WECF complementary elements to point 4.1 of European Commission Consultation on endocrine disruptors – January 2015

Complementary remarks to Aspect II: Approaches to regulatory decision-making

Since no room was provided to express concerns on these approaches if not related to "socio-economic" impacts understood in a very narrow scope, WECF would like to underline the following:

The terminology used in the Commission roadmap is problematic It has to be remained that Endocrine disrupters is first of all a health and environment issue. The very reason why the EU should today regulate EDCs is because of their adverse effects on human health and the environment. As such, WECF considers that a terminology like "management measures", "risk-benefit analysis", "desired", "stigmatised" is not appropriate when considering EDCs.

On Option A : Option A seems inadequate, since a new category of toxic compounds/substances, once existing, must necessarily imply regulatory changes, not only in 2 sectorial legislations, but far beyond.

On Option B : Option B and C both have in common to adopt the prerequisite conception that if any harmonization may occur between PPPR and BPR, it is necessarily in the sense of an amendment of the PPPR to reflect certain provisions of the BPR. Why not open the door for an "Option D" which would allow an amendment of the BPR to reflect the more health and environment protective regime of the PPPR? Is that not "desired"?

Options B and C state that current PPPR has "adverse socio-economic impacts" – not defined in the Commission paper- which are not desirable - again whose stakeholders' "desire" does it reflect ? - whereas no analysis or impact assessment has been made which would allow for such conclusions. How could it be possible to conclude even before an impact assessment has been made?

Option B seeks to undermine the use of the "hazard-based approach" by inserting "risk-based approach", first of all in the Plant Protection Products regulation, but not only. This option, even before having performed any impact assessment, already concludes on two elements which have not been investigated. First option B seems to conclude on the inadequacy of the "hazard-based approach" as well as justification/legitimation of "negligible risk" – this notion is even not defined yet under the BPR–whereas the new biocidal products regulation is just being implemented and one cannot prevail over its consequences. The mention of "management measures" is a surprisingly new terminology, since the BPR deals exactly with "exclusion criteria" in its article 5, not "management measures" in the sense that the measures of market exclusion are based on hazard classifications and dedicated to prevent impacts on human health and the environment.

On Option C: Similar remarks can be done on option C. WECF is especially surprised by the following sentence: "…to allow the placing on the market of products in situations where an Endocrine Disruptor is essential to prevent adverse socio-economic impacts.". Shall we understand that the Commission consider that an ED - a

substance that is classified as ED under any of the categories chosen in a near future has or is suspected to have adverse health effects – may be placed on the market for the benefit of a number of economic operators? WECF recommends the Commission to carefully reconsider these regulatory options, to better reflect concerns on EU citizens's health and impacts on the environment related to EDCs. As well, is key principles may be mentioned, proportionality principle is indeed important, but we recommend that the precautionary principle, which is equally important in a context of environmental health.

Remarks on Part D – initial assessment of impacts

WECF wishes to point out that no element at all in the paragraphs "preliminary impact for the different options – Aspect I EU criteria to identify ED and aspect II – Approaches to regulatory decision making" reflects considerations of impacts – positive or negative – for exposure of populations, animals and the environment to EDCs. It seems this part D narrowly focuses on "impacts on different economic sectors", searching to quantify how many substances/products would stay or have to be phased out from the market. We do strongly hope the impact assessment will allow to investigate impacts far beyond these too narrow considerations.