PAN Europe comments on the amended Commission criteria for endocrine disruption, November 8, 2016.

Our conclusion is that the amendments made by Commission on the original proposal of June 2016, are largely cosmetic. The amended proposal keeps on being based on a "risk" approach, as opposed to the "hazard" approach in the Regulation 1107/2009. As we feared already.

The biggest change made in the amended proposal is substituting "known to cause an adverse effect relevant to humans" back to "may cause adverse effects", back to the original text from the Regulation. This makes life a bit more easy for EU member states because in the final decision on a given endocrine disrupting chemical they do not need to prove that it is a "known" endocrine. Despite this change, the level of proof remains extreme high, higher than for any other dangerous chemical in Europe. Not only the demonstration of an adverse effect is needed, the regulators ALSO have to demonstrate the mode of action AND the link between those two. This is almost impossible to prove given the fact that the type of information is generally not available, especially not on mode of action. Even for accepted carcinogens, mutagens and reprotoxic chemicals, this three-double type of information is not needed. It will be much more difficult to ban an endocrine disruptor than a carcinogen.

For the rest there is not much change in the amended text. The main tests the assessments will be based upon are the decades-old reprotoxic animal testing studies which are not designed for endocrine disruption and will capture little adverse effects. Academic science plays a minor role.

A proposal by a majority of the member states to include "presumed" endocrine disruptors also didn't make it in the amended text. No mentioning is made of this category of endocrine disruptors and this makes that potential effects will in future be dismissed.

The most crucial element of the proposed criteria, going from hazard to risk, is kept in place. If risk assessment (in stead of hazard assessment) is applied as Commission keeps on proposing in the amended proposal, there will in almost every case -certainly with the decades-old reprotox studies- be a "safe dose" and approval. This use of risk assessment is violating Regulation 1107/2009 as the legal services of the EU parliament already pointed out and keeps on putting the axe at the roots of the endocrine criteria.