

PRESS RELEASE

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European Guidance Document on endocrine disruptors doomed to fail

Brussels, December 8th, 2017

Alarming concerns rises the assessment procedure given in the draft Guidance Document for the identification of pesticides and biocides that are endocrine disruptors (EDs) published yesterday by European Authorities. The document appears to have 'come from the future' as it presumes a very high level of understanding of the function of the endocrine system and of how substances cause endocrine disruption, which we currently don't have.

For PAN Europe the document will fail to identify any substance as ED in the near future, leaving Europeans and the environment unprotected from the harm caused by these chemicals. These substances are spayed on open fields and are detected in European food, and must be banned from pesticide and biocide use according to European Law.

The <u>draft guidance document (GD)</u>, which was published yesterday, December 7th, almost a year after European Food Safety Authority (EFSA) and European Chemical Agency (ECHA) received <u>the mandate by the European Commission</u>, is now open to public consultation. Despite the involvement of experts from both European Authorities, Member States and stakeholders, the GD ensures one thing: to make it impossible identifying any substance as an ED in the near future, even when there is evidence that it causes harm.

The GD, by default, is greatly limited as it only focuses on the adverse effects that are mediated through interaction with specific hormones: namely, oestrogen, androgen, thyroid and steroidogenic (EATS). As a result, chemicals will not be assessed for endocrine-related diseases of different modalities such as obesity, diabetes, cognition and behavioural dysfunction.

However, even when a substance is identified to cause EATS-mediated adverse effects in a mammalian experiment (e.g. male/female organ deformities and dysfunction) this is not considered a 'hazard' by default. Adverse effects can be overruled if there is no evidence on the key mechanism of action, even when this is yet to be identified, understood or established. Thus, the industry applicant -who has a commercial interest - will have many opportunities to use the criteria for its benefit and get its substance approved: to dismiss positive adverse effects in laboratory experiments as non-endocrine mediated or non-adverse, or as non-human relevant or not relevant for wildlife populations.

"The GD is giving too much focus in revealing the Mode of Action of a chemical" says Angeliki Lysimachou Environmental Toxicologist and Coordinator of the Endocrine Disrupting Pesticides Campaign in PAN Europe. "These studies belong to the endocrine disruption research, and not to regulatory hazard assessment of chemicals that aims to protect people and the environment from the adverse effects of chemicals and should therefore have straightforward protocols. Humans should not be treated as Guinee pigs" she adds.

Hans Muilerman, chemical officer of PAN Europe stresses "The GD completely overlooks the fact that European law is based on the precautionary principle; we don't need to understand the complete mode of action through which a chemical causes an adverse effect, in order to limit human and environmental exposure. We urge stakeholders and academics to take part in the public consultation and express their scientific concerns on this issue. This document must not go through." he concludes.

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