



**Overview Report I:
Worldwide initiatives to identify
endocrine disrupting chemicals (EDCs) and potential EDCs**

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DISCLAIMER

This is the first report within a series of three reports on EDCs that UN Environment has commissioned the International Panel on Chemical Pollution (IPCP) to prepare, in response to its commitment to the third and fourth sessions of the International Conference on Chemicals Management (ICCM 3 and 4) Resolutions that had called for international cooperative actions to provide up-to-date information and scientific expert advice to relevant stakeholders, raise awareness and facilitate science-based information exchange.

The series of reports include the following: (1) compilation of worldwide initiatives by various stakeholders to identify EDCs or potential EDCs based on the WHO/IPCS 2002 definitions; (2) a compilation of the current understanding of: the life cycle, environmental fate and distribution, environmental exposure in different regions, and evidence of adverse endocrine-related effects of EDCs and selected potential EDCs; and (3) a compilation of existing regulatory frameworks and policy initiatives on EDCs.

Given the complexity, breadth, and rapid ongoing development of this scientific field and in the regulatory frameworks, it is neither feasible nor possible for these three reports to include in-depth detail and discussion related to all the potentially relevant aspects or to predict future developments within the field. It instead provides a snapshot of the overall situation when the reports were prepared as well as references to further detailed and relevant information.

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the United Nations Environment Programme concerning the legal status of any country, territory, city or area or of its authorities, or concerning delimitation of its frontiers or boundaries. Moreover, the views expressed do not necessarily represent the decision or the stated policy of the United Nations Environment Programme, nor does citing of trade names or commercial processes constitute endorsement.

Executive Summary

Endocrine disrupting chemicals (EDCs) are chemicals that alter function(s) of the endocrine system and consequently cause adverse health effects. International research efforts to better understand the presence of EDCs and associated effects on the environment have been intensified over the past three decades and led to an increasing level of concern about and action on EDCs. In particular, at the 4th session of the International Conference on Chemicals Management (ICCM 4), a Resolution was adopted by the stakeholders inviting UN Environment to generate and disseminate information on EDCs. This report is the first within a set of three Overview Reports commissioned by UN Environment to the International Panel on Chemical Pollution (IPCP) on EDCs in response to its commitment to the ICCM 4 Resolutions. It aims to serve as a compendium of information that provides an overview of global initiatives identifying EDCs and potential EDCs, including a comparison of the existing efforts as well as highlighting current gaps.

This report reviews existing, publicly accessible initiatives by various stakeholders (governments, industry, civil society and academia) to identify EDCs. In total, 28 initiatives are identified and considered. These initiatives are qualitatively compared and grouped/categorized in terms of their scope, selection criteria, selection processes, and included chemical information.

Several general observations are made, including:

- Substantial resources have been and are being invested into identifying EDCs, as reflected by the number and diversity of the initiatives found.
- The intended purpose of individual initiatives as well as the criteria used to identify (or include) chemicals as EDCs or potential EDCs vary considerably.
- Some initiatives have already been heavily developed and publicized, whereas others are planned or currently in earlier development stages.
- Within the initiatives identified, there is a lack of input and representation from developing countries and countries with economies in transition.
- No commonly accepted criteria for the identification of EDCs are yet available, however, recently the European Commission accepted criteria for the identifications of EDCs in plant protection products (Commission Regulation (EU) 2018/605).

Furthermore, the report also identifies a set of 45 chemicals, or groups of chemicals, for use in the subsequent Overview Report II that have been identified as EDCs or potential EDCs following a thorough scientific assessment based on the WHO/IPCS 2002 definitions of EDCs and potential EDCs. Readers are encouraged to find further, relevant information in Report II on the life cycle, environmental exposure, and effects of select EDCs and potential EDCs, and in Report III on existing regulatory frameworks and policy initiatives on EDCs.

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Abbreviations

CAS – Chemicals Abstracts Service
CMR – Carcinogenic, Mutagenic, and Reprotoxic
CoRAP – Community Rolling Action Plan
EASIS – Endocrine Active Substances Information System
EASIS – Endocrine Active Substances Information System
EAT – Estrogen, Androgen and Thyroid
EC – European Commission
ECHA – European Chemicals Agency
EDC – Endocrine Disrupting Chemical
EDSP – Endocrine Disruptor Screening Program
EFSA – European Food Safety Authority
EPA – Environmental Protection Agency
EU – European Union
EXTEND – Extended Tasks on Endocrine Disruption
ICCM – International Conference on Chemicals Management
IOMC – Inter-Organization Programme for the Sound Management of Chemicals
IPCP – International Panel on Chemical Pollution
IPCS – International Programme on Chemical Safety
NGO – Non-Governmental Organization
OECD – Organisation for Economic Co-operation and Development
PBT – Persistent, Bioaccumulative, and Toxic
REACH – Registration, Evaluation, Authorisation and Restriction of Chemicals
SAICM – Strategic Approach to International Chemicals Management
SIN – Substitute It Now
SPEED – Strategic Programs on Environmental Endocrine Disruptors
SVHC – Substance of Very High Concern
TEDX – The Endocrine Disruption Exchange
UN – United Nations
UNEP – United Nations Environment Programme (UN Environment)
US – United States
UV – Ultraviolet
vPvB – very Persistent and very Bioaccumulative
WHO – World Health Organization

1. Background, Aims and Scope

Endocrine disrupting chemicals (EDCs)^A are chemicals that alter function(s) of the endocrine system and consequently cause adverse health effects. Potential EDCs^B are chemicals that possess properties that might be expected to lead to endocrine disruption. The endocrine system consists of many interacting tissues that communicate with one another and the rest of the body by means of hormones. This system is responsible for controlling a large number of processes in the body from gamete formation, to conception and early developmental processes such as organ formation, and to most tissue and organ functions throughout adulthood. EDCs interfere in some way with hormone action and in doing so can alter endocrine function and lead to adverse effects on the health of humans and wildlife. Some of the observed health effects associated with EDCs include, but are not limited to, cancer as well as reproductive, developmental, immunological, and neurological disorders. For more background information on endocrine disruption including the makeup of the endocrine system and how EDCs act, see the report “State of the Science of Endocrine Disrupting Chemicals – 2012” [1].

Over the past three decades, international research efforts to better understand EDCs have been intensified [1]. This has resulted in growing global concern regarding EDCs. In 2012, the third session of the International Conference on Chemicals Management (ICCM 3) recognised EDCs as one of the Emerging Policy Issues^C under the UN Strategic Approach to International Chemicals Management (SAICM) [2]. The fourth session (ICCM 4) in 2015 [3] affirmed to support further research and develop cooperative actions regarding EDCs. The ICCM 4 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^D 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 intersectoral 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 EDCs.

^A 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*” [63].

^B According to the WHO/IPCS 2002 definition, a potential endocrine disruptor is “*an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub)populations*” [63].

^C All SAICM Emerging Policy Issues can be found at <http://www.saicm.org> [64].

^D Regional resolutions on endocrine-disrupting chemicals from Africa (SAICM/RM/Afr.5/7), Asia-Pacific (SAICM/RM/AP.4/7), and Latin America and the Caribbean (SAICM/RM/LAC.4/11). See the SAICM website at www.old.saicm.org.

This report is the first within the set of overview reports, and it aims to provide an overview of existing national, regional and global initiatives identifying EDCs and potential EDCs and the chemicals that they have identified. It also sets the basis for the second overview report that focuses on the life-cycles, levels and trends of environmental exposure, and evidence of (potential) adverse endocrine-related impacts on wildlife of selected EDCs and potential EDCs.

To date, substantial efforts have been made by a wide variety of stakeholders across numerous sectors worldwide in identifying and categorizing EDCs; some of these initiatives have resulted from regulatory frameworks that are discussed in Report III. For example:

- Government agencies from multiple countries have established their own priority lists of chemicals, screening programmes, and knowledge bases to support ongoing discussions and research to identify EDCs.
- Non-governmental organisations (NGOs) have evaluated existing knowledge in the peer-reviewed scientific literature to identify EDCs.
- Industry bodies have published their own sets of self-regulated chemical use restrictions within their sectors or supply chains.

However, it is noted that the intended purpose and scope of these various initiatives, the criteria and processes used to develop them, and the information they provide to the public may differ considerably. In particular, while the WHO/IPCS 2002 definitions of EDCs and potential EDCs have been widely accepted by many stakeholders and consensus among international leading experts regarding the scientific principles for the identification of EDCs has recently emerged [4], no commonly accepted criteria for the identification of EDCs are yet available. For example, the regulators in the European Union (EU) have been using the WHO/IPCS 2002 definition, together with the recommendations of its Endocrine Disruptor Expert Group [5], to identify EDCs on a case-by-case basis. The EU has recently defined official criteria for EDCs in plant protection products, and ad-interim criteria are currently in effect for some European regulations until these criteria are fully implemented (see Report III). Similarly, potential EDCs identified by different stakeholders are considered to span a wide range of scientific evidence: They can include a range of chemicals from those identified as ‘indicated’ EDCs with a low degree of documentation to those identified as ‘suspected’ EDCs with substantive documentation. Consequently, individual initiatives can result in varied recognitions and associated actions or recommendations for the same chemicals, which can be challenging for stakeholders not familiar with the details of these initiatives to comprehend.

The report presented here serves as a compendium of information, providing an overview and comparison of existing national, regional and global efforts to identify EDCs and highlighting existing gaps. It consists of three major sections: *Methodology*, *Overview and Comparison of Individual Initiatives*, and *Chemicals for the Subsequent Overview Report*. The information presented here is not necessarily exhaustive or representative of all initiatives that may have been created. It should also be noted that this report does *not* intend to propose or recommend any criteria for identifying EDCs, or any harmonized set of EDCs or potential EDCs. The section *Chemicals for the Subsequent Overview Report* serves merely as the basis for the second Overview Report, and none of the chemicals have been additionally assessed by the authors. Instead, the chemicals are included in this section for having previously gone through at least one thorough scientific assessment using the WHO/IPCS definitions^{A,B}

(i.e., an assessment of associated adverse effects and their causes) that has identified them as an EDC or potential EDC (see sections 3.1 and 4).

2. Methodology

In brief, existing, publicly accessible initiatives by various stakeholders (governments, industry, civil society and academia) to identify EDCs were retrieved from a desk review and compared qualitatively in terms of selection criteria, selection process details, and included information types for a chemical. The initiatives are grouped by type into separate tables and discussed in section 3. Among chemicals identified across all of these initiatives, chemicals that have gone through at least one thorough scientific assessment using the WHO/IPCS definitions^{A,B} were selected as the basis for the second overview report (see section 4).

The search has been done across public sources with the exception of scientific journals and individual studies submitted in a regulatory context (e.g., studies submitted by manufacturers for the registration of pesticide ingredients). It is important to note that additional assessments of individual chemicals may exist in the scientific literature or as parts of regulatory processes, however they are scattered across thousands of scientific journals and databases. In this context, it is important to note that the objective of this report is to compile worldwide initiatives that identify EDCs, but not to assess individual chemicals.

3. Overview and Comparison of Individual Initiatives

In total, 28 initiatives have been identified and considered in this study. Based on their intended purpose and actual content, each has been grouped into four types that are presented in Tables 1 through 4 along with succinct explanations describing and comparing them:

- ❖ Table 1: Initiatives that include chemicals that have been identified as EDCs or potential EDCs by individual stakeholders.
- ❖ Table 2: Initiatives where the evaluation of included chemicals is ongoing to identify whether or not they shall be identified as EDCs or potential EDCs.
- ❖ Table 3: Knowledge bases and databases that focus on EDCs or endocrine activity and include tools and information such as experimental results, useable prediction models, and regulatory details.
- ❖ Table 4: Initiatives that cover a wide range of chemicals and do not themselves identify any of the chemicals included as EDCs or potential EDCs. However, they do include chemicals that have been identified as EDCs or potential EDCs by other stakeholders in Table 1.

The initiatives included in Tables 1, 2, and 3 explicitly address EDCs and/or endocrine activity, whereas the initiatives in Table 4 address toxic chemicals in general (which may include some EDCs) and may serve as sources of additional information.

Several general observations follow from the comparison of all considered initiatives:

- Significant resources have been and are being invested into identifying EDCs, as reflected by the number and diversity of the initiatives found. Many have already been heavily developed and publicized, whereas others are planned or currently in earlier development stages.
- The intended purpose of individual initiatives varies considerably. For example, some intend to highlight identified EDCs or potential EDCs (Table 1), whereas others intend to consolidate existing knowledge in relation to EDCs (Table 3).
- The selection criteria used to justify the inclusion of chemicals in an initiative vary considerably. For many, selection criteria have been clearly communicated, whereas others rely on some form of expert consultation, or did not disclose such clear selection criteria. Multi-stakeholder consultation (through government, industry and/or civil society input) occurred during the development of some of the initiatives (such as the US Endocrine Disruptor Screening Program), especially those that have direct regulatory impacts.
- The pool of chemicals considered to develop individual initiatives varies, and interlinkages exist between some initiatives. For example, the List of Potential Endocrine Disruptors from The Endocrine Disruption Exchange (TEDX) contains chemicals that have been shown to have endocrine activity in at least one experimental study in the literature, which could be any chemical in the chemical universe, whereas some initiatives (or parts of them) have been based on chemicals contained in previous initiatives (such as the list of suspected endocrine toxicants by Scorecard).
- There is a general focus across the initiatives identified here on evaluating industrial chemicals, especially in relation to the European Union’s chemicals regulation (REACH) or to manufacturing and occupational exposure. This results in a limited scope of chemicals evaluated or being evaluated for endocrine disrupting potential, and this is further discussed in section 5, which reviews such current limitations within and beyond this report.
- Existing knowledge of the endocrine system has primarily focused on the estrogen, androgen and thyroid hormone (EAT) pathways as well as on steroidogenesis, and testing guidelines have been developed and validated in these areas under the Organisation for Economic Co-operation and Development (OECD) frameworks [5]. Currently, additional assays are being developed and endpoints identified, and some of them are being validated and harmonised for use to identify potential endocrine disruption beyond these traditional pathways; for more details, see ref. [6]. However, creation and validation of standard test protocols takes time for each relevant test, and the identification of EDCs is currently relying in part on research studies that include non-standard species, endpoints or exposure regimes [7]. In turn, established initiatives may need to be reviewed and updated in the future as scientific knowledge on the topic evolves.
- Further differentiating factors among the initiatives include whether a set of chemicals within an initiative is static or updateable, uncategorized or further sub-grouped, and EDC-focused or more universal. For example, some initiatives have identified EDCs as a subset of the chemicals considered. Table 1 and Table 2 contain such initiatives, and the entries in these tables are

accompanied by information describing the total number of chemicals included within the initiative and the number of identified EDCs within this total.

- Depending on an initiative's purpose, selection criteria, pool of chemicals and endocrine sub-systems considered for selection, and other differentiating factors, the number and identity of the chemicals included varies. In total, more than 1'000 chemicals have been identified as EDCs or potential EDCs across all of these initiatives. As these initiatives have variability in the processes and assessment criteria used, the numbers of chemicals identified differ across each of the initiatives. Some chemicals are present in several initiatives, whereas some others may be included in only one. A few initiatives additionally categorize the chemicals into sub-groups based on chosen criteria or make recommendations for prioritisation.
- The naming of and reference to chemicals included across the initiatives is not always consistent. Some chemicals are referred to by many different Chemicals Abstracts Service (CAS) numbers due to varying product mixtures, and some have a wide range of isomers. Initiatives do not always specify all of the CAS numbers that may be applicable to an intended chemical or group of chemicals, and they do not consistently reference the same CAS numbers. This can make accurately comparing chemicals included across the different initiatives challenging.
- Many of the initiatives were found to include a brief description of a chemical's possible applications, and some included information on the toxicity to humans or wildlife with references to scientific literature.
- Comparison of the initiatives highlights inconsistencies in methods being used, the lack of input from developing countries and countries with economies in transition, and the need for further clarification of the meaning and purposes of the initiatives.
- Feedback from stakeholders during the commenting period of the draft report noted that additional assessments of individual chemicals may exist in the scientific literature. Additional searching and review of the many chemicals that may have been assessed across the numerous existing scientific journals could identify additional information to support the identification of EDCs and potential EDCs in future work.
- In addition to the WHO/UNEP 2012 State-of-the-Science report on EDCs [1], other publications exist that could serve as a starting place for the completion of broad-scale evaluations of these other chemicals in the future using the WHO/IPCS definitions. These include an earlier literature review of more than 100 pesticides for endocrine activity [8], an assessment of endocrine disrupting properties in the European Food Safety Authority (EFSA) conclusions on a pesticides peer review [9], and studies included in the Endocrine Active Substances Information System (EASIS) database [10]. Results of ongoing screening and evaluation programmes such as the US EPA's Endocrine Disruptor Screening Program (EDSP) [11] and the EU's Community Rolling Action Plan (CoRAP) [12] could also be reviewed.
- Identifying and making use of synergies among existing and future initiatives may be encouraged by stakeholders. This could be done through, e.g., creation of a common web portal of knowledge gained and lessons learned.

3.1 Overview of initiatives identifying EDCs or potential EDCs

The ten initiatives in Table 1 identify some or all of the chemicals they include as EDCs or potential EDCs. Five of the entries in this table are EU-based, including the European Commission (EC) Priority List of Chemicals, the REACH Substances of Very High Concern (SVHC) Candidate List for Authorisation under the European Chemicals Regulation (REACH), the assessment of the proposed Danish criteria for identification of endocrine disruptors, and the Substitute-It-Now (SIN) List from ChemSec. Three are based in the United States (US), one is the result of a government-led pilot study in Australia, and one is international.

Most of these initiatives have a clear set of selection criteria for including chemicals, such as rigorous assessment of existing scientific evidence, the details of which can be retrieved either directly from the initiative's website or by request. The extent of scientific evidence included in the assessment may vary between initiatives, in particular for identifying potential EDCs, which can range from a lower degree of evaluation (e.g. List of Potential Endocrine Disruptors from TEDX) to a more comprehensive evaluation of evidence (e.g. the EC Priority List of Chemicals). Furthermore, multi-stakeholder consultations have been conducted as part of the processes to include a chemical in the REACH SVHC Candidate List and the EC Priority List.

Among these ten initiatives, the EC Priority List, the REACH SVHC Candidate List and the TEDX List of Potential Endocrine Disruptors considered chemicals from an almost unrestricted pool of all existing chemicals, whereas the other initiatives often limited their scopes to considering chemicals already included within one or more of these former three initiatives. The EC Priority List in particular has served as the starting point for a number of other initiatives reviewed within this report.

The REACH SVHC Candidate List, SIN List, and List of Potential Endocrine Disruptors from TEDX are adaptable and continuously updated. The Trade Union Priority List has also been regularly updated and includes identified SVHCs recognised to be causes of occupational diseases in the European Union; chemicals identified as EDCs in this initiative are scored to set priority for the European Trade Union Confederation's recommendation for inclusion in the Candidate List and their prioritisation in the Authorisation List under REACH [13].

Of all the initiatives listed in Table 1, the following three initiatives have been identified in this report to have used the most robust and transparent selection criteria based on the WHO/IPCS 2002 definitions and selection processes: [i] the REACH SVHC Candidate List; [ii] the SIN List by ChemSec; and [iii] the assessment of the proposed Danish criteria for identification of endocrine disruptors by the Danish Centre on Endocrine Disruptors. Each of these three initiatives is well documented and provides accessible information (either directly or upon request) detailing the methodology, criteria, and sources used to identify the chemicals as an EDC or potential EDC [14–16]. An additional description of these three initiatives and their processes is provided below:

[i] REACH SVHC Candidate List

This list includes ten chemicals and groups of chemicals identified as SVHCs for having scientific evidence of probable serious effects to the environment and/or human health with endocrine disrupting

properties. They are identified as substances of equivalent concern to carcinogenic, mutagenic, and reprotoxic (CMR) substances, to persistent, bioaccumulative, and toxic (PBT) substances, or to very persistent and very bioaccumulative (vPvB) substances (REACH Article 57f). The identification process involves evaluating the chemicals using the WHO/IPCS 2002 definitions with available scientific studies. In addition, comments and supplementary information submitted by stakeholders are reviewed and considered in the process.

[ii] ChemSec's SIN List

ChemSec has established its SIN List of substances that may qualify as SVHCs of equivalent concern under REACH (following REACH Article 57f). In 2011, ChemSec first added 22 chemicals they identified as EDCs to the SIN List. At that point in time, there was no widespread consensus for use of the WHO/IPCS 2002 definitions, and inclusion of these chemicals in the SIN List was based on a level-of-evidence approach requiring at least three high-quality studies, of which at least two were in-vivo. The Danish Centre on Endocrine Disruptors reviewed these same chemicals in 2012 using criteria based on the WHO/IPCS 2002 definitions and confirmed ChemSec's identification of these chemicals as EDCs or potential EDCs. In 2014, an additional ten chemicals were added to the SIN List due to identified ED properties using the WHO/IPCS definitions. In all of the completed evaluations, reviews were based on publicly available, peer-reviewed scientific publications.

[iii] Assessment of the Danish Criteria

The 22 chemicals placed on the SIN List in 2011 using ChemSec's own criteria were evaluated using the proposed Danish criteria for identifying endocrine disruptors in 2012. These Danish criteria are described in detail in published reports [15,17], are based on the WHO/IPCS definitions, and are split into three categories: endocrine disruptor (Category 1), suspected endocrine disruptor (Category 2a), and indicated endocrine disruptor (Category 2b). Four other chemicals were also later evaluated against these criteria. The evaluations were completed following a wide literature search for publicly available scientific publications for each chemical, and this resulted in 25 of the 26 reviewed chemicals being categorized as an EDC (Category 1) or suspected EDC (Category 2a). This evaluation serves as a check of ChemSec's initial identification of the 22 chemicals added to the SIN List in 2011, and it positively identifies all but one of them as EDCs or suspected EDCs. The assessment also evaluated these substances using the potency cut-off criteria presented in another position paper 'Regulatory Definition of an Endocrine Disrupter in Relation to Potential Threat to Human Health' [18], which leads to fewer of the chemicals being identified as endocrine disruptors of 'high regulatory concern'. Following the WHO/IPCS 2002 definitions, potency is not part of the identification criteria for EDCs [4,5], and additional steps beyond the identification of EDCs or potential EDCs (e.g., risk characterisation and prioritisation of chemicals for regulatory action) are beyond the scope of this report. Hence, the assessment results according to the criteria proposed in this position paper [18] were considered but not included here.

Table 1. Overview of initiatives that identify chemicals as EDCs or potential EDCs

Initiative Name	Number of Chemicals or Chemical Groups Identified as EDCs or Potential EDCs	Selection Criteria and Process	Organisation Name and Related Information	Reference
BY GOVERNMENTAL ORGANISATIONS				
REACH Substances of Very High Concern (SVHC) Candidate List for Authorisation	10	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - May have serious effects on human health or the environment - Based on WHO/IPCS 2002 definition of EDCs, together with the recommendations from the Endocrine Disruptor Expert Group. <p><u>Process:</u></p> <ul style="list-style-type: none"> - A chemical is proposed by an EU member state or the European Chemicals Agency as an SVHC and opened for comments or further information. - The Member State Committee reviews the proposal and comments and must unanimously agree to identify it as an SVHC. Otherwise, the matter is referred to the European Commission [19]. 	<p><u>European Chemicals Agency (ECHA)</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - The assessment of individual chemicals is provided on the ECHA's website. - Inclusion of a substance on this list initiates legal obligations for companies that manufacture or import the substance. - The Candidate List is regularly updated. 	[14]
Priority List of Chemicals for further evaluation of their role in endocrine disruption	320	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - Highly persistent and/or high production volume substance - Scientific evidence of endocrine disruption (ED) related effects: <ul style="list-style-type: none"> • For Category 1: At least one study showing evidence of ED in an intact organism • For Category 2: In vitro data showing potential for ED in intact organisms, or in-vivo effects that may or may not be ED-mediated <p><u>Process:</u></p> <ul style="list-style-type: none"> - Working list of chemicals was compiled from suspected EDCs published by organizations and in scientific literature. They were then discussed in a stakeholder meeting with government, industry, and civil society. - Expert reviews placed the chemicals into Category 1, 2, or 3. - Category 1 chemicals were then further categorised as having high, medium, or low exposure concern for humans and wildlife [20–22]. 	<p><u>European Commission</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - First established in the year 2000. - 194 chemicals identified as Category 1 and 126 identified as Category 2. - Current database file available for download is: "EDS_2003_DHI2006.mdb". - The list is no longer updated, but it serves as basis for the EU Endocrine Active Substances Information System (EASIS); see Table 3. 	[23]

Initiative Name	Number of Chemicals or Chemical Groups Identified as EDCs or Potential EDCs	Selection Criteria and Process	Organisation Name and Related Information	Reference
Evaluation of chemical substances according to the Danish proposal for criteria for identification of endocrine disruptors	25	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - 22 substances placed on the ChemSec SIN List 2.0 due to their endocrine disrupting properties [15] and an additional 4 substances requested by the Danish EPA for review [17]. - Scientific evidence of endocrine disruption (ED) related effects [15]: <ul style="list-style-type: none"> • For Category 1: Adverse in vivo effects where an ED mode of action is highly plausible; ED mode of action in vivo that is clearly linked to adverse in vivo effects (by e.g. read-across) • For Category 2a: Adverse effects in vivo where an ED mode of action is suspected; ED mode of action in vivo that is suspected to be linked to adverse effects in vivo; ED mode of action in vitro combined with toxicokinetic in vivo data (and relevant non-test information such as read across, chemical categorisation and QSAR predictions) • For Category 2b: In vitro/in silico evidence indicating potential for endocrine disruption in intact organisms; observed effects in vivo that could be ED-mediated <p><u>Process:</u></p> <ul style="list-style-type: none"> - Selected chemicals were assessed according to Denmark's proposed criteria for identifying EDCs. 	<p><u>Danish Environmental Protection Agency (EPA)</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - Resulted in 25 of 26 assessed substances considered as known or suspected EDCs according to the Danish criteria (Hass et al., 2012). - Denmark submitted its proposal for EDC criteria to the European Commission in May 2011. - The Danish EPA contracted the Danish Centre on Endocrine Disruptors to do the assessments, and the reports were published in May 2012. - In August of 2016, the Danish EPA announced that they are planning to update the list. 	[15,24]
Most Significant EDCs	8	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - Identified to be the most significant chemicals due to their relative potency to the steroidal hormone estradiol (E2) (taken as a benchmark for estrogenic potential), concentrations detected in wastewater treatment plant effluent, and observed biological effects. <p><u>Process:</u></p> <ul style="list-style-type: none"> - Reviewed published literature for data detailing the relative potency of chemicals to E2, wastewater effluent concentrations, and reported in vivo effects. 	<p><u>Land and Water Australia</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - Published in 2007 as part of a three-year pilot study by the Australian Government. - Identified chemicals are listed in Table 3.1 of the report and are used to select target chemicals for sampling in the Australian riverine environment. - Information on follow-up studies is unclear. 	[25]

Initiative Name	Number of Chemicals or Chemical Groups Identified as EDCs or Potential EDCs	Selection Criteria and Process	Organisation Name and Related Information	Reference
BY NON-GOVERNMENTAL ORGANISATIONS				
Substitute it Now! (SIN) List	32	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - For the update in 2011, the set of chemicals listed as category 1 or 2 on the European Commission's priority list of chemicals were considered; for the second round in 2014, other initiatives including the TEDX List were considered. - Have known uses relevant to EU REACH and not used only as intermediates. - Have peer-reviewed, high quality, relevant, primary research literature showing endocrine related effect(s). In 2011, at least three studies required (two of which must be in-vivo) that pass an internal peer review by an internal research team. In 2014, the WHO/IPCS definition was used requiring studies that clearly showed endocrine mode-of-action linked to a probable serious effect. [26] <p><u>Process:</u></p> <ul style="list-style-type: none"> - Reviewed by external EDC experts following the REACH guidance document [26]. 	<p><u>International Chemical Secretariat (ChemSec)</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - First published in 2008. 14 substances having EDC properties were added to the list as "equivalent level of concern". Endocrine disruption was just one of several endpoints investigated for those substances. - Major update in 2011 adding 22 chemicals identified as EDCs to the list based on EDC properties only. - Major update in 2014 adding 10 chemicals identified as EDCs to the list based on EDC properties only. - 32 chemicals have been identified as fulfilling SVHC criteria based solely on their endocrine disruption properties. - The SIN List is regularly updated. 	[27]
List of Potential Endocrine Disruptors	1'392	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - At least one peer-reviewed study has been published demonstrating effects on the endocrine system. 	<p><u>The Endocrine Disruption Exchange (TEDX)</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - Established in 2011 and initially used two other published lists as a basis. - Regularly updated, last in March 2017. 	[28]
Widespread Pollutants with Endocrine-Disrupting Effects	86	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - Each chemical included is linked to at least one scientific publication, and a call for submissions of new chemicals and feedback exists. 	<p><u>Our Stolen Future</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - Website of the 1996 book of the same name written by Theo Colborn (founder of TEDX). - Information on updates is unclear. 	[29]

Initiative Name	Number of Chemicals or Chemical Groups Identified as EDCs or Potential EDCs	Selection Criteria and Process	Organisation Name and Related Information	Reference
Suspected Endocrine Toxicants	310	<u>Selection criteria:</u> - Each chemical included is linked to a reference source that is either a journal article or a report from a government agency or NGO.	<u>Scorecard (sponsored by GoodGuide)</u> <u>Initiative information:</u> - Information on updates is unclear.	[30]
Pesticide Action Network's List of Highly Hazardous Pesticides	52	<u>Selection criteria:</u> - Pesticide ingredient identified by PAN as being highly hazardous following PAN's published methodology. - Two criteria have been used as the selection basis for endocrine disrupting potential: i). those that have been categorized in the EU Commission's priority list as Category 1 (at least one study providing evidence of endocrine disruption in an intact organism), or ii). those that have been classified as Category 2 for Globally Harmonized System (GHS) carcinogenicity and as Category 2 for EU reproductive toxicity (following European Commission regulation 1272/2008).	<u>Pesticide Action Network (PAN)</u> <u>Initiative Information:</u> - First list published in 2009 and updated in 2015 and 2016.	[31]
Trade Union Priority List for REACH Authorisation	70	<u>Selection criteria:</u> - Listed as category 1 or 2 on the European Commission's priority list of potential endocrine disruptors and seen to meet the requirement of being an SVHC. - High production volume chemical for which a substance information exchange forum (SIEF) was formed by March 19, 2010 and was expected to be registered by December 2010. - Having a known use and not already banned by other means, not a residue or intermediate, not only used as a pesticide or biocide, and not a complex hydrocarbon distillate. <u>Process:</u> - Prioritization criteria were set and scores were given for each chemical. - Chemicals were ranked by score to set priority [32].	<u>European Trade Union Confederation (ETUC)</u> <u>Initiative information:</u> - Chemicals selected have been identified as causative agents for recognised occupational diseases in the European Union. - Objective is to reduce chemical-related occupational diseases and incentivise innovation and safer alternatives. - First established in 2009 and updated with 29 new entries in 2010.	[13]

3.2 Overview of governmental initiatives in screening or assessing the endocrine disrupting properties of chemicals

The four initiatives in Table 2 include screening programmes with chemicals to be evaluated for their endocrine disruption potential by governmental agencies in the EU, US and Japan. The chemicals included in these initiatives were often selected based on available data including chemical production and usage levels, environmental and bio-monitoring data (i.e., levels in the environment), and toxicological information (e.g. dose-response) from the scientific literature or other sources.

- The two-tiered Endocrine Disruptor Screening Program managed by the US Environmental Protection Agency (EPA) initially focused on examining pesticide ingredients used in the US. It was developed through public consultation involving a number of task forces, committees, and advisory panels with representation from multiple sectors (federal agencies, chemical companies, and environmental and public health organizations) [33], and priorities were set based on examined exposure potential [34].
- Chemicals within the European Union’s Community Rolling Action Plan (CoRAP) are scheduled to be reviewed by member states following their nomination, and it focuses on reviewing industrial chemicals under the REACH regulation [12].
- In the “Extended Tasks on Endocrine Disruption” (EXTEND 2010 and 2016) programmes by the Ministry of the Environment, Japan candidate chemicals have been selected based on detection in the aquatic environment and any indication of potential or suspected endocrine disrupting effects. Through reliability evaluation of existing knowledge and Tier-1 testing, candidate chemicals for environmental risk assessment are to be identified [35].

The approaches taken by these initiatives to screen or evaluate chemicals differ from one another. For example, the European Commission’s impact assessment is strictly on the screening level and based on existing knowledge, whereas the US EPA’s screening programme involves a two-tier experimental testing to establish quantitative dose-response relationships. The target compounds for review are also set (or prioritized) differently depending on an agency’s focus or legal mandate, and the timelines for the review processes also vary.

The intended outcomes of these initiatives also differ from one another. The evaluations completed within the EU’s CoRAP exist to determine further testing or regulation of a chemical, including listing on the REACH SVHC List. The US EDSP aims to screen chemicals to identify any interaction with the hormonal system, further quantify dose-effect relationships as needed, and use the resulting information to support risk assessments and risk management decisions. In contrast, the EXTEND programmes by the Ministry of the Environment, Government of Japan promote testing and assessment for selected candidate chemicals aiming at identifying target compounds for regulatory environmental risk assessment. Most unique is the EU’s Impact Assessment, which was specifically developed to understand what types of socio-economic impacts implementation of different EDC identification criteria might have.

Table 2. Overview of governmental initiatives designed to screen or assess the endocrine disrupting properties of chemicals

Initiative Name	Number of Chemicals or Chemical Groups Included for Screening / Assessing	Selection Criteria and Procedure	Organisation Name and Related Information	Reference
BY GOVERNMENTAL ORGANISATIONS				
Endocrine Disruptor Screening Program (EDSP)	174 (for Tier 1 screening)	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - Pesticide active ingredient, high production volume pesticide inert ingredient, or chemical identified under the Safe Drinking Water Act. - Selected at the agency’s discretion and based on identified exposure potential. - Priority given to chemicals present in all of four investigated exposure pathways. - Produced or used in the United States [34]. <p><u>Process:</u></p> <ul style="list-style-type: none"> - Two-tiered approach created to screen pesticides, chemicals, and contaminants for potential effect on estrogen, androgen, and thyroid hormone systems. - Substances found to exhibit potential to interact with any of these three hormone systems through experimental assays or other scientifically relevant information (including submissions) during Tier 1 will continue to Tier 2. - Chemicals selected for Tier 2 are tested to identify adverse endocrine-related effects and to create a quantitative relationship between the dose and adverse effect. 	<p><u>United States Environmental Protection Agency</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - Public and stakeholder consultations have taken place during the establishment of the programme. - Initial list of 67 chemicals for Tier 1 screening published in April 2009 (pesticide active ingredients and high production volume pesticide inert ingredients). - Second list of 107 chemicals for Tier 1 screening published in June 2014 (pesticide active ingredients and chemicals identified under the Safe Drinking Water Act). - Results for 52 chemicals that have completed Tier 1 screening have been published (last update September 2015). - The EPA is developing computational toxicology methods and high throughput assays to rapidly screen chemicals. The EDSP will transition to rely on these tools as they become ready for use. 	[33,36–38]
CoRAP List of Substances	319 (67 having an initial ground for concern as being a potential EDC)	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - In need of evaluation based on risk-based criteria considering hazard information, exposure information, and tonnage (following REACH Regulation Article 44(1)). - Examples include: suspected/known endocrine disrupting properties, PBTs, vPvBs, CMRs, and sensitizers; having wide dispersive use, high aggregated tonnage, high risk characterization ratio, etc [39]. <p><u>Process:</u></p> <ul style="list-style-type: none"> - Agency defines risk-based criteria and then selects substances to be evaluated (or receives nominated substances from member states for evaluation). - A member state is designated to evaluate each substance. 	<p><u>European Chemicals Agency (ECHA)</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - The first Community Rolling Action Plan (CoRAP) list was adopted in 2012 for a period of three years. - Updated each year to define new substances to be reviewed. 	[12]

Initiative Name	Number of Chemicals or Chemical Groups Included for Screening / Assessing	Selection Criteria and Procedure	Organisation Name and Related Information	Reference
Extended Tasks on Endocrine Disruption (EXTEND 2010 and EXTEND 2016)	132	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - Chemicals detected in the ambient aquatic environment are selected for testing and assessment if a certain amount of knowledge with any indication of potential or suspected endocrine disrupting effects are obtained through literature review. [35] <p><u>Process:</u></p> <ul style="list-style-type: none"> - A conservative reliability evaluation is conducted for the selected chemicals, and candidate chemicals for testing are identified. - A two tiered framework for testing and assessment of endocrine disrupting effects of chemicals to aquatic organisms was developed: Tier 1 with <i>in-vitro</i> and short-term <i>in-vivo</i> assays for detection of endocrine activity and Tier 2 for identification of adverse effects. - Relevant test protocols have been developed for the two-tiered framework, in most cases using the OECD Test Guideline Programme. - The selected candidate chemicals are subjected to Tier 1 testing. <i>In-vitro</i> assays are conducted first for prioritization of <i>in-vivo</i> assays. Via the Tier 1 assessment, candidate chemicals for Tier 2 testing are identified. - Referring to all available knowledge, including data obtained by Tier 2 <i>in-vivo</i> assays, environmental risk assessments will be conducted. [35]. 	<p><u>Ministry of the Environment, Government of Japan</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - Originally established as “SPEED’98” (May 1998), with a list of 65 suspected endocrine disruptors (now abolished). - Fully reorganized into “ExtTEND 2005” (March 2005) focusing only on environmental effects with emphasis on basic research and observation of wildlife. - Evolved into new programs “EXTEND 2010” (July 2010) and “EXTEND 2016” (June 2016), where testing and assessment have been accelerated under a newly-developed framework, aiming at future risk assessment and management. - Knowledge obtained in the program will be referred to in the existing risk assessment practices (both in the screening-level risk assessment program and in comprehensive ones for relevant regulation, such as environmental risk assessment under the Chemicals Substances Control Law and for setting Environmental Quality Standards). 	[40]
Impact Assessment on Criteria to Identify Endocrine Disruptors	630	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - Regulated under the Plant Protection Products and Biocidal Products except: substances of no concern or capacity to cause endocrine disrupting effects, low risk substances, natural extracts/mixtures/repellents, and attractants/plant hormones. - Regulated under REACH regulation and were on the Candidate List as SVHCs for endocrine disruption (ED), had opinion available from Member State Committee regarding it as an SVHC due to ED, were on the Candidate List as an SVHC due to reprotoxicity 1A/1B, were listed in AnnexXVII due to ED concern as reprotoxic 1A/1B, or were placed on CoRAP list due to ED concern. - Regulated under the Cosmetic Products Regulation and: had opinion available from the Scientific Committee on Consumer Safety (SCCS) discussing ED potential, had SCCS opinion due to 	<p><u>European Commission</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - Impact assessment launched in July 2013 on the criteria options to identify endocrine disruptors. - Goal is to assess which chemicals would fall under the different criteria options presented in the roadmap of the impact assessment [42]. - Results of the impact assessment were published in June 2016 [43]. 	[44]

Initiative Name	Number of Chemicals or Chemical Groups Included for Screening / Assessing	Selection Criteria and Procedure	Organisation Name and Related Information	Reference
		<p>potential/classification as carcinogenic/mutagenic/toxic to reproduction (CMR 1A/1B, CMR2), had concern expressed by SCCS on toxicity endpoints, or had concern raised by stakeholders/Member States on potential ED properties.</p> <p>- Regulated under the Water Framework Directive: no specific selection criteria applied.</p> <p><u>Process:</u></p> <p>- Screening of the substances followed a published, detailed methodology to identify which would be potentially categorized as endocrine disrupting under the four policy options set out in the European Commission's Roadmap [41].</p> <p>- Methodology includes detail for identifying the data sources, completing data collection, and completing data analysis.</p>		

3.3 Knowledge bases and databases that focus on EDCs or endocrine activity

Table 3 includes five initiatives in the form of knowledge bases and databases that focus on compiling and presenting existing knowledge on EDCs or endocrine activity, often including empirical results and computer simulations. Some of these initiatives have already been extensively developed, while others are planned or currently in development. They include datasets and sub-databases covering topics ranging from physicochemical properties to results from gene- and cell-proliferation assays to estrogenic and androgenic activity prediction models.

These knowledge- and databases differ regarding the information they provide and the features accessible to users. Those created by the US governmental agencies offer full sets of chemical and experimental data as well as useable prediction models as a resource for reducing dependence on animal testing and developing toxicology models. The Endocrine Active Substances Information System (EASIS) database focuses rather on collating and presenting data from published, endocrine-related experimental studies. The RISCTOX database differs in that it has a larger scope and contains not only chemicals included as EDCs based on their identification by other stakeholders but also many other chemicals, and, for many, it provides additional information regarding their health and environmental risks as well as regulatory details.

Table 3. Knowledge bases and databases that focus on EDCs or endocrine activity

Initiative Name	Number of Chemicals or Chemical Groups Included in the Knowledge base / Database	Contents	Organisation Name and Related Information	Reference
BY GOVERNMENTAL ORGANISATIONS				
The Endocrine Disruptor Knowledge Base (EDKB)	>3'000 experimental results	<ul style="list-style-type: none"> - Contains a biological activity database, quantitative structure-activity relationship training sets, experimental data (<i>in vitro</i> and <i>in vivo</i>), chemical structures, and literature references. - Serves as a resource for development of toxicology models and to reduce dependency on animal experiments. 	<u>United States Food and Drug Administration</u>	[45]
Estrogenic Activity Database (EADB)	8'212	<ul style="list-style-type: none"> - Set of estrogenic activity data from a variety of data sources. - 18'114 estrogenic-activity data points collected for 8'212 chemicals tested in 1'284 binding assays, reporter-gene assays, cell-proliferation assays, and in-vivo assays in 11 different species. 	<u>United States Food and Drug Administration</u> <u>Initiative information:</u> - Part of the Endocrine Disruptor Knowledge Base (EDKB).	[46]
Endocrine Disruption Screening Program for the 21 st Century (EDSP21) Dashboard	>1'800	<ul style="list-style-type: none"> - Contains chemical screening data from the EPA's ToxCast and Tox21 projects, chemical exposure data and prediction models, chemical structures and annotations, and a physical chemical properties database. 	<u>United States Environmental Protection Agency</u> <u>Initiative information:</u> - Part of the US EPA's Endocrine Disruptor Screening Program and created to help the programme evaluate chemicals. - Still under development to add functionality.	[47]
Endocrine Active Substances Information	513	<ul style="list-style-type: none"> - Contains data collected from over nine thousand studies with in vitro and in vivo assays from different species (including some human data). - Includes existing results from the 2000-2007 studies completed during creation of the EU Priority List of 	<u>European Commission DG Joint Research Centre</u> <u>Initiative information:</u> - Mandate to start development received in 2010. - Web-based application launched in September 2016.	[10]

Initiative Name	Number of Chemicals or Chemical Groups Included in the Knowledge base / Database	Contents	Organisation Name and Related Information	Reference
System (EASIS)		Chemicals within the EU-Strategy for Endocrine Disruptors. - Collects results from peer-reviewed studies, and more data will be added in the future either by the EU Joint Research Center (JRC) or through a crowdsourcing approach with input from stakeholders.		
<i>BY NON-GOVERNMENTAL ORGANISATIONS</i>				
RISCTOX	>100'000	- Contains toxic and hazardous substances and data regarding their health risks, environmental risks, and related regulations. - 2'281 substances are categorized within the database as endocrine disrupters based on their inclusion within other initiatives such as the EU Priority List and Scorecard list.	<u>ISTAS & the European Trade Union Institute</u> <u>Initiative information:</u> - Database commissioned by the European Trade Union Institute and developed by ISTAS.	[48]

3.4 Overview of initiatives that do not identify any of the chemicals included as EDCs or potential EDCs, but contain chemicals identified by other stakeholders as EDCs or potential EDCs

The nine initiatives included in Table 4 were created by various organisations for the identification or self-regulation of a large number of chemicals posing various types of hazards or risks. They do not identify any included chemicals as EDCs or potential EDCs, but they do contain chemicals that have been identified as EDCs or potential EDCs by other stakeholders (in Table 1) or are under review (in Table 2). In particular, five initiatives on this table originate from industry and are specifically linked with the self-regulation of chemicals used in products or manufacturing by certain brands. An association of apparel and footwear brands created a common list of chemicals restricted from intentional use during the manufacturing of their products across the supply chain [49]. Apple and the H&M Group have also published a set of substance specifications for its suppliers to follow detailing chemical restrictions in products, accessories, manufacturing products, and packaging [50,51].

Although these are not EDC-specific initiatives, they are relevant sources of information that provide additional background and insight for many identified EDCs and potential EDCs (including uses, hazardous properties, existing regulations, etc.). The EU REACH regulation requires industrial chemicals to be registered in order to be produced or imported within the European Union [52]. Many EDCs and potential EDCs identified by other stakeholders in Table 1 are registered under REACH, and the registration dossiers for these chemicals can contain additional information regarding their properties, production volumes, and hazards. The Stockholm and Rotterdam Conventions also provide significant amounts of information regarding chemicals they include [53].

Table 4. Overview of initiatives that do not identify any of the chemicals included as EDCs or potential EDCs, but contain chemicals identified by other stakeholders as EDCs or potential EDCs

Initiative Name	Number of All Chemicals or Chemical Groups Included	Selection Criteria and Procedure	Organisation Name and Related Information	Reference
BY GOVERNMENTAL ORGANISATIONS				
REACH Registered Substances	>20'000	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - Depending on the tonnage being used/imported into the European Union, industrial chemicals on the European market have different deadlines for registration and different standard information requirements under REACH. <p><u>Process:</u></p> <ul style="list-style-type: none"> - Companies are responsible for collecting information on the properties and uses of the substances they manufacture or import. This information is registered as a dossier for each chemical, and ECHA checks at least 5% of dossiers for compliance. [54] 	<p><u>European Chemicals Agency (ECHA)</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - Entered into force in 2007 and deadline for registration all of substances manufactured or imported in the EU in amounts greater than or equal to 1 tonne per year is May 31, 2018. - The public registration information can include a wide range of data on a chemical's properties, manufacture and use, classification and labelling, environmental fate, toxicology, and guidance on safe use, among others. 	[52]
Toxic Substances List – Schedule 1	133	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - Found to be toxic according to one or more criteria set out in section 64 of the Canadian Environmental Protection Act of 1999 [55]. <p><u>Process:</u></p> <ul style="list-style-type: none"> - A substance can be added to the Toxic Substances List following its assessment, a screening assessment, or the review of a decision by another jurisdiction [56]. - Can also be included if determined as equivalently toxic by incorporating elements of assessments done by or for international organizations or appropriate scientific authorities. 	<p><u>Environment and Climate Change Canada and Health Canada</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - Substances are added periodically with the last update taking place in December 2016. - Once added to the Toxic Substances List, preventive or control actions such as regulations, guidelines or codes of practice are then considered for any aspect of the substance's life cycle. - Additional information for chemicals on the Toxic Substances List may be provided and can include: a summary of their uses, applicable regulations, environmental sources, and related risk management tools, among others. 	[57]

BY INTERGOVERNMENTAL ORGANISATIONS

Initiative Name	Number of All Chemicals or Chemical Groups Included	Selection Criteria and Procedure	Organisation Name and Related Information	Reference
POPs in the Stockholm Convention	28	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - Persistent Organic Pollutant (POP): An organic chemical substance that remains intact for many years, is widely distributed throughout the environment as a result of natural processes, can bioaccumulate and biomagnify, and is toxic to both humans and wildlife. <p><u>Process:</u></p> <ul style="list-style-type: none"> - Any party of the Stockholm Convention can submit a proposal for listing a chemical. - The POP Review Committee reviews the proposal (Annex D), develops a Risk Profile (Annex E) and Risk Management Evaluation (Annex F), and makes a recommendation to the Conference of Parties for their consideration. <ul style="list-style-type: none"> - The Conference of Parties makes decisions whether to include the chemical under the Convention and amend the relevant Annex(es) (A or B, and C, if necessary) of the Convention. 	<p><u>Stockholm Convention</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - Chemicals listed in the Convention shall be regulated by parties of the Convention (currently 180 members) through either elimination, restriction, or reduction of unintentional releases. - The Convention entered into force in May 2004 with 12 initial chemicals; it has since been updated and currently contains 26 individual or groups of POPs. - Additional information is provided for listed substances including detailed reports on their full risk profile and risk management evaluation. 	[53]
Annex III Chemicals in the Rotterdam Convention	50	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - Substances that are banned or severely restricted for health or environmental reasons by two or more Parties to the Rotterdam Convention. - Approved by the Conference of the Parties to be subjected to the prior informed consent (PIC) procedure. <p><u>Process:</u></p> <ul style="list-style-type: none"> - Two notifications received for a single chemical from two member regions that meet the information requirements of Annex I. - Approval during review by the Chemical Review Committee. - Approval by the Conference of Parties. 	<p><u>Rotterdam Convention</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - The convention aims to promote shared responsibilities regarding the trade of hazardous chemicals (including creation of proper labelling, instructions, and information on bans and restrictions). - The convention entered into force in February 2004 and has 157 member parties. - Additional information is provided for listed substances including reports summarizing their properties, toxicity, control actions, and exposure pathways, among others. 	[58]

Initiative Name	Number of All Chemicals or Chemical Groups Included	Selection Criteria and Procedure	Organisation Name and Related Information	Reference
Manufacturing Restricted Substances List	>160	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - ‘Relevant’ chemicals selected from 11 priority chemical groups identified in a previous roadmap and additional substances selected through discussion with experts and signatory brands. <p><u>Process:</u></p> <ul style="list-style-type: none"> - Chemicals were selected through review with experts from a technical advisory committee and signatory brands. - Contents of the list were peer-reviewed where possible by ‘independent third-party technical experts and industry associations’. 	<p><u>Zero Discharge of Hazardous Chemicals Programme</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - Multiple apparel and footwear manufactures and industry associations are signatories. - First published in 2014 and updated in 2015. - Serves as a list of priority chemicals with specified maximum concentration limits for commercial chemical formulations during raw material processing along the supply chain. - Member brands have committed to following this set approach to chemicals management. 	[49]
Apple Regulated Substances Specification	>400	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - Chemicals included in existing regulations from ‘international laws or directives, agency or eco-label requirements’ in addition to inclusion in Apple’s policies, which are ‘based on best industry practices or toxicological properties’. - Examples of references to existing regulation in the list include: EU REACH, Canadian law, California law, French environmental code, and others. 	<p><u>Apple Inc.</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - Suppliers of Apple are required to adhere to the substance regulations outlined in the document. 	[50]
H&M Group Chemical Restrictions	>100	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - A set of chemical restrictions that ‘as a minimum’ ‘apply the strictest legal limit’ within selling countries. - The manufacturing restriction list includes ‘hazardous substances potentially used in manufacturing’. 	<p><u>H&M Group</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - 12 separate restriction lists exist for the different product groups sold. - Suppliers of H&M are required to adhere to the substance regulations outlined in the documents. 	[59]
IKEA Chemical Strategy	>10	<p><u>Selection criteria:</u></p> <ul style="list-style-type: none"> - Chemical phase-outs in products sold have included BPA in food contact items and receipts, lead, chromium 6, brominated flame retardants, and PVC. - ‘As a minimum, [IKEA] comply with the strictest laws and regulations in every country where [they] make and sell products.’ 	<p><u>Inter IKEA Systems B.V.</u></p> <p><u>Initiative information:</u></p> <ul style="list-style-type: none"> - Restrictions and phase-outs have been reported for various chemicals across IKEA products. 	[60,61]

Initiative Name	Number of All Chemicals or Chemical Groups Included	Selection Criteria and Procedure	Organisation Name and Related Information	Reference
		When one country tightens its rules, [IKEA] introduce these new requirements in all IKEA markets, if applicable.'		
Confindustria Toscana Nord Manufacturing Restricted Substances List	>400	<u>Selection criteria:</u> - Built upon the endorsement of Greenpeace's 'Detox' campaign. - Includes chemicals within 11 priority groups plus additional chemicals.	<u>Confindustria Toscana Nord</u> <u>Initiative information:</u> - Involves the members of the manufacturing company association that endorsed the Detox campaign within the Prato textile district of northern Italy. - Initiated in February 2016.	[62]

4. Chemicals for the Subsequent Overview Report

As elaborated in section 3.1, the EU REACH SVHC List, the SIN List and the assessment by the Danish Centre on Endocrine Disruptors are the most robust initiatives of those found in identifying EDCs and potential EDCs. The chemicals identified in these initiatives have gone through at least one thorough scientific assessment using the WHO/IPCS definitions regarding their endocrine disrupting properties (i.e. an assessment of their adverse effects and endocrine mode(s)-of-action). Combined, these three initiatives create a set of 45 chemicals or groups of chemicals in Tables 5 and 6 that are used as the basis for chemicals to be considered in the subsequent Overview Report. This subsequent Overview Report collects, synthesizes, and presents existing scientific information for these chemicals on their life cycles, emission sources, environmental concentrations in different regions, and evidence of (potential) adverse endocrine-related impacts on wildlife. The identification of EDCs and potential EDCs using the WHO/IPCS definitions here does not involve consideration of exposure to a chemical.

Table 5 includes the ten chemicals and groups of chemicals recognized as EDCs on the EU REACH SVHC List following a thorough scientific assessment using the WHO/IPCS definition of EDCs with multi-sector stakeholders involved (see Table 1). Table 6 includes an additional 35 chemicals that have been identified as EDCs or potential EDCs by ChemSec and/or the Danish Centre on Endocrine Disruptors following a thorough scientific assessment using the WHO/IPCS definitions of EDCs and potential EDCs (see Table 1). Perchloroethylene (CAS number 127-18-4) was the only exception that, in contrast to the SIN List, was found by the Danish Centre on Endocrine Disruptors to have insufficient evidence for endocrine disruption and was therefore not included in Table 6. Many of the chemicals in this set have also been included in other types of initiatives by other stakeholders (Tables 2–4). In addition to the chemicals' name(s) and CAS number(s), Tables 5 and 6 show which of these three initiative(s) have identified them as EDCs or potential EDCs (which forms the basis for inclusion in these tables and in the subsequent overview report), which other initiatives have previously assessed the chemical, and which initiatives have on-going or planned assessments of the chemical.

The chemicals identified as EDCs or potential EDCs within this set span a wide range of chemical groups based on structure and uses. Some of the most common groups include alkylphenols, phthalates, UV filters, bisphenols, and parabens. As all three of the initiatives used as a basis to create this set of 45 chemicals focus on the review of industrial chemicals (including those that can also be used in pesticides or biocides), this set does not include other chemical categories such as pharmaceuticals. This is further discussed in section 5 of this report, which reviews the limitations of the work presented in this report.

Table 5. Individual and groups of chemicals that have been identified as EDCs following a publicly-accessible, thorough scientific assessment using the WHO/IPCS 2002 definition of EDCs and with multi-stakeholder involvement¹

Chemical Name	CAS Number(s)	Completed assessments as the basis for inclusion	Other completed assessments	Ongoing and planned assessments
Bis(2-ethylhexyl) phthalate; DEHP	117-81-7	EU REACH SVHC	EU Impact Assessment, EU Priority List Category 1	US EDSP, Japan EXTEND
Diisobutyl phthalate; DIBP	84-69-5	EU REACH SVHC	EU Impact Assessment	
Dibutyl phthalate; DBP	84-74-2	EU REACH SVHC	EU Impact Assessment, EU Priority List Category 1	US EDSP, Japan EXTEND
Benzyl butyl phthalate; BBP	85-68-7	EU REACH SVHC	EU Impact Assessment, EU Priority List Category 1	US EDSP, Japan EXTEND
4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	EU REACH SVHC	EU Impact Assessment, EU Priority List Category 1	
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	2315-67-5/ 2315-61-9/ 9002-93-1/ 2497-59-8/ Others not specified	EU REACH SVHC		
4-Nonylphenol, branched and linear	84852-15-3/ 26543-97-5/ 104-40-5/ 17404-66-9/ 30784-30-6/ 52427-13-1/ 186825-36-5/ 142731-63-3/ 90481-04-2**/ 25154-52-3**/ Others not specified	EU REACH SVHC	EU Priority List Category 1	EU CoRAP*
4-Nonylphenol, branched and linear, ethoxylated	104-35-8/7311-27-5/ 14409-72-4/ 20427-84-3/ 26027-38-3/ 27942-27-4/ 34166-38-6/ 37205-87-1/ 127087-87-0/ 156609-10-8/ 68412-54-4**/ 9016-45-9**/ Others not specified	EU REACH SVHC	EU Priority List Category 1	EU CoRAP
4-Heptylphenol, branched and linear	6465-71-0/ 6465-74-3/ 6863-24-7/ 1987-50-4/72624-02-3/ 1824346-00-0/ 1139800-98-8/ 911371-07-8 / 911371-06-7 /911370-98-4/ 861011-60-1/ 861010-65-3/ 857629-71-1/ 854904-93-1/ 854904-92-0/ 102570-52-5/ 100532-36-3/ 72861-06-4/ 71945-81-8/ 37872-24-5/ 33104-11-9/ 30784-32-8/ 30784-31-7/ 30784-27-1	EU REACH SVHC		
p-(1,1-dimethylpropyl) phenol	80-46-6	EU REACH SVHC	EU Impact Assessment	EU CoRAP

* This initiative has chemicals included specifically due to their endocrine disrupting potentials, however, these chemicals were included in the initiative for other reasons.

** Identified as additional CAS numbers by ChemSec for these compounds on the SIN List and are not originally on the EU REACH SVHC list.

Table 6. Individual and groups of chemicals that have been identified as EDCs or potential EDCs by at least one stakeholder following a thorough scientific assessment using the WHO/IPCS 2002 definitions of EDCs and potential EDCs¹

Chemical Name	CAS Number(s)	Completed assessments as the basis for inclusion *	Other completed assessments	Ongoing and planned assessments
BENZOPHENONES				
Benzophenone-1; 2,4-Dihydroxybenzophenone; Resbenzophenone	131-56-6	SIN, Danish Criteria (Cat. 2a)	EU Priority List Category 1	
Benzophenone-2; 2,2',4,4'-tetrahydroxybenzophenone	131-55-5	SIN, Danish Criteria (Cat. 1)	EU Priority List Category 1	
Benzophenone-3; Oxybenzone	131-57-7	SIN, Danish Criteria (Cat. 2a)	EU Impact Assessment	EU CoRAP
4,4'-dihydroxybenzophenone	611-99-4	SIN, Danish Criteria (Cat. 2a)	EU Priority List Category 1	
3-BC, MBC, EHMC				
3-Benzylidene camphor (3-BC); 1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one	15087-24-8	SIN, Danish Criteria (Cat. 1)	EU Impact Assessment, EU Priority List Category 1	
3-(4-Methylbenzylidene) camphor; 1,7,7-trimethyl-3-[(4-methylphenyl) methylene]bicyclo[2.2.1] heptan-2-one	36861-47-9	SIN, Danish Criteria (Cat. 1)	EU Priority List Category 1	
2-ethylhexyl 4-methoxycinnamate	5466-77-3 / 83834-59-7	SIN, Danish Criteria (Cat. 1)	EU Impact Assessment, EU Priority List Category 1	EU CoRAP
BISPHENOLS F AND S				
Bisphenol F	620-92-8	SIN		
Bisphenol S	80-09-1	SIN	EU Impact Assessment	EU CoRAP
PARABENS				
Methylparaben	99-76-3	Danish Criteria (Cat. 2a)	EU Impact Assessment, EU Priority List Category 1	EU CoRAP
Ethylparaben	120-47-8	Danish Criteria (Cat. 2a)	EU Priority List Category 1	EU CoRAP
Propylparaben; propyl 4-hydroxybenzoate	94-13-3	SIN, Danish Criteria (Cat. 2a)	EU Impact Assessment, EU Priority List Category 1	EU CoRAP
Butylparaben; butyl 4-hydroxybenzoate	94-26-8	SIN, Danish Criteria (Cat. 1)	EU Priority List Category 1	
PHTHALATES (NON-EU REACH SVHCs)				
Diethyl phthalate (DEP)	84-66-2	SIN, Danish Criteria (Cat. 2a)	EU Impact Assessment, EU Priority List Category 1	US EDSP, Japan EXTEND
Dihexyl phthalate (DHP)	84-75-3	SIN, Danish Criteria (Cat. 1)	EU Impact Assessment, EU REACH SVHC **	Japan EXTEND
Dicyclohexyl phthalate (DCHP)	84-61-7	SIN, Danish Criteria (Cat. 1)	EU Priority List Category 1	EU CoRAP, Japan EXTEND

Diocetyl phthalate	117-84-0	SIN		
Diisodecyl phthalate (DiDP)	68515-49-1 / 26761-40-0	SIN		
Diundecyl phthalate (DuDP), branched and linear	3648-20-2	SIN		
OTHER PHENOL DERIVATIVES				
4-nitrophenol	100-02-7	SIN, Danish Criteria (Cat. 2a)		
2,4,6-tribromophenol	118-79-6	SIN		
Resorcinol	108-46-3	SIN, Danish Criteria (Cat. 1)	EU Impact Assessment, EU Priority List Category 1	EU CoRAP
BHT AND BHA				
Butylated hydroxytoluene (BHT)	128-37-0	SIN		EU CoRAP
Tert.-Butylhydroxyanisole (BHA); tert-butyl-4-methoxyphenol	25013-16-5	SIN, Danish Criteria (Cat. 1)	EU Impact Assessment, EU Priority List Category 1	EU CoRAP, US EDSP
DITHIOCARBAMATES				
Metam-sodium	137-42-8	SIN, Danish Criteria (Cat. 1)	EU Priority List Category 1	
Zineb	12122-67-7	SIN, Danish Criteria (Cat. 1)	EU Impact Assessment, EU Priority List Category 1	Japan EXTEND
Ziram	137-30-4	SIN	EU Impact Assessment	EU CoRAP, US EDSP, Japan EXTEND
Thiram	137-26-8	SIN, Danish Criteria (Cat. 1)	EU Impact Assessment, EU Priority List Category 1	
PCP, TEBUCONAZOLE, AND TRICLOSAN				
Pentachlorophenol (PCP)	87-86-5	SIN, Danish Criteria (Cat. 1)	EU Priority List Category 1	US EDSP, Japan EXTEND
Tebuconazole	107534-96-3	Danish Criteria (Cat. 1)	EU Impact Assessment	US EDSP
Triclosan	3380-34-5	Danish Criteria (Cat. 1)	EU Impact Assessment	EU CoRAP
MISCELLANEOUS				
Tert-butyl methyl ether; MTBE; 2-methoxy-2-methylpropane	1634-04-4	SIN, Danish Criteria (Cat. 1)	EU Impact Assessment, EU Priority List Category 1	EU CoRAP, US EDSP
Quadrosilan; 2,6-cis-Diphenylhexamethylcyclotetrasiloxane	33204-76-1	SIN, Danish Criteria (Cat. 1)	EU Priority List Category 1	
Carbon disulphide	75-15-0	SIN	EU Impact Assessment	EU CoRAP
Triphenyl phosphate	115-86-6	SIN	EU Impact Assessment	EU CoRAP

¹ The chemicals which appear in this table have not been identified as known or suspected EDCs as part of a regulatory review which considers and weighs all available evidence, engages external peer review and is open and responsive to public review and comment.

* Specific categorization from the Danish criteria results is provided. Cat. 1 = Category 1 (endocrine disruptor), Cat. 2a = Category 2a (suspected endocrine disruptor).

** This initiative has chemicals included specifically due to their endocrine disrupting potentials, however, these chemicals were included in the initiative for other reasons.

5. Limitations, Challenges, and Opportunities in and beyond the Report

As introduced and discussed previously in the section *Background, Aims and Scope*, this first report aims to serve as a compendium of information that provides an overview of existing worldwide initiatives to identify EDCs. Given the complexity, breadth, and rapid ongoing development of this scientific field, it is neither feasible nor possible for this single report to include in-depth detail and discussion related to all the potentially relevant aspects or to predict future developments within the field. It instead provides a snapshot of the overall situation when the report was prepared as well as references to further detailed and relevant information. This section aims to provide a summary of the current limitations and challenges that exist within and beyond this first overview report, as well as to recognize and highlight these also as opportunities for future efforts.

[i] The selection of initiatives included is not exhaustive.

As noted previously, the information presented in this report is not necessarily exhaustive of all initiatives that may have been created to identify EDCs. Additional initiatives may exist or be in development, and these could be recognized and included in future efforts.

[ii] The initiatives used to identify the chemicals for inclusion in the second overview report (Table 5 and Table 66) have a limited scope.

The set of chemicals included in the section *Chemicals for the Subsequent Overview Report* serves merely as the basis for the second overview report, and none of these chemicals have been assessed by the authors. The chemicals are included for having previously gone through at least one thorough scientific assessment using the WHO/IPCS definitions that has identified them as an EDC or potential EDC (see sections 3.1 and 4 for additional description).

- As all three of the initiatives used as a basis to create this set of chemicals focus on the review of industrial chemicals (including those that can also be used in pesticides or biocides), this set does not include other chemical categories such as pharmaceuticals or chemicals manufactured solely for use as pesticide ingredients.
- Additional, individual assessments of the chemicals included in this set may exist in the scientific literature or in submitted studies required for product registration (e.g., pesticide products) by various regulatory agencies. However, these are scattered across a wide range of scientific journals and regulatory documents. In this context, it is important to note that the objective of this report is to compile worldwide initiatives that identify EDCs, but not to assess individual chemicals.
- The set of chemicals included is not exhaustive, and further EDCs or potential EDCs are likely to exist and can be included in information disseminating efforts in the future. By taking a closer look at the context of the initiatives used as a basis to compile this set of chemicals, it is noted that substances already included under existing regulatory frameworks such as the Stockholm Convention on Persistent Organic Pollutants (POPs) were not necessarily considered for additional assessment in terms of endocrine disrupting potential in these initiatives, and were consequently not included in the set of chemicals here. However, it is acknowledged that the

management of many such chemicals (such as those listed in the Stockholm Convention including DDT, Lindane, and polychlorinated biphenyls, among others) remain an ongoing challenge especially for many developing countries and countries with economies in transition. Furthermore, some of the chemicals already regulated under such existing frameworks may also be EDCs in addition to their other, already recognized properties of concern.

[iii] No globally harmonized criteria and processes for identifying EDCs currently exist.

It should be noted that there are currently no globally harmonized criteria and processes for the identification of EDCs, nor regarding a harmonized view of the way forward within the field. In particular, no globally, harmonized approaches exist to evaluate data quality, endocrine mode-of-action, impact of systemic toxicity, or application of weight-of-evidence methods. It should also be noted that this report does *not* intend to propose or recommend any criteria for identifying EDCs, or any harmonized set of EDCs or potential EDCs.

In addition to the three points above, it should be noted that the hazard of a chemical and the exposure to a chemical are distinct aspects that are currently being considered and handled differently in the regulatory context across global regions (for an overview, see Report III).

6. Acknowledgement

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