence of provisions to that effect, from complying with the deadline set for the adoption of those delegated acts*". Given the Commission's role as guardian of the Treaties, its disregard - and indeed disrespect - for the judgement of the General Court is unacceptable.

WHO and UNEP consider the capacity of endocrine disrupting chemicals to interfere with tissue and organ development and function, and therefore the possibility to alter susceptibility to different types of diseases throughout life "*a global threat that needs to be resolved*"[1].

The threats of endocrine disruptors to human health and the environment are not new. In fact, we have legislation in various areas to protect human and animal health from endocrine disruptors (e.g. REACH, pesticides, biocides, cosmetics, water legislation).

However, leaving aside REACH and water legislation, the provisions of these laws have been undermined by the absence of clear scientific criteria for the determination of endocrine disrupting properties. For this reason, the legislator obliged the

[1] State of the Science of Endocrine Disrupting Chemicals, WHO and UNEP, 2012

Commission to develop such criteria by December 2013. This legal obligation was first laid down in 2009 in Regulation (EC) No 1107/2009 on plant protection products, and repeated in 2012 in Regulation (EU) No 528/2012 on biocidal products.

Back in 2009, the Commission duly accepted this obligation, and soon started work on this. An ad hoc group of Commission services, EU agencies and Member States was set up in 2010. On 19 February 2013, a text with possible elements for criteria for identification of endocrine disruptors was presented at the 6th meeting of the ad hoc group.

This sparked a letter of protest by certain scientists as well as aggressive lobbying by the pesticides and chemicals industry, calling for an impact assessment of the scientific criteria that were to be developed. In response to this, on 2 July 2013, Secretary-General Catherine Day instructed the Director-Generals of DG Environment and DG SANCO to do an impact assessment for the development of these criteria. As a result, the draft Commission recommendation defining criteria for endocrine disruptors, a recommendation that was ready in June 2013, was not submitted to inter-service consultation, and the whole process stalled.

In December 2015, two years after the four-year legal deadline, the impact assessment is still ongoing. In fact, the actual impact assessment (the second study) has not even started yet. According to the Commission, the impact assessment will only be finished end of 2016.

It is the very decision to launch an impact assessment that led to the unlawful failure of the Commission to act as declared by the General Court.

On 16 October 2013, 8 MEPs from four political groups wrote to President Barroso stating fundamental concerns with regard to the decision to launch an impact assessment, as the development of scientific criteria should be based on objective scientific studies with regard to endocrine disruptors, and not on an impact assessment (which assesses the socio-economic costs and benefits of a policy decision). On 20 January 2015, 11 MEPs from six political groups repeated these concerns in a letter to Commissioner Andriukaitis, stressing that economic considerations such as the socio-economic impact on the industry and the substitutability of substance are "totally irrelevant" when it comes to the scientific question of what is an endocrine disruptor.

Moreover, the decision of the Commission to conduct an (inappropriate) impact assessment not only resulted in the Commission's unlawful failure to act in accordance with the mandates laid down in pesticides and biocides legislation, but also unduly questioned the letter of these laws adopted merely one year/four years earlier. The Commission is free to do whatever assessments it wants to do, but such impact assessments may never justify disregarding the legally binding mandate given by the co-legislators, as confirmed by the court.

Most importantly, the decision in July 2013 for an impact assessment meant that the Commission has stalled effective protection of human health and the environment against the global threat of endocrine disrupters. We have already lost two years due to the Commission's unlawful failure to act. Unless you correct the Commission's

course, we may well lose another two years. We cannot accept this, all the more that the necessary preparatory work was already finalised in summer 2013.

Finally, as far as the correct scientific criteria for the identification of endocrine disruptors are concerned, we would like to reiterate that we are strictly opposed to using potency as a single criterion to limit the definition of endocrine disruptors. In its resolution on the protection of public health from endocrine disruptors of 14 March 2013, supported by a strong cross-party alliance, the Parliament clearly requested that that no single criterion should be seen as cut-off or decisive for the identification of an endocrine disrupter. Moreover, both JRC[2] and EFSA[3] did not consider potency as part of hazard identification, but rather as an element of hazard characterization. Hazard characterization is clearly different from hazard identification. Linking the identification of endocrine disruptors to potency is thus scientifically not tenable and would greatly jeopardize the necessary protection of human health and the environment.

To conclude, in light of the judgement of the General Court, we call on you to halt the impact assessment and to adopt as soon as possible scientific criteria in accordance with the Commission draft recommendation of June 2013 (following the WHO/IPCS definition with categories).

Yours sincerely,

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Michèle Rivasi MEP (Greens/EFA)
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(electronic signatures)

Cc: Commissioner Vytenis Andriukaitis
Director-General Xavier Prats Monné,
Secretary-General Alexander Italianer

[2] Report of the Endocrine Disrupters Expert Advisory Group, JRC, 2013
[3] Scientific opinion, EFSA, 28 February 2013