How will the EU identify EDCs and ban or approve their use?

The Commission cannot change the scope and basis of the mechanism through the back door.

Endocrine disrupting chemicals (EDCs) can impair brain development, cause birth defects, and lower fertility. With the aim of identifying and ending the use of EDCs, the European Parliament and European Council put measures in two regulations, The Biocides and Pesticides Products Regulations aim at ending the use of these chemicals mandating the Commission to approve scientific criteria for their identification. When certain conditions are met, derogations allow the use of these substances.

On the 15th of June, the Commission proposed these criteria in delegated and implementing legislation 30 months after its legal deadline to do so and after performing an impact assessment that the Court of Justice of the EU found to be not necessary.

ClientEarth commissioned a legal opinion to experts from the University of Applied Sciences in Darmstadt (Germany) to analyze the requirements for the scientific criteria and to apply these to the Commission's proposals. Additionally, the legal opinion assesses the 4 options for the criteria which the Commission put through an impact assessment.

The analysis finds that the proposed criteria are illegal because they limit the identification of endocrine disruptors to those that are known to cause adverse effects, excluding those presumed to cause adverse effects. Also, it found that, by proposing a change in the approval mechanism for endocrine disrupting chemicals, the Commission has exceeded its delegated powers. The proposed criteria alter the balance between environmental and health protection, and functioning of the internal market, that was democratically established by the co-legislators.

By departing from the scope of the approval mechanism, the Commission is seeking to modify essential elements of the regulations. Such crucial changes require a re-negotiation of the legal text between the decision making institutions (European Parliament and Council). Moreover, the proposed criteria and altered derogation are incompatible with the objectives of the regulations: to ensure a high level of protection for citizens and the environment and to respect the precautionary principle.

Therefore the draft proposals of 15 June 2016 should not be implemented because they are not compliant with the existing laws. If the Commission proceeds to implement its proposals, the European Court of Justice can nullify the criteria on the grounds of lack of competence.

Both regulations provide that no endocrine disrupting chemical that is known or presumed to cause adverse effects in humans or to the environment can be approved. In the case of harm to humans, this determination is usually based largely on animal data. An identical mechanism exists for determining and banning substances that are known or presumed to be carcinogenic, mutagenic, or toxic for reproduction (CMR substances). To be legally compliant, the criteria for identifying EDCs must assume a level of concern for EDCs causing an adverse effect that is

equivalent to that for CMR substances. Due to the difficulties in proving the causal relationship between chemicals and their effect on humans, most of classified CMR chemicals are only presumed to cause these effects.

Yet, the Commission's proposed criteria for endocrine disruptors state that only substances *known to have* adverse effects will not be approved and not those only presumed to cause an adverse effect. This significantly limits the scope of the regulations' approval mechanisms and affects essential elements of the laws.

In addition, the Commission proposed to change the approval procedure for Endocrine Disruptors in the pesticides regulation. The pesticides regulation allows the use of endocrine disruptors as well as CMRs when exposure is negligible. In other words, if used in a closed system or in such a way that contact with humans is excluded.

However, the Commission's proposal changes the risk management approach of the derogation, such that it would allow continued use of EDCs unless a full risk assessment would prove that there is a risk that is not negligible. This alters an essential element of the pesticides regulation, substituting one approval mechanism with another. The legislative history of the PPPR shows that the Parliament and Council clearly and deliberately rejected the principle of derogation based on specific risk assessment, and only accepted derogation based on "negligible exposure". The proposed change to the derogation therefore contradicts the basic aims of the regulation.

The Commission's draft measures of 15 June 2016 include an Impact Assessment of four Policy Options with respect to addressing the proposed criteria. Of these four Policy Options, the Commission would only avoid exceeding its mandated powers by following Option 3. Unfortunately, the proposals follow a variant of Option 2 and therefore are not acceptable.

- Policy Option 1 assumes that the interim EDC criteria are not changed and the legal obligation of the Commission to issue scientific criteria that are protective for human health and the environment.

- Policy Option 2 envisions that ED properties will be defined largely in accordance with WHO/ IPCS definitions. However, the criteria make no provision for identifying "presumed" ED as opposed to "known" EDCs, and so do not ensure identification of "presumed" EDCs. Therefore, Option 2 departs from the objectives of the regulations.

- Option 3 also envisions determining ED properties based on the WHO/ IPCS definition, but it introduces additional categories referring to the extent to which endocrine disruption mediated adverse effects of a substance can be substantiated by scientific evidence. Option 3 does ensure identification of substances *presumed to have* endocrine properties that cause adverse effects. Therefore, Option 3 does not exceed the Commission's mandates.

- Option 4 applies the WHO/ IPCS definition of ED effects but adds potency as a criterion for determining endocrine disruption. Most likely, a potency cut-off criterion would

significantly narrow the scope of the scientific criteria. In particular, the Option 4 criteria would likely not apply to "presumed" EDCs. Hence, Option 4 contradicts the objectives of the regulations. Note that the proposed criteria must be scientific. It is also questionable whether Option 4 criteria are based on scientific considerations exclusively.

It follows that the Commission has to respect the powers delegated by the basic legislation and withdraw its proposals to identify endocrine disrupting chemicals.

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