

Revising the EU Strategy on endocrine disruptors: nearing a decisive moment

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For over 10 years, endocrine disrupting chemicals (EDCs) have been on the agenda of the European Union (EU), from the funding of research concerning impacts on human health and the environment, to discussions about which policy measures are needed to reduce public exposure.

In December 1999, when the EU Commission issued the Strategy on Endocrine Disruptors¹, researchers had already recorded impacts on wildlife in polluted areas throughout the world (e.g. reproductive and immune problems in Baltic seals). Links were being drawn to human diseases and disorders, such as testicular, breast and prostate cancers, decline in sperm counts, reproductive organ deformities, thyroid dysfunction, intelligence and neurological problems.¹

Twelve years on, the volume of scientific research is enormous and continues to grow. The health conditions associated with EDCs have multiplied, and several scientific consensus statements give recommendations to policy makers, with two emerging this year.²⁻⁶

However, despite some policy advances in regulating EDCs, serious delays still exist between the publication of new science, the recognition of these hazards

in law, and reductions in public exposure to EDCs. For some, this delay is because the traditional risk assessment/risk management approach, with its use of threshold concepts and omission of low doses, critical windows and transgenerational effects, does not yet provide compelling evidence of real harm, and hence effective policies cannot be designed. Those of us who advocate for swifter action view the science and believe rather that the traditional approach has significant blind spots to the characteristics of EDCs. Moreover, it is also about protecting public health before it is too little, too late, to avoid mistakes like those made with asbestos or lead.

Over the next two years, EU decision-makers face key issues, which will collectively determine our exposure to these harmful chemicals. They can choose to reinvigorate the EU EDCs Strategy and make EU laws effective tools for swiftly phasing out EDCs, or miss important opportunities to prevent further ill-health. Given the rise of chronic diseases such as cancer or diabetes in the EU, getting renewed political commitment to reduce and ultimately eliminate exposure to EDCs is urgent.

The Community Strategy on endocrine disruptors

The objectives of the EU Strategy were to identify the problem, causes, and consequences of endocrine disruption. Another objective was to identify policy action, based on the precautionary principle, for quick and effective responses, and thereby to alleviate public concern. The EU Commission foresaw gathering scientific evidence; ensuring resources to develop agreed test methods and an EU testing strategy; and envisaging proposals to change existing EU legislation.

Of the legislative action related to the Strategy, the recent notable ones with potential to reduce EDCs exposure are the chemicals law REACH (Registration, Evaluation and Authorisation of Chemicals), and the revised laws on Pesticides and Biocides (non-agricultural pesticides). EU policy makers' awareness of EDCs translated into a "cut-off" scheme for pesticides or biocides, where those with endocrine disrupting properties will no longer be authorized (with certain exemptions). But this phase out does not start until the criteria for identifying and assessing EDCs are adopted.

So currently the deadlines for criteria in the Biocides and

Pesticides laws, which the Commission must adopt by December 2013, are driving progress on EDCs policy. Commendably, the European Commission's Directorate General for Environment is now consulting stakeholders, Member States and their experts with the stated intention of proposing criteria which apply across all relevant EU laws. The EU experience of a uniform classification for carcinogens, with attendant categories arrayed by strength of evidence, shows that horizontally-applicable criteria is not only a viable goal, but also a necessity to prevent inconsistency between different laws.

An Ailing Strategy

Since 1999, the knowledge about endocrine disruption has expanded, in part due to the funding from the Strategy. Now the body of science on the impacts of EDCs also includes diabetes & obesity, pregnancy loss and shortened gestational age, and early puberty.⁷⁻⁹ The research continues to demonstrate the hallmarks of endocrine disruption: that due to foetal sensitivity, the timing of exposure is crucial; that effects at low doses are not predictable from linear models using higher doses; that together chemicals can have greater effects; that effects can manifest later in life, and can descend through generations. Concurrently, much more human biomonitoring evidence exists, showing that the vast majority of the public is chronically exposed, even from before birth.

Meanwhile, although the EU EDC Strategy has had some achievements, including funding

over €150 million in research, important lacunae remain, mostly because of the primary focus on research and establishing the chemicals laws (see above). We still need up-to-date test methods to identify EDCs integrated into EU laws, and an EU testing strategy that addresses the complexity of the endocrine system. The assessments still tend to discriminate against research studies done in academia by a preferential scoring system that privileges OECD Organisation for Economic Co-operation and Development (OECD) validated tests.¹⁰ We also need European-level human biomonitoring and better use of existing human biomonitoring data to instigate and improve regulatory control measures.¹¹

The European Commission reports regularly on the Strategy's implementation. But although the latest report details what has been achieved, it singularly fails to convey any urgency about the continuing public exposure to EDCs.¹² Since 1999, the effective reduction of people's exposures to EDCs has been far too slow given the gravity and irreversibility of the potential implications. Few measures taken against EDCs were explicitly due solely to their endocrine disrupting properties. Public concern remains high; and awareness of the problem from the cocktail of exposures is even greater. The EU urgently needs a revised Strategy that systematically overhauls EU laws to respond swiftly to early warnings, triggering action in the absence of scientific certainty across all arenas, from printing inks for food packaging to cosmetics and toys. We need

risk assessment and risk management of total EDC exposures and of cumulative impact, commensurate with the reality of our exposure.

Remedies

In February 2012, the European Commission released an important study from leading EDCs scientists.¹³ It examines the state of the science on EDCs, and the existing EU regulatory framework in terms of environmental and human health protection. It is necessary that the valuable analysis and recommendations from this report be integrated into a revised EU EDC Strategy, and equally inform the Commission's forthcoming proposal on the criteria to identify EDCs.

The discussion on the EDCs criteria has thrown up issues key to ensuring that the necessary controls to protect human health can be taken. Mentioned already above, is the need to give non-OECD test methods due weight in hazard assessment. Another is whether to have a 'prejudiced gate keeper' triaging EDCs, or to prevent a misleading potency threshold from wrongly excluding EDCs from further scrutiny and controls. The criteria should also not rigidly adhere only to current knowledge, but be open to changes in understanding and other types of evidence.¹⁴ We urge scientists to become involved in the criteria debate to ensure fair treatment of all peer-reviewed science and to call on your governments and the EU, particularly the European Commission's Directorate General for Health and Consumers, for criteria which will protect public health. EU law requires the criteria to be

adopted by December 2013, so we will get some kind of criteria by then. However, the quality of this outcome is still open for the shaping.

The Commission has been collecting input for a review of

the Strategy. Environmental, health, consumers and trade union organisations have published our requirements for sound policy on EDCs.¹⁵ It is important that specific deadlines and goals for the identification and regulation of EDCs are established, to fulfil the ultimate

purpose of an EU EDC Strategy – an effective and speedy response to the public health threat from our exposure to these chemicals. We need a Strategy that will orient and enable effective regulatory action.

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