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REPUBLIC OF SOUTH AFRICA

DRAFT 3

Inventory of Endocrine Disrupting Compounds and Management Action Plans in South Africa



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	DOC NO:	MC_DEA_EDC_001	

TABLE OF CONTENTS

DOCUMENT IDENTIFICATION	i
LIST OF FIGURES	iv
LIST OF TABLES	v
LIST OF APPENDICES	vi
ABBREVIATIONS AND ACRONYMS	vii
1. PROJECT BACKGROUND	1
1.1. Aims and Objectives	2
1.2. Scope of Work	2
1.3. Assumptions and Limitations.....	4
2. ENDOCRINE DISRUPTING COMPOUNDS	5
2.1. Typical Exposure Pathway.....	6
2.2. State of Endocrine Disrupting Compounds in South Africa.....	9
3. STAKEHOLDER ANALYSIS.....	11
3.1. Stakeholder Participatory Platform.....	11
3.1.1. Regulatory entities and institutions across scales	13
3.1.2. Research and academic institutions.....	16
3.1.3. Production and packaging of EDCs	17
3.1.4. Consumptive sector	20
3.1.5. Waste management sector	25
4. LIFE CYCLE ANALYSIS AND PROCESSES, INCLUDING INVENTORIES AND ASSOCIATED COMPANIES	27
4.1. Introduction to Life Cycle Assessment	27
4.1.1. Goals and Scope definition of LCA for EDCs	28
4.1.2. The life cycle inventory phase.....	29
4.1.3. Impact Assessment for EDCs	29

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

4.1.4.	The results, interpretation and improvement phase.....	30
4.2.	Models and Approaches to EDCs' LCA.....	30
4.3.	New Approach to EDCs' LCA.....	31
4.4.	Prioritising and Decision making	32
4.4.1.	Step 1: Review of existing lists and other sources of information: Inventory Lists 35	
4.4.2.	Step 2: Selection of highly persistent and/or HPV substances	35
4.4.3.	Step 3: Preliminary evaluation of scientific evidence of endocrine-related effects. 35	
4.4.4.	Step 4: Preliminary evaluation of exposure to humans and wildlife	36
4.5.	LCA for the Prioritised EDCs.....	43
4.6.	Data collection strategy concerning stakeholders (companies) along the LCA.....	43
4.6.1.	The upstream sector (manufacturing)	43
4.6.2.	Midstream sector	43
4.6.3.	Downstream sector (consumption, disposal and waste management)	45
5.	REVIEW OF ENVIRONMENTALLY SOUND MANAGEMENT OF EDCS – LOCAL AND INTERNATIONAL EXPERIENCES AND BEST PRACTICES	46
5.1.	Introduction and Context.....	46
5.2.	Principles of sound management of EDCs.....	47
5.2.1.	Methods used for mapping and selection of sound management frameworks for analysis 48	
5.2.2.	Analysis of individual framework and general observations.....	49
5.3.	EDC management: International Experiences and best practices	60
5.3.1.	Europe / European Union.....	60
5.3.2.	North America.....	64
5.3.3.	South America	70
5.3.4.	Asia	71
5.3.5.	Oceania	74

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

5.4.	Guidelines towards sound management of EDCs within the Lice Cycle	75
5.4.1.	Guidelines for Upstream Users	76
5.4.2.	Guidelines for Midstream and supply chain.....	78
5.4.1.	Guidelines for downstream users.....	80
5.4.2.	Cross-section management strategies for EDCs.....	81
5.5.	The South Africa Legislative Framework for EDC Management.....	84
5.5.1.	Contextualised analysis of the identified management strategy	85
5.5.2.	Opportunities for policy and legislative reform in South Africa: A roadmap for systematic assessment and management of EDCs	86
5.5.3.	Alternatives: Chemical hazard assessment.....	88
6.	IDENTIFICATION AND MAPPING OF SITES POSSIBLY CONTAMINATED BY EPPPS IN SOUTH AFRICA	94
7.	ALTERNATIVES	95
8.	TRADE AND SOCIO-ECONOMIC CONSIDERATIONS.....	96
9.	ENVIRONMENTALLY SOUND MANAGEMENT INSTRUMENTS, STRATEGIES AND APPROACHES – INCLUDING RISK REDUCTION.....	97
10.	REFERENCES.....	98

LIST OF FIGURES

Figure 2-1: Sources of Endocrine Disrupting Compounds.....	6
Figure 2-2: Fate of Endocrine Disrupting Compounds in the environment.....	7
Figure 3-1: Life-cycle representation of Stakeholders of Endocrine Disrupting Compounds	12
Figure 4-1: Life Cycle Assessment framework as per ISO 14040 Guidelines	28
Figure 4-2: Key parameters in chemical exposure	32
Figure 4-3: Showing the four steps presented schematically.....	34
Figure 5-1: Overview of the different frameworks across three main regulatory domains that are expected to involve EDCs.	49
Figure 5-2: Illustration of the approval process of active substances including required data as outlined in the Biocidal Product Regulation ((EU) No. 283/2013).....	63

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Figure 5-3: Regulatory framework for the registration and assessment of chemical substances under K-REACH.....	73
Figure 5-4: Upstream compliance with environmental requirements by colour-gold, green, blue, red, or black—based on stated performance criteria. Gold and green facilities earn public praise. Blue facilities are just meeting regulatory criteria. Red and black facilities face both public pressure for compliance and legal enforcement.....	77
Figure 5-5: Simplified illustration of the role of distributors in a supply chain (DU; Downstream User).....	79
Figure 5-6: Schematic presentation of potential uses of a substance at different life cycle stages. The downstream user uses are marked with “(DU)”.....	80
Figure 5-7: Illustrative framework of chemical hazard assessments showing logical decision making process on whether to keep, substitute, or manage the chemical.	90
Figure 5-8: Chemical Alternatives Assessment Protocol	93

LIST OF TABLES

Table 2-1: Categories of known or potential Endocrine Disrupting Chemicals.....	5
Table 3-1: Regulatory entities relevant for the regulation of EDCs	13
Table 3-2: Academic and research institutions.....	17
Table 3-3: Production, manufacturing and packaging sector.....	18
Table 3-4: Consumptive sector	20
Table 3-5: Waste management sector	25
Table 4-1: Steps followed in the selection of the prioritised EDCs.....	33
Table 4-2: Priority LCA List for EDCs.....	38
Table 4-3: Companies/stakeholders within the manufacturing sector surveyed for data collection.....	43
Table 4-4: Companies/stakeholders within the distribution, transportation and storage sectors surveyed for data collection.....	44
Table 4-5: Stakeholders within the downstream sector surveyed for data collection.....	45
Table 5-1: Descriptors used in the analysis of EDC management frameworks.....	49
Table 5-2: Overview of the analysed explicit sound management frameworks and policy initiatives discussed in this report.....	51
Table 5-3: Policy instruments provided by CEPA for the risk management of substances. .	68
Table 5-4: Testing guidelines included in the Chinese industry standard NY/T2873-15 “Evaluation Methods of the Endocrine Disruption Effects of Pesticides”.....	72

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	
	DOC NO:	MC_DEA_EDC_001	

Table 5-5: The 5-colour code rating system utilise in Program for Pollution Control, Evaluation and Rating 76

LIST OF APPENDICES

Appendix A: Table of Chemicals including Common Names, Abbreviations, Chemical Abstract System Numbers (Cas #) as well as Class of Compound and/or Major Use 107

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department of Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

ABBREVIATIONS AND ACRONYMS

ACRONYM	DESCRIPTION
AICS	Australian Inventory of Chemicals Substances
BPR	Biocidal Products Regulation
CAS	Chemicals Abstracts Service
CEPA	Canadian Environmental Protection Act
CMR	Carcinogenic, Mutagenic, and Reprotoxic
CoRAP	Community Rolling Action Plan
CSIR	Council for Scientific and Industrial Research
DEA	Department of Environmental Affairs
DSL	Domestic Substances List
EC	European Commission
ECHA	European Chemicals Agency
EDC	Endocrine Disrupting Compound
EDSP	Endocrine Disruptor Screening Program
EEA	European Economic Area
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EPA	Environmental Protection Agency
EQS	Environmental Quality Standards
EU	European Union
EXTEND	Extended Tasks on Endocrine Disruption
FD&C	Food, Drug and Cosmetic
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
ICCM	International Conference on Chemicals Management
IMAP	Integrated Multi-tiered Assessment and Prioritisation
IOMC	Inter-Organization Programme for the Sound Management of Chemicals
IPCP	International Panel on Chemical Pollution
IPCS	International Programme on Chemical Safety
K-REACH	South Korean Regulation on the Registration and Evaluation of Chemicals
MCLG	Maximum Contaminant Level Goal

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

MLC	Maximum Level of Contaminants
MoE	Ministry of Environment.
NAP	National Action Plan
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NIEHS	National Institute of Environmental Health Sciences
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative, and Toxic
PGM	platinum-group metals
POP	Persistent Organic Pollutants
PPPR	Plant Protection Products Regulation
PSC	Project Steering Committee
QSAR	Quantitative Structure-Activity Relationship
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
SAICM	Strategic Approach to International Chemicals Management
SDWA	Safe Drinking Water Act
SEAC	Committee for Socio-Economic Analysis
SPEED	Strategic Programs on Environmental Endocrine Disruptors
SVHC	Substance of Very High Concern
ToA	Terms of Agreement
UN	United Nations
UNEA	United Nations Environment Assembly
UNEP	United Nations Environment Programme
US	United States
WFD	Water Framework Directive
WHO	World Health Organization
WRC	Water Research Commission
WWTW	Wastewater treatment works

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

1. PROJECT BACKGROUND

Endocrine Disrupting Compound¹ (EDCs) is 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. Potential EDCs are mostly man-made and only a small fraction of these chemicals is known and have been investigated in tests capable of identifying overt endocrine effects in intact organisms. EDCs are found in various materials such as pesticides, metals, additives or contaminants in food, and personal care products.

Throughout the world there is growing concern about the negative effects that EDCs may have on humans as well as on wildlife. The most challenging aspect of this problem is discovering how to eliminate these compounds from the environment and where to focus remediation efforts. According to Water Research Commission (WRC Report No. TT 742/2/17 of March 2018), emerging contaminants, such as EDCs, and their metabolites may pass through conventional wastewater treatment systems without removal and accumulate in various environmental compartments, e.g. in potable water supplies. Additional problem includes the potential for biomagnification of the EDCs throughout the food chains. Biomagnification means that the relative concentrations of EDCs increase with increasing level at the food chain, placing animals at the top of the food chain at most risk from toxic effects. This includes humans and problematic in this regard, is the uncertainty over the magnitude of risk of human and wildlife exposure to emerging contaminants of concern in treated wastewater. Air transport for EDCs has been reported international and more information is needed about this, and other transport mechanisms of EDCs environmental fate, under conditions in South Africa.

South Africa has a Constitutional mandate of ensuring an environment that is not harmful to the health and well-being of all South Africans (The Bill of Rights, 1996). As part of its modus operandi in fulfilling this constitutional mandate, the Department of Environmental Affairs (DEA) plans to develop a national inventory database of EDCs as well as associated action plans for the sound management of EDCs in South Africa. This is of critical importance for the long-term protection of human and environmental health.

¹ Also referred to as Endocrine Disrupting Chemical.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

1.1. Aims and Objectives

The primary aim of this project is to develop a national inventory of EDCs and action plans for the sound management of EDCs in South Africa. The objectives are to:

- i. Develop South African EDCs inventory and develop Environmental Risk Management action plan in South Africa;
- ii. Collect data on the life cycle information and environmental management practices (i.e. the production, prevalence, quantities, uses/applications, sources, imports, exports, packaging, waste, treatment, recycling, disposal methods, etc.);
- iii. Identify and recommend safer, affordable, accessible, technologically relevant, and environmentally sound alternatives for those EDCs that have already been identified as emerging contaminants under United Nations Environment Assembly (UNEA) and Strategic Approach to International Chemicals Management (SAICM);
- iv. Develop a framework to characterize, diagnose, and predict ecological and human exposure to EDCs; and
- v. Recommend management instrument(s) for EDCs.

1.2. Scope of Work

The scope of work is outlined below:

1. Develop a list of the chemical companies, as well as attempt to estimate the extent of the influence of unregistered operators, within the chemicals Industry that contribute to the environmental burden from EDCs in South Africa. The list will comprise of:
 - i. Company name, Producer name, exporter's and importer's name;
 - ii. Name of the producer or importer and the location of the company (city and province);
 - iii. Chemical name, trade names, common names, custom tariff codes;
 - iv. The usage or the application of the chemical and hazard properties;
 - v. The usage or the application of the chemical; and
 - vi. Toxicity and possible environment and human health impacts;
2. Collect and collate data, publications and information on identified EDCs in South Africa to formulate an informed policy position.
 - i. Collection of data on volumes used and frequency of application;
 - ii. Identify a list of EDCs used in the country;
 - iii. Identify EDCs used in various applications;

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

- iv. Identify EDC sources and possible hot-spots (highly contaminated areas);
 - v. Identify sites contaminated by EDCs;
 - vi. Identify sources and modes of contamination;
 - vii. List possible articles that we may find EDCs;
 - viii. Identify available storage, treatment and disposal facilities the country has, and needs to have for the environmentally sound management of stocks, stockpiles, hazardous waste, and contaminated equipment; and
 - ix. Develop a recommendations and strategies for managing EDCs including contaminated sites, and a remediation plan.
3. Develop risk management approaches to reduce or eliminate environmental exposures to EDCs.
 4. Identify Alternatives: Identify and recommend alternatives that are:
 - Safer;
 - Affordable;
 - Effective;
 - Accessible; and
 - Technologically relevant.
 5. Develop management instrument(s) for environmentally sound management of EDCs, such as the National Action Plan.
 6. Identify alternatives that are safer, affordable, effective, accessible, technologically relevant, and environmentally sound for those chemicals that have already been identified as emerging contaminants under UNEA and SAICM.
 - The identification of alternatives should be done taking into consideration the different industrial processes, the possible socio-economic impacts of introducing such alternatives in such processes, and South Africa's status as a middle-income country which is facing developmental challenges.
 7. Develop baseline information of EDCs in various environmental mediums.
 - i. Locally manufactured quantities on emerging contaminants and identified alternatives;
 - ii. Formulated quantities on emerging contaminants and identified alternatives;
 - iii. Import quantities on emerging contaminants and identified alternatives;
 - iv. Exported quantities on emerging contaminants and identified alternatives;
 - v. Trading partners (country) in this regard;
 - vi. Status of the chemicals (restricted, banned, etc.) in the country of origin;

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

- vii. Impact on the industrial processes should a shift to using identified alternatives be made; and
- viii. Jobs possibly affected should a shift to using identified alternatives be made.

1.3. Assumptions and Limitations

Much of the information regarding the project and quantitative data relating to EDCs on which the deliverables will be based are to be sourced from identified stakeholders, academic resources and publications, and the public domain. While every effort will be made to verify the information / data obtained, it is however assumed that all externally sourced information / data are valid and citations of sourced information / data will be provided.

The deliverables will be subject to the following additional assumptions and limitations:

- Not all identified facilities associated with EDCs will be visited. As such, all project-specific data will be based primarily on those supplied by stakeholders as well as those obtained from both academic and grey literature, and will be assumed to be accurate;
- Estimates will be provided on expected environmental quantities of EDCs including its presence in processes, wastes and effluent streams;
- The authors assume no responsibility or liability for errors in the public data utilized, information provided by the stakeholder, or statements from other external sources, or developments resulting from situations outside the scope of this project. The authors make no warranties, expressed or implied, including, without limitation, as to merchantability or fitness for a particular purpose;
- All conclusions and recommendations made represent the professional opinions of the technical experts involved with the Project, and the results of this report should not be considered a legal interpretation of existing regulations; and
- All data and information provided are assumed to be accurate and up to date.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

2. ENDOCRINE DISRUPTING COMPOUNDS

According to the United States' National Institute of Environmental Health Sciences (NIEHS), endocrine disruptors typically interfere with endocrine (or hormone) systems at certain doses. Any system in the body controlled by hormones can be derailed by hormone disruptors. These disruptions are known to cause a number of human health issues such as cancerous tumors, birth defects, and other developmental disorders (NIEHS, 2013). Specifically, endocrine disruptors may be associated with the development of learning disabilities, severe attention deficit disorder, cognitive and brain development problems; deformations of the body (including limbs); breast cancer, prostate cancer, thyroid and other cancers; sexual development problems such as feminizing of males or masculinizing effects on females, etc (Sanders, R.,2010).

A wide and varied range of substances are thought to cause endocrine disruption. Chemicals that are known endocrine disruptors can be grouped in multiple ways. As shown in **Table 2-1** known or potential EDCs are grouped into 11 categories with examples of individual EDCs provided. Chemicals that are of specific interest as EDCs are bolded.

Table 2-1: Categories of known or potential Endocrine Disrupting Chemicals

CLASSIFICATIONS	SPECIFIC EXAMPLES OF EDCS
<i>Persistent and bioaccumulative halogenated chemicals</i>	
Persistent Organic Pollutants (POPs) (Stockholm Convention)	PCDDs/PCDFs, PCBs , HCB, PFOS , PBDEs , PBBs, Chlordane, Mirex, Toxaphene, DDT/DDE , Lindane, Endosulfan
Other Persistent and Bioaccumulative Chemicals	HBCDD , SCCP, PFCAs (e.g. PFOA), Octachlorostyrene, PCB methyl sulfones
<i>Less persistent and less bioaccumulative chemicals</i>	
Plasticizers and Other Additives in Materials and Goods	Phthalate esters (DEHP , BBP, DBP, DiNP), Triphenyl phosphate, Bis(2-ethylhexyl) adipate, n-Butylbenzene, Triclocarban, Butylated hydroxyanisole.
Polycyclic Aromatic Chemicals (PACs) including PAHs	Benzo(a)pyrene , Benzo(a)anthracene, Pyrene, Anthracene
Halogenated Phenolic Chemicals (HPCs)	2,4-Dichlorophenol, Pentachlorophenol, Hydroxy-PCBs, Hydroxy- PBDEs, Tetrabromobisphenol A, 2,4,6-Tribromophenol, Triclosan
Non-halogenated Phenolic Chemicals (Non-HPCs)	Bisphenol A , Bisphenol F, Bisphenol S, Nonylphenol, Octylphenol, Resorcinol
<i>Pesticides, pharmaceuticals and personal care product ingredients</i>	
Current-use Pesticides	2,4-D, Atrazine , Carbaryl, Malathion, Mancozeb, Vinclozolin , Prochloraz, Procymidone, Chlorpyrifos, Fenitrothion, Linuron

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	DOC NO:	MC_DEA_EDC_001	

CLASSIFICATIONS	SPECIFIC EXAMPLES OF EDCS
Pharmaceuticals, Growth Promoters, and Personal Care Product Ingredients	Endocrine active (e.g. Diethylstilbestrol, Ethinylestradiol, Tamoxifen, Levonorgestrel), Selective serotonin reuptake inhibitors (SSRIs; e.g. Fluoxetine), Flutamide, 4-ethylbenzylidene camphor, Octyl-methoxycinnamate, Parabens, Cyclic methyl siloxanes (D4, D5, D6), Galaxolide, 3-Benzylidene camphor
<i>Other chemicals</i>	
Metals and Organometallic Chemicals	Arsenic, Cadmium, Lead, Mercury, Methylmercury Tributyltin, Triphenyltin
Natural Hormones	17 β -Estradiol, Estrone, Testosterone
Phytoestrogens	Isoflavones (e.g. Genistein, Daidzein), Coumestans (e.g. Coumestrol), Mycotoxins (e.g. Zearalenone), Prenylflavonoids (e.g. 8-prenylnaringenin)

Source: IOMC, 2012. Refer to **Appendix A** for full names and abbreviations of the chemicals mentioned.

2.1. Typical Exposure Pathway

Over the past decade, understanding of the types of chemicals that may be endocrine disruptors and on how humans and wildlife are exposed to them has increased dramatically. A larger number of chemicals belonging to diverse classes are now identified as EDCs, and they include additives in materials and consumer goods (pharmaceuticals, personal care products, electronics, food packaging, clothing, etc.), metals, and current-use pesticides (Figure 2-1).



Figure 2-1: Sources of Endocrine Disrupting Compounds

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

These chemicals come from a variety of sources, enter the environment during production, use or disposal of chemicals or products, and have a range of behaviours in the environment (IOMC, 2012). A typical exposure pathway is represented schematically in **Figure 2-2** and described below and triclosan, a halogenated phenolic chemical with a broad-spectrum antimicrobial action (Schweizer, 2001), is selected here to showcase a typical exposure pathway to EDCs (for other examples of EDCs refer to **Table 2-1**).

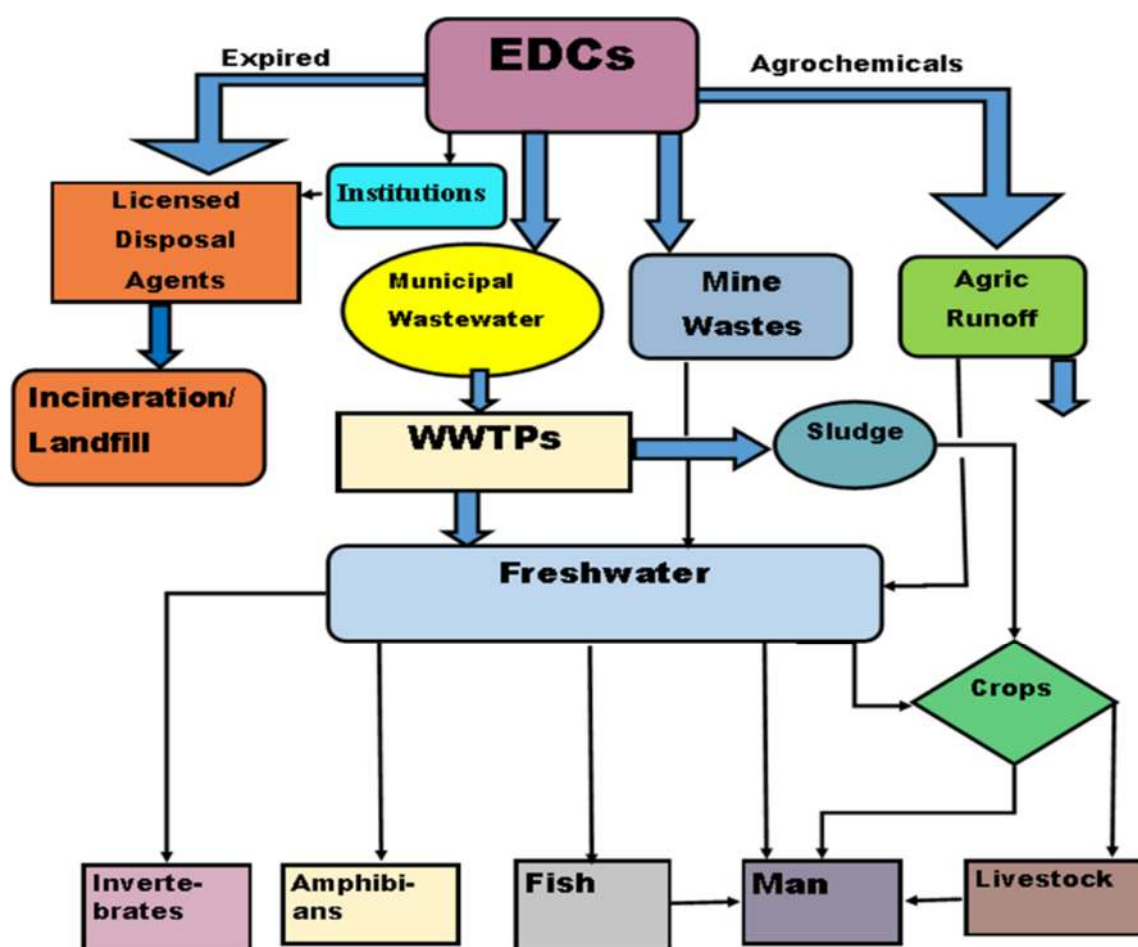


Figure 2-2: Fate of Endocrine Disrupting Compounds in the environment

Origin and application:

Triclosan is an everyday chemical and an active ingredient used in the manufacturing of a variety of health care and consumer products such as kitchen utensils, toys, bedding, socks, trash bags, soaps, shampoos and toothpaste. Triclosan has also been intensively used in improving environmental hygiene (Wu et al., 2007).

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Environmental prevalence:

Triclosan enters the natural environment when products containing the chemical are disposed on landfill and when it is washed down the drain into the municipal reticulation sewer system. Wastewater treatment works (WWTW) are not effective in the removal of triclosan and as such, the chemical is retained in sewage sludge, which are usually disposed at landfill sites (and in some instances used as organic fertilisers and for brick making) and discharged along with treated effluent into receiving water bodies contributing to the widespread occurrence of triclosan in surface waters (Wu et al., 2007). The chlorination of effluents from WWTW leads to formation of chlorinated triclosan products that are photochemically transformed to tri- and tetra-chlorinated dioxins when discharged into natural waters (Buth et al., 2011).

In the natural environment, triclosan binds readily to soils and its evaporation is limited. In aquatic environments, triclosan attaches mainly to the surface of suspended solids and sediments from where it bioaccumulates in organisms. It has also been reported that aerobic biodegradation is one of the major and most efficient biotransformation pathways for triclosan, where microbial methylation leads to the formation of more lipophilic methyl triclosan with a higher bioaccumulation potential (Lindstrom et al., 2002).

Effects:

Laboratory studies and epidemiological evidence documenting the effect of triclosan are limited. Some documented evidence is reported here:

- Triclosan has been linked to the disruption of steroidogenic enzymes, which is involved in the production of testosterone and estrogen, leading to reduced reproductive success in both males and females, respectively (Gee et al., 2008 and Dinwiddie et al., 2014).
- Triclosan has been detected in human breast milk, which raise health concerns regarding breast cancer development. The presence of triclosan in human breast milk shows how effectively the compound is absorbed by the human body (Ayoola Saheed A, 2012).
- According to Pancetti and Galán, (2001) the constant use of products or antiseptics containing triclosan, contributes to the development of antibiotic resistance in humans, and the release of triclosan into the environment will not only cause mutations which will lead to antibiotic resistance, but will also decrease the concentrations of the normal flora in the environment.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

2.2. State of Endocrine Disrupting Compounds in South Africa

Endocrine disruptors have been studied in South Africa only in the last 15 years or so. As evident in section 2.1 above, the release of EDCs into the environment occurs daily through everyday activities, e.g. use of everyday items such as soaps that contain endocrine disruptors such as Triclosan, which ends up in environmental waters because existing WWTWs are not capable or equipped to remove these compounds. Recent research indicates that steroid hormones and xeno-estrogens are prevalent in South African environment (Burger, 2010). These compounds have been shown to assert eco-toxicological response in various parts of the food chains throughout South Africa (Truter, 2016).

Management efforts in safeguarding the natural environment are summarised below:

- South Africa adopted the South African National Profile 2002-2005: A comprehensive assessment of the national infrastructure relating to the legal, administrative and technical aspects of chemicals management in South Africa and has been a party to SAICM since the respective international summit in Johannesburg in 2002.
- The National Environmental Management Act of 2008 and Waste Management legislation, requiring adherence, are well established and has laid the foundation for further advancement in the management of EDCs.
- There have been efforts to monitor selected EDCs such as DDT in the Gauteng Province of South Africa (Mahomed et al., 2008). This monitoring programme was supported/run in conjunction with the Department of Health. The Water Research Commission of South Africa has launched a monitoring programme on EDCs in South Africa, with aims similar to those in this project (Burger, 2010). However, the practical impact of this programme/initiative must still be evaluated. In addition, more monitoring and management efforts targeting EDCs are however required and more trained personnel are needed to conduct the monitoring country-wide.
- Various research efforts have been underway in public universities, the Council for Scientific and Industrial Research (CSIR) and other research institutions on the elimination of the EDCs. Examples of such research include electrochemical degradation, biological treatment and the use of nanotechnology in the elimination of EDCs from the environment.
- Many EDCs are hydrophobic in nature and therefore get sorbed onto particulate matter. This has implications on the elimination mechanisms in the WWTW, e.g. by sorption on particles of activated sludge. The accumulation of EDCs and other

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

hydrophobic contaminants poses problems with sludge management and reuse. At the same time, there is potential for environmental mobilization from sludge during rain, due to atmospheric influences.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

3. STAKEHOLDER ANALYSIS

The primary aim of this project is to develop a national inventory of EDCs and action plans for the sound management of EDCs in South Africa. A variety of stakeholders operate across the chemical value chain and contribute toward EDCs production and management thereof. This section of the report provides an analysis of the identified stakeholder and a postulated participatory platform. A preliminary list of key stakeholders involved in the EDCs chain of custody is presented and analysed in terms of EDCs life-cycles, indicating their role along the chain of custody either from cradle to cradle or from cradle to grave. It is intended that a national platform enabling effective stakeholder participation and dialogue would be created. Such a platform is critical as it enable participatory governance of EDCs in South Africa, preparing stakeholders for rapid uptake of any future government policy, strategy and perspectives. The approach to the creation of the platform is detailed and described.

3.1. Stakeholder Participatory Platform

To present a systematic and thorough analysis and reflection of critical stakeholders relevant to EDCs in South Africa, a life-cycle approach is adopted. Stakeholders are mapped onto each stage of the generic life-cycle of EDCs (**Figure 3-1**), taking account of EDCs' cradle-to-grave life span. As can be seen in the life-cycle of EDCs, at each stage, critical stakeholders can be identified. It is important at this stage to stress that there are entities that have overlapping roles and functions. For example, local municipalities are responsible for waste stream regulation through by-laws within their jurisdiction, but they are also primarily responsible for waste collection, treatment and disposal. Following the life-cycle approach, stakeholders are thus organised into the following thematic/sector areas:

- Regulatory entities and institutions across scales;
- Research and academic institutions - Knowledge production sector including universities, research councils, relevant non-government organisation (NGO) and non-for-profit organisation (NPO);
- Manufacturing/Production and packaging;
- Consumptive sector; and
- Waste management sector.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Engagement with these group of stakeholders is important due to the following, but not limited to:

- Provide independent perspective on the pressing issues and priority EDCs in South Africa;
- Raise the awareness on the hot-spots for any suspected EDC contamination in South Africa;
- Legislative challenges in the scope of EDC management in South Africa;
- Information from this group of stakeholders will add to the information foundation for the modeling of the fate of EDCs in the environment;
- End users' feedback on EDCs;
- Engagement with NGOs and NPOs provides an indication on the use of indigenous knowledge and guidance on alternative strategies for, e.g. fertilizers as EDC replacements;
- Research and Development (R&D); and
- Practical challenges in the EDC waste and wastewater treatment facilities/practices.

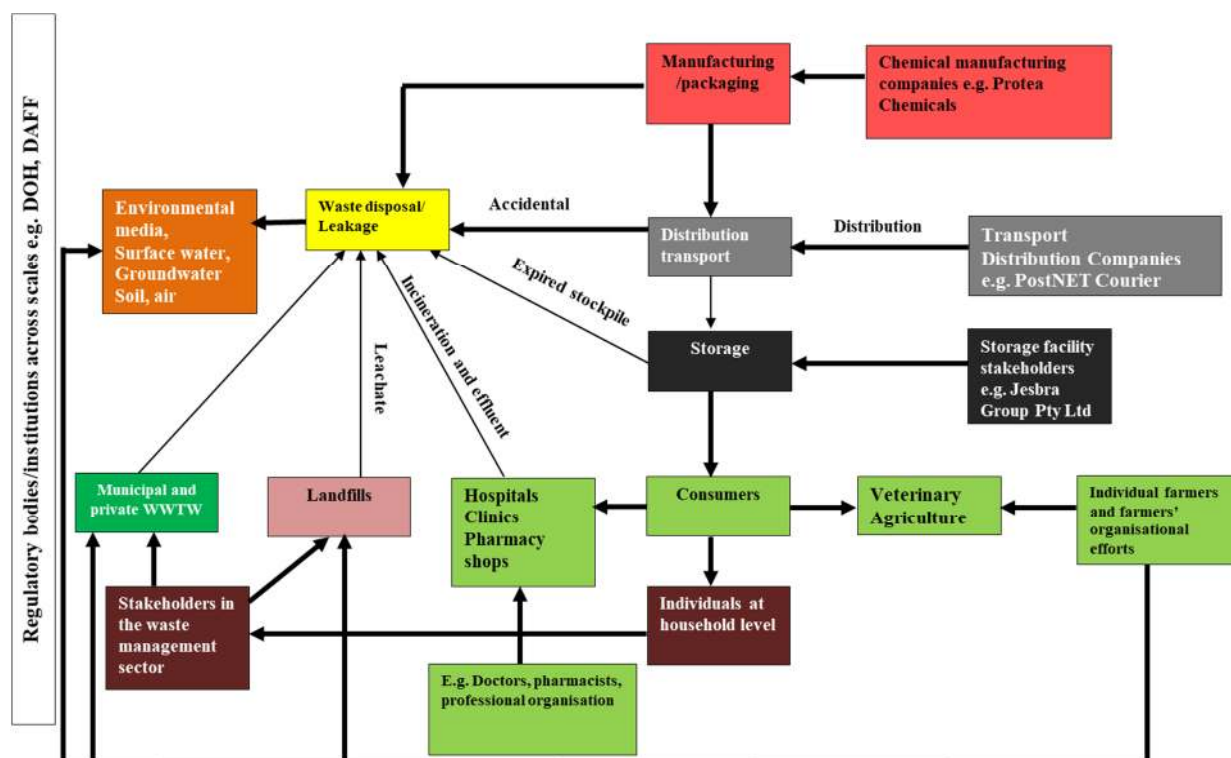


Figure 3-1: Life-cycle representation of Stakeholders of Endocrine Disrupting Compounds

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

The life-cycle from cradle-to-grave is completed by the listing of the consumers of EDCs, regulatory agencies, transporters and storage facilities, as well as disposal mechanisms through wastewater treatment works (WWTW) and the incineration to name but a few. Professional stakeholders will include the users of EDCs who are applying these chemicals in the scope of their professional activities, *e.g.* mining engineers and operators in metal refineries for the production of platinum and related platinum-group metals (PGMs). Producers and consumers will have a major influence on the type of the EDCs that are produced/used in South Africa. This will govern the class of EDCs that are likely to become environmental pollutants in South Africa. At the same time, the nature of the EDCs as environmental pollutants will have a strong influence on the environmental compartment(s), which are most at risk of contamination with particular EDCs. This in turn will control the routes of human exposure, *e.g.* air vs. water, and have a critical impact on the stages of the food chain the ecosystem that will be most impacted by the particular EDCs in South Africa. To further analyse **Figure 3-1**, preliminary lists of key stakeholders are presented in **Table 3-1** to **Table 3-5**.

3.1.1. Regulatory entities and institutions across scales

The primary purpose of stakeholders in this category is regulation of EDCs across the life-cycle described above. Stakeholders in this category play very critical role, ensuring that EDCs are manufactured, transported, distributed, stored, used and disposed of according to set standards and guidelines. These entities may operate at the national (government departments) and International level to which South Africa subscribes, *e.g.* the UNEA and the SAICM. **Table 3-1** below provides a summary of critical stakeholders in this category.

Table 3-1: Regulatory entities relevant for the regulation of EDCs

DEPARTMENT	COMMENT	CONTACT
National entities		
Government Departments are responsible for industries and environmental regulations and development of policies to ensure proper management and use of products containing EDCs within industries and the environment at large.		
Department of Agriculture, Forestry and Fisheries	Policy norms and standards for many EDCs, <i>e.g.</i> pesticides and growth promoters. Critical in this instance are the approved EDCs for use in South Africa, the route of application/administration of the respective pesticides, etc.	Directorate Plant Health Private Bag X14, Gezina, 0031 Division: Policy Norms and Standards Tel: 012 319 6164/012 319 6116 Fax: 012 319 6025

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

DEPARTMENT	COMMENT	CONTACT
Department of Health	The Department of Health regulates human health standards and the treatment of negative health outcomes of exposure to EDCs. The link between human and environmental health/pollution from various classes of EDCs will have to be applied in the context of the human toxicity and ecotoxicological impacts of EDCs. The Department of Health is thus relevant in terms of EDC toxicity in human and the prevention of human exposure.	Postal address: Private Bag X828, Pretoria, 0001 Tel: 012 395 8086 Fax: 012 395 9165
Department of Transport	This Department set regulations for transport of goods including those containing EDCs. The regulations set by the department includes those of the certification of drivers, allowed to transport EDCs, the specification of the transport vehicles involved in the transport of EDCs.	Switchboard Tel: 012 309 3000 E-mail: info@dot.gov.za Information Centre / Helpdesk Tel: 012 309 3657 / 3774 E-mail: info@dot.gov.za
Department of Environmental Affairs	Chemical and waste management is a key function of this department. In addition, the department is of the custodian of various waste management databases that are of relevance to EDC wastes produced in South Africa.	Chief Directorate: Chemicals and Waste Management Tel: +27 12 399 9759 Chief Directorate: General Waste and Municipal Support Tel: +27 12 399 9407 Chief Directorate - Hazardous Waste Management & Licensing Tel: +27 399 8993 Chief Directorate - Chemicals and Waste Policy Evaluation and Monitoring Tel: +27 12 399 9825 Chief Directorate - Chemicals Management: Tel: +27 12 399 9843 Chief Directorate - Chemicals Management Tel: +27 12 399 9843
Department of Trade and Industry	This department will play a critical role in the regulation of the ecosystem in which the chemical industries and importers and exporters of the EDCs products such as fertilisers.	Deputy Directors General: Mr Riaan le Roux (Acting: Trade and Investment South Africa) Ms Malebo Mabitje-Thompson (Industrial Development and Administration Division) Ms Xolelwa Mlumbi (International Trade and Economic Development Division)

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

DEPARTMENT	COMMENT	CONTACT
Department of Human settlements, Water and Sanitation	The department develop regulations, policies, strategies, standards and norms for the protection of South Africa's water resources, ensuring drinking water quality, wastewater effluent regulations and management. The department holds the responsibility of ensuring that EDCs in effluent discharge into receiving environment are within prescribed limits and that potable water is of prescribed quality.	National: 185 Francis Baard Street, Pretoria Tel: 012 336 7908 Eastern Cape: Private Bag X7485 King William's Town 5600 Tel: (043) 604 5400 Fax: (043) 642 6032 Free State PO Box 528 Bloemfontein 9300 Tel: (051) 405 9000 Fax: (051) 430 8146 Gauteng Private Bag X995 Pretoria. 0001 Tel: (012) 392 1300 Fax: (086) 274 3717 Kwazulu-Natal PO Box 1018 Durban. 4000 Tel: (031) 336 2700 Fax: (031) 336 2849 Mpumalanga Private Bag X11259 Nelspruit. 1200 Tel: (013) 759 7300 Fax: (013) 759 7525 North West Private Bag X5 Mmabatho. 2735 Tel: (018) 387 9500 Northern Cape Private Bag X6101 Kimberley. 8300 Tel: (053) 830 8800/6 7600 Fax: (053) 836 7692

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

DEPARTMENT	COMMENT	CONTACT
		Limpopo Private Bag X9506 Polokwane. 0700 Tel: (015) 290 1200 Fax: (015) 295 2295 Western Cape Private Bag X16 Sanlamhof. 7532 Tel: (021) 941 6000 Fax: (021) 941 6100
International entities International organisations to which South Africa is a signatory and bound to adhere to its guiding principles and standards within the international community.		
UNEA	The UNEA is the world's highest-level decision-making body on the environment. It enjoys the universal membership of all 193 UN Member States and the full involvement of major groups and stakeholders in the protection of the natural environment.	http://web.unep.org/environmentassembly/un-environment-assembly-and-governing-council
SAICM	SAICM is a global policy framework to foster the sound management of chemicals. SAICM strategic approach and scope include (i) environmental, economic, social, health and labour aspects of chemical safety, and (ii) agricultural and industrial chemicals, with a view to promoting sustainable development and covering chemicals at all stages of their life-cycle, including in products.	http://www.saicm.org/

3.1.2. Research and academic institutions

Research and academic institutions including universities, research councils/institutes, relevant NGOs and NPOs. As South Africa aims to develop a management action plan and policy direction for the effective regulation and management of EDCs in the environment, the success of such policies would depend largely on the repository of knowledge on EDCs in South African environment in terms of their occurrence, effects, toxicity, fate, sources, transport, degradation etc. As such, stakeholders within the knowledge production field are of critical relevance. Important stakeholders that would need to be consulted in this regard would

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

be universities, relevant research councils, institutes, and research-oriented NGOs and NPOs. **Table 3-2** provide a summary of some of the stakeholders identified as critical in this regard and are typically, those involved in EDC research.

Table 3-2: Academic and research institutions

INSTITUTION	COMMENT	CONTACT
Research and development institutions including Universities and other learning institutions are repositories of knowledge. They are responsible for industrial development and environmental management technologies and innovations to ensure proper management and use of products containing EDCs within industries and the environment at large.		
Nelson Mandela University	Targeted institutions will include those with research focus on environmental toxicology, specifically on EDCs. Data base research include Google/Google Scholar, SCOPUS and ISI Web of Science. Keywords: endocrine disruptors, hydrophobicity, pKa, amphiphilicity, sorption, xeno-oestrogens.	Address: University Way, Port Elizabeth, 6031, South Africa Tel: +27 41 504 3364
University of Pretoria		Address: Pretoria, South Africa Tel: +27 12 420 4111
Stellenbosch University		Stellenbosch, South Africa Tel: +27 21 808 9111
Grootfontein Agricultural Development Institute		Director, G A D I, Private Bag X529 Middelburg, Eastern Cape, 5900 Tel: +27 (0)49 802 6600
Rhodes University		Grahamstown 6140 Tel: +27466038381
Agricultural Research Council	EDCs in the agricultural sector and relevant ongoing development of new EDCs and specifically on the novel pesticides and the application strategies that are being tested throughout South Africa.	1134 Park Street, Hatfield, Pretoria P.O. Box 8787, Pretoria. 0001 South Africa
Grootfontein Agricultural Development Institute		Director, G A D I, Private Bag X529 Middelburg, Eastern Cape, 5900 Tel: +27 (0)49 802 6600, website: http://gadi.agric.za/contact-us.php .
Water Research Commission (WRC)	The WRC has major influence on the research into wastewater treatment and related topics and with key knowledge on the emerging EDCs.	Lynnwood Bridge, Bloukrans Building, 4 Darenty St, Lynnwood Manor, Pretoria, 0081 Email: info@wrc.org.za http://www.wrc.org.za/contact-us/

3.1.3. Production and packaging of EDCs

Stakeholders within this broad group are responsible for the large-scale production and packaging, including large-scale storage/stockpiles of products associated with EDCs. A selection of these group is presented in **Table 3-3** below. These stakeholders are critical for the success of any policy implementation as their input and engagement are important. It is

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

envisaged that majority of the stakeholders in this group would be private sector, and therefore, business profitability may drive their engagement and input. Policy measures must therefore emphasis the criticality of environmental sustainability as a necessary asset underpinning continuing business profitability.

Table 3-3: Production, manufacturing and packaging sector

INDUSTRY	PRODUCT	CONTACT
Industrial sectors play significant role in industrial development and re-designing of EDC products as well as the use of suitable alternatives to EDCs in product development. This includes the implementation of policies and regulations.		
Textile industries	Benzothiazole and Benzotriazole	Postal Address: P.O. Box 53 Bruma. 2026 Physical Address: 40 Seventh Avenue Edenvale. 1609 South Africa Tel: (011) 454-2342 Fax:(011) 454-2654 Email: texfed@jhbmail.co.za Website: www.texfed.co.za
Spec Systems	Cleaning products and detergents Adhesive labels Optical disc drivers	9 Kingdon Road, Johannesburg. 2135 South Africa +27 11 682 1344
SNV Plastics CC,	Plasticizers	Producer of polyethylene terephthalate bottles 17 Bell Street, New Era, Springs 1559, Gauteng. https://www.snvplastics.com
Accuplas Plastic Engineering CC	Plasticizers. Plastic fabrication company.	93 Hefer St, Rustenburg Oos-Einde, Rustenburg, 0300 Tel: 014 596 5279 Web: http://www.epmplastics.co.za/
GB Packaging	Plasticizers	Unit 1, Kiara Square, Esso Road, Montague Gardens, Montague Gardens, Cape Town, 7441. Tel: 021 551 4374 Web: www.gbpackaging.co.za ;
Mega Plastics	Plasticizers	1 Jones St, Sydenham, Port Elizabeth, 6001 Web: https://www.megaplast.co.za/
Rehau Polymers (Pty) Ltd	Plasticizers	Unit 1, Burnside, 1 Builders Way, 3610 Hillcrest Durban. Tel: +27 (0)31 765 7447, +27 (0)31 765 5218
AVPack Plastic Manufacturers	Plasticizers. Packaging company	17 Rana Rd, Isipingo, Durban, 4133 Tel: 031 902 4950

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

INDUSTRY	PRODUCT	CONTACT
		Web: https://www.avpackplastics.com/
DM Plastics	Plasticizers. Plastic fabrication company, providing a diverse product catalogue.	7 Nipper Rd, New Germany, Durban, 3610 Tel: 031 705 1446 Web: https://www.dmplastics.co.za/
Far North Plastics Manufacturing CC	Plasticizers. Packaging supply store.	39a Yester St, Polokwane Ext 10, Polokwane, 0699 Tel: 015 293 0513 Email: farnorthorders@mweb.co.za
Omega Plastics	Plasticizers	Address: 879 Emerald St, Marblehall, 0450 Tel: 013 261 1340 Web: http://www.omegaplastics.co.za/
Topline Plastics	Plasticizers Plastic fabrication Company.	4 Hartley St, Hamilton, Bloemfontein, 9301 Tel: 051 434 3203 Web: www.toplineplastics.co.za/
Eco Plastics	Plasticizers	12 Piet Human St, Hamilton, Bloemfontein, 9301 Tel: 051 435 7700 Web: http://www.ecofs.co.za/
Plastics South Africa	Plasticizers	Tel: 011 653 4784 / 011 653 4784 Web: www.plasticssa.co.za Web: https://www.plasticsinfo.co.za/
Plastics Convertors Association of South Africa	Plasticizers	18 Gazelle Ave, Corporate Park Old Pretoria Road, Midrand, Gauteng Tel: 0113140019 Web: www.pcasa.co.za
South African Coal Ash Association	Plasticizers	Unit 8 Coram Office Park, 86 Ferero Ave, Randpark Ridge, Randburg, 2194 Tel: +27 11 791 3327 Email: office@aspasa.co.za Web: http://coalash.co.za/
South African Pest Control Association	Plasticizers	141 Witch Hazel Avenue Hazel Close Office Park Building 4 Highveld Techno Park Centurion. 0169 Tel: 0126548038 Web: https://sapca.org.za/
Croplife South Africa	Plasticizers	310 Lougardia Building Cnr Hendrik Verwoerd & Embankment Rd Centurion, 0157 Tel: +27 (0)87 980 5163

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

INDUSTRY	PRODUCT	CONTACT
		Email: info@croplife.co.za Web: https://croplife.co.za/
South African Sugarcane Research Institute	Plasticizers	170 Flanders Drive Mount Edgecombe. 4300 Tel: 031 508 7400 Fax: 031 508 7597 Email: sasri@sugar.org.za Web: https://sasri.org.za/contact-us/

3.1.4. Consumptive sector

This sector can be described as encompassing the end users and for the purpose of this report, the consumptive sector is defined as organisations or individuals that buys and uses/dispenses/prescribes pharmaceutical products (healthcare) and/or allied products (agriculture including veterinary), and products containing EDCs (**Table 3-4**). These will include agricultural and healthcare institutions, households and private individuals. Based on this definition, clinics, community pharmacies hospitals, farmers, individuals and associated organizations/associations are clustered within this broad category.

Table 3-4: Consumptive sector

ENTITY	COMMENT	CONTACT
Agricultural organisations: Farmers are the primary managers of agricultural wastes at the farm scales, and a primary source of EDCs in the environments are run-offs from farmlands carrying hormones and other veterinary medicines. Farmers, particularly large-scale commercial farmers, are organised into associations that represent their interests, and through which information dissemination is achieved.		
Agri Eastern Cape	The various provincial farmers associations are critical stakeholders through which farmers are engaged.	President: Douglas Stern Tel: +27 (0)41 363 1890 Fax: +27 (0)41 363 1896 Email: Natasja.barkhuizen@agriec.co.za
Free State Agriculture		President: Francois Wilken Tel: +27 (0)51 444 4609 Fax: +27 (0)51 444 4619 Email: gernie@vslandbou.co.za
Agri Gauteng		President: Dr Willem Pretorius Tel: +27 (0)12 643 3400 Fax: +27 (0)12 663 3178 Email: ceo@agrigauteng.com

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department of Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

ENTITY	COMMENT	CONTACT
KwaZulu-Natal Agricultural Union (Kwanalu)		President: Andy Buchan Tel: +27 (0)33 342 9393 Fax: +27 (0)86 435 2237 Email: info@kwanalu.co.za
Limpopo Agriculture		President: Leon Borchers Tel: +27 (0)823784621 Email: info@limag.co.za
Agri Mpumalanga		President: Tommy Ferreira Tel: +27 (0)17 819 1295 Fax: +27 (0)86 660 5673 Email: Robert.mpl@mweb.co.za
Agri North West		P O Box 3185, Lichtenburg 2740 Tel (018) 632 2987 / 3612. Fax: 018-6322512. Email: nwlu@isdnet.co.za <i>Mr W.P. Auret</i>
Agri Northern Cape		President: Nicol Jansen Tel: +27 (0)53 832 9595 Fax: +27 (0)53 832 7126 Email: henning@agrink.co.za
Agri Western Cape		President: Cornie Swart Tel: +27 (0)21 860 3800 Fax: +27 (0)21 872 3388 Email: jannie@awk.co.za
Hospitals, clinics and pharmacy outlets: These entities are seen as consumers of pharmaceutical products in as much as they may have need to deal with un-used medications. They therefore play significant role in the use of healthcare products and the management of associated wastes. The identified stakeholders in these categories are thus mainly hospitals, clinics in urban centre, being areas where more people are likely to use these facilities and thus pressure on waste management and disposal. Some selected clinics and hospital, listed by province here.		
Northern Cape	Kimmed Private Hospital	36 Du Toitspan Rd, Civic Centre, Kimberley, 8301 Tel: 053 807 7100
	Tshwaragano Community Hospital	Battharos Village, Kuruman, 8460 Tel: 053 774 1780
	Mediclinic Upington	24 Du Toit St, Oosterville, Upington, 8801 Tel: 054 338 8900
	Kimberley Provincial Hospital	177 Du Toitspan Rd, Memorial Road Area, Kimberley, 8301 Tel: 053 802 9111
	Jane Keyser Clinic	Kakamas, Northern Cape, South Africa

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

ENTITY	COMMENT	CONTACT
		Tel: 054 431 0767
	Kimberley City Clinic	Bultfontein Rd, New Park, Kimberley, 8301 Tel: 053 830 6616
North West	Life Peglerae hospital	173 Beyers Naude Dr, Rustenburg, 0300 Tel: 014 597 7200
	Tshepong Hospital	OR Tambo &, John Orr St, Uraniaville, Klerksdorp, 2574 Tel: 018 406 3100
	Life Eugene Marais Hospital	696 5th Ave, Les Marais, Pretoria, 0084 Tel: 012 334 2777
	Potchefstroom Hospital	75 Kruis St, Potchefstroom, 2520 Tel: 018 293 4400
	Lethlabile Community Clini	Lethlabile-A, Brits Tel: 012 251 0774
Western Cape	Life Knysna Private Hospital	Hunters Estate Drive, Hunters Home, Knysna, 6570 Phone 0443025200
	Somerset Hospital	Bay Court, Portswood Rd, Green Point, Cape town 8001 Tel: 0214026911
	Christiaan Barnard Memorial Hospital	25 D.F. Malan St, Foreshore, Cape Town, 8001 Tel: 021 441 000
	Pines Clinic	Worcester, Western Cape, South Africa Tel: +27 (0)23 342 3113
	Alphen Clinic	Constantia, Cape Town, Western Cape, South Africa Tel: +27 (0)21 444 9628
	Jafmed Pharmacy	Address: 328 Ottery Rd, Ottery East, Cape Town, 7800 Tel: 021 703 9791
Eastern Cape	Netcare Greenacres Hospital	Cnr Cape Rd &, Rochelle Rd, Greenacres, Port Elizabeth, 6045 Tel: 041 390 7000
	Dora Nginza Hospital	Spondo St, New Brighton, Port Elizabeth, 6059 Tel: 041 406 4111
	Settlers Private Hospital - Medical Ward	Milner St, Grahamstown, 6139 Tel: 046 602 5000
	Dora Nginza Hospital	Spondo St, New Brighton, Port Elizabeth, 6059 Tel: 041 406 4111
	Frere Hospital	Amalinda Main Rd, Braelyn, East London, 5201 Tel: 043 709 2111

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

ENTITY	COMMENT	CONTACT
	Marie Stopes East London	14 St Matthews Rd, Southwood, East London, 5201 Tel: 080 011 7785
	Grahamstown Municipality Clinic	1 Anglo African St, Grahamstown, 6139 Tel: 046 603 6111
	Berea Pharmacy	Address: 31 Pearce St, Berea, East London, 5241 Tel: 043 721 1300
Mpumalanga	Kiaat Private Hospital	Kiaat Ridge Boulevard, Nelspruit, 1200 Tel: 013 590 9150
	Life Cosmos Hospital	OR Tambo Rd & Beatty Avenue, Witbank, Emalahleni, 1035 Tel: 013 653 8000
	Life Midmed Hospital.	O.R. Tambo Street & Joubert Street, Middelburg, 1050
	Rob Ferreira Hospital	Generaal Daan Pienaar Drive, Sonheuwel Central, Nelspruit, 1200 Tel: 013 741 6100
	Akeso Clinic Nelspruit	Nelspruit, Mpumalanga, South Africa Tel: +27 (0)87 098 0460
	Poly Clinic	Hector Rd, Lynville, Emalahleni, 1034 Tel: 013 696 3402
	Dis-Chem Pharmacy The Grove Shopping Centre	The Grove Shopping Centre – Nelspruit Address: Shop 17A The Grove, Riverside, 20 Tel: 013 757 9383
Gauteng	Louis Pasteur Private Hospital	Louis Pasteur Medical Center, 374 Francis Baard Street, Pretoria Central, Pretoria, 0002 Tel: 012 336 6000
	Charlotte Maxeke Johannesburg Academic Hospital	Jubilee Rd, Parktown, Johannesburg, 2196 Tel: 011 488 4911
	Netcare Montana Hospital	Dr Swanepoel Rd, Montana Park, Pretoria, 0159 Tel: 012 523 3000
	Tambo Memorial Hospital	39 Railway St, Plantation, Boksburg, 1459 Tel: 011 898 8000
	Cure Day Clinic	Midrand, Gauteng, South Africa Tel: +27 (0)12 940 9440
	Zuzimpilo Clinic	Ansteys Building, 59 Joubert St, Johannesburg, 2001 Tel: 011 336 2860

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

ENTITY	COMMENT	CONTACT
	Springbok Pharmacy	Shop U1-U5, Alberton Mall, Voortrekker Rd, New Redruth, Alberton, 1449 Tel: 011 861 6600
KwaZulu Natal	Busamed Gateway Private Hospital	36-38 Aurora Dr, Umhlanga Rocks, Umhlanga, 4319 Tel: 031 492 1130
	King Edward VIII Hospital	Sydney Rd, Umbilo, Durban, 4013 Tel: 031 360 3111
	Ahmed Al-Kadi Private Hospital	King Cetshwayo, 490 Jan Smuts Hwy, Mayville, Durban, 4058 Tel: 031 492 3400
	R.K.Khan Hospital	336 R K Khan Cir, Arena Park, Chatsworth, 4092 Tel: 031 459 6000
	Durdoc Clinic	Durban, Kwazulu Natal, South Africa Tel: +27 (0)31 327 5100
	Sparkport Pharmacy Overport	382 Randles Rd, Overport, Durban, 4091 Tel: 031 207 3946
Limpopo	Polokwane Hospital	Cnr. Hospital & Dorp St, Polokwane, 0699 Tel: 015 287 5000
	Lebowakgomo Hospital	Lebowakgomo, 0737 Tel: 015 633 1800
	Zoutpansberg Private Hospital	47 Joubert St, Louis Trichardt, 0920 Tel: 015 516 0720
	Tshilidzini Hospital	Phundamaria Main Road, Shayandima, Thohoyandou, 0945 Tel: 015 964 4200
	Malamulele Clinic	Xitlhelali Villiage, Malamulele, Thohoyandou, 0982 Tel: 015 851 0446
	Seshego Clinic 2	Stand 3850, Seshego, Polokwane, 0741 Tel: 015 223 4243
	Tzaneng Pharmacy	45 Boundary St, Arbor Park, Tzaneen, 0850 Tel: 015 307 4177
Free State	Busamed Harrismith Private Hospital	Cnr Vowe & Alexandra Street, Harrismith, 9880 Tel: 058 624 3000
	Pelonomi Academic Hospital.	121 Dr Belcher Rd, Heidedal, Bloemfontein, 9301 Tel: 051 405 1911
	Mediclinic Bloemfontein	Kellner Street &, Parfitt Ave, Westdene, Bloemfontein, 9301

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

ENTITY	COMMENT	CONTACT
	National Hospital District	Roth Ave & Kolbe Ave, Willows, Bloemfontein, 9301 Tel: 051 403 9601
	Riemland Clinic	Frankfort, Free State, South Africa Tel: +27 (0)58 813 2771 / 2
	Clarens Pharmacy Family	371 Main Street, Clarens, 9707 Tel: 058 256 1852
General public: The general public must be seen as critical stakeholders for they use and dispose of pharmaceutical products, containing EDCs, on a daily basis. Education, awareness raising and social learning would be critical for the success of any policy for the management and regulation of EDCs in South Africa.		

3.1.5. Waste management sector

Waste management facilities² are gate keepers in the management and abatement of waste containing EDCs entering the environment. As such, the primary purpose of stakeholders presented here is the management of wastes, including liquid / effluent and solid wastes typically containing EDCs (**Table 3-5**). It is envisaged that these stakeholders have facilities for the treating, handling and safe disposal of wastes, including pharmaceutical wastes. Municipalities are seen as the biggest stakeholders in this category because they are responsible for the overall management of all waste facilities within their jurisdiction. Nevertheless, other private organisations responsible for waste collection, disposal and management are key in this category. Note that this category excludes stakeholders whose purpose is regulatory e.g. National government departments, unless such department also treat, manage and actually dispose waste into the environment.

Table 3-5: Waste management sector

ENTITY	COMMENT	CONTACT
Municipalities	Municipal WWTWs and municipal landfill sites are critical stakeholders in the waste management sector.	All local municipalities

² Detailed list of registered waste management facilities can be found on the South Africa Waste Information Centre (www.sawic.co.za)

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Pharmaceutical Contractors.	Providers of the packaging materials, e.g. blister packs in South Africa.	44 Monteer Rd, Isando, Kempton Park. 1601 Postal Address: PO Box 427, Isando, Kempton Park.1600
Aspen Pharmacare Holdings Limited	Manufacturers of pharmaceutical in South Africa and is seen as critical stakeholders in terms of understanding how pharmaceutical waste is generated at the production level, and how such waste is treated and disposed of.	Aspen Corporate Office Durban Aspen Place, 9 Rydall Vale Park Douglas Saunders Drive, La Lucia Ridge Durban. 4019 Postal Address: PO Box 25125 Gateway 4321. Tel: +27 31 5808600 Facsimile: +27 31 5808647
Adcock Ingram		1 New Road, (c/o New Road & 7th Street), Midrand, South Africa Postal Address: Private Bag X69, Bryanston, 2021, Customer Service: 0800 113 844. Tel: +27 11 635 0000 Fax: +27 86 553 0000
Afrox (part of the Linde Group)	Manufacturer of specialty pharmaceutical agents such as gaseous anaesthetic gases (halothane) and the standard metal packaging for storage of pharmaceutical gaseous agents.	Head Office Switch board number: +27 (0)11 490 0400 Email: customer.experience@afrox.linde.com Web: http://www.afrox.co.za/en/about_afrox/index.html
Informal stakeholders in the pharmaceutical sector	A large part of the South African population relies on the informal medicine supply. Largely, information on medicinal wastes management and their disposal by this category of stakeholders will be largely based on peer reviewed publications and interviews of traditional health healers.	Various relevant NGOs and NPOs. Traditional healers are largely informal and interactions will be based on personal communications.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

4. LIFE CYCLE ANALYSIS AND PROCESSES, INCLUDING INVENTORIES AND ASSOCIATED COMPANIES

4.1. Introduction to Life Cycle Assessment

Endocrine disrupting compounds are usually categorised as emerging contaminants with far-reaching environmental implications prompting the need for EDC Life Cycle Assessment (LCA). Although present at low concentrations in the environment, EDCs exert adverse effects on living organisms. These effects impose chronic rather than acute toxicity and depend on exposure (bioavailability), susceptibility to the compounds, and the degradability of the compounds. The increased awareness of the importance of environmental protection, and the possible impacts associated with products, both manufactured and consumed, has increased interest in the development of various methods to understand and better address these impacts. One of the techniques being developed for this purpose is LCA (ISO 14010:2006 Guidelines).

LCA is an environmental management tool for assessing the widespread environmental impacts of products, processes and activities (Society of Environmental Toxicology and Chemistry (SETAC), 1993; UNEP, 1996). LCA focuses on the entire life cycle of a product, from the extraction of resources and processing of raw material, through the manufacture, distribution, and use of the product, to the final processing of the disposed of product with important applications including i) the analysis of the contribution of the life cycle stages to the overall environmental load, usually to prioritise improvements on products or processes and ii) the comparison between products for internal or external communications (Goedkoop et al., 2008).

LCA is one of several environmental management techniques (e.g. risk assessment, environmental performance evaluation, environmental auditing, and environmental impact assessment) and might not be the most appropriate technique to use in all scenarios. A limitation of LCA is that it does not address the economic or social aspects of a product. A typical LCA consist of four main phases: i) the goal and scoping phase, ii) the life cycle inventory phase, iii) the impact assessment phase and, iv) the interpretation/improvement phase. These phases are shown in the schematic in **Figure 4-1** and are briefly described in the sections that follow.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

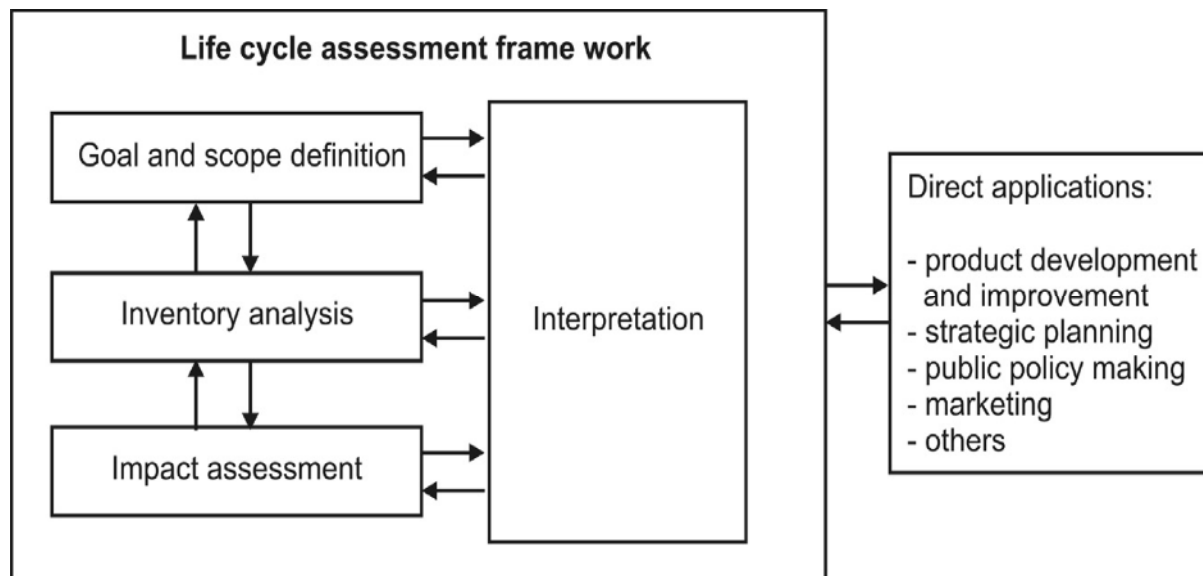


Figure 4-1: Life Cycle Assessment framework as per ISO 14040 Guidelines

4.1.1. Goals and Scope definition of LCA for EDCs

The goal and definition phase of an LCA is the first and perhaps one of the most critical steps of an LCA, as the choices and decision made at this stage affect the entire outcome of the LCA process. In this phase, the goal of the LCA process is clearly define, the object of investigation i.e. the functional unit is also clearly defined and clarified as well as the system boundary of the investigation. The functional unit allows for the reference of each input and output data. The system boundary could be spatial, technological or temporal (Hicks, 2010). Setting of the system boundary is critical because it sets limits within which the LCA process is undertaken. It is critical to note that it is at the goal and definition phase that assumptions, allocation approaches and limitation are clarified and established.

The main goals of the LCA for the EDCs are;

- i) To assess the environmental and energy performances of the EDCs life cycle as a function of the amount manufactured, transported, stored, consumed and disposed of per annum in South Africa;
- ii) To identify the relative contribution of manufacturing, transportation/distribution, storage as well as consumption and disposal/waste management to environmental quality and human health impacted, assessed through defined indicators;
- iii) Undertake a scenario analysis based on projected South Africa population growth and corresponding EDCs consumption.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

- iv) To recommend ways in which EDCs can be better managed in South Africa.

The scope of the LCA for EDCs cover various sources, and these include the following:

- i) Pesticides from chemical and agricultural industries.
- ii) Pharmaceuticals and personal care products.
- iii) Plasticisers from industries and household wastes.
- iv) Building materials.
- v) Fire retardants.
- vi) Human and animal hormones in the environment.
- vii) Heavy metals from mining and manufacturing industries.

4.1.2. The life cycle inventory phase

The Life Cycle Inventory (LCI) phase is the second phase of LCA. It is an inventory of input/output data regarding the system being studied. It involves collection of the data necessary to meet the goals of the defined study. The LCI phase is typically the most critical and time-consuming phase, characterised by data searching. The quality, credibility and robustness of the data often determines the reliability and level of confidence of the LCA outcome. In the LCI analysis phase, all the inputs and outputs data are quantified as well as calculating the emissions, energy requirements and material flows. However, before the calculations are done, data validation is required and, the data is adapted or weighed against the functional unit which is defined in the goals and scope so that the entire life cycle can be accounted for. Software such as GaBi can be used for the calculations (GaBi, 2011).

4.1.3. Impact Assessment for EDCs

The Life Cycle Impact Assessment (LCIA) phase is the third phase of the LCA. It is in this phase that a product impact is assessed in terms of resource consumption, ecosystem quality and human health impact. Impact could be categorised as midpoint or end of pipe impact categories (Hicks, 2010). Impact can be represented by means of appropriate indicators, such indicators reflecting a product impact on the environment, resource utilisation as well as human health. In the LCIA additional information is provided to help assess a product system's LCI results to better understand their environmental significance. Standardized methods and models are constructed and used for the LCIA phase. As part of standardization, impact can be weighted, normalised or grouped, depending on the specific system being investigated.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

The most important aspects of impact assessment are: i) an analysis of the contribution of the life cycle stages of the product or service to the overall environmental load, usually with the aim to prioritize improvements on products or processes; ii) comparison between products for internal use; iii) toxicity to ecosystems and humans. The environmental impacts can be calculated for each exchange and expressed for/aggregated over the whole life cycle of the products. A common metric for all environmental impacts is the Person equivalent (PE). This expresses the impact from the product compared to the annual environmental impact from an average person.

4.1.4. The results, interpretation and improvement phase

Life cycle interpretation is the final phase of the LCA procedure, in which the results of an LCI or an LCIA, or both, are summarized and discussed as a basis for conclusions, recommendations and decision-making in accordance with the goal and scope definition. Unlike the other three phases, the results, interpretation and improvement phase is a transversal phase, aimed at identifying the critical hot-spot throughout the LCA for improvement.

There are cases where the goal of an LCA can be satisfied by performing only an inventory analysis and an interpretation. This is usually referred to as an LCI study. The information developed in an LCA or LCI study can be used as part of a much more comprehensive decision process. Comparing the results of different LCA or LCI studies is only possible if the assumptions and context of each study are equivalent.

4.2. Models and Approaches to EDCs' LCA

To determine the pollution potential of EDCs, the following existing models and methods can be employed:

- Transfer models as developed by Jury et al. (1987) and Leonard (1990) meant to target the fate of the substances in the environment. In this case, detailed knowledge of the physical, chemical and microbial processes controlling their persistence and transport in the different environmental compartments is necessary. These methods concentrate on the behaviour of chemical compounds in the environment and often ignore the effect on the receptor population or ecosystem (Margni et al., 2002);
- Ranking methods as used by Kovach et al. (1992), Jouany (1995) and Newman (1995) incorporate different effects, but the weighing is often made without any reference to calculations. Also, risk assessment methods take both fate and exposure

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

into account but cannot provide insight into the trade-off between different impacts (Kolluru et al., 1996);

- Methods such as CML 92 (Heijungs et al., 1992) or Ecoindicator (Goedkoop, 1995) incorporate several EDCs, but on a very rough basis, considering only toxicological and ecotoxicological data, but not their fate in the environment (Margni et al., 2002); and
- More recent LCA methods like Ecoindicator 99 (Goedkoop et al., 1999) and USES-LCA (Huijbregts et al., 2000), evaluate chemical compounds by combining fate and exposure analysis with toxic assessment for humans and ecosystems. However, their scenario does not show direct transfer to the crops treated with chemicals, only diffuse emissions in a well-mixed one box air model are considered.

4.3. New Approach to EDCs' LCA

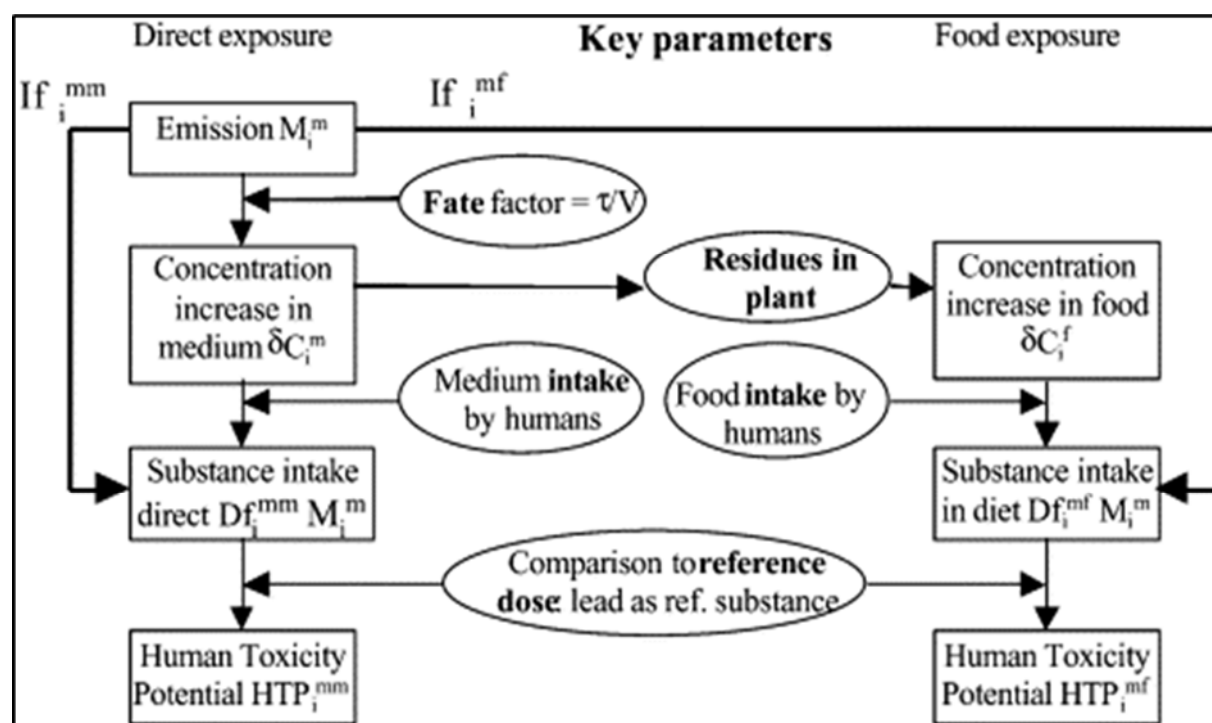
For the development of new and sustainable use of chemical compounds, a new quantified approach is needed to evaluate the overall impact on the health of humans and ecosystems. The impact of EDCs on human health and ecosystems can be fashioned after the semi-empirical method, the “critical surface time (CST)” proposed by Jolliet and Crettaz, (1997). This method includes a full fate analysis of different chemical pollutants, referring to the residence time and the dilution volume in each media (air, water and soil) and the absorbed fraction (e.g. in food). The model uses no effect concentrations (NEC) for ecotoxicity and human reference doses (HRD) for human toxicity to evaluate the different effects. Novel mathematical models were used to evaluate the residence time of these compounds in the air and to determine the inter-media transfer soil–water, coupling substances and their degradation in the soil with corresponding hydrological values.

Margni et al. (2002) proposed that equivalency models compare the different routes of exposure. According to the equivalency principles employed by the method, human toxicity can be described as the overall fraction of an emission that is inhaled or ingested by all human beings (the exposure efficiency of intake fraction divided by the yearly HRD. This ratio can also be interpreted the PE of a population that would be exposed to the HRD during one year for every kg of a substance emitted.

Figure 4-2 below shows the various parameters in chemical exposure expressed as the ratio of total human intake to total emissions and can be calculated for given media by multiplying

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

the fate factor with the amount of inhaled or ingested exposure media. This new approach represents the current Swiss model approach to LCIA of chemicals



Source: Margni et al., 2002

Figure 4-2: Key parameters in chemical exposure

4.4. Prioritising and Decision making

To evaluate EDCs damage, the three impacts (human health, aquatic and terrestrial ecosystems) needs to be considered. For the sake of this study, the first step was the creation of a working list of substances associated with endocrine disruption. This working list was compiled from lists of suspected endocrine disruptors from different organisations and countries as well as from a current literature search. Three further steps were followed by applying different selection criteria. The steps are stipulated in **Table 4-1** and **Figure 4-3**.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Table 4-1: Steps followed in the selection of the prioritised EDCs

STEP	DESCRIPTION
1.	Review of existing lists and other sources of information
2.	Selection of highly persistent and/or HPV substances
3.	Preliminary evaluation of scientific evidence of ED-related effects
4.	Preliminary evaluation of exposure to humans and wildlife

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

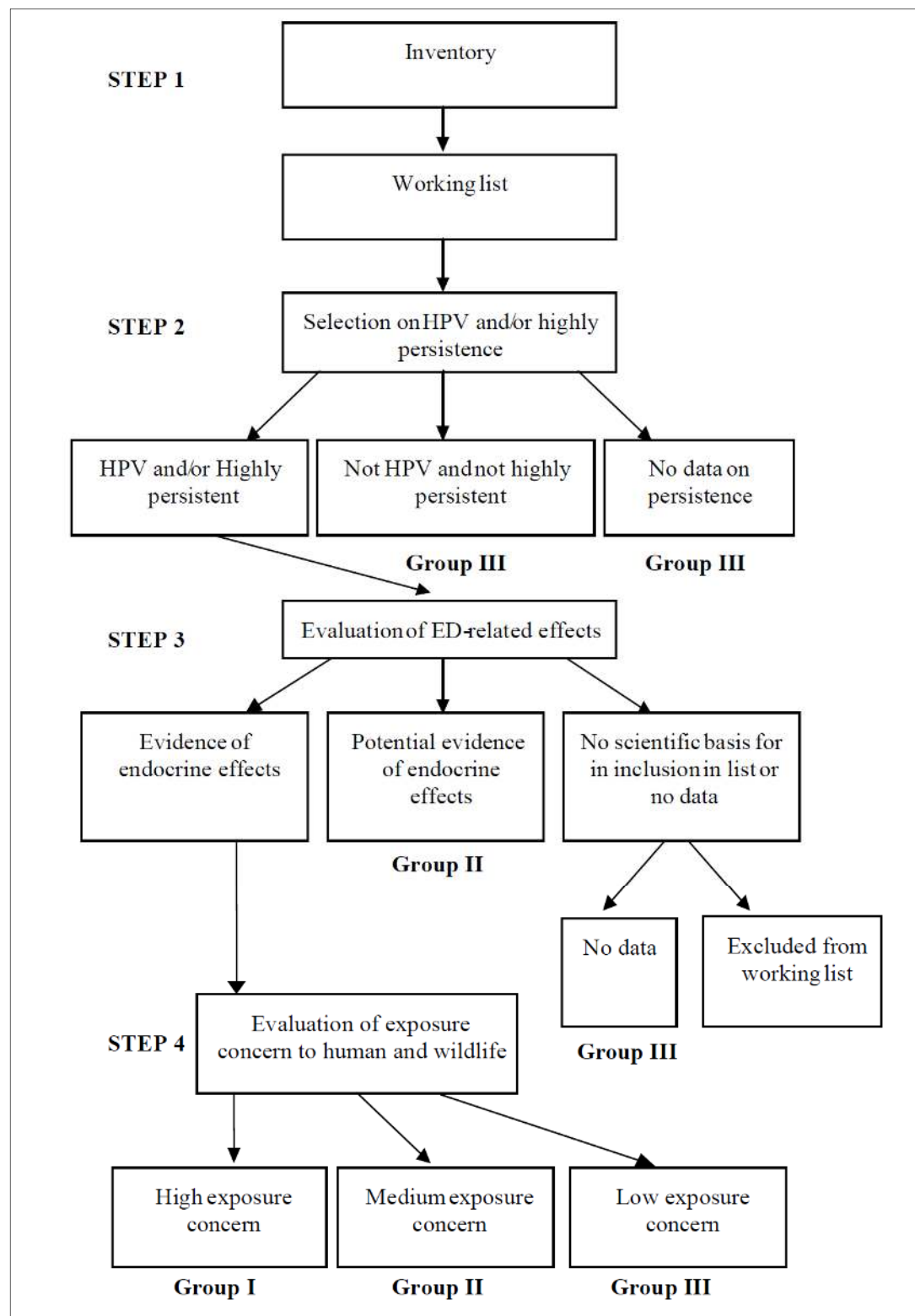


Figure 4-3: Showing the four steps presented schematically.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

4.4.1. Step 1: Review of existing lists and other sources of information: Inventory Lists

An inventory of available lists of potential endocrine disrupters and suspected endocrine disrupters from various stakeholders was made to prepare a working list. For this purpose background documents on which these lists were based, were collected. Information on human health-relevant and wildlife relevant endocrine-disrupting effects were used to validate the list. The main effects included are effects on reproduction, reproductive organs, hormone levels and fertility cycles. It should be noted that chemicals have been added to the working list based on data on endocrine disruption according to the evaluated literature.

4.4.2. Step 2: Selection of highly persistent and/or HPV substances

The first selection of chemicals was based on “high production volume” (HPV) and/or persistence. Both parameters were chosen as an indicator of exposure probability. This is explained by the assumption that human and environmental exposure to a chemical is more likely when this chemical is produced in high quantities or in case this chemical is persistent in the environment. The metals were all selected because these elements persist in the environment. At the international level, the selection of “high production volume” chemicals are based on the HPV list from Regulation No. 793/93 on chemicals with a production volume of more than 1000 tonnes per year. For the selection of persistent chemicals, Quantitative Structural Analysis Relations (QSAR) based on the Syracuse Biodegradation programme is used as a first indication of the persistence of a substance. Six of the twelve chemicals internationally under this category are commonly reported as detected are wastewater and freshwater systems.

4.4.3. Step 3: Preliminary evaluation of scientific evidence of endocrine-related effects.

The following criteria were used to group the selected chemicals:

- *Group 1.* At least one study providing evidence of endocrine disruption in an intact organism. Not a formal weight of evidence approach;
- *Group 2.* Potential for endocrine disruption. In vitro data indicating the potential for endocrine disruption in intact organisms. Also includes effects in-vivo that may, or may not, be endocrine-mediated. May include structural analyses and metabolic considerations; and
- *Group 3.* No scientific basis for inclusion in the list or no data.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

All experimental data were taken into consideration (both positive and negative test results); In case reliable in-vivo evidence for endocrine disruption was available, the respective substance was grouped into Group 1; In case less reliable in-vivo evidence for endocrine disruption was available (for example in case of contradictory test results), the respective substance was grouped into group 2; In case only in-vitro evidence for endocrine disruption was available with positive test results, the respective substance was grouped as Group 2; Substances with no evidence for endocrine disruption or no data and not related to Group 1 or 2 substances were grouped into Group 3. It must be noted that only compounds falling under c 1 and 2 were considered.

4.4.4. Step 4: Preliminary evaluation of exposure to humans and wildlife

In this step, the category one chemicals were further evaluated to identify their “concern for exposure”. Categorisation into high, medium and low concern was based on qualitative criteria, as derived from representative exposure concentrations and observed endocrine-disrupting effect concentrations reported in South Africa. Exposure concern is primarily referring to the exposure of vulnerable groups such as (breastfeeding) infants and medical patients, but also the exposure of wildlife such as sediment living organisms and top predators.

The following guidelines were used:

- High concern; Human exposure is expected: due to environmental concentrations and those in food or consumer products, also taking in consideration exposure of vulnerable groups *and/or* Wildlife exposure is expected, due to use and emission patterns and the chemical is persistent and bioaccumulative;
- Medium concern; Human exposure not expected; Wildlife exposure is expected, due to use and emission patterns, but the chemical is readily biodegradable and not bioaccumulative; and
- Low concern; No human exposure and no wildlife exposure.

For the different levels of exposure concern, the following chemical properties are identified:

Chemicals with high exposure concern are:

- Chemicals intentionally or unintentionally applied in food products or cosmetics;

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

- Chemicals applied in residential areas (e.g. herbicides for weed control on pavements);
- Chemicals in consumer products causing direct or indirect exposure (such as additives in food packaging materials or toys for children);
- Chemicals emitted in the environment and considered being persistent;
- High production volume chemicals emitted in the environment and considered being bioaccumulative;

Chemicals with medium exposure concern are:

- High production volume chemicals with no human exposure, emitted in the environment and although not considered as persistent or bioaccumulative, observed in environmental compartments;

Chemicals with low exposure concern are:

- Chemicals not causing human exposure nor wildlife exposure

Based on the gathered information, a summary profile was made. In this profile the reason for selection is presented per chemical or group of related chemicals. Furthermore, data on the chemical characteristics including endocrine-disrupting properties, persistence, environmental concentrations and reported sources and years are included. The selected list consists are shown in **Table 4-2**

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Table 4-2: Priority LCA List for EDCs.

PHARMACEUTICAL GROUP / ACTIVE INGREDIENT	CONCENTRATION (µG/L)	CONCERN	HPV	SOURCE	REFERENCE
Acetaminophen	5.8 – 58.7	High	Yes	Surface water	Agunbiade and Moodley, 2014
	5.8			WWTW influent	Matongo et al., 2015
	1.0 – 1.7			Surface water	Matongo et al., 2015
	136.9 – 343.6			WWTW influent	Archer et al., 2017
	0.02 – 0.2			Surface water	Archer et al., 2017
Aspirin	2.2 – 10.0	High	Yes	Surface water	Agunbiade and Moodley, 2014
	13.7 – 25.4			Surface water	Agunbiade and Moodley, 2016
Diclofenac	1.1 – 15.6	High	Yes	Surface water	Agunbiade and Moodley, 2014
	222.7			WWTW influent	Agunbiade and Moodley, 2016
	123.7			WWTW effluent	Agunbiade and Moodley, 2016
	0.6 – 8.2			Surface water	Agunbiade and Moodley, 2016
	2.7 – 5.6			WWTW influent	Archer et al., 2017
Ibuprofen	0.8 – 18.9	Medium	Yes	Surface water	Agunbiade and Moodley, 2014
	39.8			WWTW influent	Amdany et al., 2014
	24.6			WWTW effluent	Amdany et al., 2014
	0.02			WWTW influent	Osunmakinde et al., 2013
	1.2			WWTW influent	Agunbiade and Moodley, 2016
	0.4 – 0.7			Surface water	Agunbiade and Moodley, 2016
	62.8			WWTW influent	Matongo et al., 2015

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

PHARMACEUTICAL GROUP / ACTIVE INGREDIENT	CONCENTRATION (µG/L)	CONCERN	HPV	SOURCE	REFERENCE
	0.5 – 8.5			WWTW effluent	Matongo et al., 2015
	9.1 – 15.8			Surface water	Matongo et al., 2015
	0.1 – 0.6			WWTW influent	Archer et al., 2017
	55.0			Surface water	Archer et al., 2017
Naproxen	13.5	High	Yes	WWTW influent	Amdany et al., 2014
	52.3			WWTW effluent	Amdany et al., 2014
	0.2 – 1.9			WWTW influent	Amdany et al., 2014
	2.5 – 14.5			Surface water	Archer et al., 2017
Ampicillin	6.6	High	Yes	River water	Agunbiade and Moodley, 2014
	8.9			WWTW influent	Agunbiade and Moodley, 2016
	3.2 – 5.5			WWTW effluent	Agunbiade and Moodley, 2016
	0.5 – 10.7			Surface water	Agunbiade and Moodley, 2016
Chloramphenicol	0.6 – 22.6	High	Yes	Surface water	Agunbiade and Moodley, 2014
Erythromycin	0.6	High	No	Surface water	Agunbiade and Moodley, 2014
	0.2			WWTW influent	Matongo et al., 2015
	0.1 – 0.2			WWTW effluent	Matongo et al., 2015
	0.09 – 0.1			Surface water	Matongo et al., 2015
Fluoroquinolones	0.07 – 0.09	High	Yes	WWTW influent	Hendricks and Pool, 2012
	0.7 – 16.9			STW effluent	Hendricks and Pool, 2012
	27.1			Surface water	Agunbiade and Moodley, 2014

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

PHARMACEUTICAL GROUP / ACTIVE INGREDIENT	CONCENTRATION (µG/L)	CONCERN	HPV	SOURCE	REFERENCE
	1.7 – 30.8			WWTW influent	Agunbiade and Moodley, 2016
Nalidixic acid	29.9	Medium	Yes	Surface water	Agunbiade and Moodley, 2014
	25.2			WWTW influent	Agunbiade and Moodley, 2016
	12.4 – 23.5			WWTW effluent	Agunbiade and Moodley, 2016
	0.8 – 8.4			Surface water	Agunbiade and Moodley, 2016
Streptomycin	3.68	High	Yes	Surface water	Agunbiade and Moodley, 2014
Sulfamethoxazole	0.1 – 0.2	High	Yes	Surface water	Agunbiade and Moodley, 2014
	0.08 – 0.1			WWTW influent	Hendricks and Pool, 2012
	34.5			STW effluent	Hendricks and Pool, 2012
	1.2 – 5.3			WWTW influent	Matongo et al., 2015
	0.6 – 1.4			Surface water	Matongo et al., 2015
	0.6 – 5.7			Surface water	Archer et al., 2017
Tetracycline	78.4	High	Yes	Surface water	Agunbiade and Moodley, 2014
Triclosan	10.7	High	Yes	WWTW influent	Amdany et al., 2014
	127.7			WWTW effluent	Amdany et al., 2014
	22.9			WWTW influent	Amdany et al., 2014
	0.4 – 0.9			WWTW effluent	Amdany et al., 2014
	2.1 – 9.0			Surface water	Madikizela et al., 2014
	0.2 – 22.0			WWTW influent	Madikizela et al., 2014
Tylosin	0.02 – 0.3	High	Yes	Surface water	Agunbiade and Moodley, 2014

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

PHARMACEUTICAL GROUP / ACTIVE INGREDIENT	CONCENTRATION (µG/L)	CONCERN	HPV	SOURCE	REFERENCE
Carbamazepine	2.2	High	Yes	Drinking water	Patterton, 2013
	0.2			WWTW influent	Matongo et al., 2015
	0.003 – 0.2			WWTW influent	Agunbiade and Moodley, 2015
	1.4 – 3.0			Surface water	Agunbiade and Moodley, 2016
	0.05 – 0.4			WWTW influent	Archer et al., 2017
	0.09 – 0.24			Surface water	Archer et al., 2017
Acetochlor	0.03 – 0.54	High	Yes	Surface water	Madikizela et al., 2014
Alachlor	0.01 – 0.20	High	Yes	Surface water	Manickum and John, 2014
Atrazine	0.008 – 0.78	High	Yes	Surface water	Van Zijl et al., 2017
BBP	0.3	High	Yes	Surface water	Matongo et al., 2015
Bisphenol A	0.08	High	Yes	Surface water	Matongo et al., 2015
Lamivudine	0.05	High	Yes	Surface water	Wood et al., 2015
Stavudine	0.22 – 0.62	Medium	Yes	Surface water	Wood et al., 2015
Zidovudine	0.45 – 0.97	Medium	No	Surface water	Wood et al., 2015
	0.05			WWTW effluent	Wood et al., 2015
	0.07			Surface water	Wood et al., 2015
	0.24 – 1.48			Tap water	Wood et al., 2015
Nevirapine	0.28 – 0.31	High	Yes	Surface water	Wood et al., 2015
Lopinavir	0.001 – 0.03	High	Yes	Surface water	Wood et al., 2015
Oestrone (E1)	0.01 – 0.02	High	Yes	WWTW downstream	Manickum and John, 2014

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

PHARMACEUTICAL GROUP / ACTIVE INGREDIENT	CONCENTRATION (µG/L)	CONCERN	HPV	SOURCE	REFERENCE
	0.009 – 0.011			STW downstream	Swart et al., 2011
	0.01			STW effluent	Swart and Pool, 2007
	0.003 – 0.02			STW effluent	Swart and Pool, 2007
	0.01 – 0.35			STW effluent	Manickum et al., 2011
	0.02 – 0.02			WWTW influent	Manickum and John, 2014
	0.001 – 0.03			Drinking water	Van Zijl et al., 2017
Oestradiol (E2)	0.002 – 0.07	High	Yes	WWTW upstream	Manickum and John, 2014
	0.005			WWTW downstream	Manickum and John, 2014
	0.01 – 0.02			STW effluent	Swart and Pool, 2007
	0.02 – 0.20			STW effluent	Manickum et al., 2011
	0.001 – 0.03			WWTW influent	Manickum and John, 2014
	0.01 – 0.095			Surface water	Van Wyk et al., 2014
	0.001 – 0.008			WWTW influent	Manickum and John, 2014
	0.001 – 0.01			WWTW effluent	Manickum and John, 2014
	0.00002			Surface water	Van Wyk et al., 2014
				Drinking water	Van Zijl et al., 2017

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

4.5. LCA for the Prioritised EDCs

This is an on-going task with comprehensive data collection scheduled from November 2019. However, consultation with industries have resumed in October 2019. Depending on data availability, LCA will be conducted for the selected EDC that will be narrowed down to 10, once the data collection phase has been finalised.

4.6. Data collection strategy concerning stakeholders (companies) along the LCA

For LCA analysis for the prioritised EDCs, the stakeholders or involved companies/entities have been classified into upstream, midstream and downstream. The upstream include mainly the manufacturing sector, whereas the midstream involves the transport, storage and distribution sectors, whereas the downstream sectors include stakeholders involved in prescription, consumption, waste disposal and management.

4.6.1. The upstream sector (manufacturing)

For the LCA, a survey is designed to obtain information regarding the annual quantity of the prioritised EDCs manufactured in South Africa. Companies/stakeholders targeted for the data are shown in **Table 4-3**.

Table 4-3: Companies/stakeholders within the manufacturing sector surveyed for data collection

ENTITY	RATIONALE
Aspen Pharmacare Holdings Limited	Aspen and Adcock are two of the largest pharmaceutical companies in Africa. They manufacture different types of drugs. These two companies will be the first target of the survey for data collection, and after that through a snowballing sampling strategy, where required, new companies will be surveyed for the volume of manufactured prioritised EDCs.
Adcock Ingram	
Department of Health, Trade and Industry	For the prioritised EDCs not manufactured locally in South Africa, the Departments of Health, Trade and Industry will be surveyed for estimation of import data by the public sector.

4.6.2. Midstream sector

The midstream sector comprised of the transportation, distribution and storage of the prioritised EDCs. A survey is conducted to obtain information on the annual quantity of the prioritised EDCs transported, stored and distributed in South Africa for the baseline period. The nature of vehicles used in transporting the EDCs, estimate of fuel consumption, energy

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

utilisation during storage as well as approximate distance covered during transportation and distribution will also be collected. The stakeholders/companies targeted for the survey are indicated in **Table 4-4**. It should be noted that through a snowballing sampling strategy, where relevant, additional stakeholders may be surveyed.

Table 4-4: Companies/stakeholders within the distribution, transportation and storage sectors surveyed for data collection.

ENTITY	RATIONALE
National and Provincial Departments of Health and Agriculture	The national and provincial Departments of Health and Agriculture and Forestry are the two main government entities that primarily regulate the consumption of EDCs. They also purchase in large quantities and distribute to health facilities across the country within the public sector. Thus, they will be surveyed for estimation of the quantity of the prioritised EDCs procured, transported, distributed and stored within either government facilities or third party facilities through a third party contract with the government.
The World Courier	This entity stored and deliver healthcare, biopharmaceuticals. It will be surveyed for an estimate of the quantity of the prioritised EDCs it transported and stored during the baseline period. Additional data collected include the type of vehicle use for EDCs transportation, an estimate of fuel consumption and approximate distance covered during the baseline period.
Royale international	This entity stored and deliver healthcare and pharmaceuticals. It will be surveyed for an estimate of the quantity of the prioritised EDCs it transported and stored during the baseline period. Data on energy utilisation during storage were also collected.
DGR compliance	This entity transport dangerous goods and specimens. It will be approached for an estimation of the quantity of the prioritised EDCs it transported during the baseline period. Additional data collected include the type of vehicle use for EDCs transportation, an estimate of fuel consumption and approximate distance covered during the baseline period.
XPS logistics	This entity delivers, collect and stored pharmaceuticals. This entity is approached for an estimation of the quantity of the prioritised EDCs it transported, distributed and stored during the baseline period. Data such as the type of vehicle used for transport and distribution, as well as water and energy utilisation during storage, were also collected.
IMPERIAL logistics	This entity stores and distribute pharmaceuticals and consumer goods. This entity is approached for an estimation of the quantity of the prioritised EDCs it transported, distributed and stored during the baseline period. Data such as the type of vehicle used for transport and distribution, as well as water and energy utilisation during storage, were also collected.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

4.6.3. Downstream sector (consumption, disposal and waste management)

The downstream sector is perhaps the most complex for the LCA of the prioritised EDCs. Data collected from the downstream sector stakeholders include fuel consumption, electricity and water within facilities used for storing EDCs in hospitals and veterinary facilities, quantity of dispersed prioritised EDC, quantity of the EDCs disposed as expired/unused, or incinerated, as well as quantity transported to landfill/incineration facilities, including associated energy and fuel consumption. Selected large scale livestock farmers would be surveyed for veterinary EDCS used for livestock. **Table 4-5** indicates the stakeholders/companies which will be surveyed.

Table 4-5: Stakeholders within the downstream sector surveyed for data collection

ENTITY	RATIONALE
National and Provincial agricultural organisations	National and provincial agricultural organisation act as a conduit for access to commercial farmers in South Africa. Such organisation include Agri Eastern Cape, Free State Agriculture, Agri Gauteng, and Kwazulu-Natal Agricultural Union. These organisations will be approached for access to selected large-scale farmers. Data collected include quantity of EDCs consumed, transported and stored as well as associated energy and fuel consumption.
National and provincial Department of Health and Health facilities	The national and provincial departments of health are the primary consumers of EDCs in the public sector. Data collected include the quantity of the selected EDCs procured, dispersed, disposed of, incinerated and unused. Additional data associated with energy and fuel consumption during disposal and incineration were collected.
Large scale pharmacy and dispensary shops	These are mainly sales outlets. Quantity of the selected EDCs sold to members of the public was collected as an indicator of public consumption of the EDCs.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

5. REVIEW OF ENVIRONMENTALLY SOUND MANAGEMENT OF EDCS – LOCAL AND INTERNATIONAL EXPERIENCES AND BEST PRACTICES

5.1. Introduction and Context

Endocrine Disrupting Compounds pose a challenge to policy regulation because their dose response analysis is rather complex. Effects at a very low dose may vanish at higher doses, and effects might be very different at different doses or dose timing (one-time versus chronic, or early in life versus in adulthood). Classic chemical assessment underpinned by the assumption that “the dose makes the poison” is simply not valid for EDCs. Over the past three decades, international research efforts to better understand EDCs have been intensified (WHO, 2012). This has resulted in growing global concern regarding EDCs. In 2012, the third session of the International Conference on Chemicals Management (ICCM3) recognised EDCs as one of the Emerging Policy Issues (SACM, 2012) under the UN Strategic Approach to International Chemicals Management (SAICM) (SAICM, 2012). The fourth session (ICCM 4) in 2015 (SAICM, 2015) affirmed to support further research and develop cooperative actions regarding EDCs. The ICCM (UNEP/WHO, 2012). Resolution further requested all interested stakeholders to support cooperative actions led by the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), including to address the needs identified by developing countries and countries with economies in transition by generating and disseminating information on EDCs.

As part of its commitment to the IOMC’s work plan, the United Nations Environment Programme (UN Environment) initiated the project “Provision of Information on EDCs” in August 2015 to increase and improve intergovernmental and inter-sectorial understanding, coordination and cooperation as well as awareness of EDCs. Among other activities under the project framework, UN Environment commissioned the International Panel on Chemical Pollution (IPCP) to develop a set of three overview reports that focus on existing scientific knowledge of environmental exposure and effects as well as regulatory frameworks and policy initiatives regarding identified and potential EDCs. According to the World Health Organization/International Programme on Chemical Safety (WHO/IPCS) 2002 definition, an endocrine disruptor is “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” (WHO, 2002).

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

While current regulatory approach, around the world, has been inadequate in addressing the unique attributes associated with EDCs, there is an urgency to address all potential contributors to the epidemics of chronic endocrine-related conditions experienced in society. The solution to these effects is simply not prevented by detection of environmental prevalence but in addition, by tracing the sources and entry points of these compounds into our environment. In the context of South Africa, a life cycle management framework for EDCs is not only urgent but necessary. The aim of this deliverable is to undertake a critical review and analysis of the literature, with a view to identifying environmentally sound management practices/frameworks, analysing and synthesis such practices in line with the principles of life cycle assessment of EDCs.

This chapter systematically analyses and summarizes the characteristics (including scope, criteria and relevant processes) of existing explicit frameworks, including those in developing countries and countries with economies in transition. In particular, the chapter focuses primarily on frameworks/sound management strategies that are applicable to many types of chemicals. Overall, the report aims to provide clear, succinct information essential for understanding the basic functioning of existing frameworks in regard to EDCs, both at national; and international scales. It intends to provide a comprehensive, but not necessarily complete, overview of existing guidelines (*upstream, midstream, downstream* and *cross-stream*) addressing EDCs. Finally, this chapter presents a schematic representation and narrative on environmentally sound management of EDCs and includes management measures and a roadmap for systematic scientific assessment and management of EDCs required to source, control and regulate EDCs in South Africa.

5.2. Principles of sound management of EDCs

Country policies and management towards EDCs may vary but using common tools and methodologies to identify them facilitates the exchange of information, as a first step towards mutual understanding of regulatory decisions. Specific objectives include providing a description of the conceptual framework for evaluating chemicals for endocrine disruption, background on the standardized test methods used, and guidance for interpreting the outcome of individual tests.

South Africa's current management measures on substances linked to endocrine disruption are targeted at "control" rather than elimination or preventative measures. The South African

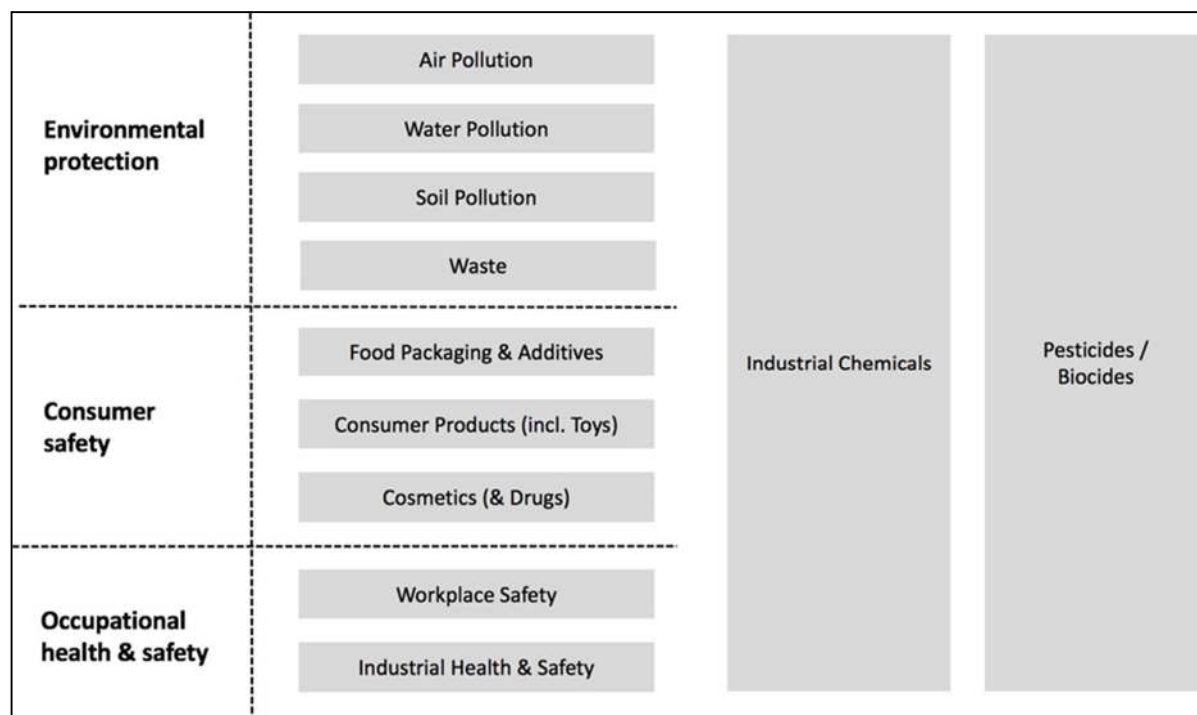
 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Legislative framework sets out to protect the environment from these compounds related to the protection of water resources, the environment and human health. However, to set out a proper.

5.2.1. Methods used for mapping and selection of sound management frameworks for analysis

As a first step, existing management frameworks and policy initiatives at the national and international levels were reviewed to identify those that have the potential to address EDCs. This was done through a systematic search for frameworks within three (3) main regulatory domains that were expected to involve EDCs which are (WHO, 2012) environmental protection, (SAICM, 2012) consumer safety, and (SAICM, 2015) occupational health and safety (see **Figure 5-1**). For example, in the context of environmental protection, EDCs can be addressed under frameworks concerning air pollution, water pollution, soil pollution and waste. Frameworks on industrial chemicals, pesticides, and biocides usually span all three (3) of these legislative domains, *i.e.*, their scopes often include the protection of the environment, consumers and professionals in occupational settings. The frameworks depicted in **Figure 5-1** can also be interconnected, and their exact content can vary across different regions of the world. For example, the management of a substance under a framework for industrial chemicals can lead to the regulation of the same substance under another framework on consumer product safety. From all frameworks identified, only existing frameworks explicitly addressing EDCs were selected and then analysed in more detail. The following countries' explicit sound management strategies for EDCs were considered: Australia, Brazil, Canada, Japan and Russia.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	



Adopted from Toda E, 2007

Figure 5-1: Overview of the different frameworks across three main regulatory domains that are expected to involve EDCs.

5.2.2. Analysis of individual framework and general observations

The in-depth analysis of identified, explicit frameworks was conducted by reviewing each framework against a set of pre-defined descriptors that cover key aspects of EDC-related concepts and processes (See **Table 5-1**).

Table 5-1: Descriptors used in the analysis of EDC management frameworks

CATEGORY	DESCRIPTOR
Regulatory concepts	Regulatory approach (e.g. risk vs. hazard based)
	Criteria for identification of EDCs
	Characterization of EDCs and/or assessment of risks
Regulatory processes	Data requirements
	Decision making process
	Instruments for risk management
	Administrating authorities
	Stakeholder involvement

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department of Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

General observation across existing EDC management framework are summaries below. Overview of the analysed explicit sound management frameworks and policy initiatives are provided in **Table 5-2** that follows.

- A number of explicit frameworks have been developed and are being implemented to address EDCs, and most are in developed countries/regions. A few have also been established in some countries with economies in transition; almost no information was found regarding developing countries. This lack of information may be caused by either a true scarcity of such frameworks in developing countries, by language barriers (i.e., frameworks exist, but are described in languages not covered during the search), or by limitations in placing such information online (e.g. websites that are not yet extensively developed);
- The terminology and characteristics (e.g., scope, approach and processes) can differ considerably across existing explicit frameworks. As no harmonized criteria for the identification of EDCs are available across jurisdictions (even though the WHO/IPCS definition has been commonly accepted by many stakeholders), there are no EDC-specific data requirements in these frameworks. According to the available information, it even remains unclear in some frameworks how they have defined EDCs;
- Many existing regulatory frameworks may address certain EDCs only implicitly, i.e., they consider or regulate substances based on adverse effects and do not require the understanding of the causes of such adverse effects. In comparison to explicit regulatory frameworks, implicit regulatory frameworks have both advantages and disadvantages;
- Publicly accessible information on existing frameworks (e.g., documents and websites) is often scattered, complex and/or inconsistently linked or referenced. This can make it challenging for stakeholders who are not familiar with them to obtain necessary background information on the creation of these frameworks, as well as on the assessment or review processes involved;
- Responsible regulatory authorities have often published outcomes of completed evaluations of individual substances within frameworks considered in this report. These publications (many publicly available on the authorities' websites) could serve as valuable sources of information for other regulatory authorities conducting substance evaluations; and
- A number of policy initiatives are working towards the creation of future explicit regulatory frameworks; some of them are in countries with economies in transition.

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Table 5-2: Overview of the analysed explicit sound management frameworks and policy initiatives discussed in this report.

REGION	SCOPE	REGULATORY APPROACH / POLICY INITIATIVE CONTENT	APPLICABLE PROCESSES	AVAILABLE MANAGEMENT OPTIONS	STREAM
European Union					
European Chemicals Regulation (REACH)	Industrial chemicals	Substances are generally evaluated for risks. EDCs can be recognized as Substances of Very High Concern (SVHC) and can be subject to authorization or restriction.	Identification as an SVHC based on hazard assessment using the WHO/IPCS 2002 definition of EDCs. Authorization and restriction based on additional risk and socio-economic assessments	(1) Recognition as an SVHC. (2) Authorization, which can include conditions for use, manufacture or import. (3) Restriction.	Upstream
Plant Protection Products Regulation (PPPR)	Active substances, safeners, synergists used in plant protection products	Substance can only be approved if it is not considered to have endocrine disrupting properties. Exemptions can be made when a substance is required in order to control a serious danger or if exposure is negligible.	Identification of EDCs based on hazard assessment. In the case of exemptions: following a risk assessment, a substance can be approved regardless of its hazards when it is necessary to control a serious danger.	Approval as an active substance, safener or synergist granted or denied.	Upstream & downstream
	Basic substances	Substance can only be recognized as a basic substance if it is not considered to have endocrine disrupting properties.	Identification of EDCs based on hazard assessment.	Approval as a basic substance granted or denied.	Downstream

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	
	DOC NO:	MC_DEA_EDC_001	

REGION	SCOPE	REGULATORY APPROACH / POLICY INITIATIVE CONTENT	APPLICABLE PROCESSES	AVAILABLE MANAGEMENT OPTIONS	STREAM
Biocides Products Regulation (BPR)	Active substances used as biocides	Substance can only be approved if: 1) it is not considered to have endocrine disrupting properties or 2) the risk for humans, animals, or the environment is negligible, or 3) not approving the substance would have disproportionate negative impacts on society compared to the risk.	Identification of an EDC based on a hazard assessment. Decision made on approval or denial of a substance based on a risk assessment.	Approval as an active substance in biocides granted or denied.	Downstream
Water Framework Directive (WDF)	pollutants of water bodies	Member States are required to prevent further deterioration of all water bodies and to implement measures for the protection, enhancement and restoration of water bodies.	EDCs are recognized as “main pollutants” and can be included in the list of priority chemicals based on an assessment of their risks to or via the aquatic environment.	Establishment of environmental quality standards (EQS) on an EU- wide or member state level.	Midstream & Downstream
		The status of water bodies is quantified by a combination of chemical and ecological parameters.		Any measure for the control and progressive reduction of emissions to water bodies on the member state level.	Downstream
United States					

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

REGION	SCOPE	REGULATORY APPROACH / POLICY INITIATIVE CONTENT	APPLICABLE PROCESSES	AVAILABLE MANAGEMENT OPTIONS	STREAM
Federal Food, Drug and Cosmetic Act (FD&C Act)	Pesticide chemicals	A pesticide can be registered if using it according to the specification will not generally cause a human dietary risk from residues. As part of the endocrine evaluation, pesticides must not pose an unreasonable risk to either human health or the environment.	Screening of pesticide chemicals for endocrine disrupting potential under the Endocrine Disruptor Screening Program (EDSP). Assessment of dietary risks considers endocrine disruption potentials and maximum residue levels in individual crops, and dietary intake across crops. It also considers potential environmental effects of endocrine-active substances.	(1) Approval or denial of pesticide registration for a specific use; (2) Imposing conditions on the use of the pesticide; (3) Setting of maximum residue levels for crops	Upstream, Midstream and Downstream
Safe Drinking Water Act	Drinking water contaminants	Drinking water contaminants can be regulated if the Environmental Protection Agency (EPA) concludes that the contaminant may have an adverse effect on human health, the contaminant is likely to occur in public water systems in concerning levels, and regulation poses a meaningful opportunity for reduction of health risk.	Screening of contaminants for endocrine disrupting potential under the Endocrine Disruptor Screening Program (EDSP) if a substantial population may be exposed. Risk assessment completed in order to determine a safe	Decision to regulate a drinking water contaminant. Setting of a maximum level contaminant goal and maximum contaminant levels in drinking water.	Downstream

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	
	DOC NO:	MC_DEA_EDC_001	

REGION	SCOPE	REGULATORY APPROACH / POLICY INITIATIVE CONTENT	APPLICABLE PROCESSES	AVAILABLE MANAGEMENT OPTIONS	STREAM
			maximum level of the contaminant.	Setting of treatment technique standards.	
Regulatory framework on new drug approval	New pharmaceutical drugs	Evaluation for the potential of unintended endocrine-related toxicity in order to be approved for use.	Evaluation performed based on the standard non-clinical battery of toxicity tests. Additional studies can be warranted following the initial assessment.	Approval of the drug granted or denied.	Upstream
Canada					
Canadian Environmental Protection Act (CEPA)	Industrial / commercial chemicals I	Evaluate whether a new or existing substance is "toxic" according to CEPA.	Completion of a risk assessment for the evaluation of new and existing substances considering endocrine disrupting effects.	(1) Establishment of pollution prevention plans or environmental performance agreements. (2) Establishment of conditions for Manufacture or import.	Upstream

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	
	DOC NO:	MC_DEA_EDC_001	

REGION	SCOPE	REGULATORY APPROACH / POLICY INITIATIVE CONTENT	APPLICABLE PROCESSES	AVAILABLE MANAGEMENT OPTIONS	STREAM
				(3) Issuance of a “significant new Activity” notice. (4) Prohibition of manufacture or Import.	
Pest Control Products Act (PCPA)	Pest control products, including chemicals, devices, and organisms	A pesticide can be registered if there is reasonable certainty that no harm to human health or the environment will result from exposure to or use of the pesticide, based on its conditions or proposed conditions of Registration.	Assessment of health and environmental risks considers endocrine disruption potential, in accordance with the OECD conceptual framework for testing and assessment of endocrine disrupters.	(1) Registration of pesticides for approved conditions of use according to label only; (2) Setting of maximum residue levels for crops	Upstream & Downstream
Proposed regulatory framework under the Food and Drug Regulations (F&DA)	Active pharmaceutical ingredients in new human and veterinary drugs.	A new active pharmaceutical ingredient would be subject to the proposed regulations when an application for a drug submission requiring a new drug identification number is made to Health Canada. This would require industry to provide data that allows for an environmental risk assessment of these substances.	Under the proposed regulatory framework, EDCs are considered special category substances, meaning Health Canada has the authority to ask for additional data that is not normally required for an environmental assessment.	To be determined at a later time.	Cross-Stream & Downstream
Brazil					

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	
	DOC NO:	MC_DEA_EDC_001	

REGION	SCOPE	REGULATORY APPROACH / POLICY INITIATIVE CONTENT	APPLICABLE PROCESSES	AVAILABLE MANAGEMENT OPTIONS	STREAM
Federal Law 7802/1989	Pesticides and their components	Pesticides and their components can only be approved if they are not considered to have endocrine disrupting properties.	Identification of EDCs based on hazard assessment.	Registration for the use in Brazilian agriculture granted or denied.	Upstream & Downstream
Initiative to establish a national legislation on industrial chemicals	Industrial chemicals	Substances on the national registry of industrial chemicals considered to have endocrine disrupting properties can be selected for risk assessment.	Risk assessment for selected chemicals.	(1) Voluntary agreements between the government and industry. (2) Providing information for substances produced or imported in quantities < 1 tons per year; (3) Prohibition or restrictions of the production, import, export, trade and uses. (4) Setting of concentration limits of a substance in intentional mixtures or finished products.	Cross-Stream

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	
	DOC NO:	MC_DEA_EDC_001	

REGION	SCOPE	REGULATORY APPROACH / POLICY INITIATIVE CONTENT	APPLICABLE PROCESSES	AVAILABLE MANAGEMENT OPTIONS	STREAM
				(5) Prior authorization for the production and imports of a substance.	
China					
13 th Five-Year Plan of National Environmental Protection	Unclear	Control pollution by EDCs.	Assessment of the endocrine disrupting properties of chemicals.	(1) Phase-out of a substance (2) Restriction of a substance (3) Replacing of a substance	Cross-Stream
Industry standard on evaluation methods of endocrine disrupting effects of pesticides	Pesticides	Testing guidelines outlining in vitro and in vivo testing kits for the evaluation of endocrine disrupting effects of pesticides.	Not applicable	Not applicable	Cross-Stream
Japan					

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

REGION	SCOPE	REGULATORY APPROACH / POLICY INITIATIVE CONTENT	APPLICABLE PROCESSES	AVAILABLE MANAGEMENT OPTIONS	STREAM
Japanese environmental regulation	Chemicals detected in the ambient aquatic environment	Adverse effects caused by endocrine disrupting effects of chemicals are expected to be considered in existing regulatory risk assessment practices.	Studies have been conducted to identify adverse effects caused by endocrine disrupting effects of chemicals under the government's programmes for testing and assessment (EXTEND 2010 and 2016).	Under development.	Downstream
South Korea					
The South Korean Regulation on the Registration and Evaluation of Chemicals (K-REACH)	Industrial / commercial chemicals	Substances are evaluated for potential risks. EDCs can be recognized as substances subject to authorization, restriction or prohibition.	Completion of a hazard evaluation and risk assessment can lead to a substance being subject to authorization, restriction or prohibition.	Authorization of a substance. Restriction of a substance. Prohibition of a substance.	Upstream
Australia					
National Industrial Chemicals Notification and Assessment Scheme (NICNAS)	Industrial / commercial chemicals	Substances on official inventory evaluated for risks they pose.	Consideration of potential endocrine disrupting activity (as determined by the European Commission) as a hazard indicator, automatically causing a substance to be further	Make recommendations of measures for regulators in individual states and territories.	Upstream

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

REGION	SCOPE	REGULATORY APPROACH / POLICY INITIATIVE CONTENT	APPLICABLE PROCESSES	AVAILABLE MANAGEMENT OPTIONS	STREAM
			evaluated in a risk assessment.		
	Ultraviolet filters for cosmetics	Substances used in cosmetics evaluated for risks they pose.	Evaluation and assessment of the risk of potential endocrine activity.	Creation of recommended measures for regulators in individual states and territories.	Downstream

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

5.3. EDC management: International Experiences and best practices

Explicit frameworks from countries and regions across five (5) continents are identified and information essential for understanding their basic functioning is summarized (including their scope and general processes, public participation and stakeholder involvement, processes relevant for EDCs, criteria utilized, and data requirements).

5.3.1. Europe / European Union

Within the politico-economic European Union (EU), an internal single market has been established over the course of the past decades, and a standardized system of regulatory frameworks has been established and implemented in all EU Member States. In general, the EU's standardized system of regulatory frameworks covers all the domains in **Figure 5-1** above, and the following sub-sections analyse the three EU frameworks that explicitly address EDCs.

Within the EU's standardized system of regulatory frameworks, EDCs are explicitly addressed within the frameworks on industrial chemicals, plant protection products, biocidal products, and water pollutants. These frameworks are governed by the following regulations:

- **Industrial chemicals:** Regulation (EC) 1907/2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
- **Plant protection products:** Regulation (EC) 1107/2009, concerning the placing of plant protection products on the market;
- **Biocidal products:** Regulation (EU) 528/2012, concerning the making available on the market and use of biocidal products; and
- **Water framework:** Directive 2000/60/EC, establishing a framework for Community action in the field of water policy.

5.3.1.1. *Registration, Evaluation, Authorization and Restriction of Chemicals (EC 1907/2006)*

Framework for the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) established by the European Union. It requires the registration and management of all chemical substances used in business to conform to safety standards. Under REACH, every substance to be manufactured or imported into the EU in a quantity above 1 tonne per year (t/yr) must be registered with the European Chemicals Agency (ECHA) before it can be

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

placed on the market. For this registration, information on physicochemical properties and uses of the substance must be provided by the registrant. The exact information requirements for an assessment of hazards and risks are dependent on the substance quantity (i.e., >1 t/yr, >100 t/yr, or >1000 t/yr). Registered substances can be selected by ECHA or the EU member states and be placed on the list of the Community Rolling Action Plan (CoRAP) for substance evaluation. This selection process is carried out according to defined hazard- and risk-based criteria by ECHA and the Member States. Selected substances are then evaluated individually by Member State(s) to clarify whether the use of such substances poses a risk to human health or the environment. There are three possible outcomes of a substance evaluation:

- If the existing information is sufficient to come to the conclusion that the initial concern was non-justified, then the substance evaluation is terminated without further action;
- If the existing information is sufficient to conclude that the initial concern was justified, appropriate risk management measures are considered, including:
 - harmonized classification and labelling (not relevant for EDCs as there is no harmonized classification for endocrine disrupting effects),
 - to identify the substance as a Substance of Very High Concern (SVHC),
 - to restrict the substance, or
 - actions outside the scope of REACH, such as a proposal for EU-wide occupational exposure limits, national measures, or voluntary industry actions.
- If the initial concern cannot be resolved based on existing information, the Registrant is requested to provide additional information (e.g. test data). This request for further data is decided by the Member State Committee.

5.3.1.2. Plant Protection Product Regulations (EC 1107/2009)

The Plant Protection Product Regulation (PPPR) sets rules for the authorization of commercial plant protection products, their placement on the market, as well as use and control within the European Union. It also lays down provisions for the approval of individual components of plant protection products, namely active substances, safeners, synergists, basic substances, co-formulants and adjuvants. To place a plant protection product on the market, it has to be evaluated and subsequently granted an authorization. This evaluation and authorization take place on the basis of geographical zones. In an individual zone, a Member State can evaluate and authorize a plant protection product, and other Member States can then recognize that authorization. A plant protection product can be granted authorization only if all of its components (i.e., active ingredients, safeners and synergists, and basics substances) have

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

been evaluated and granted a separate approval. This evaluation and approval of takes place on the EU-wide level, and the evaluation is conducted by one Member State on behalf of all other member states with the final decision on approval made by the European Commission.

5.3.1.3. The Biocidal Products Regulations (EU No. 528/2012)

The Biocidal Products Regulation (BPR) EU No. 528/2012 sets the rules and provisions regarding the placement on the market and use of biocidal products. These products are intended to protect humans, animals, materials or articles against harmful organisms such as pests or bacteria (ECHA, 2016). It also sets provisions for the approval of active substances contained in biocidal products.

All biocidal products must be authorized before they can be placed on the market as illustrated in **Figure 5-2**. This authorization is granted by individual EU Member States and can also be recognized by other Member States (ECHA, 2016). If an applicant for authorization intends to place the product on the market of several Member States, they can also apply directly for union-wide authorization. In this case, the evaluation process is carried out by the competent authority of a Member State on behalf of all other Member States. The European Commission takes the final decision on granting a union-wide authorization.

A biocidal product can be granted authorization only if the active ingredients contained have been evaluated and granted a separate approval. The evaluation and approval of active ingredients takes place on a EU-wide level. The evaluation is conducted by one Member State on behalf of all other member states, and the final decision on approval is made by the European Commission. A brief explanation of the approval process of active substances including required data under the BPR (EU No. 283/2013) is provided below and illustrated in **Figure 5-2**:

- The applicant submits the application to the ECHA, which is then evaluated by the competent authority of a Member State;
- The competent authority evaluates if the applied active substance fulfils the provisions laid down in the BPR and compiles a draft assessment report with its conclusions. The applicant is given the opportunity to provide written comments on the draft assessment report;
- The draft assessment report undergoes a peer review by the Biocidal Products Committee. If the evaluated substance has been designated as candidate for

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

substitution, the peer reviewed assessment report is made open for public commenting;

- The Biocidal Products Committee finalizes an opinion based on the peer-reviewed assessment report; and
- The European Commission takes a final decision on the EU-wide approval of the substance.

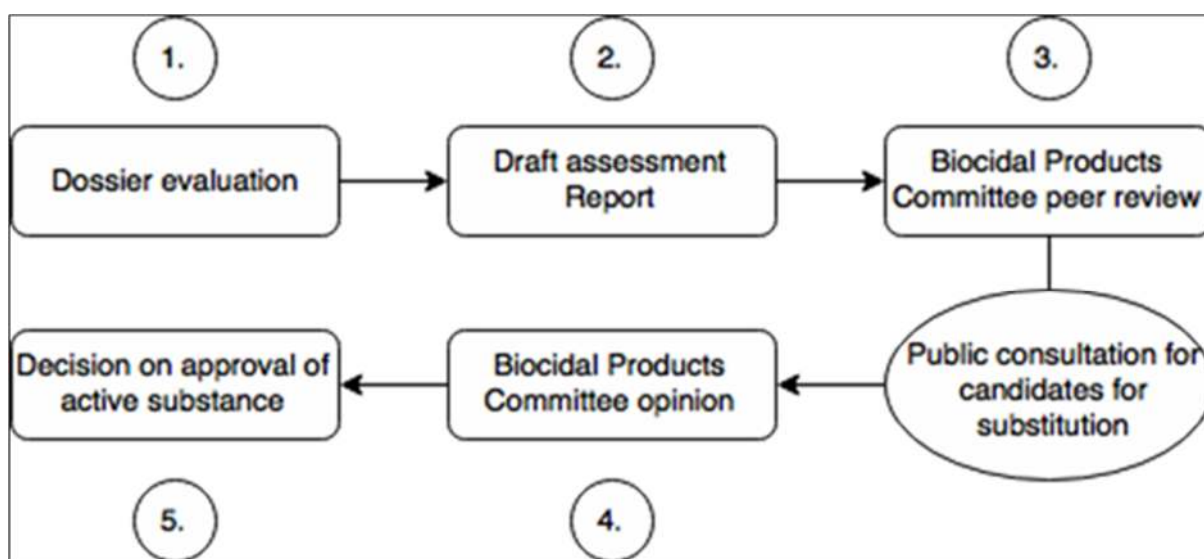


Figure 5-2: Illustration of the approval process of active substances including required data as outlined in the Biocidal Product Regulation ((EU) No. 283/2013)

5.3.1.4. The Water Framework Directive (2000/60/EC)

The Water Framework Directive (WFD) lays down the goals and processes for the EU-wide protection and management of water bodies. It institutionalizes ecosystem-based objectives and planning processes for the protection of inland surface waters, transitional waters, coastal waters, and groundwater. Specifically, the main goals (WFD: 2000/60/EC, Art. 4) are:

- the prevention of further deterioration of water bodies;
- the protection, enhancement and restoration of water bodies and the achievement of “good status” for all waters; and
- the reduction, limitation or prevention of pollution of all water bodies.

The status of a surface water body is determined by its ecological and chemical status, whereas the status of a groundwater body is determined by its quantitative and chemical

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

status. To achieve the stated objectives, Member States are required to establish monitoring programmes, as well as programmes of measures and management plans on the basis of river basins or catchment areas (WFD2000/60/EC, Art. 2). In order to prevent the deterioration of water bodies by chemical pollution, Member States are required to regulate the discharge of pollutants into water bodies (WFD: 2000/60/EC, Art. 11). Furthermore, the WFD mandates the European Parliament and Council to establish specific measures against pollution by individual pollutants or groups of pollutants that present a significant risk to or via the aquatic environment (WFD:2000/60/EC, Art. 16). For this, the European Commission establishes a list of priority substances that present such a significant risk. The Commission is also mandated to identify a sub-set of priority hazardous substances from the list of priority substances. Based on these lists, the Commission establishes controls for (1) the progressive reduction of discharges of priority substances and (SAICM, 2012) the cessation and phasing-out of discharges of priority hazardous substances. Furthermore, the Commission also sets EU-wide Environmental Quality Standards (EQS) for all priority substances in surface waters, sediments or biota (WFD: 2000/60/EC, Art. 16(5)). In order to achieve the goal of “good status”, all surface water bodies must not exceed these EQS. Individual Member States must therefore integrate measures concerning the control, reduction, or cessation of discharges of priority substances or priority hazardous substances into their programmes of measures. Such measures can also include the establishment of environmental quality standards at the level of individual Member States.

Due to its integrated ecosystem-based approach, the WFD is closely linked to a number of other EU directives, including directives relating to the protection of habitats, specific water uses, and directives concerned with the release of chemical substances into the environment. In order to protect against the effects caused by such an endocrine mode-of-action (EC, 2011).

5.3.2. North America

5.3.2.1. United States of America

In the United States of America (US), EDCs are explicitly addressed in the regulatory frameworks on pesticides, drinking water contaminants and for approval of new drugs.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Regulatory framework on pesticides

The US regulatory framework on pesticides consists of two (2) statutes: The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA, 1996) and the Federal Food, Drug and Cosmetic Act (FD&C Act 1938, as amended in 2019). FIFRA requires conventional chemical pesticides, bio-pesticides, and antimicrobial pesticides to be registered by the US Environmental Protection Agency (US EPA) for a specific application before they can be placed on the market. In brief, the US EPA develops a risk assessment with data provided by the pesticide producer (*i.e.* the applicant for the registration) to check that the use of the pesticide according to the specifications US EPA, 2017):

- i. will not pose any unreasonable risks to humans or the environment, taking into account the economic, social and environmental costs and benefits of using the pesticide, and
- ii. will not pose a human dietary risk from residues that result from using the pesticide that would be inconsistent with the respective provisions of the FD&C Act.

Based on the risk assessment outcomes, the US EPA makes a decision whether to approve or deny the registration of the pesticide for a specific use and sets tolerances (also called maximum residue limits in many other countries) on the amount of pesticides that may remain in or on foods that are sold within the US. A registration can also be classified for “restricted use” (40 CFR 152.160 – 152.175), whereby the pesticide is only to be used by certified applicators (US EPA, 2016; US EPA, 2017). There are three (3) types of applications for registration (US EPA, 2016):

- **New chemical or new active ingredient:** a pesticide registration application for a product that contains a pesticide active ingredient that is not contained in any other product currently registered;
- **New use:** a pesticide product containing one or more previously registered active ingredient(s), where the requested use is a “New Use” (*i.e.* any use pattern that the active ingredient is currently not registered for or would change the level or route of exposure for humans or any other organisms); and
- **Identical or substantially similar product:** a pesticide product that is identical or substantially similar in its uses and formulation to one or more products currently registered.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Regulatory framework on drinking water contaminants

The US regulatory framework on drinking water contaminants is governed by the Safe Drinking Water Act (SDWA 1996) to ensure safe drinking water for the public (US EPA, 2016). It gives the US EPA the authority to establish a regulation of either non-enforceable health goals or enforceable standards for the levels of a contaminant in public drinking water if it finds:

- i. the contaminant may have an adverse effect on the health of persons;
- ii. the contaminant is known to occur or is likely to occur in public water systems with a frequency at levels of concern to public health; and
- iii. the regulation of a contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

When the US EPA decides to regulate a drinking water contaminant, it first determines a maximum contaminant level goal (MCLG). This is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of a person would occur. For carcinogens, the MCLG is set at zero, and for non-carcinogen contaminants, the MCLG is based on a reference dose (*i.e.* the estimated amount that a person can be exposed to on a daily basis that is not anticipated to cause an adverse effect). The MCLG is a non-enforceable health goal (US EPA, 2016).

Based on the established MCLG, the US EPA may then set an enforceable standard. This standard is a maximum level of contaminants (MLC) allowed in any public drinking water system. If there is no reliable economically or technically feasible method for the measurement of the contaminant at the required concentrations, the US EPA sets a “treatment technique”. This technique is an enforceable procedure or level of technological performance that public drinking water systems must follow in order to ensure control of a contaminant (US EPA, 2016).

Regulatory framework on new drug approval

EDCs are explicitly addressed in the US’ regulatory framework on new drug approval based on the Federal Food, Drugs and Cosmetics Act (FD&C Act 2019, as amended). According to this statute, every new drug must be approved by the Food and Drug Administration (FDA) before it can be placed on the market. This approval is based on the evaluation of extensive non-clinical and clinical test data demonstrating the drug’s safety and effectiveness for its proposed use and that its benefits outweigh the risks (US FDA, 2017).

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

5.3.2.2. Canada

EDCs are addressed in several regulatory frameworks in Canada including the Canadian Environmental Protection Act of 1999 (CEPA), the Pest Control Products Act (PCPA), and the proposed framework within the Food and Drugs Act (F&DA).

Canadian Environmental Protection Act of 1999

CEPA aims at preventing pollution and protecting the environment and human health and includes specific requirements for the assessment and management of substances (CEPA, 1999). Under CEPA, Environment and Climate Change Canada (ECCC) and Health Canada conduct risk assessments of substances proposed for introduction to the Canadian market (new substances) or present in Canada (existing substances), to determine whether these substances present or may present a risk to the environment or to human health (Government of Canada, 2013). CEPA (and associated regulations) defines the process for notification and evaluation of substances and activities that are new to Canada. These notifications are received on a continuing basis and require risk assessment under CEPA (Environment and Climate Change Canada, 2017). CEPA also requires that a screening assessment be conducted on existing substances identified as priorities through the Categorization process, which was a goal set under CEPA to sort through or "categorize" all 23,000 chemical substances on the Domestic Substances List (DSL) (Government of Canada, 2017). In addition to Categorization, other mechanisms exist for the identification of priorities for risk assessment such as decisions of other jurisdictions and emerging science and monitoring (Government of Canada, 2013).

CEPA provides the Minister of ECCC and the Minister of Health Canada with the authority to determine if a new or existing substance is toxic, and it defines regulatory instruments for risk management as needed ((Government of Canada, 2013; Meek E, 2007). If a substance is found to be toxic under CEPA, it can be added to the "List of Toxic Substances" and regulatory actions can be taken for any aspect of the substance's life cycle (Environment and Climate Change Canada, 2016). A substance is considered 'toxic' if it is entering or may enter the environment in a quantity or concentration or under conditions that (CEPA, 1999, section 64):

- i. have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or
- ii. constitute or may constitute a danger to the environment on which life depends; or
- iii. constitute or may constitute a danger in Canada to human life or health

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

If determined to be toxic or capable of becoming toxic, then risk management measures are considered to reduce, eliminate or prevent risks identified. Follow up activities may be undertaken for those substances recognized for their potential effects of concern (Government of Canada, 2013). Examples of policy instruments for risk management are outlined in **Table 5-3**. For new substances specifically, when no actions for risk management are needed, the substance can be added to the DSL.

Table 5-3: Policy instruments provided by CEPA for the risk management of substances.

POLICY INSTRUMENT	COMMENT
Regulations	Enforceable laws that can restrict the use or release of a chemical substance, set limits on the concentrations allowed under various conditions, or prevent the use of chemical substances in certain products.
Pollution prevention planning notices	Require companies to prepare and implement a pollution prevention plan in order to minimize or avoid the creation of pollution or waste.
Release guidelines or codes of practice	Recommend limits and best practices to manage the use, release or disposal of a chemical substance.
Significant new activity notices	Require any major changes in the way a chemical substance is used to be reported so that the government can decide whether to control the new use.
Environmental performance agreement	Agreement negotiated among parties to achieve specific environmental results. Can address a variety of environmental issues, such as reducing use or emissions, advancing product stewardship or conserving sensitive habitats.
Permission for manufacturing / importing under certain conditions	Applicable conditions can include restrictions on certain uses or emissions regulations.
Request for additional information	Mandatory surveys issued under section 71 of the CEPA gather information needed to inform priority setting, risk assessment and, if necessary, subsequent risk management activities for substances that are toxic or proposed to be toxic as defined under section 64 of CEPA 1999.
Prohibition of manufacture / import	As per Section 84 of CEPA, the Ministers may prohibit the import or manufacture of a substance suspected of being toxic or capable of becoming toxic, or request additional information or submission of results of any testing that the Ministers consider necessary for the purpose of assessing whether the substance is toxic or capable of becoming toxic.
Ministerial Condition	As per Section 84 of CEPA, manufacture or import of the toxic substance is subject to any conditions that the Ministers may specify.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Pest Control Products Act of 2002

The Pest Control Products Act (PCPA) prohibits the manufacture, import, and use of, amongst other things, any unregistered pest control product. Before a pesticide is considered for registration in Canada, it must undergo testing to determine the risks posed to human health and the environment and the pesticide's value (including efficacy of product claims). Decision to register or deny registration is based on an objective scientific assessment of the risks and the value.

Health Canada applies quantitative risk assessment principles when determining whether a product can be registered for use in Canada, or to determine if it can remain registered (in the case of post-market evaluation). This involves determining the amount of human exposure to a given pesticide through both dietary and non-dietary (*i.e.*, occupational & residential / bystander) exposures, as well as assessing environmental exposures.

Additionally, as part of the assessment process, prior to the registration of a pesticide, Health Canada must determine whether or not the consumption of the maximum amount of residues expected to remain on food products (when a pesticide is used according to label directions) will be a concern to human health. This maximum amount of residues expected is then legally established as an MRL and is regulated under the PCPA.

For chemicals exhibiting endocrine-mediated effects, the environmental risk assessment considers any observed endocrine effect(s) that directly relates or results in a measurable holistic effect endpoint (*e.g.*, reproduction, growth development, behavioural) that would potentially cause harm at the community/population level and at environmentally relevant concentrations.

Food and Drugs Act of 2003

Canada's Food and Drugs Act (F&DA) and regulations govern the sale and advertisement of foods, drugs, cosmetics, natural health products, and medical devices. Currently, the potential environmental risk of new substances in F&DA products is assessed and managed under the New Substances Notification Regulations (NSNR) of CEPA.

Health Canada is in the process of developing a proposed regulatory framework that would allow for environmental assessment of active pharmaceutical ingredients in human and veterinary drugs to be conducted at the time when an application for a drug submission requiring a new Drug Identification Number (DIN) is made to Health Canada (Environment and

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Climate Change Canada, 2017). Under the proposed regulatory framework, EDCs are considered special category substances because their risk to the environment may not be fully characterized by the proposed data requirements normally required for an environmental assessment. Therefore, drug submissions for EDCs may be subject to provide additional data to Health Canada. The challenge within this framework remains to define EDCs and the scope of substances that would be subject to this special category. Test data requirements for EDCs are still under development.

5.3.3. South America

5.3.3.1. Brazil

Regulatory framework on pesticides

The Brazilian regulatory framework on pesticides consists of the Federal Law 7802/1989 (and the Decree 4074/2002 (Presidência da República Brazil, 1989). It sets provisions for pesticides and their components in Brazil, including rules on their production, import, packaging and labelling, use, and disposal.

The Federal Law 7802/1989 requires a pesticide and their components to be registered before they can be produced, imported, marketed or used, which consists of an efficacy assessment by the Ministry of Agriculture, a toxicological assessment by the Ministry of Health, and an assessment of potential environmental hazards by the Ministry of Environment. The data required for this registration process must be provided by the registrant. The final registration is granted by the Ministry of Agriculture after consultation with the two other Ministries involved in the assessment process (Paleaz et al, 2013). Once granted, a registration does not have an expiration date. However, a pesticide may be re-evaluated when the responsible authorities might have indications that the pesticide poses harm to human health or the environment, or that its agronomical efficiency is no longer sufficient (Presidência da República Brazil, 1989; Paleaz et al, 2013).

Initiative to establish a national legislation on industrial chemicals

Despite several regulatory schemes and instruments for regulating specific chemical substances and uses, no systematic framework for regulating industrial chemicals currently exists in Brazil. In 2014, the Ministry of Environment along with the National Commission on Chemical Safety established a working group with the mandate to draft a new legislation in view of managing industrial chemicals in Brazil. Among other things, the legislation intends to establish: (a) a national register for industrial chemicals produced and imported into Brazil, (b)

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

a risk assessment process, and (c) a risk management programme to regulate chemicals and impose use restrictions. The risk management options proposed in the draft encompass (Communication by the Brazilian Ministry of Foreign Affairs, 2017): (a) voluntary agreements between the government and industry, (b) providing information in the national registry for substances produced or imported in quantities below 1 tonne per year, (c) prohibition of production, import, export, trade and uses of a substance, (d) restrictions on the production, import, export, trade and uses of a substance, (e) limit of concentration of a substance in intentional mixtures or finished products, and (f) prior authorization for the production and import of a substance.

5.3.4. Asia

5.3.4.1. China

In China, EDCs are addressed in the context of a policy initiative on environmental protection and in an industry standard.

13th Five-Year Plan of National Environmental Protection

EDCs are explicitly addressed in the 13th Five-Year Plan of National Environmental Protection released by the State Council of the People's Republic of China in November 2016. The plan states that the pollution by endocrine disrupting chemicals will be strictly controlled. Furthermore, it lays out intended actions including completing a survey of the production and use of EDCs, monitoring and evaluating risks at water source and aquaculture regions and agricultural planting zones, and the implementation of measures including phase-out, restriction and replacement of EDCs by 2017 (P.R. of C.S. Council, 2017). This policy initiative has been publicly released in a rather high-level formulation with no technical details reported.

Industry standard on evaluation methods of endocrine disruption effects of pesticides

In December 2015, the publication of industry standard NY/T2873-2015 "Evaluation Methods of the Endocrine Disruption Effects of Pesticides" was announced by the Chinese Ministry of Agriculture. This standard entered into force on 1 April 2016. It comprises a two-tiered approach with seven in-vitro or in-vivo testing guidelines for the evaluation of endocrine disruption effects of pesticides (**Table 5-4**).

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Table 5-4: Testing guidelines included in the Chinese industry standard NY/T2873-15 “Evaluation Methods of the Endocrine Disruption Effects of Pesticides”.

STAGE	TITLE
Tier 1 in-vitro testing	Oestrogen receptor transactivation
	Steroidogenesis in-vitro
Tier 2 in-vivo testing	Hershberger assay
	Uterotrophic assay
	Female pubertal assay & thyroid functionality testing
	Male pubertal assay & thyroid functionality testing
	Two-generation in-vivo testing

5.3.4.2. Japan

Adverse effects caused by endocrine disrupting properties of chemicals are expected to be considered in the regulatory risk assessment within Japanese regulations. The government has launched several consecutive national programmes investigating EDCs since the first strategic programme (SPEED '98) announced in May 1998. The recent national programmes (EXTEND 2010 and 2016) have, among others, focused on testing and assessment under the newly developed programme to identify EDCs based on the WHO/IPCS definition (Environment and Climate Change Canada, 2017). Similarly, to the US EDSP, the Japanese programme is based on a two-tiered testing strategy including in vitro and in vivo tests. The focus of the first tier of testing is the confirmation of an effect of a substance on the endocrine system. The second tier aims to identify adverse effects caused by the endocrine disrupting properties of chemicals. The programme generally focuses on effects on reproduction, the thyroid system, and growth. Some of the test methods and guidelines are still under development (Government of Canada, 2017). Knowledge obtained in the programme, especially results of the Tier 2 testing and assessment, will be referred to existing risk assessment practices for relevant regulation (Environment and Climate Change Canada, 2017).

5.3.4.3. South Korea

In the South Korean regulatory frameworks, EDCs are addressed in the Act on the Registration and Evaluation of Chemicals (K-REACH) of 2015, administered by the South Korean Ministry of Environment (MoE) in accordance with the framework illustrated in **Figure 5-3**. It set provisions on the registration and assessment of chemicals on the South Korean

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

market. It also includes regulatory instruments for the management of potential risk posed by these chemicals.

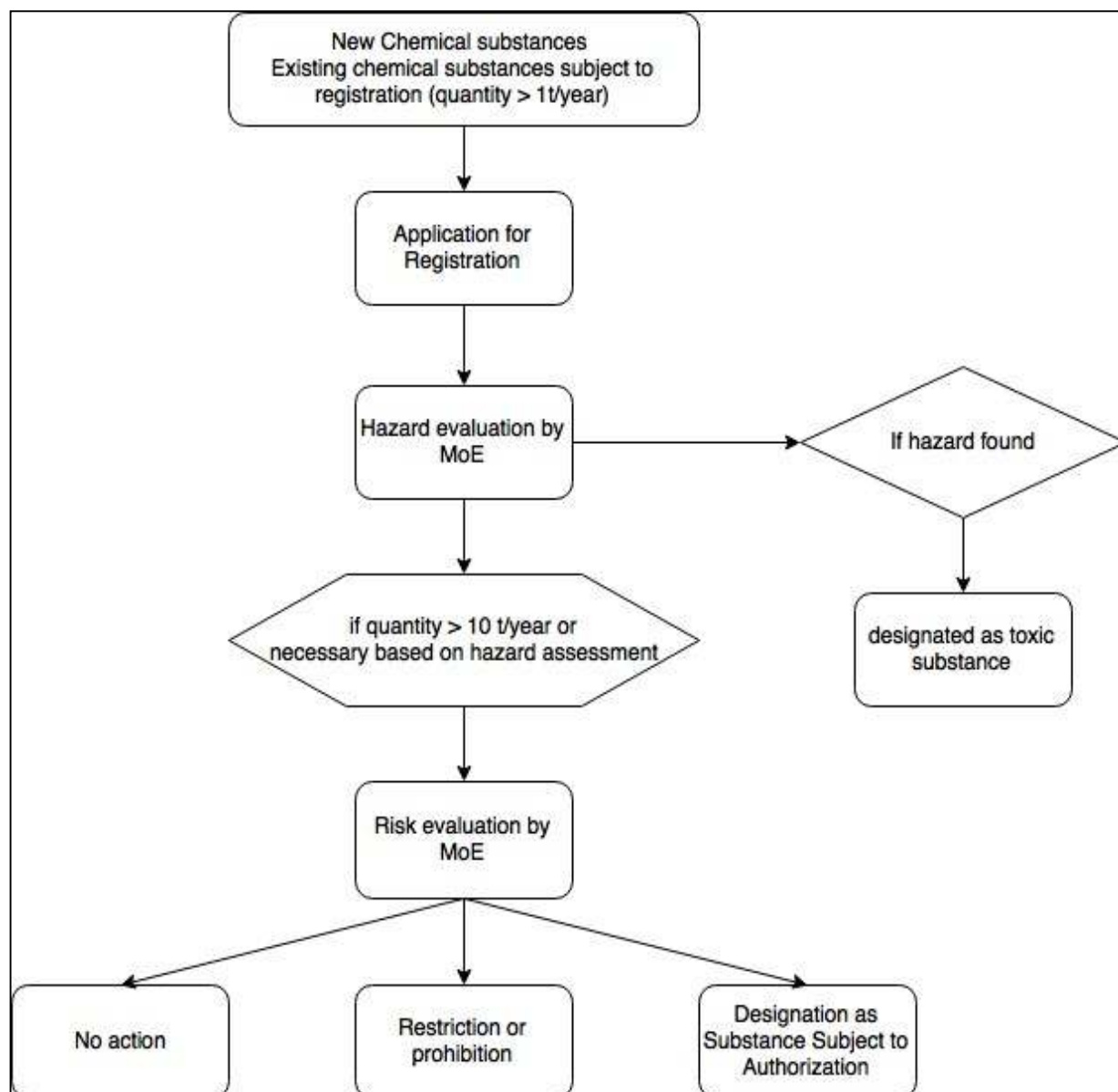


Figure 5-3: Regulatory framework for the registration and assessment of chemical substances under K-REACH.

K-REACH regulates chemical substances, which are defined as: i) elements, ii) compounds and substances from artificial chemical reactions, or iii) substances obtained by chemical modification, extraction, or purification of substances in their natural state. In addition, it includes provisions for chemical substances in products. It does not apply to pharmaceuticals, cosmetics, pesticides, fertilizers, or food and animal feeds.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Similarly, to many other regulatory frameworks, K-REACH distinguishes between “existing chemical substances” and “new chemical substances”. The category of “existing chemical substances” includes all substances that were on the Korean market before February 2, 1991 or that have been subject to hazard reviews under the former Toxic Chemicals Control Act. “New chemical substances” include all substances which are not “existing chemical substances” (K-REACH, 2013).

K-REACH requires every person who intends to manufacture or import a new chemical substance, or at least 1 tonne per year of certain existing chemical substances, to apply for registration with the MoE before the start of manufacture or import. Such a registration is also required for the manufacture or import of products that contain a hazardous substance in the quantity of >1 tonne per year, if the hazardous substance can be released from the product. Within the registration, data on hazard properties and risks (such as exposure scenarios, controls, and management actions over the course of the life cycle of the chemical substance) have to be provided to the MoE. Following the registration, an assessment of hazards and, if necessary, risks is performed by the MoE. When the MoE determines that the substance fulfils certain hazard categories or poses a risk, the substance will be regulated. Regulatory instruments include placement on the authorization list, restriction of use, or prohibition of the substance (K-REACH, 2013).

5.3.5. Oceania

5.3.5.1. Australia

In Australia, EDCs are explicitly addressed under the assessment framework of industrial chemicals, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

Industrial Chemicals (Notification and Assessment) Act 1989

In 1989, the Australian government enacted the Industrial Chemicals (Notification and Assessment) Act 1989 (ICNA Act), which led to the establishment of NICNAS in 1990. The aim of NICNAS is to protect the Australian people and the environment from risks posed by industrial chemicals and to provide information to promote safe use of these chemicals. The scope of NICNAS includes industrial chemicals and any substances used in cosmetics, soaps or consumer products, and it excludes articles, pesticides or veterinary chemicals, medicines and medicinal products, food, and food additives. The main aspects of NICNAS are the registration and assessment of health and environmental risks posed by chemical substances newly introduced to Australia, the maintenance of the Australian Inventory of Chemicals

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

Substances (AICS), and the assessment of existing substances (Australian Government, 1989).

Under the current system, all new chemicals (i.e. chemicals that are not already included in the AICS) must be notified to NICNAS prior to their import or manufacture in Australia. The NICNAS provides the NICNAS Director with the authority to assess the new substance for its human health-related and environmental risks. Under the Industrial Chemicals (Notification and Assessment) Act of 1989, chemicals that are already listed in AICS may be used for any industrial purpose (subject to conditions of use, if any) without further assessment by NICNAS. However, such chemicals may be subject to review (e.g. under Inventory Multi-tiered Assessment and Prioritisation). However, NICNAS does not have authority to regulate industrial chemicals. Instead, the Director can make recommendations on policy instruments for risk management to other competent authorities (Australian Government, 1989; Australian Department of Health, 2017). Once a substance has passed the assessment under NICNAS, it can be imported to or manufactured in Australia. During the first five (5) years as a new substance, all imports and production must be notified to the Ministry. After 5 years, the substance can then be listed on the AICS and is available for anyone to introduce into Australia without further notification and assessment under NICNAS. The Director of NICNAS may, however, include a “condition of use” in the AICS listing of the substance. Any use of the substance differing from the “condition of use” is regarded as a new chemical and requires a notification and assessment under NICNAS (Australian Government, 2017; AICS, 2016).

NICNAS also provides the authority to its Director to identify and assess substances on the AICS (i.e. existing chemical substances) for their human health-related or environmental risks under the Integrated Multi-tiered Assessment and Prioritisation (IMAP) framework (IMAP Framework, 2013). Similarly, to the assessment of new chemicals, NICNAS does not have any authority to regulate existing chemical substances, but only to make recommendations on policy instruments for risk management to other competent authorities (IMAP Framework, 2013)

5.4. Guidelines towards sound management of EDCs within the Lice Cycle

In order to organise the review systematically, a life-cycle approach combining a policy mix of source-directed, use-orientated and end-of-pipe measures is followed. The reviewed environmentally sound management strategies/practices are thus organised into upstream

	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	
	DOC NO:	MC_DEA_EDC_001	

sector (mainly manufacturing sector of EDCs), mid-stream sector (*i.e.* the transporting, storage and distribution), downstream sector (dispensing, use, disposal and waste management) as well as cross-stream strategies.

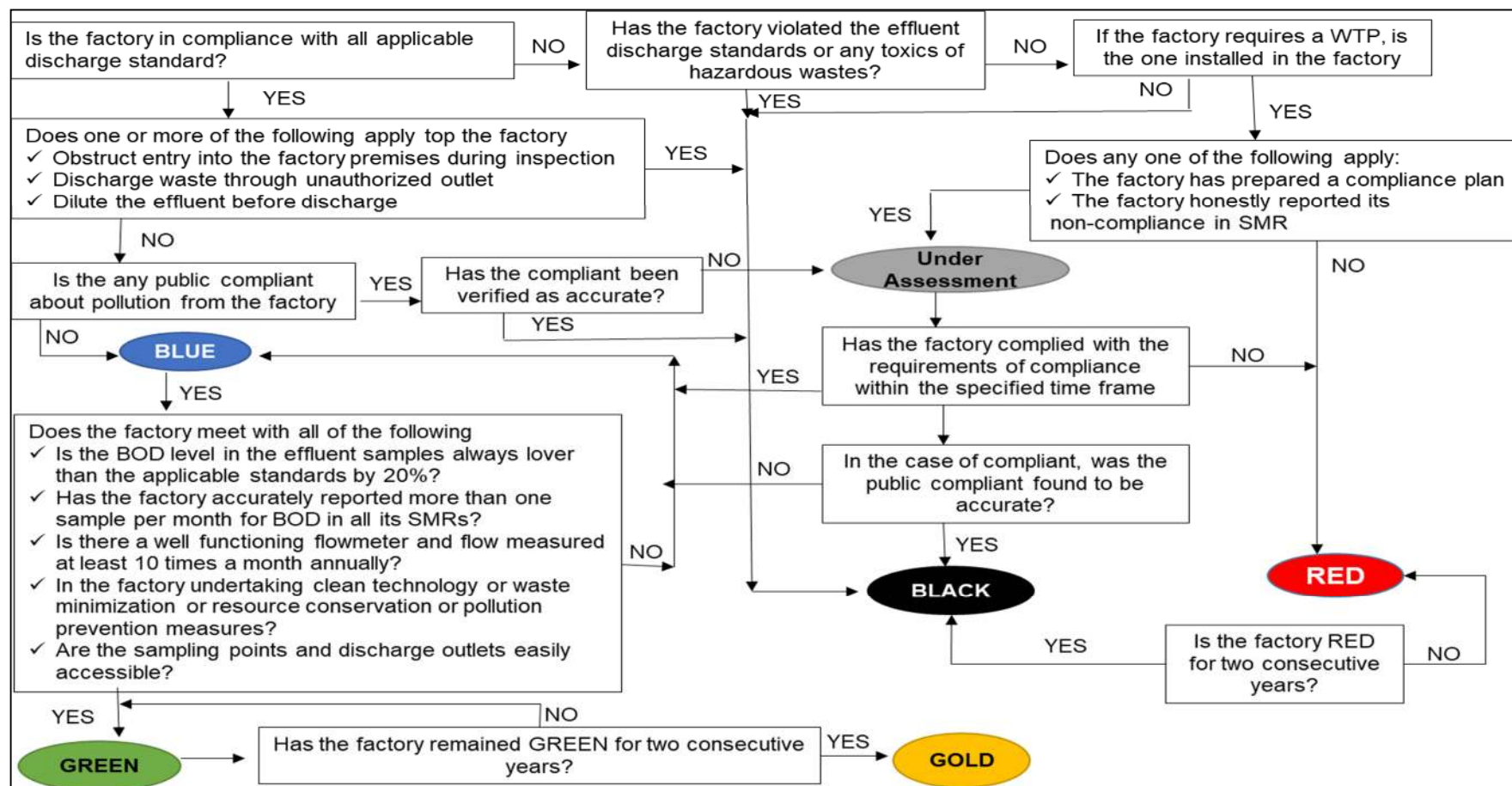
5.4.1. Guidelines for Upstream Users

The management of upstream industrial and manufacturing pollution can be achieved through monitoring compliance of upstream users. **Figure 5-4** shows the upstream compliance system with environmental requirements using the Program for Pollution Control, Evaluation and Rating (PROPER) system as practiced in Indonesia. PROPER is a reputational incentive system with two objectives: To encourage general compliance with the regulations, and to create incentives for pollution reduction in excess of regulatory requirements through adoption of additional end-of-pipe treatment, clean technology, and methods for waste minimization. With these policy objectives in mind, a 5-colour rating system was adopted and based on criteria shown.

Table 5-5: The 5-colour code rating system utilise in Program for Pollution Control, Evaluation and Rating

COMPLIANCE STATUS	COLOUR RATING	PERFORMANCE CRITERIA
NOT IN COMPLIANCE	BLACK	Polluter makes no effort to control pollution or causes serious environmental damage.
	RED	Polluter makes some effort to control pollution, but not sufficiently to achieve compliance
IN COMPLIANCE	BLUE	Polluter only applies effort sufficient to meet the standard
	GREEN	Pollution level is lower than the discharge standards by at least 50%. Polluter also ensures proper disposal of sludge; good housekeeping; accurate pollution records; and reasonable maintenance of the wastewater treatment system.
	GOLD	All requirements of Green, plus similar levels of pollution control for air and hazardous waste. Polluter reaches high international standards by making extensive use of clean technology, waste minimization pollution prevention, recycling, etc.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	



Source: Zoeller et al., 2012

Figure 5-4: Upstream compliance with environmental requirements by colour—gold, green, blue, red, or black—based on stated performance criteria. Gold and green facilities earn public praise. Blue facilities are just meeting regulatory criteria. Red and black facilities face both public pressure for compliance and legal enforcement.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

The system obtains pollution data from and about facilities (focusing on regulatory compliance), rates their performance in a simple 5-colour system, and publishes the resulting ratings. Although not a Pollutant Release and Transfer Register (PRTR) system, PROPER's emphasis on public disclosure offers useful insights for PRTR dissemination.

By announcing positive results (blue, green, and gold facilities) first and then giving a six-month grace period before publicly naming the first red and black facilities, improvements were encouraged. Publication of the results also proceeded industry-by-industry, rather than rating all facilities at once. NGOs and media have had access to PROPER's system from its inception and can retrieve the ratings for any facility.

PROPER publicly ranks Indonesian facilities on their compliance with environmental requirements by colour—gold, green, blue, red, or black—based on stated performance criteria. Gold and green facilities earn public praise. Blue facilities are just meeting regulatory criteria. Red and black facilities face both public pressure for compliance and legal enforcement. Indonesia developed PROPER from the conviction that these “reputational incentives” would work through both community pressure—via the media, non-governmental organisations, and local governments—and market forces, to bring about environmental improvement.

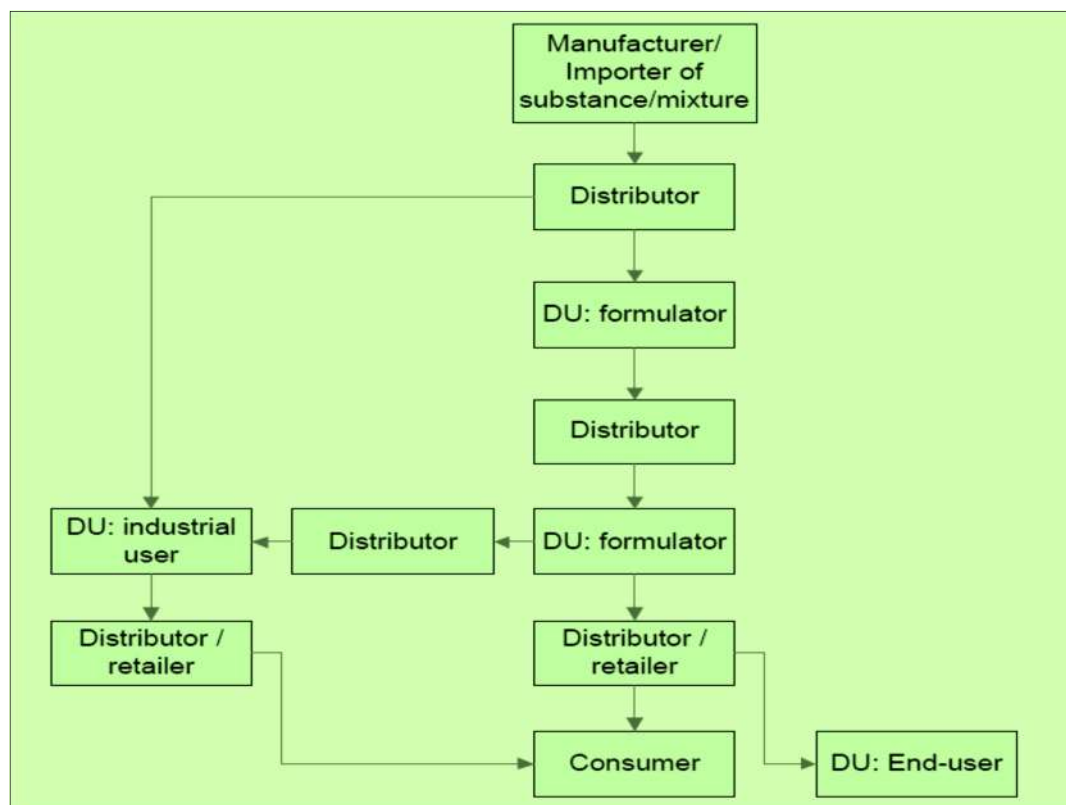
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5.4.2. Guidelines for Midstream and supply chain

Communication up and down the supply chain is a critical point for the success of REACH and distributors represent a fundamental link between suppliers and downstream users in many supply chains (**Figure 5-5**). The downstream user could be a formulator of mixtures, as well as an end user of substances and mixtures, and he may need to communicate with the supplier for different reasons. If this is the case, it is the role as a distributor to pass the request for further information from the customer to the supplier and to deliver the response of the supplier to the same customer (*i.e.* the downstream user). As a distributor, the following communications are key between the upstream manufacture/importer and the downstream user.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

- Information related to the identification of uses, either from manufacturers / importers to downstream users via questionnaires or from downstream users to suppliers, for example via standard brief general descriptions of use;
- Health and safety information on possible hazards and risks of the product up and down the supply chain. The distributor has the duty to pass on information about hazards and safe handling received from the supplier to your customers. This may include the safety data sheet (with or without the exposure scenario) if appropriate. Furthermore, you may have to pass on information on authorisation or restrictions applying to a substance; and
- Additionally, to communicate and keep records of the amounts of products/EDCs transferred at any given point, take stock of any accidents in which case chemicals are disposed in the environment and where the accident has taken place.



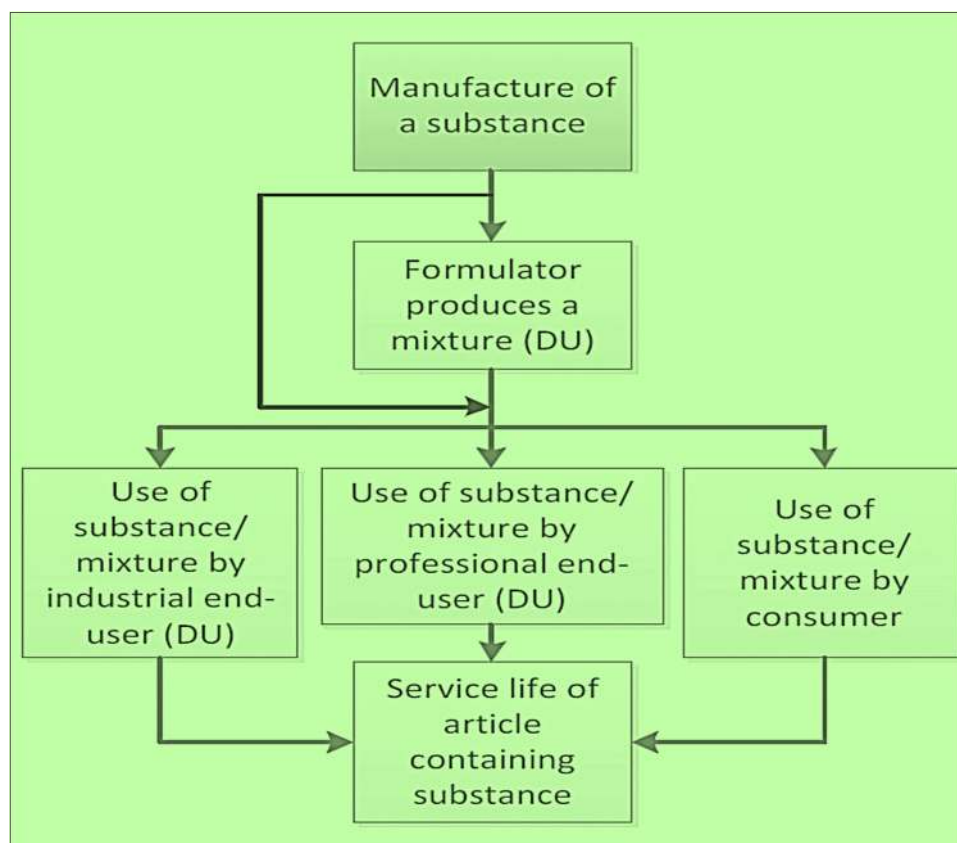
Source: REACH, 2011

Figure 5-5: Simplified illustration of the role of distributors in a supply chain (DU; Downstream User).

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

5.4.1. Guidelines for downstream users

Potential uses of substance at different stages of the EDC life cycle are depicted in Figure 5.6 and a summary of the various stages which can be monitored closely to control and manage EDCs in the environment, follow.



Source: REACH, 2011

Figure 5-6: Schematic presentation of potential uses of a substance at different life cycle stages. The downstream user uses are marked with “(DU)”.

- **Manufacture:** A substance is manufactured from raw materials and/or intermediates. Activities with the substance during the manufacture, such as chemical processing or substance transfers are considered manufacturing. This life cycle stage has no relevance for the downstream users.
- **Formulation:** A substance is transferred and mixed with other substances in order to be placed on the market in a mixture. This is the activity of formulators.
- **Use at industrial sites:** This life cycle stage covers all uses of a substance carried out at industrial sites. The substance may be used in many ways including: as a raw

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

material in a process; as a processing aid; for cleaning or sterilising; for incorporation into an article. In summary, use at industrial sites covers activities of industrial end-users, including producers of articles.

- **Uses by professional workers:** As the name implies, this life-cycle stage covers all activities of a substance carried out by professional workers. These activities do not take place at industrial sites, and hence the nature of exposure stemming from them is different: they can take place anywhere, the potential group of users is large, and the amount used by a single user is typically low compared to industrial use. This life-cycle stage covers the activities of professional end-users, including craftsmen, cleaners, employees in public administration and self-employed.
- **Consumer uses:** This life cycle stage covers all uses of the substance carried out by consumers.
- **Article service life:** If a substance ends up in an article, the so-called service life of that article is to be considered under this life cycle stage. In layman terminology this means using the article (either by industrial users, professional users or consumers), but it must be noted that using an article does not mean “use” as defined under 3(24) of REACH.

5.4.2. Cross-section management strategies for EDCs

The Pollutant Release and Transfer Register (PRTR) system is an integrated and cross-stream system currently being implemented OECD countries, augmenting government efforts to integrate environmental management and promote pollution prevention (OECD 1999; 2000). The PRTR system represent a new generation of environmental efforts for governments, industry and the public alike. It is an environmental database or inventory of potentially harmful /hazardous releases to air, water and soil as well as wastes transported to treatment and disposal sites (OECD 1996). Facilities releasing one or more hazardous substances report periodically as to what was released, how much, and to which environmental media. Data are then made available to interested parties. In addition to reports from stationary sources, some PRTR versions include diffuse releases such as transport and agricultural releases which are estimated based on specific data and statistics. The PRTR system is an initiative of the OECD in response to the United Nation Environmental declaration in Rio and has been implemented in a number of OECD countries including the USA, Canada, Ireland, Norway and the Netherlands (OECD 2001). The system can be regarded as a

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

comprehensive management strategy design to track all pollutants, facilities and associated activities.

When the PRTR system exist, a number of advantages are accrued to the government. For example, through the PRTR system, regulatory authorities have been able to develop indicators for monitoring the environmental performance of industry derived from PRTR results. The system also captures accidental releases such as spills or emissions from a fire at an industrial facility, allowing these incidences to be better tracked and managed. The register results can also be used to plan for possible emergencies by providing insight into the kinds of releases that could occur under emergency circumstances. Data from the PRTR could illustrate environmental performance of particular government and industry policies. The PRTR data have aided during land-use planning activities and in licensing potential sources of pollutants.

In countries where the PRTR system has been implemented, it has aided industries in collecting and reporting release allowing the identification of material loss which equates to waste -- or lost revenue. With regard to industry standards, many companies have confirmed that a PRTR can provide a template for environmental reporting under ISO 14 000 and perhaps help to set the basic framework for integrated pollution reporting. The existence of a PRTR could spur reporting facilities to improve internal auditing activities and set corresponding performance measures. PRTR outputs can stimulate the private sector, especially small and medium-sized enterprises (SMEs), to develop leak detection programmes and install “good housekeeping” procedures. Further, since members of the public have access to the PRTR system, it can aid access to useful data, enabling informed decision making.

OECD has established 14 principles for developing and implementing a PRTR system:

- i. PRTR systems should provide data to support the identification and assessment of possible risks to humans and the environment by identifying sources and amounts of potentially harmful releases and transfers to all environmental media.
- ii. The PRTR data should be used to promote prevention of pollution at source, e.g. by encouraging implementation of cleaner technologies. National governments might use PRTR data to evaluate the progress of environmental

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

policies and to assess to what extent national environmental goals are or can be achieved.

- iii. In devising PRTR systems, governments should Co-operate with affected and interested parties to develop a set of goals and objectives for the system and estimate potential benefits and costs to reporters, government and society as a whole.
- iv. PRTR systems should include coverage of an appropriate number of substances which may be potentially harmful to humans and/or the environment which are released and or transferred.
- v. PRTR systems should involve both the public and private sectors as appropriate and include those facilities which might release and/or transfer substances of interest, as well as diffuse sources, if appropriate.
- vi. To reduce duplicative reporting, PRTR systems should be integrated to the degree practicable with existing information sources such as licenses or operating permits.
- vii. Both voluntary and mandatory reporting mechanisms for providing PRTR inputs should be considered with a view as to how best to meet the goals and objectives of the system.
- viii. The comprehensiveness of any PRTR in helping to meet environmental policy goals should be taken into account, e.g. whether to include releases from diffuse sources ought to be determined by national conditions and the need for such data.
- ix. The results of a PRTR should be made accessible to all affected and interested parties on a timely and regular basis.
- x. Any PRTR system should allow for mid-course evaluation and have the flexibility to be altered by affected and interested parties in response to changing needs.
- xi. The data handling and management capabilities of the system should allow for verification of inputs and outputs and be capable of identifying geographical distribution of releases and transfers.
- xii. PRTR systems should allow as far as possible comparison and Co-operation with other national PRTR systems and possible harmonization harmonisation with similar international data bases.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

- xiii. A compliance mechanism to best meet the needs of the goals and objectives should be agreed by affected and interested parties.
- xiv. The entire process of establishing the PRTR system and its implementation and operation should be transparent and objective.

5.5. The South Africa Legislative Framework for EDC Management

A number of applicable laws and regulations that flow from such laws exist for the management of EDCs, whether at the upstream, midstream or downstream level. Some of these laws are not specifically design for the management of EDCs but are flexible enough to be extended to the EDCs arena. The principal legislative frameworks are:

- The Constitution of the Republic of South Africa as amended;
- 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);
- Hazardous Substances Act (Act 15 of 1973);
- National Environmental Management: Integrated Coastal Management Act (Act No. of 24 2008); and
- Marine Living Resources Act (Act 18 of 1998).

Even though South Africa has existing legislative framework, within which EDC can be managed appropriately, the major challenges are that of implementation, integration and coordination across sectors, spheres of government, and between government, civil society and ordinary citizen. A policy framework, and a systemic integration and implementation plan is thus needed for the sound management of EDCs in South Africa.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

5.5.1. Contextualised analysis of the identified management strategy

In order to suggest policy instruments and a coordinated management strategy that are applicable for the sound management of EDCs in South Africa, it is critical to evaluate environmental and economic impacts and social acceptance the reviewed management strategies and policy instruments. South Africa is a water scarce country and demand its water resources are increasing, limiting options requiring water as input, and placing premium on the protection of water resources. Management strategies and policy instruments for protecting water resources and the delivery of water services flow from the National Water Act (Act No. 36 of 1998; and the Water Services Act, Act 108 of 1997). Current South African water quality guidelines, whether for freshwater ecosystems or otherwise do not contain EDCs (cite). By following a procedure similar to that of Ncube et al., (2012) it is possible to select and prioritise EDCs, intermediates and metabolites, for which guidelines and resource quality objectives (RQOs) can be developed, and for which WTTWs can be optimised for their removal.

The majority of WTTWs in South Africa have followed the conventional design, and indicated earlier, the conventional design is not effective for the removal of EDCs. Besides optimal functionality of WTTWs in South Africa remain a challenge, despite the implementation of the Green Drop Programme. About 25% of South Africa's WTTWs are in a 'critical state', and another 25% are described as 'high risk' in terms of disorder (Mavuso 2018). It is clear that South Africa cannot afford upgrading to expensive water treatment plants.

Landfill sites in South Africa are under pressure because of excessive volumes of wastes that are sent to landfill. The South African Government already has a target of zero waste to landfill (Ludick, 2015). If this approach is used, wastes can end up on the streets as well as in random sites for months, as most municipal waste collection system usually fail due to service delivery protests. Further leaching of untreated pharmaceuticals into groundwater and potential run-off into nearby surface water resources remain a challenge for managing landfills in South Africa. **Table 5-1** provides a summarised contextualised analysis of the management options and strategies.

A Take Back programmes could be jeopardised if consumers lack access to pharmacy, and this might be the case for South Africans that reside in the remote areas of the country. In order for a 'disposal and destruction' system to be successful, individual choices and socially constructed and maintained habits must be considered. Health campaigns and grass-roots strategies, e.g. clean out your medicines day, reminder stickers, could encourage regular

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

return of unwanted household medicines; increase awareness address misconceptions and promote appropriate medicine storage, use and disposal of unwanted and expired.

Furthermore, there has been evidences that Government funding of medicines disposal supports appropriate disposal, compared to when the financial burden has to be on distributors, retailers or wholesalers (Kelly et al. 2018). It is critical to encourage patients and educate them to understand that it is acceptable and desirable to return medications to the pharmacy for the take back programs to succeed locally (Seehusen and Edwards 2006). There are several possible ways that this education could be conducted. For example, providers and pharmacy personnel could discuss medication disposal with patients, and written education could be distributed with medications in a manner similar to what was described above. Or, innovative solutions, such as placing disposal information on medication labels or pill bottles, might prove effective.

5.5.2. Opportunities for policy and legislative reform in South Africa: A roadmap for systematic assessment and management of EDCs

To address the systematic assessment and management of EDCs in South Africa, four (4) key steps are described below:

5.5.2.1. STEP 1: Identification and evaluation of endocrine disruption as an adverse effect

Develop chemical testing and assessment criteria with greater emphasis on hazard associated with endocrine disruption, rather than a regulatory focus solely on presumed monotonic potency and potential exposure:

- Screen chemicals based on primary indicators of harm using molecular biological techniques to identify hormone disruption or epigenetic changes, in order to recognize chemicals that might contribute to risk of illness, rather than relying only on traditional disease endpoints (e.g. tumours);
- Screen pharmacological properties (entry, absorption, metabolism and elimination) of both new substances and those already in circulation. These include nanotechnologies and biological technologies;
- Mandate assessments that consider timing of exposure, cumulative or synergistic exposures, high- and low-dose effects, and underlying susceptibility factors (age, occupation, race, socio-economic status, gender, and other social determinants of health); and

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

- Review EDC potential of existing and new substances (including nanomaterials) in the market. This would be similar to categorization requirements focused on persistence, bioaccumulation and inherent toxicity and potential exposure of substances.

5.5.2.2. Step 2: Precautionary Principle, Pollution Prevention and Elimination goals should guide management of EDCs

Apply the precautionary principle and the substitution principle in all government decisions related to chemical assessment, management and regulation, especially with respect to EDCs:

- Identify potential EDCs in South Africa;
- Identify populations at heightened risk of exposure to EDCs;
- Require all ingredient and contaminant identification for materials and goods;
- Take protective actions by requiring inherently safer substitutes (including consideration of the null alternative), and elimination of potentially hazardous EDCs substances. These actions should be undertaken when there is an association and plausible link with harm, rather than awaiting the extensive human disease and associated research necessary to achieve (if ever) absolute proof of harm;
- Establish a registration program (EDC inventory) process for chemicals known or suspected of being EDCs;
- Include explicit language to identify endocrine disrupting chemicals through hazard assessment and their regulation through virtual elimination; and
- Collect and report on EDC levels according to existing inventories including the National Pollutants Release Inventory and Environmental Emergency Plans.

5.5.2.3. Step 3: Adopt Informed Substitution to achieve Prevention and Elimination of EDCs

Adopt a regulatory focus that shifts from chemical-by-chemical management, to comprehensive pollution prevention strategies by allocating significant resources to the elimination or significant reduction of exposures to toxic chemicals via:

- Assess need and best practices to achieve identified ends;
- Green chemistry research and development;
- Best innovative practices, alternatives assessment and informed chemical substitution;
- Toxic use reduction programs;

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

- Primary pollution prevention in all endeavors subject to national government assessment and oversight (e.g. transporting chemical compounds); Prohibited substance regulation, remediation and enforcement; and
- Improving national-provincial jurisdictional arrangements for regulatory control of chemicals.

5.5.2.4. Step 4: Achieving Transparency, Accountability and Effective Public Engagement on EDCs Identification, Assessment and Management

Increase scientific rigor, validity and transparency, and public engagement and participation (particularly for populations at elevated risks) in health and safety assessment, and chemicals management processes by all levels of government and academia:

- Employing Systematic Scientific Review processes and reporting, to improve rigor of chemical assessments, and to increase transparency and accessibility of information on chemical substances and government actions;
- Provide information and meaningful public engagement on the significant parameters of decision-making;
- Provide financial and technical support for groups to engage effectively to address chemical hazard primary prevention as well as risk management;
- Address elevated risk associated with vulnerable populations (e.g. vulnerabilities due to life stage, socio-economic situation, occupational exposure, morbidities) in chemical assessment and management;
- Apply the precautionary principle and substitution principle within all phases of the assessment and management of EDCs; and
- Include high-risk groups and representatives in advisory and technical roles related to assessment and management of chemicals.

5.5.3. Alternatives: Chemical hazard assessment

South Africa need to consider Chemical hazard assessment to identify and prioritize chemical substances for possible replacement with safer alternatives as this is increasingly required by retailers, brands, and material suppliers in response to both consumer pressure and regulatory requirements. A guidance must be developed to support informed chemicals management decisions that will lead to safer chemical choices and proactive management of chemicals in the supply chain. While this guidance is not a substitute for regulatory requirements concerning Alternatives Assessments, it can form the foundation for responding to regulatory

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

requirements. The results of chemical hazard and exposure/risk assessments will need to be examined from a life cycle perspective, because substitutions may require trade-offs with other impacts, such as water or energy use or wastewater treatment. For example, there may be a safer alternative, but if the alternative is substituted into a process that does not include adequate wastewater treatment, discharging too much sugar into a waterway could raise the biochemical oxygen demand (BOD) to levels that might result in aquatic toxicity. Another example is that a persistent chemical might be used in a process, which would allow energy savings, thus avoiding greenhouse gas emissions. There may also be socio-economic impacts associated with potential substitution. **Figure 5-7** shows how chemical hazard assessments fit into the overall framework logic of a chemicals management system to classify chemicals and make decisions on whether to keep, substitute, or manage the chemical.

The in-depth discussion on best practices for Alternatives will be covered in chapter 6.

An effective chemicals management program requires organizational motivation and drive to move beyond legal compliance and maintain that trajectory over time. This comes in many forms, including organizational mission, internal champions, and implementation of a chemicals policy or guideline. Chemicals of high concern are so prevalent in our global economy that it is common for a product have a chemical of high concern in it. Finding chemicals of high concern in products is not the challenge for downstream users. The challenge is determining which ones to target first. Environmental organizations, government agencies, institutional consumers, and other companies are all good sources for identifying emerging and existing chemicals of high concern.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

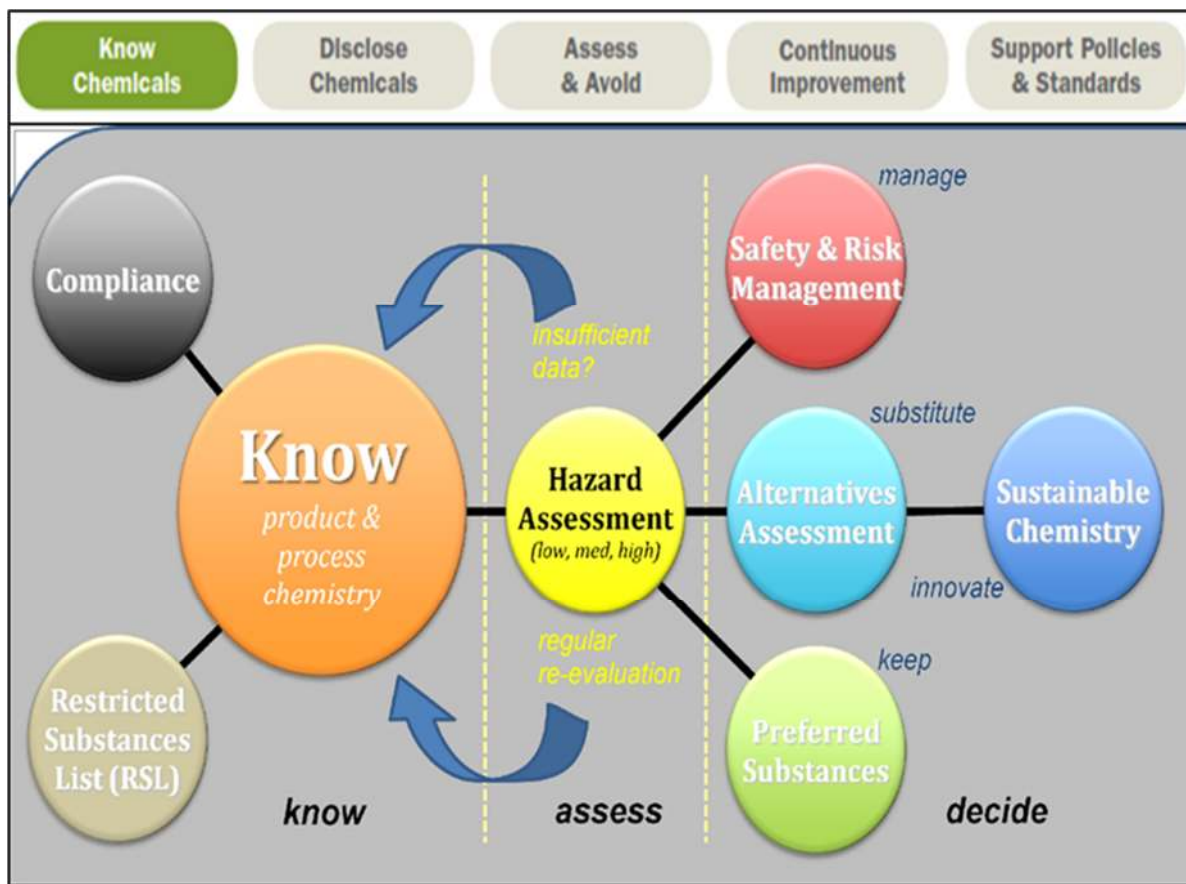


Figure 5-7: Illustrative framework of chemical hazard assessments showing logical decision making process on whether to keep, substitute, or manage the chemical.

For many years institutional and individual consumers have highlighted the problems with polyvinyl chloride (PVC), phthalates, brominated flame retardants, Bisphenol A (BPA), formaldehyde, and per fluorinated compounds. These are all plasticizer di-2-ethylhexyl phthalate (DEHP) for reduction they confronted a vast array of products. PVC and DEHP are found in everything from medical devices to building products to packaging and within each of those categories there can be thousands of individual product types with PVC/DEHP in them. Replicable and scalable systems are essential to moving beyond a handful of chemicals of high concern. Systems for collecting and managing data, identifying EDCs of high concern, evaluating alternatives, and selecting safer alternatives are needed and these include:

- Know and disclose:** Know and Disclose Product Chemistry— “know” refers to the sharing of chemical information from business-to-business and “disclose” refers to the reporting of chemical information to the public. “Knowing” the life cycle chemistry of a product includes knowing the: 1) feedstocks: sources of and chemicals used in extraction and processing; 2) chemicals in processes: chemicals used across the

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

supply chain in manufacturing processes; 3) chemicals in product: chemicals contained in the product; and 4) by- products that can form during the degradation (1) of the chemical at any point in its life cycle, including end of life management.

- Asses and Avoid:** The intent is for manufacturers use chemicals in products, processes, and feedstocks that are inherently safer for human health and the environment, and purchasers prefer these products, processes, and feedstocks. Furthermore, it is to compel downstream users to know the hazards of chemicals and select and implement inherently safer alternatives to chemicals of high concern. A safer alternative includes replacing the chemical with an inherently less hazardous chemical, eliminating the need for the chemical through material change, product re-design, or product replacement; or eliminating the chemical by altering the functional demands for the product through changes in consumer demand, workplace organization, or product use.
- Continuous Improvement:** Ideally organizations will have to set goals for safer alternatives to chemicals of concern to human health or the environment, have clear metrics for measuring progress to those goals, provide transparent data that supports their progress to their goals, and publicly report on their progress to those goals. The intent will therefore is to engage organizations in setting goals to safer alternatives to chemicals of concern and publicly reporting on their progress towards those goals.
- Support Public Policies and Voluntary Initiatives:** In the ideal scenario business and health care leaders join with NGO, government, and academic leaders to support the implementation of the safe environment principles or their equivalent in public policies and voluntary initiatives such as industry standards. The leadership these organizations demonstrate internally to change their products, processes, and feedstocks, finds its way into external engagement. Efforts are made to transform the civic foundations of the safer chemicals economy including public policies, Eco labels, industry standards and certifications, and voluntary sustainability initiatives.

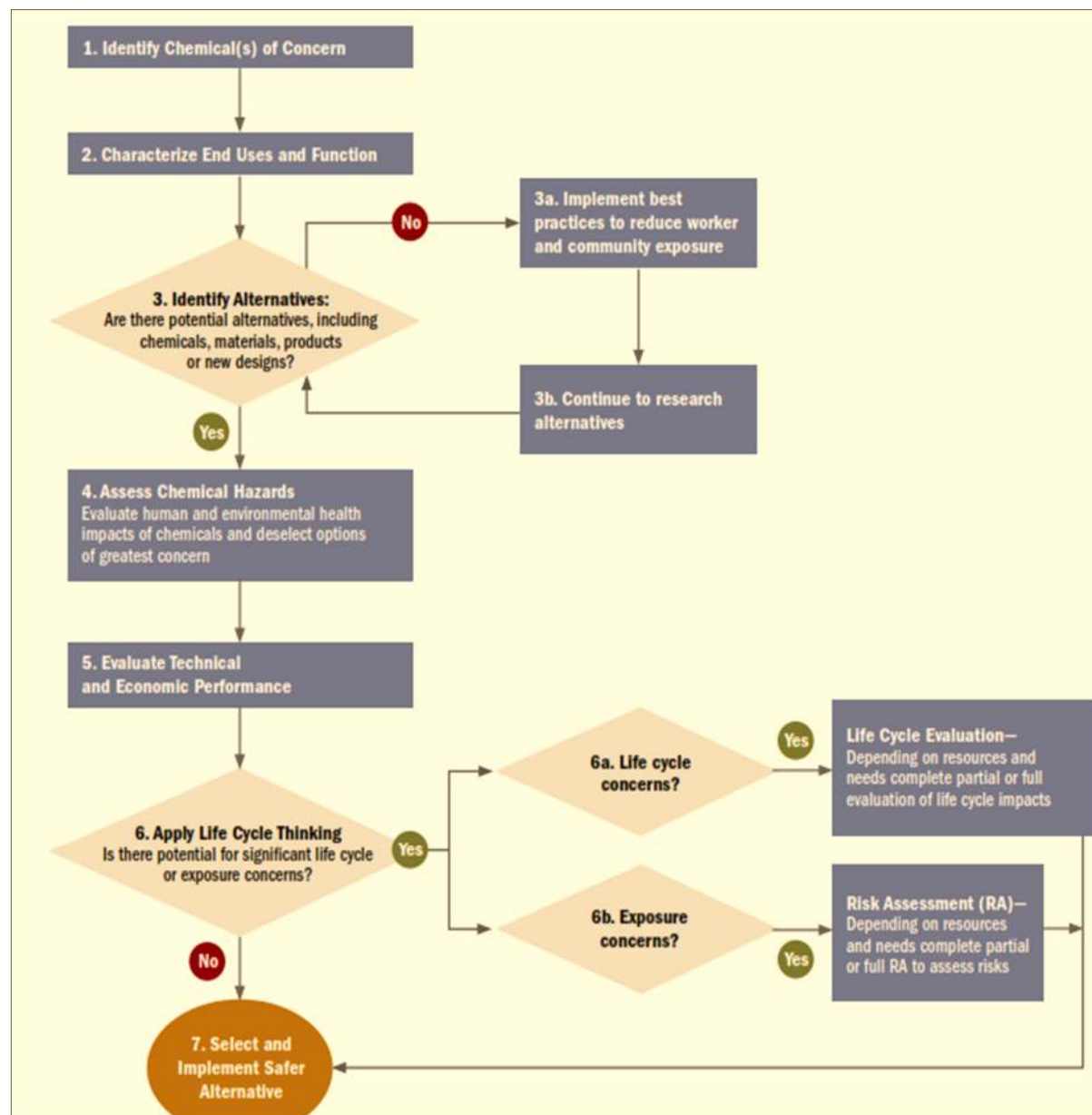
5.5.3.1. Chemical Alternatives Assessment Protocol (BizNGO)

Once alternatives are identified they need to be evaluated for hazards as well as other human and environmental concerns to ensure companies avoid regrettable substitutions—where the alternative is equal to or worse for human and environmental health than the chemical it is meant to replace. A question then emerges of how to undertake the assessment and common tools for assessing alternatives are LCA and risk assessment.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

The BizNGO Protocol is a “decision framework for substituting chemicals of concern to human health and environmental health with safer alternatives. It “describes a process for identifying alternatives to a chemical of concern, screening out equally hazardous alternatives, and selecting an alternative that is technically and economically viable and does not have the potential for causing significant environmental or human health impact. The Protocol, as illustrated in **Figure 5-8**, highlights the primacy of hazard assessment in relation to LCA and risk assessment by positioning it as a step before LCA or exposure assessment. From the alternatives assessment some alternatives will hopefully emerge that are safer, healthier, and more environmentally preferable, as well as technically and economically viable, to the existing chemical of high concern. Companies then select the safer alternative(s) and either manufacture it or require their suppliers to use it. Companies can specify the preferred solutions they want from suppliers and/or specify the criteria by which suppliers evaluate their alternatives to a chemical of high concern. A critical element in the implementation of a safer alternatives program is the frameworks and tools that organizations use to inform their identification of chemicals of high concern, evaluation of alternatives, and the selection and implementation of safer alternatives

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	



Adapted from the BizNGO protocol

Figure 5-8: Chemical Alternatives Assessment Protocol

Detailed concepts and steps will be discussed in the Alternatives chapter.

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

6. IDENTIFICATION AND MAPPING OF SITES POSSIBLY CONTAMINATED BY EPPPS IN SOUTH AFRICA

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

7. ALTERNATIVES

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

8. TRADE AND SOCIO-ECONOMIC CONSIDERATIONS

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department: Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

9. ENVIRONMENTALLY SOUND MANAGEMENT INSTRUMENTS, STRATEGIES AND APPROACHES – INCLUDING RISK REDUCTION

 Mamadi & Company	DOCUMENT TITLE:	Development of Inventory of Endocrine Disrupting Compounds and its Management Action Plans in South Africa	 environmental affairs Department of Environmental Affairs REPUBLIC OF SOUTH AFRICA
	DOC NO:	MC_DEA_EDC_001	

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Appendix A: Table of Chemicals including Common Names, Abbreviations, Chemical Abstract System Numbers (Cas #) as well as Class of Compound and/or Major Use

COMMON NAMES	CHEMICAL NAME; OR OTHER COMMON NAME	CAS #	CLASS OR USE	ABBREVIATION
2,4,6-Tribromophenol	1,3,5-Tribromo-2-hydroxybenzene	118-79-6	BFR, Natural product	2,4,6-TBP
2,4'-DDT (o,p'-DDT)	2-(2-Chlorophenyl)-2-(4-chlorophenyl)-1,1,1-dichloroethane	789-02-6	Organochlorine Insecticide	o,p'-DDT 2,4'-DDT
2,4-D	2,4-Dichlorophenoxy)acetic acid	94-75-7	Herbicide	2,4-D
2,4-Dichlorophenol	1,3-Dichloro-4-hydroxybenzene	120-83-2	Chlorophenol	2,4-DCP
4,4'-DDE (p,p'-DDE)	2,2-Bis-(4-chlorophenyl)-1,1-dichloroethene	72-55-9	Organochlorine Insecticide	p,p'-DDE 4,4'-DDE
4,4'-DDT (p,p'-DDT)	2,2-Bis(4-chlorophenyl)-1,1,1-trichloroethane	50-29-3	Organochlorine Insecticide	p,p'-DDT 4,4'-DDT
8-Prenylnaringenin	(2S)-5,7-Dihydroxy-2-(4-hydroxyphenyl)-8-(3-methylbut-2-en-1-yl) -3,4-dihydro-2H-1-benzopyran-4-one; 8-Isopenenylnaringenin	53846-50-7	Prenylflavonoid	
Anthracene	Paranaphthalene	120-12-7	PAH	
Aroclor 1254	Polychlorinated biphenyls	11094-69-1	PCB mixture	PCBs
Arsenic (As)	-	7440-38-2	Heavy metal	
Atrazine	1-Chloro-3-ethylamino-5-isopropylamino-2,4,6-triazine	1912-24-9	Herbicide	ATR
BB-153	2,2',4,4',5,5'-Hexabromobiphenyl	59080-40-9	PBB	
Benzo(a)anthracene	Benzanthracene; Benzanthrene; 1,2-Benzanthracene; Benzo[b] phenanthrene; Tetraphene	56-55-3	PAH	BaA
Benzo(a)pyrene	3,4-Benz[a]pyrene	50-32-8	PAH	BaP
Benzyl butyl phthalate	n-Benzyl butyl phthalate	85-68-7	Phthalate	BBP
Benzylidene camphor	(3E)-1,7,7-Trimethyl-3-[(4-methylphenyl methylene]-2-norbornanone	36275-29-3	UV filter	3-Benzylidene camphor
Bisphenol A	2,2-Bis(4-hydroxyphenyl)propane	80-05-7	Plastics monomer	BPA
Bisphenol F	Bis(4-hydroxydiphenyl)methane	87139-40-0	Plastics monomer	BPF
Bisphenol S	4,4'-Sulfonylbisphenol	80-09-1	Plastics monomer	BPS
Butylated hydroxyanisole	2(3)-tert-Butyl-4-hydroxyanisole	25013-16-5	Antioxidant	BHA
Cadmium (Cd)	Cadmium chloride	10108-64-2	Heavy metal	
Carbaryl	1-Naphthyl methylcarbamate	63-25-2	Insecticide	
Chlordane	cis/trans-Chlordane	5103-71-9, 5103-74-2	Organochlorine Insecticide	
Chlorpyrifos	O,O-Diethyl O-3,5,6-trichloropyridin-2-yl phosphorothioate	2921-88-2	Insecticide	
Coumestrol	3,9-Dihydroxy-6-benzofurano[3,2-c]chromenone	479-13-0	Coumestans/Phytosterogen	
D4	Octamethylcyclotetrasiloxane	556-67-2	Cyclic siloxane	
D5	Decamethylcyclopentasiloxane	541-02-6	Cyclic siloxane	
D6	Dodecamethylcyclohexasiloxane	540-97-6	Cyclic siloxane	

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Daidzein	7-Hydroxy-3-(4-hydroxyphenyl) chromen-4-one	486-66-8	Isoflavones/phytestrogen	
Di-(2-ethylhexyl)adipate	Bis(2-ethylhexyl) adipate	103-23-1	Plasticizer	DEHA
Dibutyl phthalate	Di-n-butyl phthalate	84-74-2	Phthalate	DBP
Diethyl hexyl phthalate	Bis(2-ethylhexyl)phthalate	117-81-7	Phthalate	DEHP
Diethylstilbestrol	4,4'-(3E)-Hex-3-ene-3,4-diylidiphenol	56-53-1	Synthetic estrogen	DES
Diisononyl phthalate	Bis(7-methyloctyl) phthalate	28553-12-0	Phthalate	DiNP
Endosulfan (alpha/beta)	6,7,8,9,10,10-Hexachloro-1,5,5a,6,9,9a-hexahydro- 6,9-methano- 2,4,3-benzodioxathiepine-3-oxide	115-29-7	Organochlorine Insecticide	
Estradiol	17B-Estradiol, (17β)-estra-1, 3,5(10)-triene-3,17-diol	50-28-2	Natural hormone	
Estrone	3-Hydroxy-13-methyl- 6,7,8,9,11,12,13,14,15,16- decahydrocyclopenta [a] phenanthren- 17- one	53-16-7	Natural hormone	E1
Ethinylestradiol	19-Nor-17α-pregna-1,3,5(10)-trien-20-yne-3,17-diol	57-63-6	Synthetic hormone	EE2
Ethylparaben	Ethyl 4-hydroxybenzoate	120-47-8	Antifungal Preservative	Parabens
Fenitrothion	O,O-Dimethyl O-(3-methyl-4-nitrophenyl) phosphorothioate	122-14-5	Organophosphate Insecticide	
Fluoxetine	(RS)-N-methyl-3-phenyl-3-[4-(trifluoromethyl)phenoxy] propan-1-amine	54910-89-3	Pharmaceutical	
Flutamide	2-Methyl-N-[4-nitro-3-(trifluoromethyl)phenyl]-propanamide	13311-84-7	Pharmaceutical	
Galaxolide	1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-Hexamethylcyclopenta[g]- 2-benzopyran	1222-05-5	Synthetic musk	HHCB
Genistein	5,7-Dihydroxy-3-(4-hydroxyphenyl)chromen-4-one	446-72-0	Isoflavones, Phyttestrogen	
Hexabromocyclododecane	1,2,5,6,9,10-Hexabromocyclododecane	25637-99-4	BFR	HBCDD
Hexachlorobenzene		118-74-1	Chlorinated Aromatic	HCB
Lead (Pb)	-	7439-92-1	Heavy metal	
Levonorgestrel	13-Ethyl-17-ethynyl-17-hydroxy- 1,2,6,7,8,9,10,11,12,13,14,15,16, 17-tetradecahydrocyclopenta[a] phenanthren-3-one	797-63-7	Synthetic Estrogen	
Lindane	gamma-Hexachlorocyclohexane	58-89-9	Organochlorine Insecticide	γ-HCH
Linuron	3-(3,4-Dichlorophenyl)-1-methoxy-1-methylurea	330-55-2	Herbicide	
Malathion	Diethyl 2-[(dimethoxyphosphorothioyl)sulfanyl]butanedioate	121-75-5	Organophosphate Insecticide	
Mancozeb	Manganese ethylenebis(dithiocarbamate)	8018-01-7	Herbicide	
Methylbenzylidene camphor	(3E)-1,7,7-Trimethyl-3-[(4-methylphenyl)methylene]- 2-norbornanone	36861-47-9	UV filter	4-ethylbenzylidene camphor
Methylsulfonyl-DDE	3-Methylsulfonyl-2,2'-bis(4-chlorophenyl)-1,1'-dichloroethene	62938-14-1	DDE Metabolite	MeSO ₂ -DDE
Mirex	1,1a,2,2,3,3a,4,5,5,5a,5b,6-dodecachlorooctahydro-1H-1,3,4- (methanetriyl) cyclobuta[cd]pentalene	2385-85-5	Organochlorine Insecticide	
n-Butylbenzene	n-Butylbenzene;Butylbenzene;1-Phenylbutane	104-51-8	Chemical Synthesis Intermediate	
Nonylphenol	p-Nonylphenol; 4-Nonylphenol	104-40-5	Surfactant	NP
Octachlorostyrene	1,2,3,4,5-Pentachloro-6-(trichlorovinyl)benzene	29082-74-4	Chlorinated Aromatic	OCS
Octyl-methoxycinnamate	2-Ethylhexyl (2E)-3-(4-methoxyphenyl)prop-2-enoate	5466-77-3	UV filter	
Octylphenol	p-Octylphenol; 4-n-Octylphenol	1806-26-4	Surfactant	OP

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PCB methyl sulfones	4-Methylsulfonyl-2,2',3,4',5',6-hexachlorobiphenyl	116806-76-9	PCB metabolite	MeSO ₂ -PCB
Pentachlorophenol	2,3,4,5,6-Pentachlorophenol	87-86-5	Herbicide, fungicide	PCP
PFOA	Perfluorooctanoate/-octanoic acid	335-67-1	PFAS	
PFOS	Perfluorooctane sulfonate/-sulfonic acid	2795-39-3, 1763-23-1	PFAS	PFOS
Procloraz	N-Propyl-N-[2-(2, 4,6-trichlorophenoxy)ethyl]-1H-imidazole- 1-carboxamide	67747-09-5	Fungicide	
Procymidone	3-(3,5-Dichlorophenyl)-1,5-dimethyl-3-azabicyclo[3.1.0] hexane-2,4-dione	32809-16-8	Fungicide	
Pyrene	Benzo[def]phenanthrene	129-00-0	PAH	
Resorcinol	1,3-Dihydroxybenzene	108-46-3	Disinfectant, Chemical intermediate	
Short chain chlorinated paraffins	Polychlorinated n-alkanes, C10 to C13, 50-60% chlorine	63449-39-8, 85535-84-8	Flame Retardant; plasticizer	SCCP
Tamoxifen	(Z)-2-[4-(1,2-Diphenylbut-1-enyl)phenoxy]-N,N-dimethylethanamine	10540-29-1	Pharmaceutical	
Testosterone	(8R,9S,10R,13S,14S,17S)- 17-Hydroxy-10,13-dimethyl- 1,2,6,7,8,9,11, 12,14,15, 16,17- dodecahydrocyclopenta[a]phenanthren-3-one	58-22-0	Natural hormone	
Tetrabromobisphenol A	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol	79-94-7	BFR	TBBPA
Toxaphene	Polychlorinated bornanes	8001-35-2	Organochlorine Insecticide	
Tributyltin	Bis(tri-n-butyltin)oxide	56-35-9	Fungicide	TBT Methylmercury Tributyltin
Triclocarban	3-(4-Chlorophenyl)-1-(3,4-dichlorophenyl)urea	101-20-2	Microbicide	
Triclosan	5-Chloro-2-(2,4-dichlorophenoxy)phenol	3380-34-5	Microbicide	
Triphenyl phosphate	Phosphoric acid, triphenyl ester	115-86-6	Flame retardant	TPP
Vinclozolin	RS)-3-(3,5-Dichlorophenyl)-5-methyl- 5-vinyloxazolidine-2,4- dione	50471-44-8	Fungicide	
Zearalenone	(3S,11E)-14,16-Dihydroxy-3-methyl-3,4,5,6,9,10-hexahydro- 1H-2-benzoxacyclotetradecine-1,7(8H)-dione	17924-92-4	Mycotoxins	