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The WRC operates in terms of the Water Research Act (Act 34 of 1971) and its mandate is to support water research and development as well as the building of a sustainable water research capacity in South Africa.

TECHNICAL BRIEF

Water and health

EDCs Health Risk Assessment Framework

A framework for producing guidelines to deal with EDCs in South Africa has been developed through WRC-funded research.

EDCs – what is known and what is not known

Both natural and synthetic endocrine active chemicals are ubiquitous in the environment. Many of these chemicals have shown endocrine disrupting properties, with adverse effects in animals that range from developmental and reproductive abnormalities to structural deformities, cancer and immune system deficiencies.

Numerous wildlife species, including mammals, birds, fish, reptiles, and molluscs have already been affected. It is therefore anticipated that endocrine disrupting chemicals (EDCs) would also affect humans, even though a definite link between exposure to these chemicals and human health has not, as yet, been scientifically proven. Nevertheless, there is a need to take preventative measures, such as the establishment of safe water treatment technologies and treatment levels. Water authorities need to ensure that people are not exposed to unsafe drinking water.

In South Africa, endocrine activity, as well as the presence of EDCs, has been detected in river waters in different areas of the country. Control of these chemicals would have to be initiated once there is clear evidence of an adverse effect of sufficiently large magnitude.

Dealing with EDCs: some options

Several countries have drawn up lists of chemicals suspected of having endocrine disrupting properties that might elicit adverse health effects in humans and wildlife. In South Africa, the Department of Water Affairs has produced a list of 33 potential EDCs. It could be foreseen that once adverse effects of suspected endocrine disruptors have been demonstrated with a sufficient degree of certainty, a management policy would be established and implemented to provide a framework for the banning or reduction of the chemicals concerned. Besides the control of endocrine disruptors, an EDC management policy would also have to make provision for appropriate monitoring and analysis programmes.

A further desirable approach to dealing with the EDCs would be human health risk assessment leading to the development of guideline values for EDCs in drinking water, analogous to the approach used for many other hazardous water quality constituents. Generally speaking, quality guidelines for drinking water indicate safe levels for microbiological, physical and chemical properties of water, thus helping to ensure that the water people drink is safe and that even lifetime exposure to this water would not cause adverse health effects.

Guidelines also provide water treatment operators with treatment targets that would ensure the provision of safe drinking water. In general, and especially with regard to EDCs, these treatment targets should have to be reasonable in terms of acceptable risk, cost, the country's circumstances and target attainability, given the water treatment technology available.

Deriving guideline values to protect human health generally requires data from well conducted studies, preferably where clear dose-response relationships have been demonstrated, such as the many studies directed at establishing effects of toxic or carcinogenic chemicals.

It has not been possible to establish such relationships in the case of EDCs. Moreover, a review of literature confirms the need to clear up numerous other uncertainties that prevent current risk assessment approaches from being adapted for use in deriving guideline values for EDCs.

Weighing the options

Given that endocrine disruption is cause for serious concern, a different approach to managing endocrine disruptors is needed, at least for the interim. To provide the foundation on which to develop and recommend a framework for producing guidelines to deal with EDCs in South Africa, information from an international literature review has been distilled and reproduced, with

specific focus on the following:

- Available methods used internationally for setting guideline values for potentially harmful chemicals;
- Available methods for determining potential health risks associated with endrocrine disruptors in particular;
- How the current health risk assessment process has traditionally been used to develop guideline values for chemicals in water; and
- Uncertainties and drawbacks associated with the traditional use of the current health risk assessment approach in the case of endocrine functioning.

International approaches considered in seeking to develop South African guidelines for dealing with EDCs, generally fall into two categories:

- The **precautionary** or hazard-based approach entails the institution of preventative measures prior to assessing the potential risk or impact of the potential EDCs on human or environmental health, e.g. prohibiting the use of these chemicals even before negative impacts of their use have been experienced or proven. The precautionary principle thus seeks to trigger proactive action before any irreversible damage to human health occurs;
- The **health risk assessment approach**, by contrast, takes the view that in order to develop policy to protect humans and the environment from EDCs, it is necessary to first determine the risk to human and environmental health by proceeding through the following phases of conventional risk assessment:
  - **Hazard identification, which would establish whether exposure to** an EDC can cause harm and, if so, what the properties of the EDC are and what acute and chronic health effects are likely to be experienced;
  - Dose-response assessment, which would characterise the relationships between the EDC dose and incidence of adverse effect in the exposed population;
  - Exposure assessment, which would estimate the intensity, frequency and duration of human contact with the EDC in the environment; and
  - Risk characterisation, which would provide an indication of the incidence of the health effect, given the assessed exposure and established dose-response relationship.

Despite its desirability and potential appropriateness, this conventional risk assessment methodology is currently not suitable for EDCs, being fraught with numerous uncertainties that relate, among others, to the following issues:

- Limited epidemiological evidence;
- Inapplicability of conventional threshold and linear response model assumptions;
- Possibility of trans-generational impacts;
- Timing of exposure related to developmental stages;
- Inability to deal with synergistic and additive effects associated with multi-chemical exposure;
- Difficulty in ascertaining appropriate end-points when conducting dose-response assessments; and
- Uncertain applicability of ***in vitro*** testing.

A recommended protocol for South Africa

After taking all available information into consideration, the framework proposed as a starting point for developing EDC guidelines for South Africa is based on a first level screening for reproductive endocrine disrupting capability, rather than on measuring individual EDC concentrations. Positive detection of endocrine disruption should then be followed up with a more detailed assessment.

The initial screening should use a battery of ***in vitro*** and ***in vivo***, tests, results of which should be expressed quantitatively in terms of the relative potency of endocrine activity (i.e. oestrogen equivalency units) in a water sample containing a mixture of chemicals. A 'trigger value' (provisionally set at 0,5 µg/***l*** oestrogen equivalents) would define the activity above which a more detailed assessment is required.

Recommendations for future research

While acknowledging that the proposed framework has severe shortcomings, it provides a departure point for managing EDCs in South Africa's water. The framework needs to be tested, however, for its feasibility within the domestic water quality arena and would also need to be re-assessed periodically as new methods and more data become available.

It is recommended that the current investigation of a battery of tests be continued with a view to their inclusion in a screening protocol for endocrine activity, and that these tests incorporate a number of taxa. Endocrine effects other than reproduction, such as thyroid and immune-system effects, also need to be accommodated.

Finally, research needs to address the issue of adapting potentially suitable risk assessment methods in a way that overcomes uncertainties associated with complex endocrine-mediated effects, such as trans-generational effects of EDCs.

Further reading:
To obtain the report, ***Health Risk Assessment Protocol for Endocrine Disrupting Chemicals (EDCs)*** **(Report No: KV 206/08)**, contact Publications at Tel: (012) 330-0340; Fax: (012) 331-2565; E-mail: orders@wrc.org.za; or Visit: www.wrc.org.za