Introduction to the management of EDCs

Volume I

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by

Golder Associates Africa

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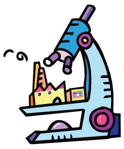
EDC GUIDELINE VOLUMES

The primary purpose of these guideline volumes is to facilitate appropriate water resource management in South Africa relating to EDCs. They present a consolidation of EDC research, current knowledge and best practices.

Volume I: Introduction

Volume II: Sampling Guide

Volume III: Bioassay Toolkit



Volume IV: Monitoring and Assessment

Volume V: EDC Management in Catchments

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Abbreviations

ADI	allowable daily intake
AOP	advanced oxidation processes
API	American Petroleum Institute
BPA	bisphenol A
BPB	bisphenol B
BPF	bisphenol F
CCP	critical control point
COD	chemical oxygen demand
CRF	critical risk factor
DDT	1,1,1-trichloro-2,2-bis(chlorodiphenyl)ethane
DES	diethylstilbestrol
DWA	Department of Water Affairs
CARA	Conservation of Agricultural Resources Act
DMP	dimethyl phthalate
ED	endocrine disrupting
EDC	endocrine-disrupting chemical (also known as endocrine-disrupting compound)
EDM	endocrine-disruptive metals
EMS	environmental management system
ERL	environmental risk level
eWQMS	electronic water-quality management system
GAC	granular activated carbon
GWRC	Global Water Research Coalition
GMP	good manufacturing practice
IRS	indoor residual spraying
ISO	International Standards Organization
IWQM model	integrated water-quality management model
MCC	Medicines Control Council
NAWQA	National Ambient Water Quality Assessment (USGS Program)
NDP	National Drug Policy
NEMA	National Environmental Management Act
NOC	N-nitroso compounds
NOEL	no-observed-effect-level
NWA	National Water Act

NWRS	National Water Resources Strategy
PAC	powdered activated carbon
PAH	polyaromatic hydrocarbons
PCB	polychlorinated biphenyls
POE	point of entry
POU	point of use
PPCP	pharmaceuticals and personal care products
REACH	Regulation, Evaluation, Authorisation and Restriction of Chemicals (European Union Regulation of 18 December 2006)
RO	reverse osmosis
RQO	resource quality objectives
RWQOs	resource water-quality objectives
SABS	South African Bureau of Standards
SNAEL	suggested no-adverse effect levels
SRT	sludge retention time
TCBPA	tetrachlorobisphenol A
TOC	total organic carbon
US EPA	United States Environmental Protection Agency
UV	ultraviolet
VTG	vitellogenin (a type of protein)
WCW	water-care works
WMA	water management area
WHO	World Health Organization
WRC	Water Research Commission
WSA	Water Services Act
WTW	water-treatment works
WWTW	wastewater treatment works

Glossary

Endocrine disrupting chemical (EDC)	An endocrine disrupting substance is a compound, either natural or synthetic, which, through environmental or inappropriate developmental exposures, alters the hormonal and homeostatic systems that enable the organism to communicate with and respond to its environment
Endocrine system	A control system of ductless endocrine glands that secrete chemical messengers called hormones which circulate within the body via the bloodstream to affect distant organs. It does not include exocrine glands such as salivary glands, sweat glands and glands within the gastrointestinal tract.
Duty of care	The responsibility of those who make, supply, import or use chemicals to provide sufficient information to evaluate risks to health and environment resulting from their manufacture and intended use.
Exposure	Contact between a substance and an individual or a population.
Hazard	An adverse impact on human or environmental health that can result from exposure to a substance.
Point-of-use (POU) treatment unit	This unit treats water at a particular tap. It is typically installed on kitchen taps.
Point-of-entry (POE) treatment unit	This unit treats all of the water entering a facility, such as a household or office building, before distribution to the taps.
Risk communication	Risk communication is the act of conveying or transmitting information between interested parties about: • Levels of health or environmental risks. • The significance or meaning of health or environmental risks. • Decisions, actions or policies aimed at managing or controlling health or environmental risks.
Risk	A measure of the hazard to health (or the environment) from exposure to a substance and the probability of its occurrence (the likelihood of a hazardous event occurring).
Perceived risk	An impression or intuitive judgement about the nature and magnitude of a health or environmental risk.

Overview

The past three decades have seen increasing numbers of scientific statements expressing concerns about adverse health effects resulting from exposure to chemicals due to their potential to change the functioning of the endocrine system. The awareness that environmental chemicals could have these effects on wildlife, and that human health is inextricably linked to environmental health, was highlighted by the publication of Rachel Carson's *Silent Spring* published in 1962. These concerns may have arisen primarily due to the observation of adverse effects in some wildlife species, fish and ecosystems, but the increased incidence of some endocrine-related human diseases has also been reported. Laboratory experiments have also demonstrated endocrine disruption following exposure to some environmental chemicals. These concerns prompted the Endocrine Society of the USA to produce a scientific statement in 2009, stating that:

> *To date, no chemical in use has been thoroughly tested for its endocrine disrupting effects, so the true threat of EDCs is unknown.*
>
> *Low doses are the most pertinent when exposure occurs to developing organisms. In some cases, these organisms normally have no exposure to some hormones — and exposure to tiny amounts of an endocrine disruptor changes the way these organisms will develop and potentially predispose them to develop a disease later in life.*

The Water Research Commission (WRC) has been investigating these concerns as they relate to water, water users and water uses for over a decade. The reader is referred to the list of WRC reports and other publications in the Literature Review Report (available on CD from the WRC) for further details. The information contained in these EDC Guideline Volumes is thus not intended to provide an exhaustive review or overly technical reference documentation, but rather aims to stimulate further EDC research in South Africa.

The definition of an EDC used throughout the five volumes is:

> *an endocrine-disrupting substance is a compound, either* ***natural or synthetic****, which, through environmental or inappropriate developmental exposures,* ***alters*** *the hormonal and homeostatic systems that enable the organism to communicate with and respond to its environment* (Endocrine Society).

Suspected EDCs can be found in pesticides, fertilisers, pharmaceuticals such as birth-control pills, personal-care products such as medicines, lotions, cosmetics and sun-blocks, and industrial substances including plasticisers, fabric softeners, fire retardants and cooling agents. EDCs find their way into the environment and water resources via runoff, atmospheric deposition and direct discharges. In this respect every person is in all probability exposed via ingestion, skin contact and breathing to a combination of potential EDCs through various media, on a daily basis.

In this volume, the section entitled ***Legislative framework*** sets out the South African legislation related to the protection of water resources, the environment and human health. However, in many cases the implementation thereof is very poor. The legislative section summarises the South African legislation relevant to the regulation of EDC management, including the following:

- National Environmental Management Act (Act No. 107 of 1998)
- National Health Act (Act No. 61 of 2003)
- Water Services Act (Act No. 108 of 1997)
- National Water Act (Act No. 36 of 1998)
- Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies (Act No. 36 of 1947)
- National Drug Policy for South Africa (1996)

- Foodstuffs, Cosmetics and Disinfectants Act (Act No. 54 of 1972)
- Conservation of Agricultural Resources Act (Act No. 43 of 1983)
- National Environmental Management Act: Air Quality Act (Act No. 39 of 2004)
- National Environmental Management Act: Waste Act (Act No. 59 of 2008)

Further supporting documents include:

- SANS 241: 2011 Parts 1 and 2
- South African Water Quality Guidelines, 1996
- Quality of Domestic Water Supplies: Series of Guides
- Guidelines for the Utilisation and Disposal of Wastewater Sludge

The section entitled ***Alertness to impacts*** in this volume summarises signs that would alert the relevant organisations to some type of assessment and monitoring for EDCs, including aspects relating to uncertainty, selection of relevant EDCs for South Africa, criteria for including a compound on the EDC priority list and the relevancy of data produced about EDC effects.

- Presence of a potential EDC whether naturally occurring, synthetic or anthropogenic.
- Indication of *in vivo* EDC effects including the effect of EDCs on the thyroid function and immune system.
- Proof of past or present use: banned substances should not be excluded from the list as some of the persistent organic pollutants such as organochlorine pesticides (DDT, dieldrin) are banned and are known to cause harm.
- Persistence in the environment and/or accumulation in the organism.
- Disruption in wildlife should be a warning signal for human health.
- Presence of elements that may not have direct EDC activity; however, they might have an impact on toxicokinetics and toxicodynamics of those chemicals which have disruptive activity. Their presence may therefore either enhance or diminish the EDC effect of specific compounds.

This EDC Guideline Volume series comprises five volumes set out in one file so that newly developed sampling and analytical methods can easily be added or existing methods updated as they are tested:

- **Volume I**: Introduction
- **Volume II**: Sampling Guide
- **Volume III**: Bioassay Toolkit
- **Volume IV**: Monitoring and Assessment
- **Volume V**: EDC Management in Catchments

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SETTING THE SCENE

Introduction

The past three decades have seen increasing numbers of scientific statements expressing concerns about adverse health effects resulting from exposure to chemicals due to their potential to change the functioning of the endocrine system. The awareness that environmental chemicals could have these effects on wildlife, and that human health is inextricably linked to environmental health, was highlighted by the publication of Rachel Carson's *Silent Spring* published in 1962.

These concerns may have arisen primarily due to the observation of adverse effects in some wildlife species, fish and ecosystems, but the increased incidence of some endocrine-related human diseases has also been reported. Laboratory experiments have also demonstrated endocrine disruption following exposure to some environmental chemicals. These concerns prompted the Endocrine Society of the USA to produce a scientific statement in 2009, stating that:

> *To date, no chemical in use has been thoroughly tested for its endocrine disrupting effects, so the true threat of EDCs is unknown.*
>
> *Low doses are the most pertinent when exposure occurs to developing organisms. In some cases, these organisms normally have no exposure to some hormones — and exposure to tiny amounts of an endocrine disruptor changes the way these organisms will develop and potentially predispose them to develop a disease later in life.*

These chemicals are generally termed EDCs or endocrine disrupting chemicals. The concept that chemicals not produced in the body but released into the environment could disrupt the endocrine system of mammals and wildlife led to the term 'endocrine-disrupting contaminants'. The United States Environmental Protection Agency uses the term 'endocrine disrupting compounds' whilst the World Health Organization prefers the term 'endocrine disrupting chemicals'. Both the Endocrine Society of the USA and the International Programme on Chemical Safety (IPCS) use the term 'endocrine-disrupting chemicals'.

The Water Research Commission (WRC) has been investigating these concerns as they relate to water, water users and water uses for over a decade. The reader is referred to the list of WRC reports and other publications in the Literature Review Report (available on CD from the WRC) for further details. The information contained in this EDC Guideline Volume series is thus not intended to provide an exhaustive review or overly technical reference documentation, but rather aims to stimulate further EDC research in South Africa.

Although the topic is contentious with conflicting scientific opinions having led to much public debate, this manual concerns itself with scientifically accepted methods for sampling and conducting bioassays and analytical determination in order to appropriately monitor, assess and manage EDCs in water resources. These volumes thus deal specifically with the potential of chemicals present in water to interfere with the endocrine system.

What is an EDC?

A chemical is a substance with a distinct molecular composition whilst a compound is a substance consisting of atoms or ions of two or more different elements in definite proportions.

The term 'disrupt' in the physiological context implies that a biological process has been interrupted to the extent that it has either been stopped, or been prevented from normal continuance.

The term 'endocrine' relates to a specific system within the body where internal secretions occur that are distributed in the body via the bloodstream, often taken to refer to hormones. An endocrinologist studies the physiology and pathology of internal secretions and endocrine glands.

In a World Health Organization global assessment on endocrine disruption the International Programme on Chemical Safety defined an endocrine disruptor as:

- *an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.*

Since many reported instances of endocrine disruption have not yielded unequivocal evidence of adverse effects, this definition may be modified to read:

- *an exogenous substance or mixture that alters function(s) of the endocrine system and consequently may cause, or potentially result in, adverse health effects in an intact organism, or its progeny, or (sub)populations.*

This global assessment went on to define a potential endocrine disruptor as:

- *an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny or (sub)populations.*

The initial definition of an endocrine-disrupting compound by the US Environmental Protection Agency was:

- *an exogenous agent that interferes with synthesis, secretion, transport, metabolism, binding action, or elimination of natural blood-borne hormones that are present in the body and are responsible for homeostasis, reproduction and developmental process.*

The Endocrine Society of the USA now recognises much broader mechanisms. Thus, in addition to nuclear hormone receptors (such as oestrogen and androgen receptors, progesterone receptors and thyroid receptors) effects "via nuclear receptors, non-nuclear steroid hormone receptors (e.g. membrane ERs), non-steroid receptors (e.g. neurotransmitter receptors), orphan receptors (e.g. aryl hydrocarbon receptor), enzymatic pathways involved in steroid biosynthesis and/or metabolism, and numerous other mechanisms that converge upon endocrine and reproductive systems" are also recognised, with the definition accepted from a physiological perspective as:

> *An endocrine-disrupting substance is a compound, either* ***natural or synthetic****, which, through environmental or inappropriate developmental exposures,* ***alters*** *the hormonal and homeostatic systems that enable the organism to communicate with and respond to its environment.*

Multidisciplinarity

It has been observed that EDCs present the scientific community with less of a new field, but rather with more of an integration of numerous multidisciplinary fields. These are too numerous to list but include biology, chemistry, epidemiology, and atmospheric and earth sciences.

As scientists strive to explain the complexities of our impact on the environment, increasing collaboration among the various disciplines has led to new understanding and inevitably new questions, theories and hypotheses. It is therefore not surprising that a single study cannot provide all the necessary information on EDCs, and that there are continual assessments of the entire body of knowledge published by collaborative groups.

Overview

This EDC Guideline Volume series consists of five volumes set out in one file so that newly developed sampling and analytical methods can easily be added or existing methods updated as they are tested.

Volume I: Introduction

This volume has been compiled to introduce the reader to EDCs and their potential sources, pathways, receptors and impacts. It also highlights the relevant legislation that could be used in the control and management of EDCs in the environment. It addresses a number of frequently asked questions in short fact sheets. This volume also introduces the other four volumes.

Volume II: Sampling Guide

This volume sets out the objectives of a sampling programme. The guideline includes the methods for sampling water, sediment, air and biological tissue samples, including:

- pre-field preparation
- site selection
- sample collection
- transport and storage
- analysis

In addition, **Volume II** includes several examples of data-capture sheets and considerations for EDC sampling in South Africa such as sampler training and accredited laboratories available to undertake the analyses.

Volume III: Bioassay Toolkit

Analysis in the context of this project includes bioassays, organics and inorganics, all given as separate chapters that can be easily removed and replaced should updates be made available.

The bioassay toolkit sets out various biological methods to assess the oestrogenicity of water including drinking water, groundwater and wastewater. The following four biological methods are currently included:

  - the recombinant yeast oestrogen screen (YES)
  - the T47D-KBluc reporter gene assay
  - E-screen assay for oestrogenicity
  - fish VTG screen for oestrogenicity

This volume presents guidelines for chemical analyses of endocrine-disruptor chemicals in water resources, including:

- preparation of samples
- extraction and clean-up
- instrumental detection
- multi-residue methods
- enzyme-linked immunosorbent assay (ELISA) techniques
- calculations

Volume III also includes a section relating to determination of inorganic parameters, including sampling and laboratory procedures for inorganic compounds and interpretation of the results.

Volume IV: Monitoring and Assessment

This volume presents the basic principles applicable to EDCs and the physiological systems that can be affected by these chemicals, describing the following key concepts relating to EDCs and physiology:

- routes of exposure and absorption
- distribution and storage
- biochemical transformations
- receptor-chemical interactions

A current EDC overview outlines the types of known or suspected EDCs with particular reference to animal health, including inorganic water-quality constituents, pesticides, herbicides, disinfectants, insecticides and fungicides.

Volume V: EDC Management in Catchments

The primary objective of this volume for EDC management in catchments is to provide the target audience with a common understanding of the main EDC-related management issues. The guideline does not only deal with catchment-management processes but is also intended to ensure that information about EDCs can be conveyed to the general public and water users in a consistent, accurate and meaningful manner.

In this respect **Volume V** highlights matters relating to management strategies. These include the introduction of adaptive management, a naturally sensible framework within which learning can take place, and an integrated water-quality management model (Boyd et al., 2011). Considering the inherent uncertainties associated with EDCs, adaptive management is seen as an appropriate framework.

Various non-regulatory options including duty of care; self-regulatory options; incentive-based regulation; wastewater risk-abatement planning; support options; best management practices; and the precautionary principle are introduced. Risk is also introduced bringing in the concepts of risk perception and acceptable risk.

This guideline volume brings a structured approach to effective risk management in which the four main steps are: catchment characterisation; screening for potential EDC contamination; risk mitigation; and risk prioritisation. These are closely linked to how risk is communicated. A discussion on how to communicate the potential risk of EDCs without causing undue fear to the public or manipulation of facts is included, and the message map is introduced as a potential tool.

Frequently asked questions

Water-resource managers will need specific questions answered in order to make informed and rational decisions with regard to EDC contamination and be able to answer questions from the public. Several fact sheets attached to the document summarise answers to some frequently asked questions.

SOURCES, PATHWAYS AND RECEPTORS

Chemicals are commonplace in all aspects of life. Suspected EDCs can be found in pesticides, fertilisers, pharmaceuticals such as birth-control pills, personal-care products such as medicines, lotions, cosmetics and sun-blocks, and industrial substances including plasticisers, fabric softeners, fire retardants and cooling agents. EDCs find their way into the environment and water resources via runoff, atmospheric deposition and direct discharges. In this respect every person is in all probability exposed via ingestion, skin contact and breathing to a combination of potential EDCs through various media, on a daily basis. This is illustrated schematically in Figure 1.

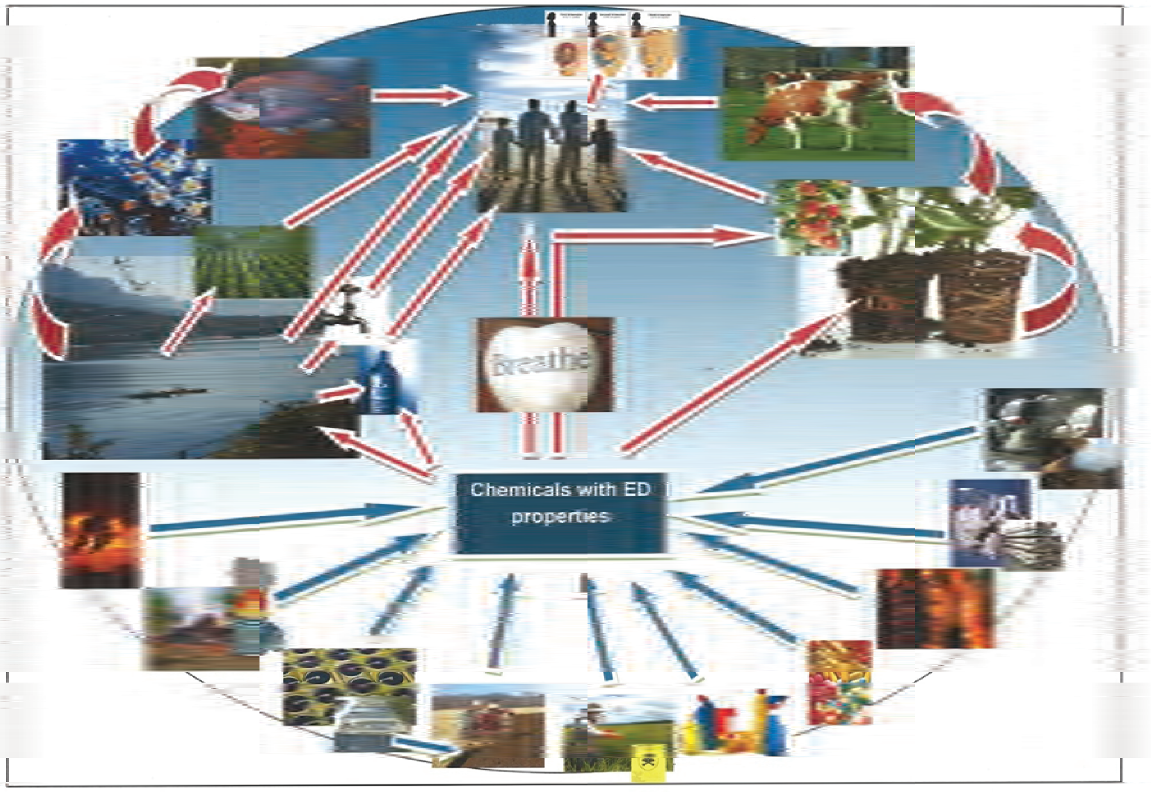

Figure 1: Illustration showing various sources of EDCs and potential pathways

LEGISLATIVE FRAMEWORK

South Africa has some of the best legislation in the world, especially related to protection of water resources. However, in many cases the implementation thereof is very poor. The section to follow summarises the South African legislation relevant to the regulation of EDC management.

National Environmental Management Act (No. 107 of 1998)

Section 23 of the National Environmental Management Act, 1998, (No. 107 of 1998) (NEMA) (as part of Integrated Environmental Management), defines the general objective of the Act to be the application of appropriate environmental management tools to ensure the integrated environmental management of activities. Section 23(2)(b) further recognises the need to identify, predict and evaluate the actual and potential impact of activities on the environment and then takes steps to mitigate potential impacts, with a view to minimising negative impacts, maximising benefits, and promoting compliance with the principles of environmental management.

Furthermore, according to Section 24(2) and (7) of the Act, there are specific procedures that must be followed when assessing impacts on the environment that may occur due to activities that require authorisation or permission by law.

National Health Act (No. 61 of 2003)

According to Section 70(1) of the Act, which outlines 'National Health Research Information', the National Health Research Committee is tasked with identifying health-research priorities. It is also mentioned, according to Section 70(1)(a) and (e), that in identifying health-research priorities, the committee must have regard to the burden of disease and the health needs of the communities. It is imminent that the occurrence of EDCs will or is already at a level that is deemed a national priority, not only in South Africa but also internationally. The challenge, however, is that this priority has not been fully understood.

With regards to compliance and monitoring, according to Section 81 and Section 82(1)(d), routine inspections by a health officer are required to be conducted and a sample taken which is seen to be relevant to the inspection.

Water Services Act (No. 108 of 1997)

The Water Services Act, 1997 (No. 108 of 1997) (WSA), recognises 'the rights of access to basic water supply and basic sanitation necessary to ensure sufficient water and an environment not harmful to health or well-being'. In addition, the WSA recognises that 'the provision of water supply and sanitation services - although an activity distinct from the overall management of water resources - must be undertaken in a manner consistent with the broader goals of water resource management.'

Currently, according to Section 27(a) to (d), the Act has made provision for water services authorities to 'monitor the performance of water services providers and water services intermediaries within its area of control.'

Section 9(1)(b) of the Water Services Act allows the Minister to set compulsory national standards regarding the quality of water taken from or discharged into any water services or water resource system. As stated in Section 9(1)(d), the Act makes provision for the prescription of national standards relating to the nature, operation, sustainability, operational efficiency and economic viability of water services.

The Guidelines for Compulsory Standards published by the Department of Water Affairs (DWA, 2002), set under Section 9 of the Act, state that water services institutions should take measures to prevent 'objectionable substances (substances that are unsuitable for discharge into watercourses without treatment which may include sewage, domestic water, petroleum products, chemicals, and leachates) from entering watercourses.' EDCs, although not fully understood, form part of this category and should be handled as such. A linkage to Section 21(f) of the National Water Act with regard to discharging of effluent into a watercourse is also relevant.

Furthermore, in relation to management, jurisdiction is given to water services authorities to introduce appropriate by-laws that prohibit consumers at all levels to discharge any substances other than uncontaminated stormwater into the stormwater system (DWAF, 2002).

National Water Act (No. 36 of 1998)

As the most significant Act underpinning the overall water management in South Africa, the National Water Act, 1998 (No. 36 of 1998)(NWA) includes all if not most of the regulations required to manage and protect water resources. The Act also gives guidelines on the determination and establishment of resource water-quality objectives (RWQOs) for all South African water resources. However, the methodologies used to determine these water-quality objectives do not currently include EDC levels in water.

The detail entailed in the NWA which has a bearing in the efficient management of EDCs in South Africa includes but is not limited to Sections 6, 13, 19, 20 and 26.

Section 6 relates to the development of the national water-resource strategy (NWRS) which ultimately provides the framework for the protection, use, development, conservation, management and control of water resources for the country as a whole. Importantly, and especially in the context of this document, the NWRS provides the framework within which water will be managed at regional or catchment level, in defined water-management areas. The NWRS, which must be formally reviewed from time to time, is binding on all authorities and institutions exercising powers or performing duties under this Act.

Chapter 3 of the NWA relates very specifically to the protection of water resources in relation to their use, development, conservation, management and control. The chapter lays down a series of measures which are together intended to ensure the comprehensive protection of all water resources. These measures are to be developed progressively within the contexts of the national water-resource strategy and the catchment management strategies provided for in Chapter 2 of the NWA. The chapter also deals with measures to prevent the pollution of water resources and measures to remedy the effects of pollution of water resources.

Part 1 of Chapter 3 provides for the first stage in the protection process: classification of the nation's water resources. The system provides guidelines and procedures for determining different classes of water resources. Under Section 13(1) this classification system must then be used to determine the class and resource-quality objectives (RQOs) of all or part of water resources considered to be significant. These RQOs will then guide the establishment of clear goals relating to the quality of the relevant water resources (Section 13(3)). It is important, however, that in determining resource-quality objectives, a balance between the need to protect and sustain water resources on the one hand, and the need to develop and use them on the other, is established. Once the class of a water resource and the RQOs have been determined, they are binding on all authorities and institutions when exercising any power or performing any duty under the NWA**.**

Pollution prevention, especially where pollution of a water resource occurs or might occur as a result of activities on land, is dealt with in Section 19 of the NWA noting that the person who owns, controls, occupies or uses the land in question is responsible for taking measures to prevent pollution of water resources. If these measures are not taken, the catchment management agency (CMA) concerned may itself do whatever is necessary to prevent the pollution or to remedy its effects. In addition, the CMA may recover all reasonable costs from the person(s) responsible for the pollution.

Chapter 4 is of central significance to the NWA in that it lays the basis for regulating water use. Section 21 defines water use broadly and includes taking and storing water, activities which reduce streamflow, waste discharges and disposals, controlled activities (activities which impact detrimentally on a water resource), altering a watercourse, removing water found underground for specific purposes, and recreation.

Section 26 of the NWA defines the various opportunities for regulation of water use.

National Drug Policy for South Africa, 1996

The National Drug Policy (NDP) aims to ensure that drugs reaching patients are safe, effective and meet approved standards and specifications. As stated in Section 3 of the NDP, it is primarily the responsibility of the Medicines Control Council (MCC) to ‘facilitate the harmonisation of drug regulation and control in Southern Africa’, the process of which also includes the adoption of criteria for drug evaluation and for good manufacturing practice (GMP). It is also mentioned in Section 3.4 that ‘drug legislation and regulations will be supported by an adequate and effective drug inspection service, under the direction of the MCC’.

It is imminent that in terms of regulation, control and inspection service at manufacturing facilities and end-use facilities there will come a time when storage duration of drugs will exceed the time for safe consumer use. Therefore proper monitoring and evaluation of waste-stream disposal is critical to eliminate any occurrence of pharmaceuticals within the receiving environment. EDCs will typically exist where drug manufacturing is concerned. The NDP recognises the need for proper disposal of waste. According to Section 6.6 of the NDP, the Government will legislatively ensure that ‘the removal and/or disposal of drugs, medical supplies and medical waste takes place in such a manner that is neither harmful nor dangerous to the community or environment*.’*

In addition, the NDP states that inspectors ‘will carry out regular inspections to ensure that the disposal of unwanted items takes place according to prescribed guidelines’. It still remains to be documented whether the presence of EDCs in these water streams is being monitored, since large amounts of these EDCs can originate from drug manufacturing and/or end-use facilities such as hospitals.

The exposure of humans as a possible direct receptor to EDCs can also take place via voluntary intake of substances that may possibly have endocrine-disrupting effects. The use of traditional medicines can have effects that may not be acutely seen, since the lack of testing of these medicines is not routinely conducted. The NDP also makes reference to the establishment of a national reference centre for traditional medicines which aims to test for toxicity and efficacy of medicines. However, it remains uncertain as to whether or not screening and testing occur.

Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act (No. 36 of 1947)

This Act was put in place in 1947 to provide for the appointment of a Registrar of Fertilizers, Farm Feeds and Agricultural Remedies, as well as to provide for the registration of fertilisers, farm feeds, agricultural remedies, stock remedies, sterilising plants and pest-control operators. The Act also allows for the regulation or prohibition on the importation, sale, acquisition, disposal or use of fertilisers, farm feeds, agricultural remedies and stock remedies. The Act provides for the designation of technical advisers and analysts; and for matters incidental thereto. Of particular relevance to this project is Section 23 relating to the power to issue regulations.

Foodstuffs, Cosmetics and Disinfectants Act (No. 54 of 1972)

The objectives of the Foodstuffs, Cosmetics and Disinfectants Act (No. 54 of 1972), as amended by the Foodstuffs, Cosmetics and Disinfectants Amendment Act (Act 32 of 1981) and Transfer of Powers of Duties of the State President Act (Act 97 of 1986), are to control the safe manufacture and importation of foodstuffs, cosmetics and disinfectants; and to provide for incidental matters. Of particular relevance to the regulation of EDCs are Sections 2 and 15.

Section 2 deals with the prohibition of sale, manufacture or importation of particular articles in the foodstuffs, cosmetics and disinfectants market. This includes product content concentrations as well as various treatments that may be used in the production of the product.

Section 15 relates to regulations that may be made in respect of:

- Prescribing the nature and composition of any foodstuffs, cosmetic or disinfectant.
- Prescribing standards for the composition, strength, purity or quality or any other attribute of any foodstuff, cosmetic or disinfectant or any ingredient or part of a foodstuff, cosmetic or disinfectant.
- Prescribing any foodstuff, cosmetic or substance as foodstuff, cosmetic or substance which shall for the purpose of this Act be deemed to be harmful or injurious to human health.
- Prohibiting the sale of any particular foodstuff, cosmetic or disinfectant, or of any foodstuff, cosmetic or disinfectant of a particular nature or class.

Conservation of Agricultural Resources Act (No. 43 of 1983)

The Conservation of Agricultural Resources Act, 1983 (No. 43 of 1983) (CARA) is focused on the control of the utilisation of the natural agricultural resources of South Africa in order to promote the conservation of the soil, water sources and vegetation, and the combating of weeds and invader plants and associated matters. Section 6(2) sets out the control measures that are needed to achieve the objectives of the Act.

Section 7 refers to the issuing of directions (direction order) whereby a land user will be compelled to comply with a particular control measure which is binding on him or with regard to the land specified in such direction.

National Environmental Management: Air Quality Act (No. 39 of 2004)

This Act was put in place to reform the law regulating air quality in order to protect the environment by providing reasonable measures for the prevention of pollution and ecological degradation and for securing ecologically sustainable development while promoting justifiable economic and social development; to provide for national norms and standards regulating air quality monitoring, management and control by all spheres of government; for specific air quality measures; and for matters incidental thereto.

National Environmental Management: Waste Act (No. 59 of 2008)

This Act was promulgated to reform the law regulating waste management in order to protect health and the environment by providing reasonable measures for the prevention of pollution and ecological degradation and for securing ecologically sustainable development; to provide for institutional arrangements and planning matters; to provide for national norms and standards for regulating the management of waste by all spheres of government; to provide for specific waste management measures; to provide for the licensing and control of waste management activities; to provide for the remediation of contaminated land; to provide for the national waste information system; to provide for compliance and enforcement; and to provide for matters connected therewith.

Further supporting documents

SANS 241-1 and 241-2: 2011

The South African National Standards (SANS) for Drinking Water (SANS 241-1 and SANS 241-2: Edition 1, 2011) have been published by the SABS Standards Division. The Standard specifies the quality of acceptable drinking water and consists of the following parts, under the general title *Drinking water:*

- *Part 1: Microbiological, physical, aesthetic and chemical determinands*
- *Part 2: Application of SANS 241-1*

Part 1 specifies the quality of acceptable drinking water, defined in terms of microbiological, physical, aesthetic and chemical determinands, at the point of delivery. Water that complies with Part 1 of SANS 241 is deemed to present an acceptable health risk for lifetime consumption (this implies an average consumption of 2 ℓ of water per day for 70 years by a person that weighs 60 kg).

Water services institutions and water services intermediaries ensure that water provided by them complies with the numerical limits given in Part 1 (SANS 241-1) of SANS 241. Water services institutions and water services intermediaries monitor and maintain monitoring programmes informed by the routine monitoring programme and risk assessment processes described in Part 2 (SANS 241-2).

The standard set for each represents a numerical limit for each listed determinand that, if met, will safeguard the health of the consumer over a lifetime of consumption. This means that the health-related standards are based on the consumption of 2 ℓ of water per day by a person of a mass of 60 kg over a period of 70 years. Standards for some chemical determinands such as lead and nitrate are set to be protective for susceptible subpopulations. These standards are also protective of the general population over a lifetime of consumption. Part 2 of SANS 241 addresses the evaluation of water-quality risks, monitoring and verification of water quality to enable the management of the identified water-quality risks.

However, in respect of the physiological effects of EDCs on human health (described in **Volume IV**) these limits would therefore not be effective.

South African Water Quality Guidelines, 1996

The South African Water Quality Guidelines for Domestic Water Use (DWAF, 1996) are essentially a user needs specification of the quality of water required for different domestic uses. The document is intended to provide the information required to make judgments as to the fitness of water to be used for domestic purposes, primarily for human consumption but also for bathing and other household uses. The guidelines are applicable to any water that is used for domestic purposes, irrespective of its source (such as municipal supply, borehole and river) or whether or not it has been treated. However, the guidelines do not address water which is sold as a beverage in bottles, and water in swimming pools.

The South African Water Quality Guidelines are used by the Department of Water Affairs as its primary source of information and decision-support to judge the fitness of water for use and for other water quality management purposes. The Guidelines contain similar information to what is available in the international literature. However, the information contained in the guidelines is more detailed, and not only provides information on the ideal water quality for water uses but also provides background information to help users of the guidelines make informed decisions about the fitness of water for use.

For each of the water-quality constituents contained in the guideline there is a No Effect Range (NER) given. This is the range of concentrations or levels at which the presence of that constituent would have no known or anticipated adverse effect on the fitness of water for a particular use or on the protection of aquatic ecosystems. These ranges were determined by assuming long-term continuous use (lifelong exposure) and incorporate a margin of safety. As for the SANS 241 standards, the water-quality guidelines do not take into consideration the very sensitive receptors among humans, namely infants and children.

As a matter of policy, the Department strives to maintain the quality of South Africa's water resources such that they remain within the NER. In the guidelines the NER is referred to as the Target Water Quality Range (TWQR). It is included, and highlighted as such in the water-quality criteria provided for each of the constituents in the guidelines. Users of the South African Water Quality Guidelines should note that an important implication of setting the TWQR equal to the NER is that it specifies good or ideal water quality instead of water quality that is merely acceptable.

The information contained in the Guidelines for each constituent is set out in relation to background information which contains supporting information required to make decisions relating to the fitness for use of the water; information on the effects of the constituent (including the criteria) on domestic water uses and additional sources of information.

Quality of Domestic Water Supplies: Series of Guides

This series of guides is intended to provide water-supply agencies, water-resource managers, workers in health-related fields, as well as communities throughout South Africa, with the information they need to sample, analyse, assess and interpret the quality of domestic water supplies.

The following documents form the series:

- Quality of Domestic Water Supplies – Volume 1: *Assessment Guide*
- Quality of Domestic Water Supplies – Volume 2: *Sampling Guide*
- Quality of Domestic Water Supplies – Volume 3: *Analysis Guide*
- Quality of Domestic Water Supplies – Volume 4: *Treatment Guide*
- Quality of Domestic Water Supplies – Volume 5: *Management Guide*

The purpose of the guides is to answer the questions on the suitability of the water for domestic use; and if not suitable, what can be done to make it suitable?

This Series of Guides allows the quality of water supplied for domestic use to be assessed by using a simple, colour-coded classification system. The system shows the nature of the effects of water quality on the domestic user for a range of concentration values for those substances commonly encountered in water. The information is presented in a simplified format so that a wide spectrum of users of the Guides will be able to understand the underlying concepts of water quality as it affects the domestic user.

The *Assessment Guide* (Volume 1 in this Series of Guides) is divided into two parts: Part 1 describes a procedure to assess and interpret domestic water quality and includes water-quality guidelines presented in the form of a simple, colour-coded classification system (Part 1 Section C). Part 2 of this *Assessment Guide* contains the ‘tools’ to assess the quality of domestic water supply. The tools consist of 21 water-quality guidelines for substances that are generally found in water and that are most relevant in the assessment of the quality of domestic water supplies. The suitability for domestic use of each of the 21 key substances is expressed in terms of the colour-coded classes. In the system used water is classified to:

- Establish how suitable it is for the various domestic uses, namely drinking, food preparation, bathing and for washing clothes.
- Make it easy to communicate water-quality information to the public and other role-players.
- Aid in decision-making regarding the management of the quality of domestic water supplies.

Water quality does not suddenly change from good to bad when a given concentration or value is exceeded. There is generally a gradual change from water which is of ideal quality, and which will not have negative effects on any users, to water which is dangerous to all users – even if used only once. Between these two values, there is an area where the risk of using the water gradually increases. The classification system used in the *Assessment Guide* allows for this gradual change.

In a community different people react differently to the same water. For example, babies and people with heart or kidney disease may be affected at much lower concentrations than healthy adults. In hot, dry climates people drink more water thus increasing the risk of accumulating substances in the body, which can cause chronic effects. The water-quality guidelines in Part 2 of the *Assessment Guide* are presented in terms of a simple colour-coded classification system for the substances outlined in Part 1 as important for domestic users. The classification is based on increasing concentrations of these substances, and allows for classifying the:

- Health effects of water used for drinking, as well as aesthetic effects of water used for drinking.
- Health and aesthetic effects of water used for food preparation.
- Health and aesthetic effects of water used for bathing.
- Health and aesthetic effects of water used for washing clothes.

Sludge guidelines

Domestic wastewater sludge (sewage sludge) disposal is managed in South Africa in terms of the Guidelines for the Utilisation and Disposal of Wastewater Sludge, Volumes 1 to 5 (Snyman and Herselman, 2006):

- Volume 1: Selection of management options
- Volume 2: Requirements for the agricultural use of sludge
- Volume 3: Requirements for the on-site and off-site disposal of sludge
- Volume 4: Requirements for the beneficial use of sludge
- Volume 5: Requirements for thermal sludge management practices and for commercial products containing sludge

Volume 1 of the guidelines serves as a starting point where management options relating to the handling of sludge are concerned. However, over and above the selection of an appropriate management option, cognisance should be taken of the absence of explicit guidelines with regard to the presence of EDCs within sludge.

Regulatory requirements, especially in terms of the beneficial use of sludge in agriculture (Volume 2) and its disposal (Volume 4), need to be regulated such that EDC constraints are introduced. This has to be conducted with consideration of all other relevant supporting legislation. The current status of legislation, in terms of these two latter volumes, is discussed below.

Volume 2: **Requirements for the agricultural use of sludge**

This guideline volume was specifically developed to encourage the responsible use of wastewater sludge in agricultural practices. Although the potential benefits of the nutrients (nitrogen, phosphorus and potassium) and the high organic carbon content of sludge have been well demonstrated, recent studies indicate that some of these nutrient levels may have negative endocrine-disrupting effects. Previous studies also implicate the use of manure as a pertinent source of EDCs.

ALERTNESS TO IMPACTS

In summary, the following should be signs that would alert the relevant organisations to the fact that some type of assessment and monitoring is required:

- Presence of a potential EDC whether naturally occurring, synthetic or anthropogenic.
- Indication of *in vivo* EDC effects, including the effect of EDCs on the thyroid function and immune system.
- Proof of past or present use: banned substances should not be excluded from the list as some of the persistent organic pollutants such as organochlorine pesticides (DDT, dieldrin) are banned and are known to cause harm.
- EDCs persistently present in the environment and/or accumulation in the organism.
- Disruption in wildlife should be a warning signal for human health.
- Presence of elements that may not have direct EDC activity; however, they may have an impact on toxicokinetics and toxicodynamics of those chemicals which have disruptive activity. Their presence may therefore either enhance or diminish the EDC effect of particular compounds.

The subsections to follow give a brief explanation on reasons for including these alert scenarios.

Uncertainty

What has emanated from many EDC-related studies is that there is still a great deal of uncertainty. All risk estimates involve some degree of uncertainty and uncertainty exists at numerous levels (Fatoki et al., 2010).

- Uncertainty regarding exposure which has two primary sources:
    - Uncertainty about contamination, including concentrations of chemicals to which the potential population may be exposed over the duration of the exposed period.
    - Uncertainty about the exposed population (Fatoki et al., 2010). In several of the studies both of these were significant. The exposed population could not be studied and the health risk is based solely on hypothetical exposure scenarios, so that uncertainty in the results may be substantial (Risk*Assistant (TM), 1995).
- Uncertainty in dose-response (carcinogenic and toxicological) data also exists. Where reference doses are used the uncertainty factors are in the order of 1 or 2 orders of magnitude.
- The various assumptions used, such as a lifetime of 70 years and a body weight of 70 kg, increases the uncertainties involved in the assessment process (Risk*Assistant (TM), 1995). Thus the results provided in many of the studies are an indication of the potential health risk associated with potential exposure to river waters if used for domestic and other purposes.
- Several studies consider specific chemicals and do not take into consideration some kind of cumulative impact. It is therefore possible that these risks predicted may be an underrepresentation of health risks.

In 2005 a report was written which summarises some of the difficulties relating to EDC studies undertaken in South Africa and makes specific recommendations (Burger, 2005). These aspects are discussed below.

Taking the detrimental influence of EDCs on human and animal health into account, it is important to determine the occurrence and levels of EDCs as well as other toxicants which do not have endocrine-disruptive (ED) effects in drinking water in order to take the necessary steps to protect its population. Importantly, it must also be remembered that a large portion of the population does not have access to purified water and still relies on surface water for drinking-water purposes. Any study on EDCs in water should therefore also include the occurrence and levels of EDCs in surface-water resources. It is estimated that more the 4 000 chemicals might have EDC properties and the list is expanding daily.

The relevancy of data produced about EDC effects

Although much information is available on the occurrence of contaminants such as pesticides, heavy metals, PCBs and PAHs, the data were generated for fitness for human consumption and values were often measured against the ADI (allowable daily intake) and ERL (environmental risk level) levels. Most of these levels are set for possible carcinogenic effects and not for oestrogenic effects. The level at which these compounds may have oestrogenic effects may be up to a million times lower than the levels at which carcinogenic effects occur. The data produced may thus contain a number of false negative values, because the detection limits used by the various laboratories were too high.

Criteria for including a compound on the EDC priority list

The following criteria are important when considering the inclusion of an EDC on a priority list:

- The substance should give some indication of *in vivo* EDC effect. The effect of EDCs on the thyroid function and immune system should also be taken into account. Any of the biochemical tests and/or animal studies may be utilised to establish these effects. **Volumes III** and **IV** of this EDC Guideline Volume series provide further information on this aspect.

- There must be proof of past or present use and banned substances should not be excluded as some of the persistent organic pollutants such as organochlorine pesticides (DDT and dieldrin) are banned, but are still used in malaria-infected areas. The use of PCB compounds has been phased out, but because of the long half-life of these compounds, they are still present in the environment.

- There must be proof that the substance is persistently present in the environment and/or accumulates in the organism. There are, however, indications that frequent exposure to non-persistent chemicals may have the same detrimental effect as chemicals that persist in the environment. It is therefore recommended that data on frequency of use in the case of a non-persistent compound should be taken into account as well as the fate of the substance in the environment and/or water or wastewater treatment works. The mechanism of action should also be investigated to determine at which level the compound would be active. There are indications that some of the breakdown components of a chemical may have more potent EDC effects than the mother compound.

- Substances to be included could be naturally occurring, synthetic or anthropogenic. Some researchers define an EDC as a synthetic compound; however, it would be unwise to disregard compounds such as hormones, phytoestrogens and some metals because they are not synthetic compounds.

- With respect to monitoring of drinking water an additional criterion regarding water solubility/mobility should be added. This is because the lipophilic compounds such as organochlorine pesticides and PCBs adhere to solid particles and may be found in large amounts in environmental water and sewage sludge, but are easily removed if the drinking-water treatment process is adequately designed.

Generating EDC data

When a sample is tested for trace levels of contaminants, it is subjected to concentration and clean-up procedures. Great care must be taken that the contaminant is not lost by absorption, or is contaminated by impure solvents or contaminated glassware. This is even more crucial for EDCs since contamination can occur very easily. Analytical methods should be validated for repeatability, robustness, selectivity and sensitivity. Instruments should be regularly validated for drift and contamination. Positive results should be verified by mass spectrometer in order to avoid the reporting of false positives. Only results produced under these conditions can be credible. Very few laboratories in South Africa are accredited to conduct analyses according to these standards.

Additional limitations to be considered

The following additional limitations should be considered (Burger, 2005):

- Disruption in wildlife is no longer disputed and should be a warning signal for human health. In this respect both the effect on humans and/or animals should be taken into account.

- The ability to control the substance in the environment should not be used as a reason to include or exclude a substance from being on the list. Some substances such as heavy metals and phytoestrogens occur naturally in the environment and may be virtually impossible to control. Procedures, however, exist to minimise these compounds in drinking-water and wastewater treatment processes. In addition, apart from their EDC properties, the heavy metals are also toxic and should be monitored in drinking water.

- The unavailability of an analytical procedure to analyse for the substance at the necessary low detection limit should not be used as a reason to exclude a substance from the list. Some chemicals show EDC effects at levels a thousand to a million times lower than the ADI (allowable daily intake). The majority of analytical procedures were developed to meet the toxic endpoints of a compound (ADI, NOEL (no-observed-effect-level values)). These methods will not necessarily meet the low detection limits needed for EDC analysis. In these cases it is suggested that new methodology be developed rather than excluding a substance from the list, because there is not at present an appropriate analytical method. A list of EDC substances was compiled taking into consideration the usage in South Africa (present and past) and adding to these compounds those which may be deemed important for monitoring by the main trading partners of South Africa.

- Information regarding manufacture and usage of pesticides in South Africa is obtainable from the Department of Agriculture and the Department of Health. However, at the time of publishing the report (Burger, 2011) only limited information regarding the tonnages of industrial chemicals manufactured and used in the country could be obtained, as this information is not freely available. This is a concern that needs to be discussed within the various organisations.

- Many elements do not have direct EDC activity, but do have an impact on the toxicokinetics and toxicodynamics of those chemicals which have disruptive activity. Their presence may therefore either enhance or diminish the EDC effect of particular compounds.

Selection of methods to determine EDC activity and occurrence

EDC activity is mostly determined by biochemical (*in vitro*) methods. EDC effects are determined by biological (*in vivo*) means and occurrence of individual chemicals is determined by chemical analyses. The selection of the appropriate and relevant method is of crucial importance when conducting research on EDCs. Determination of EDC activity can be undertaken using various methods. In summary:

- Bioassays are a valuable tool to measure total activity (estrogenic as well as androgenic) resulting from all of the EDCs present, including unknowns. The assessment of EDC activity is made by *in vitro* and *in vivo* methods. *In vitro* methods are mostly based on the interaction of a chemical with the endocrine system at cellular level using cell cultures. They are based on the binding of the EDC to the specific receptor inside the test cell.
- EDC effects in *in vivo* experiments are measured in the whole animal by measuring a variety of endpoints such as the increase in uterus weight. *In vivo* tests have the major advantage because they take into account absorption, metabolism and excretion, but they are expensive and time-consuming (GWRC, 2003).
- Depending on the volatility and other properties of the specific compounds, levels of EDCs may be determined by gas chromatography (GC) or high-performance liquid chromatography (HPLC). Confirmation of the identity of a specific compound is normally done by GC-MS (gas chromatography-mass spectrometry) or HPLC-MS, but because of the extremely low levels at which

these compounds are active it is often very difficult to achieve this confirmation due to the limits of the MS (mass spectrometer). The properties of some compounds such as volatility, polarity and solubility also limit the scope of analysis. It is, therefore, practically impossible to analyse for all EDCs in one run.

- Elements and minerals are normally detected by atomic absorption (AA) or AAICP methods.

Further details on the detection methods are available in **Volume III** of this EDC Guideline Volume series.

CONCLUSIONS

It is clear that considerable research has already been undertaken in relation to EDCs in South Africa; however, we have barely seen the tip of the iceberg and there are still far more unknowns than knowns. With respect to South African legislation, the relevant legislation allows for research, assessment and monitoring as well as implementation of specific actions related to minimising impacts of EDCs on both the environment and human health. However, constraints related to implementation of the legislation include lack of capacity, and commitment, as well as social and economic concerns, in both the government and the private sector.

As discussed in the report, a desirable approach to dealing with EDCs would be the conventional human-health risk assessment, comparable to the approach used for many other hazardous water-quality constituents, ultimately leading to the development of guideline values for EDCs in raw water and drinking water. However, the limited data available for EDCs in terms of demonstrating clear dose-response relationships as well as other uncertainty factors relating to issues such as trans-generational impacts, timing of exposure related to developmental stages, and the inability to deal with synergistic and additive effects associated with multiple chemicals, means that in the interim a different approach is needed.

The notion of duty of care where each producer of EDCs, whether directly or indirectly, has a duty of care towards the environment and the health of the population that they may impact on is a concept that needs to be explored. This would mean that improved management of EDCs at source is one option that can and must be taken forward. The integrated water-quality management model (Boyd et al., 2011) is a mechanism that could be used in this respect to underpin the efforts aimed at reducing EDCs at source.

Reduction of EDCs at source is essential; however, where areas have been identified as being priority areas for EDC contamination, whether from historical contamination or because of an activity that is taking place, such as ongoing pesticide spraying, assessment and monitoring must take place at a more micro-scale level. **Volumes II**, **III** and **IV** of this EDC Guideline Volume series should therefore be used to ensure that correct sampling techniques, analyses and assessment methods are being used.

This must be done to gain a better understanding of the impacts of EDCs on human development, and to improve our knowledge of the presence and effects of EDCs on the environment. This information can then be used by decision-makers to ensure that these chemicals are controlled effectively through legislation to reduce risk of exposure and potential environmental and human-health impacts.

RECOMMENDATIONS

Recommendations for future research include:

- Catchment assessments in relation to the *status quo* of EDCs: it would be of great importance to establish the pesticide load and industrial waste-pollution sources in the sites chosen for any comprehensive study on EDC contamination.
- The current edition of SANS 241 has a limited requirement in terms of organics determination; it is recommended that these EDC issues be considered more thoroughly in the next edition.
- Ongoing assessment and monitoring of EDCs in hot-spot catchments, especially before and after mitigation, using **Volumes II**, **III** and **IV** of this EDC Guideline Volume series.
- Further assess the ability of the treatment technologies to remove EDCs and the costs associated.
- Assess skills related to the ability of:

- DWA/CMAs to implement requirements of the NWA; and
    - process controllers to operate and maintain WCW
- Laboratory assessment: capacity and capabilities.
- Funding for research projects and cost of analysis.
- The issue of EDCs is interdisciplinary, requiring expertise from a variety of scientific disciplines; therefore a programme to coordinate researchers and projects should be instituted.
- Cooperation agreement between particular industries, especially the chemical industries, and regulators to obtain relevant information relating to potential EDCs used in a particular catchment.
- Toxicity data for oestrogenicity.
- Methodology to determine total oestrogenic load in aquatic systems.

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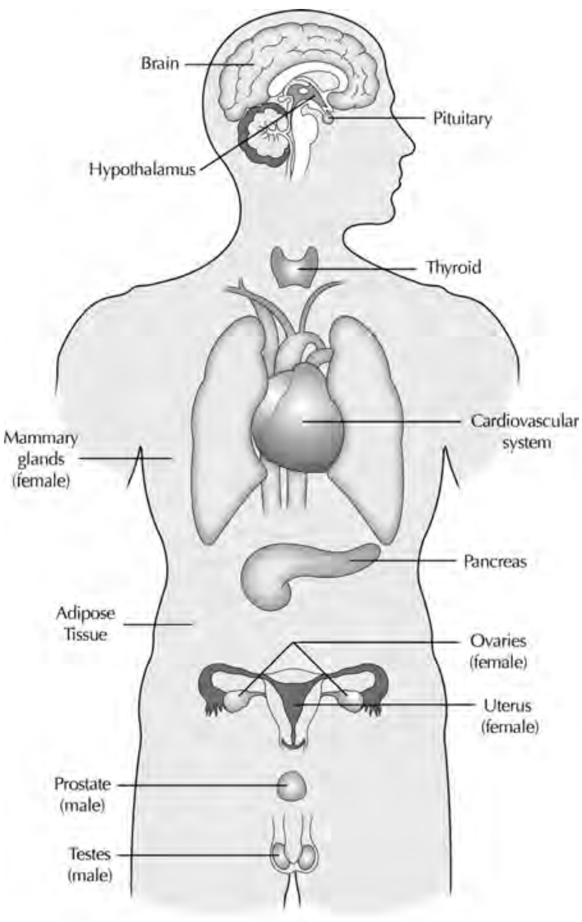
FACT SHEET 1 What are endocrine disrupting compounds (EDCs) and how do they impact on humans?

Endocrine disruptors are chemicals that interfere with the synthesis, secretion, transport, binding, action or elimination of natural hormones in the body. These hormones are responsible for development, behaviour, fertility and maintenance of homeostasis (normal cell metabolism) (Crisp et al., 1998). They are sometimes also referred to as hormonally active agents (Krimsky, 2001), endocrine-disrupting chemicals (Diamanti-Kandarakis et al., 2009) or endocrine-disrupting compounds (EDCs) as used in these WRC **Volumes I to V**.



These disruptions can cause cancerous tumours, birth defects and other developmental disorders. In other words, any system in the body controlled by hormones can be disrupted by EDCs. The critical period of development for most organisms is the transition from a fertilised egg into a fully formed infant. As the cells begin to grow and differentiate there are critical balances of hormones and protein changes that must occur. Therefore, a dose of EDCs can do substantial damage to a developing foetus; however, the same dose may not significantly affect the adult mother.

EDC studies have shown that endocrine disruptors can cause adverse biological effects in animals, and low-level exposures also cause similar effects in human beings (WHO, 2002).

The figure to the left shows a model of the endocrine systems targeted by endocrine-disrupting chemicals. This figure demonstrates that all hormone-sensitive physiological systems are vulnerable to EDCs, including brain and hypothalamic neuroendocrine systems; pituitary; thyroid; cardiovascular system; mammary gland; adipose tissue; pancreas; ovary and uterus in females; and testes and prostate in males (Diamanti-Kandarakis et al., 2009).

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FACT SHEET 2 What chemicals act as EDCs?

EDCs represent a broad class of molecules such as organochlorinated pesticides and industrial chemicals, plastics and plasticisers, fuels, and many other chemicals that are present in the environment or are in widespread use (Diamanti-Kandarakis et al., 2009).

In this respect, potential EDCs are found in many of the everyday products we use, including some plastic bottles and containers, liners of metal food cans, detergents, flame retardants, food, toys, cosmetics, and pesticides.

Chemicals that are known endocrine disruptors include diethylstilbestrol (the synthetic oestrogen DES), dioxin and dioxin-like compounds, polychlorinated biphenyls (PCBs), DDT, and some other pesticides.

Bisphenol A (BPA) is a chemical produced in large quantities for use primarily in the production of polycarbonate plastics and epoxy resins. The NTP Center for the Evaluation of Risks to Human Reproduction completed a review of BPA in September 2008. The NTP expressed '*some concern'* for effects on the brain, behaviour, and prostate gland in foetuses, infants, and children at current levels of human exposure to bisphenol A (Diamanti-Kandarakis et al., 2009).

Di(2-ethylhexyl) phthalate (DEHP) is a high-production-volume chemical used in the manufacture of a wide variety of consumer food packaging, some children's products, and some polyvinyl chloride (PVC) medical devices. In 2006, the NTP found that DEHP may pose a risk to human development, especially to critically ill male infants (NIH, 2006).

There are natural chemicals in plants that have hormone-like activity. These chemicals, mostly phytoestrogens, are found in high levels in broccoli, cauliflower, soybeans, carrots, oats, rice, onions, legumes, apples, potatoes, beer, and coffee. Most phytoestrogens have weak activity (low potency) and people who consume diets rich in these substances may have a reduced risk of developing some hormone-related diseases. However, the actual health risk or benefit of a diet rich in plant hormones is largely unknown. Some researchers argue that dietary consumption of plant hormones dwarfs the potential exposure from man-made sources.

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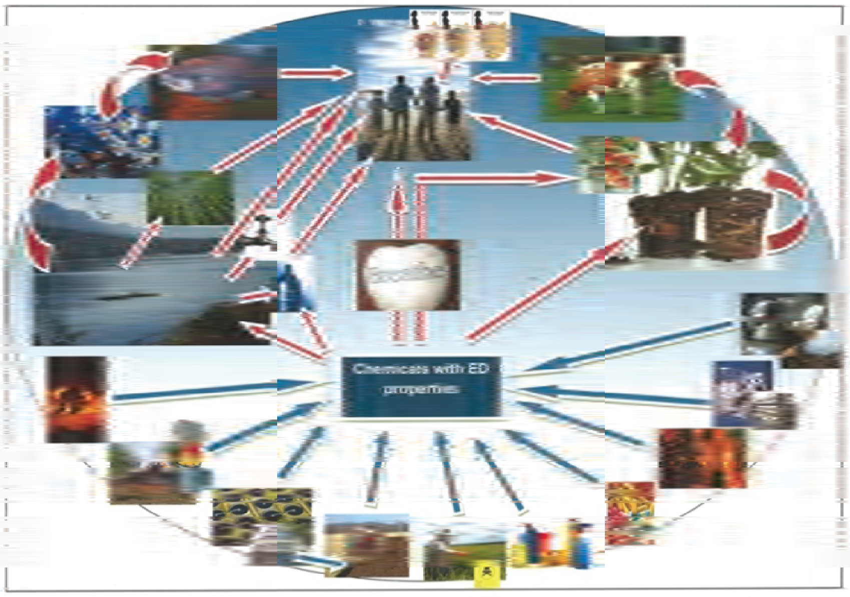
FACT SHEET 3 What are the sources and pathways of EDCs and how can exposure be avoided?

The number of chemicals that have been implicated as potential endocrine disruptors is substantial and there are many opportunities for exposure to these chemicals, both singly and as mixtures, albeit usually at very low levels. Globally, data on the magnitude and trends of human or wildlife exposure are limited. Potential sources of exposure are through contaminated food, contaminated groundwater, combustion sources and contaminants in consumer products (Damstra et al., 2002). Information on exposure during critical development periods is generally lacking. The exposure data sets that exist are primarily for the various environmental media of air, food and water, rather than the most relevant internal exposure of blood and tissue. Limited exceptions are human breast milk and adipose tissue samples.



Exposure to EDCs during the period when ‘programming’ of the endocrine system is in progress may result in a permanent change of function or sensitivity to stimulatory or inhibitory signals:

- Exposure in adulthood may be compensated for by normal homeostatic mechanisms and may therefore not result in any significant or detectable effects.
- Exposure to the same level of an endocrine signal during different life history stages or during different seasons may produce different effects.
- Because of cross-talk between different components of the endocrine systems, effects may occur unpredictably in endocrine target tissues other than the system predicted to be affected (Damstra et al., 2002).

In summary, the most important issues that complicate assessing exposure to EDCs in both wildlife and humans are the level, timing, and duration of exposure relative to the developmental stage of the organism. Exposure during fixed time frames in development when programming of the endocrine system is occurring may result in permanent changes, whereas exposure during ‘non-programming’ time periods may not result in any significant or detectable effect (Damstra et al., 2002). For wildlife, critical periods of development may include *in utero* or *in ovo* exposures, exposure at different stages of the life cycle, or exposure at different stages of the reproductive cycle that may have a strong seasonal element.

REFERENCES

Damstra T, Barlow S, Bergman A, Kavlock R and Van der Kraak G (2002) Global Assessment of the State-of-the-Science of Endocrine Disruptors. WHO Publication No. WHO/PCS/EDC/02.2. World Health Organization, Geneva, Switzerland.

FACT SHEET 4 What uncertainties are related to EDC detection and results interpretation?

Although data are available on the occurrence of contaminants such as pesticides, heavy metals, PCBs and PAHs, the data have most often been generated for fitness for human consumption and values were often measured against the ADI (allowable daily intake) and ERL (environmental risk level) levels. Most of these levels are set for possible carcinogenic effects and not for estrogenic effects which can be considerably lower. In this respect the major limiting factor in drawing any conclusions about human reproductive health effects and putative links to EDCs is the absence of exposure data. Another major problem common to many of the human studies is that sample sizes are often too small to permit detection of an effect, even if one was present. Thus, the currently available human data are inadequate to support a conclusion that human reproductive health has been adversely affected by exposure to EDCs. Similarly, although there is evidence for geographical differences and temporal trends in some aspects of human reproduction, there has been no systematic attempt to look for evidence that the mechanisms behind these changes involve endocrine pathways (Damstra et al., 2002).

All risk estimates involve some degree of uncertainty and uncertainty exists at numerous levels (Fatoki et al., 2010). There remains uncertainty about cause-and-effect relationships on a broader population basis, and there remains a need to better document the relationship between ambient exposure levels and effects on wildlife at the population level and the impact of pollution relative to other stressors, such as habitat destruction. In humans, the evidence for direct cause-and-effect relationships from environmental exposures remains generally lacking (Daston et al., 2003). Answers to the following questions still produce uncertainties (Daston et al., 2003):

- What effects are occurring in populations?
- What are the chemical classes and their potencies?
- What are the dose-response characteristics in the low-dose region?
- Do our testing guidelines adequately evaluate potential endocrine-mediated effects?
- What extrapolation tools are needed?
- What are the effects of exposure to multiple EDCs, and will a toxic equivalency factor (TEF) approach be feasible?
- How and to what degree are human and wildlife populations exposed to EDCs?
- What are the major sources and environmental fates of EDCs?
- How can unreasonable risks be managed?

Although a good deal of information on the nature and extent of the endocrine disruptor hypothesis has been generated over the past decade, more focused research is still needed to bring clarity to the issue. What is important is that the field of EDC research requires specialists from various fields to work collaboratively to gain a better understanding of the sources, pathways and receptors involved as well as the timelines associated with the potential effects.

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Daston GP, Cook JC and Kavlock RJ (2003) Uncertainties for endocrine disrupters: Our view on progress. *Toxicol. Sci*. 74**:** 245–252.Fatoki OS, Bornman M, Ravandhalala L, Chimuka L, Genthe B and Adeniyi A (2010) Phthalate ester plasticizers in freshwater systems of Venda, South Africa and potential health effects. *Water SA* 36 (1): 117-126.

FACT SHEET 5 Are there targeted remedial actions for drinking water and environmental protection against EDCs?

The section relating to *Management strategies* in **Volume V** of the EDC Guideline Volume series brings in various strategies. These include the introduction of adaptive management, a naturally sensible framework within which learning can take place. Adaptive management is forward-looking, explicit in its purpose, inclusive, based on co-learning, realistic, action-oriented, flexible, and continually improving (Roux et al., 2010). Considering the inherent uncertainties associated with EDCs, adaptive management is seen as an appropriate framework.

An integrated water-quality management model (Boyd et al., 2011) is briefly described. The model is based on the premise that good water quality is in everyone's best interests and divides water management into smaller management units while establishing both a horizontal and vertical reporting framework. In addition, while ultimately focusing on raw- and drinking-water quality, the model is linked to land use and the impacts that the land-use activities may have on water quality.

Various non-regulatory options are introduced, including duty of care; self-regulatory options; incentive-based regulation; wastewater risk-abatement planning; support options; best management practices and the precautionary principle.

Risk management

The concept of risk is introduced bringing in the concepts of risk perception and acceptable risk. It is highlighted that perception of risk may be very different for different people. In the final analysis, regulatory authorities must respond to the way in which the citizens understand the nature and variety of risks in the environment, how they rank each type of risk in relation to others and how they expect public authorities to manage or control those risks. Where acceptable risk is based on the assumption that a small but non-zero probability of an untoward event of some sort occurring exists, below which level the general population is willing, implicitly or explicitly, to accept risk.

Effective risk management requires effective risk assessment: the identification of all potential hazards, their sources and hazardous events, as well as an assessment of the level of risk presented by each, and risk communication. A structured approach is important to ensure that significant issues are not overlooked and that areas of greatest risk are identified. In this respect it is necessary to undertake a pre-screening and prioritisation level assessment in order to prioritise areas of greatest risk for which more detailed assessment would then need to be undertaken. The four main steps proposed for the risk-assessment methodology are catchment characterisation, screening for potential EDC contamination, risk mitigation and risk prioritisation.

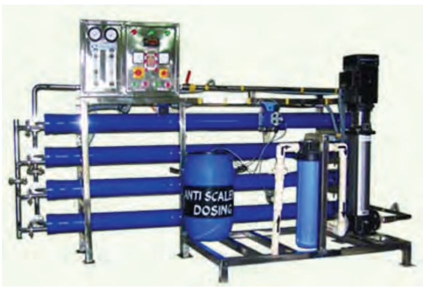
REFERENCES

Roux DJ, Murray K and Hill L (2010) A Learning Strategy Framework for Natural Resource Management Organisations. WRC Report No. TT 427/09. Water Research Commission, Pretoria, South Africa.

Boyd L, Tompkins R, Padayachee D, Malete O and Heath R (2011) Integrated Water Quality Management: A Mindset Change. Testing a Refined Conceptual Model. WRC Report No. TT 501/11. Water Research Commission, Pretoria, South Africa.

FACT SHEET 6 What are the recommendations on drinking water treatment?

For the treatment of potable water granular activated carbon (GAC) is the best available technology for the removal of all or many EDCs. However, other technologies such as coagulation/filtration and lime softening, used in the multistep process of treating water to potable quality, enhance its performance (Minnesota Wastewater Treatment Best Practices, 2011). When considering operating costs of granular activated carbon, these depend heavily on various issues such as: quantity and nature of organic compounds present in the raw water; the type of carbon employed; rate of carbon exhaustion; frequency and efficiency of regeneration; and process losses. Usually pilot-plant trials (lasting several months) have to be undertaken on the specific water source to be treated in order to estimate these variables. Even then, predicted operational parameters may differ significantly upon scale-up.



Reverse osmosis (RO) appears to be a viable treatment for the removal of most EDCs and pharmaceuticals and personal-care products (PPCP) in drinking water, except for neutral low-molecular-weight compounds. Reverse osmosis achieved >90% removal of natural steroid hormones in one study. A combination of reverse osmosis with nanofiltration can result in very efficient PPCP removal, including a wide range of pesticides, alkyl phthalates, and oestrogens (Minnesota Wastewater Treatment Best Practices, 2011).

Ozonation has been, in some cases, very effective in removing pharmaceuticals diclofenac and carbamazepine (>90%) and bezafibrate (50%). Clofibric acid was stable even at high ozone doses. Ethinyl estradiol and estradiol are expected to be completely transformed and nonylphenols have also been effectively removed. However, pairing ozonation with UV or H_2O_2 (peroxide, such as is done in advanced oxidation processes) may be required to achieve the most effective transformation of pollutants. For example, ozonation alone did not remove clofibric acid, but when pairing O_3 with H_2O_2, improved removal of clofibric acid and other compounds was achieved (Minnesota Wastewater Treatment Best Practices, 2011).

REFERENCES

Minnesota Wastewater Treatment Best Practices (2011) *The Minnesota Water Sustainability Framework – A Plan for Clean, Abundant Water for Today and Generations to Come.* Water Resources Center, University of Minnesota, US. URL: http://wrc.umn.edu/watersustainabilityframework/

FACT SHEET 7 What are the recommendations on domestic wastewater treatment?

Natural oestrogens have been noted to make up the majority of wastewater effluent oestrogenicity (Minnesota Wastewater Treatment Best Practices, 2011). Activated sludge processes have been shown to remove more than 77% and 90% of the natural oestrogen compounds, oestrone and estradiol across all biological field treatment types (Minnesota Wastewater Treatment Best Practices, 2011). Another study reports that activated sludge can consistently remove more than 85% of estradiol, oestriol, and ethinyl estradiol (synthetic oestrogen used for birth-control pills), while oestrone is more variable.

Estradiol removal efficiencies in a Canadian study of 16 WWTWs found estradiol removal rates to be in the order of 40% to 99%, and oestrone removal rates from net production of 98%. Nitrification has been correlated with successful oestrone and estradiol removal. Estradiol is noted to require similar conditions as those that result in nitrification.

In general, removal of oestrogenic activity is highly variable during conventional secondary treatment. Natural steroid estrogens degrade slowly (in order of rapidity: oestrone>estradiol>ethinyl estradiol, with complete removal of ethinyl estradiol taking up to a few days). Overall, some estradiol and oestrone are expected to persist following conventional activated sludge treatment, with relatively lower estradiol persistence (<10%). Cited studies show estradiol removal rates of 70%, 87%, 88%; oestrone rates of 74% and 61%; oestriol rates of 80% to 95%; and ethinyl estradiol rates of 30% to 85%. Assessment of natural oestrogen removal is complicated by the possibility that these compounds are being transformed among their different chemical forms inside the WWTWs.

WWTWs using activated sludge with nitrification/denitrification processes have been shown to have increased removal of EDCs and nitrate compared to WWTWs without nitrification/denitrification. Many studies have confirmed that more than 90% of oestrone, estradiol, and ethinyl estradiol will be removed from activated sludge treatment plants with nitrification/denitrification. Sludge age (same as solids retention time), hydraulic retention time, temperature, nitrification/denitrification, and phosphate elimination are thought to be factors affecting removal rates of contaminants in activated sludge systems.

Synthetic EDCs such as alkylphenols (non-ionic detergent surfactant additives and their stable breakdown products which can constitute up to 5% to 10% of dissolved organic carbon in the raw sewage) are less water-soluble and tend to accumulate more in sludge than the natural oestrogens. These chemicals tend to persist in anaerobic sludge environments, although subsequent land distribution may result in more than 90% degradation over a one- to three-month period.

In summary, overall removal rates of EDCs and PPCPs in conventional WWTWs with activated sludge vary significantly, and elimination is often incomplete. The more polar the molecule, the more likely it is to remain soluble in effluent. Activated sludge processes can result in high EDC removal, but are not likely to achieve concentrations below maximum allowable levels for some oestrogens, alkylphenols, or BPA (Minnesota Wastewater Treatment Best Practices, 2011).

REFERENCE

Minnesota Wastewater Treatment Best Practices (2011) *The Minnesota Water Sustainability Framework – A Plan for Clean, Abundant Water for Today and Generations to Come. Water Resource Center,* University of Minnesota, US. URL: http://wrc.umn.edu/watersustainabilityframework/

FACT SHEET 8 How should risk related to EDCs be communicated?

Simply stated, risk communication is the process of informing people about potential hazards to their person, property, or community. People under stress typically want to know that you care before they care about what you know. People under stress typically have difficulty hearing, understanding and remembering information; and risk communication is therefore central to informed decision-making (Covello and Allen, 1988).

Many of the obstacles to effective risk communication derive from the complexity, incompleteness and uncertainty of data. In addressing uncertainty, the following guidelines are useful:

- Acknowledge rather than hide uncertainty.
- Explain that risks are often hard to assess and estimate.
- Explain how the risk estimates were obtained and by whom.
- Announce problems and share risk information promptly, with appropriate reservations about uncertainty.
- Tell people that what you believe is either:
    1. certain
    2. nearly certain
    3. not known
    4. may never be known
    5. likely
    6. unlikely
    7. is highly improbable
- Tell them what can be done to reduce the uncertainty.
- Tell people that what you believe now may turn out to be wrong later.

In this respect some fundamental rules for effective risk communication are described (Covello and Allen, 1988):

- **Accept and involve** the receiver of risk information as a partner as people have the right to participate in decisions that affect their lives.
- **Plan and adapt** risk-communication strategies as different goals, stakeholders, and communication channels require different risk communication strategies.
- **Listen** to your stakeholders: people are usually more concerned about psychological factors, such as trust, credibility, control, voluntariness, dread, familiarity, uncertainty, ethics, responsiveness, fairness, caring and compassion, than about the technical details of a risk.
- **Be honest and open**, as trust and credibility are among the most valuable assets of a risk communicator.
- **Coordinate and collaborate** with other credible sources as communication about risks is enhanced when accompanied by referrals to credible, neutral sources of information. Few things hurt credibility more than conflicts and disagreements among information sources.
- **Plan for media influence**, as the media play a major role in disseminating risk information to the public. It is critical to know what messages the media deliver and to establish how to deliver risk messages effectively through the media.
- **Speak clearly and with compassion**, as technical language and slang are major barriers to effective risk communication. Abstract and unfeeling language often offends people. Acknowledging emotions, such as fear, anger, and helplessness are typically far more effective.

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Covello VT and Allen F (1988) Seven Cardinal Rules of Risk Communication. US Environmental Protection Agency, Office of Policy Analysis, Washington, DC.

FACT SHEET 9 What is the situation on EDCs in South Africa and where can further information on EDCs be obtained?

While assessment of EDCs in South Africa has been ongoing for many years, the actual situation within South Africa is far from known and considerable work is still needed to obtain a satisfactory picture of which EDCs can be found where, in what concentrations and what the impacts are on people and the environment. The need for accurate information is fundamental in guiding public health policy decisions and especially in communicating potential impacts to a community.

A number of EDCs have in fact been detected in South African surface water and effluent discharges. Significant oestrogenic activity has also been demonstrated in both surface waters and domestic or industrial effluent discharges through the use of *in vitro* and *in vivo* biological/biochemical techniques. The presence of EDCs and oestrogenic activity in sources of drinking water is therefore a matter of grave concern and poses the question of how effectively the potentially harmful chemicals are removed by conventional water-treatment methods. Owing to the wide structural diversity of EDCs, it is possible that more than a single treatment process will be required for their removal.

In a study undertaken by Burger and Nel in 2008 the results indicated that a large number of pesticides with known endocrine-disruptor properties were registered for use in all the water management areas (WMA) of the country. Considerable EDC focus has been on the Limpopo Province and especially the Luvuvhu/Letaba WMA where the pesticide, DDT, has been used annually in the control of malaria since 1945.

Various studies have noted that the following endocrine-disrupting compounds have been detected in South African water resources: pp-DDT, DDE, DDD, endosulfan, endrin, oestrone, oestriol, estradiol, EDM (endocrine-disrupting metals), phthalates, atrazine, p-nonylphenol (p-NP), DEHP, DBP, lindane, chlorpyrifos, polychlorinated biphenyls (PCBs), chlordanes and heptachlor. In most cases, however, the actual concentrations are not known, the reasons being that the analytical procedures to determine the concentrations are expensive and there are very few laboratories in South Africa that can undertake the requisite tests.

Further information can be obtained from:

- Water Research Commission: http://www.wrc.org.za/Pages/KnowledgeHub.aspx
- Endocrine Society: The Endocrine Society – Devoted to Hormone Research and the Clinical Practice of Endocrinology

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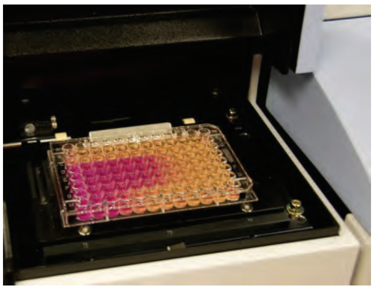
Burger AEC and Nel A (2008) Scoping Study to Determine the Potential Impact of Agricultural Chemical Substances (Pesticides) with Endocrine Disruptor Properties on the Water Resources of South Africa. WRC Report No. 1774/1/08. Water Research Commission, Pretoria, South Africa.

FACT SHEET 10 How do we test for EDCS?

EDCs include various types of natural and synthetic chemical compounds presenting the mimicking or inhibition of the reproductive action of the endocrine system in animals and humans. The ubiquitous presence with trace-level concentrations and the wide diversity are the reported characteristics of EDCs. Biologically based assays seem to be a promising method for the identification of EDCs. On the other hand, mass-based analytical methods show excellent sensitivity and precision for their quantification. Several extraction techniques for the instrumental analysis have been developed since they are crucial in determining overall analytical performances (Chang et al., 2009).



Analysis is dealt with in **Volume III: Bioassay Toolkit** of the EDC Guideline Volume series and includes bioassays, organics and inorganics all as separate chapters that can be easily removed and replaced should updates be made available.

The bioassay toolkit (De Jager et al., 2011) sets out various biological methods to assess the oestrogenicity of water including drinking water, ground water and wastewater. The following four biological methods are currently included:

- the recombinant yeast oestrogen screen (YES)
- the T47D-KBluc reporter gene assay
- E-screen assay for oestrogenicity
- fish VTG screen for oestrogenicity

The volume includes guidelines for chemical analysis of endocrine-disruptor chemicals in water resources, including:

- preparation of samples
- extraction and clean-up
- instrumental detection
- multi-residue methods
- enzyme-linked immunosorbent assay (ELISA) techniques
- calculations

Volume III also includes a section relating to determination of inorganic parameters, including sampling and laboratory procedures for inorganic compounds and interpretation of the results.

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