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EU regulation of endocrine disruptors: a missed opportunity

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The European Commission (EC) has missed a unique opportunity to develop a regulatory system that sets new standards in the protection against endocrine-disrupting chemicals. The proposed amendments to the European Union (EU) pesticide law and the criteria for the identification of endocrine disruptors that the EC published on June 15, 2016, after a delay of almost 3 years,[1] ensure that hardly any endocrine disruptors used as pesticides will be barred from commerce.

EU legislation requires that all chemicals used as pesticides and biocides are approved through a risk-assessment procedure that estimates a safe level of exposure. However, by a hazard-based exclusion clause, substances identified as carcinogens, mutagens, reproductive toxicants, and endocrine disruptors do not enter this complex risk-assessment process. To minimise exposure to these hazardous substances via food, these substances [A: ok?] are generally refused approval, but specific derogations exist [A: please specify what you mean by derogations. Can we change to 'exemptions' for clarity?]. For pesticides, approval can still be granted if exposure is negligible. Since there is no exposure via food, this rule is somewhat relaxed for biocides, for which approval can be given if the risk is judged negligible.

In violation of the hazard-based exclusion philosophy of the pesticide law, the EC has now proposed an amendment that extends the relaxation for biocides to endocrine disruptors in pesticides. These substances will be treated less restrictively than carcinogens, mutagens, and reproductive toxicants, and exactly like other pesticide substances that have less hazardous properties. In practice, this means that exposures via food will continue to occur. This outcome is of concern because some pesticides can produce irreversible endocrine-disrupting effects. An example is the organophosphate chlorpyrifos, which can affect thyroid hormone concentrations [A: change from 'levles' ok?],[2] which in pregnant women can significantly affect children's IQ and brain structure.[3] Similarly, some widely used pesticides can antagonise the androgen receptor and suppress prostaglandin synthesis, with potentially irreversible consequences for male sexual development in fetal life.[4]

Previously, the EC had listed four options to define regulatory criteria for endocrine disruptors, of which two (labelled 2 and 3) rely on the WHO definition of endocrine disrupters. Earlier, we favoured option 3, which allows differentiation between known, presumed, and suspected endocrine disruptors.[5] The EC now supports option 2, with a single category for endocrine disrupters, but with a twist that will raise the degree of proof required for a chemical to be classified as an endocrine disrupter. The proposed option 2 differs from how carcinogens, mutagens, and reproductive toxicants are currently categorised in EU law. The strictest hazard category 1 differentiates between known (1a) and presumed (1b) carcinogens, mutagens, or reproductive toxicants. The evidence required for category 1a is normally based on human studies, whereas category 1b relies on data from animal studies, but categorisation as 1a or 1b triggers the same regulatory restrictions. The draft endocrine disrupter criteria depart from this distinction and replace the requirement for a presumption with the much stronger demand that a chemical must be known to cause an endocrine-disrupting adverse effect relevant for human health.

Should these proposals be adopted, many endocrine disrupters with human exposure will escape identification, thus eroding the high level of protection enshrined in the EU pesticide and biocide laws, and violating the demand for scientifically-based endocrine disrupter criteria.

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