



**Strategic Approach  
to International  
Chemicals Management**

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**Open-ended Working Group of the International Conference  
on Chemicals Management**

**Third meeting**

Montevideo, 2–4 April 2019

Item 4 of the provisional agenda\*

**Progress towards the achievement of the 2020  
overall objective of the sound management of  
chemicals**

**Submission of the International Council of Chemical  
Associations (ICCA) and the United Nations Environment  
Programme (UNEP): Knowledge Management and  
Information Sharing for the Sound Management of Industrial  
Chemicals**

**Note by the secretariat**

1. The secretariat has the honour to circulate, in the annex to the present note, a report received from the International Council of Chemical Associations (ICCA) and the United Nations Environment Programme (UNEP) on Knowledge Management and Information Sharing for the Sound Management of Industrial Chemicals.
2. The annexed report aims to improve the understanding of the number of chemicals in commerce; to inventory and review publicly available environmental, health and safety (EHS) sources on industrial chemicals at national, regional and global levels; to review the scope, applicability and accessibility of the EHS information provided by each source; to establish criteria for quality and review each source of information according to those criteria; and to compare to the extent possible, the availability of information at the launch of Strategic Approach to International Chemicals Management (SAICM) in 2006, with information available today, to demonstrate the progress made since SAICM began.
3. The draft outline of the report was provided to SAICM stakeholders in May-June 2018 for comment and input. Stakeholders were also consulted on the first full draft of the report between 4 December 2018 to 7 February 2019. Any final comments to the attached report are invited by 15 April 2019.
4. The report is presented in the annex as received from the ICCA and UNEP and has not been edited by the secretariat.

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\* SAICM/OEWG.3/1.

## Annex



# Knowledge Management and Information Sharing for the Sound Management of Industrial Chemicals

UN Environment  
and  
the International Council of Chemical Associations

**Disclaimer**

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## **Acknowledgements**

Review and comments were solicited from all SAICM stakeholders on the outline of the report and comments were gratefully received from IPEN, UNITAR, WHO, and representatives from the national governments of Canada, Germany, Iraq, Columbia, Russia, Mexico, Mauritius and the Republic of Congo. Feedback was also solicited from all SAICM stakeholders on a draft of the final report and comments were gratefully received from OECD, Crop Life International, IPEN, and representatives from the national governments of Madagascar and Tanzania.

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## Executive Summary

### INDUSTRIAL CHEMICALS IN COMMERCE KEY FACTS

- There are an estimated 40,000 to 60,000 industrial chemicals in commerce globally.
- An estimated 6,000 of them account for more than 99% of the total volume of industrial chemicals in commerce globally.
- A number of factors contribute to the uncertainty in the estimates of the numbers of chemicals, including:
  - a lack of chemical inventories for many countries in the world;
  - uncertain and variable definitions of industrial chemicals in commerce (i.e., different scopes);
  - varying volume thresholds for reporting;
  - uncertainty as to whether or not listed chemicals are actually on the market; and
  - lack of reporting or misreporting to government authorities.
- There are EHS data existing to support varying degrees of screening level hazard and risk assessment for the majority of the highest production volume chemicals and while knowledge gaps still exist for many lower volume chemicals, they are rapidly being addressed by:
  - Recently adopted legislation and regulations (e.g., EU REACH, K-REACH, China-REACH, etc.);
  - market forces (e.g., demand for “Green Chemistry”); and
  - newly developing predictive hazard identification tools (e.g., computational toxicology) that are quicker and more resource efficient.
- There is a need for more and better chemical hazard, use and exposure information, particularly from developing countries, to improve hazard and risk assessment and risk management.
- This report identifies more than 100 publicly available EHS information sources, spanning nearly 50 countries spread across 4 continents. The report provides profiles of 41 of the largest and most comprehensive of them:
  - 7 are portals which provide easy access to multiple, third-party owned databases;
  - 10 provide access to EHS-type regulatory decisions, but not to any specific EHS data per se;
  - the remaining 24 represent primary EHS information sources:
    - 7 of them are managed by inter-governmental organizations, 14 by regional or national governments and 3 by NGO’s;
    - the largest and most comprehensive databases were launched after SAICM was adopted in 2006;
    - ECHA’S CHEM is the largest and most comprehensive with hazard, use, exposure, risk and risk management information for the 21,000 plus chemicals produced or imported into the EU;
    - the majority of sources include EHS information on a broader group of chemicals found in the environment, regardless of whether they remain in commerce;
    - several are designed to assist those who are looking to substitute less hazardous chemicals for more hazardous ones and four of them increase transparency of the identity and hazard characteristics of chemicals used in specific categories of consumer products.

Chemistry provides benefits to society and is critical to solving some of humanity's greatest challenges. Yet it must be practiced responsibly to minimize adverse effects on human health and the environment. Adopted by the First International Conference on Chemicals Management (ICCM1) on 6 February 2006 in Dubai, the Strategic Approach to International Chemicals Management (SAICM) is a policy framework to promote chemical safety around the world and provide a high-level international forum for multi-stakeholder and multi-sectoral discussion and exchange of experience on chemicals management issues.

SAICM supports achievement of the 2020 goal agreed to at the 2002 Johannesburg World Summit on Sustainable Development. The overall objective is the achievement of the sound management of chemicals throughout their life cycle so that by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health.

Knowledge and information sharing are critical components of the SAICM goal. Since the inception of SAICM, there have been advances in the availability and quality of chemical safety information. However, information gaps remain and there is a large discrepancy in the understanding of the number of chemicals in commerce amongst the various stakeholders. There is a need to draw upon experiences from various regulatory approaches that exist across the globe to have a better understanding and collective overview. The current analysis was undertaken to provide information on where to find environmental, health and safety (EHS) information.

This study helps by providing an inventory of the available databases of industrial chemicals in commerce that include EHS information. It identifies general issues that may present barriers to gaining the type of clarity that stakeholders seek on these questions and defines, as appropriate, areas where more EHS information is required.

This report has been written primarily to serve the needs of those who are seeking to find EHS and regulatory information on industrial chemicals and aspires to be a helpful guide for locating and using publicly available information sources.

Furthermore, the study provides instrumental information to inform the Global Chemicals Outlook-II which was launched at the Fourth Session of the UN Environment Assembly (UNEA-4)<sup>1</sup>.

The description and information on the scope, strengths, and limitations of each database will inform policy makers on how such databases on chemicals have been developed and how they are fit for purpose, which can support further developments in chemicals management policies at the national and global level. It will assist:

- authorities in developing countries gain ready access to EHS information on a wide range of industrial chemicals in commerce for use in GHS implementation;
- as well as help them to develop strategies for gathering local use and exposure information critical for conducting risk assessments and prioritizing chemicals for further risk management;
- those who wish to pursue more complete EHS data sets to know where to find the most comprehensive information that is available and to identify remaining data for prioritized action to close them.

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<sup>1</sup> SAICM/OEWG.3/INF/3

This study provides policy-makers with sources of EHS information to assist their discussions on specific chemicals and chemical classes identified as concerns to SAICM (e.g., brominated flame retardants, perfluorinated chemicals, and others).

This report identifies the challenges to enumerating the numbers of industrial chemicals in commerce which include: a lack of chemical inventories for many countries in the world, uncertain and variable definitions of what's included under the rubrics of chemicals and even "Industrial Chemicals", varying volume thresholds for reporting, uncertainty as to whether chemicals initially notified to various governments still remain on the market, whether new chemicals notified since then were even ever brought to the market, duplicates, chemical identity being claimed as CBI, and unintended incentives for companies to over-report.

Considering recent initiatives in the United States of America (US) and in the European Union (EU) that focus on quantifying the actual numbers of chemicals active on their markets, as well as estimates from Canada, Japan and China, and making varying assumptions about the overlap of chemicals produced and used across them and the rest of the world, yield an estimate likely in the range of 40,000-60,000 chemicals in commerce globally. It is further estimated that about 6000 of those chemicals account for more than 99% of the total volume produced and marketed.

The report identifies more than 100 individual databases containing EHS and/or EHS-type regulatory information on industrial chemicals in commerce. They include databases developed and maintained by inter-governmental organizations, regional groups, national governments and NGOs.

Forty-one of the largest and most comprehensive of those databases have been individually profiled and objectively evaluated against pre-determined quality criteria, including: the scope of chemicals addressed, ease of access and use, breadth and depth of EHS information available, quality of the underlying information and procedures to keep them current with new information.

The scopes of the databases vary markedly. Fifteen of them are restricted to industrial chemicals currently in commerce, with clearly articulated exemptions. The remaining 26 have broader scopes and include polymers, pesticides, by-products and/or obsolete chemicals.

All of the databases were found to be easily accessed and used, although some sources provide published user guides to more easily facilitate basic and advanced searches.

The breadth and depth of EHS information varies considerably, ranging from simple chemical identity and basic regulatory decisions to more detailed mammalian and environmental hazard, exposure and risk assessments.

The quality of the underlying EHS information also varies somewhat, but was generally considered to be good when judged against the pre-established criteria. Most governmental organizations provide for some type of peer review and solicit and incorporate public comment on their work, whereas the NGO databases and the ICCA GPS Portal, did not include an external peer review process.

About half of the owners of the databases provide adequate descriptions of their procedures for keeping the information up to date. Some of the databases are intentionally static, with no intent to update the information they contain, and so users need to exercise caution when referencing information that is available from them.

Each of the databases was classified in the Study into one of three distinct categories: (1) information portals that provide users the ability to simultaneously search multiple, third party owned and managed EHS databases; (2) single, primary sources which provide access to EHS information on chemical substances; and (3) single, primary sources which provide access to EHS-type regulatory decisions made about chemical substances.

(1) The seven portals reviewed provide users with the capability of searching many disparate individual EHS information sources (collectively more than 100) simultaneously, thereby increasing global reach, scale and efficiency. Such portals represent a helpful starting point for those who need a quick overview of the information that might be available on a particular chemical substance. However, users must be cautious with interpreting and applying the output of their searches from these portals and must first consult the websites of the individual third-party sources to fully understand the strengths and limitations of the underlying information.

(2) Twenty-four single, primary sources of EHS information were reviewed. With a few exceptions, most of them are from inter-governmental organizations or individual government agencies which have regulatory authority within their jurisdictions. Three of them are from NGOs, and one is from a US government, non-regulatory agency. About half of them pre-date the inception of SAICM in 2006; however, the largest and most comprehensive of these databases were developed post-SAICM.

Of those 24 databases, ECHA's CHEM, which provides EHS information on the 21,500 plus chemicals registered to meet EU REACH obligations, is the most comprehensive and should be among the first searched by users who seek both mammalian and environmental hazard, use, exposure, risk assessment and risk management information. It can be accessed directly or via several of the portals discussed above. Substantial hazard, use/exposure and risk information is available for chemicals that are produced or imported at or above 1000 metric tonnes/year, somewhat less so for lower volume substances, and substances below 10 metric tonnes/year have reduced information requirements. Even so, ECHA requires and makes publicly available an assessment of the risks of exposure for a full range of uses and exposure scenarios.

EPA's ACToR database is unique and distinct among the 24 because it is focused on helping users predict toxicity of a chemical substance that currently lacks mammalian and eco-toxicity data. It does so by making inferences from chemicals that have been well-studied to other, structurally similar classes of chemicals. Databases such as ACToR, and the suite of new tools and methods available from them, may gain increasing use in the next few years and offer promise for closing remaining information gaps.

Some of the databases reviewed have been developed for the express purpose of promoting safer alternatives to existing chemicals considered as risky for consumer exposures. Furthermore, at least four of them (EWG's Skin-Deep, GoodGuide, National Library of Medicine's Household Products database (accessible from TOXNET) and California DTSC) place their focus on increasing transparency of the identity and hazard characteristics of chemicals used in specific consumer products, thereby directly addressing the SAICM emerging policy issue of Chemicals in Products.

(3) The final category of EHS information sources reviewed includes ten databases that provide EHS-type regulatory decisions on specific chemicals. They do not provide users with EHS information per se, but instead provide key decisions that, when combined with knowledge of the regulatory criteria used to make those decisions, give users insight as to how other governments view those chemicals and are taking regulatory actions to further investigate and manage the risks they pose to human health and/or

the environment. Of those ten, Canada's Categorization Results database (Table 3 and Appendix B5) may be relevant for many users because it presents regulatory decisions on all 23,000 plus chemical substances identified as being in commerce in Canada. Many governments around the world continue to struggle with characterizing the hazard and risks of chemicals and the results of Canada's efforts possibly can be leveraged by them for their own purposes.

Strengths of the study include providing an estimation of the number of 'chemicals in commerce', its focus on industrial chemicals which has seen an increasing concern from the public; the comprehensiveness of the inventory of publicly accessible EHS databases assembled (i.e. breadth of geographic coverage, and type of EHS information); the objective assessment of the quality of those databases, and the reports' orientation toward helping information seekers navigate the complex data landscape to optimize their efforts.

This study and the databases themselves are not without their limitations and they have been identified and thoroughly discussed in the report. Some knowledge gaps exist in the breadth, depth and the quality of the EHS information and characteristics of individual chemicals in commerce likely exist. This study makes recommendations on some of these knowledge gaps for future studies (see chapter 6). The Confidential Business Information claims for some chemicals can limit the information available to the general public. A lack of information on uses and exposures to chemicals in developing countries is especially challenging. The overwhelming majority of EHS information sources identified derive from countries with developed chemical control regulatory schemes. The hazard information available from these databases is relevant and can be leveraged for application by developing countries (i.e., hazard properties are intrinsic to the substances). The presence of comprehensive EHS information for industrial chemicals in commerce can help the developing countries with their capacity-building efforts so as to strengthen their national regulations and safety management practices.

Nevertheless, there are several reasons to be optimistic that going forward information gaps can be closed at an accelerated rate. The combined effect of recently adopted legislation in multiple regions and countries (e.g., EU, US, Korea and China) that requires manufacturers and importers to collect and publicly report hazard, use, exposure and risk information on their chemicals; the increasing focus on safe substitution and greener chemistry; as well as the advent and acceptance of new tools and methods (e.g. read across, computational toxicology) provide excellent opportunities to close such information gaps more rapidly than in the past.

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Figure 2 — Environmental, Health and Safety (EHS) Information Sources on Industrial Chemicals, Publicly Available in English

Figure B1 — Screen Shot of Search Page

Figure B2 — Screen Shot of Substance Information

Figure B3 — Screen Shot of Available EHS Information

Table B1 — REACH Standard Information Requirements

## Abbreviations and Acronyms

ACC — American Chemistry Council	
ACE — Assessment of Chemical Exposures program (US ATSDR)	
ACToR— Aggregated Computational Toxicology Resource	
AC50 — chemical concentration producing 50% of the maximum activity in a particular assay	
AICS — Australian Inventory of Chemical Substances	
AJCSD — Asean-Japan Chemical Safety Database	
AQSIQ — General Administration of Quality Supervision, Inspection and Quarantine (China)	
ATSDR — US Agency for Toxic Substances & Disease Registry	
BIAC — Business and Industry Advisory Committee to OECD	
CAAC — Chemical Assessment Advisory Committee (USEPA)	
CalEPA — California Environmental Protection Agency	
CAS — Chemical Abstract Service Registry	
CBI — Confidential Business Information	
CCA — Chemical Control Act (South Korea)	
CCID —Chemical Classification and Information Database (New Zealand)	
CCOHS — Canadian Centre for Occupational Health and Safety	
CCR — Categorization Results from the Canadian Domestic Substance List	
CCRIS — Chemical Carcinogenesis Research Information System (TOXNET)	
CDC — US Centers for Disease Control and Prevention (CDC)	
CEBS — Chemical Effects in Biological Systems	
CEFIC — European Chemical Industry Council	
CEPA — Canadian Environmental Protection Act	
CERCLA — US Comprehensive Environmental Response, Compensation, and Liabilities Act or Superfund” law	
CHRIP® — CHemical Risk Information Platform (Japan)	
CICADS — Concise International Chemical Assessment Documents	
	CIR — Cosmetic Ingredient Review
	CIT — Chemical Information Tool
	CLP — Classification, Labelling and Packaging (EU)
	CMC — Japan Chemicals Management Center
	CMP — Chemical Management Plan (Canada)
	CMR — Carcinogen, Mutagen or Toxic to Reproduction
	COC — Chemical of Concern (COC)
	CoCAM — Cooperative Chemicals Assessment Meeting
	COPHES - Consortium to Perform Human Biomonitoring on a European Scale
	CPCAT — Chemical Product Category
	CPDP — Carcinogenic Potency Database (TOXNET)
	CSA — Chemical Safety Assessments (EU REACH)
	CSCL — Chemical Substances Control Law (Japan)
	CSEM — Case Study in Environmental Medicine (ATSDR)
	CTD — Comparative Toxicogenomics Database (TOXNET)
	DART — Developmental and Reproductive Toxicology (TOXNET)
	DEMOCOPHES — DEMOnstration of a study to COordinate and Perform Human Biomonitoring on a European Scale
	DOD — Department of Defense (US)
	DSL — Canadian Domestic Substances List
	DTSC — Department of Toxic Substances Control (California)
	ECHA — European Chemicals Agency
	EC — European Commission or less often European Community
	ECOTOX — Eco-toxicity
	EEU – Eurasian Economic Union
	EHS — Environment, Health and Safety
	EHC — Environmental Health Criteria Monographs

EINECS — European Inventory of Existing Commercial Substances  
 EPA — Environmental Protection Agency  
 EWG — Environmental Working Group  
 EU — European Union  
 FAO — Food and Agriculture Organization of the United Nations  
 FDA — Food and Drug Administration  
 GCO — Global Chemical Outlook  
 GENE-TOX — Genetic Toxicology (TOXNET)  
 GHS — Globally Harmonized System of Classification and Labelling of Chemicals  
 GLP — Good Laboratory Practices  
 GPS — Global Product Strategy (ICCA)  
 GREM — Grand Rounds in Environmental Medicine (US ATSDR)  
 HazChem — Hazardous Chemicals (China)  
 HPV — High Production Volume Chemicals Program  
 HSDB — Hazardous Substances Data Bank (TOXNET)  
 HSGs — Health and Safety Guides  
 HSNO — Hazardous Substances and New Organisms Act (New Zealand)  
 IARC — International Agency for Research on Cancer  
 ICCA — International Council of Chemical Associations  
 ICCM — International Conference on Chemicals Management (UN Environment)  
 ICSC — International Chemical Safety Cards  
 IECSC — Inventory of Existing Chemical Substances in China  
 IFCS — Intergovernmental Forum on Chemical Safety  
 ILO — International Labor Organization  
 IMAP — Inventory Multi-tiered Assessment and Prioritization (Australia)  
 INCI — International Nomenclature for Cosmetic Ingredients  
 InChI — IUPAC International Chemical Identifier  
 IPCS — International Programme on Chemical Safety  
 IRIS — Integrated Risk Information System  
 ITER — International Toxicology Estimates for Risk (TOXNET)  
 IUPAC — International Union of Pure and Applied Chemistry  
 IUR — Inhalation Unit Risk  
 J-CHECK — Japan’s Chemicals Collaborative Knowledge Database  
 JECDB — Japan Existing Chemicals Database  
 JECFA — Joint Expert Committee on Food Additives  
 JMPR — Joint Meeting on Pesticide Residues  
 K-PBR — Korea Consumer Chemical Products and Biocides Safety Act  
 KCMA — Korea Chemical Management Association  
 KE — Korea Existing chemicals numbers  
 KECI — Korea Existing Chemicals Registry  
 KECL — Korea Existing Chemicals List  
 KEMI — Swedish Chemicals Agency  
 K-REACH — South Korea’s Act on Registration, Evaluation, Authorization of Chemicals  
 LOAEL — Lowest Observable Adverse Exposure Level  
 MEE — Ministry of Ecology and Environment (China)  
 METI — Japan Ministry of Economy, Trade and Industry  
 MHLW — Japan Ministry of Health, Labor and Welfare  
 MHMIs — Managing Hazardous Materials Incidents (US ATSDR)  
 MMGs — Medical Management Guidelines (US ATSDR)  
 MNM — Manufactured NanoMaterial  
 MOE — Ministry of the Environment (Japan, South Korea)  
 MOL — Ministry of Labor (South Korea)  
 MPS — Ministry of Public Security (MPS)  
 MRLs — Minimal Risk Levels (US ATSDR)  
 MSDS — Material Safety Data Sheet  
 NAS — US National Academy of Sciences  
 NCEA — National Center for Environmental Assessment (US)  
 NCEH — National Center for Environmental Health (US)  
 NCELs — New Chemical Exposure Limits  
 NCIS — National Chemical Information System (South Korea)  
 NEG — Nordic Expert Group  
 NF — National Formulary  
 NGO — Non-Governmental Organizations

NICNAS — National Industrial Chemicals Notification and Assessment Scheme (Australia)  
NIER — National Institute for Environmental Research (South Korea)  
NIH — US National Institutes of Health  
NITE — Japan National Institute of Technology and Evaluation  
NOAA — National Oceanographic and Atmospheric Association  
NOAEL — No Observable Adverse Exposure Level  
NONS — Notified under the EU Dangerous Substances Directive  
NRC — National Research Council (NRC)  
NRCC — National Registration Center of Chemicals (China)  
NZEPA — New Zealand Environmental Protection Authority  
NZIoC — New Zealand Inventory of Chemicals  
OctaDBE – Octadibromodiphenyl ether  
OEL — Occupational Exposure Limits  
OECD — Organization for Economic Cooperation and Development  
OR — Only-Representative (EU REACH)  
ORD — Office of Research and Development (USEPA)  
OSF — Oral Slope Factor  
OSHA — Occupational Safety and Health Act or Administration (US and South Korea)  
P2 — Pollution Prevention  
PBT — Persistent, Bioaccumulative and Toxic  
PCB — PolyChlorinated Biphenyls  
PECs — Priority Existing Chemicals (Australia)  
PEHT — Pediatric Environmental Health Toolkit (US ATSDR)  
PETA — People for the Ethical Treatment of Animals  
PIM — Poisons Information Monographs  
PMN — Pre-Manufacture Notification (USEPA)  
POPs — Persistent Organic Pollutants  
POW — Octanol-Water Partition Co-efficient  
PSL — Canadian Priority Substances List  
QA/QC — Quality Assurance/Quality Control  
QSR — Quantitative Structure Activity Relationships  
RfC — Reference concentration  
RfCA<sub>n</sub> — Reference concentration, including sensitive sub-groups  
RfD — Reference dose  
REACH — Registration Evaluation, Authorization and Restriction of CHemicals (EU, China and South Korea)  
R&D — Research and Development  
SAB — Science Advisory Board (USEPA)  
SARA — Superfund Amendments and Reauthorization Act of 1986  
SAWS — State Administration for Work Safety (China)  
SCC — Solid Waste and Chemical Management Center (China)  
SCP — California’s Safer Consumer Protection law  
SDS — Safety Data Sheet  
SIDS — Screening Information Data Set  
SIN — ChemSec’s Substitute it Now list  
SAICM — Strategic Approach to International Chemicals Management  
SMEs — Small and Medium Sized Enterprises  
SMILES — Simplified Molecular Input Line Entry System  
SNUN — Significant New Use Notice (USEPA)  
SNUR — Significant New Use Rule (USEPA)  
SRS — Substance Registry Services (USEPA)  
SU — Sector End Use  
SVHC — Substances of Very High Concern (EU REACH)  
SWEA — Swedish Work Environment Authority  
SWG — Swedish Criteria Group  
SWI — Safe Work Instrument (New Zealand)  
TCCA — Toxic Chemicals Control Act (South Korea)  
TIC — Toxics Information Clearinghouse  
ToxFAQs<sup>TM</sup> — Toxicological Frequently Asked Question documents (US ATSDR)  
TOXNET — TOXicology Data NETwork  
ToxProfiles<sup>TM</sup> — Toxicological Profiles (US ATSDR)  
TRI — Toxics Release Inventory (USEPA)  
TSCA — Toxic Substances Control Act  
TSN — Taxonomic Serial Number  
UKPID — UK Poison Information Documents  
UNCED — United Nations Conference on Environment and Development  
UNIDO — United Nations Industrial Development Organization  
UN — United Nations

UPC — Universal Product Codes

US — United States of America

USDA — United States Department of  
Agriculture

USGS — United States Geological Survey

USP — United States Pharmacopeia

UVCB — (chemical of) Unknown or Variable  
Composition, complex reaction products or  
Biological material

vPvB — very Persistent, very Bioaccumulative

WHO — World Health Organization

WSSD — World Summit on Sustainable  
Development

## 1. Background, Aims and Scope

Working collaboratively with other partners, ICCA, UN Environment and SAICM are jointly committed to the goal established in 2002 at the Johannesburg World Summit on Sustainable Development (WSSD) that, by the year 2020, chemicals should be “used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment.” Guiding this journey is the Strategic Approach to International Chemicals Management (SAICM), a policy framework that calls on the most advanced countries and other stakeholders to step up and share their knowledge and expertise with developing countries and countries with economies in transition to help promote chemical safety around the world. The Global Chemical Outlook (GCO-II) and the Independent Evaluation of the Strategic Approach from 2006-2015 remarked that the 2020 goal will not be reached<sup>2,3,4</sup>, given the extent and pace of progress made so far and considering the limited remaining time in run-up to 2020.

Knowledge and information sharing along the life-cycle and to all stakeholders are critical components of the SAICM goal. The study reported herein provides an important contribution to improve the collective understanding of the number and nature of chemicals in commerce and the availability of environmental, health and safety (EHS) information for those chemicals. Since the inception of SAICM in 2006, there have been advances in the availability and quality of chemical safety information. However, information gaps remain and there is a large discrepancy in the understanding of the number of chemicals in commerce amongst the various stakeholders. There is a need to draw upon experiences from various regulatory approaches that exist across the globe to have a better understanding and collective overview. This analysis should provide guidance to all stakeholders, particularly in developing countries on where to find which kind of EHS information.

EHS information — For the purposes of this study, environmental, health and safety information include all data and knowledge which are available to identify and assess chemical hazards and risks and to make risk management decisions.

This study investigated the publicly available EHS information on industrial chemicals, i.e. chemicals produced and used in a wide range of applications, with a few exceptions (see chapter 5). Note: this definition was employed principally to estimate the numbers of chemicals in commerce.

### “Chemicals in commerce”

For the purposes of this study, the following definition of “chemicals in commerce” is used based on language taken from EU REACH and the US Toxic Substances Control Act (TSCA).

*Any organic or inorganic substance of a particular molecular identity, including any combination of these substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical that has been manufactured or processed above 1 metric tonne per annum, anywhere in the world, during the past ten years.*

Therefore, the study aims to:

- Improve the understanding of the number of chemicals in commerce;

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<sup>2</sup> SAICM/OEWG.3/3

<sup>3</sup> SAICM/OEWG.3/INF/1

<sup>4</sup> SAICM/OEWG.3/INF/3

- Inventory and review publicly available EHS information sources on industrial chemicals at national, regional and global levels;
- Review the scope, applicability and accessibility of the EHS information provided by each source;
- Establish criteria for quality and review each source of information according to those criteria (e.g., scope of chemicals addressed; ease of access and use; breadth and depth and quality of the information, etc.) and
- Compare to the extent possible, the availability of information at the launch of SAICM in 2006, with information available today, to demonstrate the progress made since SAICM began.

This study helped inventorying the available data bases of industrial chemicals that include EHS information and identify general issues that may present barriers to gaining the type of clarity that stakeholders seek on these questions and identify, as appropriate, areas where more EHS information is required.

Even though, this study focused on the analysis of EHS information (i.e. scope, breadth, depth and quality) available for the sources which, at a minimum, include the industrial chemicals in commerce as defined by EU REACH and the US Toxic Substances Control Act (TSCA), many of the EHS information sources that have been included in this report cover a much broader scope of chemicals (e.g. banned chemicals or chemicals that are not produced for more than 10 years, safer alternatives to existing chemicals) than industrial chemicals in commerce and this is noted in the accompanying descriptions (see chapter 5). In addition, this study identified multiple databases and initiations that provide information on chemicals in products (see chapter 5).

This study also made the best attempt to identify and discuss the multiple knowledge gaps in EHS information of chemicals in broader context than this current definition in order to facilitate addressing them in the future studies (see chapters 5 and 6).

There are significant concerns expressed about the impacts of chemicals in other sectors, e.g., chemicals used to control pests in agriculture and in and around domiciles, and with chemicals used to control microbial agents in a variety of settings. In fact, the pesticides and antimicrobials receive far greater scrutiny from regulatory agencies and, in general, there exists considerably more EHS information about them compared with industrial chemicals.

## 2. Methodology

Possibly relevant EHS information sources on chemicals in commerce were identified using the following means:

1. A search of the internet using specific terms: information on chemicals; toxicity information on chemicals, environmental information on chemicals; chemical risk information; and sources of information on chemicals.
2. The results of the search described in Step 1 identified several secondary sources (e.g., portals that provide links to multiple, third party owned and managed databases) which referenced additional potential primary information sources that were then individually investigated to determine if they should be included for analysis.

3. More than 200 SAICM stakeholders were solicited by e-mail asking them to suggest any additional possible EHS information sources not previously identified in Steps 1 and 2 above.

Every attempt was made to identify and include for analysis the major, globally-recognized sources of EHS information; however, not all potential information sources that were identified were included for analysis. Appendix A provides a list of information sources that were suggested for inclusion by some stakeholders but were excluded for analysis. Some only listed chemicals in commerce within a particular jurisdiction yet provided no relevant EHS information on them. Other sources provided information only on chemical substances that were considered out of scope for the study. Such sources were excluded from the analysis. Other sources provided information that was considered redundant with sources already included for analysis and were therefore excluded.

Prior to starting the project, it was anticipated that the various identified EHS information sources would differ with respect to the breadth, depth and quality of EHS information that they make publicly available. Such differences have important implications for the relevance and utility of the source for assessing and managing chemical risks. Therefore, each information source was scrutinized against the five quality criteria described below.

No effort was made to rate or rank the respective information sources on these criteria. Rather instead, the characteristics of each source are narratively described using information that was publicly available from the websites maintained by each source. In some instances, the websites lacked necessary details to provide adequate descriptions. Because of time and resource constraints, no effort was made to reach out directly to the owners of the databases to request additional details.

#### Quality Criteria:

1. *Scope of Chemicals Addressed — Is the scope clearly described? What type of chemicals are included/excluded? What proportion of the total chemicals of that type that are in commerce are included? What are the gaps? Are there plans to address those gaps in a reasonable time frame and how likely are they to succeed?*
2. *Ease of Access and Use of Chemical Information — How easy is it to find the relevant information? How can the database be searched? Are access and use self-explanatory or are there adequate user instructions available? How might the information be made more easily usable?*
3. *Breadth and Depth of EHS Information Available — What EHS information are available and how are they presented? Do the data span the breadth of health and environmental endpoints of interest or are they more limited? Acute and chronic animal and environmental toxicology? Dose-response data? Mechanistic data? Human epidemiology data? Raw and/or summarized data? Are links provided to the underlying sources of data (e.g., published studies or sponsor submitted studies)? Are hazard assessments included? Are recommended exposure limits available for relevant scenarios? Are intended use, reasonably foreseeable misuse and/or exposure information available? Are exposure scenarios/assessments included? Are completed risk assessments available? What information gaps exist and how might they be addressed in the future?*

4. *Quality of the Underlying EHS Information — Is the source of the underlying data adequately described? How was the literature searched to find all relevant data? What criteria were applied in selecting the studies that were relied upon for the data chosen for inclusion? To what extent has systematic review methodology been applied to conduct hazard assessments? Was there any scoring of the quality of studies relied upon (e.g., Klimisch or other?) How were data generated from OECD test guideline studies conducted according to Good Laboratory Practices (GLP) weighed against data from non-guideline, non GLP studies? How was animal and human evidence integrated to conduct any hazard characterization done? Was any external peer review done? Is there opportunity for external stakeholder input to improve the quality of information?*
5. *Procedures for Updating the Database with New Information — How often and what are the mechanisms used to update the information source with newly generated scientific information? How robust are they? What gaps exist and how might they be addressed in the future?*

During the analysis it was found that each of the EHS information sources could be categorized as to one of three different types:

1. Information portals that provide users the ability to simultaneously search multiple, third-party owned and managed EHS databases;
2. Single, primary sources which provide access to EHS information on chemical substances; and
3. Single, primary sources which provide access to EHS-type regulatory decisions made about chemical substances, but which do not provide any direct EHS information per se.

Separate tables were prepared to summarize the narrative descriptions of each of the three categories of databases.

Another aim of the study was to improve understanding of the number of industrial chemicals in commerce globally. At present, credible estimates are lacking. The starting point for estimates derived for this report were the USEPA TSCA Inventory, EU REACH registrations, Canada's DSL, and the chemical inventories for Japan and China (IECSC). Collectively, these nations/regions account for nearly 75% of annual chemicals sales globally, and greater than 90% of total, annual chemical-related research and development spending.

ECHA's CHEM database was considered to provide the most accurate count for the purpose of this particular report because it excludes polymers, non-isolated intermediates and very low volume substances (i.e., < 1 ton/year) and the time and resources required from companies to register a substance makes it likely that the number of registered substances is close to the actual number of industrial chemicals in regional commerce. By contrast, inventories from the USEPA, Canada, Japan and China include substances that may have been produced or imported at one time, but are no longer active in commerce and thus reliance on them likely leads to an overestimate of the count. Those inventories also include very low volume substances, thus further inflating their counts compared with the EU. Inventories from USEPA, Canada, Japan and China also include polymers and non-isolated intermediates. An effort was made to remove polymers to gain more precise estimates of industrial chemicals. This was relatively straight forward for the USEPA and Japan, but for Canada and China there is no notation about polymer status in their inventories, so polymers were identified as any substance with "poly" in the chemical name. None of the inventories include a designation for non-isolated intermediates, so nothing could be done to remove them from the counts.

Because of the global nature of the industry there is considerable overlap in the identity of chemicals produced and sold. Simply adding the numbers of industrial chemicals listed on individual inventories across nations and regions will produce a gross overestimate of the count of chemicals in commerce. The precise amount of overlap is unknown. To obtain some estimate of the degree of overlap, comparisons were made between Chemical Abstract Service Numbers (CAS#'s) listed on the USEPA TSCA inventory and those listed on ECHA CHEM and Canada's DSL. Note, such comparisons could not be done with the Japan and China inventories due to limitations in searching them, and so assumptions were made about the amount of overlap by extrapolating the findings from the US, Canada and EU.

To address uncertainties, lower bound and upper bound estimates were calculated by making two different sets of assumptions. There is a high degree of confidence that the true number lies somewhere between the lower and upper bounds.

For the upper bound estimate, it was assumed that all listed chemicals on the China and Canada inventories are actually on their markets. This is a very conservative assumption since experience with the recent update to the USEPA TSCA inventory and with EU REACH registrations has shown that many chemicals reported to government agencies have been removed from the market for one reason or another over the years. To compensate for a lack of information about numbers of chemicals from countries in the rest of the world, the estimate was increased by 10% to account for any unique chemicals not otherwise produced or imported in the US, EU, Canada, Japan and China. Once again, this assumption appears conservative given the heavy concentration of research and development spending among those countries/regions compared with elsewhere.

The lower bound estimate was calculated using data solely from the US, EU and Japan and ignoring the Canadian and China inventories because they have not been updated to remove chemicals no longer on the market. To compensate for a lack of information from other countries, the estimate was increased by 5%, a figure deliberately chosen to be less conservative than the 10% figure chosen for making the upper bound estimate.

Finally, the upper and lower bound estimates were rounded off to the nearest thousand to avoid given the impression that they are more precise than is warranted given the underlying assumptions.

### **3. Observations and Discussion**

Appendix B provides detailed profiles and reviews of each of the 41 EHS databases that were selected for analysis and evaluation. For discussion purposes, they have been classified into three distinct categories:

1. information portals that provide users the ability to simultaneously search multiple, third party owned and managed EHS databases;
2. single, primary sources which provide access to EHS information on chemical substances; and
3. single, primary sources which provide access to EHS-type regulatory decisions made about chemical substances.

### **3.1 Portals Providing Access to Third Party EHS information Sources**

Seven of the information sources included for evaluation— the OECD eChemPortal, IPCS INCHEM, California DTSC's CIT and TIC, the ICCA GPS Chemical Portal, AJCSD, and TOXNET — are distinctive from the others because they provide only a search engine which directs users to databases owned and maintained by third parties.

Table 1 provides a summary of information about how these portals compare to the quality criteria established for analysis. Also included are web-links to each of the portals.

With the sole exception of the IPCS INCHEM portal, all of them became operational only after the advent of SAICM in 2006 which demonstrates the important role SAICM plays in sharing knowledge and information among stakeholders.

These portals provide users seeking EHS information on chemicals in commerce with the capability of searching many disparate individual sources (collectively >100) simultaneously, thereby increasing global reach, scale and efficiency. Although there are very few shared database sources between the OECD eChemPortal and IPCS INCHEM, a query of IPCS INCHEM of specific substances can be launched from eChemPortal, there is considerable overlap between the two of them combined and the two portals — CIT and TIC — owned and maintained by California's DTSC. There is also overlap between TOXNET and California's CIT and TIC. The AJCSD provides access to databases maintained by Japan and 10 ASEAN countries. Some of the Japanese databases also participate in the eChemPortal. The ICCA's GPS Portal provides access to unique sources of EHS information — from member companies who voluntarily participate.

All seven portals are relatively easy and intuitive to use and offer options for searching on a variety of terms. Published user guidance for conducting searches is available for the OECD eChemPortal, IPCS INCHEM, California DTSC's CIT, AJCSD and TOXNET. The US National Library of Medicine even offers on-line classes for those wishing to learn more about searching TOXNET.

The EHS output from searches conducted with these portals varies considerably depending on what is available from each of the contributing third-party sources. Similarly, the quality of the underlying EHS information available from these sources also differs, and the vigilance with which they are updated with newly available scientific information also varies. Users must be cautious with interpreting and applying the output of their searches from these portals and must first consult the websites of the individual third-party sources to fully understand the strengths and limitations of the underlying information.

The most comprehensive of the third-party information sources that participate through these portals have been individually reviewed in Appendix B of this report and are the subject of discussion in the following sections.

Table 1 — Summary of EHS Information Sources that Operate as Portals to Third-Party Owned and Maintained Databases.

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Number of Third-Party Databases	Ease of Access	Types of Databases
OECD	<a href="#">eChemPortal</a>	2007	Existing chemicals, new industrial chemicals, pesticides and biocides. Unknown number of unique chemicals, but it provides access to 683,634 substance records, 1,136,073 data endpoint records and 33,727 classification records. It also provides 133,910 synonyms in Czech, Danish, Dutch, French, German, Greek, Italian, Japanese, Korean, Portuguese, Slovak, and Spanish.	34. Each database is owned and managed by a separate organization with contributions from the governments of Australia, Canada, the European Union, Finland, France, Germany, Japan, New Zealand, the Nordic countries, United Kingdom and the United States, in addition to several international entities (e.g., OECD itself, Un Environment, World Health Organization and others). Four of the databases contribute data endpoint records: CCR (Categorization Results from the Canadian Domestic Substance List), ECHA CHEM (ECHA's dissemination portal with information on chemicals registered under REACH), J-CHECK (Japan's CHemicals Collaborative Knowledge Database), and OECD SIDS (Existing Screening Information Data Set Database). In addition, two of the databases (ECHA and GHS-J) contribute reviewed GHS classifications: ECHA C&L inventory (Public C&L Inventory according to the EU CLP Regulation (EC) No 1272/2008) and GHS-J (GHS Classification Results by the Japanese Government).	Allows searches not only by substance name and identification number, but also by classification and chemical property. Users can select specific search criteria for chemical endpoint properties or classifications. <a href="#">Detailed guidance is available for conducting searches, including video tutorials.</a>	Variable. Raw data measuring the properties of chemicals (physical chemical properties, environmental fate and behavior, eco-toxicity, and mammalian toxicology) from a full range of tests and models (e.g., Quantitative Structure Activity Relationships, Computational toxicology methods, etc.) are available, as well as robust summaries of those data, hazard and exposure characterizations and risk assessments. eChemPortal also provides access to national/regional classification results according to national / regional hazard classification schemes or according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). In addition, eChemPortal provides exposure and use information on chemicals.

Table 1 — Summary of EHS Information Sources that Operate as Portals to Third-Party Owned and Maintained Databases.

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Number of Third-Party Databases	Ease of Access	Types of Databases
IPCS	<a href="#">INCHEM</a>	1997. The listed motivation for establishing IPCS INCHEM was UNCED's Agenda 21, Chapter 19 which was adopted in 1992.	Very broad and includes chemicals commonly used throughout the world, which may occur as contaminants in the environment. Thus, it includes: industrial chemicals, biocides, pesticides and other substances.	13. Includes: Concise International Chemical Assessment Documents (CICADS); Environmental Health Criteria (EHC) Monographs; Harmonization Project Publications Health and Safety Guides (HSGs); International Agency for Research on Cancer (IARC) — Summaries and Evaluations; International Chemical Safety Cards (IFCS); IPCS/CEC Evaluation of Antidote Series; Joint Expert Committee on Food Additives (JECFA) — Monographs and Evaluations; Joint Meeting on Pesticide Residues; (JMPR) — Monographs and Evaluations; Kemi-Riskline; Poisons Information Monographs (PIMs); Screening Information Data Sets (SIDS) for High Production Volume Chemicals; UK Poison Information Documents (UKPID)	Searches may be done of all of the participating databases at once or by specifying individual databases. The search tool is quite powerful and flexible using the powerful Verity Query Language to find the information users may be looking for. <a href="#">The Quick Reference Card</a> starts with an overview of searching and moves from simple searches using a single word or phrase to more complicated searches using many search terms. Many examples are available as an aid for users to formulate their own searches.  <a href="#">A more in-depth guide</a> is available for those who want to conduct more advanced searches	Variable. Toxicological evaluations. Hazard Assessments, Exposure Assessments and Risk Assessments on specific chemicals. Risk Assessment Methods. Cancer hazard assessments on approximately 1000 chemical and physical agents. Poison antidote and treatment information. Occupational exposure standards Screening Information Datasets.
California DTSC	<a href="#">Chemical Information Tool</a>	2011	Industrial chemicals that are ingredients in consumer products produced or sold in California. Products exempt from SCP include: drugs, medical devices, dental restoratives, food and pesticides. The focus is on ~2300 Candidate Chemicals which by definition exhibit a hazard trait and/or environmental or toxicological endpoint.	56 separate "authoritative sources" accessing chemical toxicity information available on the Web.	Search function by chemical name or Chemical Abstract Service Registration Number (CASRN) Search results shown as links to information in publicly available data collections. The links are displayed by: 1) Hazard traits, toxicological endpoints or physical-chemical parameters; or, 2) Authoritative organizations (governmental entities only). DTSC has published some <a href="#">guidance to assist with searches</a> of CIT	The breadth and depth of EH&S information available varies considerably based on the contributing data source and substance being queried.  Hazard traits, toxicological endpoints and physical-chemical parameters are not available for every chemical. The CIT does not store electronic copies of journals, articles, or documents locally.  The Search results are displayed by the most recent date of publication as a default.

Table 1 — Summary of EHS Information Sources that Operate as Portals to Third-Party Owned and Maintained Databases.

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Number of Third-Party Databases	Ease of Access	Types of Databases
California DTSC	<a href="#">Toxicology Information Clearinghouse</a>	2011	Industrial chemicals that are ingredients in consumer products produced or sold in California. Products exempt from SCP include: drugs, medical devices, dental restoratives, food and pesticides. The focus is on ~2300 Candidate Chemicals which by definition exhibit a hazard trait and/or environmental or toxicological endpoint.	62. Dynamically searches accessible data collections created and maintained by authoritative organizations, which are state, national, and international governmental entities.	Can be searched by Information Type or by Sources of Information.  Information Type  Chemical and physical properties Source information, fate and exposure Toxicology, epidemiology and hazard Eco-toxicology, ecology and resource damage Laws, regulations, policies, lists, approaches, tools  Sources of Information  Governments Private Sector Academic NGOs	The breadth and depth of EH&S information available varies considerably based on the contributing data source and substance being queried.  Hazard traits, toxicological endpoints and physical-chemical parameters are not available for every chemical. A search yields a list of third-party information sources and links to their websites which must then be searched individually to locate EHS chemical information.
ICCA	<a href="#">GPS Chemical Portal</a>	2008	Focus is on industrial chemicals in commerce; however, each participating company is free to define the scope of their substances to best meet its own particular needs. Some companies have elected to include the full range of products they manufacture and sell (e.g., pesticides, biocides, polymers, seeds, articles that contain chemicals, etc.), while others have chosen to restrict their scope to industrial chemicals. More than 4500 GPS Safety Summaries are currently available.	Unknown. Users are directed from the Portal to individual company websites. GPS Safety Summaries are only available from companies that voluntarily agree to participate.	It is searchable for substances by:  Chemical Name Chemical Abstract Number (CASN) Chemical EINECS (European Inventory of Existing Commercial Substances) Number Brand/Product Name Product Category (39 separate categories)  The following terms can be used to narrow a search and return fewer results:  Organization/Company Language  There is currently no published search guidance available from the GPS Global Chemical Portal website; however, the search process is rather intuitive. ICCA can be contacted directly for assistance if users experience any difficulties with searching the portal.	The format, breadth and depth of EH&S information contained in the GPS Safety Summary varies from company to company, although most often the user will find the following information described:  An executive type summary of the information contained in the GPS Safety Summary Manufacturing information, sometimes including production process, capacity and where the product is manufactured A description of the product, including physico-chemical properties Intended uses for the product How the public might be exposed to the product under various scenarios Human health information (e.g., mammalian toxicology and epidemiology) Environmental information (environmental fate and eco-toxicity) Physical hazard information (e.g., reactivity, flammability, etc.) Regulatory information Web links to references, Safety Data Sheets and other relevant information about the product No external peer review is described nor do they discuss soliciting public input.

Table 1 — Summary of EHS Information Sources that Operate as Portals to Third-Party Owned and Maintained Databases.

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Number of Third-Party Databases	Ease of Access	Types of Databases
Asean-Japan	<a href="#">AJCSD</a>	April 2016	Industrial chemicals are the focus; however, users should consult the definition of scope provided by each of the participating countries for clarification.	58 separate databases contributed by 11 different countries: Brunei, Cambodia, Indonesia, Japan, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam.	There is an English language user's manual available to assist with searches. Searches may be done by CAS#, chemical name or molecular formula.	Names, CAS# and structural formula; Sample SDS; GHS classification results from Japan, Malaysia and Myanmar; hazardous and risk assessment results from Japan. How each country regulates the chemical substance.
US National Library of Medicine	<a href="#">TOXNET</a>	Unknown	Very broad and includes chemicals in commerce, chemical contaminants found in the environment, biological agents, drugs, pesticides, biocides, diseases, genes and proteins.	15 primarily US government databases	Individual databases may be searched one at a time or multiple databases may be searched simultaneously using single or multiple keywords, chemical name or CAS#. There is an abundance of help with search strategies available from the website at <a href="https://toxnet.nlm.nih.gov/newtoxnet/toxnetallsearch.html">https://toxnet.nlm.nih.gov/newtoxnet/toxnetallsearch.html</a> . Can be searched from mobile devices at <a href="https://toxnet.nlm.nih.gov/pda/">https://toxnet.nlm.nih.gov/pda/</a> .  Detailed training and guidance are available	May be used to find: Specific chemicals, mixtures, and products, Chemical nomenclature, Chemicals that may be associated with a disease, condition or symptom, Chemicals associated with consumer products, occupations, hobbies, and more, Special toxic effects of chemicals in humans and/or animals, Citations from the scientific literature

### **3.2 Primary EHS Information Sources on Chemicals in Commerce**

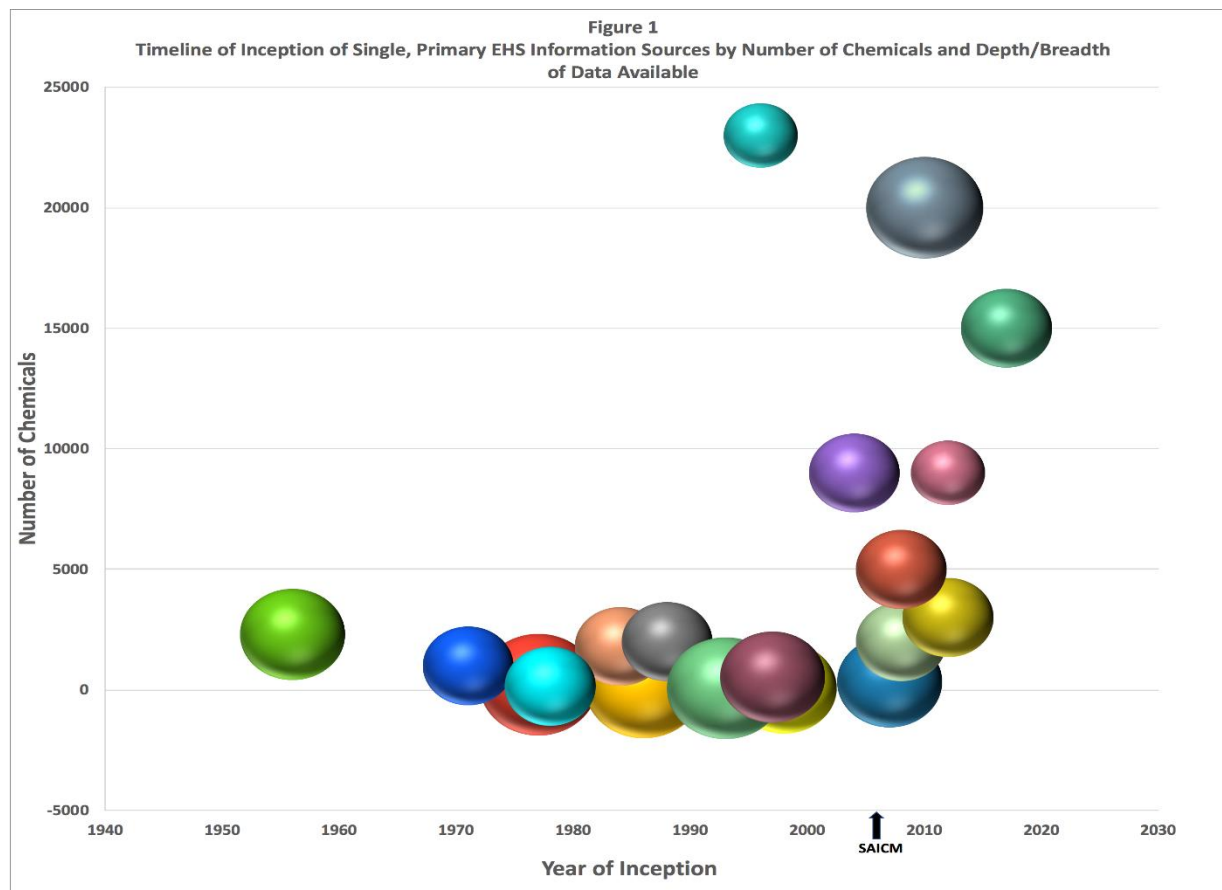
Twenty-four individual primary sources of EHS information on chemicals were identified and included for analysis. Many of them participate as part of and are accessible from one or more of the portals discussed above, but also can be accessed and searched directly from websites hosted by the organizations which developed and maintain them.

Table 2 provides a summary of information about how these primary EHS information sources compare to the quality criteria established for analysis. It also includes Weblinks directly to each them.

With a few exceptions, most of these primary EHS sources are from inter-governmental organizations (WHO, IPCS, IARC, OECD) or individual government agencies which have regulatory authority (ECHA, Canada, Japan NITE, USEPA, Australia, and New Zealand). Three of them are from NGOs (EWG, ChemSec, and GoodGuide), and one is from a US government, non-regulatory agency (ATSDR).

The date of inception could not be determined from the websites for four of the databases (J-CHECK, CHRIP, JECDB, and the ATSDR Toxic Substances Portal). More than half of the others became operational prior to the advent of SAICM in 2006. However, there is good evidence that the pace at which each of them has added new EHS information on substances has accelerated since, first in the early 2000's when the HPV challenge programs were instituted, second after SAICM was established in 2006, and more recently, with increased initiatives on "green" chemistry. The ECHA CHEM, USEPA CHEMVIEW and ACToR, Canadian Screening Level Assessments, Australia IMAP, EWG Skin-Deep, ChemSec SIN List and GoodGuide databases were clearly established during the post SAICM era.

Figure 1 displays the timeline of inception of single, primary EHS information sources by numbers of chemicals covered and by breadth/depth of data available and clearly shows that the largest and most comprehensive were assembled after SAICM was adopted in 2006.



Footnote to Figure 1: Each sphere represents one of the 19 single, primary sources of EHS information for which a date of inception could be confidently determined from publicly available information (see Table 2). There is no significance to the color of the spheres, the sole intention of which is to distinguish one data source from another. The size of each sphere is dictated by the relative depth/breadth of EHS information available from each source. Each source was rated on a scale of 1-5 with 1 representing minimal human and/or ecological hazard information available (e.g., raw test data), 5-representing the full suite of hazard, exposure and risk assessment information and the other scores representing the range of information in between. Extensive human health and ecological hazard information, absent any exposure or risk information scored a 3 on the scale.

Since it was one of the qualifying criteria for inclusion, all of the primary EHS information sources at a minimum include industrial chemicals, and they are the primary focus for a little less than half of them (OECD Existing Chemicals, ECHA CHEM, Canada, J-CHECK, CHRIP, JECDB, USEPA databases, and the ChemSec SIN list). The others include a wider range of chemical and/or physical agents, and one (IARC) even includes lifestyle factors. The Australia databases include polymers. The New Zealand databases include pesticides, polymers, and non-infectious organisms.

The ECHA CHEM, J-CHECK, CHRIP, and USEPA CHEMVIEW databases include EHS information on the largest number of chemicals (i.e., tens of thousands) as their owners are government agencies with responsibility and authority to regulate all industrial chemicals produced or imported within their jurisdictions. Persons who seek EHS information on specific chemical substances are likely to find these sources to be the most productive for data mining.

The EWG Skin-Deep and GoodGuide databases also have information on a relatively large number of substances that are contained in personal care and household products. The remainder of primary EHS

sources have information available on a more limited number of substances (ranging from hundreds to as many as several thousand). Although the USEPA's ACToR database provides access to information on over 700,000 chemicals, that information is rather unique as is discussed in further detail below.

Each of the databases is relatively easy to access and search via a number of terms (e.g., CAS#, chemical name or synonyms, etc.), or is otherwise restricted in size so that it can be easily scanned to visually locate the chemical substances of interest. Most of the larger databases include guides or help pages with detailed instructions to assist users with conducting their searches. Some of the more sophisticated databases (e.g., ECHA CHEM) include additional features (e.g., pop-up text boxes) which make navigation even more user-friendly.

The breadth and depth of EHS information available from each source varies considerably. Some sources are focused solely on hazard identification, and do not include any exposure information or risk characterization/assessment. Of this group, some are focused exclusively on human health hazards (IPCS CICADS, IPSC/EC ISCS, WHO HSGs, IARC Monographs, JECFA Monographs, KEMI-Riskline, JECDB and GoodGuide), and one focuses solely on environmental hazards (J-CHECK). Still others (OECD Existing Chemicals Database, EPA IRIS, EWG's Skin-Deep, ChemSec SIN List) include both human and environmental health information, but do not address uses, exposure and/or risk characterization/assessment.

JECFA Monographs/Summary Evaluations and USEPA IRIS both present point of departure estimates (e.g., RfC, etc.), and IPCS CICADS present dose-response information so that others may conduct risk assessments. These values are available collectively for about 3000 of the highest volume substances.

Even among the information sources that provide human health and environmental risk assessment information there is variability in breadth and depth of coverage. Canada presents screening level assessments (Chemicals-at-a-Glance sheets) for more than 300 chemicals and has more detailed risk assessments available for 69 chemicals, with plans to conduct more by 2020. The results of the Screening Level Assessments are written for general audiences rather than for technical experts.

The amount of information available on a given industrial chemical from ECHA CHEM is largely dependent on the volume of that chemical produced or imported to the EU. Substantial hazard, use/exposure and risk information is available for chemicals at or above 1000 metric tonnes, somewhat less so for lower volume substances, and substances below 10 metric tonnes have reduced information requirements. Even so, ECHA requires and makes publicly available an assessment of the risks of exposure for a full range of uses and exposure scenarios.

ATSDR has published toxicological profiles, including risk assessments, for nearly 200 substances. Although it presents some information on environmental fate, the focus is primarily on human health consistent with ATSDR's basic mission.

ECHA CHEM, USEPA CHEMVIEW, ATSDR Toxic Substances Portal, Australia IMAP and the two New Zealand databases present their information in a layered fashion according to the anticipated needs of different types of users. This spans the range from members of the general public, through physicians to technical experts in the fields of toxicology, environmental sciences and risk assessment.

EPA's ACToR is unique and distinct because it is focused on helping users predict toxicity of a chemical substance that currently lacks mammalian and eco-toxicity data. It does so based largely on structural

and other similarities (see Appendix B7 for a fuller discussion) to other chemicals that have been tested. It is not necessarily directed at general EHS information seekers, but instead to chemists and other experts who have specialized knowledge. It has been included for the purposes of this project because of the vast number of chemicals covered in the ACToR database and because the suite of tools available from ACToR are widely expected to gain increasing use in the next few years. Commercial organizations, such as Underwriters Laboratory are also beginning to offer similar tools to assist companies to evaluate existing and new chemicals and others can be expected to follow suit.

As noted above, most of the primary sources of EHS information are government regulatory agencies or inter-governmental organizations. With a few exceptions, these organizations either directly employ, contract with or invite experienced scientific experts who evaluate the available health and environmental evidence and conduct the hazard, exposure and risk characterization/assessments that are made publicly accessible. All of them describe processes they use for peer-review of the information. Some of them (e.g., IARC, JECFA, Canada, USEPA, Australia) have also published detailed technical guidance documents outlining the steps they take to carry out their work.

Many SIDS dossiers for the various HPV Challenge programs were voluntarily prepared by the companies that produce the chemicals. Those dossiers were then reviewed and discussed by government scientists at biannual meetings to agree on hazard conclusions prior to finalizing and publishing them.

To comply with EU REACH, companies that produce or import the chemicals into the EU must come together in Substance Information Exchange Fora, share data and jointly prepare the registration dossiers and Chemical Safety Assessments. Those companies are accountable for the accuracy of the EHS information submitted to ECHA. ECHA and the national authorities have various processes and procedures in place to check on the completeness and quality of the information submitted. They can require companies to conduct additional testing to fill data gaps, submit additional EHS information, re-do safety assessments and implement additional risk management, even including restricting or banning sales of substances that cannot be managed safely. K-REACH and China REACH have similar aspirations, but are still a few years away from full implementation. Their documents are also largely restricted to the local language, with uncertain future plans to also make them available in English.

EWG, ChemSec and GoodGuide rely on internal processes to ensure the quality of the EHS information they publish and none of them describes any external peer-review. GoodGuide invites public feedback and has processes in place to correct errors. Presumably, EWG and ChemSec would also be responsive to public feedback regarding any errors or inaccuracies that are identified, but they do not explicitly describe any processes they have in place to deal with it.

Scientific methods continue to evolve, and many chemicals are subject to ongoing testing and research which makes it a challenge for EHS information sources to maintain current data and perspectives. While acknowledging this challenge, many of the information sources reviewed in this report (e.g., ECHA CHEM, USEPA's CHEMVIEW and IRIS, ATSDR's Toxicology Profiles, Japan's databases, EWG's Skin-Deep, ChemSec's SIN List, Australia IMAP, New Zealand, and GoodGuide) do have well-developed procedures in an effort to stay current. However, others (e.g., IPCS CICADS, IPCS EHCs, WHO HEGs, Canada's risk assessments) completed their work ten or more years ago and no effort is being expended to update the information. Users always need to exercise caution when referencing materials that could be many years out of date.

Table 2 — Summary of Single, Primary EHS Information Sources

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	EHS Information	Information Quality	Procedures for Updating	Date of Last Update
IPCS	<a href="#">CICADS</a>	1998	Mostly industrial chemicals.	78	Accessible through searching IPCS INCHEM or directly from the WHO/IPCS website.	Concise documents that provide summaries of the relevant scientific information concerning the potential effects of chemicals upon human health and/or the environment. They are based on selected national or regional evaluation documents or on existing EHCs. The primary objective is characterization of hazard and dose-response from exposure to a chemical. They include only that information considered critical for characterization of the risk posed by the chemical. The critical studies are, however, presented in sufficient detail to support the conclusions drawn. Examples of exposure estimation and risk characterization are provided, whenever possible. These examples cannot be considered as representing all possible exposure situations but are provided as guidance only.	Before acceptance for publication, these documents have undergone extensive peer review by internationally selected experts to ensure their completeness, accuracy in the way in which the original data are represented, and the validity of the conclusions drawn.	While every effort is made to ensure that the documents represent the current status of knowledge, new information is being developed constantly. Unless otherwise stated, the documents are based on a search of the scientific literature to the date shown in the executive summary.	Documents carry dates between 1998 and 2010. Note, nearly all of these documents were authored more than 10 years ago and thus caution should be exercised since it is unlikely that they contain the most up to date scientific information available.
IPCS	<a href="#">EHC</a>	1977	Wide range of chemicals, groups of chemicals, biological and physical agents.	~220 plus another 20+ focused on risk assessment methods.	Accessible through searching IPCS INCHEM or directly from the WHO/IPCS website.	EHC monographs are based on a comprehensive search of available original publications, scientific literature and reviews and examine: the physical and chemical properties and analytical methods; sources of environmental and industrial exposure and environmental transport, chemo-biokinetics and metabolism including absorption, distribution, transformation and elimination; short and long term effects on animals (carcinogenicity, mutagenicity, and teratogenicity); and finally, an evaluation of risks for human health and the effects on the environment.	Before acceptance for publication, these documents have undergone extensive peer review by internationally selected experts to ensure their completeness, accuracy in the way in which the original data are represented, and the validity of the conclusions drawn.	While every effort is made to ensure that the documents represent the current status of knowledge, new information is being developed constantly. Unless otherwise stated, the documents are based on a search of the scientific literature to the date shown in the executive summary.	Documents carry dates between 1977 and 2011. Note, nearly all of these documents were authored more than 10 years ago and thus caution should be exercised since it is unlikely that they contain the most up to date scientific information available.

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WHO	<a href="#">HSGs</a>	1986	Mostly industrial chemicals.	~110	Accessible through searching the IPCS INCHEM website.	Provide concise information in non-technical language, for decision-makers on risks from exposure to chemicals, with practical advice on medical and administrative issues.	Before acceptance for publication, these documents have undergone extensive peer review by internationally selected experts to ensure their completeness, accuracy in the way in which the original data are represented, and the validity of the conclusions drawn.	While every effort is made to ensure that the documents represent the current status of knowledge, new information is being developed constantly. Unless otherwise stated, the documents are based on a search of the scientific literature to the date shown in the executive summary.	Documents carry dates between 1986 and 1999. Note, nearly all of these documents were authored more than 20 years ago and thus caution should be exercised since it is unlikely that they contain the most up to date scientific information available.
IARC	<a href="#">Monographs</a>	1971	Environmental factors including: chemicals, complex mixtures, occupational exposures, physical agents, biological agents, and lifestyle factors.	More than 1000 environmental factors.	Accessible through searching the IPCS INCHEM website or directly via the IARC website.	Provide a classification (i.e., known, probable, possible, not classifiable, probably not) of the strength of evidence that an agent causes human cancer. Seeks to identify cancer hazards, meaning the potential for the exposure to cause cancer. However, it does not indicate the level of risk associated with exposure. The cancer risk associated with substances or agents assigned the same classification may be very different, depending on factors such as the type and extent of exposure and the strength of the effect of the agent.	The evaluation is carried out by a Working Group of independent international experts who consider only evidence already published in the peer review literature. The experts prepare draft documents in advance, based on the available scientific evidence, and subsequently gather for eight days at IARC in Lyon to discuss and finalize their assessment of whether a specific agent causes cancer. They critically review the scientific evidence according to strict criteria, which focus on determining the strength of the available evidence that the agent causes cancer.	IARC works with international experts to identify priorities from among agents suspected of causing cancer, based on the availability of scientific evidence of carcinogenicity and evidence that people may be exposed to the agent. Agents for which substantial new scientific information has become available may be prioritized for re-evaluation.	Ongoing. Monographs carry dates between 1971 and the present.

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IPCS/EC	<a href="#">ICSC</a>	This project began during the 1980s with the objective of developing a product to disseminate the appropriate hazard information on chemicals at the workplace in an understandable and precise way.	Mostly industrial chemicals and some pesticides	~1800	<p>Accessible through searching the IPCS INCHEM website or directly via the ILO website. Searches may be done by:            ICSC number, or CAS number            Chemical name or synonym</p> <p>Results may be sorted by card no. or chemical name</p>	Identity of the chemical Fire and explosion hazards Acute health hazards    Spillage disposal, storage and packaging Preventive measures Firefighting First aid Classification and labelling Physical and chemical properties and dangers Short-term and long-term health effects Regulatory information Environmental data	Draft versions of the card containing a summary of health and safety information are prepared by cooperating scientific institutions. These institutions have the task of collecting and validating the relevant information. The cards are then peer-reviewed by a committee consisting of internationally- recognized experts who take into account advice given by manufacturers, workers' representatives and poisons centers.	Developed to provide online access to the collection of ICSC from a single, continuously-updated source. This permits newly created or amended ICSCs to be made available as soon as they have been validated for publication.	Ongoing. A sampling of documents showed they carry dates from the mid-1990's until the present.

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OECD	<a href="#">Existing Chemicals Database</a>	1988	The scope includes High Production Volume (HPV) chemicals as well as non-HPV, new and existing industrial chemicals. HPV chemicals are defined as all chemicals reported to be produced or imported at levels greater than 1,000 tonnes per year in at least one OECD member country or in the European Union region.	Conclusions and assessment reports have been published for nearly 2000 chemicals.	Accessible through searching the eChemPortal, IPCS IINCHEM or from the OECD website. The database has a comprehensive search facility allowing searches for chemical information based on selected criteria. For example, data on individual chemicals can be searched, or the chemical information can be searched according to whether it has been sponsored (e.g. in the case of HPV chemical), who sponsored it, its SIDS process status, ICCA status, or type of assessment (targeted/non-targeted). Further information on search criteria is included in the "Help" section.	The SIDS content is organized under five headings: Substance Information (including exposure through use patterns), Physical Chemical Properties, Environmental Fate, Environmental Toxicology and Mammalian Toxicology (acute and repeated dose toxicity, in vitro genetic toxicity, conditionally in vivo genetic toxicity, and reproductive/developmental toxicity and any available human epidemiology evidence). Robust study summaries for each entry of the Dossier are prepared.	A Cooperative Chemicals Assessment Meeting (CoCAM) was organized twice a year to discuss draft chemical assessments submitted by sponsors and to agree on hazard conclusions. The hazard conclusions agreed at a CoCAM are endorsed by both the Working Party on Hazard Assessment, the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology consecutively. Summary conclusions were then published in the OECD Existing Chemicals Database. When the hazard assessment (including the assessment report and study summaries) was finalized, it was made available to the public via the Existing Chemicals database.	New information is included in the database only when it has been notified to OECD by Member Countries.	A search of the database finds that many of the published assessments are 15-20 years old, and thus some caution should be exercised since it is unlikely that they all contain the most up to date scientific information available.
Joint WHO/FAO	<a href="#">JECFA Monographs</a>	1956	Food additives, natural toxicants and food contaminants and of residues of veterinary drugs in food	Nearly 1200 JECFA Monographs are available and JECFA Summary Evaluations are available for approximately 2300 chemical substances	Accessible through searching the IPCS INCHEM website or directly via the WHO website. The database is searchable by partial name or CAS number, by first character (letter or symbol), or by functional class.	Provide the toxicological information upon which the JECFA makes its evaluations. Each summary contains basic chemical information, safe exposure levels, links to the most recent reports and monographs as well as to the specification database, and a history of JECFA evaluations.	Prepared by scientific experts and peer reviewed at the JECFA meetings. FAO and WHO initiated a project to update, harmonize and consolidate principles and methods used by JECFA for the risk assessment of food additives, food contaminants, natural toxicants and residues of pesticides and veterinary drugs. The monograph EHC 240: Principles and methods for risk assessment of chemicals in food is the outcome of that project.	JECFA normally meets twice a year with individual agendas covering either (i) food additives, contaminants and naturally occurring toxicants in food or (ii) residues of veterinary drugs in food. To keep abreast in the variety of scientific disciplines necessary for the conduct of up-to-date risk assessments, continuous review and update of the evaluation processes are necessary.	1956-Present.

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Sweden/Nordic	<a href="#">Keml-Riskline</a>	1978	Chemical substances of interest to the Nordic regulatory authorities. The availability of scientific data, recently published criteria documents and ongoing activities at the international level are also considered.	There are approximately 55 documents available; however, some most of them provide evaluations of several chemicals each so the total number of chemicals covered likely exceeds 150.	Accessible through searching IPCS INCHEM or directly from the Swedish Work Authority website.	The documents comprise data on physical and chemical properties, occurrence and use, analytical methods, occupational exposure, toxicokinetics, biological monitoring, and effects in animals and man. Finally, an evaluation of human health risks based on dose-effect/dose-response relationships and the identification of the critical effect(s) is made. No numerical values on OELs are given, as this is done at the national level, according to country-specific procedures. No information on environmental fate and effects is included.	Scientific experts from the Nordic countries (Denmark, Finland, Norway and Sweden) representing different fields of science, such as toxicology, epidemiology and occupational medicine evaluate all relevant published original papers for a substance found in searches in relevant databases. A draft consensus report (or sometimes a more comprehensive criteria document) is written by the secretariat or by a scientist appointed by the secretariat. After discussions, the draft is approved and accepted as a consensus report from the group.	These documents were authored at various points in time during the past 30 years and thus caution should be exercised since it is unlikely that they all contain the most up to date scientific information available. Moreover, this database is no longer being updated.	Ongoing. Documents available carry dates from 1978-2016.

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ECHA	<a href="#">CHEM</a>	2010	<p>Registration is required for all substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer unless they are exempted from the scope of registration (see Appendix A for a list of exemptions).</p> <p>The registration requirement applies to all substances irrespective of whether they are hazardous or not. This includes substances on their own, in mixtures or substances in articles when they are intended to be released under normal or reasonably foreseeable conditions of use.</p>	As of 20 August 2018, ECHA's database of registered substances contained 21,248 unique substances and information from nearly 90,000 dossiers. The difference between the number of unique substances registered and the number of dossiers is easily explained and is due to the fact that, while REACH requires multiple producers or importers of the same substance to work together to submit a common registration, individual companies must still file their own dossiers.	Accessible by searching OCED's eChemPortal, California's DSTC CIT or TIC databases directly via the ECHA website. Navigating the ECHA database is straightforward, easy and self-explanatory. It can be searched by Chemical Abstract Service (CAS) number, European Community number or name. Scrolling over selected data fields often produces pop-up text boxes which provide fuller explanations and definitions of those fields and possible limitations of the data that may exist.	The breadth and depth of environmental, health and safety information available on each registered substance will vary depending on REACH requirements which are largely dictated by its volume (see Table 1). Different layers of information are available, i.e. ECHA Info Cards (providing one-page summary) as well as disseminated dossiers containing detailed information for each relevant end-point using OECD-harmonized templates. Chemicals Safety Assessments (CSA) address the manufacture of a substance and all the identified uses at all stages of the life cycle of the substance. It compares the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance considering implemented and recommended risk management measures and operational conditions.	Companies who manufacture/import/use chemicals are accountable for the accuracy of the EHS information submitted to ECHA. ECHA and the national authorities have various processes and procedures in place to check on the completeness and quality of the information submitted. They can require companies to conduct additional testing to fill data gaps, submit additional EHS information, re-do safety assessments and implement additional risk management, up to and including restricting or banning sales of substances that cannot be managed safely.	Registrants have an obligation to keep the information in the registration dossier submitted to ECHA up-to-date. They must consider their registration dossiers as "living documents" and regularly update them whenever new information is available or a need to improve the quality of data is identified. If the registrant becomes aware of information that could lead to other or different risks for human health or the environment caused by the substance they manufacture or import, such as monitoring data in the environment or epidemiological studies, they need to take those data into account and evaluate the appropriateness of the risk management measures put in place or recommended down the supply chain.	Ongoing. Registration dossiers are being added to the database and updated constantly.

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Canada	<a href="#">Screening Level Assessments</a>	Following categorization which was completed in 2006.	Substances used, imported or manufactured in Canada for commercial purposes between January 1, 1984, and December 31, 1986 at a quantity of greater than 100 kilograms per year. It includes discrete organic compounds, inorganic substances, organometallic substances, polymers, and unknown or variable composition complex reaction products or biological material such as acetone or iron. Approximately 4,300 chemical substances that were determined after categorization as warranting further attention	Chemical at a Glance sheets summarizing Screening Level Assessments are available for approximately 330 substances or families of related substances.	This database is not searchable, and the user must scroll down the page to look for the name of their chemical substance of interest. A click on the name of the substance or microorganism produces a fact sheet that is written in layman's language.	Screening level assessments have been done on these substances and the results are summarized in Chemicals-at-a glance sheets which are a series of short fact sheets about chemical substances and micro-organisms that are being (or have been) assessed in Canada for their possible risks to human health and the environment. generally, provide answers to the following questions: What is it? How is it used? Why is the government of Canada assessing it? How are Canadians exposed to it? What are the results of the assessment? What is the government of Canada doing? What can Canadians do?	The available EHS information and assessment reports have been peer-reviewed by the governmental authorities and/or independent Canadian or international experts.	Chemicals-at-a-glance information sheets are revised, from time to time, as substances move through the various technical and regulatory stages of the risk assessment and risk management processes. Canada describes multiples ways in which it acquires new information that may update prior risk assessments, or which may affect the prioritization of substances for future risk assessments. Such information can come from a variety of sources	Ongoing. Screening Level Assessments and Chemical at a Glance Sheets continue to be completed and modified.

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Canada	Risk Assessments for Priority Substances <a href="#">PSL1</a> and <a href="#">PSL2</a>	PSL1 was first published in 1989 and risk assessments were completed for the 44 substances within 5 years. PSL2 was first published in 1995 and risk assessments for the 25 substances were completed by 2002.	CEPA requires the Ministers of the Environment and of Health to establish a Priority Substances List (PSL) that identifies substances to be assessed on a priority basis to determine whether they are toxic and pose a risk to the health of Canadians or to the environment.	Risk Assessments are available for 69 chemicals identified as Priority Substance List 1 (44) or Priority Substance List 2 (25)	Accessible from the OECD eChemPortal or the Health Canada website. The PSL1 and PSL2 Lists are not searchable, but users can locate the chemical name of interest by scrolling down the page to find a match. Downloadable files containing the risk assessments are accessed by clicking on the substance name.	The complexity and the depth of assessments can vary depending on the specific type of assessment. PSL Assessments are usually fairly comprehensive and include: - Substance identity - Physical chemical properties, - Use patterns and sources, - Releases to the environment, - Environmental fate, - Persistence and bioaccumulation potential, - Human health exposure characterization, - Quantification of potential adverse effects on human health and/or non-human organisms resulting from exposure to various concentrations, doses or intake rates of a substance through the exposure pathways identified in the exposure assessment, - Risk characterization, - Uncertainties, - References.	All risk assessments are based on sound-science, consider multiple lines of evidence and uncertainties, and apply precaution. Furthermore, they are all conducted to evaluate the potential of a substance or a group of substances to cause harm to Canadians and/or the Canadian environment. A weight-of-evidence approach, and precaution are applied throughout the assessment process. The available EHS information and assessment reports have been peer-reviewed by the governmental authorities and/or independent Canadian or international experts.	Canada describes multiples ways in which it acquires new information that may update prior risk assessments, or which may affect the prioritization of substances for future risk assessments. Such information can come from a variety of sources	The original 69 risk assessments have been archived and there are no plans to update them. The next phase (sometimes referred to as the third phase) of the CMP, launched in May 2016, will address the remaining 1,550 priority chemicals out of the original 4300 chemicals identified as priorities during the categorization. The Minister of Health and the Minister of Environment and Climate Change have committed to addressing these chemicals by 2020.

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Japan CMC	<a href="#">J-CHECK</a>	Could not be determined from website.	The focus of these databases is on what the Japanese government estimates are the 7,000-8,000 industrial chemicals produced or imported above 1 tonne per annum that are on the market.	~7,000-8,000	<p>Accessible through searching OECD eChemPortal or directly from the Japan CMC website.</p> <p>Search capabilities</p> <ul style="list-style-type: none"> <li>List and classification of CSCL</li> <li>List of Japan HPV Challenge program</li> <li>CAS Registry Number</li> <li>MITI number</li> <li>Chemical Substance name (Exact match, Substructure match)</li> <li>Search by structure</li> <li>Regulatory Classification</li> <li>Endpoints</li> </ul> <p>User instructions for conducting searches of J-CHECK are available at <a href="http://www.nite.go.jp/en/chem/chrip/chrip_search/dt/pdf/other/EN_manual.pdf">http://www.nite.go.jp/en/chem/chrip/chrip_search/dt/pdf/other/EN_manual.pdf</a>.</p>	<p>Environmental Hazard information</p> <ul style="list-style-type: none"> <li>Biodegradation</li> <li>Bioaccumulation</li> <li>Partition coefficient</li> <li>Algae growth inhibition test</li> <li>Daphnia Acute Immobilization test</li> <li>Daphnia Reproduction test</li> <li>Fish Acute toxicity test</li> <li>Fish prolonged toxicity test</li> <li>Fish early life stage toxicity test</li> <li>Other tests, if available</li> </ul>	Not all data of Existing Chemicals Survey Program Conducted by the Japanese Government are peer reviewed. Data of Japan HPV Challenge Program are not reviewed.	Maintenance of the database is the responsibility of the National Institute of Technology and Evaluation (NITE), Japan. Procedures for updating could not be located. Aiming to keep the content of this site accurate and up to date, NITE makes no warranties or representations regarding the quality, accuracy, completeness or reliability of information on the site.	Ongoing. A history of updates to the database is accessible to users.

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Japan CMC	<a href="#">CHRIP®</a>	Could not be determined from website.	The focus of these databases is on what the Japanese government estimates are 7,000-8,000 industrial chemicals produced or imported above 1 tonne per annum that are on the market.	As of this writing, it contains EHS information on approximately 250,000 substances.	<p>Accessible from searching the California DTSC's CIT or TIC databases or directly from the Japan CMC website. Users can search the comprehensive information on a target chemical substance (information on hazardous property/hazard assessments or regulations, etc.) by entering its number or name as a keyword. Searches may be done by using the following item as a keyword.</p> <ul style="list-style-type: none"> <li>· CHRIP_ID</li> <li>· Chemical Substance Name</li> <li>· CAS No.</li> <li>· MITI No.</li> <li>· ISHA No.</li> <li>· EC No.</li> <li>· UN No.</li> </ul> <p>The controlled chemical substances by each law or the assessed substances by each organization, etc. will be displayed in an individual list. Specifying a substance on a list, you can also see comprehensive information (contains information on hazard assessments or regulations, etc.).</p> <p>There are very helpful search instructions available at <a href="http://www.nite.go.jp/en/chem/chrp/chrp_search/html/naviHelp.html#srhInput">http://www.nite.go.jp/en/chem/chrp/chrp_search/html/naviHelp.html#srhInput</a></p>	The information related to the selected substance is displayed in a tree format and includes the following: Substance Identity and Structure Chemical Hazard and Risk Information GHS Classification according to the Japanese government. Hazard and Risk Assessment Reports from other Countries	Provides reliable data published by national and international authorities. The quality of the database is ensured by regular updates performed once every two months, and by a continual verification process.	Maintenance of the database is the responsibility of the National Institute of Technology and Evaluation (NITE), Japan. The quality of the database is ensured by regular updates performed once every two months, and by a continual verification process.	Ongoing. A history of updates to the database is accessible to users.

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USEPA	<a href="#">CHEMVIEW</a>	2017	Although USEPA has authority to regulate a wide range of substances, for the purposes of the current project the interest is restricted to their authority under TSCA. The scope of TSCA is restricted to chemical substances which are manufactured, imported, or processed "for a commercial purpose". Excluded from scope are drugs, tobacco, nuclear materials, munitions, food additives, cosmetics or chemicals used solely as pesticides.	USEPA is populating the database in phases, and it currently contains information on ~15,000 chemicals.	Accessible through the California TIC or directly from the USEPA website. Searches may be done by: Chemical Name or Identifier (including CAS, Accession, or PMN numbers) Use (52 separate categories) Functional use and use categories for Significant New Use Notification (20 separate categories) Chemical Group (8 separate categories) Effects/Endpoints (5 separate categories of health or environmental effects). A Users Guide ( <a href="https://chemview.epa.gov/chemview/resources/ChemView%20Public%20UJ%20Guide.pdf">https://chemview.epa.gov/chemview/resources/ChemView%20Public%20UJ%20Guide.pdf</a> ) to make it easy to search the ChemView database.	Provides key information in a layered summary format and provides links to underlying studies or other source documents. Data Submitted to USEPA, USEPA Assessments, USEPA Actions Manufacturing, Processing, Use, and Release Data Maintained by USEPA ChemView expands its search capabilities to include the Other Sources tab. The public is able to gain access simultaneously to searches of reports and dataset information provided by other federal organizations. This expanded search allows users to view, compare, and analyze multiple source chemical data, increasing safer chemical decision-making.	EPA must evaluate both hazard and exposure, exclude consideration of costs or other non-risk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, and ensure decisions are based on the weight-of-scientific-evidence. All EPA evaluations undergo peer review and are subject to a minimum 60-day public comment period.	EPA updates its assessments whenever they become aware of significant new substantial risk information, which includes new scientific information that impact the hazard assessment or significant new use/exposure information.	Ongoing.

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USEPA	<a href="#">ACToR</a>	2012 (although earlier versions date to 2002)	Although USEPA has authority to regulate a wide range of substances, for the purposes of the current project the interest is restricted to their authority under TSCA. The scope of TSCA is restricted to chemical substances which are manufactured, imported, or processed "for a commercial purpose". Excluded from scope are drugs, tobacco, nuclear materials, munitions, food additives, cosmetics or chemicals used solely as pesticides.	The Chemistry Dashboard ( <a href="https://comptox.epa.gov/dashboard">https://comptox.epa.gov/dashboard</a> ) provides access to a variety of information on over 700,000 chemicals currently in use. ToxCast Dashboard has data on over 9,000 chemicals and information from more than 1,000 high-throughput assay endpoint components.	Accessible by searching OCED's eChemPortal, California's DSTC CIT or TIC databases or directly via the US EPA website. Searchable by chemical name, CASRN, or structure. Users may browse assays by toxicity, category, or data collection. USEPA has created a video tutorial ( <a href="https://www.youtube.com/watch?v=IzCdGf4gILw&amp;feature=youtu.be">https://www.youtube.com/watch?v=IzCdGf4gILw&amp;feature=youtu.be</a> ) to assist those wishing to conduct advanced searches of the Chemistry Dashboard database.	Within the Chemistry Dashboard, users can access chemical structures, experimental and predicted physicochemical and toxicity data, and additional links to relevant websites and applications. The ToxCast Dashboard summarizes chemical information. Chemical structure and data such as CASRN, simplified molecular input line entry system (SMILES), IUPAC International Chemical Identifier (InChI), chemical structures, chemical annotations, quality control information on the chemical tested, information on the chemical sample, and physicochemical properties. <ul style="list-style-type: none"> <li>• Chemical assay activity summaries and charts for the selected chemicals.</li> <li>• Chemical Product Category (CPCAT) information listing product use category for the selected chemicals.</li> </ul> Exposure estimations based on manufacture and use information for the chemicals selected. ToxCast users can select assays of interest using a number of filters. Assay filters include gene symbol, intended target, assay name, tissue, and 'actives' only.	The Computational Toxicology work being done by USEPA that underpins ACToR, Chemistry and ToxCast Dashboards is leading edge science. USEPA points to a long list of peer-reviewed journal publications that have been written about uses for the Dashboard. ACToR itself is not peer reviewed; ACToR only contains publicly available datasets which have been previously published.	These databases are maintained by the National Center for Computational Toxicology. EPA's efforts actively engage a wide-range of partners including EPA regions and program offices, industry, academia, trade associations, other federal agencies, state and local government agencies and non-governmental organizations to help make this new chemical information more understandable and useable. EPA's computational toxicology stakeholder outreach includes workshops, webinars and training for partners as well as opportunities for stakeholders to provide suggestions for enhancing the research activities. Monthly Communities of Practice webinars are held and anyone with an interest in computational toxicology research can participate.	Ongoing. Computational toxicology tools continue to expand and offer the potential to replace animal testing. More recently, ACToR has incorporated new tools for screening chemicals for potential interaction with endocrine systems.

Table 2 — Summary of Single, Primary EHS Information Sources

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	EHS Information	Information Quality	Procedures for Updating	Date of Last Update
US ATSDR	<a href="#">ATSDR Toxic Substances Portal</a>	Could not be determined from the website, although Congress first authorized ATSDR to establish, maintain and disseminate toxicological databases in 1986.	Substances that are most commonly found at facilities on the National Priority List (NPL) and which are determined to pose the most significant potential threat to human health due to their known or suspected toxicity and potential for human exposure at these NPL sites.	Toxicological Profiles are published for nearly 200 substances or chemical families (e.g., polycyclic aromatic hydrocarbons) and profiles are under development for approximately 30 more substances.	Accessible by searching California DTSC TIC or directly via the ATSDR website. The Portal may be searched for substances by: Alphabetical Listing (A-Z) Chemical Abstracts Service Number (CAS#) Substance Name Synonym Tradename Individual States where they have been found in communities. Alternatively, the Portal may be searched for toxicological information by: Effects on Organ Systems and their Development Cancer Classification Structures, Properties or Use (14 separate categories) Audience (i.e., community members, emergency responders, toxicological and health professionals, and health care providers) Although no user guide to assist in conducting searches could be located, the search process is intuitive using point and click on text descriptors supplemented with icons.	Each ATSDR Toxicological Profile has the following chapters: <ul style="list-style-type: none"> <li>▪ Preface</li> <li>▪ Public Health Statement</li> <li>▪ Relevance to Public Health</li> <li>▪ Health Effects</li> <li>▪ Chemical and Physical Information <ul style="list-style-type: none"> <li>▪ Production, Import, Use, and Disposal</li> <li>▪ Potential for Human Exposure</li> </ul> </li> <li>▪ Analytical Methods</li> <li>▪ Regulations and Advisories</li> <li>▪ References</li> <li>▪ Glossary</li> <li>▪ Appendices <ul style="list-style-type: none"> <li>○ References</li> <li>○ Disclaimer</li> <li>○ Where can I get more information?</li> </ul> </li> </ul>	ATSDR has published detailed guidance for preparing toxicology profiles <a href="https://www.atsdr.cdc.gov/toxprofiles/guidance/profile_development_guidance.pdf">https://www.atsdr.cdc.gov/toxprofiles/guidance/profile_development_guidance.pdf</a> . They outline how ATSDR evaluates the quality of individual studies and how they apply a weight of evidence approach. All toxicology profiles are peer-reviewed and a subject to a 90-day public comment period.	The purpose of Toxicological Profiles Addenda is to provide, to the public and other federal, state, and local agencies a non-peer reviewed supplement of the scientific data that were published in the open peer-reviewed literature since the release of the profile.  ATSDR encourages users of their Toxicology Profiles that, if they are aware of new or additional studies that will contribute to the database please send them the information.	Ongoing. Toxicology profiles carry dates from as early as 1989 to the present.

Table 2 — Summary of Single, Primary EHS Information Sources

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	EHS Information	Information Quality	Procedures for Updating	Date of Last Update
EWG	<a href="#">Skin-Deep™</a>	2004	Focus is on chemical ingredients found in 74,032 cosmetics and personal care products in the U.S. divided into some 130 product categories (e.g., shampoo, toothpaste, deodorant, etc.).	Contains information on ~9,000 personal care product ingredients	Accessible through searching California DTSC's TIC or directly from the EWG website. Can be searched by: <ul style="list-style-type: none"> <li>Product name</li> <li>Ingredient</li> <li>Name of Company Marketing the Product</li> <li>Product Category A user's guide to assist with searches is available <a href="http://www.ewg.org/skindeep/users-guide-to-skin-deep/#.WqK6A2aZNBw">http://www.ewg.org/skindeep/users-guide-to-skin-deep/#.WqK6A2aZNBw</a>.</li> </ul>	<ul style="list-style-type: none"> <li>Chemical structure</li> <li>Chemical/Physical Properties</li> <li>Function/Uses</li> <li>Synonyms</li> <li>Rating (Low, Moderate or High) of Health Concerns:</li> <li>Overall Hazard</li> <li>Cancer</li> <li>Developmental and Reproductive Toxicity</li> <li>Allergies and Immunotoxicity</li> <li>Use Restrictions</li> <li>Data Gaps</li> <li>Eco-toxicity</li> <li>Multiple Additive Exposure Sources</li> <li>Organ System Toxicity (excluding Reproductive Toxicity)</li> <li>Persistence and Bioaccumulation</li> <li>References</li> <li>Data Sources</li> </ul> <p>Absent is any discussion of safe levels of exposure, typical exposure levels encountered during normal use or of risk assessments that may have been conducted by any parties.</p>	EWG has worked to ensure the accuracy of the information it provides through its Skin-Deep database. EWG assigned numeric hazard scores for each scoring category based on professional judgment of the relative importance of each with respect to potential health concerns. These scores were informed by a number of factors, including the weight of the evidence associated with each scoring category (e.g. whether the chemical categorization is derived from a full government assessment or from a single peer-reviewed study), and by other hazard classification systems, such as the Nordic Substances Database. No external peer review is described nor, do they discuss soliciting public input.	EWG notes that the database is dynamic, and that product ratings on any of these properties may change based on evolving science, new information, or other factors. The product ratings, images, conclusions, recommendations, and findings that appear in Skin-Deep reflect EWG's research at the time of publication. They advise that this information frequently relies on data obtained from many sources, and accordingly, EWG cannot guarantee the accuracy of the information provided or any analysis based thereon. Moreover, in light of evolving regulatory and market conditions, subsequent product reformulations, and other factors, this information may no longer be current. EWG makes no representations or warranties about Skin-Deep.	Ongoing.

Table 2 — Summary of Single, Primary EHS Information Sources

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	EHS Information	Information Quality	Procedures for Updating	Date of Last Update
USEPA	<a href="#">IRIS</a>	1985 (available on the internet since 1997)	Although USEPA has authority to regulate a wide range of substances, for the purposes of the current project the interest is restricted to their authority under TSCA. The scope of TSCA is restricted to chemical substances which are manufactured, imported, or processed "for a commercial purpose". Excluded from scope are drugs, tobacco, nuclear materials, munitions, food additives, cosmetics or chemicals used solely as pesticides.	Final IRIS Assessments are available for 511 substances or families of substances. Another 22 Assessments are listed as in development.	Accessible by searching OCED's eChemPortal, California's DSTC CIT or TIC databases or directly via the US EPA website. It can be searched by Chemical Name, CASN or Keyword or by Noncancer or Cancer, Route of Exposure, Organ/System Affected, Toxicity Value Noncancer, Uncertainty Factor Value, Weight of Evidence Carcinogenicity, and Toxicity Value Cancer. Searches using filters for organ/system affected are limited to effects (or tumor sites) used to derive the RfD, RfC, oral slope factor, or inhalation unit risk. IRIS Advanced Search searches only final IRIS assessments; to look for information on draft assessments, see <a href="https://cfpub.epa.gov/ncea/iris2/atoz.cfm">https://cfpub.epa.gov/ncea/iris2/atoz.cfm</a> .	IRIS assessments provide the following toxicity values for health effects resulting from chronic exposure to chemicals: Reference Concentration (RfC) Reference Dose (RfD) Cancer descriptors Oral slope factor (OSF) Inhalation unit risk (IUR)	USEPA has numerous guidance documents available for conducting IRIS assessments ( <a href="https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system">https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system</a> ). All EPA evaluations undergo peer review and are subject to a minimum 60-day public comment period. USEPA has been implementing a plan to respond to criticisms of IRIS that have been leveled by a number of stakeholders.	EPA updates its assessments whenever they become aware of significant new substantial risk information, which includes new scientific information that impact the hazard assessment or significant new use/exposure information.	Ongoing. Assessments carry dates from as early as 1987 to the present.

Table 2 — Summary of Single, Primary EHS Information Sources

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	EHS Information	Information Quality	Procedures for Updating	Date of Last Update
ChemSec	<a href="#">SIN List</a>	2008	Only substances covered by the authorization provisions in EU REACH are candidates for inclusion on the SIN list. Substances exempt or otherwise not regulated by REACH, such as pesticides, intermediates and unintentionally produced substances, are not included. Includes only chemicals judged as fulfilling the criteria for Substances of Very High Concern (SVHC), as described in REACH. Either Carcinogenic, Mutagenic or Toxic to Reproduction; Persistent, Bio-accumulative and Toxic or very Persistent and very Bio-accumulative; or "substances of equivalent concern"	There are 916 substances included on the SIN list. ChemSec speculates that over time, the SIN list could grow to an estimated 2000 substances.	Can be searched by: <ul style="list-style-type: none"> <li>CAS Number</li> <li>Chemical Name</li> </ul> Searches can also be filtered by: <ul style="list-style-type: none"> <li>Health and Environmental Concerns (e.g., endocrine disruptor, carcinogen, mutagenic, toxic to reproduction, PBT/vPvB, etc.)</li> <li>Uses (9 categories)</li> <li>REACH status</li> <li>Date of first appearance on the SIN list</li> <li>Production Volume (4 categories)</li> <li>SIN List Groups (see below for description)</li> <li>Producers (alphabetized list</li> </ul> No users guide for conducting searches could be located, but the search process is very intuitive.	Only a limited amount of information is generated by a search, including: <p>A short description of the reason for inclusion on the SIN List</p> <ul style="list-style-type: none"> <li>REACH status</li> <li>Hazard class and category code(s)</li> <li>Synonyms</li> <li>EC number</li> <li>CAS #</li> <li>Hazard statement code(s)</li> <li>Registered production volume</li> <li>(Bio)monitoring data, if available</li> <li>Possible uses</li> <li>Registered use(s) - Sector End Use (SU)</li> <li>Chemical formula</li> <li>Substitution options (if identified by ChemSec)</li> <li>Producers (company names)</li> </ul> Absent is any discussion of safe levels of exposure, typical exposure levels encountered during normal use or of risk assessments that may have been conducted.	Developed in close collaboration with scientists and technical experts, as well as an NGO advisory committee of leading environmental, health, women and consumer organizations mainly in Europe but also in the US. The list is based on credible, publicly available information from existing databases and scientific studies, as well as new research. Users will not find the scientific references to substantiate the reasons for each substance in the database but are encouraged to contact ChemSec by e-mail. Note that for substances having already an official classification as being CMR – this is enough for inclusion on the SIN List and ChemSec does not have additional background data.	ChemSec recognizes the need to regularly update their list with new scientific and regulatory information. Updates have been episodic and have employed different procedures at various points in time.	The SIN List has been updated in 2009, 2011, 2013, 2014, 2015, 2016 and 2017.

Table 2 — Summary of Single, Primary EHS Information Sources

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	EHS Information	Information Quality	Procedures for Updating	Date of Last Update
Australia	<a href="#">Chemical Information</a>	2012	Industrial chemicals listed in AICS, including polymers, regardless of volume	PEC Assessments are available for 43 chemicals or chemical families. Tier I IMAP Assessments are available for ~3000 chemicals; Tier II assessments are available for selected chemicals or chemical families; Tier III assessments are available for ~16 chemicals. Other Assessments are available for another 30 or so chemicals.	Access to IMPA Assessments may be done through the OECD eChemPortal or directly from the Australian Chemical Information website. Searches of the Tier I IMAP Assessments may be done by CAS# or chemical name. The PEC, Tier II, Tier III and Other Assessments are available in spreadsheets that can be sorted using a number of terms.	Tier I IMAP Assessments list chemicals that have been found not to present an unreasonable risk to human health or the environment and provide limited EHS information. All other Assessments provide a full range of EHS information, including hazards, use and exposure, hazard and risk assessments and risk management recommendations.	NICNAS takes a scientifically robust approach, providing for peer-review and public comment at the appropriate times.	Companies must notify NICNAS of significant new uses, volumes or new hazard information. NICNAS updates its assessments in response to significant new information.	Ongoing. PEC Assessments span dates from the mid-1990's to the present. IMAP Assessments started in 2012 and are ongoing.

Table 2 — Summary of Single, Primary EHS Information Sources

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	EHS Information	Information Quality	Procedures for Updating	Date of Last Update
<b>New Zealand</b>	<a href="#">CCID</a>	HSNO was adopted in 1996	Includes hazardous and non-hazardous chemicals, pesticides, polymers, non-infectious organisms, and veterinary medicines. Excludes medicines intended for humans, radioactive materials, Food, manufactured articles, infectious organisms.	~28,000	Accessible from the OECD eChemPortal or from the New Zealand CCID website. Can be searched by CAS# or Name. No guidance to assist with searches could be located.	A determination as to whether the substance meets the definition of hazardous and what restrictions apply. Includes a more substantive discussion of the scientific evidence that supports a hazardous classification with reference to specific studies and relevant findings.	NZEPA is committed to science and risk-based decision making and draws on local and international scientific information and expertise. Determinations are peer-reviewed and include opportunity for public comment.	All new hazardous substances must be notified to NZEPA. Anyone can apply for a reassessment based on new information. NZEPA has well-developed procedures in place for conducting reassessments.	Ongoing.
<b>GoodGuide</b>	<a href="#">GoodGuide</a>	2008	GoodGuide focuses on rating everyday household consumer products, and their chemical ingredients, bought either from offline or online retail outlets like supermarkets or e-commerce sites. Their core product categories are personal care, household chemical and food products.	Unknown, but likely in the thousands	GoodGuide may be searched in any number of ways: product category, subcategory, keywords, CAS# and chemical name. Indexes are also available by Category, Company, Brand, Product and Ingredient. No users guide could be found.	A search of information on chemical ingredients will yield GoodGuide's rating of health concerns (high, medium, low or none); a listing of health hazard statements, the product category in which it is found as an ingredient and specific brand name of products that contain it. Note: GoodGuide typically does not provide access to the entire set of data used to determine health concern levels assigned to ingredients	They strive to be the most reliable source of information on consumer products. They employ quality assurance and quality control (QA/QC) processes to ensure that the highest standards of data integrity are met and maintained. GoodGuide assesses the quality and credibility of each contributing data source based on the source's data collection process, public reputation and reviews received by experts in relevant fields.	The age of data used by GoodGuide varies by source. Their stated goal is to refresh product-level information at least once every 18 months.	Ongoing

### **3.3 Primary Sources Which Provide Access to EHS-Type Regulatory Decisions**

The final category of EHS information sources reviewed are the databases that provide EHS-type regulatory decisions on specific chemicals. Ten such databases are included in this report (ECHA's Substances Restricted Under REACH List and Candidate SVHC List, Canada's Categorization Results, California DTSC Candidate List, USEPA's SRS, South Korea's NCIS, Australia's AICS, New Zealand's HSNO Register and NZIoC, and China's IECSC) and are summarized against the quality criteria in Table 3. These databases do not provide users with EHS information per se. Instead they provide key decisions that, when combined with regulatory criteria used to make those decisions, give users insight as to how other governments view those chemicals. They also provide insights into how those governments are taking regulatory actions to further investigate and manage the risks they pose to human health and/or the environment. Those actions may or may not be of relevance to other users.

Each of the ten databases is easily accessed and searched using commonly available terms; however, the China IECSC is officially only available in Chinese (an unofficial version can be obtained from several consulting firms as noted in Appendix B16.).

Canada's Categorization Results database may be the most relevant for many users because it presents regulatory decisions on all 23,000 chemical substances identified as being in commerce in Canada. All such substances were categorized to identify those that were: (1) inherently toxic to humans or to the environment and that might be persistent and/or bioaccumulative; or (2) presented the greatest potential for human exposure; or (3) considered a priority for assessment based on other health concerns. Many governments around the world have been looking for simpler, less expensive and quicker approaches to characterizing the hazard and risks of chemicals and the results of Canada's efforts can possibly be leveraged by them for their own purposes.

The Republic of Korea's database represents an inventory of all chemicals, including polymers, that have been notified as being on their market at any time since before 1991 to the present down to volumes as low as 0.01 ton per year. Some substances are designated as toxic, restricted or prohibited, or subject to accident preparation; however, not all substances on the inventory have been assessed, so some caution needs to be undertaken in interpreting the data.

Australia's AICS also represents an inventory of all chemicals, including polymers, regardless of volume produced or imported. It provides conditions of use for a subset of chemicals that are considered to pose unacceptable risks unless well controlled.

New Zealand's NZIoC also represents an inventory of all chemical substances and non-infectious organisms, including pesticides, polymers, and other non-industrial chemicals regardless of volume produced or imported. NZEPA ensures that all chemical substances notified have been classified as to whether they meet their definition for hazardous. NZIoC contains the hazardous classification and any restrictions placed on those chemicals, but does not provide the rationale for the classification.

ECHA maintains two databases of regulatory decisions. The first contains information on the 66 substances currently restricted under REACH. Available for each entry is a description of the regulatory conditions that have been placed on them. ECHA also maintains a database of the substances that are candidates for making the list of Substances of Very High Concern (i.e., CMRs, PBTs, vPvB, and

substances of “equivalent concern”). Each entry in this database includes a link to the REACH dossier for that substance. Again, some governments are likely to find these two databases useful to their efforts to prioritize chemicals for further scrutiny, risk assessment and risk management.

California DTSC’s Candidate Chemicals List identifies approximately 2,300 chemicals found in consumer products. The list was developed from 23 “authoritative lists”, which fall into one of two categories: lists based on hazard traits (15 lists), and lists based on potential exposure concerns (8 lists). A Candidate Chemical must appear on one or more of these lists and must exhibit a hazard trait and/or environmental or toxicological endpoint. The next step is identification of consumer products that contain one or more Candidate Chemicals. Producers of such products must then complete an Alternatives Assessment and submit it to DTSC for review and action. Some users may be intrigued by the process that DTSC used and find value in its Candidate Chemical list, again for prioritizing chemicals for additional evaluation.

Although USEPA’s SRS shares some features with the other databases included in this category (e.g., it does not provide EHS information per se), it is somewhat unique in that it provides links, when known, from each SRS substance record to external sites and fact sheets. These external sites may be for USEPA programs, other U.S. agencies, or international organizations.

There is a record in the SRS for every substance that is tracked or regulated at USEPA. Each record provides basic information about that substance, such as the Chemical Abstract Service (CAS) number for a chemical or the Taxonomic Serial Number (TSN) for a biological organism. Each record also identifies standardized nomenclature about the substance and any synonyms in use at USEPA. The initial purpose of the SRS is, as the name implies, to register substances. The SRS is a registry or catalog of the substances that are identified by a U.S. federal environmental statute or that are tracked or regulated by any program at USEPA. The SRS does not contain the programmatic data for the substances; it simply identifies the substances; identifies the USEPA programs that track or regulate those substances; and identifies the names used for those substances by those programs.

Table 3 — Summary of Information Sources that Provide EHS Regulatory Decisions

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	Regulatory Decision	Other Information Available	Procedures for Updating	Date of Last Update
ECHA	<a href="#">Substances Restricted Under REACH</a>	Directive 76/769/EEC was adopted in 1976 and was replaced by EU REACH in 2007.	Includes all the restrictions adopted in the framework of REACH and the previous legislation, Directive 76/769/EEC.	66 substances or substance families.	List can be filtered by Name, CAS#, EC Number and Entry Number in Annex VIII. Alternatively, the list may be viewed alphabetically.	Each entry shows a substance or a group of substances or a substance in a mixture, and the consequent restriction conditions placed on it prior to being able to market it in the EU.	Substance identity.	A Member State, or ECHA, at the request of the European Commission, can start the restriction procedure when they are concerned that a certain substance poses an unacceptable risk to human health or the environment. ECHA can also propose a restriction on articles containing substances that are on the Authorization List. The intention to prepare a restriction proposal is made public in the registry of intentions before the proposal file itself is prepared so as to give an advance warning. The dossier proposing the restriction contains background information such as the identity of the substance and justifications for the proposed restrictions. It includes the identified risks, any information on alternatives to the substance and the costs, as well as the environmental and human health benefits, resulting from the restriction. The dossier needs to be prepared according to the REACH Regulation (Annex XV) and has to be submitted to ECHA within 12 months of the intention to prepare the proposal was notified.	Ongoing.

Table 3 — Summary of Information Sources that Provide EHS Regulatory Decisions

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	Regulatory Decision	Other Information Available	Procedures for Updating	Date of Last Update
ECHA	<a href="#">Candidate List of Substances of Very High Concern</a>	2008	Only substances covered by the authorization provisions in EU REACH are candidates for inclusion on the list. Substances exempt or otherwise not regulated by REACH, such as pesticides, intermediates and unintentionally produced substances, are not included. Includes only chemicals judged as fulfilling the criteria for Substances of Very High Concern (SVHC), as described in REACH. Either Carcinogenic, Mutagenic or Toxic to Reproduction; Persistent, Bio-accumulative and Toxic or very Persistent and very Bio-accumulative; or "substances of equivalent concern". The route to authorization starts when a Member State or ECHA, at the request of the Commission, proposes a substance to be identified as an SVHC.	181 Substances	List can be filtered by Name, CAS#, EC Number, Intrinsic Properties, Date of Inclusion on the list. Alternatively, the list may be viewed alphabetically.	Substances included on this list have been nominated as candidates for Authorization under REACH.	A link to the IUCLID dataset for the listed substances.	The intention to propose a substance for identification as an SVHC is published in the registry of intentions before the proposal is submitted, to inform industry and other stakeholders in advance of the submission. The first part of the proposal provides the data and justification for identifying the substance as an SVHC. The second part, examined during the follow-up steps after the identification, includes information on volumes on the EU market, the uses and possible alternatives to the substance. After publication of the proposal, anyone can comment on it or provide further information during the 45-day consultation. When comments are received that provide new information or challenge the basis for the identification as an SVHC, both the proposal and the comments are referred to the Member State Committee (MSC) to agree on the identification of the substance as an SVHC. If the committee reaches a unanimous agreement, the substance is added to the Candidate List. If the committee does not reach a unanimous agreement, the matter is referred to the Commission.	Ongoing since 2008.

Table 3 — Summary of Information Sources that Provide EHS Regulatory Decisions

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	Regulatory Decision	Other Information Available	Procedures for Updating	Date of Last Update
Canada	<a href="#">Categorization Results</a>	2006	Substances used, imported or manufactured in Canada for commercial purposes between January 1, 1984, and December 31, 1986 at a quantity of greater than 100 kilograms per year. It includes discrete organic compounds, inorganic substances, organometallic substances, polymers, and unknown or variable composition complex reaction products or biological material such as acetone or iron. Approximately 4,300 chemical substances that were determined after categorization as warranting further attention	~23,000 substances	<p>Accessed through OECD's eChemPortal or directly via Health Canada's website. Searches may be done by entering a chemical name and the CAS (Chemical Abstracts Service Registry) number to obtain categorization results for a particular substance.</p> <p>A number of pre-set searches are provided, to narrow the search results to smaller, more specific categories, such as Ecological Categorization Results, Human Health Categorization Results and others.</p>	<p>Substances were categorized to identify those that were:</p> <ul style="list-style-type: none"> <li>• inherently toxic to humans or to the environment and that might be: <ul style="list-style-type: none"> <li>◦ persistent (take a very long time to break down), and/or</li> <li>◦ bioaccumulative (collect in living organisms and end up in the food chain)</li> </ul> </li> <li>• substances to which people might have greatest potential for exposure. Additionally, substances considered a priority for assessment based on other health concerns were considered as part of this prioritization exercise.</li> </ul>	<p>Meets CEPA Categorization Criteria? (Y/N)  Meets Human Health Categorization Criteria? (Y/N)  Human Health Priorities (Visit Health Canada for more information)  Meets Environmental Criteria for Categorization Persistent? (Y/N)  Bioaccumulative ? (Y/N)  Inherently Toxic to Aquatic Organisms? (Y/N)</p>	<p>Using information from Canadian industry, academic research and other countries, Canadian government scientists work with partners in applying a set of rigorous tools to conduct categorization, screening level assessments and risk assessments for priority list substances. Information and assessment reports have been peer-reviewed by the governmental authorities and/or independent Canadian or international experts. Details of the peer-review process can be found in the introduction of each report. Additionally, under the CEPA 1999, the assessment reports are subject to a mandatory 60-day public comment period in which the assessments are published on the Departmental websites permitting comments from the public, stakeholders and concerned groups on the scientific findings</p>	<p>Ongoing. Although the initial categorization was completed in 2006, and the data is not planned to be updated, the Canadian government has changed the categorization of some substances when presented with new scientific information. In addition, all new substances entering the Canadian market since 2006 must undergo categorization.</p>

Table 3 — Summary of Information Sources that Provide EHS Regulatory Decisions

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	Regulatory Decision	Other Information Available	Procedures for Updating	Date of Last Update
California DTSC	<a href="#">Candidate Chemical List</a>	2013	Industrial chemicals that are ingredients in consumer products produced or sold in California. Products exempt from SCP include: drugs, medical devices, dental restoratives, food and pesticides. The focus is on ~2300 Candidate Chemicals which by definition exhibit a hazard trait and/or environmental or toxicological endpoint.	~1,100 grouped Candidate Chemicals, which includes group names and Candidate Chemicals that are not in a group. There are ~2,300 Candidate Chemicals if all Candidate Chemicals (regardless of the group association) are counted. The list is expected to grow with time.	Can be searched by: CAS# and Chemical Name, Group Name, Chemicals of Concern, by hazard traits, authoritative lists, or by potentially excluded Candidate Chemicals. Alternatively, users may download the entire list for exporting to an Excel file for viewing or printing. Help for conducting searches may be found at <a href="https://calsafer.dtsc.ca.gov/cms/faq/">https://calsafer.dtsc.ca.gov/cms/faq/</a>	List was developed from 23 authoritative lists, which fall into one of two categories: lists based on hazard traits (15 lists), and lists based on potential exposure concerns (8 lists). A Candidate Chemical must appear on one or more of these lists and must exhibit a hazard trait and/or environmental or toxicological endpoint. Candidate chemicals. The next step is identification of consumer products that contain one or more Candidate Chemicals. Producers of such products must then complete an Alternatives Assessment and submit it to DTSC for review and action.	CAS#, Chemical group, whether a potential exclusion applies, the particular hazard trait, and names of authoritative bodies that served as the source of information.	The List is updated when there are changes to the authoritative lists. DTSC reviews and updates the Informational List quarterly to reflect these changes. DTSC may add individual chemicals or chemical source lists to the Candidate Chemicals list or remove them by adopting new regulations. These revisions may be a result of DTSC research or a petition submitted by an external stakeholder. Anyone wishing DTSC to revise the Candidate Chemicals list may submit a petition. DTSC will add to or remove Candidate Chemicals from the Informational List after regulations have been adopted and they take effect.	Ongoing.

Table 3 — Summary of Information Sources that Provide EHS Regulatory Decisions

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	Regulatory Decision	Other Information Available	Procedures for Updating	Date of Last Update
USEPA	<a href="#">SRS</a>	Could not be determined from website.	Although USEPA has authority to regulate a wide range of substances, for the purposes of the current project the interest is restricted to their authority under TSCA. The scope of TSCA is restricted to chemical substances which are manufactured, imported, or processed "for a commercial purpose". Excluded from scope are drugs, tobacco, nuclear materials, munitions, food additives, and cosmetics.	>100,000	Accessible by searching OCED's eChemPortal, California's DSTC CIT or TIC databases or directly via the US EPA website. It may be searched by chemical, substance, or biological name or ID (CAS #, EPA ID, TSN, or internal tracking number) by single entry or multiple entries or by chemical/substance lists. USEPA has a number of published resources available to assist with searches of the database.	Makes it possible to identify which USEPA data systems, environmental statutes, or other sources have information about a substance and which synonym is used by that system or statute. It becomes possible therefore to map substance data across EPA programs regardless of synonym.	Hazard information is not available in the SRS. However, the SRS provides links, when known, from each SRS substance record to external sites and fact sheets. These external sites may be for USEPA programs, other U.S. agencies, or international organizations.	Quality for SRS data is an on-going effort. With more than 100,000 records in SRS there are enormous opportunities for error. EPA focuses on quality in three areas for SRS: Quality of the information provided by SRS; Assessment of the accuracy of the synonyms that are used by EPA programs; Value of the available information; e.g., links to related websites. Core metadata (e.g., CAS name, CAS number, molecular weight) for a majority of the chemicals is made available from a program office at the US EPA that obtains the data from the Chemical Abstract Service. Data quality for core metadata for other chemicals is reviewed on a periodic basis. Programmatic information (e.g., the synonym used by a particular EPA program office) is managed within the SRS by designated stewards from that program office.	Ongoing.
South Korea	<a href="#">NCIS</a>	2008	In scope are substances produced or imported into the Korean market as low as 0.01 ton/year as well as polymers. Out of scope are naturally occurring substances and chemicals regulated under other Acts such as pesticides, pharmaceuticals, medical devices, fertilizers, radioactive substances, etc.	More than 44,000 chemical substances.	Searches may be done using CAS#, Chemical Name in Korean or English, and unique chemical number. Searching is intuitive and there is no English language help document available.	Phase in substance subject to registration. Toxic Substances Restricted Substances Prohibited Substances. . Substances requiring preparation for accidents.	For restricted and prohibited substances there is an explanation of the conditions placed on production, import and use.	All new chemicals must be notified to MOE and are then added to NCIS. Companies are required to notify MOE of any significant changes in production or import volume, and any changes in use, hazard or risk. Failure to comply is subject to civil and criminal penalties and fines.	Ongoing.

Table 3 — Summary of Information Sources that Provide EHS Regulatory Decisions

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	Regulatory Decision	Other Information Available	Procedures for Updating	Date of Last Update
Australia	<a href="#">AICS</a>	Late 1990's	All industrial chemicals, including polymers, regardless of the volume manufactured or imported. Excluded are chemicals used solely for the following purposes: pesticides, agricultural products, veterinary medicines, food for animals, pool sanitizers, medical devices (including disinfectants and sterilizers), medicines, biologicals, sunscreen products, and food for humans.	~40,000	Can be searched by CAS#, CAS Name, or Molecular Formula	If Secondary Notification Conditions apply and the nature of any stipulated conditions of use.	None	All new chemicals must be notified to NICNAS prior to manufacture, import or use. Significant new uses, volumes or new hazard information must also be notified.	Ongoing.
New Zealand	<a href="#">HSNO Application Register NZIoC</a>	HSNO Act was adopted in 1996	Includes hazardous and non-hazardous chemicals, pesticides, polymers, non-infectious organisms, and veterinary medicines. Excludes medicines intended for humans, radioactive materials, Food, manufactured articles, infectious organisms.	~28,000	Can be searched by CAS# or Name. No guidance to assist with searches could be located.	A determination as to whether the substance meets the definition of hazardous and what restrictions apply.	The HSNO Application Register includes a very brief description of the basis for the hazardous substance determination.	All new hazardous substances must be notified to NZEPA. Anyone can apply for a reassessment based on new information. NZEPA has well-developed procedures in place for conducting reassessments.	Ongoing.

Table 3 — Summary of Information Sources that Provide EHS Regulatory Decisions

EHS Information Source	Database Name (weblink)	Date of Inception	Scope	Estimated Number of Chemicals	Ease of Access	Regulatory Decision	Other Information Available	Procedures for Updating	Date of Last Update
China	<a href="#">IECSC</a>	2011	All chemicals on the Chinese market, including polymers, regardless of the volume they are produced or imported. Excluded are pesticides, pharmaceuticals, cosmetics, food additives, naturally occurring substances, etc.	45,612 substances in IECSC. No CAS# were available for 8,486 of them. Any substance that is not listed on IECSC is regarded as a new substance in China and requires notification in accordance with China MEP Order 7 (China REACH).	A major impediment to using IECSC and the Catalogue of Hazardous Chemicals is that they are not generally available in English. Both may be downloaded and searched by Chinese chemical name or CAS#. No English language help is available for conducting the searches.	There is no English language information available from either IECSC or the Catalogue of Hazardous Chemicals.	Unknown	IECSC is updated with new chemicals only 5 years after the commencement of manufacture or import. Moreover, the availability of publicly accessible updated IECSC or Catalogue of Hazardous Chemicals is at the discretion of MEE and SAWS, respectively.	Ongoing, but IECSC is only updated every 5 years.



## 4. Estimating the Number of Industrial Chemicals in Commerce

Many audiences have expressed an interest in knowing the number of industrial chemicals currently in commerce, ostensibly so they can better quantify the gaps that exists in the collective knowledge of their hazards and risks. As has been demonstrated in section 3 above and in Appendix B, there now exists publicly available EHS information on tens of thousands of chemicals, particularly on those produced, imported and used in the largest quantities. But how large is the denominator?

Providing a credible estimate of the number of industrial chemicals in commerce has been problematic for a number of reasons. In a published article, [Goldman](#), Former Assistant Administrator for Toxic Substances at the U.S. Environmental Protection Agency (EPA), has recounted her experience at the USEPA and cited the following as barriers: uncertain and variable definitions of what's included under the rubrics of chemicals and even "industrial chemicals", varying volume thresholds for reporting, uncertainty as to whether chemicals initially notified to USEPA in 1976 still remain on the market, and whether new chemicals notified since then were even ever brought to the market. She lamented the lack of a good estimate and speculated that the number was likely to be in the range of 25,000 to 84,000 chemicals in the US. [Dennison](#), Lead Senior Scientist at the NGO Environmental Defense Fund, has provided an estimated range of 7,700 to 85,000 chemicals as being on the US market.

Unmentioned by either Goldman or Dennison was the tremendous incentive that existed for manufacturers or importers to over-report chemicals as being in commerce to the initial TSCA Inventory in 1976. Anything that was not included on the Inventory was then by definition considered a new chemical and could not be manufactured or imported until a PMN was filed with USEPA and reviewed. Many companies wished to avoid that uncertainty and to maintain their options. The approximate 62,000 chemicals first notified was therefore likely an over-estimate of the actual number of chemicals in commerce at that time. [The American Chemistry Council](#) has also pointed to what it suspects are a large number of duplicate entries in the TSCA Inventory.

Although a direct attribution could not be located, at least [one article](#) has reported that ECHA had at one time estimated that there were approximately 144,000 man-made chemicals in existence. However, the basis for that estimate was not provided.

ECHA maintains the European Community Inventory which, as of 11 August 2017, contained 106,211 unique substances/entries and is comprised of: the European INventory of Existing Commercial chemical Substances (EINECS<sup>5</sup>) which lists chemicals that were deemed to be on the European Community market between 1 January 1971 and 18 September 1981, the European List of Notified Chemical Substances which lists those substances which were notified under Directive 67/548/EEC, the Dangerous Substances Directive Notification of New Substances (NONS) that became commercially available after 18 September 1981, and No-Longer Polymers list which includes substances previously considered to be polymers were no longer excluded from regulation. The latter consists of such substances that were commercially available between 18 September 1981 and 31 October 1993. Because the European

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<sup>5</sup> Note: substances listed in EINECS are considered phase-in substances under REACH.

Community Inventory has not been updated to remove chemicals that are no longer on the market, reliance on it will likely over-estimate the number of chemicals currently in commerce.

The UN Environment Programme's [Global Chemicals Outlook 2013 report](#) provided an estimated range of 30,000 to 140,000 chemicals in commerce, globally.

Two separate initiatives, one in the US and the other in the EU, may provide a starting point to generate more current and robust estimates of the numbers of industrial chemicals in commerce.

US TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, requires USEPA to designate chemical substances on the TSCA Chemical Substance Inventory as either "active" or "inactive" in U.S. commerce. To accomplish that, [EPA finalized a rule](#) requiring industry to report on chemicals that were on the TSCA Inventory in June of 2016 and were manufactured (including imported) or processed in the U.S. at some time during the past 10 years, ending on June 21, 2016. This reporting is being used to identify which chemical substances on the TSCA Inventory are "active" in U.S. commerce and will help to inform the prioritization of chemicals for risk evaluation. The mandatory reporting period for manufacturers (includes importers) ended on February 7, 2018, and the voluntary reporting period for processors ended on October 5, 2018. Additionally, active and inactive designations for each chemical substance will be included as part of USEPA's regular publications of the TSCA Inventory.

With some exceptions, the USEPA TSCA Inventory update excludes chemicals that are categorized as:

- drugs
- tobacco
- nuclear material
- munitions
- food additives
- cosmetics or
- used solely as pesticides
- formed during the manufacture (or import) of an article
- manufactured solely for export
- formed by an incidental reaction or end-use reaction
- a mixture, impurity, naturally-occurring material, by-product or a non-isolated intermediate
- manufactured or processed in small quantities solely for research and development.
- manufactured or processed solely for test marketing purposes.

The original TSCA Inventory also provided some exemptions for chemicals produced or imported below 10 metric tonnes per year, although the recent update included no volume threshold for reporting chemicals that met the definition of "active" in commerce.

As of April 2018, USEPA made available a Microsoft Access file containing an update to the TSCA Inventory. This version of includes a new field designating which chemical substances were "active" in U.S. commerce, based on:

- Reporting from 2012 and 2016 Chemical Data Reporting cycles;
- Notices of Commencement received since June 21, 2006; and
- Notice of forms completed by manufacturers and importer received through February 7, 2018, per the TSCA Inventory Notifications (Active-Inactive) rule.

The updated TSCA Inventory shows 38,304 chemicals as active in commerce in the U.S. at some time during the 2006-2016 time frame. However, an analysis of it discovered the following:

- Approximately 31,000 chemical substances were added to the Non-CBI Active Inventory and approximately 7,300 chemicals to the CBI Active Inventory.
- 7,500 of them are polymers which are generally considered to be of “lower concern” in all regulatory schemes across the globe.
- Production and/or import volume information are available for 13,000 of the 31,000 Non-CBI Active substances and for 560 of the 7,500 CBI Active substances, with the remaining substances being either low volume or designated as “lower concern”. The vast majority of the total annual volume (99.8%) is concentrated among approximately 3,900 HPV chemicals, the vast majority of which are also in commerce in other jurisdictions.

For some perspective, by comparison, there are currently approximately 1,500 registered pesticide active ingredients in the US, including conventional chemicals (approximately 840), antimicrobials (approximately 320), and biopesticides (approximately 360).

Where known, the numbers of active pesticide ingredients are also presented below for other nations/regions to provide perspective. Because many governments more tightly regulate pesticide active ingredients, obtaining an accurate count of those that are in commerce is much easier to obtain than for industrial chemicals.

[ECHA maintains statistics](#) on the numbers of EU REACH registrations, and the number of substances that are covered by those registrations. The exemptions for EU REACH registration are fairly similar to those in place for TSCA notification, with the exception of volume where the original TSCA Inventory had a 10 tonne/year reporting threshold whereas EU REACH registers substances as low as 1 tonne per year. As of 20 August 2018, there were 21,248 unique substances registered for EU REACH. Manufacturers and importers had until May 31, 2018 to register substances in the 1-100 tonne/year tonnage band, and it can be expected that some additional substances will be registered after this deadline.

There are currently 443 registered active ingredient plant protection pesticides in the EU and 228 registered active ingredient biocidal (antimicrobial) products.

Although the US and EU estimates are the most current and reliable, there is some perspective to be gained by comparing them with other numerical estimates from other countries/regions.

The most recently released version (2015) of the Canadian DSL lists approximately 27,000 chemicals, 24,000 of which have a CAS# available. The remaining 3,000 chemicals are CBI substances with generic names and Canadian CBI identifiers. There is an overlap of 15,300 CAS#'s between the TSCA Non-CBI Active list and the Canadian DSL lists. Some of the discrepancy in numbers of chemicals between Canada and the US can be explained by Canada's low reporting threshold of 100 kilograms (0.1 metric tonnes) per year. Its definition is more expansive than that for either TSCA or EU REACH and includes discrete organic compounds, inorganic substances, organometallic substances, polymers, and unknown or variable composition complex reaction products or biological material such as acetone or iron. A major uncertainty with the Canadian DSL is how many of the listed chemicals remain active on the Canadian market.

For perspective, Canada lists 656 unique active pesticide ingredients as registered for use.

In Japan, it was estimated in 1973 that there were about 7,000-8,000 industrial chemicals with production or import above 1 tonne per year on their market requiring safety examination through a series of toxicity tests. More recently, Japan MOE has provided an estimate that in Fiscal Year 2012, there were 11,897 General Chemical Substances (i.e., industrial use) for which the sum of the quantities manufactured and imported was one ton or more. Of those substances, there were 7,699 General Chemical Substances for which the sum of the quantities manufactured and imported exceeded 10 tons. Japan also reported 565 agricultural pesticides were registered for use in 2012.

Australia's chemical inventory, AICS, lists approximately 40,000 chemical substances, including polymers, regardless of the volume of that substance that is manufactured or imported. No information could be located to determine which or how many of those listed substances are still active on the Australian market.

New Zealand's chemical inventory (NZIoC) includes approximately 28,000 substances, but this number is not directly comparable to estimates from other countries because their inventory includes many categories of substances that are excluded from the others, including: pesticides, polymers, veterinary medicines and non-infectious organisms. Furthermore, there was no volume threshold for reporting. No information could be located to determine which or how many of those listed substances are still active on the New Zealand market.

The Republic of Korea's chemical inventory, NCIS, lists more than 44,000 chemical substances. It also includes polymers, and chemicals that are produced or imported in volumes in excess of 0.01 tonnes/year. It excludes pesticides, pharmaceuticals and other substances that are regulated under other government regulations. NCIS was begun in 2008 and no information could be located to determine which or how many of the listed substances are still active on the South Korean market.

As of 2016, China's chemical inventory, IECSC, lists more than 45,000 substances. Included are all chemicals on the Chinese market, including polymers, regardless of the volume they are produced or imported. Excluded are pesticides, pharmaceuticals, cosmetics, food additives, naturally occurring substances, etc. (Please reference Appendix B16. for a complete list of exclusions). IECSC began in 2011 and is updated with new chemicals added to the Chinese market 5 years after the commencement of manufacture or import. A lack of English language translation is an impediment to using the database. No information could be located to determine which or how many of the listed chemicals substances are still active on the Chinese market

Countries in Central and South America have yet to adopt chemical management regimes, including inventories of chemicals on their markets. Thus, these countries cannot yet contribute to our knowledge about the number of chemicals in commerce. An apparent exception is Mexico, which began an inventory of chemicals in late 2011 and estimated it had 15,000 industrial chemicals on the market (no English language details to support this estimate could be found from the website of its Institute of Ecology and Climate Change). Columbia just published a draft decree that will, within one year, establish a register of industrial chemicals on the market, and within two years after that, put in place risk assessment and risk management processes.

The Russian Federation also maintains a register of potentially hazardous chemicals and biological substances. Unfortunately, it is only available in Russian and has not been translated into English. Purportedly, it includes data on properties of chemical substances and mixtures including information

on prohibition, restriction or permission in the territory of the Russian Federation. As of the end of 2016, the current register contains about 10,560 substances which were placed on the Russian market for the first time since 1992. It can be searched online by substance name (Russian), CAS# or EC number.

In October of 2016, Russia passed a new technical regulation for chemical product safety that will create an inventory based on the current register plus newly introduced substances. The new regulation does not come into force until July of 2021. Once the inventory is finalized, any new substances which are not listed on the inventory will require REACH-like notification before they can be placed on the Russian market.

In 2017, the Eurasian Economic Union (EEU includes Armenia, Belarus, Russia, Kazakhstan, Kyrgyzstan) adopted a Technical Regulation for chemical product safety. This technical regulation establishes uniform requirements for chemical products released into circulation in the EEU customs territory, as well as rules and forms for assessing its compliance, identification rules, requirements for terminology, labeling and application rules. The Eurasian Economic Commission, together with the governments of the EEU Member States, are expected to develop and approve the procedure for creating and maintaining the register of chemicals and mixtures of the EEU and the procedure for notifying new chemicals, ensuring their entry into force before December 1, 2018.

The preceding paragraphs summarized available estimates from single countries or regions.

From all of the estimates above, one can make a tentative estimate of the range of numbers of industrial chemicals in commerce, globally. To do so, some assumptions must be made about the amount of overlap between the chemicals produced and used between various regions and countries. It is unreasonable to assume that there is either 0% or 100% overlap, especially since as was noted in the GCO Report I, chemicals are increasingly being produced and traded globally. This is especially true of the 4,000-6,000 chemicals produced in the highest volumes.

A comparison of CAS#'s between the updated USEPA TSCA Inventory and EU REACH registrations found 61% overlap. Similarly, a comparison between the updated USEPA TSCA Inventory and substances on the Canadian DSL found 61% overlap. Because of limitations in the structure of the Japanese and Chinese inventory databases, it was not possible to make direct comparisons between them and the USEPA, EU and Canadian databases to determine the amount of overlap that exists. Thus, for purposes of making estimates of numbers of chemicals in commerce an assumption was made that there was 60% overlap in chemical identity amongst all of them.

If one uses the number of ECHA REACH registrations (N = 21,500), an analysis of the USEPA TSCA Inventory Update (N = 26,200), data available from the Canadian DSL (N = 19,500), Japan MOE's estimate (N = 12,000), and an analysis of China's IECSC (N = 35,700) after removing polymers, and assume a 60% overlap of industrial chemicals among them, and then adding 10% of that total to factor in possible unique chemicals from the rest of the world, yields an upper-bound estimate of approximately 60,000 unique chemicals in commerce globally. At the other extreme, using the same information solely from the number of ECHA REACH registrations, updated USEPA TSCA Inventory and Japan (adjusted for an assumed 60% overlap) and then adding 5% of that total for the rest of the world yields a lower-bound estimate of 40,000 industrial chemicals in commerce.

A sole focus on estimates of total numbers of chemicals in commerce ignores a key point that the vast majority of total annual volume of chemicals produced and sold is concentrated in a much smaller number of commercial chemicals. In his 2015 book *Chemicals without Harm, Policies for a Sustainable World*, Geiser estimated that 2,500 chemicals account for more than 95% of chemical volumes, globally. Reliable volume data are only available from the USEPA, ECHA REACH and Japan. Combining their data and again assuming 60% overlap in chemical identity among them yields an estimate of approximately 6000 chemicals that account for greater than 99% of the total volume produced or imported globally.

## **5. Perspectives on the Strengths and Limitations of this Study and of**

### **EHS Databases**

The present study, and the databases themselves, enjoy some particular strengths, but also have some limitations which need to be thoroughly discussed and considered.

#### **5.1 Strengths of the Study and of EHS Databases**

One particular advantage of this study, that is also discussed as a limitation below, is its narrow focus on industrial chemicals in commerce. Although there continue to be significant concerns expressed about the impacts of chemicals in other sectors, e.g., chemicals used to control pests in agriculture and in and around domiciles, and with chemicals used to control microbial agents in a variety of settings, the reality is that pesticides and antimicrobials receive far greater scrutiny from regulatory agencies and, in general, there exists considerably more EHS information about them compared with industrial chemicals. As the production and uses of industrial chemicals has expanded during the past 50 years, and greater numbers of the public have had the potential for exposure to them, the gaps in our knowledge about their hazards and risks have garnered increasing attention from multiple stakeholders. By focusing more narrowly on industrial chemicals, this study contributes to the collective understanding of the types of EHS and regulatory information that is already publicly accessible and identifies priorities for further work to close the remaining gaps.

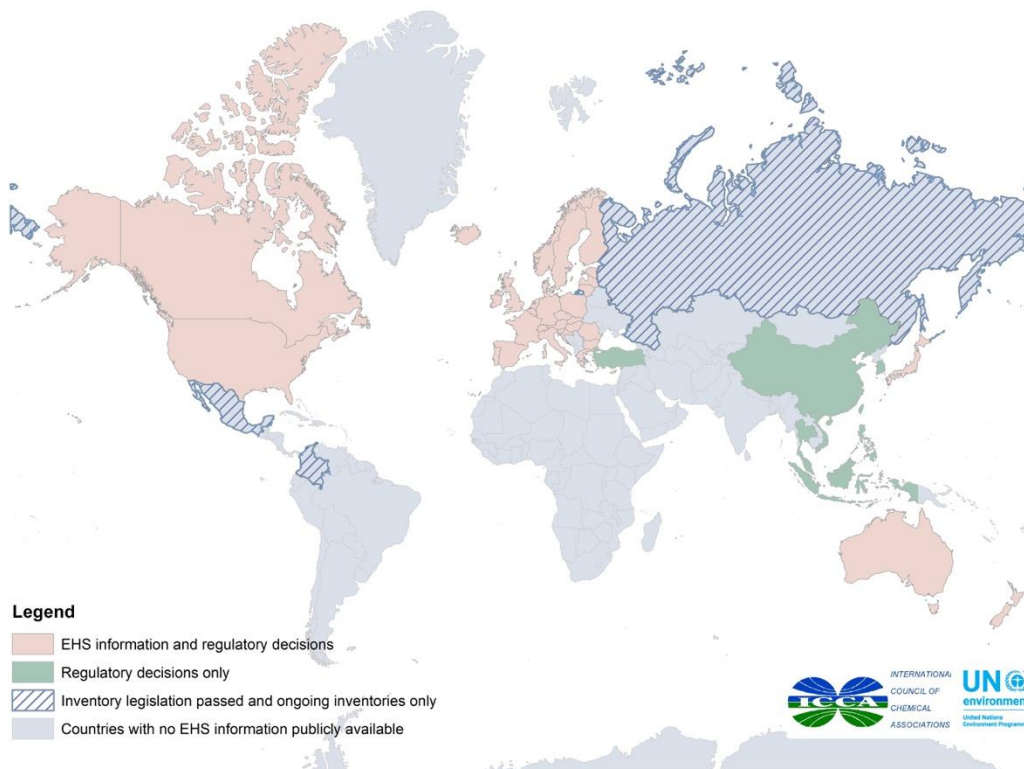
Another strength of this study is the comprehensiveness of the search for available EHS and regulatory databases that can be easily accessed by those seeking information on industrial chemicals. In addition to more conventional methods of searching (i.e., scouring the web using various search terms), suggestions were sought and received by the SAICM Secretariat from their extensive, geographically representative network of stakeholders which is composed primarily of national governments and NGOs. This substantially reduced the possibility of missing important data sources.

In fact, the study found links to more than 100 such EHS and regulatory databases and provides in-depth profiles for 41 of the largest and most comprehensive among them, including evaluations against pre-established quality criteria. The evaluations were carried out objectively using neutral narratives to highlight their strengths and potential opportunities for improvement.

These databases are operated by a mix of intergovernmental organizations (e.g., OECD, WHO, UN Environment, etc.), trading blocs (EU and Asean-Japan), individual countries, and NGOs. The breadth of geographic coverage of these databases is impressive, spanning nearly 50 countries spread across 4 continents. Figure 2 displays a map showing the sources of information available.

Figure 2

## Publicly Available Environment, Health and Safety (EHS) Information Sources on Industrial Chemicals



Inventory – List of chemical substances that are manufactured or imported into a country or region, and used primarily to distinguish between new and existing chemicals. Inventory of chemicals that are used exclusively as pesticides, biocides or as active ingredients in human or veterinary medicines and not otherwise used for other purposes that would qualify them as industrial chemicals are excluded in this map.

The profiled databases represent the full spectrum of conventional EHS and regulatory information, including hazards, exposures and risks, to include some that offer newer read across, *in chemico*, *in vitro*, *in silico* tools and “high-throughput screening” and “high-content methods” (e.g. genomics, proteomics, metabolomics) to predict and evaluate hazards and risks more rapidly and economically than traditional animal-based testing can accomplish. Many of these tools and methods involve interpolation or extrapolation of data from chemicals that have undergone more traditional testing to structurally similar chemicals that haven’t been as thoroughly tested.

Some of the databases (e.g., EWG’s Skin-Deep, ChemSec’s SIN list, GoodGuide, USEPA’s Safer Choice Program, and those maintained by California’s DTSC) have been developed for the express purpose of promoting safer alternatives to existing chemicals considered as possibly risky for consumer exposures. Furthermore, several of them (e.g., EWG’s Skin-Deep, GoodGuide, National Library of Medicine’s Household Products database (accessible from TOXNET) and California DTSC) place their focus on increasing transparency of the identity and hazard characteristics of chemicals used in specific consumer

products. Other websites exist that also promote substitution to purportedly safer products, e.g., [SubSPort](#), [BASTA](#), [GreenScreen](#). These sites are referenced here (and in Appendix A) for readers who may be interested in learning more about them, but they were not included for analysis and evaluation in the current study because, although they offer potentially useful methods and tools for evaluating EHS characteristics of products, they do not provide searchable databases of EHS information on chemicals. More recently, a [Chemicals associated with Plastic Packaging database](#) has been announced “as a work in progress” and is the outcome of a collaboration between NGOs and research organizations in Europe and the US (The Food Packaging Forum; ChemTrust; ChemSec; University of Gothenburg; and Vrije University). It currently includes 148 substances ranked according to toxicity.

The combined effect of recently adopted legislation (e.g., EU-, Korea- and China- REACH, and the Lautenberg Chemical Safety Act) that requires manufacturers and importers to collect and publicly report hazard, use, exposure and risk information on their chemicals, the increasing focus on Green Chemistry, as well as the advent and acceptance of new tools and methods (e.g., read across, QSAR, “high throughput” and “high-content” screening), provides the best opportunity in decades to close the remaining gaps in our knowledge base about industrial chemicals.

The report is written primarily to serve the needs of someone who is seeking to find EHS and regulatory information on one or more specific chemicals of interest to them and aspires to be a helpful guide for locating and using publicly available information sources. Another priority for the study is to provide policymakers with some perspective on the extent of EHS information that is available and the gaps that remain.

## ***5.2 The Knowledge Gaps, the Limitations of the study and of EHS Databases***

One metric tonne is the limit most commonly used by regulatory agencies across the globe. Such a relatively small volume was based on the assumption that relatively few persons will be exposed to small volume of chemicals. However, this may not be essentially true about emerging chemicals such as nanomaterials whose threshold of their potential harms such as toxic concentrations are still under investigations and might be different from the same material in bulk form.

The estimate of number of chemicals in commerce and also analysis of the EHS sources compiled in this study do not account exclusively for the chemicals that are no longer manufactured or processed since ten years, chemicals produced above 1 tonne per annum that are used solely for product and process orientated research and development, non-isolated intermediates, isolated intermediates that are handled or transported under strictly controlled conditions, polymers (as defined under EU REACH), unintentional byproducts that are converted or treated on site under strictly controlled conditions and chemicals that are produced below 1 tonne per annum. Moreover, Individual Safety Data Sheets for chemicals in commerce were not analyzed as a source of EHS information for chemicals in commerce.

This chapter discusses the limitations of EHS databases, as well as the extent of available information and the existing knowledge gaps in regard to chemicals that are no longer manufactured for more than ten years, chemicals in products, nanomaterials, privately held information on industrial chemicals (Confidential Business information), combined exposure to multiple chemicals, risk management measures, other barriers to accessing and deploying EHS information, and estimation of number of industrial chemicals in commerce.

The current study and the analysis helped to identify certain unanswered questions in regard to chemicals in commerce which need a collective or separate research into each of these questions. Therefore, it is recommended to be the subject of future studies.

- What portion and how many chemicals on the market are hazardous, i.e. would need to be labelled according to the GHS?
- How many chemicals have complete risk assessments that have been prepared at the international or national levels?
- How many chemicals are on priority lists for potential phase out or severe restriction?

Currently there is limited coherent knowledge on each of these questions, because of the lack of a single, global repository for such information. This study has succeeded to compile and categorize the most comprehensive publicly available sources of EHS information which can facilitate the research into each of these knowledge gaps in future studies.

### **Limitation of EHS Databases**

Certain gaps exist in EHS information available on specific industrial chemicals in commerce such as limited hazard information and lack of detailed toxicology information on a large number of these chemicals due to several factors such as: limited exposure to justify more extensive testing, the relatively high cost of some chronic toxicity tests, lack of advanced technologies or methodologies for risk assessment for certain chemicals (i.e. nanomaterials), the growing desire to reduce or replace animals used in testing, among many more. This is discussed more thoroughly by the scientists at the USEPA and was reported in 2012. As noted above, the gaps are shrinking with the implementation of EU REACH, Korea REACH, China REACH and new USEPA TSCA authority to more easily mandate that manufacturers generate data. Gap reductions are also likely to accelerate with increased adoption and acceptance of the *in vitro* and *in silico* predictive tools discussed above.

In general, the EHS databases included in this study provide findings predominantly from experimental toxicology studies and fewer results from human observational epidemiology studies. There are notable exceptions to this (e.g., IARC monographs, EU REACH dossiers, IRIS Assessments and others). The reasons for this are many and are often justified (e.g., epidemiology evidence is not feasible for newly introduced chemicals). Additionally, regulatory agencies around the globe admittedly have had difficulty assessing the quality and relevance of epidemiology evidence and integrating it with experimental evidence. However, in very recent years this has been changing with the adaption and use of systematic review and integration methods by [US](#) and [EU](#) regulators. It should be expected that epidemiology evidence will be more commonly reflected in EHS databases in the future.

### **Restricted and/or Banned Chemicals and the Chemicals Not Manufactured within the Past Ten Years**

As mentioned above, while the focus on ‘industrial chemicals in commerce’ provides some advantages, it also presents some limitations. Foremost among them is that it can discount important public exposures via contaminated air, water and soil to chemical by-products, wastes, and chemicals which may have been restricted, banned or voluntarily phased-out in the past, and yet remain in the environment at levels of concern due to their persistence and bioaccumulation potential or because they remain in products that people come into contact with on a regular basis.

A time limit on production of industrial chemicals in commerce is necessary and the choice of ten years was largely dictated by the rules for EU REACH registration and the USEPA reset of the Toxic Substances Control Act (TSCA) Inventory. However, the ten-year limits the scope because it then excludes the specific exemptions for chemicals banned under the Stockholm Convention, yet their use or recycling of waste containing such chemicals is still allowed. A good example of the out of commerce chemicals for more than ten years is the commercial octabromodiphenyl ether (OctaBDE) listed in the Stockholm Convention for global elimination in 2009. However, OctaBDE was recently detected in toys available on the market in developing and developed countries, in products made of recycled plastic.

It should be noted, however, that many of the EHS databases included in this study do include information on hazards, exposures and risks associated with such chemicals. In fact, some of those chemicals and chemical families (e.g., brominated flame retardants such as OctaBDE, dioxins, furans, PCBs, Polycyclic Aromatic Hydrocarbons, etc.) are among the most thoroughly studied and characterized chemicals and EHS information about them is readily accessible from many of the databases that have been inventoried here. Even so, there remain important gaps in our knowledge about the hazards, exposures and risks posed by some of them.

### **Geographic and Languages Representation of EHS Databases**

Despite the broad geographic representation highlighted above, some regions (notably India, countries in the Middle-East, Africa and Latin America) currently contribute little to no EHS or regulatory information. This is likely to change in the not too distant future as several important chemical manufacturing countries (e.g., China, Brazil, Russia, etc.) and others (e.g., Colombia) either have recently adopted or are planning to adopt more robust industrial chemicals management legislation and regulations. Even still, important gaps in our knowledge of how chemicals are used and of exposures, particularly in developing countries remain that need to be addressed by collecting such information. A study published in 2012 by EPA scientists also highlighted the need for better exposure information.

This study collected the EHS information sources and databases for which English language descriptions were available. Even though this study included and briefly profiled the databases from China and Russia that are not in English, the focus of the current study has been compiling the most comprehensive information on EHS available in English, as the stepping stone. Evaluation of the databases from China and Russia was hampered due to existing language barriers. In the case of China, some commercial consulting firms that offer companies regulatory services have made unofficial English translations of some materials and summaries of them are included along in this report with links to their websites. Moreover, a new website [chemreg.net](http://chemreg.net) has recently been launched that has a searchable database of over 16,000 local regulations from 122 countries covering a wide range of scope and the owners have combined this with technologies that make it possible to search within the PDF files in any language, thereby effectively removing linguistic barriers and improving access.

Nevertheless, it would be useful in a future study, to inventory all the sources in UN languages rather than English (i.e. Arabic, Chinese, French, Russian and Spanish) and make them available to the public to ensure accessibility of information coming from different countries and regions. This future attempt will require the presence of a panel of experts with an excellent command of knowledge of the five UN languages in order to be able to conduct a thorough search and analysis of the EHS information available.

The study was also limited to EHS information sources that are accessible via the internet. It must be acknowledged that some areas of the world still have limited internet availability and for those who live there this can present a barrier to accessing the information.

The list of databases evaluated in the present study did not include sources of biomonitoring data<sup>6</sup>, e.g., US CDC's National Biomonitoring Program or EU's [COPHES and DEMOCOPHES](#), as it was judged that these data are likely to be very geographically-specific due to differences in local chemical use and exposure scenarios. As a consequence, the findings from those biomonitoring programs are not as generalizable to other contexts as compared to intrinsic hazard data which is more universally applicable. The weblinks to these databases have been provided above for those who may wish to explore their utility for their personal purposes.

Similarly, the current study did not emphasize chemical pollutant release and transfer databases, because again these data are likely to be very geographically specific and the data is not so easily extrapolated to other parts of the world. Moreover, advances in technology and emission measurement methods over time likely render the data difficult to compare. Nevertheless, several of the portals that have been included and profiled in the report do provide access to such databases. For example, the California DTSC's CIT includes links to multiple state, national and international pollutant and release databases, and both the USEPA's CHEMVIEW and the National Library of Medicine's TOXNET sites provide links to U.S. national data. The EU also maintains a similar web-based database called the European Pollutant Release and Transfer Register (E-PRTR).

## Chemicals in Products

There is a growing need/concern over available EHS information on several categories of chemicals including but not limited to chemicals in products (e.g. with the priority focus made on children's products, cosmetic and cleaning products, feminine hygienic products). Those who seek EHS and safe use information about everyday consumer products are often frustrated by a lack of information available about the identity of specific chemical ingredients used in those products. Indeed, this is an emerging issue that is being worked on through the SAICM framework and the Chemicals in Products Program of UN Environment where activities focus on increasing the availability and access to the information actors need – throughout the life-cycle of products – so that they can properly manage those products and the chemicals in them.

At their current state, a majority of the existing databases with EHS information profiled in this study, require the users to search the specific chemical ingredients in a certain product to be able to find the EHS information, if such information exists for that specific chemical ingredient.

To address this current gap to some extent, the current study made an attempt to identify several of databases which provide information on chemical ingredients in products and also voluntary initiatives by certain consumer and personal product sectors, individual producers and retailers who are working toward increased disclosure of the chemical ingredients in their products. Nonetheless, there is room for more work and information sharing to address growing consumer demands for transparency.

The EWG's Skin-Deep database, GoodGuide, the National Library of Medicine's Household Products database (accessible via TOXNET) and California's DTSC's Candidate Chemical list may offer possible models for providing users access to the EHS information they seek on consumer products. Within the

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<sup>6</sup> The measurement of biomarkers of chemical exposure in human blood, hair, saliva or urine.

US, some states (e.g., [California](#), [Washington](#) and [New York](#)) have recently adopted laws requiring manufacturers of certain products to disclose ingredients on their websites. Additionally, certain consumer and personal product sectors, as well as individual producers and retailers have voluntary initiatives underway to increase transparency of the chemical ingredients they use as well as across their global supply chains (e.g., see American Cleaning Institute's [Consumer Product Communication Initiative](#), International Fragrance Association's [Transparency List](#), [Seventh Generation](#), [Reckitt Benckiser](#), [Henkel](#), [Walmart](#), [Target](#), [Clorox](#), [DowDupont](#), [P&G](#), [SC Johnson](#), [Unilever](#)). Globally, the trend toward increasing ingredient disclosure is growing rapidly based on consumer demand for healthier products and full ingredient disclosure.

### **Nanomaterials**

In recent years, concerns have been growing about possible risks from exposures to nanomaterials. The term nanomaterials refers to materials that have at least one dimension (height, width or length) that is smaller than 100 nanometres ( $10^{-7}$  meter). This particular size dimension represents a major characteristic of manufactured nanomaterials (MNMs). The unique properties of MNMs may result in better performing products. However, for the same reason, MNMs may also present health hazards that differ from those of the substance in bulk form, and may require different test methods for hazard, exposure and risk assessment from their bulk material counterparts.

[As noted by WHO](#), there is currently a lack of precise information about human exposure pathways for MNMs, their fate in the human body and their ability to induce unwanted biological effects. Data from *in vitro*, animal and human MNM inhalation studies are available for only a few MNMs. So far, no long-term adverse health effects in humans have been observed. However, this could be due to the recent introduction of MNMs, the precautionary approach to avoid exposure and/or ethical concerns about conducting studies on humans. Health recommendations must, therefore, be based on extrapolation of the evidence from *in vitro*, animal or other studies from fields that involve exposure to nanoscale particles, such as air pollution, to the possible effects in humans. Workers who handle MNMs are likely to have the highest exposures, possibly placing them at increased risk for potential adverse health effects. Therefore, [the WHO recently promulgated guidelines](#) and has proposed them to policy makers and professionals in the field of occupational health and safety with recommendations on how best to protect workers from the potential risks of MNMs. The guidelines include an evaluation of EHS information that is presently available for approximately ten of the most commonly encountered MNMs. Even though, there is not yet a global registry specifically providing comprehensive information on nanomaterials, the EU has been developing an [Observatory for Nanomaterials](#) as well as [other activities under REACH to manage nanomaterials safely](#) in accordance with REACH and the CLP Regulation and to assess possible further legislative modifications.

### **Confidential Business Information (CBI) on Industrial Chemicals**

Confidential Business Information (CBI) claims can present a barrier to public access to some EHS information, however, CBI is a complex and frequently misunderstood or mischaracterized topic.

The Dubai Declaration, paragraph 22, states that: “we will ensure that, when information is made available, confidential commercial and industrial information and knowledge are protected in accordance with national laws or regulations or, in the absence of such laws and regulations, are protected in accordance with international provisions. In making information available, information on

chemicals relating to the health and safety of humans and the environment should not be regarded as confidential.”

Nearly all stakeholders, including business and industry, believe that EHS information that is necessary to recognize and successfully manage risks should be publicly accessible. A key chemical safety principle agreed by all SAICM stakeholders and included in the SAICM CiP Programme is that health and safety information about chemicals should not be regarded as CBI. However, there is disagreement among broader audiences on whether certain details beyond merely a summary of that information can be legitimately claimed as CBI. For example, business and industry and governments believe that, under certain circumstances, some information, such as specific chemical formulations (including specific ingredients and their proportions in the formulated product) and the underlying EHS study reports (e.g., animal test data) represent substantial financial investments, have commercial value and should be afforded CBI protection in order to encourage innovation. Although such detailed information is made available to the regulatory agencies on a case by case basis, only general descriptors or summaries are available to the public. Some stakeholders object to this.<sup>7</sup>

Regulatory agencies across the globe have strict rules in place that are intended to discourage CBI claims except when they can be truly justified. All such claims are heavily scrutinized by authorities and many are rejected. Even when CBI is granted, regulatory agencies retain the authority and discretion to publicly disclose CBI information in cases where urgent action is essential to protect human health, safety or the environment, such as emergency situations. Chemical control regulators also readily provide such information to other national regulatory bodies, including foreign governments, so that they have access to it to fulfill their own responsibilities. For example, amendments to the Toxic Substances Control Act (TSCA) expanded the categories of people who may now access information claimed as confidential business information (CBI) under TSCA. Information that a business claims as CBI under TSCA is protected from disclosure until the business withdraws the CBI claim, until the CBI claim expires, until EPA determines that the claim is not entitled to confidential treatment, or as authorized under TSCA and EPA regulations.

TSCA allows EPA, under certain conditions, to disclose CBI to:

- state, tribal, and local governments;
- environmental, health, and medical professionals; and
- emergency responders.

USEPA has [published its rules for claiming CBI under TSCA](#). Health and safety studies, information from health and safety studies, and certain other information may not be protected as CBI under TSCA. All claims of CBI must be substantiated by the manufacturer. Any non-exempt CBI claim that is submitted without a substantiation will be considered deficient, and USEPA will send a notice of deficiency to the affected business. The notice will inform the affected business that:

- it must submit its substantiation within 30 calendar days in order to remedy its deficient CBI claim; and
- if a timely substantiation has not been received by EPA within 30 days of receipt of the letter, any CBI claims not substantiated will be considered withdrawn, and the information may be made public with no further notice to the affected business.

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<sup>7</sup> A recent case is glyphosate (i.e. an active substance widely used in herbicides and its comprehensive re-evaluation on health risk assessment by [the German Federal Institute for Risk Assessment \(BfR\)](#)).

Although chemical identity can be claimed as CBI in some jurisdictions, chemical family must still be disclosed. CBI claims did not significantly inhibit the ability to estimate the numbers of industrial chemicals in commerce for this study, because even those chemicals for which CBI claims have been made are noted in the foundational databases (e.g., REACH and TSCA inventory) and can be enumerated.

Even when CBI has been claimed, there is still often useful EHS information publicly available for that chemical. For example, under EU REACH, even when CBI has been claimed, ECHA still has the legal obligation to make the following information publicly available:

- a. the name in the IUPAC nomenclature for substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:
  - I. hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.15 types A to F;
  - II. hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
  - III. hazard class 4.1;
  - IV. hazard class 5.1;
  - V. if applicable, the name of the substance as given in EINECS;
  - VI. the classification and labelling of the substance;
  - VII. physicochemical data concerning the substance and on pathways and environmental fate;
  - VIII. the result of each toxicological and ecotoxicological study;
  - IX. any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I;
  - X. the guidance on safe use provided in accordance with sections 4 and 5 of Annex VI;
  - XI. analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a hazardous substance when discharged into the environment as well as to determine the direct exposure of humans.

### **Combined Exposure to Multiple Chemicals**

As was noted in the [Global Chemicals Outlook 2013 report](#), most existing EHS information sources are limited to presenting hazards and risks associated with exposures to single chemical substances or simple mixtures and ignore the real-world reality that people have combined exposures to hundreds or thousands of chemicals simultaneously. Evaluating health effects from mixed exposures is a very complicated topic, because it isn't practical or feasible to test all or even a few possible permutations of combined exposures.

At OECD, the Working Party on Hazard Assessment in collaboration with the Working Party on Exposure Assessment has launched a formal program of work on risk assessment from combined exposures to multiple chemicals. A project team was formed and conducted information gathering, collected case studies and has held discussions on problem formulation and scoping, hazard, exposure and risk assessment in the context of combined exposures. A document has been developed on considerations for problem formulation and scoping, hazard assessment, exposure assessment, and risk characterization of combined exposure to multiple chemicals. The document was published in December 2018 and is available on the [OECD website](#). The major conclusions are as follows.

“There are an infinite number of chemical combinations to which humans and the environment can be exposed. Ensuring that the individual chemicals are adequately assessed and managed is a critical component of ensuring protection of human health and the environment. However, it is also important to consider the impacts of combinations of these chemicals. This document has provided elements to consider when assessing combined exposure to multiple chemicals. Given the diversity of possible combinations, and the diversity of ways of prioritising their examination (e.g. based on uses, releases vs similar effect profiles), the elements have not been presented in a strict manner; the application of different approaches and methods will depend on the assessment context and the problem formulation. However, it is clear that a tiered approach should be applied in order to identify where additional resources should be targeted for the refinement of assessment approaches, further data generation or gathering, or the consideration of risk management activities.”

USEPA is required by statute to evaluate exposures under certain circumstances: aggregate, that is combined exposures to a single agent from multiple routes and multiple pathways; and cumulative, that is combined exposure to multiple stressors (chemical and non-chemical) via multiple exposure pathways that affect a single biological target. They have developed a thoughtful and [rigorous approach](#) that may be useful for others to consider when they are faced with combined exposure scenarios.

In the EU, in 2012 three prominent scientific committees of the European Commission (on Consumer Safety, on Emerging and Newly Identified Health Risks, and on Health and Environmental Risks) studied the issue of combined exposures and issued a [consensus report](#) entitled *Toxicity and Assessment of Chemical Mixtures* in which they concluded the following:

1. Under certain conditions, chemicals will act jointly in a way that the overall level of toxicity is affected.
2. Chemicals with common modes of action will act jointly to produce combination effects that are larger than the effects of each mixture component applied singly. These effects can be described by dose/concentration addition.
3. For chemicals with different modes of action (independently acting), no robust evidence is available that exposure to a mixture of such substances is of health or environmental concern if the individual chemicals are present at or below their zero- effect levels.
4. Interactions (including antagonism, potentiation, and synergies) usually occur at medium or high dose levels (relative to the lowest effect levels). At low exposure levels, they are either unlikely to occur or are toxicologically insignificant.
5. In view of the almost infinite number of possible combinations of chemicals to which humans and environmental species are exposed, some form of initial filter to allow a focus on mixtures of potential concern is necessary. Several criteria for such screening are offered.
6. With regard to the assessment of chemical mixtures, a major knowledge gap at the present time is the lack of exposure information and the rather limited number of chemicals for which there is sufficient information on their mode of action. Currently, there is neither an agreed inventory of mode of actions, nor a defined set of criteria how to characterize or predict a mode of action for data-poor chemicals.
7. If no mode of action information is available, the dose/concentration addition method should be preferred over the independent action approach. Prediction of possible interaction requires expert judgement and hence needs to be considered on a case-by- case basis.

Based upon the above conclusions, the authors of the report proposed a decision tree for evaluating the risk of chemical mixtures. Once again, others who are faced with having to address combined exposures may find this information helpful to them.

The [EU member states are considering](#) whether ECHA should develop a searchable database for EHS information on chemical mixtures. Presently, under EU REACH, importers and downstream users are obliged to submit information on hazardous chemical mixtures to "appointed bodies" in each of the member states where the products are marketed. This information is made available to poison centers for use in emergencies involving those mixtures. The portal could have various functionalities, in particular it could dispatch captured information to the relevant appointed bodies, or it could store the information, and make it available to those bodies using a searchable database. Such a database could create efficiency gains for member states by shifting responsibility to ECHA for the management of submitted data.

### **Risk Management Measures**

Recommended risk management measures were not a particular focus of the current study, although they could be important to some information seekers, especially from developing countries. Fortunately, several of the databases (e.g., available from IPCS INCHEM, ICCA GPS Portal, and the databases which provide EHS regulatory decisions – see Table 3) do provide related information such as recommended exposure controls, restrictions on uses, and/or conditions for safe use.

### **Other Barriers to Accessing and Deploying EHS Information**

Although the current study has identified and evaluated numerous EHS information sources and this should benefit stakeholders who have a need for such information, it does not address other barriers that may exist to accessing and deploying this information. It has been suggested that some stakeholders may not use such data because it wasn't generated locally and/or for other reasons related to a lack of trust. This report has tried to describe the quality of information available from each source without rating or ranking it. Each stakeholder will need to conduct its own quality assessment according to its own specific needs. Such assessments should be conducted objectively and without bias.

### **Estimating Numbers of Industrial Chemicals in Commerce**

With respect to estimating the range of numbers of industrial chemicals in commerce, a variety of assumptions had to be made to compensate for a lack of verifiable data. The approach taken was to bracket the estimates by making two sets of assumptions, one of which was likely to err on the side of underestimating the count and the other which was likely to overestimate the count. Both sets of assumptions may be criticized on a number of grounds, but any alternative estimates that are offered by others will have to also make assumptions regarding the same missing parameters, i.e., degree of overlap in chemical identity between national/regional chemical inventories, absence of inventories for many parts of the world and uncertainty as to whether the inventories accurately reflect chemicals that are actually in commerce.

## **6. Conclusions and Recommendations**

This report has been written primarily to serve the needs of those who are seeking to find EHS and related regulatory information on one or more specific chemicals of interest to them and aspires to be a

helpful guide for locating and using publicly available information sources. It also aimed at improving the knowledge on the number of chemicals in commerce globally.

Strengthening the objective on Knowledge and Information Sharing of the Strategic Approach to International Chemicals Management (SAICM), this report improves access to knowledge on chemicals.

- This report identifies, describes and evaluates the largest and most comprehensive publicly available EHS information sources existing primarily in English, which has never been done before and will thereby improve access to the widest range of information for those who seek such information on industrial chemicals in commerce.

Of the more than 100 databases identified for analysis, forty-one make available EHS information and/or EHS-type regulatory decision information on industrial chemicals in commerce, including databases developed and maintained by inter-governmental organizations, regional groups, national governments and NGOs.

Each of the databases was classified into one of three distinct categories: (1) information portals that provide users the ability to simultaneously search multiple, third-party owned and managed EHS databases; (2) single, primary sources which provide access to EHS information on chemical substances; and (3) single, primary sources which provide access to EHS-type regulatory decisions made about chemical substances.

- The report offers information seekers with a strategy to make their searches for EHS information more efficient and productive.
- The quality criteria and differentiation of these databases on the basis of these criteria will help users to more readily find the EHS information that is relevant to their specific needs. The quality criteria included: scope of chemicals addressed, ease of access and use, breadth and depth of EHS information available, quality of the underlying information and procedures to update that information.

The seven information portals reviewed (the OECD eChemPortal, IPCS INCHEM, California DTSC's CIT and TIC, the ICCA GPS Chemical Portal, AJCSD, and TOXNET) provide users with the capability of searching many disparate individual EHS information sources (collectively >100) simultaneously, thereby increasing global reach, scale and efficiency. Such portals represent a helpful starting point for those who need a quick overview of what information might be available on a particular chemical substance. However, users should be cautious with interpreting and applying the output of their searches from these portals and must first consult the websites of the individual third party sources to fully understand the strengths and limitations of the underlying information.

The scope of the evaluated databases varies markedly. All of them were found to be easily accessed and used, although some sources provide published user guides to more easily facilitate basic and advanced searches. Breadth and depth of information vary considerably ranging from simple chemical identity and basic regulatory decisions to more detailed hazard, exposure and risk assessments and everything in between. The quality of the underlying EHS information also varies somewhat, but was generally considered to be good when judged against the pre-established criteria.

Twenty-four single, primary sources of EHS information were reviewed. Of those 24 databases, ECHA's CHEM, which provides EHS information on the 21,200 plus unique chemicals registered to meet EU REACH obligations, is the most comprehensive and should be among the first searched by users who seek both mammalian and environmental hazard, use, exposure, risk assessment and risk management information. It can be accessed directly or via several of the portals discussed above. Substantial hazard, use/exposure and risk information is available for chemicals at or above 1000 metric tonnes. Somewhat less information is available for lower volume substances, and substances below 10 metric tonnes have reduced information requirements (see Table B1). Even so, ECHA requires and makes publicly available an assessment of the risks of exposure for a full range of uses and exposure scenarios.

Ten databases (ECHA's Substances Restricted Under REACH List and Candidate SVHC List, Canada's Categorization Results, California DTSC Candidate List, USEPA's SRS, South Korea's NCIS, Australia's AICS, New Zealand's HSNO Register and NZIoC, and China's IECSC) provide EHS-type regulatory decisions on specific chemicals. They do not provide users with EHS information per se, but instead they provide key decisions that when combined with knowledge of the regulatory criteria used to make those decisions, give users insight as to how other governments view those chemicals and are taking regulatory actions to further investigate and manage the risks they pose to human health and/or the environment. Of those ten, Canada's Categorization Results database may be the most relevant for many users because it presents regulatory decisions on all 23,000 plus chemical substances identified as being in commerce in Canada. Many governments around the world continue to be challenged with characterizing the hazard and risks of chemicals and the results of Canada's efforts can possibly be leveraged by them for their own purposes.

- The report provides help to those who are looking for alternatives to more hazardous and risky chemicals by including several databases which focus on that goal. It also provides information on databases that are of interest for the Chemicals in Products programme of UN Environment.

Some of the databases reviewed (e.g., EWG's Skin-Deep, ChemSec's SIN list, GoodGuide, USEPA's Safer Choice Program, and those maintained by California's DTSC) have been developed for the express purpose of promoting safer alternatives to existing chemicals considered as possibly too hazardous or risky for consumer exposures. Furthermore, at least four of them (e.g., EWG's Skin-Deep, GoodGuide, National Library of Medicine's Household Products database (accessible from TOXNET) and California DTSC) place their focus on increasing transparency of the identity and hazard characteristics of chemicals used in specific consumer products.

- The report describes the various procedures that exist to validate the quality of EHS information, which helps juxtapose existing standards with opportunities for improvement of procedures and transparency globally.

Most governmental organizations provide for some type of peer review and solicit and incorporate public comment on their work, whereas the NGO databases, and the ICCA GPS Portal, do not include an external peer review process. About half of the sources of databases provide adequate descriptions of their procedures for keeping the information up to date. A few databases are intentionally static, with no intent to update the information they contain, and so users need to exercise caution when referencing information that is available from them.

- The report describes the latest tool developments and opportunities for alternatives to generating EHS knowledge which can more quickly and inexpensively close EHS information gaps and also supports further research and innovation in this area.

EPA's ACToR database is unique and distinct among the twenty-four primary EHS information sources because it is focused on helping users predict toxicity of a chemical substance that currently lacks mammalian and eco-toxicity data. Databases such as ACToR, and the suite of new tools and methods available from them, will likely gain increasing use in the next few years and offer great promise for rapidly closing remaining information gaps.

- The description and information on the scope, strengths, and limitations of each database will inform policy makers on how such databases on chemicals have been developed and how they are fit for purpose, which can support further developments in chemicals management policies at the national and global level. It will assist:
  - authorities in developing countries to access to EHS information on a wide range of industrial chemicals in commerce for use in GHS implementation;
  - to develop strategies for gathering local use and exposure information critical for conducting risk assessments and prioritizing chemicals for further risk management;
  - those who wish to pursue more complete EHS data sets to know where to find the most comprehensive information that is available and to identify remaining data for prioritized action to close them.
- This study provides policy-makers with sources of EHS information to assist their discussions on specific chemicals and chemical classes identified as concerns to SAICM (e.g., brominated flame retardants, perfluorinated chemicals, and others).

In addition, the report confirms that many gaps in EHS information have been reduced since the inception of SAICM in 2006. While nearly half of the 24 primary sources of EHS information pre-date the inception of SAICM in 2006, the largest and most comprehensive of them (e.g., The ECHA CHEM, USEPA CHEMVIEW and ACToR, Canadian Screening Level Assessments, Australia IMAP, EWG Skin-Deep, ChemSec SIN List and GoodGuide databases were clearly established during the post SAICM era were developed post-SAICM.

- The report further highlights policy and knowledge gaps, most notably on the number of industrial chemicals in commerce.

The estimated range found in this study is 40,000-60,000. These estimates vary based on the assumptions made about the degree of overlap between the chemicals produced and used across the globe. The main difficulties identified with enumerating the numbers of industrial chemicals in commerce and with comparing various competing estimates are discussed in the report and include: a lack of inventories of chemicals for many countries, uncertain and variable definitions of what's included under the rubrics of chemicals and even "industrial chemicals", varying volume thresholds for reporting, uncertainty as to whether chemicals initially notified to various governments still remain on the market, whether new chemicals notified since then were even ever brought to the market, duplicates, chemical identity being claimed as CBI, and unintended incentives for companies to over-report.

Not to be overlooked is a key fact that the vast majority of the total volume of production and sales is concentrated in a much smaller subset. Indeed, it is estimated that 6000 chemicals account for greater than 99% of the total volume produced and traded globally.

## **6.1. Recommendations**

All stakeholders may wish to quantify the size of the gaps in the EHS data and knowledge that exist for industrial chemicals in commerce. Such data and knowledge are critical to assessing chemicals to identify their potential hazards and risks so that they can be managed to protect human health and the environment.

Stakeholders also may wish to know whether enough is being done to prioritize the subset of chemicals that pose the greatest potential risks so that appropriate actions can be taken. Although individual national and regional government authorities are trying to identify and fill the gaps that exist, and while there are efforts underway globally to try to coordinate these efforts to avoid duplication and increase efficiency, there currently is no central repository for EHS information on chemicals in commerce. This is a barrier to advancing collective understanding of the scope and size of the problem.

One recommendation for future studies could be investigating the pressing gaps that exist in EHS information available on specific industrial chemicals in commerce such as for a group of chemicals considered as high priority (e.g. widely used chemicals in consumer products). A logical next step could be envisioned by selecting a statistically meaningful, random sample of chemical substances from one of the larger chemical inventories, e.g., USEPA TSCA and compare them against the EHS databases identified by this study to determine the percentage of chemicals that have information available, and the breadth, depth and quality of that information.

This study provided a comprehensive review of publicly accessible repositories of EHS information on chemicals in commerce which can act as a stepping stone for future research and studies into addressing several existing knowledge gaps in regard to chemicals in commerce such as (i) the number of hazardous chemicals on the market which would need to be labelled according to the GHS; (ii) the number of chemicals with complete risk assessments that have been prepared at the international or national levels; (iii) the number of chemicals that are on priority lists for potential phase out or severe restriction.

The chemical sector through several global initiatives and programmes on product stewardship (e.g. ICCA's Global Product Strategy, hazard identification and risk assessment trainings to build capacity, and its Responsible Care Programme) has been working toward the sound management of chemicals during the use and the end-of-life of chemicals. These efforts have identified that while the gaps in information on hazards have been shrinking, gaps in knowledge on chemicals uses and exposure scenarios persist. Global Chemical Outlook (GCO-II) discusses this topic in detail and introduces the sources of information on exposure. There is a gap in our knowledge and understanding on the exposure to the chemicals that have been phased-out or banned (i.e. legacy chemicals). Although there may be extensive hazard and risk information on these chemicals in existing EHS databases, as has been described in this study, exposure to these chemicals still can take place through unexpected pathways such as contamination of recycled products. This underscores a need to investigate the occurrence and levels of these type of

chemicals in recycled products and conduct exposure and risk assessments to ensure adequate protection of human health and the environment.

This study introduced multiple ongoing initiatives and databases which aim to share information with the public on chemicals used in consumer products. While these efforts are currently somewhat narrow in scope, the trend is toward greater transparency and fuller disclosure of ingredients due to public interest and demand. Consideration should be given to creating a central, comprehensive database (or several databases) to more easily facilitate consumer access to hazard, exposure and risk information on the chemical ingredients used in the products they purchase and use, perhaps with emphasis on children's products, cosmetic and cleaning products, and feminine hygiene products.

This study aims to inform information seekers on EHS and regulatory information on industrial chemicals and aspires to be a helpful guide for locating and using publicly available information sources. As a result, a next step for a deeper outreach with a broader audience, in particular consumers, could be to: publish a summary in the scientific, peer-review literature; and to develop media content such as a policy summary and/or a user-friendly web-based display of the EHS databases discussed in this study.

## Appendix A: Other Databases/Websites Identified by Various Stakeholders for Analysis

Database/Website	Brief Description	Reason for Exclusion
<a href="https://www.subsport.eu">https://www.subsport.eu</a>	SUBSPORT is a free-of-charge, multilingual platform for information exchange on alternative substances and technologies, as well as tools and guidance for substance evaluation and substitution management.	Does not provide EHS information on industrial chemicals in commerce.
<a href="http://www.bastaonline.se/about-basta/about-basta/?lang=en">http://www.bastaonline.se/about-basta/about-basta/?lang=en</a>	BASTA is a system for anyone who wants to make conscious product selections with the aim of phasing out substances of concern – for example building owners, contractors, architects, structural engineers or individuals.	Does not provide EHS information on industrial chemicals in commerce.
<a href="http://www.greenscreenchemicals.org/certified">http://www.greenscreenchemicals.org/certified</a>	GreenScreen® for Safer Chemicals is a method for chemical hazard assessment designed to identify chemicals of high concern and safer alternatives.	It is a methodology rather than an EHS information source on industrial chemicals in commerce.
<a href="http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/search-rechercheReq.do">http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/search-rechercheReq.do</a>	The Natural Health Product Ingredient Database provides an electronic tool which enables members of the public to access information on acceptable medicinal and non-medicinal	The scope of chemicals covered by this database is outside that of the study which focuses on industrial

Database/Website	Brief Description	Reason for Exclusion
	ingredients used in Natural Health Products (NHP)	chemicals in commerce.
<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/applications-submissions/product-licensing/licensed-natural-health-products-database.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/applications-submissions/product-licensing/licensed-natural-health-products-database.html</a>	The Licensed Natural Health Products Database contains information about natural health products that have been issued a product license by Health Canada.	The scope of chemicals covered by this database is outside that of the study which focuses on industrial chemicals in commerce.
<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html</a>	The Drug Product Database (DPD) to find drugs authorized for sale by Health Canada.	The scope of chemicals covered by this database is outside that of the study which focuses on industrial chemicals in commerce.
<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted.html</a>	The Lists of permitted food additives are Health Canada's official repository of substances that are permitted for use as additives in or on foods marketed in Canada.	The scope of chemicals covered by this database is outside that of the study which focuses on industrial chemicals in commerce.

Database/Website	Brief Description	Reason for Exclusion
<a href="http://pr-rp.hc-sc.gc.ca/pi-ip/index-eng.php">http://pr-rp.hc-sc.gc.ca/pi-ip/index-eng.php</a>	<p>The Pesticide Product Information Database was developed to allow interested members of the public to browse information on specific products, active ingredients, or programs related to pesticides that are regulated by Health Canada.</p>	<p>The scope of chemicals covered by this database is outside that of the study which focuses on industrial chemicals in commerce.</p>
<a href="http://www.cosmostox.eu/home/welcome/">http://www.cosmostox.eu/home/welcome/</a>	<p>COSMOS is a European Union project developing methods for determining the safety of cosmetic ingredients for humans, without the use of animals, using computational models.</p>	<p>The scope of chemicals covered by this database is outside that of the study which focuses on industrial chemicals in commerce.</p>
<a href="https://www.umweltbundesamt.de/en/portal/pop-dioxins-database-of-the-german-federation">https://www.umweltbundesamt.de/en/portal/pop-dioxins-database-of-the-german-federation</a>	<p>This site provides detailed information on persistent organic pollutants (POP) and explains the scientific background and criteria for evaluation of these pollutants. Site also features reports on these toxins as they pertain to the environment and health as well as a database with the conclusive results of tests.</p>	<p>The scope of chemicals covered by this database is outside that of the study which focuses on industrial chemicals in commerce.</p>

Database/Website	Brief Description	Reason for Exclusion
<a href="https://www.umweltprobenbank.de/en">https://www.umweltprobenbank.de/en</a>	<p>The long-term storage of environmental and human specimens is regarded as the main task of the German Environmental Specimen Bank: The Environmental Specimen Bank provides a continuous historical record of the state of the environment in Germany.</p>	<p>This database of tissue specimens was judged to be too geographically specific (i.e., to Germany) to include in the analysis.</p>
<a href="https://www.umweltbundesamt.de/en/database-pharmaceuticals-in-the-environment-0">https://www.umweltbundesamt.de/en/database-pharmaceuticals-in-the-environment-0</a>	<p>In a comprehensive literature review of 1016 original publications and 150 review articles, the German government compiled measured environmental concentrations of human and veterinary pharmaceutical residues reported worldwide in surface water, groundwater, tap/drinking water, manure, soil, and other environmental matrices in a systematic database.</p>	<p>The scope of chemicals covered by this database is outside that of the study which focuses on industrial chemicals in commerce.</p>
<a href="http://canais.abiquim.org.br/braz_new/">http://canais.abiquim.org.br/braz_new/</a>	<p>ABIQUIM, the Brazilian chemical industry association, maintains a database of chemical products that are produced or imported by its members.</p>	<p>No English language description could be found of the scope or methods by which the database was compiled or maintained.</p>

Database/Website	Brief Description	Reason for Exclusion
<a href="https://rifmdatabase.rifm.org/rifmweb/">https://rifmdatabase.rifm.org/rifmweb/</a>	The RIFM Database is the most comprehensive, worldwide source of toxicology data, literature and general information on fragrance and flavor raw materials.	The scope of chemicals covered by this database is outside that of the study which focuses on industrial chemicals in commerce.
<a href="http://scorecard.goodguide.com/chemical-profiles/">http://scorecard.goodguide.com/chemical-profiles/</a>	Scorecard provides detailed information on more than 11,200 chemicals, including all the chemicals used in large amounts in the United States and all the chemicals regulated under major environmental laws.	This database was judged to be redundant with information available from USEPA's CHEMVIEW database.

## Appendix B: Narrative Description and Evaluation of EHS Information

### Sources

This section of the report presents narrative descriptions of each of the EHS information sources that met the criteria for inclusion. Evaluation of the source compared to the quality criteria described above is preceded by an overview/description of that source.

#### ***B1. OECD eChemPortal***

The information presented below represents a summary of key information about the EHS information on industrial chemicals that is available from the Organisation for Economic Co-operation and Development's (OECD) [eChemPortal](#) – "The Global Portal to Information on Chemical Substances". For more detailed information, the reader should consult directly with the [OECD website](#).

The reader should also be aware that several of the most comprehensive data sources contributing information to the eChemPortal (e.g., ECHA CHEM, US EPA IRIS, OECD SIDS, etc.) are reviewed in greater detail in subsequent sections of this report.

##### ***B1.1. Overview/Description***

First launched in 2007, [eChemPortal](#) provides free public access to information on chemical properties and direct links to collections of information prepared for government chemical review programs at national, regional, and international levels. Access to information on existing chemicals, new industrial chemicals, pesticides and biocides is provided. eChemPortal also makes available national/regional classification results according to national/regional hazard classification schemes or according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). In addition, eChemPortal also provides exposure and use information on chemicals.

There are currently 34 databases participating and contributing information to eChemPortal. Each database is owned and managed by a separate organization with contributions from the governments of Australia, Canada, the European Union, Finland, France, Germany, Japan, New Zealand, the Nordic countries, United Kingdom and the United States, in addition to several international entities (e.g., OECD itself, UN Environment, World Health Organization and others).

eChemPortal provides links to individual websites for each of these databases as well as descriptions of the databases and review of data stored in them. The portal website also includes links that lead to existing scheduling information of national/regional and international assessments notified to the OECD by OECD member countries and stakeholders. They are provided with the aim to assist governments in avoiding duplication across national/regional programs in the area of chemical assessment.

The main objectives of eChemPortal are to:

- 1) make this information on existing chemicals publicly available and free of charge;
- 2) enable quick and efficient use of this information; and

3) enable efficient exchange of this information.

Though the eChemPortal web site is written in English, it can be searched by chemical names or synonyms in several languages (Czech, Danish, Dutch, French, German, Greek, Italian, Japanese, Korean, Portuguese, Slovak and Spanish).

The stated vision for eChemPortal is as follows: “eChemPortal maximizes access to information on chemicals for all stakeholders for whom such information is critical, regulators and industry, and benefits academics, international organizations and the general public - regardless of geography or purpose.

The OECD and its member countries are dedicated to protecting human health and the environment by promoting chemical safety worldwide. eChemPortal is a key OECD tool supporting this work. For all stakeholders, including in developing countries, eChemPortal will be the key tool for finding information to support health and environment decisions concerning chemicals.

eChemPortal aims to be the global Internet portal that provides free easy access to all existing information of regulatory relevance on chemicals by linking directly to collections of information prepared for government and international organization chemical programmes at national, regional, and international levels.

eChemPortal will expand the ability of governments to efficiently access information in order to share the burden of work, ensure resource efficiencies, and avoid duplication of work on assessment and, subsequently, reduce animal testing.

eChemPortal can help transform data into knowledge by encouraging users to build knowledge sharing communities around eChemPortal.

To facilitate the sharing of chemical data, eChemPortal was implemented using the common electronic data formats prescribed by the OECD Harmonized Templates for Reporting Chemical Test Summaries. This facilitates linking to databases with structured chemical property data also implemented according to the OECD Templates. eChemPortal was developed with the financial assistance of the European Chemicals Agency (ECHA) and has benefited from the contributions of governments, international organizations, non-governmental organizations and the chemical industry.

OECD is responsible for the development of the Portal itself. The data sources linked to eChemPortal are maintained by the participating organizations that create them. Each participating organization is responsible for the software and hardware running locally and interfacing with the Portal. The data and information stored in each participating data source are the responsibility of the data owner.

ECHA is responsible for the hosting of eChemPortal.

Proposals for linking new sources of data to eChemPortal can be made by any stakeholder represented at the OECD Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. The decisions on proposed extensions will be taken by the OECD Working Party on Hazard Assessment.

OECD actively encourages additional participation. Certain obligations come with participation.

### ***B1.2. Scope of Chemicals Addressed***

The scope of eChemPortal includes existing chemicals, new industrial chemicals, pesticides and biocides.

As of 4 June 2018, eChemPortal reports being able to access 683,634 substance records (not unique substances), 1,136,073 data endpoint records and 33,727 classification records. Four of the databases contribute EHS data endpoint records: CCR (Categorization Results from the Canadian Domestic Substance List), ECHA CHEM (ECHA's dissemination portal with information on chemicals registered under REACH), J-CHECK (Japan's CHEMicals Collaborative Knowledge Database), and OECD SIDS (Existing Chemicals Screening Information Data Set Database). Two of the databases contribute reviewed GHS classifications: ECHA C&L inventory (Public C&L Inventory according to the EU CLP Regulation (EC) No 1272/2008)) and GHS-J (GHS Classification Results by the Japanese Government).

### ***B1.3. Ease of Access and Use of Chemical Information***

eChemPortal allows searches not only by substance name and identification number but also by chemical property. Users can select specific search criteria for chemical endpoint properties. As with the search by substance, search results offer links to the complete data set in the participating data sources' local systems. In order to provide this search, data sources submit and eChemPortal stores property data in [the OECD Harmonized Template format](#).

A search by GHS classification was added to eChemPortal in 12 June 2015. This search allows users, for an individual chemical, to view GHS classifications which have undergone a review by a regulatory body or intergovernmental organization and offers direct links to the full information in the participating data sources.

[Detailed guidance](#) is available for those wishing to search the eChemPortal database.

### ***B1.4. Breadth and Depth of EHS Information Available***

The breadth and depth of EHS information available at eChemPortal varies considerably based on the contributing data source and substance being queried. Generalizing somewhat, extensive EHS data are available for pesticides, biocides, high volume chemicals and those chemicals that have been produced and used for longer durations and have been subject to more intensive government agency scrutiny based on their uses/exposures and suspected hazard properties.

Raw data measuring the properties of chemicals (physical chemical properties, environmental fate and behavior, eco-toxicity, and mammalian toxicology) from a full range of tests and models (e.g., Quantitative Structure Activity Relationships (QSR), computational toxicology methods, etc.) are available, as well as robust summaries of those data, hazard and exposure characterizations and risk assessments. eChemPortal also provides access to national/regional classification results according to national/regional hazard classification schemes or according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). In addition, eChemPortal provides also exposure and use information on chemicals.

A clear advantage of eChemPortal is that it can provide the user with rapid access to the full gamut of EHS information that is available on a particular substance from governments operating across a wide swath of the developed world.

### ***B1.5. Quality of the Underlying EHS Information***

In general, eChemPortal provides access to information that has been submitted to government chemical review programs. The data and information stored in each participating data source are the responsibility of the data owner. OECD cannot guarantee the correctness of the data and provides explicit warnings that it cannot be held responsible or liable for errors.

eChemPortal provides descriptions of the sources and of the peer review that the data has undergone on the pages describing each participating data source. Most governments have extensive procedures in place to assure the quality and reliability of the information they rely upon for making chemical safety assessments; however, users of the information should confirm the robustness of those procedures by checking with the relevant sources.

### ***B1.6. Procedures for Updating the Database with New Information***

Different data sources in eChemPortal use different methods to maintain and provide updates of their data with new information.

The methods vary from an automatic update via the Internet, semi-automatic update via the Internet, to a manual import of data files, depending on participating data source resources and the frequency of updates. Users are urged to consult with the individual participating data sources if they need to be assured that they have the most up-to-date information on a substance.

## ***B2 International Programme on Chemical Safety (IPCS)***

The information presented below represents a summary of key information about the EHS information on industrial chemicals that is available from the IPCS INCHEM Portal. For more detailed information, the reader should consult directly with the IPCS INCHEM website at <http://www.inchem.org/pages/about.html>.

The International Programme on Chemical Safety (IPCS) is a cooperative venture of the World Health Organization (WHO), the International Labour Organisation (ILO), and the United Nations Environment Programme (UN Environment). The central unit for IPCS is located at WHO in Geneva.

The IPCS was established following the international concern about chemicals expressed at the United Nations Conference on the Human Environment in 1972 and in response to the resolution of the World Health Assembly. It was set up to provide international assessments of the risks to health and the environment of chemicals and to strengthen capabilities and capacities in countries for sound management of chemicals.

The main objective of the IPCS is to carry out and disseminate evaluations of the effects of chemicals on human health and the quality of the environment. Supporting activities include the development of epidemiological, experimental laboratory, and risk-assessment methods that could produce internationally comparable results, and the development of manpower in the field of toxicology. Other activities carried out by the IPCS include the development of know-how for coping with chemical accidents, coordination of laboratory testing and epidemiological studies, and promotion of research on the mechanisms of the biological action of chemicals.

IPCS INCHEM was produced in order to consolidate relevant data on chemical information which are available from international bodies. It is a portal that provides a means of rapid access to information on chemicals commonly used throughout the world, which may occur as contaminants in the environment.

### ***B2.1. Overview/Description***

The United Nations Conference on Environment and Development (UNCED), held in 1992, elaborated strategies and measures to increase national and international efforts to promote sustainable and environmentally sound development in all countries. Environmentally sound management of chemicals was one of the issues where an international strategy was elaborated, and six programme areas were proposed for strengthened national and international efforts, including information exchange on toxic chemicals and chemical risks.

Among the recommendations of UNCED was that the collaboration between WHO, ILO and UN Environment on the IPCS should be the nucleus for strengthened international cooperation and that an intergovernmental mechanism for risk assessment and management of chemicals should be established.

In response to these recommendations, a mechanism for strengthened collaboration among international programmes has been set up through the Inter-Organization Management Committee (IOMC), in which the three IPCS Collaborating Organizations WHO, ILO and UN Environment have joined with the Food and Agriculture Organization of the United Nations (FAO), the United Nations Industrial Development Organization (UNIDO), and the Organization for Economic Co-operation and Development (OECD). Further, an Intergovernmental Forum on Chemical Safety (IFCS or the Forum) has been established as a mechanism for cooperation among governments for promotion of risk assessment and sound management of chemicals.

One of the recommendations of the IFCS in relation to information exchange on toxic chemicals and chemical risks was that relevant data from international bodies should be consolidated, if economically feasible, by 1997 on CD-ROM or other appropriate electronic media, together with suitable searching and updating facilities. As of this writing, IPCS provides a portal for searching for EHS information from 13 separate databases which are described further below.

### ***B2.2. Scope of Chemicals Addressed***

The scope of chemicals addressed by IPCS INCHEM is very broad and includes chemicals commonly used throughout the world, which may occur as contaminants in the environment. Thus, it includes: industrial chemicals, biocides, pesticides and other substances.

### ***B2.3. Ease of Access and Use of Chemical Information***

The IPCS INCHEM is available on CD-ROM and [online](#). The CD-ROM and the website have been developed with the cooperation of the Canadian Centre for Occupational Health and Safety (CCOHS) and as a result of financial support from a number of donors to the IPCS, particularly the governments of Canada, Netherlands, Norway and the United Kingdom.

IPCS INCHEM offers quick and easy electronic access to thousands of searchable full-text documents on chemical risks and the sound management of chemicals, helping countries fulfill their commitments under UNCED's Agenda 21, Chapter 19.

Searches may be done for all of the participating databases at once or by specifying individual databases. The search tool is quite powerful and flexible using the Verity Query Language to find the information users may be looking for. [The Quick Reference Card](#) starts with an overview of searching options and moves from simple searches using a single word or phrase to more complicated searches using many search terms. Many examples are available as an aid for users to formulate their own searches.

[A more in-depth guide](#) is available for those who want to conduct more advanced searches.

### ***B.2.4. Breadth and Depth of EHS Information Available***

(For ease of presentation, the information pertinent to sections B.2.4, B.2.5 and B.2.6 have been combined below)

### ***B.2.5. Quality of the Underlying EHS Information***

(See below)

### ***B.2.6. Procedures for Updating the Database with New Information***

IPCS INCHEM provides access to the following sources of EHS information on chemicals.

- Concise International Chemical Assessment Documents (CICADS)
- Environmental Health Criteria (EHC) Monographs
- Harmonization Project Publications
- Health and Safety Guides (HSGs)
- International Agency for Research on Cancer (IARC) — Summaries and Evaluations
- International Chemical Safety Cards (IFCS)
- IPCS/CEC Evaluation of Antidote Series
- Joint Expert Committee on Food Additives (JECFA) — Monographs and Evaluations
- Joint Meeting on Pesticide Residues (JMPR) — Monographs and Evaluations
- Kemi-Riskline
- Poisons Information Monographs (PIMs)
- Screening Information Data Sets (SIDS) for High Production Volume Chemicals
- UK Poison Information Documents (UKPID)

EHS information available from each of these 13 sources are described below.

### **B.2.6.1. Concise International Chemical Assessment Documents (CICADS)**

CICADS represent the latest in a family of publications from IPCS and join the Environmental Health Criteria documents (EHCs) as authoritative documents on the risk assessment of chemicals. They are available for approximately 80 chemicals or chemical families.

CICADs are concise documents that provide summaries of the relevant scientific information concerning the potential effects of chemicals upon human health and/or the environment. They are based on selected national or regional evaluation documents or on existing EHCs. Before acceptance for publication as CICADs by IPCS, these documents have undergone extensive peer review by internationally selected experts to ensure their completeness, accuracy in the way in which the original data are represented, and the validity of the conclusions drawn.

The primary objective of CICADs is characterization of hazard and dose-response from exposure to a chemical. CICADs are not a summary of all available data on a particular chemical, rather, they include only that information considered critical for characterization of the risk posed by the chemical. The critical studies are, however, presented in sufficient detail to support the conclusions drawn. For additional information, the reader should consult the identified source documents upon which the CICAD has been based.

Risks posed to human health and the environment will vary considerably depending upon the type and extent of exposure. Responsible authorities are strongly encouraged to characterize risk on the basis of locally measured or predicted exposure scenarios. To assist the reader, examples of exposure estimation and risk characterization are provided in CICADs, whenever possible. These examples cannot be considered as representing all possible exposure situations, but are provided as guidance only.

While every effort is made to ensure that CICADs represent the current status of knowledge, new information is being developed constantly. Unless otherwise stated, CICADs are based on a search of the scientific literature to the date shown in the executive summary. In the event that a reader becomes aware of new information that would change the conclusions drawn in a CICAD, the reader is requested to contact the IPCS to inform it of the new information.

### **B.2.6.2 Environmental Health Criteria (EHC) Monographs**

EHC publications are monographs containing comprehensive data from scientific sources and are designed for scientists and administrators responsible for the establishment of safety standards and regulations. This series issued by the International Programme on Chemical Safety (IPCS), provides basic scientific risk evaluation of a wide range of chemicals, groups of chemicals, biological and physical agents. EHC monographs are available on approximately 200 agents and a further 20 or more EHC's are written to address various methodological issues in hazard characterization and risk assessment.

EHC monographs are based on a comprehensive search of available original publications, scientific literature and reviews and examine: the physical and chemical properties and analytical methods; sources of environmental and industrial exposure and environmental transport, chemo-biokinetics and metabolism including absorption, distribution, transformation and elimination; short and long term

effects on animals (carcinogenicity, mutagenicity, and teratogenicity); and finally, an evaluation of risks for human health and the effects on the environment.

The EHC series are published by the WHO and hard copies can be obtained from the Office of Distribution and Sales, World Health Organization, 1211 Geneva 27, Switzerland.

### **B.2.6.3. Harmonization Project Publications**

The WHO/IPCS Project on the Harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals ("Harmonization Project"), aims to harmonize global approaches to risk assessment by:

- increasing understanding and agreement on basic risk assessment principles
- developing international guidance documents on specific issues.

The Project enables risk assessments to be performed using internationally accepted methods and these assessments can then be shared to avoid duplication of effort. It translates\* advances in scientific knowledge into new harmonized methods, promotes transparency in risk assessment, and reduces unnecessary testing of chemicals. The project benefits all those involved in chemical hazard/risk assessment (chemical assessment authorities and other risk assessment bodies, professionals, and researchers).

Although these publications are of keen interest to those who practice chemical risk assessments, they do not contain EHS information on specific chemicals and therefore are not directly relevant for purposes of the current project on knowledge management and information sharing for sound management of chemicals.

### **B.2.6.4. Health and Safety Guides (HSGs)**

HSGs provide concise information in non-technical language, for decision-makers on risks from exposure to chemicals, with practical advice on medical and administrative issues. They are available for approximately 110 chemicals and physical agents. Note, nearly all of these documents were authored from the mid-1980's to the mid-1990's and thus caution should be exercised since it is unlikely that they contain the most up to date scientific information available. They are published by WHO and hard copies can be obtained from the Office of Distribution and Sales, World Health Organization, 1211 Geneva 27, Switzerland.

### **B.2.6.5. International Agency for Research on Cancer (IARC) - Summaries and Evaluations**

The IARC Monographs identify environmental factors that can increase the risk of human cancer. These include chemicals, complex mixtures, occupational exposures, physical agents, biological agents, and lifestyle factors. National health agencies can use this information as scientific support for their actions to prevent exposure to potential carcinogens.

Interdisciplinary working groups of expert scientists review the published studies and evaluate the weight of the evidence that an agent can increase the risk of cancer. The principles, procedures, and scientific criteria that guide the evaluations are described in the Preamble to the IARC Monographs.

Since 1971, more than 1000 agents have been evaluated, of which more than 400 have been identified as carcinogenic, probably carcinogenic, or possibly carcinogenic to humans.

For answers to commonly asked questions on the evaluation process, read [the IARC Monographs Q&A](#).

Funding for IARC Monographs has been received from:

- United States National Cancer Institute
- United States National Institute of Environmental Health Sciences
- European Commission Directorate-General for Social Affairs, and Inclusion (initially from the Unit of Health, Safety and Hygiene at Work, and since 2014, from the European Union programme for Employment and Social innovation)

### **B.2.6.6. International Chemical Safety Cards (ICSC)**

ICSC are developed cooperatively by the IPCS, the Commission of the European Union (EC), WHO and ILO. They summarize essential health and safety information on chemical substances in a clear way, and are not only intended to be used at the "shop floor" level by workers, but also by other interested parties in factories, agriculture, construction and other places of work. They are available for approximately 1800 chemicals.

Draft versions of the card containing a summary of health and safety information are prepared by cooperating scientific institutions. These institutions have the task of collecting and validating the relevant information. The cards are then peer-reviewed by a committee consisting of internationally-recognized experts who consider advice given by manufacturers, workers' representatives and poisons centers.

ICPS are published by the Commission of the European Union, and hard copies can be obtained from the Office for Official Publications of the European Union, 2 rue Mercier, L-2985 Luxembourg.

### **B.2.6.7. IPCS/EC Evaluation of Antidotes Series**

This series provides definitive and authoritative guidance on the use of antidotes to treat poisoning. IPCS and EC are jointly undertaking a major project to evaluate antidotes used clinically in the treatment of poisoning. The aim of this project is to identify and evaluate for the first time in a scientific and rigorous way the efficacy and use of a wide range of antidotes. This series summarizes and assesses, on an antidote-by-antidote basis, their clinical use, mode of action and efficacy. The aim is to provide an authoritative consensus statement which will greatly assist in the selection and administration of an appropriate antidote. This scientific assessment is complemented by detailed clinical information on routes of administration, contra-indications and precautions. The series collates a wealth of useful information which will be of immense practical use to clinical toxicologists and all those involved in the treatment and management of poisoning. As of this writing, evaluations of fewer than 10 antidotes are available.

The IPCS/EC Antidotes Series are published by Cambridge University Press and hard copies can be obtained from Cambridge University Press, Cambridge CB2 2RU, England.

#### **B.2.6.8. JECFA (Joint Expert Committee on Food Additives) - Monographs and Evaluations**

Toxicological evaluations of food additives and contaminants and of residues of veterinary drugs in food, produced by the Joint WHO/FAO Expert Committee on Food Additives JECFA, are used by the Codex Alimentarius Commission and national governments to set international food standards and safe levels for protection of the consumer.

The monographs provide the toxicological information upon which the JECFA makes its evaluations. These monographs are prepared by scientific experts and peer reviewed at the JECFA meetings.

As of this writing, nearly 1200 JECFA Monographs are available and JECFA Summary Evaluations are available for approximately 2300 chemical substances.

#### **B.2.6.9. JMPR (Joint Meeting on Pesticide Residues) - Monographs and Evaluations**

Toxicological evaluations of pesticides, produced by the WHO/FAO Joint Meeting on Pesticide Residues JMPR, are used by the Codex Alimentarius Commission and national governments to set international food standards and safe levels for protection of the consumer.

The monographs provide the toxicological information upon which the JMPR makes its evaluations. These monographs are prepared by scientific experts and peer reviewed at the JMPR meetings.

As of this writing, monographs are available for more than 1000 pesticides. Although pesticides are explicitly excluded from the scope of the current project, they remain an interest of many SAICM stakeholders and thus these monographs and evaluations will have utility for some readers of this report.

#### **B.2.6.10. Kemi-Riskline**

The Swedish Criteria Group for Occupational Standards – consensus reports and criteria documents. These documents are produced by the Swedish Criteria Group (SCG) and the Nordic Expert Group (NEG).

The SCG consists of about 15 scientific experts representing different fields of science, such as toxicology, occupational hygiene and occupational medicine. Their main task is to produce consensus reports and criteria documents to be used by the Swedish Work Environment Authority (SWEA) as the scientific basis for setting occupational exposure limits (OELs) for chemical substances in Sweden. The secretariat of the group is run by the SWEA and is located at Karolinska Institute in Stockholm, Sweden.

In most cases, a document is produced on request to the group from the SWEA. Evaluations are made of all relevant published original papers for a substance found in searches in relevant databases. Consensus reports are concise documents that summarize and evaluate scientific data relevant for setting an occupational exposure limit. They do not give a summary of all available data on a particular chemical,

but the particular studies that are important for establishing dose-effect/dose-response relationships and critical effect(s), are described in detail.

A draft consensus report (or sometimes a more comprehensive criteria document) is written by the secretariat or by a scientist appointed by the secretariat. A qualified evaluation is made of the information in the references. After discussions in the SCG, the draft is approved and accepted as a consensus report from the group. The SCG does not propose a numerical occupational exposure limit value for a substance, but, as far as possible, provides a dose-response/dose-effect relationship and the critical effect of occupational exposure. The documents are published in English, as well as in Swedish, by the University of Gothenburg in the scientific serial *Arbete och Hälsa*.

The main task of the NEG for Criteria Documentation of Health Risks from Chemicals is to produce criteria documents to be used by the regulatory authorities of the Nordic countries as the scientific basis for setting occupational exposure limits (OELs) for chemical substances. NEG consists of scientific experts from the Nordic countries (Denmark, Finland, Norway and Sweden) representing different fields of science, such as toxicology, epidemiology and occupational medicine.

The documents are risk evaluation reports, and constitute comprehensive reviews based on a thorough search of the scientific literature. The documents comprise data on physical and chemical properties, occurrence and use, analytical methods, occupational exposure, toxicokinetics, biological monitoring, and effects in animals and man. Finally, an evaluation of human health risks based on dose-effect/dose-response relationships and the identification of the critical effect(s) is made. No numerical values on OELs are given, as this is done at the national level, according to country-specific procedures. No information on environmental fate and effects is included.

The documents are published by the University of Gothenburg in the scientific serial *Arbete och Hälsa*.

The scientific serial *Arbete och Hälsa* is also available in the Kemi-Riskline database.

There are approximately 55 documents available; however, most provide evaluations of several chemicals each, so the total number of chemicals covered exceeds 150. Note, these documents were authored at various points in time during the past 30 years and thus caution should be exercised since it is unlikely that they all contain the most up to date scientific information available. Moreover, this database is no longer being updated.

#### **B.2.6.11. Poisons Information Monographs (PIMs)**

This is a global database with evaluated information on substances (chemicals, pharmaceuticals, poisonous plants, and poisonous and venomous animals) commonly involved in cases of poisoning. A PIM is a concise, practical document designed to facilitate the work of poisons information specialists, clinicians, and analysts.

The PIM is more than a simple monograph and part of a database. It is a dynamic document which represents an international consensus on the diagnosis, management and prevention of poisonings. It also constitutes the basis for training, a source of scientific reference and a stimulus for international cooperation amongst poisons centers and clinical toxicology units around the world.

The PIMs are prepared by collaborating poisons information centers and other experts throughout the world and are subjected to individual and peer review. PIMs summarize the physico-chemical and toxicological properties of the substance, the medical features of the effects produced by various routes of exposure to the substance, the patient management and the supporting laboratory investigations.

PIMs are available for approximately 80 chemicals, 100 pharmaceutical agents, 6 poisonous animals and more than 30 poisonous plants.

#### **B.2.6.12. OECD Screening Information Data Sets (SIDS)**

Note: for a fuller description of the SIDS program please reference the chapter on OECD Existing Chemicals (SIDS) below.

These documents summarize the literature on high production chemicals and provide an initial assessment for decision-makers. Only a small part of the SIDS is available from this source for approximately 400 chemicals. Note, since these documents were authored between 10 and 20 years ago and have not been updated, caution should be exercised in using them since it is unlikely that they contain the most up to date scientific information available. All the SIDS published until 2014 are available in the OECD Existing Chemicals database, searchable also through the OECD's eChemPortal.

#### **B.2.6.13. UK Poison Information Documents (UKPID)**

UKPID are detailed chemical and pharmaceutical monographs produced for poison centers by the UK National Poisons Information Service Centers. They are available for approximately 85 chemicals. No information could be found on how the UKPID are produced or updated.

### ***B3 OECD Existing Chemicals Screening Information Dataset (SIDS) Database***

The information presented below represents a summary of key information about the environmental, health and safety information on industrial chemicals that is available from the Organization for Economic Cooperation and Development's (OECD) Existing Chemicals Database.

#### ***B.3.1. Overview/Description***

From 1988 to 1998, the program focused primarily on the investigation of high production volume (HPV) chemicals, based on the assumption that production volume is a surrogate for data on occupational, consumer and environmental exposure.

For a few years prior to 2010, regulatory-binding comprehensive chemical assessment programmes (e.g., EU REACH, Canada's efforts to screen all chemicals on its market, etc.) started to be implemented at the national or regional levels, making the voluntary OECD HPV Chemicals Programme less attractive for sponsors to participate in the way it was initially designed.

This evolution forced led the OECD to invent ways to adapt the programme to maximize the usefulness of national or regional products for synergy between national or regional chemicals assessment programs and the OECD HPV Chemicals Programme. In 2010, the Cooperative Chemicals Assessment Programme was established, based on the previous High Production Volume (HPV) Chemicals Programme to better respond to the changing needs of member countries; it addresses a number of member country challenges, such as: assessing more chemicals in a shorter period of time; addressing all chemicals on the market; and avoiding duplication of on-going work in other countries. This evolution also promoted integrated approaches to testing and assessment. These approaches encourage the regulatory acceptance of non-test data, allow reduction of animal testing, and enable the assessment of larger numbers of chemicals based on e.g. similarity in structure, mode of action, metabolic pathways, etc.

Since From 2010 - 2014, the Programme continued to examine full SIDS assessments, and also encompasses assessments covering a sub-set of SIDS endpoints or non SIDS endpoints (targeted assessment) for chemicals of sufficient global interest, be they HPV or non HPV chemicals. Another new feature was the assessment of groups of chemicals for a sub-set of SIDS or non SIDS endpoints (e.g. bioaccumulation or carcinogenicity).

At the end of 2014, the Programme was again updated. A focus of the Working Party on Hazard Assessment includes to facilitate and support the work of the OECD on the hazard assessment of chemicals including:

- harmonization of hazard assessment methodologies and integrated approaches to testing and assessment
- elaboration of OECD-wide agreed hazard assessments
- improving sharing of and access to information on chemicals

This includes the development of harmonized novel methodologies for assessing the hazards of chemicals to:

- ensure consistency
- generate confidence and support for integrating novel tools and approaches into regulatory decision-making
- increase the mutual acceptance of hazard assessments in order to avoid duplication of efforts

Types of Output:

- Case studies on using novel methods for regulatory decision-making
- Application of Adverse Outcome Pathways
- Integrated approaches to testing and assessment
- QSAR Toolbox

The focus of the current COCAP programme is the development of case studies on Integrated Approaches to Testing and Assessment ([see OECD Website](#)) and assessment of combined exposures to multiple chemicals. A strong focus of the new OECD Programme is also the use of in silico methods such as the (Q)SAR Application Toolbox for predicting or estimating (eco-)toxic or fate properties, or simply to support weak experimental results.

Going forward there are four main program areas:

- I. Elaboration and dissemination of OECD-wide agreed conclusions on hazards of chemicals;

II. Development and application of integrated approaches to testing and assessment;

III. Avoiding duplication; and

IV. Providing a forum to exchange experience in member countries

V. Elaboration and dissemination of OECD-wide agreed conclusions on hazards of chemicals:

Until 2014, the focus of the Programme is to derive OECD-wide agreed hazard assessments of chemicals; its scope includes HPV chemicals as well as non-HPV, new and existing industrial chemicals. There continues to remain a possibility for countries to elaborate agreed hazard assessments.

The Screening Information Data Set (SIDS) is the reference data set to perform an initial assessment. Full SIDS initial assessments, which address all SIDS endpoints for chemicals and chemical categories, are sponsored and prepared by member countries and the chemical industry. Hazard assessments prepared by the chemical industry and authorities (in the context of national/regional and industry programmes) were submitted to the programme with minimal rewriting and reformatting. However, the general objectives of the SIDS Initial Assessment Report and SIDS Dossier had to be met when submitting full SIDS assessments.

The Programme generated targeted assessments, i.e. hazard assessments that address a limited number of hazard endpoints short of the full SIDS assessment, or for other non-SIDS hazard endpoints. The purpose of elaborating targeted assessments is to increase the availability of internationally agreed hazard assessments (even if it is on a limited number of endpoints) and improve efficiency. Specific types of chemicals, such as metals/inorganics, petroleum substances or polymers are also addressed in addition to developing the necessary guidance to assess the hazards of these substances.

Member countries and industry shared the task of elaborating and reviewing hazard assessments for chemicals, while maintaining the current OECD high quality of assessments. Industry could submit draft assessments either via a sponsor country, which performed a first review of the assessment, or directly through the Business and Industry Advisory Committee to OECD (BIAC).

The status of all chemicals being assessed in the Programme as well as access to final agreed assessments is available in the [OECD Existing Chemical Database](#). OECD-wide agreed hazard assessments are also disseminated via the OECD eChemPortal.

Agreed conclusions were regularly published in a collection of cooperative chemicals assessments in the OECD Series on Testing and Assessment.

I. Development and application of Integrated Approaches to Testing and Assessment:

The Programme develops integrated approaches to testing and assessment and improves their regulatory acceptance by applying them to actual hazard assessments elaborated within the Programme.

Efforts continue to focus on expanding the chemical category concept, which has proven so successful over the last 10 years. New ways of grouping chemicals into toxicologically appropriate categories, e.g. according to mechanisms or modes of action, are also being investigated.

The Programme continues to improve the expertise in and regulatory acceptance of (Q)SAR methodologies in general, via an improved collaboration between (Q)SAR experts and hazard assessors and trainings.

As new types of data such as genomics or high-throughput in vitro test results become available, the Programme investigates how such data sets can be used to characterize the hazards of chemicals.

## II. Avoiding Duplication

As member countries implement their national/regional programmes to assess more chemicals in a shorter timeframe, the potential for duplication of work increases, the eChemPortal continues to improve access to existing hazard information and assessments, including GHS classifications and underlying datasets. The Programme is also a forum to share future plans for chemical assessment within countries and regions and to discuss possible partnerships, so contributing to the goal of avoiding duplication.

## III. Providing a Forum to exchange experience in Member countries

The Programme is a forum to exchange experience among member countries to avoid duplication of effort and identify issues for collaborative work. Examples of topics for exchange of information and experience are:

- National/regional and industry-developed methodologies for hazard assessment
- Priority setting
- Categorization of inventories
- GHS classifications
- Effects from exposure to multiple chemicals
- Assessment of endocrine disruptors
- Case study assessments of nanomaterials

### ***B3.2. Scope of Chemicals Addressed***

The scope included HPV chemicals as well as non-HPV, new and existing industrial chemicals. HPV chemicals are defined as all chemicals reported to be produced or imported at levels greater than 1,000 tonnes per year in at least one OECD member country or in the EU region. The decision means that member countries cooperatively:

- selected the chemicals to be investigated;
- collected characterization, effects and exposure information from government and public sources and encouraged industry to provide information from their files;
- completed the agreed dossier for the Screening Information Data Set (SIDS) by testing; and
- made an initial assessment of the potential hazard of each chemical investigated.

Targeted assessments for other specific types of chemicals, such as metals/inorganics, petroleum substances or polymers may also be addressed in addition to developing the necessary guidance to assess the hazards of these substances. As of this writing, conclusions and assessment reports have been published for nearly 1500 chemicals.

### ***B3.3. Ease of Access and Use of Chemical Information***

The database has a comprehensive search facility allowing searches for chemical information based on selected criteria. For example, data on individual chemicals can be searched, or the chemical information can be searched according to whether it has been sponsored (e.g. in the case of HPV chemical), who sponsored it, its SIDS process status, ICCA status, or type of assessment (targeted/non-targeted). Further information on search criteria is included in the “Help” section.

In addition to searching for specific user-defined information, the database also contains several useful lists and reports, for example, users can view a list of all sponsored chemicals by country or an alphabetical list of all chemical categories. Under “Reports”, for example, the “Overall Status” report allows users to view the statistics on the status of all chemicals that have been assessed in the programme.

### ***B3.4. Breadth and Depth of EHS Information Available***

The content of the Screening Information Data Set (SIDS) was adopted in November 1989 and revised in February 2000. The SIDS content is organized under five headings:

- Substance Information (identity, quantity, and exposure through use patterns),
- Physical Chemical Properties (melting point, boiling point, vapor pressure, partition coefficient, water solubility, dissociation constant, and Redox potential),
- Environmental Fate (photo-degradation, stability in water, transport and distribution between environmental compartments, including distribution pathways and aerobic biodegradation),
- Environmental Toxicology (acute toxicity to fish and aquatic invertebrates (e.g. Daphnia), toxicity to aquatic plants (e.g., Algae), and conditionally chronic toxicity to terrestrial species, fish and invertebrates) and
- Mammalian Toxicology (acute and repeated dose toxicity, in vitro genetic toxicity, conditionally in vivo genetic toxicity, and reproductive/developmental toxicity and any available human epidemiology evidence).

Detailed information on SIDS required content is available online.

For physical-chemical properties, environmental fate and environmental toxicity, a cautionary statement is added whenever modeled data on inorganic substances are provided, as the model used may have limitations (e.g. outside the applicability domain) for inorganic chemicals.

For the purpose of gathering data for compiling a SIDS Dossier for either a full SIDS assessment or a targeted assessment, robust study summaries for each entry of the Dossier were prepared. OECD Templates exist for this purpose. These templates exist for all hazard endpoints, SIDS and non SIDS.

A chemical assessment contains: i) an assessment report discussing the key findings for each hazard endpoint covered in the assessment, ii) a profile summarizing the conclusions for each hazard endpoint,

and iii) study summaries or robust study summaries for data gathered on each hazard endpoint covered in the assessment (either separately or as part of the assessment report).

When a draft chemical hazard assessment was available from a sponsor, an initial assessment of the information was undertaken, and conclusions are drawn on the potential hazard(s) posed by the chemical. The chemical assessment can cover all SIDS endpoints or a subset of SIDS endpoints (i.e. targeted assessment), with the addition of non-SIDS endpoints occasionally. Until 2014, a Cooperative Chemicals Assessment Meeting (CoCAM) was organized twice a year to discuss draft chemical assessments submitted by sponsors and to agree on hazard conclusions. The conclusions present a summary of the hazard(s) of the chemical, written with sufficient detail and clarity as to be informative and to assist countries with classification work and other hazard- based national decision making; and succinct exposure information to put the hazard information into context (e.g. on use of the chemical(s) in the sponsor country).

### ***B3.5. Quality of Underlying EHS Information***

The hazard conclusions agreed at a CoCAM were endorsed by both the Working Party on Hazard Assessment (formerly the Task Force on Hazard Assessment) and the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology consecutively. Summary conclusions were published in the OECD Existing Chemicals Database. When the hazard assessment (including the assessment report and study summaries) was finalized, it was made available to the public via the Existing Chemicals database. The hazard assessment itself can be lodged on a government website, in the Existing Chemicals database itself or on the UNEP Chemicals website. Once agreed and finalized in the OECD, the database contains all documents associated with the final published assessment (profiles, assessment reports and dossiers).

This database tracks all chemicals in the OECD cooperative Chemicals Assessment Programme. High production volume (HPV) chemicals are tracked from the time that they are identified as an HPV to OECD until a full SIDS assessment has been completed. Other chemicals (such as targeted assessments) are tracked from either the time they are identified to OECD or when they are submitted for discussion at a CoCAM through completion. The database contains any annotations on each chemical provided to the Secretariat by member countries.

The summaries and evaluations contained in this assessment report may be based on unpublished proprietary data submitted for the purpose of the OECD assessment.

In many cases, national/regional regulatory authorities will not accept a regulatory submission based on the summaries and evaluation of unpublished proprietary data contained in this [these] assessment report[s] unless they have received the data on which the summaries and evaluation are based, either from:

- the owner of the data; or
- a second party that has obtained permission from the owner of the data for this purpose; or
- alternatively, the applicant has received permission from the data owner that the summary and evaluation contained in this [these] assessment report[s] may be used in lieu of the data; or
- following expiry of any period of exclusive use, mandatory compensation, where required, has been offered unless the period of protection for the proprietary data concerned has expired.

### ***B3.6. Procedures for Updating the Database with New Information***

New information is included in the database only when it has been notified to OECD by Member Countries. A search of the database finds that many of the published assessments are 15-20 years old, and thus some caution should be exercised since it is unlikely that they all contain the most up to date scientific information available.

### ***B4 European Chemicals Agency (ECHA) EHS Databases***

The information presented below represents a summary of key information about the environmental, health and safety information on industrial chemicals that is available from ECHA.

ECHA is an agency of the European Union which manages the technical, scientific and administrative aspects of the implementation of the European Union regulation called Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). ECHA is the driving force among regulatory authorities in implementing the EU's chemicals legislation. ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern. It is located in Helsinki, Finland. The Agency started working on 1 June 2007.

For a fuller discussion of ECHA and REACH, please consult directly with the [ECHA website](#).

#### ***B4.1. Overview/ Description***

The main piece of legislation in the European Union (EU) for regulating chemicals is known as REACH, which stands for Registration, Evaluation, Authorization and Restriction of Chemicals. REACH was formally adopted and came into force on 1 June 2007.

Companies are responsible for collecting information on the properties and uses of the substances they manufacture, import or use above one tonne a year. They also have to assess the hazards and potential risks presented by the substance. This information is communicated to ECHA through a registration dossier containing the hazard information and, where relevant, an assessment of the risks that the uses of the substance may pose and how these risks should be controlled.

There is a special transitional regime for substances which were already manufactured or placed on the market before 1 June 2007 when REACH entered into force. Such substances are called “phase-in” substances. For these “phase-in” substances, the REACH Regulation established the following registration deadlines:

30 November 2010

Deadline for registering substances manufactured or imported at 1,000 tonnes or more a year; substances that are carcinogenic, mutagenic or toxic to reproduction above 1 tonne a year; and substances dangerous to aquatic organisms or the environment above 100 tonnes a year.

31 May 2013

Deadline for registering substances manufactured or imported at 100-1,000 tonnes a year.

31 May 2018

Deadline for registering substances manufactured or imported at 1-100 tonnes a year.

If a manufacturer or importer does not register by the deadlines, the substance may not be manufactured in the EU or placed on the EU market until after it has been registered.

All substances that did not meet the criteria for “phase-in” substances were considered as “non-phase-in” substances. Normally, “non-phase-in” substances were not manufactured, placed on the market or used in the EU before 1 June 2008, (unless they were notified under the Dangerous Substances Directive). Potential manufacturers and importers of “non-phase-in” substances must submit an inquiry to ECHA and subsequently register the substance before they can manufacture or import the substance. All substances notified under the Dangerous Substances Directive (also called NONS) are considered to be registered under REACH and ECHA assigned registration numbers to all the notifications.

ECHA receives and evaluates individual registration dossiers from companies or, if the company is not based in the EU, from only-representatives (OR), to ensure compliance, and the EU Member States evaluate selected “prioritized” substances to clarify initial concerns for human health or for the environment. Authorities and ECHA's scientific committees assess whether the risks of substances can be managed. Authorities can ban hazardous substances if their risks are unmanageable. They can also decide to restrict a use or make it subject to a prior authorization.

## ***B4.2. Scope of Chemicals Addressed***

The scope of chemicals addressed by REACH is very clearly described and is quite comprehensive. Registration is required for all substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer unless they are exempted from the scope of registration (see below for a list of exemptions). The registration requirement applies to all substances irrespective of whether they are hazardous or not. This includes substances on their own, in mixtures or substances in articles when they are intended to be released under normal or reasonably foreseeable conditions of use.

For all registrations, a registration dossier has to be prepared and submitted electronically to ECHA. The information that the registrant has to provide in the registration dossier will depend on the volume (tonnes manufactured or imported per year) of the substance to be registered.

The definition of a substance under REACH is very broad and includes not only chemicals whether hazardous or not, but every type of substance manufactured in or imported into the EU.

It includes substances which are already closely regulated by other legislation such as radioactive substances, medicines, food or foodstuffs, biocides or pesticides. These substances are completely or partially exempted from REACH registration requirements, because they were already heavily regulated by other pieces of EU regulation. Other substances within the scope of specific pieces of legislation, e.g. food-packaging and cosmetics, although subject to registration, have reduced risk assessment requirements under REACH.

Registration is based on the "one substance, one registration" principle. This means that manufacturers and importers of the same substance have to submit their registration jointly. The analytical and spectral information provided must be consistent and sufficient to confirm the identity of the substance.

Accurate identification of a substance is a pre-requisite for REACH registration. In particular, it enables joint registrations to be prepared efficiently and correctly and ensures that test data is appropriate for the substance registered under REACH. This leads to a robust hazard and risk assessment of the registered substance.

Typically, the identity of a substance can be described by:

- chemical name, for example, benzene;
- number, for example, European Community (EC) number 200-753-7, and
- chemical composition, for example, >99 % benzene and <1% toluene. The composition is determined by chemical analysis.

A fee is usually charged for substance registration

The registration obligations apply to the individual substances themselves, independent of whether they are on their own, in a mixture or in an article. In other words, only substances have to be registered under REACH, mixtures or articles do not.

Substance means a chemical element and its compounds. The term substance includes both substances obtained by a manufacturing process (for example formaldehyde or methanol) and substances in their natural state. The term substance also includes its additives and impurities where these are part of its manufacturing process, but excludes any solvent which can be separated without affecting the stability of the substance or changing its composition. Detailed guidance on substances and substance identity can be found in the Guidance on identification and naming of substances under REACH and Classification, Labelling and Packaging (CLP).

Mixture means a mixture or solution composed of two or more substances. Typical examples of mixtures under REACH include paints, varnishes and inks. REACH obligations apply individually to each of the substances contained in the mixture depending on whether the individual substances are within the scope of REACH.

When contained in a mixture, each individual substance needs to be registered if the threshold of one tonne per year is reached. The registration obligation applies to the manufacturer or importer of each individual substance, or in case that the mixture is imported as such, to the importer of the mixture.

An article is an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition (e.g. manufactured goods such as textiles, electronic chips, furniture, books, toys, kitchen equipment). An individual substance in an article is subject to the registration obligations in case it is present in the article in quantities over one tonne per year and the substance is intended to be released under normal or reasonably foreseeable conditions of use. The registration obligation applies to the producer of the article or, in case the article is imported, to the importer, insofar as the substance has not been registered for that use.

The following substances are exempt from REACH:

- Radioactive substances
- Substances under customs supervision (e.g., in temporary storage, in a free zone or a free warehouse with a view to re-exportation, etc.)
- substances used in the interest of defense and covered by national exemptions
- waste (any substance or object which the holder discards or intends or is required to discard)
- non-isolated intermediates (an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place)
- transported substances (unless they are manufactured, imported or used within the EU).
- substances that present minimum risk because of their intrinsic properties (like water, nitrogen, etc.).
- substances for which registration is deemed inappropriate or unnecessary (such as substances occurring in nature like minerals, ores and ores concentrates if they are not chemically modified).
- polymers (however, monomer substances or any other substances they consist of must be registered under certain conditions).
- certain substances that are adequately regulated under other pieces of legislation, like substances used in food or foodstuffs or in medicinal products.
- Additional exemptions from registration apply to substances that are already registered and are either exported and re-imported into the EU or recovered through a recovery process in the EU.
- substances used for the purpose of research and development
- substances which are considered the active ingredients in biocides and plant protection products (these substances are already considered to be registered because they have undergone extensive evaluation and risk assessment under the auspices of other pieces of EU legislation)
- substances which were notified according to Directive 67/548/EEC which introduced a notification requirement for so-called new substances, which were substances not appearing on the European Inventory of Existing Commercial Chemical Substances (EINECS). (The EINECS list contains, in principle, all substances on the Community market on 18 September 1981. Notifications made in accordance with Directive 67/548/EEC contain much of the technical dossier information which the REACH Regulation aims to have assembled by registrants through the registration requirement.)

### ***B4.3. Ease of Access and Use of Chemical Information***

ECHA maintains a database of pertinent information on substances registered under REACH that is easily accessible and searchable.

Navigating the database is straightforward, easy and self-explanatory. Scrolling over selected data fields often produces pop-up text boxes which provide fuller explanations and definitions of those fields and possible limitations of the data that may exist. It is difficult to envision how it could be made simpler for users.

The data comes from registration dossiers submitted to ECHA by companies who registered their substances. ECHA publishes information included in the registrations dossiers on its website to make it freely available for the public so they can have access to information on any potential risks of the chemicals that they are using. The information ECHA has published covers the identity of the substance, the results of studies on its intrinsic properties and hazard profiles, the levels where no adverse effects are expected for human health or the environment, its classification and labelling, as well as guidance on

its safe use. If not claimed confidential, ECHA will also publish on the substance its degree of purity essential for classification and labelling, total tonnage band, (robust) study summaries, information in the safety data sheet and the trade name.

Before submitting their dossiers, registrants have the opportunity to request that certain data be kept confidential and to check what information will be publicly available. Requesting confidentiality applies only to a limited set of data and requires a justification, which will be evaluated by ECHA. In case the confidentiality request(s) is rejected by ECHA, the registrant can ask the Agency to review the rejection decision.

ECHA warns visitors to its website “Please note that some of the information on registered substances may belong to third parties. The use of such information may therefore require the prior permission of the third-party owners. Please consult the Legal Notice for further information.”

As of 20 August 2018, ECHA’s database of registered substances contained 21,248 unique substances and information from 88,851 dossiers. The difference between the number of unique substances registered and the number of dossiers is easily explained and is due to the fact that, while REACH requires multiple producers or importers of the same substance to work together to submit a common registration, individual companies must still file their own dossiers.

ECHA’s database is searchable by any of the following (see Figure B1):

- **Substance Identity**
  - substance name (EC Name, regulatory process names, non-confidential IUPAC names and all public names provided by registrants). Full or partial names can be used to search the data base.
  - Chemical Abstract Service (CAS) registry number (format nnnnxx-xx-x).
  - European Community (EC) number or list number (format xxx-xxx-x). EC assigned numbers start with 2, 3, 4 or 5. Those starting with 6, 7, 8 or 9 have been assigned by ECHA.
  - other numerical identifiers such as Classification, Labelling and Packaging (CLP) Annex VI Index number. If more than one type of identifier is selected, the results will include substances where at least one match is found for one of the selected types.
  
- **Administrative Data**
  - registration type (REACH Full registration, REACH Intermediate registration, NONS notification).
  - submission type (individual or joint)
  - country in which the registrant is registered.
  - First published date
  - Last update date
  - Name of registrant(s) (name of those companies which have registered the substance or which are suppliers of the substance. Full or partial company names can be used.)
  - Registration number (REACH registration number. Full or partial registration numbers can be used.)
  
- **Substance Data**
  - Tonnage band (tonnage band manufactured and / or imported per year to the European Economic Area (EEA) (EU 27 + Iceland, Liechtenstein and Norway).)

- Tonnage band range (extracted for the last year reported on the tonnage manufactured or imported, unless the tonnage band has been claimed confidential. The Total Tonnage band published does not necessarily reflect the registered tonnage band(s).)
- Substance has nanoform (yes or no; reported as Nanomaterial in a composition or physical state, or there is a Nanomaterial Endpoint Study reported on a registered substance.)
- PBT (Persistent Bioaccumulative Toxic) assessment outcome (Note that data on PBT assessment outcome may be claimed confidential and is not yet available for all disseminated substances since the relevant field was only made available from the IUCLID 5.4 release.)
- CAS (Chemical Safety Assessment) performed (yes, no or confidential).
- **Uses and Exposure**
  - Life-cycle (If a life cycle is selected, searches return substances with registered dossiers where there is at least one use within the selected life cycle category.)
    - Consumer Uses
    - Article service life
    - Widespread uses by professional workers
    - Formulation or re-packing
    - Uses at industrial sites
    - Manufacture
  - Search operator (And/Or; The search operator applies to both Lifecycle and Category. If the search operator is defined as AND, searches will return substances with at least one use for all selected life cycle categories AND containing uses with all selected use descriptors. If the search operator is defined as OR searches will return substances where there is at least one use reported in the registered dossier matching any of the selected search criteria.
  - Category (Search for registered substances with specific uses and exposure.)
  - Product category (42 separate product use categories)
  - Sector of use (24 separate sector of use categories)
  - Process category (28 separate process categories)
  - Environmental release category (26 separate environmental release categories)
  - Article category (81 separate article categories)

## Figure B1 Screen Shot of Search Page

REGULATIONS
PUBLIC CONSULTATIONS
INFORMATION ON CHEMICALS
SUPPORT

[ECHA](#) > [Information on Chemicals](#) > [Registered substances](#)

### Registered substances

The data comes from registration dossiers submitted to ECHA by the date indicated as last update. The Total Tonnage Band is compiled from all the dossiers with two exceptions; any tonnages claimed confidential and any quantity used as an intermediate to produce a different chemical. The Total Tonnage band published does not necessarily reflect the registered tonnage band(s).

Please note that some of the information on registered substances may belong to third parties. The use of such information may therefore require the prior permission of the third party owners. Please consult the *Legal Notice* for further information.

Please note that information on chemical properties of registered substances is directly accessible via *eChemPortal*.

[Chemical Property Data Search](#)

**FURTHER INFORMATION**

- [Registered substances information](#)
- [How to determine what will be published \(Data Submission Manual 15\)](#)
- [Understanding REACH Regulation](#)
- [Q&A on registered substances](#)
- [Give us your feedback](#)
- [eChemPortal](#)
- [REACH study results download](#)

Last updated 01 February 2018. Database contains 17535 unique substances and contains information from 67053 dossiers.

**Substance Identity**

Substance name:  CAS number:

EC / List number:  Other Numerical Identifiers:

**Administrative data**

Registration type:

Submission type:  Individual  Joint

Country in which registered:

First published date: - from -  - to -

Last update date: - from -  - to -

Registrant name:

Registration number:

**Substance data**

Tonnage band:

Select total tonnage band range:

Substance has nanoform:

PBT assessment outcome:

CSA performed:

**Uses and exposure**

Life cycle:  Consumer Uses  
 Article service life  
 Widespread uses by professional workers  
 Formulation or re-packing  
 Uses at industrial sites  
 Manufacture

Category:

Search operator:

[View all Registered Substances](#)

Although one could forgo the use of the search tools and simply scroll through the list of registered substances to find a substance of interest, the enormous size of the database would make this a rather daunting task.

Once one is able to locate the substance(s) of interest, a simple click of the mouse on the name of the substance opens additional tabs which contain substance-specific information as described below.

#### B4.4. Breadth and Depth of EHS Information Available

The breadth and depth of environmental, health and safety information available on each registered substance will vary depending on REACH requirements which are largely dictated by its volume, somewhat modified by uses and exposures. The potential data available can be vast and deep or rather superficial if exposures and risks are likely to be minimal. For instance, substances manufactured/imported/used at quantities less than 10 tonnes per year have reduced information requirements. Table B1 below [summarizes the information](#) required for substances produced and/or imported within specified tonnage bands. Note that since this table was published, ECHA now accepts an extended one-generation reproductive toxicity test in lieu of the two-generation test.

**Table B1**  
**REACH standard information requirements**

REACH standard information requirements				
The requirements below have to be adapted, waived or increased, according to the rules given in columns 1 and 2 of annexes VII to X and according to annex XI.				
≥ 1000 t/year (annexes VII + VIII + IX + X)				
100-1000 t/year (annexes VII + VIII + IX)				
10-100 t/year (annexes VII + VIII)				
1-10 t/year (annex VII)				
Toxicological information	<ul style="list-style-type: none"> <li>Skin irritation or skin corrosion (in vitro)</li> <li>Eye irritation (in vitro)</li> <li>Skin sensitisation</li> <li>Mutagenicity (in vitro, gene mutation bacteria)</li> <li>Acute toxicity (oral route)</li> </ul>	<ul style="list-style-type: none"> <li>Skin irritation (in vivo)</li> <li>Eye irritation (in vivo)</li> <li>Mutagenicity (in vitro, cytogenicity mammalian cells or micronucleus)</li> <li>Mutagenicity (in vitro, gene mutation mammalian cells)</li> <li>Acute toxicity (inhalation)</li> <li>Acute toxicity (dermal route)</li> <li>Repeated dose toxicity (28 days, one species)</li> <li>Reproductive toxicity (screening, one species)</li> <li>Toxicokinetics (assessment from available information)</li> </ul>	<ul style="list-style-type: none"> <li>Repeated dose toxicity (28 days, one species)*</li> <li>Repeated dose toxicity (90 days, one species, rodent)</li> <li>Reproductive toxicity (pre-natal development, one species)</li> <li>Reproductive toxicity (two generations, one species)</li> </ul>	<ul style="list-style-type: none"> <li>Reproductive toxicity (developmental, one species)</li> <li>Reproductive toxicity (two generations, one species)*</li> <li>Carcinogenicity study</li> </ul>
	<small>* These studies have to be carried out if they have not been completed for the lower tonnage band because of waiving</small>			
Ecotoxicological information	<ul style="list-style-type: none"> <li>Aquatic toxicity (short term, invertebrates)</li> <li>Aquatic toxicity (short term, aquatic plants)</li> <li>Degradation (biotic, readily biodegradability)</li> </ul>	<ul style="list-style-type: none"> <li>Aquatic toxicity (short term, fish)</li> <li>Aquatic toxicity (activated sludge respiration, inhibition testing)</li> <li>Degradation (abiotic, hydrolysis function of pH)</li> <li>Fate and behaviour in the environment (adsorption/desorption screening)</li> </ul>	<ul style="list-style-type: none"> <li>Aquatic toxicity (long term, invertebrates)</li> <li>Aquatic toxicity (long term, fish)</li> <li>Degradation (biotic, surface water)</li> <li>Degradation (biotic, soil)</li> <li>Degradation (biotic, sediment)</li> <li>Degradation (biotic, identification of degradation products)</li> <li>Fate and behaviour in the environment (bioaccumulation, aquatic species)</li> <li>Fate and behaviour in the environment (further information on adsorption/desorption)</li> <li>Effects on terrestrial organisms (short term, invertebrates)</li> <li>Effects on terrestrial organisms (soil micro-organisms)</li> <li>Effects on terrestrial organisms (short term, plants)</li> </ul>	<ul style="list-style-type: none"> <li>Degradation (biotic, further testing)</li> <li>Fate and behaviour in the environment (further information)</li> <li>Effects on terrestrial organisms (long term, invertebrates)</li> <li>Effects on terrestrial organisms (long term, plants)</li> <li>Effects on sediment organisms (long term)</li> <li>Effects on birds (long term or reproductive)</li> </ul>
	Physico-chemical properties	<ul style="list-style-type: none"> <li>State of the substance at 20°C and 101.3 kPa</li> <li>Melting/freezing point</li> <li>Boiling point</li> <li>Relative density</li> <li>Vapour pressure</li> <li>Surface tension</li> <li>Water solubility</li> <li>Partition coefficient n-octanol/water</li> <li>Flash-point</li> <li>Flammability</li> <li>Explosive properties</li> <li>Self-ignition temperature</li> <li>Oxidising properties</li> <li>Granulometry</li> </ul>	<ul style="list-style-type: none"> <li>Stability in organic solvents and identity of relevant degradation products (if substance stability is considered to be critical)</li> <li>Dissociation constant</li> <li>Viscosity</li> </ul>	

ECHA presents the information in a layered manner, with progressively more detailed information available to the user as they click their way through the links.

Once the user clicks on the name of the substance, they are taken to a summary page that lists the following information (note clicking on some of the information will take the user to additional information -- see Figure B2):

- Substance identity, including EC list number, CAS number and Molecular formula
- Hazard classification and labeling warnings, including iconographic symbols
- Properties of concern (e.g., carcinogenic, reproductive hazard, etc.)
- Important to know (e.g., use restrictions under REACH)
- Precautionary measures to be taken
- Guidance on safe use of the substance
- Tonnage data (unless declared confidential)
- Consumer uses
- Article service life
- Widespread uses by professional workers
- Formulation and re-packing
- Uses at industrial sites
- Manufacture
- Regulation and Regulatory Activities (i.e., CLP, REACH, Existing Substances Regulation (ESR))
- Other names for the substance (if they exist)

## Figure B2

### Screen Shot of Substance Information

An agency of the European Union English (en)

**ECHA**  
EUROPEAN CHEMICALS AGENCY

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REGULATIONS: REACH CLP BPR PIC PUBLIC CONSULTATIONS INFORMATION ON CHEMICALS SUPPORT

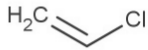



ECHA > Substance Information

## Substance information

Infocards are automatically generated based on industry data. [What is an infocard?](#) RSS

**Chloroethylene**  
Vinyl Chloride

Other names: Regulatory process names [4] Trade names [24] Other names [2] IUPAC names [14] BP

<p><b>Substance identity</b> ?</p> <p><b>EC / List no.:</b> 200-831-0</p> <p><b>CAS no.:</b> 75-01-4</p> <p><b>Mol. formula:</b> C<sub>2</sub>H<sub>3</sub>Cl</p> <p></p>	<p><b>Hazard classification &amp; labelling</b> ?</p> <p> </p> <p><i>Danger!</i> According to the <b>harmonised classification and labelling (CLP00)</b> approved by the European Union, this substance may cause cancer and is an extremely flammable gas.</p> <p></p>	<p><b>Properties of concern</b> ?</p> <p>C</p> <p><b>Important to know</b> ?</p> <ul style="list-style-type: none"> <li>Some uses of this substance are restricted under <a href="#">Annex XVII of REACH</a>.</li> </ul> <p><b>How to use it safely</b> ?</p> <ul style="list-style-type: none"> <li><a href="#">Precautionary measures</a> suggested by manufacturers and importers of this substance.</li> <li><a href="#">Guidance on the safe use of the substance</a> provided by manufacturers and importers of this substance.</li> </ul>
--	--	--

**About this substance** ?

This substance is manufactured and/or imported in the European Economic Area in 1 000 000 - 10 000 000 tonnes per year.

This substance is used in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

**Consumer Uses**

ECHA has no public registered data indicating whether or in which chemical products the substance might be used. ECHA has no public registered data on the routes by which this substance is most likely to be released to the environment.

**Article service life**

Release to the environment of this substance can occur from industrial use: manufacturing of the substance, for thermoplastic manufacture and in the production of articles. Other release to the environment of this substance is likely to occur from: indoor use in close systems with minimal release (e.g. cooling liquids in refrigerators, oil-based electric heaters), outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials) and [...](#)

about INFOCARD - Last updated: 18/12/2017


Near the bottom of the page there is a link to the REACH registration dossier (alternatively the user can click on the symbol for an eye on the right-hand side of the line listing the name of the chemical). A click on the dossier opens an additional tab that contains the following information (see Figure B3):


**Figure B3**  
**Screen Shot of Available EHS Information**


Use of this information is subject to copyright laws and may require the permission of the owner of the information, as described in the ECHA Legal Notice.


## Chloroethylene


EC number: 200-831-0 | CAS number: 75-01-4  
Vinyl Chloride


  
General information


  
Classification & Labelling & PBT assessment


  
Manufacture, use & exposure


  
Physical & Chemical properties


  
Environmental fate & pathways


  
Ecotoxicological information

  
Toxicological information

  
Analytical methods

  
Guidance on safe use

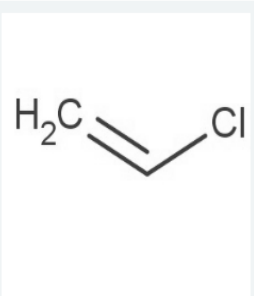
  
Assessment reports

  
Reference substances

### General information

[Identification](#) | 
 [Compositions](#) | 
 [Registration data](#) | 
 [Administrative data](#) | 
 [Contact Persons responsible for the SDS](#)

#### Identification



Display Name:	Chloroethylene
EC Number:	200-831-0
EC Name:	Chloroethylene
CAS Number:	75-01-4
Molecular formula:	C2H3Cl
IUPAC Name:	chloroethene

#### Type of substance

Composition:	mono-constituent substance
Origin:	organic

#### Other names

Trade names:	1-Chloroethene
	1-Chloroethylene
	chlorek winylu
	Chlorethene
	chloroethene

- 
- General Information (substance identification, trade names, tonnage band, publication dates, type of REACH registration, chemical safety assessment completed, names of registrants, administrative data (see above for description), contact person for Safety Data Sheets)
  - Classification and Labelling and PBT Assessment
  - Manufacture, Use and Exposure information, including uses advised against
  - Physical and Chemical Properties (an extensive list is available)
  - Environmental Fate and Pathways
    - Endpoint summary
    - Stability
    - Biodegradation
    - Bioaccumulation
    - Transport and distribution
    - Environmental data
    - Additional information on environmental fate and behavior
  - Ecotoxicological Information
    - Ecotoxicological Summary
    - Aquatic toxicity
    - Sediment toxicity
    - Terrestrial toxicity
    - Biological effects monitoring
    - Biotransformation and kinetics
    - Additional ecotoxicological information
  - Toxicological Information (includes human epidemiology information, if available)
    - Toxicological Summary
    - Toxicokinetics, metabolism and distribution
    - Acute Toxicity
    - Irritation / corrosion
    - Sensitization
    - Repeated dose toxicity
    - Genetic toxicity
    - Carcinogenicity
    - Toxicity to reproduction
    - Specific investigations
    - Exposure related observations in humans
    - Toxic effects on livestock and pets
    - Additional toxicological data
  - Analytical Methods
  - Guidance on Safe Use
    - First-aid measures
    - Fire-fighting measures
    - Accidental release measures
    - Handling and storage
    - Transport information
    - Exposure controls / personal protection
    - Stability and reactivity
    - Disposal considerations

- Assessment Reports
- Reference Substances

A further click on each of the sections above expands the data available for viewing by the user. Often times, there will be an endpoint summary available that provides a high-level narrative overview of the environmental, health and safety evidence that exists which can be very useful for those users who need only a synopsis.

There are literally dozens of documents and thousands of pages available from the ECHA website that provide guidance for registrants on how to prepare their registration dossiers and chemical safety assessments (CSA). It is very complex. Separate documents describe strategies and methods for searching the literature to identify existing EHS evidence on substances, how to document such searches, evaluating and rating individual studies for quality and reliability, using Quantitative Structure Activity Relationship models and other read across techniques, identifying data gaps vs REACH information requirements, determining whether additional ecotoxicology or toxicology testing is required, developing testing strategies, specifying test methods that must be used and dictating Good Laboratory Practices are followed, testing waiving proposals, and how to conduct weight of the evidence evaluations. Registrants are strongly encouraged to provide information sources, reference to test methods and justifications as appropriate in the hazard assessment. If they deviate from the standard method, they are encouraged to provide information that can be understood by an independent reviewer.

At the heart of the registration dossier is the CSA. According to ECHA, “The chemical safety assessment (CSA) of a manufacturer shall address the manufacture of a substance and all the identified uses. The chemical safety assessment of an importer shall address all identified uses. The chemical safety assessment shall consider the use of the substance on its own (including any major impurities and additives) and in mixtures. The assessment shall consider all stages of the life cycle of the substance resulting from the manufacture and identified uses, including the service life of the substance in articles and the waste life stage. The chemical safety assessment shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance considering implemented and recommended risk management measures and operational conditions.”

According to REACH guidance, for each environmental protection target (e.g., organisms ranging from microorganisms through aquatic and terrestrial predators), a conclusion on the substance hazard has to be reported and can be one of the following:

- A Predicted No-Effect Concentration (PNEC) can be derived (judged by ECHA to be the most common situation): quantitative risk characterization is carried out. This consists of comparing the actual predicted substance exposure concentration (PEC) in an environmental compartment (water, soil or air) with the related PNEC. This is done separately for each of eleven environmental protection targets or
- No PNEC can be derived and: No hazard is identified for that protection target; therefore, no exposure assessment is required; A hazard is identified or cannot be excluded and therefore a qualitative risk characterization has to be carried out.

A description of the derived PNECs and PECs and/or qualitative risk characterizations can be found under the ecotoxicological information section listed above.

In addition, for substances that are manufactured/imported/used in quantities of 10 tonnes per year or more a Derived Minimum Effect Level (DN(M)EL) must be calculate for the CSA for every relevant human population and every relevant route, duration and frequency of exposure, if feasible. REACH requires a risk characterization be completed for the leading health effect (i.e., the toxicological effect that results in the most critical DNEL) for a given exposure pattern (duration, frequency, route and exposed human population) associated with an exposure scenario (ES). It is to be noted that one exposure pattern can fit to more than one ES.

For workplace exposure, there may already exist occupational exposure limits (OELs). Under certain circumstances OELs and/or the underlying information used for setting the OELs can be used to derive the DNEL.

REACH requires differences between effect assessment data and the real human exposure situation to be addressed, considering variability and uncertainty within and between species.

In order to address these differences, assessment factors (AF) should be applied accounting for (1) inter-species differences; (2) intra-species differences; (3) differences in duration of exposure; (4) issues related to dose-response estimation; and (5) the quality of the entire database. The applied AFs only correct for uncertainties/variability in the effect data, not for exposure uncertainties.

In conclusion, for threshold substances, a DNEL is a level of exposure which should not be exceeded, indicating control of risks. For non-threshold substances, a DMEL is a risk-related reference value that should be used to better target risk management measures. Exposure levels below a DMEL are judged to be of very low concern, due to a high likelihood that effects are avoided for the particular ES under consideration.

A description of the derivation of DN(M)ELs, ESs, AFs and risk characterizations can be found under the toxicological information section listed above.

ECHA has different layers of information available, i.e. ECHA Info Cards (providing one-page summary) as well as disseminated dossiers containing detailed information for each relevant end-point using OECD-harmonized templates.

At the heart of the registration dossier is the Chemicals Safety Assessment (CSA) which addresses the manufacture of a substance and all the identified uses at all stages of the life cycle of the substance. It compares the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance considering implemented and recommended risk management measures and operational conditions.

For higher tonnage substances, the database contains extensive information, including:

- Classification and Labelling and PBT Assessment
- Manufacture, Use and Exposure information, including uses advised against
- Physical and Chemical Properties Environmental Fate and Pathways
- Ecotoxicological Information
- Toxicological Information (includes human epidemiology information, if available)
- Analytical Methods
- Guidance on Safe Use

### ***B4.5. Quality of the Underlying EHS Information***

As has been described above, companies who manufacture/import/use chemicals are responsible for compiling and submitting the EHS information in the form of dossiers to support their REACH substance registrations. They are accountable for the accuracy of the information submitted.

Because of the technical complexity of REACH, the work of completing the dossiers and especially of conducting the CSAs, is usually done by professional eco- and mammalian- toxicologists, risk assessment experts, exposure scientists, industrial hygienists, occupational physicians and others who are either directly employed by the companies or by independent contractors who specialize in this work. Such experts usually take great pride in the quality of their work and often belong to pertinent professional societies, many of which have codes of ethical conduct to which they must adhere.

ECHA and the national authorities have various processes and procedures in place to check on the completeness and quality of the information submitted. They can require companies to conduct additional testing to fill data gaps, submit additional EHS information, re-do safety assessments and implement additional risk management, up to and including restricting or banning sales of substances that cannot be managed safely.

Once a registration dossier is submitted, ECHA performs a completeness check to ensure that all the information required for registration has been provided, and that the registration fee is paid before the registration number is issued. Registrants are required to jointly submit information on the hazardous properties of the substance, its classification and labelling and potential testing proposals and ECHA also enforces this during the completeness check. Registrants whose dossiers fail the check have a specified time to bring them into compliance or they may have to cease manufacture/import/use. During the completeness check, ECHA does not assess the quality or adequacy of the data submitted.

During the Evaluation step of REACH, ECHA and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to evaluate if a given substance constitutes a risk to human health or the environment. Evaluation under REACH focuses on three different areas:

- Examination of testing proposals submitted by registrants (ECHA publishes every testing proposal that involves vertebrate animals and invites third parties to submit scientifically valid information or studies addressing the substance and hazard endpoints in question that could be considered by ECHA in preparing its decision on the testing proposal. The information has to be submitted within 45 days. The options for the draft decision area:
  - Acceptance of the testing proposal
  - Acceptance of the testing proposal with modifications of the testing conditions
  - Acceptance or rejection of the testing proposal but requiring one or more additional tests
  - Rejection of the testing proposal.
  - ECHA then adopts a decision based on the original proposal and the information submitted by third parties.)
- Compliance check of the dossiers submitted by registrants (ECHA may examine any registration dossier to verify if the information submitted by registrants is compliant with the legal

requirements. Compliance checks evaluate the substance identity description and the safety information in the dossier including the chemical safety report or specific parts of the dossier, for example the information related to the protection of human health. According to REACH, ECHA must check at least 5% of the registration dossiers of each tonnage band. Dossier selection for compliance check is either random or concern based (targeted). In the targeted compliance checks, ECHA evaluates only a specific part of the registration dossier (e.g. either specific endpoints in IUCLID or in the chemical safety report (CSR)) based on a specified concern. This allows ECHA to target endpoints which are identified as relevant for the safe use of substances.)

- Substance evaluation (Member States evaluate certain substances prioritized by ECHA, to clarify whether their use poses a risk to human health or the environment. The objective is to request further information from the registrants of the substance to verify the suspected concern, if necessary. The following options may address the concern:
  - A proposal for harmonized classification and labelling for carcinogenic, mutagenic or toxic to reproductions, respiratory sensitizers or other effects.
  - A proposal to identify the substance as a substance of very high concern (SVHC).
  - A proposal to restrict the substance.
  - Actions outside the scope of REACH such as a proposal for EU-wide occupational exposure limits, national measures or voluntary industry actions.)

An evaluation process may conclude that additional information is needed either to decide on a testing proposal, to clarify a concern on a substance or to bring a registration dossier into compliance with REACH. In the cases of compliance checks and testing proposal examinations, ECHA will draft a decision to request further information from registrants. In the substance evaluation process, the evaluating Member State will draft the decision.

Throughout the process, ECHA will ensure that the decision is finalized via the decision-making procedure established by REACH and that a harmonized approach is maintained for all evaluation cases.

The procedure also ensures that testing is tailored to real information needs. Therefore, the registrant cannot commence any testing or submit any new testing proposals until the decision on substance evaluation is finalized. However, if ECHA has taken or takes other parallel decisions as a result of dossier evaluation, registrants must perform the requested tests by the deadline given in the decisions.

Where a registrant or potential registrant disagrees with certain decisions issued by ECHA, he can appeal against the decision to ECHA's Board of Appeal.

Annually, ECHA must publish a report on the progress it has made over the previous calendar year on its obligations in relation to evaluation. ECHA is specifically required to include recommendations to potential registrants to foster improvement in the quality of future registrations, in these reports.

The Authorization process under REACH aims to ensure that substances of very high concern (SVHCs) are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available. The route to authorization starts when a Member State or ECHA, at the request of the Commission, proposes a substance to be identified as an SVHC.

Substances with the following hazard properties may be identified as SVHCs:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B in accordance with the CLP Regulation.

- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII.
- Substances on a case-by-case basis, that cause an equivalent level of concern as CMR (e.g. endocrine disruptors) or PBT/vPvB substances.

The SVHC identification process includes a 45-day public consultation. Once a substance is identified as an SVHC, it is included in the Candidate List. ECHA maintains a database of Candidate List substances which also may be searched. As of 1 September 2018, there were 191 substances on that list. Registrants may have immediate legal obligations relating to risk management actions following the inclusion of a substance in the Candidate List.

Member States are ultimately charged with enforcing compliance with REACH. Each Member State has determined the penalties that would apply to the infringement of REACH provisions and must take all measures necessary to ensure that they are implemented. The penalties must be "effective, proportionate and dissuasive". The Member States had to notify their provisions to the European Commission and must also notify any subsequent amendment. ECHA has no enforcement responsibilities, however, it does host a Forum composed of representatives of national enforcement authorities, which works towards coordinating the enforcement of REACH and CLP in the EU Member States, Norway, Iceland and Liechtenstein.

#### ***B4.6. Procedures for Updating the Database with New Information***

Registrants have an obligation to keep the information in the registration dossier submitted to ECHA up-to-date. They must consider their registration dossiers as "living documents" and regularly update them whenever new information is available or a need to improve the quality of data is identified. ECHA advises that special attention should be paid to the following areas of the registration dossier: substance identity, uses, exposure information and justifications for adaptations to information requirements and for using alternative methods.

If the composition of the substance changes, the registrant is obligated to inform ECHA, consider whether and how this change affects the intrinsic properties of the substance and resubmit an updated registration dossier that reflects all relevant changes.

Each year, registrants need to calculate their yearly tonnage as the average over the three preceding years. A registrant needs to update their registration without undue delay as soon as the 'annual or total quantities' they manufacture or import reach the next tonnage band threshold (i.e., >10 tonnes, >100 tonnes, > 1000 tonnes) as this may trigger additional EHS data collection requirements. As soon as the annual volume of a substance that has already been registered (regardless of its phase-in status before registration) reaches the next tonnage threshold, the manufacturer or importer has the duty to immediately inform ECHA of the additional data required.

After a registrant has submitted their registration dossier to ECHA they may realize that they made a mistake during its preparation such as citing faulty data in the CSA. In this case the registrant is obligated to, without undue delay, submit an amended dossier indicating in the dossier header the reason(s) why they are spontaneously updating it as well as the references of the previous valid submission (i.e. the "last submission number").

If the registrant becomes aware of information that could lead to other or different risks for human health or the environment caused by the substance they manufacture or import, such as monitoring data in the environment or epidemiological studies, they need to take those data into account and evaluate the appropriateness of the risk management measures put in place or recommended down the supply chain. New information triggering a revision of the CSA or the safety data sheet could also be the result of an international review such as International Programme on Chemical Safety (IPCS) review or an OECD dossier, or any kind of publication dealing with the release and exposure or hazard of the substance. Even if the initial registration has been completed accurately there will be an on-going need to update the CSA/CSR and the SDS as new or additional information on the risks of the substance becomes available that has an impact on the results of the CSA.

In some cases, even if higher level studies are not required by REACH, i.e. due to lower tonnage band, they still might be considered as necessary in the opinion of the registrant in order to control the risks arising from the manufacture and use(s) of the substance. In such a case when the registrant identifies the need to perform a higher-level study, they must submit to ECHA an update of the registration dossier including a specific proposal for this test, documentation showing that all non-animal methods have been considered and justification for proceeding to an animal study.

The registrant must also update their registration dossier as a consequence of an ECHA or a Commission decision under the evaluation procedure but also, when relevant, following any decision made in accordance with the authorization and the restriction processes. These updates must be submitted within the deadline specified by ECHA/the Commission in the decision.

Once an updated dossier is submitted to ECHA, they must undertake a completeness check within three weeks of the submission date.

## ***B5. Canadian Government EHS Databases***

The information presented below represents a summary of key information about the EHS information on industrial chemicals that is available from the Canadian government's efforts to assess and manage risks posed by exposures to them. There are three distinct databases that contain relevant EHS information on chemical substances:

- (1) results of Canada's efforts to categorize environmental or human health concerns of the 23,000 plus "existing substances";
- (2) results from screening level risk assessments conducted for the approximately 4,300 chemical substances that were determined after categorization as warranting further attention; and
- (3) risk assessment reports that are conducted on substances that have been added to the Canada's Priority Substances List (PSL).

For more detailed information, the reader should consult directly with the [Health Canada website](#).

### ***B5.1. Overview/Description***

In 2006, Canada completed a major task of systematically sorting through the approximately 23,000 “existing substances” in use in Canada between January 1, 1984 and December 31, 1986, when the original Canadian Environmental Protection Act was being created. The law calls these “existing substances,” and they were registered on the Domestic Substances (DSL). By definition, substances newly manufactured or imported after 1994 are not included on the DSL, but have been and continue to be assessed by ongoing review processes.

Using information from industry, academic research and other countries, Canadian government scientists worked with partners in applying a set of rigorous tools to the 23,000 plus chemical substances on the DSL. They were categorized to identify those that were:

- inherently toxic to humans or to the environment and that might be:
  - persistent (take a very long time to break down), and/or
  - bioaccumulative (collect in living organisms and end up in the food chain)
- substances to which people might have greatest potential for exposure.

Additionally, substances considered a priority for assessment based on other health concerns were considered as part of this prioritization exercise.

Through categorization, the Government of Canada has identified approximately 4,300 of the 23,000 plus chemical substances on the DSL as meeting their criteria for further attention. Canadian experts have decided that many existing substances (roughly 19,000) do not need further action.

The chemical substances identified through the categorization process as needing a more thorough examination were also sorted to ensure those with the greatest potential for concern were examined first. The next step for these substances was to conduct a screening assessment, further research and, if needed, measures to control the use or release of a chemical substance. Among the actions taken for some of these substances was a determination that there is no risk to human health and the environment, and no additional risk management was warranted.

The Chemicals Management Plan (CMP) is a Government of Canada initiative aimed at reducing the risks posed by chemicals to Canadians and their environment. Approximately 4,300 substances were identified as requiring screening assessment following this prioritization exercise.

The core of the risk assessment work currently being conducted under the CMP is comprised of these approximately 4,300 prioritized substances, along with the annual receipt of 400 to 500 New Substance Notifications. Screening level assessments have been done on these substances and the results are summarized in Chemicals-at-a-glance sheets which are a series of short fact sheets about chemical substances and micro-organisms that are being (or have been) assessed in Canada for their possible risks to human health and the environment. The information sheets will be revised, from time to time, as substances move through the various technical and regulatory stages of the risk assessment and risk management processes.

The next phase (sometimes referred to as the third phase) of the CMP, launched in May 2016, will address the remaining 1,550 priority chemicals out of the original 4300 chemicals identified as priorities

during the categorization. The Minister of Health and the Minister of Environment and Climate Change have committed to addressing these chemicals by 2020.

## ***B5.2. Scope of Chemicals Addressed***

The CEPA categorization process pertained to a compilation of about 23,000 substances used, imported or manufactured in Canada for commercial purposes between January 1, 1984, and December 31, 1986 (before CEPA came into existence), at a quantity of greater than 100 kilograms per year. It includes discrete organic compounds, inorganic substances, organometallic substances, polymers, and unknown or variable composition complex reaction products or biological material such as acetone or iron.

## ***B5.3. Ease of Access and Use of Chemical Information***

### **B5.3.1. Categorization Results**

Searches of the [categorization results database](#) may be done by entering a chemical name and the CAS (Chemical Abstracts Service Registry) number to obtain categorization results for a particular substance. A number of pre-set searches are provided, to narrow the search results to smaller, more specific categories, such as Ecological Categorization Results, Human Health Categorization Results and others.

### **B5.3.2. Screening Level Assessment Results**

[Chemicals-at-a glance sheets](#), which are a series of short fact sheets about chemical substances and micro-organisms that are being (or have been) assessed in Canada for their possible risks to human health and the environment, are available.

This database is not searchable and the user must scroll down the page to look for the name of their chemical substance of interest. A click on the name of the substance or microorganism produces a fact sheet that is written in layman's language.

### **B5.3.3. Risk Assessment Reports for Priority Substance List Chemicals**

[Risk assessments conducted on 44 PSL1 and 25 PSL2 substances can be found on the website](#). The PSL1 and PSL2 Lists are not searchable, but users can locate the chemical name of interest by scrolling down the page to find a match. Downloadable files containing the risk assessments are accessed by clicking on the substance name.

## ***B5.4. Breadth and Depth of EHS Information Available***

### **B5.4.1. Categorization Results**

This Database contains the categorization results for substances on the Canadian Domestic substance list and the supporting data on:

- Inherent toxicity
- Persistency

- Bioaccumulation

These results state, for each substance, whether or not it meets the Government of Canada criteria for categorization, and if so, whether the decision was made based on environmental or human health concerns (or both). In addition, the results show which environmental categorization criteria were met for each substance (in other words, the basis on which the decision was reached).

#### **B5.4.2. Screening Level Assessment Results**

Chemicals-at-a glance sheets are written in layman's language and generally provide answers to the following questions:

- What is it?
- How is it used?
- Why is the government of Canada assessing it?
- How are Canadians exposed to it?
- What are the results of the assessment?
- What is the government of Canada doing?
- What can Canadians do?

#### **B5.4.3. Risk Assessment Reports for Priority Substance List Chemicals**

The complexity and the depth of assessments can vary depending on the specific type of assessment. PSL Assessments are usually fairly comprehensive and include:

- Substance identity
- Physical chemical properties,
- Use patterns and sources,
- Releases to the environment,
- Environmental fate,
- Persistence and bioaccumulation potential,
- Human health exposure characterization,
- Quantification of potential adverse effects on human health and/or non-human organisms resulting from exposure to various concentrations, doses or intake rates of a substance through the exposure pathways identified in the exposure assessment,
- Risk characterization,
- Uncertainties,
- References.

#### ***B5.5. Quality of the Underlying EHS Information***

Using information from Canadian industry, academic research and other countries, Canadian government scientists work with partners in applying a set of rigorous tools to conduct categorization, screening level assessments and risk assessments for priority list substances.

The available EHS information and assessment reports have been peer-reviewed by the governmental authorities and/or independent Canadian or international experts. Details of the peer-review process can be found in the introduction of each report. Additionally, under the CEPA 1999, the assessment reports are subject to a mandatory 60-day public comment period in which the assessments are

published on the Departmental websites permitting comments from the public, stakeholders and concerned groups on the scientific findings.

### **B5.5.1. Screening Level Assessment Results**

A screening assessment is conducted to determine if a substance is toxic or capable of becoming toxic. It is not intended to represent an exhaustive or critical review of all available data. Rather, it presents the most critical studies and lines of evidence pertinent to the conclusion. A screening assessment is fit-for-purpose, in that it may address one to hundreds of substances and will follow an approach that is most appropriate for the substance(s). Screening assessments can range from simple to very complex technical analyses. Screening assessments include a regulatory conclusion on the substance(s).

### **B5.5.2. Risk Assessments for Priority Substance List Chemicals**

All risk assessments are based on sound-science, consider multiple lines of evidence and uncertainties, and apply precaution. Furthermore, they are all conducted to evaluate the potential of a substance or a group of substances to cause harm to Canadians and/or the Canadian environment. A weight-of-evidence approach and precaution are applied throughout the assessment process. The risk assessment program under CEPA is conducted in collaboration by both Environment Canada and Health Canada.

## ***B5.6. Procedures for Updating the Database with New Information***

### **B5.6.1. Categorization Results**

The Government of Canada is responsible for the content of their database containing Categorization Results from the Canadian Domestic Substance List. Categorization was completed in 2006 and the data is not planned to be updated.

### **B5.6.2. Screening Level Assessment Results**

Chemicals-at-a-glance information sheets are revised, from time to time, as substances move through the various technical and regulatory stages of the risk assessment and risk management processes.

### **B5.6.3. Risk Assessments of Priority Substance List Chemicals**

Canada describes multiples ways in which it acquires new information that may update prior risk assessments or which may affect the prioritization of substances for future risk assessments.

Such information can come from a variety of sources, including:

- provincial/territorial and international organizations;
- through participation in a variety of international activities and relationships with other national regulators;
- partnerships with the OECD which facilitate co-operation in the area of information and data sharing with other member countries;
- monitoring of publicly available information sources;
- work done by government scientists to generate new data;
- attendance at scientific conferences;
- industry;

- health and environmental organizations;
- the public.

On a continual basis, staff at Environment Canada and Health Canada review the new information obtained on substances for indications of imminent and/or widespread potential for harm. Generally, the development of scientific knowledge is incremental and iterative, so it is unlikely that a single new piece of information collected in this process would prompt immediate intervention; however, if this type of information were acquired, mitigating action would be pursued in a timely manner.

The most typical evaluation process is the result of a periodic analysis of the information that has been acquired. A series of factors are considered and weighed, and judgments made on the relative importance of different indicators. Evaluation can be complex, as substances will have entirely different types of information available and prior activities on a substance are considered. Prioritization decisions are guided by a set of principles and considerations.

## ***B6. Japanese Government EHS Databases***

The information presented below represents a summary of key information about the EHS information on industrial chemicals that is available from the Japanese government's efforts to assess and manage risks posed by exposures to them. An excellent overview of Japan's approach to chemicals management has been published.

There are three databases that contain relevant EHS information on chemical substances:

- (1) Japan CHEmicals Collaborative Knowledge (J-CHECK) database
- (2) CHEmical Risk Information Platform (CHRIP®)
- (3) Japan Existing Chemicals Database (JECDB)

More detailed information is available about Japan's approach to managing chemicals.

### ***B6.1. Overview/Description***

During the 1950's and 1960's, Japan experienced several serious environmental pollution problems with methylmercury and polychlorinated biphenyls (PCB) which raised societal awareness of the need for enhanced chemical safety management both domestically and globally. As a direct consequence, in 1973 Japan enacted new legislation, the Chemical Substances Control Law (CSCL), which was intended to prevent pollution by chemical substances with similar properties to PCBs, including high persistency, high accumulation, and long-term toxicity. It also established requirements for newly manufactured or imported chemical substances so that their safety would be assessed before import and/or introduction to the market, and those with PCB-like properties are regulated for their manufacturing, import and use.

Pollution of ground water caused by chlorinated solvents, including trichloroethylene, was recognized in the 1970's and this led to greater strengthening of the CSCL in 1986 to include the regulation of chemical substances that are not highly accumulative, but that are persistently toxic.

In 2003, CSCL was further amended to stay abreast of international trends and current OECD recommendations on chemical management. Thereby an assessment and regulation system was introduced to focus on the impact of chemical substances on flora and fauna, and the possibility of discharges into the environment.

The Japan Chemicals Management Center (CMC) provides technical support to ensure appropriate operation of the law under the jurisdiction of the Ministry of Health, Labor and Welfare (MHLW), the Ministry of Economy, Trade and Industry (METI), and the Ministry of the Environment (MOE).

CMC promotes the efficient assessment of new chemical substances through its database on safety inspection and the assessment results of new chemical substances that are specified in the CSCL. In addition, the CMC has developed a database that facilitates information sharing between three key government authorities, MHLW, METI, and MOE. By utilizing the database, the CMC investigates the information required for the assessment of new chemical substances and compiles assessment materials on chemical safety.

In addition, the CMC also functions as a consultation and liaison organization between the three ministries and business operations engaged in the "notification" process for new chemical substances. The CMC receives inquiries from business operations prior to notification, and conducts interviews during the process of notification. The CMC also assigns officially prepared names to new chemical substances.

#### **B6.1.1. Operations related to Good Laboratory Practice (GLP)**

The CSCL stipulates that any safety inspection data used to assess new chemical substances should be obtained from testing facilities conforming to Good Laboratory Practice (GLP). The CMC conducts the inspections of GLP facilities to assure reliability of test results and international compatibility.

#### **B6.1.2. Other operations related to observance and enforcement of the CSCL**

To be able to manufacture or import any new chemical substances, business operators need to make their notification of the new chemical substances under the CSCL as well the Industrial Safety and Health Act. The names of these substances are designated according to each of the laws. Though their designated names are given based on the IUPAC (International Union of Pure and Applied Chemistry) nomenclature system, there may be multiple naming conventions for the same chemical structure, so a single chemical substance may be designated with different names. Therefore, the CMC supports the creation of the commonality rules of the nomenclature between the Industrial Safety and Health Act and the CSCL in collaboration with MHLW and METI.

In addition, the CMC also compiles study reports on the relations between bioconcentration and n-octanol/water (log POW), and between bioconcentration and molecular weight, and submits them to the Chemical Substances Council to contribute to the review of assessment standards. These contributions ensure that prompt and proper assessment procedures are implemented.

### **B6.1.3. Operations related to risk assessments**

The CMC supports operations related to risk assessments under the CSCL, which require the knowledge of chemical substances and assessment methods. The CMC supports the enforcement of the CSCL by the state as the core institution of risk assessments under the CSCL by performing "confirmation and aggregation of the notified data, etc. of annual manufacturing and import volumes according to the CSCL," "arrangement of emission factors to estimate the released amounts into the environment and estimations of the released amounts," "estimation of exposure doses and risks to human and ecosystems," etc.

### **B6.1.4. Operations related to the utilization of (Quantitative) Structure-Activity Relationship ((Q)SAR) and category approaches**

In order to ensure safe and efficient chemical management in Japan, the CMC makes efforts to develop hazard assessment methods based on (Q)SAR and category approaches.

The CMC also summarizes the results of predictions of biodegradation/bioconcentration of new chemical substances and existing chemical substances subject to the reviews of the CSCL by various (Q)SAR models and category approaches, and submits them as review reference materials to the committee of the CSCL.

CMC reports the following covers progress in recent safety programs for existing and new chemicals.

Under CSCL, the manufacture or import of new chemicals must be submitted to the designated country agencies, which then examine the chemicals on the basis of the submissions. MHLW examines toxicity and METI examines decomposition and accumulation.

With respect to toxicity examination, the data from two kinds of genetic toxicity tests (both bacterial and non-bacterial in vitro tests) and a 28-day repeat dose toxicity test are submitted for initial screening by the expert committee on chemicals of the living environment council. After this examination, any chemical which is difficult to decompose, tends to accumulate and may be harmful to human health with chronic exposure is classified into "Class I specified chemical substances", while those which have low accumulation but do not readily decompose corresponding to those which may be harmful to human health when continually taken, are classified into "Designated chemical substances". The hazard potential of some designated chemical substances are examined as deemed necessary from the environmental point of view. Some of them are placed in the "Class II specified chemical substances" category. New chemicals are all assessed for safety assurance through the above described prior examination system.

The "Class I specified chemical substances" category contains 9 substances including PCB, chlordane and tributyltin oxide. The "Class II specified chemical substances" category designates 23 substances including trichloroethylene, tetrachloroethylene, carbon tetrachloride, 7 triphenyltin compounds and 13 tributyltin compounds. Moreover, the "Designated chemical substances" category contains 257 substances including chloroform.

In Japan, it is estimated that about 23,000 chemicals with production or import above 1 tonne per annum are now on the market. About 19,000 of them were already on the market before establishment

of the CSCL, requiring safety examination through a series of toxicity tests. These chemicals have successively been examined by the responsible agencies and classified into the "Class I specified chemical substances" category as appropriate.

In addition to the OECD HPV chemicals testing program described earlier (see Chapter on OECD Existing Chemicals SIDS), Japan has had its own HPV program, and all such widely used chemicals have had a SIDS assessment.

In Japan, the Biological Safety Research Center, National Institute of Health Sciences, plays a leading role in conducting the safety tests and classifying chemicals which may affect human health into Designated chemical substances or Class II specified chemical substances. The results of the safety tests are announced in the annual reports of the Biological Safety Research Center, National Institute of Health Sciences and in scientific journals where appropriate.

Article 3 of the Law for the Control of Household Products Containing Harmful Substances stipulates responsibilities of manufacturers and importers to secure safety of household products. They must study chemicals which are contained in household products and how they might affect human health, and take measures to prevent injury caused by such chemicals. Thus, the law prescribes that manufacturers and importers must have a full understanding of the manufacturing methods of household goods, chemicals contained therein and their toxicity. Moreover, the law designates harmful chemicals from the view of human health and prescribes standards for allowable contents of chemicals and containers of the products. Sales of products which do not meet the standards are prohibited. Contents and containers have been prescribed for 17 chemicals.

Surveillance officers in each city or prefecture strictly check and survey the household products which are sold in the departments, supermarkets and retail stores, for the above standards, and give instructions where appropriate.

Groups of manufacturers and importers in relevant industries have been promoting self-support efforts in safety programs in order to prevent injury caused by chemicals in household goods. The MHLW welcomes voluntary standards for safety assurance, so the MHLW provides guidance and advice for the establishment of such standards, which are already in place for household goods such as wet wipes, bacteria and mildew removal agents for home use, insecticides for home use, rinsing agents for home use, spot removers for home use, perfumes/deodorants/deodorizers, bacteria and mildew proof agents for home use, and rinsing agents and/or preservatives for contact lenses.

The standards generally include ingredients, contents, quality control such as test items for quality assurance, labeling, containers and manufacturing processes. Moreover, some voluntary standards indicate the use of certification marks.

The Material Safety Data Sheet (MSDS) system was established, effective as from April 1993, by MHLW, METI and MOL, in order to enhance safety for treatment of chemicals. The system requires manufacturers and importers to prepare MSDSs and deliver them to their downstream customers and processors. The MSDS should contain information on safety procedures for chemicals which present a danger or hazard in items of explosion, ignition and acute/chronic toxicity properties. The information includes the name of the product, types of danger or hazard, treatment in case of emergency, treatment in case of a fire, notes for treatment and storage, preventive measures for exposure and notes for disposal.

CMC owns and manages the J-CHECK and CHemical Risk Information Platform (CHRIP®) databases.

J-CHECK is a database developed to provide the information regarding CSCL, such as the list of CSCL substances, chemical safety information obtained in the existing chemicals survey program, risk assessment, etc. in cooperation with eChemPortal by OECD.

CHRIP® feeds information to J-CHECK, and is directed at companies operating in Japan, municipalities and citizens. CMC collects the reliable information on the domestic and foreign laws and regulations related to chemical management and the risks of chemical substances. It provides this information through CHRIP® for compliance with the chemical management laws and regulation by business operators, municipalities, and people and appropriate assessments and voluntary management of risks. CMC provides the general information such as the name, CAS Registry Number, etc. of chemical substances, domestic and foreign laws and regulations information, hazard information, and exposure-related information. CMC confirms and updates the listed data regularly, and secures the reliability of the database.

MHWL manages the JECDB database which includes results of toxicity screening tests for both Japan's existing chemicals safety program and the OECD HPV chemicals program.

### ***B6.2. Scope of Chemicals Addressed***

The focus of these databases is on what the Japanese government estimates are the 23,000 industrial chemicals produced or imported above 1 tonne per annum that are on the market.

### ***B6.3. Ease of Access and Use of Chemical Information***

#### **J-CHECK**

Search capabilities

- List and classification of CSCL
- List of Japan HPV Challenge program
- CAS Registry Number
- MITI number
- Chemical Substance name (Exact match, Substructure match)
- Search by structure
- Regulatory Classification
- Endpoints

User instructions for conducting searches of J-CHECK are available online.

#### **CHRIP®**

Users can search the comprehensive information on a target chemical substance (information on hazardous property/hazard assessments or regulations, etc.) by entering its number or name as a keyword.

Searches may be done by using the following item as a keyword.

- CHRIP\_ID
- Chemical Substance Name
- CAS No.
- MITI No.
- ISHA No.
- EC No.
- UN No.

The controlled chemical substances by each law or the assessed substances by each organization, etc. will be displayed in an individual list. Specifying a substance on a list, you can also see comprehensive information (contains information on hazard assessments or regulations, etc.). Search instructions are available.

#### **JECDB**

A search is available by CAS Registry Number, by Name, by Toxicity test. The user may also browse a list of chemical substances tested and a list of toxicity test reports.

A user's guide could not be located to help with searches, however, the search process appears rather intuitive.

### ***B6.4. Breadth and Depth of EHS Information Available***

#### **J-CHECK**

Environmental Hazard information

- Biodegradation
- Bioaccumulation
- Partition coefficient
- Algae growth inhibition test
- Daphnia Acute Immobilization test
- Daphnia Reproduction test
- Fish Acute toxicity test
- Fish prolonged toxicity test
- Fish early life stage toxicity test
- Other tests, if available

#### **CHRIP®**

The information related to the selected substance is displayed in a tree format and includes the following:

- Substance Identity and Structure
- Chemical Hazard and Risk Information
- GHS Classification according to the Japanese government.
- Hazard and Risk Assessment Reports from other Countries

**JECDB**

JECDB makes available the mammalian toxicity test reports from Japan's existing chemicals safety program. Each report consists of the nomenclature of the chemical, abstracts and summarized data from the studies in English. Individual study reports are available in Japanese.

For each chemical, results are compiled from several studies, including, in most cases, a single dose toxicity test, a 28-day repeat dose toxicity test, a reproductive/developmental toxicity test and mutagenicity tests.

***B6.5. Quality of Underlying EHS Information*****J-CHECK**

Not all data of Existing Chemicals Survey Program Conducted by the Japanese Government are peer reviewed. Data of Japan HPV Challenge Program are not reviewed.

**CHRIP®**

CHRIP® provides reliable data published by national and international authorities. As of this writing, it contains EHS information on approximately 250,000 substances. The quality of the database is ensured by regular updates performed once every two months, and by a continual verification process.

**JCEDB**

JCEDB provides toxicity test information for approximately 350 chemical substances. All the toxicity tests reported were performed in accordance with the test methods in which new chemicals should be tested for submission to the country agencies under the Law concerning Examination and Regulation of Manufacture, etc. of Chemical Substances, and each guideline of the OECD chemicals programs.

The study results are reviewed by scientists from the Japan National Institute of Health Sciences and other institutes

Users are free to utilize and cite the results of the existing chemicals survey conducted by the three Ministries for any purpose. At the time of citation, users must be aware of the following:

- The user must clearly state that the information cited by him/her is referred to the results of existing chemicals survey conducted by the Japanese Government.
- The user shall be responsible for any losses that may occur through the use of the information.

***B6.6. Procedures for Updating the Database with New Information*****J-CHECK**

Maintenance of the database is the responsibility of the National Institute of Technology and Evaluation (NITE).

**CHRIP®**

Maintenance of the database is the responsibility of NITE. The quality of the database is ensured by regular updates performed once every two months, and by a continual verification process.

### **JECDB**

Maintenance of the database is the responsibility of MHLW. Unfortunately, the English abstracts summarizing the available test data on each substance do not list a calendar date; and no update procedures could be located.

## **B7. USEPA Databases**

The information presented below represents a summary of key information about the environmental, health and safety information on industrial chemicals that is available from the United States Environmental Protection Agency (USEPA).

Specific databases reviewed in this section include:

- ChemView
- ACToR and ToxCast Dashboard
- Integrated Risk Information System (IRIS); and
- Substance Registry Services (SRS)

For more detailed information, the reader should consult directly with the [EPA website](#).

### **B7.1. Overview/Description**

Under the Toxic Substances Control Act (TSCA), the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and the Pollution Prevention Act, USEPA evaluates potential risks from “new” and “existing” chemicals and finds ways to prevent or reduce pollution before it gets into the environment.

USEPA classifies chemical substances as either “existing” chemicals or “new” chemicals. “Existing” chemicals are chemicals that were already in commerce when TSCA was enacted in 1976 or chemicals that have undergone a Pre-Manufacture Notification (PMN) review and are listed on the TSCA Inventory. Any substance that is not on the TSCA Inventory is classified as a “new” chemical. Prior to manufacture (including import) of a new chemical for general commercial use, a notice must be filed with USEPA.

#### **New Chemicals**

USEPA's New Chemicals program helps manage the potential risk to human health and the environment from chemicals new to the marketplace. The program functions as a “gatekeeper” that can identify conditions, up to and including a ban on production, to be placed on the use of a new chemical before it is entered into commerce.

The PMN Program to review new chemicals has evolved into an efficient mechanism for identifying those new chemicals which are of greatest concern early on in the 90-day review process. A detailed analysis is focused on these cases with the ultimate goal of identifying and controlling unreasonable risks. EPA uses an integrated approach that draws on knowledge and experience across disciplinary and

organizational lines to identify and evaluate concerns regarding health and environmental effects, exposure and release and economic impacts.

Following receipt of a PMN or exemption notice, USEPA scientists and program managers meet to evaluate the notice and the notice undergoes the following steps in the Agency's 90-day review process. USEPA groups PMN chemicals with shared chemical and toxicological properties into categories in order to streamline the process for Agency review of new chemical substances. USEPA has developed assessment methods, databases, and predictive tools to help evaluate what happens to chemicals when they are used and released to the environment and how workers, citizens, and the environment might be exposed to and affected by them. These tools may be helpful when laboratory studies or monitoring data are not available or need to be supplemented. The New Chemicals Program is actively carrying out USEPA's strategy to prevent pollution before it can occur. The New Chemicals Program strongly encourages industry efforts to prevent pollution.

USEPA may make one of several different decisions upon completion of its PMN review:

- a determination that a new chemical or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation under the conditions of use.
- a determination that a new chemical or significant new use presents unreasonable risk of injury to health or the environment without consideration of cost or other non-risk factors, including an unreasonable risk to a potentially exposed subpopulation under the conditions of use, USEPA may (a) limit the amount manufactured/processed/distributed in commerce or impose other restrictions on the substance via an immediately effective proposed rule under section 6 of TSCA, or (b) issue an order to prohibit or limit the manufacture, processing or distribution in commerce to take effect on the expiration of the applicable review period.
- issue a Significant New Use Rule (SNUR) for new chemicals following the Agency's review or during they review period. Promulgation of a SNUR can be an effective and efficient way to address reasonably foreseen conditions of use about which USEPA has concerns, as part of the basis for them to conclude that the chemical is not likely to present an unreasonable risk of injury to health and the environment under the conditions of use. A SNUR requires that any manufacturer or processor – including the PMN submitter – who intends to undertake the activities subject to the SNUR must submit to EPA a significant new use notice (SNUN). EPA must either conclude, following review of a SNUN, that the activities are not likely to present an unreasonable risk, or take appropriate action to protect against any unreasonable risk. The review would factor in the conditions of use of the chemical specifically associated with the significant new use and, as appropriate, any other conditions of use relevant to the evaluation of the significant new use of the chemical substance within the applicable review period. The review of the SNUN would be the same as described above.
- a determination that:
  - the information in the PMN is insufficient to allow the Agency to make a reasoned evaluation of the health and environmental effects of the new chemical substance or the significant new use,
  - or
  - in the absence of sufficient information, the manufacture, processing, distribution in commerce, use or disposal of the chemical may present an unreasonable risk to health or the environment, or

the chemical substance is or will be produced in substantial quantities and will either enter the environment in substantial quantities or there may be significant or substantial human exposure to the substance.

Should USEPA make one of these determinations, then they must issue an order under TSCA section 5(e). These orders are typically issued on consent. A section 5(e) order typically contains some or all of the following requirements as conditions:

- Testing for toxicity or environmental fate once a certain production volume or time period is reached
- Use of worker personal protective equipment
- New Chemical Exposure Limits (NCELs) for worker protection
- Hazard communication language
- Distribution and use restrictions
- Restrictions on releases to water, air and/or land, and
- Record-keeping.

### **Existing Chemicals**

TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, requires USEPA to evaluate the safety of “existing” chemicals via a three-stage process. The three stages of EPA’s process for ensuring the safety of existing chemicals are prioritization, risk evaluation, and risk management. The statute also includes a variety of new EPA authorities to drive forward progress on evaluating and ensuring the safety of existing chemicals.

The first step in USEPA’s process for evaluating the safety of existing chemicals is prioritization. Prioritization is a risk-based screening process for designating chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluation is not warranted at the time. TSCA requires USEPA to give certain preferences to prioritizing chemicals on the 2014 TSCA Work Plan, to consider certain criteria such as hazard/exposure, persistence and bioaccumulation, but otherwise does not significantly limit USEPA’s discretion to choose which chemicals enter the prioritization process. TSCA further prohibits USEPA from considering non-risk factors (e.g., costs/benefits) during prioritization. Once initiated, the process provides stakeholders with ample notice of any USEPA risk evaluation activity, as well as two opportunities for the public to submit relevant information to the Agency. The process has been designed to ensure that the Agency’s limited resources are focused on chemicals with the greatest potential for risk.

Chemical substances with low hazard and/or exposure that meet the definition of Low-Priority Substances are taken out of consideration for further assessment at this time. This gives the public notice of chemical substances for which the hazard and/or exposure potential is anticipated to be low or nonexistent, and provides insight into which chemical substances are likely not to need additional evaluation and risk management.

The second step in USEPA’s process for evaluating the safety of existing chemicals is risk evaluation. If USEPA designates a chemical as a High-Priority Substance, the chemical moves immediately to the risk evaluation phase. At the conclusion of the risk evaluation phase, USEPA must use the risk evaluation as a basis to determine whether or not the chemical presents an unreasonable risk to health or the environment under the chemical’s conditions of use. TSCA prohibits USEPA from considering non-risk factors (e.g., costs/benefits) during risk evaluation. This includes risks to subpopulations who may be at greater risks than the general population, such as children and workers. The risk evaluation process has the following components:

- a scope document that provides the public with information on the focus of the risk evaluation;
- hazard and exposure assessments and a risk characterization to inform the risk determination; and
- a risk determination stating whether or not a chemical substance presents an unreasonable risk to health or the environment under its conditions of use.

In addition to USEPA's prioritization process, TSCA allows manufacturers to request that USEPA conduct a risk evaluation on a particular chemical. When this happens, manufacturers are required to provide USEPA with the information necessary to conduct a risk evaluation on those conditions of use that are of interest to them. Like the prioritization process, the risk evaluation process affords opportunities for public comment and submission of relevant information.

The third step in USEPA's existing chemicals process is risk management. If at the end of the risk evaluation process, USEPA determines that a chemical presents an unreasonable risk to health or the environment, the chemical must immediately move to risk management action under TSCA. USEPA is required to implement, via regulation, regulatory restrictions on the manufacture, processing, distribution, use or disposal of the chemical to eliminate the unreasonable risk. USEPA is given a range of risk management options under TSCA, including labeling, record-keeping or notice requirements, actions to reduce human exposure or environmental release, and a ban of the chemical or of certain uses. Like the prioritization and risk evaluation processes, there is an opportunity for public comment on any proposed risk management actions.

### **ChemView**

ChemView is a database that provides one-stop shopping for information on chemical health and safety data received by USEPA and USEPA's assessments and regulatory actions for specific chemicals under TSCA. ChemView contains no confidential business information (CBI). ChemView contains information USEPA receives and develops about chemicals including those on USEPA's Safer Chemical Ingredient List. USEPA is populating the ChemView database in phases, and it currently contains information on 12,000 chemicals. ChemView provides key information in a layered summary format and provides links to underlying studies or other source documents.

### **ACToR, Chemistry Dashboard and ToxCast Dashboard**

ACToR compiles data (both quantitative and qualitative) from a large number of sources (called data collections), including USEPA databases, PubChem, other NIH and FDA databases, state and other national sources, and from academic groups. One novel data collection is ToxRefDB, which includes detailed information on in vivo guideline study results for pesticides and other potentially toxic chemicals that has been assembled by the National Center of Computational Toxicology. ACToR is also the primary repository of data being produced by the EPA ToxCast chemical prioritization program.

Thousands of chemicals are currently in use, and hundreds more are introduced into commerce every year. Due to the time and resource intensive nature of chemical safety testing, only a small fraction of chemicals has been thoroughly evaluated for potential human health effects. Through its computational toxicology research, the USEPA is developing ground-breaking approaches to change how chemicals are evaluated for potential health effects.

The foundation of chemical safety testing relies on chemistry information such as high-quality chemical structures and physical chemical properties. Chemical structures and properties are used in computational models to predict a range of hazard, pharmacokinetic, and exposure-related endpoints that are necessary to understand potential health risks. The USEPA has recently expanded and curated

its chemical structure and physicochemical property database. The public can now access these data through the Chemistry Dashboard. The Chemistry Dashboard is part of a suite of dashboards to enable stakeholders to interact with a variety of safety-related data being collected and collated on the thousands of chemicals in use. The Chemistry Dashboard provides access to a variety of information on over 700,000 chemicals currently in use.

Another publicly available Dashboard is the ToxCast Dashboard. The ToxCast Dashboard provides access to data from automated chemical screening technologies, called “high-throughput screening assays,” that expose living cells or isolated proteins to chemicals to determine potential biological activity. The ToxCast Dashboard helps users access and visualize the data generated from high-throughput screening data in order to help inform decisions related to potential chemical risks. It helps users examine high-throughput assay data to inform chemical safety decisions.

To date, the ToxCast Dashboard has data on over 9,000 chemicals and information from more than 1,000 high-throughput assay endpoint components. Users of the ToxCast Dashboard can explore the data from a chemical or an assay viewpoint. Once the user selects the chemicals and assays of interest, they can then explore the biological activity for the chemical-assay combinations. Results from the selections are shown with tables, graphs and charts that can be downloaded by the user.

USEPA’s ToxCast effort contributes to the Toxicology in the 21st Century (Tox21) federal agency consortium. Through Tox21, the USEPA, National Toxicology Program at the National Institute of Environmental Health Science, the National Institutes of Health’s National Center for Advancing Translational Sciences, and the Food and Drug Administration are using robotic technology to screen tens of thousands of chemicals. These approaches have generated vast amounts of data on thousands of chemicals.

### **IRIS**

USEPA’s IRIS Program supports their mission by identifying and characterizing the health hazards of chemicals found in the environment. Each IRIS assessment can cover a chemical, a group of related chemicals, or a complex mixture. USEPA has numerous guidance documents available for conducting IRIS assessments. IRIS assessments are the preferred source of toxicity information used by USEPA and an important source of toxicity information used by state and local health agencies, other federal agencies, and international health organizations

The IRIS Program is located within USEPA’s National Center for Environmental Assessment (NCEA) in the Office of Research and Development (ORD). The placement of the IRIS Program in ORD is intentional. It ensures that IRIS can develop impartial toxicity information independent of its use by USEPA’s program and regional offices to set national standards and clean up hazardous sites.

### **SRS**

The Substance Registry Services (SRS) is USEPA’s authoritative resource for information about chemicals, biological organisms, and others substance tracked or regulated by USEPA. The SRS makes it possible to identify which USEPA data systems, environmental statutes, or other sources have information about a substance and which synonym is used by that system or statute. It becomes possible therefore to map substance data across EPA programs regardless of synonym.

## ***B7.2. Scope of Chemicals Addressed***

Although USEPA has authority to regulate a wide range of substances, for the purposes of the current project the interest is restricted to their authority under TSCA. The scope of TSCA is restricted to chemical substances which are manufactured, imported, or processed “for a commercial purpose”.

Excluded from scope are drugs, tobacco, nuclear materials, munitions, food additives, cosmetics or chemicals used solely as pesticides.

The substance may have a conditional or limited exemption if:

- it is formed solely as the result of manufacture (or import) of an article; manufactured solely for export, formed by an incidental reaction or end-use reactions; or a mixture, impurity or naturally-occurring material, by-product, or non-isolated intermediate.
- it is manufactured or imported in small quantities solely for research and development.
- it is manufactured (and imported) in quantities of less than 10,000 Kilograms per year.
- it has low environmental release and low human exposure during its manufacture, distribution, processing, use and disposal.
- it is manufactured (including imported) solely for test marketing.
- it is a polymer.

## ***B7.3. Ease of Access and Use of Chemical Information***

### **ChemView**

USEPA has published a User’s Guide to make it easy to search the ChemView database. Searches may be done by:

- Chemical Name or Identifier (including CAS, Accession, or PMN numbers)
- Use (52 separate categories)
- Functional use and use categories for Significant New Use Notification (20 separate categories)
- Chemical Group (8 separate categories)
- Effects/Endpoints (5 separate categories of health or environmental effects)

Output selections include:

- Data Submitted to USEPA
- USEPA Assessments
- USEPA Actions
- Manufacturing, Processing, Use, and Release Data Maintained by USEPA

ChemView can be used to:

- Tailor a search by using various combinations from the criteria listed above
- Identify chemicals by searching for certain health effects (endpoints)
- Compare data for multiple chemicals
- Identify specific actions USEPA has taken on the chemical
- Export data for additional analysis
- Identify and view documents on safer chemical ingredients
- Identify and view TSCA-related information
- Obtain source documents
- Identify and view information provided by the USEPA and other federal organizations

ChemView's expands its search capabilities to include the Other Sources tab. The public is able to gain access simultaneously to searches of reports and dataset information provided by other federal organizations via ChemView. This expanded search allows users to view, compare, and analyze multiple source chemical data, increasing safer chemical decision-making. Other Sources currently holds datasets from six federal government related data portals, including:

- NIH's ChemIDPlus
- OSHA's Occupational Chemical Database
- PubChem
- NIH's Chemical Effects in Biological Systems (CEBS)
- USEPA's TRI Pollution Prevention activity search tool
- USEPA's ECOTOX knowledge-base

If a search of ChemView does not produce results for a particular chemical, it does not mean USEPA does not have information on that chemical; the data may not be posted yet, but will be available in the future as USEPA continues to populate the database.

### **ACToR, Chemistry Dashboard and ToxCast Dashboard**

ACToR is searchable by chemical name, CAS#, or structure. Users may browse assays by toxicity, category, or data collection. To get the best possible experience using the ACToR application users are advised to use Mozilla Firefox, Google Chrome or Mac OS Safari.

The Chemistry Dashboard (name changed recently to CompTox Dashboard) includes search capabilities allowing the user to filter results by chemical name, mass or molecular formula, or by chemical identifiers including CAS#, systematic and common names, and InChIKeys. If data relevant to a search query is identified in the database, a detailed results page with associated information for the chemical is generated. In addition, the Chemistry Dashboard has a series of navigation tabs providing access to additional chemical information including Physical Properties, External Links to additional resources, Synonyms, Biological Activities, Articles, and Patents. USEPA has created a [video tutorial](#) to assist those wishing to conduct advanced searches of the Chemistry Dashboard database.

ToxCast users can select chemicals of interest using a number of filters. Chemical data filters include CAS #, chemical name, chemical category, use category, and physicochemical properties such as the octanol-water partition coefficient (log POW)

### **IRIS**

The [IRIS database](#) can be found on the EPA website. It can be searched by Chemical Name, CAS# or Keyword or by Noncancer or Cancer, Route of Exposure, Organ/System Affected, Toxicity Value Noncancer, Uncertainty Factor Value, Weight of Evidence Carcinogenicity, and Toxicity Value Cancer. Searches using filters for organ/system affected are limited to effects (or tumor sites) used to derive the RfD, RfC, oral slope factor, or inhalation unit risk. Other effects associated with chemicals in the IRIS database that were not used as the basis for a toxicity value are not searchable with organ/system filters. IRIS Advanced Search searches only final IRIS assessments; draft assessments are available online.

### **SRS**

The [SRS database](#) may be searched by chemical, substance, or biological name or ID (CAS #, EPA ID, TSN, or internal tracking number) by single entry or multiple entries or by chemical/substance lists. USEPA has a number of published resources available to assist with searches of the database.

### ***B7.4. Breadth and Depth of EHS Information Available***

#### **ChemView**

ChemView provides key information in a layered summary format and provides links to underlying studies or other source documents. At this time, users can find information organized in templates for the following:

##### Data Submitted to EPA

- Test rule and voluntary data for 178 chemicals
- TSCA §8(e) substantial risk notices for 2,400 chemicals, which include 600 submissions with fully templated data details
- TSCA §8(d) health and safety studies submitted under TSCA for 140 chemicals
- High Production Volume Information System voluntary submissions for 1,513 chemicals

#### **EPA Assessments**

- Hazard Characterizations for 1,018 chemicals
- Design for the Environment Alternatives Assessments for 48 Chemicals
- Integrated Risk Information System (IRIS) Assessments for 546 chemicals
- Design for the Environment List of Safer Chemical Ingredients for 659 chemicals
- USEPA Actions
- Significant New Use Rules for over 1,900 chemicals, representing actions on new chemicals and existing chemicals from 2000-present.
- Consent Orders for 245 chemicals. (Consent Orders represent the outcome of USEPA's review of a PMN for a new chemical substance where an order under TSCA §5(e) is issued
- A current list of all the chemicals subject to TSCA §12(b) export notification requirements is available, including the TSCA section 12(b) notification name, related regulatory CFR citation, and related TSCA Inventory name (if applicable). In addition, users will find a subset of over 2,800 chemicals which have additional information available in ChemView from across program offices.
- Manufacturing, Processing, Use, and Release Data
- Chemical Data Reporting for 7,235 chemicals is presented in a more user-friendly format for ChemView
- Toxics Release Inventory data for 609 chemicals
- Pollution Prevention (P2) information for 347 TRI chemicals

#### **ACToR, Chemistry Dashboard and ToxCast Dashboard**

ACToR incorporates chemical hazard information from a variety of sources, including US federal agencies such as the CDC, FDA, DOD, EPA, NIH, NOAA, OSHA, USDA, and USGS, as well as state level agencies such as the California EPA. It also includes datasets from ECHA, Environment and Health Canada, the Danish EPA, and the Australian Department of Sustainability, Environment, Water, Population, and Communities. Hazard information published by NGOs (e.g., EWG) and other similar groups is available as well. For a full listing of hazard data, [search the database](#) under the 'Hazard' Category.

Within the Chemistry Dashboard, users can access chemical structures, experimental and predicted physicochemical and toxicity data, and additional links to relevant websites and applications. It maps curated physicochemical property data associated with chemical substances to their corresponding chemical structures. Millions of predicted physical- chemical properties developed using machine-learning modeling of highly curated datasets are also mapped to chemicals. These data provide valuable information for analytical scientists involved in structure identification and can support targeted and non-targeted screening identification of environmental chemicals.

These data are compiled from sources including the USEPA's computational toxicology research databases, and public domain databases such as the National Center for Biotechnology Information's PubChem database. The database includes quality assurance flags that indicate the degree of curation and confidence associated with the data.

For each chemical, the ToxCast Dashboard summarizes chemical information.

- Chemical structure and data such as CAS#, simplified molecular input line entry system (SMILES), IUPAC International Chemical Identifier (InChI), chemical structures, chemical annotations, quality control information on the chemical tested, information on the chemical sample, and physicochemical properties.
- Chemical assay activity summaries and charts for the selected chemicals.
- Chemical Product Category (CPCAT) information listing product use category for the selected chemicals.

Exposure estimations based on manufacture and use information for the chemicals selected.

ToxCast users can select assays of interest using a number of filters. Assay filters include gene symbol, intended target, assay name, tissue, and 'actives' only. For each assay, the ToxCast Dashboard summarizes assay information.

- Assay data including assay descriptions, reagents used, citations from scientific papers that conducted an analysis of the assay data, and descriptions of methods used to process the assay data.
- Assay summary charts that show summaries of the assay activity for all the chemicals screened in the selected assay and a list of chemicals tested in the selected assay.

The biological activity function of selected chemical and assay pairs is summarized in the ToxCast Dashboard. Examples of summary information include hit calls, AC50 (chemical concentration producing 50% of the maximum activity in the assay), statistical model used to fit the activity data, and a plot of biological activity. If a user selects multiple chemical and assay pairs, the biological activity for each pair is added to the summary charts, which are downloadable and interactive.

## IRIS

IRIS assessments provide the following toxicity values for health effects resulting from chronic exposure to chemicals.

- Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a No Observable Adverse Exposure Level (NOAEL), Lowest Observable Adverse

Exposure Level (LOAEL), or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used.

- Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used.]
- Cancer descriptors characterize the chemical as:
  - Carcinogenic to Humans
  - Likely to Be Carcinogenic to Humans
  - Suggestive Evidence of Carcinogenic Potential
  - Inadequate Information to Assess Carcinogenic Potential
  - Not Likely to Be Carcinogenic to Humans
- Oral slope factor (OSF) is an estimate of the increased cancer risk from oral exposure to a dose of 1 mg/kg-day for a lifetime. The OSF can be multiplied by an estimate of lifetime exposure (in mg/kg-day) to estimate the lifetime cancer risk.
- Inhalation unit risk (IUR) is an estimate of the increased cancer risk from inhalation exposure to a concentration of 1 µg/m<sup>3</sup> for a lifetime. The IUR can be multiplied by an estimate of lifetime exposure (in µg/m<sup>3</sup>) to estimate the lifetime cancer risk.

IRIS plays a critical role in USEPA risk assessments which are a four-step process described as "the characterization of the potential adverse health effects of human exposures to environmental hazards." Characterizing risk involves integrating information on hazard, dose-response, and exposure.

An IRIS assessment includes the first two steps of the risk assessment process:

- Hazard Identification, which identifies credible health hazards associated with exposure to a chemical, and
- Dose-Response Assessment, which characterizes the quantitative relationship between chemical exposure and each credible health hazard. These quantitative relationships are then used to derive toxicity values.

USEPA's program and regional offices identify human exposure pathways and estimate the amount of human exposure under different exposure scenarios (Exposure Assessment). Then they combine their exposure assessment with the hazard information and toxicity values from IRIS to characterize potential public health risks (Risk Characterization).

## **SRS**

Hazard information is not available in the SRS. However, the SRS provides links, when known, from each SRS substance record to external sites and fact sheets. These external sites may be for USEPA programs, other U.S. agencies, or international organizations.

There is a record in the SRS for every substance that is tracked or regulated at USEPA. Each record provides basic information about that substance, such as the Chemical Abstract Service (CAS) number for a chemical or the TSN for a biological organism. Each record also identifies standardized nomenclature about the substance and any synonyms in use at USEPA. When available, there also are links to fact sheets or other documentation available from other web sites.

The SRS provides a range of services to users:

Search and retrieval of:

- Single substances
- Programmatic, statutory or other lists of substances
- Groups of substances
- Information about creating machine-to-machine integration between the SRS and other systems
- Outreach and education material to gain a better understanding of the SRS and its services
- Links to related regulatory information within USEPA and other federal agencies and states

The initial purpose of the SRS is, as the name implies, to register substances. The SRS is a registry or catalog of the substances that are identified by a federal environmental statute or that are tracked or regulated by any program at USEPA. The SRS does not contain the programmatic data for the substances; it simply identifies the substances; identifies the USEPA programs that track or regulate those substances; and identifies the names used for those substances by those programs.

## ***B7.5. Quality of the Underlying EHS Information***

### **ChemView**

EPA must evaluate both hazard and exposure, exclude consideration of costs or other non-risk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, and ensure decisions are based on the weight-of-scientific-evidence. All EPA evaluations undergo peer review and are subject to a minimum 60 day public comment period.

### **ACToR, Chemistry Dashboard and ToxCast Dashboard**

The Computational Toxicology work being done by USEPA that underpins ACToR, Chemistry and ToxCast Dashboards is leading edge science. USEPA points to a long list of peer-reviewed journal publications that have been written about uses for the Dashboard.

Nevertheless, USEPA cautions that with respect to documents available from the ACToR server, neither the United States Government nor any of their employees, makes any warranty, express or implied, including the warranties of merchantability and fitness for a particular purpose, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights.

ACToR itself is not peer reviewed; ACToR only contains publicly available datasets which have been previously published.

### **IRIS**

The IRIS program has been continuously evolving since its inception. Numerous guidance and policy documents have been prepared over the years to ensure IRIS uses the best scientific approaches

available. These documents have undergone review by various USEPA Advisory Panels and have been subjected to public review and comment.

Draft IRIS assessments are released for public review and comment. USEPA announces the availability of the draft assessment and draft peer review charge questions for public review and comment on the IRIS website. A public meeting is held to discuss the draft assessment, draft peer review charge questions, and specific science questions raised by the assessment. The IRIS Program revises the draft assessment and peer review charge questions in response to the public's comments. Additionally, USEPA prepares a response to major public comments received during the public comment period.

Subsequently, the draft assessment and peer review charge questions are released for external peer review by the USEPA's Scientific Advisory Board (SAB) Chemical Assessment Advisory Committee (CAAC). During external peer review, a public external peer review meeting is held; the public is allowed to attend the peer reviewers' discussion of the draft assessment and provide comments. The SAB announces the dates and location of the peer review meeting.

For the last several years, numerous stakeholders, including industry, NGOs, state health officials, and others, have noted the importance of a strong and transparent assessment development process that produces high quality and timely products based on best available science to inform Agency decision-making. Mirroring this interest, the US Congress has also requested information and periodic updates on the IRIS Program's progress responding to recommendations, most notably from the National Academies (NAS) National Research Council. In the Consolidated Appropriations Act of 2017, as well as accompanying explanatory language, Congress requested actions related to the IRIS Program's implementation: of NAS recommendations, focused on:

- Peer review for the draft IRIS assessment of formaldehyde;
- Implementation of NAS recommendations in other IRIS assessments; and,
- a review of implementation of NAS recommendations by an interagency working group.

During the past several years, USEPA has been working to address the NAS recommendations as follows:

- Increase the transparency of assessments by fully implementing the principles of systematic review
- The IRIS Program has adapted or developed standardized approaches that foster consistency across the IRIS Program; enabling active and new assessments to meet all systematic review-related recommendations from the 2011 and 2014 NAS reports.
- Developing standard operating procedures (IRIS Handbook) and chemical assessment specific protocols that provide consistency across assessments.
- Modernize the IRIS Program. The IRIS Program is developing and using automation and machine-learning tools to expedite systematic review and incorporate emerging data types.
- Modularize product lines. IRIS implemented a portfolio of chemical evaluation products that optimize the application of the best available science and technology. These products will allow IRIS to remain flexible and responsive to customers within EPA as well as the diverse stakeholders beyond EPA, including states, tribal nations, and other federal agencies.
- Enhance accessibility

IRIS is providing outreach and training within and outside EPA to build familiarity and acceptance of systematic review practices.

In January of 2018, USEPA submitted an update on its actions to Congress. NAS just completed a two day workshop on 1-2 February 2018 to review advances made to the IRIS process and on March 18, 2018 EPA held another public meeting to hear comments.

## **SRS**

Quality for SRS data is an on-going effort. With more than 100,000 records in SRS there are enormous opportunities for error. EPA focuses on quality in three areas for SRS:

- Quality of the information provided by SRS
- Assessment of the accuracy of the synonyms that are used by USEPA programs and which are thus published in SRS
- Value of the available information; e.g., links to related websites

Core information is the fundamental metadata about a substance. These data items remain static regardless of environmental statute or USEPA system. Examples of core metadata are the SRS Registry Name, the molecular weight, and the EPA Identifier.

The SRS Registry Name (a standard name USEPA adopts for each chemical and biological organism) requires high quality. To determine these names and to ensure their accuracy, there are workgroups with representatives from USEPA programs and state agencies that meet monthly. The workgroup participants include chemists, staff with extensive knowledge of laboratory analyses, plus other staff with long experience. This complement of diverse skills is necessary for making sound decisions.

Other core data intrinsic to the substance (e.g., molecular weight and molecular formula) are not generated by EPA but are maintained in SRS. To keep this information current and accurate, USEPA employs various processes for quality checking and updating of the information.

Future plans include evaluating the quality of the synonyms in the SRS. These synonyms, whether found in environmental statutes or in USEPA data systems, are not always correct. A name in an USEPA data system, submitted by a facility or other organization, may be misspelled. An environmental law may have used an ambiguous or inaccurate synonym. A review and quality assignment rating (e.g., valid, misspelled, ambiguous) of each synonym will help the users of SRS to decide whether or not to adopt a particular synonym.

Quality also means ensuring that the information in SRS is of value to users. Since one of the most widely used features of SRS is the fact sheets about substances, SRS will link to additional internal and external sources that provide fact sheets or other documentation about substances.

SRS will also either store other federal agencies' substance identification information or create links to their substance registries. The result will be the ability to go to SRS as a one-stop registry to discover substance information for the entire Federal government.

### ***B7.6. Procedures for Updating the Database with New Information***

#### **ChemView**

EPA updates its assessments whenever they become aware of significant new substantial risk information, which includes new scientific information that impact the hazard assessment or significant new use/exposure information.

### **ACToR, Chemistry Dashboard and ToxCast Dashboard**

These databases are maintained by the National Center for Computational Toxicology.

### **IRIS**

The IRIS program maintains the integrity of the chemical assessments by following the 2009 IRIS process prior to posting updated or new assessments to the IRIS Web site and database. These are announced on the IRIS Agenda and then can be tracked as they follow the IRIS Process for development through IRISTrack. The final assessments are then posted throughout the year. The IRIS Program is managed by USEPA's NCEA.

### **SRS**

The USEPA maintains the database. Maintaining the substance lists in SRS is another area that demands quality assurance. Discovering which substances are named in a particular statute or which substances are tracked by a certain EPA database is a principal use of SRS. EPA has determined that the best approach to managing the substance lists is through stewardship. Each substance list has at least one steward who manages a specific list within SRS. Normally, the steward is from the organization that is responsible for, or has the best information about, the substance list.

## ***B8. U.S. Agency for Toxic Substances & Disease Registry (ATSDR) Toxic Substances Portal***

The information presented below represents a summary of key information about the EHS information on industrial chemicals that is available from ATSDR, an agency of the US government that protects communities from harmful health effects related to exposure to natural and man-made hazardous substances. ATSDR maintains a Toxic Substances Portal which includes important information about toxic substances and how they affect human health. [More detailed information is available about ATSDR from their website.](#)

### ***B8.1. Overview/Description***

ATSDR, based in Atlanta, Georgia, is an agency of the U.S. Department of Health and Human Services. ATSDR protects communities from harmful health effects related to exposure to natural and man-made hazardous substances. They do this by responding to environmental health emergencies; investigating emerging environmental health threats; conducting research on the health impacts of hazardous waste sites; and building capabilities of and providing actionable guidance to state and local health partners.

In response to widespread environmental contamination at Love Canal, New York and Times Beach, Missouri, Congress passed the Comprehensive Environmental Response, Compensation, and Liabilities Act (CERCLA or "Superfund" law) in 1980. This law created ATSDR, which was formally organized in 1985. Superfund and the Superfund Amendments and Reauthorization Act of 1986 (SARA) gave the U.S. Environmental Protection Agency (EPA) the responsibility for identifying, investigating, and cleaning up

contaminated sites on the National Priorities List and created ATSDR as a non-regulatory public health agency to

- Conduct health assessments,
- Conduct health consultations,
- Produce toxicological profiles,
- Conduct epidemiological studies, and
- Establish registries and conduct health surveillance.

At first, ATSDR focused on evaluating toxic exposure just for communities near Superfund sites. As time went on, the agency began to assess requests from EPA; state, tribal or local agencies; residents; and communities. In total, ATSDR has addressed health concerns about chemical exposure in more than 6,000 communities.

Most of ATSDR's work in communities focuses on understanding whether people are or have been exposed to harmful chemicals. ATSDR does not respond to all requests. Once a request is received, they review existing environmental and health information to find out if people are at risk because of their exposures. And when appropriate, ATSDR makes recommendations to EPA; state, regulatory and health agencies; and other organizations for preventing the harmful exposures.

Sometimes ATSDR assessments identify important missing information that keep them from answering questions about health risks, so they conduct or recommend further investigation.

They evaluate environmental health issues that differ widely in scope, size, and exposure type, including

- Large projects with many steps and reviews, such as public health assessments
- Long-term studies of possible environmental health effects in a larger population, such as our investigations of asbestos exposure in Libby, Montana, and ongoing investigations of exposure to contaminated drinking water at Camp Lejeune, North Carolina.
- Studies of connections between exposures and health, such as our study of exposure to uranium and other metals and pregnancy outcomes in the Navajo Nation.
- Much smaller projects, like helping to determine whether one or two families with private wells can safely drink their well water.

ATSDR works closely with local residents, setting them apart from many other federal agencies. At exposure sites, they

- Talk to individual community members to find out how environmental exposures affect them.
- Establish community assistance panels to help guide our work when they conduct more detailed investigations.
- Hold public meetings to explain their findings and recommendations.
- Work with health providers near exposure sites to help them answer patients' questions and provide effective treatment.

Although much of ATSDR's work focuses on assessing community exposures, their toxicologists, medical officers, and other scientists also respond to environmental emergencies, like the oil pipeline breach near the Yellowstone River in Montana.

ATSDR's Assessment of Chemical Exposures (ACE) program provides resources and technical help to rapidly assess health effects from toxic spills or releases. ACE can quickly assemble a team of experts to help state and local health departments either from Atlanta or at the scene.

ATSDR is known world-wide for its research and contributions to scientific and technical knowledge, including the latest information about toxicology, environmental science, and environmental medicine.

ATSDR maintains a Toxic Substances Portal which includes important information about toxic substances and how they affect human health.

- ATSDR toxicological profiles (ToxProfiles™) are used by scientists, health providers, and regulators around the world.
- Also available in the portal are short summaries of the profiles (ToxFAQs™) that answer major questions about the health risks of hazardous substances.

In addition, ATSDR offers support for healthcare providers nationwide to diagnose and treat environmentally linked health concerns, including

- Pediatric Environmental Health Specialty Units (PEHSUs) for clinical consultations to physicians;
- Case Studies in Environmental Medicine online, plus continuing education courses for diagnosing and treating environmental exposures; and
- Medical Management Guidelines to help emergency departments and health providers manage acute exposures from chemical incidents, plus comprehensive evaluation and treatment guidelines.
- Other technical resources include geospatial analyses to identify contamination and estimate how many people are exposed; computational toxicology; exposure modeling, and biomonitoring.

ATSDR's partnership with the National Center for Environmental Health (NCEH) allows the agency to use Centers for Disease Control (CDC) resources to protect communities. ATSDR often relies on NCEH's state-of-the-art environmental laboratory to evaluate biological samples, such as children's blood for lead and other metals.

NCEH/ATSDR confronts environmental health challenges and addresses the risks Americans face from chemicals in their environment. Their work advances the science of environmental health and translates that science into practice by developing tools, conducting research, and partnering with local health departments, officials, and practitioners.

ATSDR is directed by congressional mandate to perform specific functions concerning the effect on public health of hazardous substances in the environment. These functions include public health assessments of waste sites, health consultations concerning specific hazardous substances, health surveillance and registries, response to emergency releases of hazardous substances, applied research in support of public health assessments, information development and dissemination, and education and training concerning hazardous substances.

A significant goal is to reduce morbidity and mortality related to exposure to natural and man-made toxic substances. Partnerships between ATSDR and with others in the CDC and with states, territories, localities, tribes, academic institutions, and other organizations are essential to achieving its mission and goals.

ATSDR's Toxic Substances Portal provides access to a number and variety of resources for Toxic Substances as described below. Those resources which directly provide EHS information on chemical substances have been bolded and are the focus of the remainder of this chapter.

Case Study in Environmental Medicine (CSEM) — Self-instructional publication designed to increase primary care provider's knowledge of a hazardous substance in the environment and to aid in the evaluation of potentially exposed patients.

Community Environmental Health Presentations (CEHPs) — CEHPs include information about specific types of exposures to hazardous substances, exposure routes and pathways, health effects, and how to prevent and minimize exposures.

Grand Rounds in Environmental Medicine (GREM) — are 1-hour seminars designed to increase the primary care provider's knowledge of hazardous substances in the environment and to aid in the evaluation of potentially exposed patients. The GREM seminars are available and downloadable online in two versions. The first version is scripted PowerPoint presentations ready for medical educators to use in face-to-face sessions with primary health-care providers, medical students, and others. The second version is a video recorded presentation that can be viewed online by individuals or groups. Both versions offer approved continuing education credits.

Interaction Profiles — Succinctly characterizes the toxicologic and adverse health effects information for mixtures of hazardous substances.

Managing Hazardous Materials Incidents (MHMIs) The MHMI series is a three volume set (with a video) comprised of recommendations for on-scene (pre-hospital), and hospital medical management of patients exposed during a hazardous materials incident.

Medical Management Guidelines (MMG) for Acute Chemical Exposure — This publication is intended to aid emergency department physicians and other emergency healthcare professionals who manage acute exposures.

Minimal Risk Levels (MRL) which are estimates of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse, non-cancer health effects over a specified duration of exposure. The information in this MRL serves as a screening tool to help public health professionals decide where to look more closely to evaluate possible risk of adverse health effects from human exposure.

Mixtures Guidance Manual — Provides guidance for assessment of joint toxicity of environmental chemicals to determine whether exposure to chemical mixtures may impact public health.

Patient Education and Care Instruction Sheet — Complement the newly developed or revised CSEM and GREM topics. These job aids provide general information on various environmental medicine topics and give health-care providers quick, ready-to-use materials to aid in patient care and instruction. Patient Education and Care Instruction Sheets are available and downloadable online. These education sheets are made available for use with patients and do not offer continuing education credit for their use.

Pediatric Environmental Health Training— provides in-depth information The Pediatric Environmental Health Toolkit (PEHT) offers health-care providers detailed examples about how to best deliver anticipatory guidance on a range of environmental health issues, especially during regularly scheduled healthy child examinations.

Priority Data Needs — represent essential information to improve the database for conducting public health assessments.

Priority List of Hazardous Substances — based on a combination of their frequency, toxicity, and potential for human exposure at National Priorities List (NPL) sites.

**Public Health Statement** — Summary about a hazardous substance taken from Chapter One of its respective ATSDR Toxicological Profile.

**ToxFAQs** — The ATSDR ToxFAQs are summaries about hazardous substances developed by the ATSDR Division of Toxicology and Human Health Sciences. Information for this series is excerpted from the ATSDR Toxicological Profiles and Public Health Statements. Answers are provided to the most frequently asked questions (FAQs) about exposure to hazardous substances found around hazardous waste sites and the effects of exposure on human health.

**ToxGuide** — Quick reference guide providing information such as chemical and physical properties, sources of exposure, routes of exposure, minimal risk levels, children's health, and health effects for a substance.

**Toxicological Profile**<sup>1</sup> — Succinctly characterizes the toxicologic and adverse health effects information for a hazardous substance.

**Addendum to the Profile** — provides to the public and other federal, state, and local agencies a non-peer reviewed supplement of the scientific data that were published in the open peer-reviewed literature since the release of the Toxicological Profile.

Toxicology Curriculum for Communities Trainer's Manual — provides four training modules for lectures or seminars for communities, on the topic of toxicology and issues surrounding environmental exposures.

**ToxZine** — Summary of health effects, exposure, and recommendations in an easy-to-read magazine format.

<sup>1</sup> By Congressional mandate, ATSDR produces "toxicological profiles" for hazardous substances found at National Priorities List (NPL) sites. These hazardous substances are ranked based on frequency of occurrence at NPL sites, toxicity, and potential for human exposure. Toxicological profiles are developed from a priority list of 275 substances. ATSDR also prepares toxicological profiles for the Department of Defense (DOD) and the Department of Energy (DOE) on substances related to federal sites.

## ***B8.2. Scope of Chemicals Addressed***

Federal law (CERCLA) requires ATSDR and the EPA to prepare a list, in order of priority, of substances that are most commonly found at facilities on the NPL and which are determined to pose the most significant potential threat to human health due to their known or suspected toxicity and potential for human exposure at these NPL sites. CERCLA also requires this list to be revised periodically to reflect additional information on hazardous substances. In CERCLA, it is called the priority list of hazardous substances that will be candidates for toxicological profiles.

This substance priority list is revised and published on a 2-year basis, with a yearly informal review and revision. (No list was published in 2009 while ATSDR transitioned to a new agency science database.) Each substance on the list is a candidate to become the subject of a toxicological profile prepared by ATSDR. It should be noted that this priority list is not a list of “most toxic” substances, but rather a prioritization of substances based on a combination of their frequency, toxicity, and potential for human exposure at NPL sites. Thus, it is possible for substances with low toxicity but high NPL frequency of occurrence and exposure to be on this priority list. The objective of this priority list is to rank substances across all NPL hazardous waste sites to provide guidance in selecting which substances will be the subject of toxicological profiles prepared by ATSDR.

ATSDR’s mission extends to all chemical substances, man-made and natural, that may pose risks to humans community settings. This includes industrial chemicals in commerce, but also to pesticides, biocides, and chemicals that are no longer in commerce and others that have never been produced, imported or sold commercially (e.g., chlorinated dioxins and furans, polycyclic aromatic hydrocarbons and other substances).

### ***B8.3. Ease of Access and Use of Chemical Information***

ATSDR’s Toxic Substances Portal is easily accessed.

The Portal may be searched for substances by:

- Alphabetical Listing (A-Z)
- CAS#
- Substance Name
- Synonym
- Tradename
- Individual States where they have been found in communities

Alternatively, the Portal may be searched for toxicological information by:

- Effects on Organ Systems and their Development
- Cancer Classification
- Structures, Properties or Use (14 separate categories)
- Audience (i.e., community members, emergency responders, toxicological and health professionals, and health care providers)

Although no user guide to assist in conducting searches could be located, the search process is intuitive using point and click on text descriptors supplemented with icons.

### ***B8.4. Breadth and Depth of EHS Information Available***

The ATSDR toxicological profile succinctly characterizes the toxicologic and adverse health effects information for the hazardous substances included in the ATSDR database. Each peer-reviewed profile identifies and reviews the key literature that describes a hazardous substance’s toxicologic properties. Other pertinent literature is also presented, but is described in less detail than the key studies.

The focus of the profile is on health and toxicologic information. Therefore, each profile begins with a Public Health Statement that summarizes in nontechnical language, a substance's relevant properties.

A useful two-page information sheet, the ToxFAQs is also available, as are ToxGuides™ which are quick reference guides providing information such as chemical and physical properties, sources of exposure, routes of exposure, minimal risk levels, children's health, and health effects. The ToxGuides™ also discuss how the substance might interact in the environment. Furthermore, a summary of health effects, exposure, and recommendations in an easy-to-read magazine format ToxZine are available for a dozen or so chemical substances.

Each ATSDR Toxicological Profile has the following chapters:

- Preface
- Public Health Statement
- Relevance to Public Health
- Health Effects
- Chemical and Physical Information
- Production, Import, Use, and Disposal
- Potential for Human Exposure
- Analytical Methods
- Regulations and Advisories
- References
- Glossary
- Appendices
- References
- Disclaimer
- Where can I get more information?

As of February 20, 2018, ATSDR has prepared and published Toxicological Profiles for nearly 200 substances or chemical families (e.g., polycyclic aromatic hydrocarbons) and has profiles under development for approximately 30 more substances.

### ***B8.5. Quality of Underlying EHS Information***

Toxicological profiles are developed in two stages:

**DRAFTS:** The toxicological profiles are first produced as drafts. ATSDR announces in the Federal Register the release of these draft profiles for a 90-day public comment period.

**FINALS:** After the 90-day comment period, ATSDR considers incorporating all comments into the documents. ATSDR finalizes the profiles. ATSDR has published detailed guidance for preparing toxicology profiles.

ATSDR has adopted the National Research Council's (NRC's) "Guidelines for Assessing the Quality of Individual Studies," which appear in TOXICITY TESTING: Strategies to Determine Needs and Priorities, published by NRC in 1984. ATSDR agrees with the NRC that judging the quality of past and future studies solely by today's standards is inappropriate. The NRC considers a report of scientific findings adequate for use in health hazard assessment if the report meets the following basic criteria:

- All elements of exposure are clearly described.

- Results in test subjects are predictive of human response, and test subjects are sensitive to the effects of the substance.
- Controls are comparable with test subjects in all respects except the treatment variable.
- End points answer the specific questions addressed in the study, and observed effects are sufficient in number or degree to establish a dose-response relationship that can be used in estimating the hazard to the target species.
- Both the design and the interpretation of the study allow for appropriate statistical analysis of the data.

Where appropriate, these criteria should be applied to judgments on the quality of data from epidemiological investigations and other scientific studies of relevance to ATSDR's toxicological profiles. The reliability of epidemiological data in hazard identification is increased when results are obtained from studies that have the following characteristics:

- Are derived from well-designed and well-executed case control or cohort studies that are free from bias.
- Display a strong association unlikely to be due to chance variation.
- Follow a logical, temporal sequence of exposure-response.
- Have been replicated in a variety of settings.
- Exhibit a dose-response relationship, using valid estimates of exposure and dose.
- Are toxicologically plausible.
- Where possible, include an examination of causality.

In addition, ATSDR recognizes the following desirable factors of studies or reports of scientific findings as set forth in the NRC guidelines:

- Subjective elements should be minimized.
- Peer review of scientific papers and of reports is desirable. Note: CERCLA mandates the peer review of toxicologic testing results that ATSDR uses.
- Results reported have increased credibility if they are supported by findings from other investigations.
- Similarity of results to those of tests conducted on structurally related compounds increases scientific confidence.
- Evidence of adherence to good laboratory practices improves confidence in results.

### ***B8.6. Procedures for Updating the Database with New Information***

The purpose of Toxicological Profiles Addenda is to provide, to the public and other federal, state, and local agencies a non-peer reviewed supplement of the scientific data that were published in the open peer-reviewed literature since the release of the profile.

ATSDR encourages users of their Toxicology Profiles that, if they are aware of new or additional studies that will contribute to the database to send them to:

**Agency for Toxic Substances and Disease Registry**

Division of Toxicology and Human Health Sciences

1600 Clifton Road NE, Mailstop F-57

Atlanta, GA 30333

FAX 770 488-4178

[additionalreference@cdc.gov](mailto:additionalreference@cdc.gov)

## ***B9. California Department of Toxic Substances Control Chemical Information Tool and Toxics Information Clearinghouse***

The information presented below represents a summary of key information about the EHS information on industrial chemicals that is available from the State of California's Department of Toxic Substances Control (DTSC), which is a part of California Environmental Protection Agency (CalEPA). DTSC maintains a Chemical Information Tool and a Toxics Information Clearinghouse, both of which provide access to EHS information about chemicals in commerce. [More detailed information about DTSC is available from their website.](#)

### ***B9.1. Overview/Description***

The mission of DTSC is to protect California's people and environment from harmful effects of toxic substances by restoring contaminated resources, enforcing hazardous waste laws, reducing hazardous waste generation, and encouraging the manufacture of chemically safer products. DTSC takes enforcement action against violators; oversees cleanup of hazardous wastes on contaminated properties; makes decisions on permit applications from companies that want to store, treat or dispose of hazardous waste; and protects consumers against toxic ingredients in everyday products. The department is committed to engaging the public in a way that gives those most affected by its decisions opportunities to voice their concerns and ask questions.

Among DTSC's responsibilities is implementation of California's Safer Consumer Products (SCP) law. The California legislature passed the Green Chemistry Law in 2008 to implement two key recommendations of the California Green Chemistry Initiative Final Report:

- Accelerate the search for safer products
- Create an online toxics clearinghouse

The regulations and authorizing statutes implement recommendation #5 of the California Green Chemistry Initiative Final Report—Accelerate the Quest for Safer Products. They also create a systematic, science-based process to evaluate Chemicals of Concern (COC), and identify safer alternatives. The law authorizes and requires DTSC to adopt regulations to identify and prioritize chemicals in consumer products.

The DTSC's SCP regulations took effect October 1, 2013 and are being implemented based on the various regulatory requirements.

The goals of this program are to:

- Reduce toxic chemicals in consumer products
- Create new business opportunities in the emerging safer consumer products industry
- Help consumers and businesses identify what is in the products they buy for their families and customers

To accomplish these goals, the SCP Program relies on reports submitted by responsible entities, such as manufacturers. DTSC hopes the information in these reports will increase the use of safer chemicals in

products used in homes, schools, and workplaces, and result in significant environmental and economic benefits.

DTSC followed through by developing a process for evaluating COC in consumer products and their possible alternatives. The initial set of "priority products" was released in the Spring of 2014 and in September of that year DTSC released a draft three-year work plan that identifies product categories that will be the focus of future priority products.

The regulations provide for a continuous four-step, science-based, ongoing process to identify safer consumer product alternatives. The process includes:

1. Immediate identification of a list of Candidate Chemicals (about 1,100 chemicals) based on the work of authoritative organizations, and specify a DTSC process to add to the list over time. Candidate chemicals have at least one quality that can cause harm to human health or the environment referred to as a hazard trait. The Candidate list may be found on the DTSC website.
2. Identification of Priority Products which are products that contain one or more Candidate Chemicals. A Candidate Chemical found in a Priority Product is called a COC. Before a Priority Product is finalized it must go through a rule-making process that can take up to a year. Sixty days after a Priority Product is finalized, responsible entities (e.g., manufacturers) must submit Priority Product Notifications.
3. Priority Product responsible entities must then perform Alternatives Analysis on any and all COCs in their products to determine how to limit exposure or reduce the level of public health and/or environmental harm.
4. DTSC must identify regulatory responses that will protect public health and/or the environment and maximize the use of acceptable and feasible alternatives of least concern. DTSC may require regulatory responses if the manufacturer decides to retain the COC in their product, or for an alternative product selected to replace it.
5. Alternatives Analysis is a process for comparing an existing Priority Product with potential alternatives such as chemical substitution or product redesign. The process uses factors which are evaluated at each stage of the product's life cycle. When the Alternatives Analysis is complete, the manufacturer or another responsible entity will select an alternative chemical ingredient or alternative product design or decide to retain the existing product-chemical combination.

Each responsible entity is required to submit a report on the completed Alternatives Analysis to DTSC. DTSC will evaluate the report to determine if the chosen alternative creates adverse public health or environmental impacts that need to be remedied by a regulatory response.

DTSC has developed the Chemical Information Tool (CIT) and the Toxics Information Clearinghouse to assist responsible entities with their Alternatives Assessments.

## ***B9.2. Scope of Chemicals Addressed***

One area of ambiguity and concern is the regulations' definition of consumer products. The SCP embraces the definition of consumer product specified in section 25251 of the state Health and Safety Code, which says it is a "product or part of the product that is used, brought, or leased for use by a person for any purposes." The regulations also define consumer products to include "a component of an assembled" product. Products exempt from SCP include: drugs, medical devices, dental restoratives, food and pesticides.

The Candidate Chemicals identified in the SCP Regulations were developed using 23 authoritative lists, which fall into one of two categories: lists based on hazard traits (15 lists), and lists based on potential exposure concerns (8 lists).

A Candidate Chemical must appear on one or more of these lists and must exhibit a hazard trait and/or environmental or toxicological endpoint.

As of this writing, the list contains ~1,100 grouped Candidate Chemicals, which includes group names and Candidate Chemicals that are not in a group. There are ~2,300 Candidate Chemicals if all individual chemicals (regardless of the group association) are counted.

## ***B9.3. Ease of Access and Use of Chemical Information***

The Candidate Chemical List may be searched by:

- CAS# and Chemical Name,
- Group Name,
- COC,
- hazard traits,
- authoritative lists, or
- potentially excluded Candidate Chemicals.

Alternatively, users may download the entire list for exporting to an Excel file for viewing or printing.

The Chemical Information Tool (CIT) is an online system with information on chemicals, including hazard traits and toxicological endpoints. It is a search engine accessing chemical toxicity information available on the Web from 56 separate third party information sources.

The CIT allows users to search and find information about chemicals and associated hazard traits, if known. Submit a search for a chemical or its hazard traits, and the user will receive links to relevant websites of governmental organizations, peer reviewed articles, university publications, industry sources, and non-governmental organizations.

Accordingly, a user can search the following hazard trait categories:

1. Toxicological Hazard Traits—Carcinogenicity, Developmental Toxicity, and Reproductive Toxicity;
2. Other Toxicological Hazard Traits;
3. Environmental Hazard Traits;
4. Exposure Potential Hazard Traits; and,
5. Physical Hazard Traits.

The CIT includes:

- A Search function by chemical name or CAS#
- Search results shown as links to information in publicly available data collections.

The links are displayed by:

- Hazard traits, toxicological endpoints or physical-chemical parameters; or,
- Authoritative organizations (governmental entities only).

DTSC has published some guidance to assist with searches of CIT.

DTSC notes that a high number of search results does not necessarily mean that a chemical is more toxic. The search results reflect the information found in the data collections that were searched. The results may not be unique and do not represent the completeness or quality of analytical test results. A single “result,” or synthesis of results, may be repeated in many data collections.

The intent of DTSC’s Toxics Information Clearinghouse (TIC) is to provide a diverse and wide-ranging collection of chemical information sources including specific chemical hazard traits and environmental and toxicological end-point data.

TIC shares many characteristics of OECD’s eChemical Portal and IPSC’s INCHEM Portal in that it provides links to databases that are owned and maintained by third parties. Many of those databases have been reviewed in other chapters of this report.

The TIC can be searched by Information Type or by Sources of Information.

#### **Information Type**

- Chemical and physical properties
- Source information, fate and exposure
- Toxicology, epidemiology and hazard
- Eco-toxicology, ecology and resource damage
- Laws, regulations, policies, lists, approaches, tools

#### **Sources of Information**

- Governments
- Private Sector
- Academic
- NGOs

A search of TIC yields a list of third-party information sources and links to their websites which must then be searched individually to locate EHS chemical information.

### ***B9.4. Breadth and Depth of EHS Information Available***

The breadth and depth of EHS information available from searches of CIT and TIC varies considerably based on the contributing data source and substance being queried. Hazard traits, toxicological endpoints and physical-chemical parameters are not available for every chemical. The CIT does not

store electronic copies of journals, articles, or documents locally. The search results are displayed by the most recent date of publication as a default.

### ***B9.5. Quality of the Underlying EHS Information***

The quality of EHS information that is available from searches of CIT and TIC varies considerably based on the contributing data source and substance being queried. DTSC makes no warranty or representation, express or implied, regarding the completeness, reliability and/or accuracy of the information provided in the CIT website. Any action taken based on the information in the database is at the user's own risk. DTSC will not be liable for any losses or damages in connection with the use of the database.

DTSC's inclusion of a link within either CIT or TIC is not an endorsement of the claims, contents or the provider of the information within the linked site. Nor does DTSC assume any responsibility for any claims or losses arising out of reliance on the information within the linked site or the provider. DTSC has not undertaken an independent review of the accuracy of the information within the linked sites or any of the provider's representations and claims.

CIT and TIC dynamically search accessible data collections created and maintained by authoritative organizations, which are state, national, and international governmental entities.

Authoritative organizations have set standards and methods for scientifically valid studies and information. These entities use such information in making determinations about risks or hazards for chemical substances and in regulating threats to public health or the environment posed by chemical substances.

### ***B9.6. Procedures for Updating the Database with New Information***

Different data sources linked to CIT and/or TIC use different methods to maintain and provide updates of their data with new information.

The methods vary from an automatic update via the Internet, semi-automatic update via the Internet, to a manual import of data files, depending on participating data source resources and the frequency of updates. Users are urged to consult with the individual participating data sources if they need to be assured that they have the most up-to-date information on a substance.

DTSC may change or update the information in CIT or TIC without notice. Users are encouraged to contact DTSC should they have additional EHS information to share about a specific chemical.

## ***B10. Environmental Working Group's (EWG) Skin-Deep™ Database***

The information presented below represents a summary of key information about the environmental, health and safety information on industrial chemicals that is available from EWG's Skin-Deep Database. For more detailed information on Skin-Deep, the reader should consult directly with the [EWG website](#).

### ***B10.1. Overview/Description***

EWG describes itself as a non-profit, non-partisan organization dedicated to protecting human health and the environment. Their self-described mission is to empower people to live healthier lives in a healthier environment. With breakthrough research and education, they aim to drive consumer choice and civic action.

Through their reports, online databases, mobile apps and communications campaigns, EWG is educating and empowering consumers to make safer and more informed decisions about the products they buy and the companies they support. In response to consumer pressure, companies are giving up potentially dangerous chemical ingredients in their products and improving their practices.

EWG's Skin-Deep database gives consumers practical solutions to protect themselves and their families from everyday exposures to chemicals. EWG launched Skin-Deep in 2004 to create online profiles for cosmetics and personal care products and their potential hazards and health concerns. Their aim is to fill in where industry and government leave off.

EWG staff scientists compare the ingredients on personal care product labels and websites to information in nearly 60 toxicity and regulatory databases. Now in its eighth year, EWG's Skin-Deep database provides consumers with easy-to-navigate ratings for a wide range of products and ingredients on the market. Since the focus of the current report is on EHS information sources, the EWG product ratings are not described or discussed further.

The core of Skin-Deep is an electronic product database that contains ingredients in 74,032 products. EWG obtained detailed information on these products from online retailers, manufacturers, product packaging, and, to a lesser extent, through other methods described below. In most cases the information EWG obtains includes a brand name, product name, directions for use, warnings, ingredients, package/advertising text, and indications (cosmeceuticals).

Every product added to Skin-Deep is carefully reviewed by EWG staff to identify product type, product use and composition, target demographic, and special product claims.

**Product type:** EWG categorizes each product into one or more of 130 product categories (e.g., shampoo, toothpaste, deodorant). For ease of navigation, these product categories are organized into ten major product categories - sun protection, makeup, skin care, hair, eye care, nails, fragrance, babies & moms, oral care, and mens.

**Product use/composition:** EWG records information on how each product is typically used. Many hazards or safety recommendations associated with chemicals depend on a product's use and/or composition. For instance, chemicals that are hazardous when they are inhaled would be a concern for products that are sprayed or that are in powder form. For each product EWG records:

- **Body areas exposed:** skin, face, lips, around the eyes, hair or scalp, in the mouth, on damaged or cracked skin, on nails or cuticles, or on areas for feminine hygiene.
- **Type of exposure:** product left on after application, rinsed off, or wiped off.
- **Form of the product:** solid, cream, liquid, gel, mousse, packed powder, loose powder, spray, aerosol.

Target demographic: EWG compiles demographic information on the product's intended users, recording if the product is intended primarily for women or men, or if the product is marketed for use by people of color, teenagers, children (2 to 12), or infants (0 to 2). The demographic data are used to score ingredients with demographic restrictions (especially those which should be avoided by infants) and in specialized displays of product information.

Special product claims: For some product types EWG compiles information about claims made by manufacturers. For example, with each sunscreen product we store SPF claims, water resistance, and other sun protection claims.

Brand and company information: Skin-Deep currently holds products sold under 2,143 brand names and manufactured by 1,608 companies. Skin-Deep contains a brand and company database created by EWG researchers, built primarily through online research into each brand contained in Skin-Deep.

Because animal testing is an issue of concern for many consumers, EWG also incorporates into Skin-Deep information on company and brand stances on animal testing. Information on company positions on animal testing is obtained from People for the Ethical Treatment of Animals' (PETA) and Leaping Bunny's listings. EWG periodically updates their Skin-Deep database to reflect the most current PETA and Leaping Bunny listings.

Skin-Deep currently contains information on 8,983 personal care product ingredients, culled from ingredient labels on products and from the scientific and industry literature on personal care products. EWG assign a standardized name to each ingredient in the Skin-Deep database, generally taken as the International Nomenclature for Cosmetic Ingredients (INCI) standard, with some exceptions where alternate names are more easily recognized by consumers. Each of these ingredient names is associated with a unique ingredient identification number in their database. The processing steps for ingredients are described below.

Skin-Deep's ingredient database is constructed from the sources listed below:

- Product ingredient listings. EWG researchers have parsed ingredient lists from products contained in the Skin-Deep product database to construct a database of all unique ingredients listed on the product labels. They have reviewed each ingredient, corrected misspellings in ingredient names, and combined ingredients that are synonyms into a single unique chemical that is assigned a unique chemical identification number in Skin-Deep. The database currently contains 152,566 unique chemicals. This means that each ingredient is shown an average of 23 different ways (various spellings and synonyms) on the labels of the various products containing it.
- Industry ingredient listings. The International Cosmetics Ingredient Dictionary and Handbook (Tenth Edition, 2004, published by the Cosmetic, Toiletry, and Fragrance Association, Inc.) contains "name monographs" for 491 ingredients listed under their INCI designations. EWG researchers include these ingredients in the Skin-Deep ingredient database.
- Industry-reviewed ingredients. The personal care product industry's (Personal Care Product Council's) internal safety panel, the Cosmetic Ingredient Review, had assessed the safety of ingredients as of their latest compendium publication (Cosmetic Ingredient Review (CIR), 2009 CIR Compendium, Washington, DC). EWG researchers entered each of these ingredients (and accompanying safety findings made by the panel) into Skin-Deep's ingredient database.

- Ingredients from toxicity, regulatory, and study availability databases. EWG imported additional ingredients into the database from the nearly 60 data sources they have compiled on the toxicity, regulatory status and study availability of chemicals in personal care products. These sources are listed below under a section titled "Data Sources."
- Manufacturer-entered ingredients. Skin-Deep contains information on ingredients in products entered into the site by manufacturers via data entry tools EWG makes available to companies that have signed the Compact for Safe Cosmetics via the Campaign for Safe Cosmetics. Most of these ingredients are also found in other ingredient sources listed above; some are unique, found in none of our other data sources.

Additional data stored with a product's ingredient list: In the Skin-Deep ingredient database EWG also stores information how each ingredient is used in each product - for instance, its status as an "active ingredient" in the product; its listing under "may contain," or "organic" under USDA standards; or its association with modifiers that indicate manufacturing methods, like USP for United States Pharmacopeia standards or NF for National Formulary standards.

EWG created a core, integrated database of chemical hazards, regulatory status, and study availability by pooling the data of nearly 60 third party databases and sources from government agencies, industry panels, academic institutions, or other credible bodies. Collectively, these data sources detail more than 1,535 unique chemical classifications. EWG uses these databases to assess potential health hazards and data gaps for cosmetic ingredients.

EWG cross-linked the chemicals in their ingredient database with the compounds contained in the toxicity, regulatory, and study availability databases they compiled. These pairs form the basis for the hazard assessment ratings and data availability ratings shown in Skin-Deep.

### ***B10.2. Scope of Chemicals Addressed***

The focus of Skin-Deep is on chemical ingredients found in 74,032 cosmetics and personal care products in the U.S. divided into some 130 product categories (e.g., shampoo, toothpaste, deodorant, etc.).

### ***B10.3. Ease of Access and Use of Chemical Information***

EWG provides a user's guide to assist in searching its Skin-Deep database. In brief, the database can be searched by:

- Product name
- Ingredient
- Name of Company Marketing the Product
- Product Category

### ***B10.4. Breadth and Depth of EHS Information Available***

A search of Skin-Deep by ingredient name yields the following EHS information (if available) mostly described in layperson's language:

- Chemical structure

- Chemical/Physical Properties
- Function/Uses
- Synonyms
- Rating (Low, Moderate or High) of Health Concerns:
- Overall Hazard
- Cancer
- Developmental and Reproductive Toxicity
- Allergies and Immunotoxicity
- Use Restrictions
- Data Gaps
- Eco-toxicity
- Multiple Additive Exposure Sources
- Organ System Toxicity (excluding Reproductive Toxicity)
- Persistence and Bioaccumulation
- References
- Data Sources

Absent is any discussion of safe levels of exposure, typical exposure levels encountered during normal use or of risk assessments that may have been conducted by any parties.

### ***B10.5. Quality of the Underlying EHS Information***

EWG employs experts in toxicology and environmental sciences. Working together they created a core, integrated database of chemical hazards, regulatory status, and study availability by pooling the data of nearly 60 third party databases and sources from government agencies, industry panels, academic institutions, or other credible bodies.

EWG assigned numeric hazard scores for each scoring category based on professional judgment of the relative importance of each with respect to potential health concerns. These scores were informed by a number of factors, including the weight of the evidence associated with each scoring category (e.g. whether the chemical categorization is derived from a full government assessment or from a single peer-reviewed study), and by other hazard classification systems, such as the Nordic Substances Database.

For most types of hazards, EWG assigns scores as a function of the lowest known harmful dose where that information is available, the weight of the evidence (limited, moderate, and strong evidence), and the source of the data (individual study; literature review, industry review panel, or major government study; and comprehensive government assessment).

### ***B10.6. Procedures for Updating the Database with New Information***

EWG notes that its Skin-Deep database (including all of its web-based materials and applications) is dynamic, and that product ratings on any of these properties may change based on evolving science, new information, or other factors. The product ratings, images, conclusions, recommendations, and findings that appear in Skin-Deep reflect EWG's research at the time of publication. They advise that this information frequently relies on data obtained from many sources, and accordingly, EWG cannot guarantee the accuracy of the information provided or any analysis based thereon. Moreover, in light of

evolving regulatory and market conditions, subsequent product reformulations, and other factors, this information may no longer be current. EWG makes no representations or warranties about Skin-Deep.

In order for Skin-Deep users to easily find the most current products on the market, EWG will mark any products that have been in the database for longer than 3 years as "old formulation." Products that have not been verified in the last 6 years will be removed from the database. This will ensure that the most up-to-date products show up first on when consumers search the database.

No commitment by EWG to regularly update the EHS information on ingredients could be located on its website.

## ***B11. ChemSec Substitute it Now! (SIN) List***

The information presented below represents a summary of key information about the environmental, health and safety information on industrial chemicals that is available from the [ChemSec SIN List](#). For more detailed information, the reader should consult directly with the [ChemSec website](#).

### ***B11.1. Overview/Description***

ChemSec – the International Chemical Secretariat – is an independent non-profit organization that advocates for a world free from hazardous chemicals. ChemSec believes these substances represent one of the biggest and most serious threats to our health and environment. Through independent research, cross-border collaboration and practical tools, ChemSec is driving the development of more progressive chemicals legislation and pushing businesses towards the transition to non-toxic alternatives.

ChemSec considers that hazardous chemicals can be found in clothing, consumer electronics, packaging and many other products which surround people in their everyday lives. Hazardous chemicals spread throughout the environment, increasing the risk of cancer and infertility, among other things. ChemSec wants to prevent this from happening.

ChemSec operates globally to facilitate contact between decision makers, companies and research in the fight against hazardous chemicals. They advocate for progressive legislation, sustainable corporate chemicals management and offer guidance to companies committed to changing the way they work with chemicals. Among other things, ChemSec are developing the SIN List and a host of other online tools, which guide companies forward and show how they can reduce the use hazardous chemicals in their products and supply chains. They also pursue dialogue with investors seeking to avoid the financial risks associated with production and the use of toxic chemicals.

Based in Göteborg, Sweden and founded in 2002, ChemSec engages the work of chemists, political scientists, business experts and communicators, among others. Their organization is run with financial support from the Swedish Government, foundations, private individuals and other non-profit organizations. The World Wide Fund for Nature, the Swedish Society for Nature Conservation, Friends of the Earth Sweden and Nature & Youth Sweden are represented on the ChemSec board of directors.

Among the employees of ChemSec are one chemical engineer and a toxicologist.

The SIN List is a globally used database of chemicals likely to be banned or restricted in the near future. The chemicals on the SIN List have been identified by ChemSec as Substances of Very High Concern (SVHC) based on the criteria established by the EU chemicals regulation REACH.

The aim of the SIN List is to spark innovation towards products without hazardous chemicals by speeding up legislative processes and giving guidance to companies and other stakeholders on which chemicals to start substituting. According to ChemSec more than 10,000 users search the SIN List every year — it is a publicly available, free-of-charge database.

The SIN List is a comprehensive list of substances that have been identified by ChemSec as fulfilling the criteria for SVHC, as described in the EU chemicals regulation REACH article 57. Three categories are included in REACH article 57, and the SIN List encompasses substances from them.

The first category is chemicals that can cause cancer, alter DNA or damage reproductive systems. These are called CMR substances (Carcinogenic, Mutagenic or Toxic to reproduction.) The second category are harmful substances that do not easily break down and accumulate in the food chain. These are known as PBT substances (short for Persistent, Bio-accumulative and Toxic). There is also the abbreviation vPvB, short for very Persistent and very Bio-accumulative.

The third category is called “substances of equivalent concern”. This category covers substances that are not automatically covered by the other two categories, but which nonetheless give rise to equivalent level of concern in terms of potential damage to health and environment. For example, this category includes potential endocrine disrupting chemicals.

All substances on the SIN List have been screened to identify substances covered by the authorization provisions in REACH. Substances exempt or otherwise not regulated by REACH, such as pesticides, intermediates and unintentionally produced substances, are not included.

All information used for selection and assessment of substances for the SIN List is publicly available. For CMRs the official CLP (Classification, Labelling and Packaging) classification has been used. These substances have been agreed on an EU-wide basis to have properties corresponding to the SVHC criteria.

PBT and vPvB chemicals for the first version of the SIN List were added directly from the European PBT Working Group List which was developed by the former European Chemicals Bureau (ECB), the duties of which have since been taken over by ECHA.

Equivalent level of concern substances (REACH article 57f) added to the SIN List have undergone a more in-depth scientific evaluation and case-by-case assessment, based on publicly available peer-reviewed scientific studies. This has also been the case for evaluation of PBTs/vPvBs in 2014.

ChemSec states that the absence of the substance on the SIN List does not indicate that this is a non-hazardous chemical. There are several reasons for why a substance has not been added: it was never present in the “starting material” for an update (typically other priority lists, reports and review studies) or it was assessed but there was at the time not enough available data to include it on the SIN List. Therefore, the SIN List should not be considered as a final list, but rather an important first step towards a more comprehensive list of SVHCs in need of regulation.

ChemSec has published a more detailed description of the methodology employed for inclusion of substances on the SIN List.

According to ChemSec companies use the SIN List as a hands-on instrument to identify chemicals before they are classified as SVHCs and placed on the Candidate List. ChemSec asserts that substitution of chemicals is a complex task and it recommends companies to start developing new solutions well ahead of legislation.

ChemSec states that investors and financial analysts are using the SIN List to avoid investing in companies producing substances likely to be banned, and the financial risk that implies.

They further say that regulators and authorities use the SIN List in the EU but also beyond: in legislative processes foremost in the US and Asia.

ChemSec states that health, environmental and consumer NGOs are using the SIN List as a campaign tool when prioritizing individual chemicals or groups of chemicals for campaigning urging safer products and stronger chemicals regulations.

ChemSec also offers users access to SINimilarity which is a new tool to make it easier to avoid non-sustainable and regrettable substitution. When using ChemSec's online search function and searching for a substance that is not on the SIN List, users can find out how similar it is to the substances on the SIN List. This is now possible for about 500,000 substances. For substances that are similar to those already on the SIN List in terms of structure and function ChemSec recommends further investigations before use.

ChemSec cautions that the SIN groups "Petroleum" and "Mineral fibres" contain substances of very complex chemical composition. Substances in these groups are for this reason not used in the SINimilarity tool. Inorganic compounds and many salts are not suited for the similarity methods used in SINimilarity. This is especially true for many compounds in the metal groups. The similarity will be too low to be shown. If the substance contains a group specific metal, it will be identified, which is the most useful information on metals in the majority of all cases.

### ***B11.2. Scope of Chemicals Addressed***

Only substances covered by the authorization provisions in REACH are candidates for inclusion on the SIN list. Substances exempt or otherwise not regulated by REACH, such as pesticides, intermediates and unintentionally produced substances, are not included. For a more detailed description of the scope of substances covered please reference the chapter entitled European Chemicals Agency (ECHA) Website on EHS Information on Chemicals.

As of this writing, there are 916 substances included on the SIN list. ChemSec speculates that over time the SIN list could grow to an estimated 2000 substances.

### ***B11.3. Ease of Access and Use of Chemical Information***

The SIN List can be searched by:

- CAS#

- Chemical Name

It can also be filtered by:

- Health and Environmental Concerns (e.g., endocrine disruptor, carcinogen, mutagenic, toxic to reproduction, PBT/vPvB, etc.)
- Uses (9 categories)
- REACH status
- Date of first appearance on the SIN list
- Production Volume (4 categories)
- SIN List Groups (see below for description)
- Producers (alphabetized list)

The substances on the SIN List are grouped according to structural similarity (SIN List Groups), to make the list as user-friendly as possible. Almost all of the SIN List substances are divided into 31 groups, and some SIN chemicals belongs to several groups. Examples of these groups are bisphenols, phthalates and perfluorinated compounds.

Icons are available for clicking on to view the entire SIN list or to create an Excel Spreadsheet with the results of a users' search.

No users guide for conducting searches could be located, but the search process is very intuitive.

#### ***B11.4 Breadth and Depth of EHS Information Available***

Only a limited amount of EHS information is available from a search of the SIN List database, including:

- A short description of the reason for inclusion on the SIN List
- REACH status
- Hazard class and category code(s)
- Synonyms
- EC number
- CAS#
- Hazard statement code(s)
- Registered production volume
- (Bio)monitoring data, if available
- Possible uses
- Registered use(s) - Sector End Use (SU)
- Chemical formula
- Substitution options (if identified by ChemSec)
- Producers (company names)

Absent from the database is any discussion of safe levels of exposure, typical exposure levels encountered during normal use or of risk assessments that may have been conducted by any parties.

#### ***B11.5. Quality of Underlying EHS Information***

The SIN List is developed by ChemSec in close collaboration with scientists and technical experts, as well as an NGO advisory committee of leading environmental, health, women and consumer organizations

mainly in Europe but also in the US. The list is based on publicly available information from existing databases and scientific studies, as well as new research.

Users will not find the scientific references to substantiate the reasons for each substance in the SIN List database, but ChemSec encourages those who wish to have the references send them an email, and they will forward the background data for the substances of interest. Note that for substances having already an official classification as being CMR – this is enough for inclusion on the SIN List and ChemSec does not have additional background data.

### ***B11.6. Procedures for Updating the Database with New Information***

Over time, new information on the hazardous properties becomes available. The political discussions and the interpretation of REACH criteria can also be slightly modified over time. In order to keep the SIN List up-to-date with the developments, regular updates are needed.

The SIN List was first developed in 2008, and was been updated in 2009, 2011, 2013, 2014 and 2017. Different procedures for updating have been used at various points of time.

## ***B12. International Council of Chemical Associations (ICCA) Global Product Strategy (GPS) and Global Chemicals Portal***

The information presented below represents a summary of key information about the environmental, health and safety (EHS) information on industrial chemicals that is available from the International Council of Chemical Associations' (ICCA) Global Product Strategy (GPS) and Global Chemicals Portal.

For more detailed information, the reader should consult directly with the [ICCA website](#).

### ***B12.1. Overview/Description***

ICCA describes itself as the worldwide voice of the chemical industry. It represents chemical manufacturers and producers around the world. It's members account for more than 90% of global chemical sales, and more than 20 million people around the globe are employed directly or indirectly by this industry.

In February 2006 in Dubai, the International Conference on Chemicals Management, meeting under the auspices of the United Nations, adopted the Strategic Approach to International Management (SAICM), a framework for global chemicals management. At that meeting, the chemical industry represented by ICCA, introduced its GPS initiative to address public concerns regarding chemicals in commerce and to meet evolving national, regional and international chemical management policy pressures.

The product stewardship activities under GPS and also ICCA's Responsible Care® Global Charter are industry's global voluntary initiatives that will contribute to SAICM implementation. The GPS is also the program under which ICCA has established and promoted its Principles for Chemical Management Systems, sponsors "capacity building" initiatives and establishes partnerships with intergovernmental organizations. GPS also provides a platform for ICCA advocacy and communication.

The centerpiece of GPS is the enhancement and expansion of product stewardship best practices within the industry and throughout the value chain. The effort unites several current stewardship initiatives under the auspices of the Responsible Care® program, builds a foundation for continual improvement in product stewardship, fosters greater transparency to external stakeholders and marks a major drive to take product stewardship to a higher level within the industry.

The ultimate purpose of GPS is to increase public and stakeholder awareness of, and confidence in, the safe management of chemicals throughout their lifecycle by demonstrably increasing chemical industry performance and transparency.

Through its signature capacity building workshops and accompanying guidance materials, GPS is designed to help those countries which may lack the capacity to manage chemicals safely to learn how to put that capacity into place – and maximize the social, economic and environmental benefits that come with a safe, strong and sustainable manufacturing industry.

To accomplish its mission, ICCA is focused on achieving progress in four key areas:

- **Product Stewardship:** The responsibility to understand, manage and communicate the health and environmental impacts of chemical products at each point in their life cycle. Product stewardship is the practice of making health, safety and environmental protection an integral part of the life cycle of chemicals. It is an integral component of the global chemical industry's Responsible Care® initiative and includes evaluations of risks and the development of actions to protect human health and the environment commensurate with those risks. Product stewardship is described by ICCA as a shared responsibility between chemical producers, their suppliers and their customers. It requires the development of close, sustained dialogue and working relationships with suppliers, customers, and others in relevant value chains. These parties should share information up and down the value chain to ensure that chemicals are used and managed safely throughout their life-cycle. In doing so, they will also help companies and their partners meet the increasing demand for safe and environmentally-sustainable uses of chemicals.
- **Risk Assessment and Risk Management:** The scientific evaluation of a chemical's hazards, uses and exposures to determine the probability that it will cause adverse effects under real-world conditions, which determines if steps are needed to reduce the risk of harm or misuse.
- **Stronger Chemicals Management Globally:** Promoting risk-based chemicals management through a mix of government rules, voluntary industry programs, and publicly-sponsored training and recognition programs, particularly in countries without robust chemical management systems.
- **Transparency:** Providing health, safety and environmental information about chemicals to stakeholders and the public to enable customers, regulators and consumers to understand how chemistries can and should be used safely.

ICCA has delivered a number of work products to further its GPS goals, including:

- 1) Global Product Stewardship Guidelines. The guidelines address only product stewardship and assume that companies have effective programs addressing worker health and safety, process safety, pollution prevention and other aspects of the industry's Responsible Care® initiative that are also necessary to achieve the 2020 goal. The product stewardship guidelines were developed to facilitate improvement in industry performance. They are based on common elements of existing ICCA member association programs and include principals to be applied to

research and development, raw materials procurement, manufacturing, sales, distribution, handling, use, disposal and recycling of chemicals. The guidelines were also designed with enough flexibility to be implemented by small and medium-sized enterprises (SMEs). These guidelines are provided to ICCA member associations for use in the development of their own regional or country-specific product stewardship programs, to be implemented by their member companies. The voluntary regional and country programs based on these guidelines should be designed with enough flexibility to account for national and regional legal, societal, economic and cultural conditions. The eventual adoption of product stewardship programs by ICCA member associations and the implementation of product stewardship programs by ICCA member companies will demonstrate the global industry's commitment to the safe management of chemicals.

- 2) Guidance on Risk Assessment. This guidance document was written for use by small- and medium-size companies and governments in developing economies. It provides a step-by-step guide for conducting chemical risk assessment and management. Since the first International Conference on Chemicals Management (ICCM-1) was held in 2006, ICCA has conducted more than 170 capacity building projects and events in 46 countries. Capacity building is a tool for companies to share best EHS practices and improve product stewardship performance throughout the supply chain, supporting the goals of SAICM.
- 3) Regulatory Toolbox. The guidance provides governments in developing economies who are considering introducing or revising their legislation/regulation on chemicals management. It covers principles as well as a detailed description of GPS elements and how they can be integrated into national legislation/regulation. The toolbox consists of modules in order to take the different situations of countries into account.
- 4) The GPS Chemical Portal -- The GPS Chemicals Portal is a publicly accessible online database with detailed product summaries for more than 90 percent of the world's most highly traded chemicals (as of April 2016). The summaries provide the most relevant product safety information from companies on the chemical products they manufacture in a language that non-specialists will find easy to understand. Anyone can access the GPS portal to find out more about chemical products in use today.

ICCA has established the GPS Chemicals Portal to provide the public with easy access to science-based, reliable information on chemicals. The GPS Safety Summaries contained on the Portal provide the most relevant product safety information from individual companies on the chemical products they manufacture in a language that non-specialists will find easy to understand.

To date, more than 4,500 GPS Safety Summaries are available on the GPS Chemicals Portal, and ICCA member companies continue to post summaries to the site. Establishing a base set of information and publishing GPS Safety Summaries for their chemicals in commerce is part of the GPS commitment of ICCA member companies – and part of the chemical industry's commitment to transparency.

### ***B12.2. Scope of Chemicals Addressed***

The focus of GPS and the Global Chemicals Portal is on industrial chemicals in commerce; however, each participating company is free to define the scope of their substances to best meet its own particular needs. Some companies have elected to include the full range of products they manufacture and sell (e.g., pesticides, biocides, polymers, seeds, articles that contain chemicals, etc.), while others have chosen to restrict their scope to industrial chemicals. Users are directed to individual company websites to determine the scope of products covered. Of course, GPS Safety Summaries are only available from companies that voluntarily agree to participate.

### ***B12.3. Ease of Access and Use of Chemical Information***

The [ICCA GPS Chemical Portal](#) is searchable for substances by:

- Chemical Name
- CAS#
- Chemical EINECS (European Inventory of Existing Commercial Substances) Number
- Brand/Product Name
- Product Category (39 separate categories)

The following terms can be used to narrow a search and return fewer results:

- Organization/Company
- Language

There is currently no published search guidance available from the GPS Global Chemical Portal website; however, the search process is rather intuitive. ICCA can be contacted directly for assistance if users experience any difficulties with searching the portal.

The output from a search of the GPS Portal is a report of the chemicals that meet the user's specified search criteria and the names of the companies associated with those chemicals. A click on each company name takes the user to a page that includes a link to the available GPS Safety Summary for that substance.

### ***B12.4. Breadth and Depth of EHS Information Available***

The format, breadth and depth of EHS information contained in the GPS Safety Summary varies from company to company, although most often the user will find the following information described:

- An executive type summary of the information contained in the GPS Safety Summary
- Manufacturing information, sometimes including production process, capacity and where the product is manufactured
- A description of the product, including physico-chemical properties
- Intended uses for the product
- How the public might be exposed to the product under various scenarios
- Human health information (e.g., mammalian toxicology and epidemiology)
- Environmental information (environmental fate and eco-toxicity)
- Physical hazard information (e.g., reactivity, flammability, etc.)
- Regulatory information
- Web links to references, Safety Data Sheets and other relevant information about the product

In an effort to facilitate the preparation of GPS Safety Summaries, the European Chemical Industry Council (CEFIC) has developed and made available tools that assist companies to transfer the relevant information from EU REACH dossiers.

### ***B12.5. Quality of Underlying EHS Information***

ICCA includes the following disclaimer on its website:

“This portal is intended to provide the user with access to product stewardship information available to the public on ICCA member company or association websites.

ICCA is not responsible for the content posted on these other websites, does not warrant the accuracy of information posted on these other websites, and does not monitor the content posted on these other websites.

Information for the chemicals listed has been developed independently by each company (or in some cases, a group of companies). Each company is responsible for the content of its own GPS Safety Summary.

For more information about the content on these other websites, users should contact the companies that post the information.”

Because the information derives from companies which manufacture and sell these chemicals, some stakeholders may perceive them to have a potential conflict of interest and may view the quality of EHS information skeptically. On the other hand, other stakeholders may recognize that these companies have regulatory obligations that can carry substantial fines and penalties should they publish false or misleading information. Furthermore, in some countries (e.g., US), those companies can face extensive criminal and civil liability if they are found guilty of failing to adequately warn the public about risks associated with exposures to their products. This liability may extend to GPS Safety Summaries.

### ***B12.6. Procedures for Updating Database with New Information***

It is up to each company that participates in the ICCA Global Chemical Portal to maintain the currency of EHS information it posts for its products on its web site. Users should consult individual company websites to determine how they do this. Companies have strong incentives to keep the information up to date as they face both regulatory obligations and criminal and civil liability if the information is inaccurate and/or misleading.

## ***B13. The Republic of Korea Government EHS Databases***

The information presented below represents a summary of key information about the environmental, health and safety information on industrial chemicals that is available from the South Korean government.

The main database maintained by Korea is called the National Chemicals Information System (NCIS).

### ***B13.1. Overview/Description***

The Korean Toxic Chemicals Control Act (TCCA) was implemented in 1991 by the Ministry of Environment (MOE) for the overall management and control of industrial chemicals in Korea. The latest revised version took effect on 21 Mar 2008. The purpose of this Act is to prevent any risk caused by chemicals to human health.

The National Institute of Environmental Research (NIER) is responsible for new chemical notification under the Act). The Korea Chemicals Management Association (KCMA) of MOE is responsible for accepting declaration for details of other chemicals and application for confirmation certificate.

On January 1, 2015, the TCCA was divided into Korea REACH (also known as K-REACH) and the Chemicals Control Act (CCA). K-REACH focuses on registration and evaluation of substances while CCA focuses on the control of hazardous substance and prevention and response to chemical accidents. K-REACH was substantially amended and will now come into force on 1 Jan 2019.

Under amended K-REACH, any person who intends to manufacture or import a new chemical substance or at least one ton per year of an existing chemical substance shall register the chemical substance ("registration") according to the following requirements:

- New substances must be registered prior to manufacture or import.  
<100kg/y new substances only require notification and do not need to go through hazard evaluation.
- All  $\geq 1$ t/y existing chemical substances (excluding exempt substances) must be registered within given grace periods.
- To benefit from the grace periods for existing substances, manufacturers and importers of  $\geq 1$ t/y existing chemical substances must notify their company info, substance name, volume, classification and use info to the MoE in advance ("pre-notification").  
Foreign manufacturers who export chemical substances to Korea may appoint a Korea-based representative to submit pre-notification or registrations.

The Korea Existing Chemicals Inventory (KECI) is issued jointly by the MOE and Ministry of Labor (MOL) and currently includes more than 44,000 chemicals substances. The free online inventory is available for searching.

Korea MOE estimates that approximately 400 new chemicals are produced or imported annually in Korea, and that Korea has slightly fewer than 300 HPV ( $>1,000$  tons/year) chemicals in commerce.

Under Korea CCA, an existing chemical is a chemical that was domestically commercialized prior to February 2, 1991 and was designated and published by the MOE in consultation with the MOL. The current KECI consists of three parts:

- Chemical substances which were placed on Korean market before Feb. 2, 1991, and notified by the MOE on Dec. 23, 1996 ( $>35,661$  chemical substances); Korean Existing chemical numbers (KE) numbers are given.
- Chemical substances which were notified after review of hazard by the MOE, after Feb. 2, 1991 ( $>3,603$  chemical substances); NIER numbers are given.
- Chemical substances which were notified on Nov. 21, 2005, by the President of the NIER, to be added to the KECI ( $>1,360$  chemical substances); KE numbers are given.

Pursuant to the CCA, manufacturers or importers of new chemical substances are required to make notification to relevant authorities prior to the commencement of their commercial activities if the volume of the new substance exceeds 0.1 ton per year. KE numbers and NIER numbers are necessary for customs clearance.

Dangerous chemicals are currently classified into 900 types of poisonous substances and substances requiring preparation for accidents, 6,000 types of single dangerous substances, and energy and high-pressure gases.

Target substances and control methods vary among government ministries. In the case of the MOE, chemicals that have a high likelihood of accidents or are likely to cause major damage are designated as substances requiring preparation for accidents (69 types). Any facility that handles a certain amount or more is required to formulate and submit a self-prevention plan containing information on the toxicity of the substance concerned, status of control facilities and equipment owned, safety control organizations, staff and organization charts, and emergency measures to address any accidents.

Toxic chemicals are classified into poisonous substances and substances under observation according to the degree of toxicity identified in toxicity examination and safety tests (i.e., acute oral toxicity, genetic toxicity, biodegradability, fish acute toxicity, daphnia toxicity, algae toxicity). In order to import any poisonous substance, the type and purpose thereof must be declared to KCMA. The production or use of any such substance requires a poisonous substance business registration at the local government. According to a 2013 performance report, 45,046 thousand tons of poisonous chemicals were distributed, with 37,675 thousand tons manufactured and 7,371 thousand tons imported. There are 7,200 businesses selling poisonous substances.

Substances that are deemed likely to be carcinogenic are designated as substances under observation. The manufacture or import of any substance under observation must be declared to KCMA, but unlike poisonous substances, there are no special regulations regarding business operation.

There are special provisions for substances that are identified as being particularly harmful according to the results of risk assessments and those that are restricted or prohibited by international organizations and international agreements. Restricted substances are significantly harmful when used for certain purposes and therefore distribution and use is prohibited for these specific purposes, while prohibited substances are prohibited under all circumstances. Currently 12 types of restricted substances and 60 types of prohibited substances have been designated.

New substances notified under TCCA are regarded as notified under Korea REACH.

The purpose of Korea REACH is to protect public health and the environment through these provisions:

- Registration of chemical Substances;
- Screening of hazardous chemical substances;
- Hazard and risk assessment of products containing chemical substances and hazardous substances;
- Sharing information about chemical substances.

Manufacturers or importers in Korea must register the follow substances:

New chemical substances;

Designated existing substances manufactured, imported or sold more than 1 ton per annum.

**Important notes:**

- The difference between registration and notification registration requires submission of hazard data. Notification only involves submission of some administrative information.
- Like EU REACH, K-REACH also restricts the use of certain hazardous chemical substances in consumer products and articles.
- The latest K-REACH restricted substances list (2017 version) restricts 12 chemical substances in various products such as paints, furniture and household products.

The 12 chemical substances are:

- Malachite green (CAS 10309-95-2) and its salts
- Methyl bromide (CAS 74-83-9)
- Carbon tetrachloride (CAS 56-23-5)
- Tributyltin compounds (CAS 4782-29-0 and other CAS)
- Formaldehyde (CAS 50-00-0)
  - Nonylphenol and nonylphenol ethoxylate (CAS 104-40-5 and other)
- Chrysotile (CAS 12001-29-5)
- Lead (CAS 7439-92-1)
- Cadmium (CAS 7440-43-9)
- Chromium (VI) compounds (CAS 18540-29-9 and other)
- Trichlorethylene (CAS 79-01-6)
- Tetrachlorethylene (CAS 127-18-4)

The detailed restriction conditions for the above chemical substances may be found by inputting their CAS# to the NCIS.

New substances must be registered prior to production or importation. Designated existing substances must be registered within a given grace period (Maximum of 8 years).

Similar to EU REACH, foreign manufacturers exporting chemical substances or products containing hazardous chemical substance into South Korea may appoint an Only Representative to fulfill relevant obligations under K-REACH. Only designated existing substances imported or manufactured above 1t/y require registration in South Korea. Even for designated existing substances ( $\geq 1t/y$ ), registration can be waived if the substances meets any of the following criteria:

- Chemical substances imported as incorporated in machines;
- Chemical substances imported along with machines or devices for test runs;
- Substances contained in a product in a solid form to perform a certain function without being released during normal use.
- Chemical substance manufactured or imported less than 10 tons per year and exported in its entirety. In this case, an application of exemption from K-REACH must be submitted to the MOE.

Note: Chemical substance ( $\leq 1$  ton/y) must also be registered if considered to cause significant damage to human beings health or the environment.

Note: Polymers must also be registered as substances under Korea REACH. This is different from EU REACH, under which only monomers are registered.

A new substance is defined as a substance that is not on the following lists:

- Chemical substances which were placed on Korean market before Feb. 2, 1991, and notified by the MOE on December 23, 1996; and

- Chemical substances which have undergone the examination of toxicity under the former provisions or the provisions of the TCCA after February 2, 1991 and were announced by the MOE.

The following information is required for registration:

- The name, address and representative of a manufacturer or an importer or an only representative;
- Information that identifies a chemical substance including its name, molecular formula and graphic formula;
- Identified uses of the chemical substance;
- Classification and labeling of the chemical substance;
- Physical and chemical properties;
- Hazard data (mammalian toxicology./eco-toxicology data);
- Risk associated with the chemical substance including exposure scenarios describing how to handle and control it (Applicable only when the substance is manufactured or imported in 10 tons or more per year);
- Guidance on safe uses (including protective equipment, response to an explosion, a fire or a leak);
- Other information specified in the Environment Ministerial Decree
- Data requirements for some specific chemical substances designated by Presidential Decree will be reduced;
- Test proposals including test information and schedules may replace certain data endpoints.

Note: the deadlines of risk assessment are separated from the deadlines of registration.

Note: For some new substances and designated existing substances (i.e., <1t/y new substance, substance for R&D, new polymer of low concern, i.e.), registration data can be reduced according to presidential decree.

Similar to EU REACH, Korea REACH also requires joint submission if there are multiple producers/importers of that substance.

- Hazard data must be submitted by a lead registrant on behalf of other registrants and joint registrants will submit their own dossier individually;
- Any person who intends to submit a registration later may use registration data submitted by another applicant after obtaining the owner's permission;
- Any person who intends to submit a registration may inquire of the MOE about previous registration data of the same chemical substance;

Individual submission (or opt out) is possible when:

- Exposure of CBI causes commercial damage;
- Joint submission costs more than individual submission;
- Other cases are listed in Presidential Decree;

However, a "Confirmation of Individual Submission" from the MOE is required for individual submission.

Deadlines of registration for designated existing substances have been set by MOE as follows:

- First 510 existing substances  $\geq 1\text{t/y}$ : 1 July 2018
- $\geq 1000\text{t/y}$  and CMR substances  $\geq 1\text{t/y}$ : 31 December 2021
- 100-1000t/y: 31 December 2024

- 1-100t/y: 31 December 2030

As of the morning of 28 June, 2018 **MOE reported** that there had been 321 submissions, 194 of which were reported as complete registrations.

Note: Some substances and uses (i.e., R&D substance, export-only use, polymer of low concern) are exempt from full registration. However, companies need to apply for confirmation on exemption.

Any person who intends to manufacture or import an existing chemical substance to be registered will be allowed to manufacture or import without registration during the above grace period.

Note: The MOE will designate existing substances to be registered in three lists based on:  
Chemical substance circulation in Korea; and  
Results of hazard assessment and risk assessment.

Risk assessment are conducted if a chemical substance is:

- Manufactured or imported in 10 tons or more per year; or
- Deemed as one requiring risk assessment after hazard assessment.

If necessary, the MOE may request additional data for the risk assessment.

The MOE is responsible for the evaluation of registration data received. Based on the results of hazard assessment and risk assessment, substances may be put into the following categories after evaluation:

- Toxic substance: designated by MOE after hazard evaluation;
- Authorization substance: means a chemical substance listed by the MOE after consultation with the head of the relevant central authority and deliberation by the Chemical Substance Assessment Committee (part of NIER) as one potentially hazardous and thus requiring permission from the Minister before its manufacture, import or use;
- Restricted substance: means a chemical substance as listed by the MOE after consultation with the head of the relevant central authority and deliberation by the Chemical Substance Assessment Committee as one deemed highly hazardous if used for a specific purpose and thus required to be banned from its manufacture, import, sales, stocking, storage, transport or use for that purpose;
- Prohibition substance: means a chemical substance as listed by the MOE after consultation with the head of the relevant central authority and the deliberation by the Chemical Substance Assessment Committee as one deemed highly hazardous and thus required to be banned from its manufacture, import, sales, stocking, storage, transport or use for any purpose.

Anyone who transfers a registered chemical substance or preparation containing the substance must provide the following information to downstream users:

- registration number;
- substance name;
- information about hazard and risk;
- safety control information;

In the event that a safety data sheet (SDS) is required under the Occupational Safety and Health Act (OSHA), the information mentioned above must be provided through the SDS.

Supply of information on chemical substances must be made only when the relevant chemical substance or preparation is transferred to be used as raw material for a product or for final consumption at the transferee's workplace.

For repeated transfer, the information may be provided only once at the first transfer.

Any person who provided or received information must inform the other party of any change in the provided information within one month from when they become aware of it. This must be done within one month from when the change was found.

Unlike EU REACH, K-REACH has special provisions for products. A product means an item used by an end user or its component or part with a possibility to cause consumers to be exposed to a chemical substance and the product could be a preparation or an article. There are two requirements for products: product notification and risk assessment.

Anyone who produces or imports a product containing a hazardous substance at one ton or more per year must notify to the MOE the name and content of the substance, the type of hazard, and its uses before they start producing or importing the article. An article that does contain any substance intended to be released under normal conditions of use is excluded from reporting.

Any product may be produced or imported as set out in the Environment Ministerial Decree without reporting because:

- Exposure to human beings or environment can be avoided under normal conditions of use; or
- The chemical substance has been registered for that use.

However, an application of exemption needs to be submitted to MOE for the above two cases.

Risk assessment must be performed on "risk-concerned" products by institutions or experts appointed by the MOE. A potentially risky product means a chemical product listed by the MOE after consultation with the head of the relevant central authorities as one deemed potentially hazardous to people or the environment, including, but not limited to:

- Consumer product: A product used by consumers on their daily lives such as a detergent, an air freshener, an adhesive, a polisher, a deodorant, a bleach or a fabric softener.
- Biocidal product: A product used to kill, interrupt or immobilize harmful organisms except for human beings and animals such as an insect repellent, a sanitizer or a preservative.

After risk assessment, the MOE must establish safety and labelling standards for risk-concerned products. The safety and labelling standards specify, for example, hazardous chemical substances that cannot be used in certain products and the content, yield or evaporation of hazardous chemical substances contained in the article. Once safety and marking standards have been published, MOE can take actions (sales ban or recall) against:

- any product not compliant with the safety and labelling standards.
- any product with no such standards in place and thus deemed likely to cause damage to people or environment.

The Consumer Chemical Products and Biocides Safety Act is a new chemical regulation proposed by the MOE in South Korea. Also known as K-BPR, the Act regulates consumer chemical products, biocidal products and biocide-treated articles. It is expected to be published in 2018 and come into force on 1 Jan 2019.

The consumer chemical product part is proposed to be transferred from K-REACH while the biocide part is taken from EU biocidal products regulation (BPR). For consumer chemical products, the Act requires that companies comply with relevant product safety and labelling standards and confirm compliance to authority by carrying out testing once every 3 years. For biocidal products (both active substances and formulated products), the Act requires that companies apply for pre-market approval from the Ministry of Environment (MOE). In addition, the Act has set some rules for biocide-treated articles.

### ***B13.2. Scope of Chemicals Addressed***

CCA covers new chemicals, toxic chemicals, chemicals under observation (as defined above) and restricted or banned chemicals.

The following products are out of scope for CCA:

- Radioactive substances as prescribed by the Atomic Energy Act
- Medicines, non-pharmaceutical drugs, and cosmetics as prescribed by the Pharmaceutical Affairs Act
- Narcotics and psychotropic drugs as prescribed by the Act on the Control of Narcotic Drugs and Other Analogous Substances
- Cosmetics as prescribed by the Cosmetics Act
- Technical ingredients and agrochemicals as prescribed by the Agrochemicals Control Act
- Fertilizers as prescribed by the Fertilizer Control Act
- Foods and food additives as prescribed by the Food Sanitation Act
- Livestock feeds as prescribed by the Control of Livestock and Fish Feed Act
- Explosives as prescribed by the Control of Firearms, Swords, Explosives, etc. Act
- Toxic gases as prescribed by the High-Pressure Gas Safety Control Act
- Scope of K-REACH

#### **In Scope:**

Substance on its own, including new substances<sup>1</sup> and existing substances

Substances in mixtures

Product<sup>2</sup> containing a priority control substance

#### **Out of scope:**

Naturally occurring substances

Chemicals subject to other laws: cosmetics and raw materials, pesticides, pharmaceuticals, medical devices, fertilizer, etc.;

<sup>1</sup>New substance' is a substance that is not listed on Korean Existing Chemicals List (KECL). More info about KECL can be found here.

<sup>2</sup>'Product' is a unique concept under K-REACH. A product means a mixture or an article used by consumers or a component of the mixture or the article that may expose consumers to chemical

substances. Manufacturers and importers of products containing >0.1% and >=1t/y priority control substances shall submit product notification to the MoE.

### ***B13.3. Ease of Access and Use of Chemical Information***

The Korean NCIS can be searched using CAS#, Chemical name in Korean, Chemical name in English, Chemical Number (Toxic substance, Phase-in substance, and Chemical's unique number, etc.). Searches are intuitive and there is no English language guidance available for assisting users.

- Currently, there are records available for 44,356 chemical substances. These substances have been classified as:
- Phase in substances subject to registration — N = 523
- Toxic substances — N = 1,861
- Restricted substances — N = 100
- Prohibited substances — N = 106
- Substances requiring preparation for accidents — N = 99

### ***B13.4. Breadth and Depth of EHS Information Available***

Currently, there is very little EHS information available from a search of NCIS. Instead, one can only learn the regulatory classification of substances as noted above, and the nature of any restrictions or prohibitions that have been placed on the manufacture, importation or use of those substances. Presumably, at some point in the future, the MOE will make the results of its risk assessments publicly available, but it is not known whether they will be translated into English.

### ***B13.5. Quality of the Underlying EHS Information***

Companies that produce or import chemical substances are required to provide MOE with chemical substance identity, classification and labelling, available hazard use and exposure information and proposed risk management measures. MOE and the Chemical Substance Assessment Committee are responsible for evaluation of the information received, for conducting a hazard assessment and for deciding the regulatory classification of each chemical substance. Risk assessments must be performed on "risk-concerned" products by institutions or experts appointed by the MOE. As of this writing, English language documents that specify procedures for conducting this work, including peer review and opportunities for public comment, could not be located.

### ***B13.6. Procedures for Updating the Database with New Information***

New chemicals must be notified to MOE prior to their manufacture or import and are then added to the NCIS database.

CCA requires companies to notify the MOE of any changes affecting their safe manufacture of substances.

K-REACH requires companies to notify MOE of any of the following changes affecting substances which they have registered:

- If the annual amount of substance manufactured or imported changes beyond the range prescribed by MOE;
- If there is a change in the uses, hazards, and risks of the substance; or
- If there is a change in the name, location, or representative of the registrant.

There are fines and penalties prescribed for companies which fail to comply with CCA or K-REACH, including possible imprisonment for responsible parties.

## ***B14. Australian Government EHS Databases***

The information presented below represents a summary of key information about the environmental, health and safety information on industrial chemicals that is available from the Australian government.

The main approach to industrial chemicals management taken in Australia is called the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). It helps protect the Australian people and the environment by assessing the risks of industrial chemicals and providing information to promote their safe use. NICNAS is administered by the Australian Department of Health.

NICNAS' focus is the industrial use of chemicals. This covers a broad range of chemicals used in inks, plastics, adhesives, paints, glues, solvents, cosmetics, soaps and many other products. [For more detailed information about NICNAS, the reader is directed to their website.](#)

### ***B14.1. Overview/Description***

Beginning in the late 1980's and continuing through the 1990's and 2000's, the Australian government adopted several laws and regulations to ensure the safe management of chemicals.

These laws empower NICNAS to:

- provide a national system to assess new industrial chemicals for health and environmental risks;
- maintain the Australian Inventory of Chemical Substances (AICS);
- manage the Register of Industrial Chemical Introducers;
- compel commercial importers and/or manufacturers to notify industrial chemicals that are new to Australia;
- provide information and make recommendations about chemicals to other government agencies responsible for the regulation of industrial chemicals;
- administer the Cosmetic Standard 2007;
- collect statistics on the use of industrial chemicals in Australia;
- and ensure Australia meets its obligations under international agreements about Chemicals.

In Australia the introduction of chemicals—whether by importation and/or manufacture—is regulated at a national level. Four schemes make up the Australian Government's regulatory framework for chemicals at the national level, with each scheme focusing on particular areas of use. NICNAS is part of this framework and is responsible for industrial chemicals.

NICNAS is not responsible for the following uses of chemicals. If a chemical has multiple uses the requirements of each applicable scheme must be followed.

- Pesticides, agricultural products, veterinary medicine, food for animals, pool sanitizers.

Chemicals used for the following purposes are not regulated by NICNAS. They are regulated by the Therapeutic Goods Administration.

- Medical devices (including sterilants and disinfectants) and in vitro diagnostic devices
- Medicines (includes prescription, over-the-counter and complementary/alternative medicines)
- Biologicals
- Primary sunscreen products
- Sterilants and disinfectants.
- Food for humans

NICNAS does not regulate the use or disposal of chemicals. Instead, it promotes the safe use of industrial chemicals by providing information and recommendations to other regulators. NICNAS works closely with a range of regulatory partners at all levels of government.

The full costs of administering NICNAS are recovered through fees and charges paid by industrial chemical importers and manufacturers. Their main fees are generated through chemical registrations and assessments. NICNAS also collect fees for services provided to new industrial chemical notifiers, holders of confidence and other parties, based on 'fee for service' schedules in accordance with the administered regulations.

There are 5 program areas at NICNAS with 3 areas focused primarily on scientific assessment:

- 1) New Chemicals Program — assesses new industrial chemicals notified to NICNAS by importers and/or manufacturers.
- 2) Existing Chemicals Program — conducts assessments of chemicals on AICS which have not previously been assessed in Australia; assesses Priority Existing Chemicals (PECs); and prioritizes and assesses chemicals using the Inventory Multi-tiered and Prioritization (IMAP) framework.
- 3) Targeted Assessment Program — conducts secondary notification risk assessments; assesses chemicals on behalf of other government agencies; and manages the AICS.
- 4) Regulatory Strategy Program — manages business planning, finance, Information Technology, library services and the NICNAS website; works with other government agencies and key stakeholders; coordinates national and international engagement activities; and oversees NICNAS Reforms.
- 5) Registration, Outreach and Reporting Program — manages the registration of introducers; undertakes compliance monitoring and investigates non-compliance; and administers Australia's obligations under the Rotterdam Convention.

A PEC is an industrial chemical that has been identified as requiring an assessment because there are reasonable grounds for believing that manufacturing, handling, storing, using or disposing of the chemical could be a risk to health and/or the environment. Following a chemical assessment by NICNAS, there could be changes in circumstances that would later require particular aspects of a chemical to be re-assessed. This process is called secondary notification and assessment.

NICNAS established the IMAP framework to accelerate the assessment of chemicals listed on the AICS. The objectives of IMAP are to identify and rapidly assess existing chemicals of concern, and support the risk management of industrial chemicals in Australia by enhancing the flow of chemical safety information.

IMAP arose from recommendations of an independent review of the NICNAS Existing Chemicals Program and a subsequent research report by the Productivity Commission.

The IMAP framework was developed in consultation with stakeholders and technical experts and is a science and risk based framework for the assessment and prioritization of chemicals on the AICS.

The IMAP framework provides a more flexible and transparent approach to prioritizing the large number of chemicals on the AICS for assessment in a way that is responsive to the needs of industry (including workers), community and government.

In 2012, NICNAS started assessing about 3,000 chemicals using the IMAP Framework. These so called Stage 1 chemicals were identified based on characteristics agreed by stakeholders as priorities for early consideration and sources subsequently identified by NICNAS and stakeholders.

Companies wishing to commercially import or manufacture a new industrial chemical (that is, a chemical that is not listed on AICS), or a product containing a new chemical, must first check whether it has already been notified to NICNAS and if there are conditions stipulated for using it by [searching AICS](#). Unless an exemption applies, the new industrial chemical will need to be assessed by NICNAS for risks to the environment and human health before it can be imported and/or manufactured.

NICNAS has several databases that present varying levels of EHS information on subsets of chemicals listed in AICS as follows:

PEC Assessments. There are PEC Assessments available for 43 chemicals or chemical families dating from the mid-1990's through the recent past. Most PEC assessments are accompanied by an easy-to-understand fact sheet which summarizes key recommendations for a non-scientific audience.

Tier I IMAP Human Health Assessments. Chemicals listed in this database are not considered to pose an unreasonable risk to the health of workers and public health on the basis of the Tier I IMAP assessment. The Tier I assessment considers both the intrinsic hazard of the chemical and potential human exposure. As such, where hazardous chemicals are included in the list below, all requirements under workplace health and safety and poisons legislation as adopted by the relevant state or territory should be met to minimize risk. The list also contains chemicals which are assessed as posing no unreasonable risk on the basis that there is no exposure to humans or the environment from industrial uses in Australia. This includes: chemicals for which the uses identified are considered excluded under the Industrial Chemicals (Notification and Assessment) Act (1989); and chemicals for which no Australian use, import, or manufacture was reported under previous NICNAS mandatory calls for information. It is important to note that some of these chemicals may be also governed in Australia by other legislation or Australia's commitment under international treaties. Controls on their production, import, export, use and disposal may apply. The list (which is the Tier I assessment output) contains the key information used in the Tier I assessment to determine the potential for exposure (exposure band), including the highest use category that has been considered. More information on exposure bands and use categories are provided in the IMAP Framework document which can be downloaded from their website.

- Tier I IMAP Environmental Assessments. Chemicals included in this spreadsheet are considered not to pose an unreasonable risk to the environment from their notified uses; however, they

could be considered for Tier II assessments in the future should new information become available.

- Tier II IMAP Human Health and Environmental Assessments. The approximately 3300 chemicals included in this spreadsheet were assessed in greater detail because the Tier I assessment indicated a need for further investigation.
- Tier III IMAP Human Health Assessments. The approximately 16 chemicals included in this spreadsheet were assessed in even greater depth because the Tier II assessment indicated a need for further investigation.

Other Assessments include: secondary notification assessments of chemicals previously assessed by NICNAS and targeted assessments (focused on hazard, exposure or use) of existing chemicals for which there were potential health or environmental concerns or relevant new data.

### ***B14.2. Scope of Chemicals Addressed***

According to the Australian law, a chemical can be:

- a chemical element, including a chemical element contained in a mixture.  
Examples include:
  - a chemical element (such as lead)
  - a chemical compound, including polymers (such as succinic acid or poly(vinyl chloride))
  - a chemical complex, such as ferric ammonium oxalate.
- a compound or complex of a chemical element, including such a compound or complex contained in a mixture.  
Examples include:
  - a chemical element in a mixture, such as oxygen in a mixture of gases
  - a chemical compound in a mixture, such as the plasticizer dibutyl phthalate in a poly(vinyl chloride) blend
  - a chemical complex in a mixture, such as ferric ammonium oxalate in an aqueous solution.
- a chemical of unknown or variable composition, complex reaction products or biological material—otherwise known as a UVCB.  
Examples include:
  - an unknown or variable composition substance, such as chlorinated paraffin sodium sulfonate, where the degree of chlorination varies
  - a complex product of a chemical reaction, such as tall oil products in reaction with diethanolamine, where the product of a chemical reaction is in a mixture with its reactants
  - biological material (except if is a whole or a whole animal).
- a naturally-occurring chemical, meaning an unprocessed chemical occurring in nature, or a chemical occurring in nature that has been extracted from the parent material through certain defined processes without chemical change.  
Examples include:
  - a naturally-occurring biological chemical
  - an inorganic chemical in soil
  - a mineral extracted from ore by a physical process such as dissolution or flotation.

The law also defines what is not considered a chemical as follows:

- an article. This means an item which, due to its use, has been manufactured into a certain shape or design, and which does not change its chemical composition during use.  
Examples include:
  - steel ball bearings;
  - compound plastic pipe;
  - adhesive film.
- a radioactive chemical, meaning a chemical with a specific activity greater than 35 becquerels/g.
- a mixture. This means a physical combination of chemicals resulting from deliberate mixing or from chemical reactions, but not a UVCB. However, the components within the mixture may be relevant industrial chemicals.

Furthermore, for the purposes of NICNAS, the law defines what is not a relevant chemical as:

- a naturally-occurring chemical
- biological material that is a whole plant or a whole animal
- an incidentally-produced chemical
- a reaction intermediate, or
- a chemical intended for an excluded use, meaning it is used solely as:
  - an agricultural chemical (includes pesticides and pool sanitizing chemicals)
  - a veterinary chemical
  - a medicine or therapeutic, or
  - a food or food additive.

There are records of approximately 40,000 chemical substances listed in AICS.

### ***B14.3. Ease of Access and Use of Chemical Information***

There are two sections of the AICS—public and confidential. If there are no results in the public AICS, users can apply to NICNAS to search the confidential AICS. They will search the confidential AICS if they are satisfied the users are genuinely intending to manufacture and/or import a chemical.

The best option for searching AICS is to use the CAS#. The next best option is to use the CAS Name for the chemical. Users can also search by molecular formula e.g. C<sub>12</sub>H<sub>12</sub>N<sub>2</sub>O<sub>3</sub>, but may get a very large number of results.

NICNAS has published helpful guidance for searching AICS.

Searches of the Tier I IMAP Assessments, PEC Assessments and Other Assessments may be done by CAS# or CAS name for the chemical. Tier II and Tier III IMAP Assessments are available from spreadsheets that can be sorted by tranche, CAS#, CAS name, Australian use, assessment outcome, or IMAP stage.

### ***B14.4. Breadth and Depth of EHS Information Available***

There is only limited information available from a search of AICS as follows:

- CAS#
- CAS Name — preferred chemical name
- Associated Names — common or other names that the chemical is known by (note this information is not displayed for all chemicals on AICS).
- Molecular Formula — identifies each type of element by its chemical symbol and identifies the number of atoms of each element found in one discrete molecule of the substance.
- If Secondary Notification Conditions Apply — if YES, companies must contact NICNAS before they manufacture or import this chemical into Australia to find out if they have additional notification requirements. A secondary notification means a chemical may need to be reassessed if the circumstances under which it was originally assessed has changed including where:
  - A significant change of use or new use occurs
  - A significant increase in production occurs
  - New information arises on the hazardous properties of a chemical.
- Conditions of Use — Upon opening the AICS listing - if there is a condition of use it will be described. A condition of use means the chemical can only be used for a specific purpose. If a company's intended use for the chemical is different to the condition of use, it will need to be assessed as a new chemical before import or manufacture by us unless the chemical falls into an exemption category.

To conduct its risk assessments NICNAS reviews information and data provided by the industrial chemicals industry, as well as information from other regulatory bodies both in Australia and overseas. NICNAS does not perform laboratory testing. NICNAS' findings are published in a range of detailed scientific reports. They also provide simplified versions of some reports for chemicals of concern to the community.

NICNAS assesses chemicals that have been newly introduced to Australia, and they are continuing to produce reports on existing chemicals that are listed on AICS.

PEC Assessments — there is substantial EHS information available from these documents, including:

- Chemical identity
- Physical and chemical properties
- Manufacture, import and use
- Public exposure
- Human health hazard characterization
- Human health risk characterization
- Public health risk management
- References

Tier I IMAP Human Health and Environment Assessments — there is limited EHS information available from these assessments — principally the regulatory decision that they do not pose an unreasonable risk to human health or the environment.

Tier II IMAP Human Health and Environment Assessments — there is considerably more EHS information available from these assessments which are organized into the following sections:

- Preface

- Chemical Identity
- Import, Manufacture and Use
- Restrictions
- Existing Work Health and Safety Controls
- Health Hazard Information
- Risk Characterization
- NICNAS Recommendation
- References

Tier III IMAP Human Health Assessments — there is even more EHS information available from these assessments which are organized into the following sections:

- Preface
- Synopsis
- Rationale for Tier III Assessment
- Chemical Identity
- Import, Manufacture and Use
- Public Exposure
- Health Hazard Information
- Public Risk Characterization
- NICNAS Recommendation
- References

### ***B14.5. Quality of the Underlying EHS Information***

NICNAS has published a document that outlines how it conducts its IMAP Assessments. It can be downloaded from the following website <https://www.nicnas.gov.au/chemical-information/imap-assessments>. In brief, IMAP Assessments have the following characteristics:

Scientifically robust risk-based approach — the framework uses simple and transparent criteria to determine the potential exposure and risks from chemicals to human health and the environment. The framework also allows for expert judgement, such as peer review to be applied where appropriate.

Achieving assessment outcomes early in the framework — this approach considers advice and requests from stakeholders, including industry and the community, to produce assessment outcomes early in the program and for each tier. The effort and resources being used should match the potential risk of the chemical. At each successive tier, the comprehensiveness (and hence resource intensiveness) of the assessments increases, while the number of chemicals requiring assessment decreases.

Using overseas data — a number of other countries and international agencies are generating or gathering information about the human health and environmental effects of a broad range of chemicals. To ensure efficiency and reduce duplication of effort, NICNAS is using this information (where appropriate) in the Australian context. To maximize this information, the framework's human health and environmental scientific criteria are aligned with existing hazard classification frameworks already in use across industry and internationally.

Advancements in assessment methodologies — to ensure best practice in assessing chemicals in Australia, internationally recognized assessment tools are used to fill gaps in data on a number of

human health and environmental hazard indicators. Tools and approaches being used are QSAR models or computational models for predicting toxicity and data from suitable analogue (similar) chemicals.

A flexible approach to exposure information (actual, surrogate or default). The greatest challenge when assessing the risks of chemicals on AICS is limited information on identity, volume and usage on chemicals currently being imported and/or manufactured in Australia. The framework uses surrogate information to estimate exposure, such as from overseas sources, or conservative default values (where actual or surrogate information is not available) in the early stages (Tier I and Tier II assessments).

#### ***B14.6. Procedures for Updating the Database with New Information***

Companies that manufacture or import chemicals in Australia have an obligation to notify new chemicals, and to make a secondary notification if the circumstances under which it was originally assessed has changed including where: a significant change of use or new use occurs; a significant increase in production occurs; or if new information arises on the hazardous properties of a chemical.

NICNAS conducts secondary notification assessments of chemicals previously assessed and targeted assessments (focused on hazard, exposure or use) of existing chemicals for which there were potential health or environmental concerns or relevant new data.

### ***B15. New Zealand Government EHS Databases***

The information presented below represents a summary of key information about the environmental, health and safety information on industrial chemicals that is available from the New Zealand government.

[For more detailed information about how New Zealand manages hazardous chemicals visit their website.](#)

#### ***B15.1. Overview/Description***

New Zealand's Environmental Protection Authority (NZEPA) and WorkSafe New Zealand have complementary roles to play to manage risks from exposures to hazardous substances. Hazardous substances are any chemical, or mixture of chemicals, that meets New Zealand's hazardous classification criteria. These criteria include: explosiveness, flammability, toxicity to people, ability to cause cancer, toxicity to the environment and their ability to generate a different hazardous substance on contact with air or water.

Hazardous substances—including petrol, solvents, explosives, industrial chemicals, fireworks, agri-chemicals, household cleaners and cosmetics—need to be approved before they can be used in New Zealand. The role of the NZEPA is to regulate pesticides, household chemicals and other dangerous goods and substances under the Hazardous Substances and New Organisms Act (HSNO). NZEPA makes decisions on whether to approve new hazardous substances. They put rules in place called controls to manage the risks of hazardous substances and to safeguard people and the environment.

NZEPA also reassess substances and makes new decisions about whether the controls need to be updated, and even if they need to be banned. NZEPA also administers hazardous waste and ozone-depleting substances.

Under HSNO, a hazardous substance is any substance that has one or more of the following properties above specified levels:

- an explosive nature (including fireworks)
- flammability
- ability to oxidize (i.e. accelerate a fire)
- corrosiveness
- acute or chronic toxicity (toxic to humans)
- ecotoxicity, with or without bioaccumulation (i.e. can kill living things either directly or by building up in the environment)
- can generate a hazardous substance on contact with air or water.

Hazardous substances can have more than one hazardous property. For example, methylated spirits and petrol are flammable and toxic.

New Zealand groups substances into physical, health and environmental hazards, and assigns a classification number to each type of hazard. If the substance has any hazardous properties, then it is a hazardous substance under the law. If it doesn't have any hazardous properties, then the substance can be considered non-hazardous and companies seeking to manufacture, import or use it don't need to worry about approval.

Companies wishing to import or manufacture a substance must determine whether it is hazardous. When a hazardous substance is approved (either under a group standard or individually), controls (or rules) are put in place for their use, so that the risks are managed. Examples of controls include:

- Hazardous substances must be appropriately packaged.
- Hazardous substances must be used in such a way to minimize environmental effects.
- Sites storing large quantities of liquid hazardous substances not in a workplace must have signage and secondary containment (bunding) in place.
- Labelling and other information must clearly indicate the hazards of the substances.

Each substance has a basic set of controls, known as default controls, depending on the hazard classification of the substance. Similar controls can also be found in group standards to manage the risk of the particular type of group standards. When a substance is approved, these default controls are often modified to make sure they are appropriate for the particular substance being approved. Additional controls may be assigned to them or deleted.

Any site containing large quantities of eco-toxic (class 9) hazardous substances needs appropriate emergency management. Emergency management involves preventing accidents and incidents as well as limiting the adverse effects of incidents, should they occur.

Requirements for emergency management are split between WorkSafe New Zealand (if a toxic substance - class 6 - and in workplaces) and the NZEPA (if exotoxic - class 9 - and not in workplaces).

Emergency management requirements include:

- Emergency information on labels, such as first instructions
- Emergency information on safety data sheets, such as spill response procedures

- Equipment, such as fire-extinguishers
- Signage
- Secondary containment (bundling)
- Emergency response plans.

The level of emergency management required depends on the quantity and type of hazardous substances at the location. Where a substance has more than one hazard classification, the lowest threshold quantity is used.

Threshold quantities are based on the aggregated quantity of all hazardous substances held at that location for:

- Fire extinguishers
- Emergency response plans
- Secondary containment
- Signage requirements

The supplier of the hazardous substance is responsible for providing labelling and safety data sheets and ensuring they meet the required performance standards. The person in charge is responsible for ensuring emergency management procedures are in place, wherever threshold quantities are exceeded, including:

- Labelling requirements continue to be met
- Safety data sheets are available
- The right number and type of fire extinguishers are present and correctly located
- Emergency response plan has been prepared, tested and is available to staff
- The site has appropriate signage
- The site has appropriate secondary containment.

An emergency response plan is needed for sites where large quantities of hazardous substances are present. The plan describes the emergency procedures for the site and must cover all hazardous substances held, or likely to be held, at the site. The plan must be tested at least every 12 months or within three months of a change to the plan. The plan can be part of emergency planning documentation required under other legislation

WorkSafe New Zealand administer the rules for the use of hazardous substances in the workplace.

During the application process, NZEPA works collaboratively with WorkSafe NZ and advises them about the risk assessment for the hazardous substance. From the risk assessment, WorkSafe checks to see if the requirements in the regulations will manage the risks to people in workplaces sufficiently. In some situations, WorkSafe New Zealand may decide that additional requirements are needed to protect workers and other people from the potential harm from a substance. In this case, they may advise the NZEPA that a Safe Work Instrument (SWI) should be developed to address the work-related human health risks identified. An SWI may modify or set some additional requirements to those provided in the regulations. If an SWI is required, WorkSafe will need time to develop one and to obtain the Minister's agreement before the substance can be approved.

Tracking of hazardous substances in workplaces is now administered by WorkSafe New Zealand, however if a person supplies a substance that triggers a certain threshold, they are required to retain a written record.

Polychlorinated Biphenyls (PCBs) are one of a number of persistent organic pollutants (POPs) which are serious environmental pollutants and are banned in New Zealand. However, it is likely that small amounts of PCBs, as with other POPs, will continue to be found and there is a framework to manage their storage and disposal.

Companies wishing to manufacture or import substances into New Zealand must:

1. Provide the NZEPA with their business contact information
2. Know the ingredients of their product and if they are hazardous
3. Get a current safety data sheet
4. Label their hazardous substances correctly
5. Package their product properly

NZEPA maintains several on-line, searchable databases. Among the databases are the following:

The HSNO Application Register — Search for every hazardous substance and new organism application decided under Part 5 of the HSNO Act.

Chemical Classification and Information Database (CCID) — Search the CCID to find detailed hazard and physical information about single chemicals for use in hazard classifications and safety information.

New Zealand Inventory of Chemicals (NZIoC)— Search for single chemicals here to see if they can be used in products assigned to Group Standards.

Group standards are approvals for a group of hazardous substances of a similar nature, type or use. Manufacturers and importers carry out their own assessment and assign their product to certain group standards based on the hazards and intended uses of the products. Once a group standard has been found, they need to keep a record why a particular group standard has been assigned.

There are a range of offenses and penalties under HSNO and various other New Zealand regulations. Penalties are dependent on the nature of the offense, and the duty holder of the offender, but can include infringement notices, infringement fees and/or court-imposed orders. Furthermore, court imposed orders may include orders for restoration (put right the offense), adverse publicity (publicly acknowledge the offense), injunctions (stop the offense) and training orders. Maximum penalties range between NZD 5000 (for an individual) and NZD 500 000 (for a company). Prison sentences are reserved for very serious offenses, including reckless conduct without 'reasonable' excuse.

## ***B15.2. Scope of Chemicals Addressed***

In Scope

The NZIoC is a database of all the hazardous chemical components of products, including pesticides, polymers, and non-infectious organisms that have been approved under group standards. Note that non-hazardous chemicals are not required to be listed, although not all substances listed in the NZIoC are classified as hazardous. There are approximately 28,000 chemicals listed in the NZIoC database.

Note that the term "hazardous substances" under HSNO is unique in the world. It covers both single-component chemical substances and formulated products. New Zealand's chemical approval system is also quite different from other countries. A new single-component chemical substance that is not hazardous does not require approval.

#### Out of Scope

Some hazardous substances are exempt or excluded from the HSNO. An approval is not needed to import or manufacture these substances.

Exempt substances include:

- Hazardous substances for use in an exempt laboratory
- Radioactive material
- Medicine intended for people
- Food
- Infectious substances
- Manufactured articles
- Non-hazardous substances

### ***B15.3. Ease of Access and Use of Chemical Information***

Each of the three New Zealand databases — HSNO Application Register, CCID, and NZIoC can be searched by CAS# or chemical name. No guidance document could be located to assist with searches.

### ***B15.4. Breadth and Depth of EHS Information Available***

The amount of EHS information available varies among the three databases as follows:

HSNO Application Register — presents the results of the determination of whether the substance meets the definition of hazardous and a very brief basis for that determination.

CCID — presents the results of the determination of whether the substances meets the definition of a hazardous substance and includes a more substantial discussion of the scientific evidence available that supports that determination, including references to specific research studies and findings.

NZIoC —presents no EHS information, simply the CAS#, Name, Synonyms, Approval Status, Restrictions and Date of Approval.

### ***B15.5. Quality of the Underlying EHS Information***

NZEPA draws on world-class expertise and information on chemicals from local and international science communities and similar government environmental agencies around the world. NZEPA also contributes to the world- wide body of shared knowledge through many international connections. They are committed to science and risk based decision making that is transparent and offers the public the opportunity to participate.

### ***B15.6. Procedures for Updating the Database with New Information***

All hazardous substances must be notified to NZEPA prior to their manufacture or import.

Over time, new information about a hazardous substance may emerge which suggests that the risks to human health and/or the environment may not be appropriately managed by the existing controls for the substance.

Similarly, new information may become available on the benefits of a substance. When this happens, the EPA may reassess the approval for the substance.

An amendment makes a change to a hazardous substance approval that is 'minor in effect' or corrects a minor or technical error in the approval.

A reassessment is an assessment of the effects of an approved hazardous substance and the controls that have been imposed on it. This includes reconsideration of the risks, costs and benefits of the substance. If anyone believes the approval for a hazardous substance should be reassessed, the first step is to outline the reasons. This is called 'applying for grounds'. Anyone can apply to have a substance reassessed or an approval amended. Some applications are initiated by the NZEPA Chief Executive.

## ***B16. People's Republic of China Government EHS Databases***

The information presented below represents a summary of key information about the environmental, health and safety information on industrial chemicals that is available from the Chinese government. Unfortunately, as of this writing, the Chinese government has made only a relatively small amount of information available in the English language. Two independent contractor sources relied upon for compiling the information are [ChemSafetyPro](#) and [CIRS](#).

### ***B16.1. Overview/Description***

In March of 2011, the State Council of China published its Regulations on Safe Management of Hazardous Chemicals (China Decree 591) and it entered into force on 1 Dec 2011. Decree 591 is the highest chemical control law in China and it regulates hazardous chemicals through the entire supply chain, from manufacture, importation, distribution, storage to transportation and use.

Decree 591 is not a single law. It is supported by dozens of ministerial regulations (including China MEP order 7, i.e., China REACH) and numerous guidance documents. Three main ministries involved are the Ministry of Ecology and Environment (MEE), the State Administration of Work Safety (SAWS) and the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ).

Decree 591 requires businesses which handle hazardous chemicals to apply for licenses to operate ("license system") and submit HazChem registrations separately to two ministries (MEE and SAWS). Decree 591 also implements GHS in China requiring companies to provide SDSs and labels prepared in accordance with relevant national standards.

In Decree 591, hazardous chemicals are defined as highly toxic chemicals and other chemicals which are toxic, corrosive, explosive, flammable and do harm to human body, facilities and environment. All chemicals meeting GHS hazard classification criteria may fall within its scope.

In Jan 2013, China MEE published the updated version of the Inventory of Existing Chemical Substances in China (IECSC). It is only available from them in Chinese, but may be downloaded from this website  
Some consultants will make an English language version of IECSC available if contacted directly.

As of the beginning of 2013, there were 45,612 substances in IECSC. No CAS# were available for 8,486 of them. Any substance that is not listed on IECSC is regarded as a new substance in China and requires notification in accordance with China MEP Order 7 (China REACH).

Among all hazardous chemicals placed on the Chinese market, more than 2800 chemicals have been added to the Catalogue of Hazardous Chemicals. This Catalogue is for administrative licensing purposes. Businesses who handle hazardous chemicals listed in the Catalogue are subject to various license requirements.

Some hazardous chemicals in the Catalogue belong to highly toxic chemicals, explosives precursors and priority hazardous chemicals for environmental management and are subject to more stringent requirements.

- Catalogue of Hazardous Chemicals (2015);
- Highly Toxic Chemicals Management;
- Explosives Precursors Management;
- Priority Hazardous Chemicals for Environmental Management;

Any legal entity producing, importing, distributing or using hazardous chemicals in the Catalogue of Hazardous Chemicals in China must obtain a license from local Administration of Work Safety. There are three main types of licenses:

- Production license for producers;
- Operation license for importers, distributors, sellers, etc.;
- Safe use license for certain downstream users(\*)

\*A safe use license is only required if the volume of certain hazardous chemicals used exceeds certain amounts and the industry sector of the user is on the list of applicable industry sectors.

Articles 66 and 67 of Decree 591 require domestic manufacturers and importers of hazardous chemicals to register hazardous chemicals with the National Registration Center of Chemicals (NRCC) of SAWS prior to manufacturing or importation. Detailed registration requirements and procedures are outlined in SAWS's order 53 - The Measures for the Administration of Registration of Hazardous Chemicals.

This HazChem registration is required for both hazardous substances and mixtures regardless of whether they are included in the Catalogue or not. There is no small volume exemption either.

China MEE order 22 was revoked on 15 July 2016. Companies no longer need to register hazardous chemicals with environmental protection authorities.

Decree 591 is the most important law implementing GHS in China. Article 15 requires chemical manufacturers to provide Safety Data Sheets and labels prepared in accordance with the relevant national standards. Article 37 prohibits distributors from selling hazardous chemicals without SDSs or labels. Companies who fail to classify, label and package hazardous chemicals in accordance with those standards would face a maximum penalty of 50,000 Yuan or a ban.

In addition, Decree 591 gives power to AQSIQ to conduct inspections on imported and exported hazardous chemicals and their packages at ports. SDSs and labels are the main things they inspect. Non-compliant SDSs and labels may result in a delay of customs clearance or returned goods.

SAWS issued its revised Catalogue of Hazardous Chemicals in March of 2015. This Catalogue includes 2,828 entries covering more than 2,800 hazardous substances and some mixtures. The Catalogue came into force on 1 May 2015. In Sept 2015, SAWS issued a guidance document containing official GHS classifications for chemicals in the Catalogue. At present, only a Chinese language version of the Catalogue is available from SAWS, although some consulting organizations offer an English language version if contacted directly.

The Catalogue is for administrative licensing purposes and does not represent a complete list of hazardous chemicals in China. For example, chemicals classified with acute toxicity GHS category 4 do not meet criteria for inclusion in the Catalogue. However, they are still hazardous and subject to mandatory SDSs and labelling requirements under Decree 591.

The Catalogue includes mostly substances. Only a few mixtures are included.

A substance refers to an industrial product as it is produced. There is no minimum concentration set for a product to meet the definition of a substance.

The Catalogue is also a compulsory GHS classification list in China. For chemicals listed in the Catalogue, industry must use the published classifications or more severe ones to classify their chemicals and prepare safety data sheets.

HazChem registration is not limited to those hazardous chemicals listed in the Catalogue. Under SAWS's order 53, manufacturers and importers of hazardous chemicals must register such chemicals with the NRCC of SAWS prior to production and importation.

Not every hazardous chemical in the Catalogue is treated the same. Hazardous chemicals which are indicated as "Highly Toxic" in the Catalogue and explosives precursors are subject to additional license and reporting requirements on storage, sales and purchase under the State Council Decree 591. The Catalogue also includes some chemical weapons precursors and drug precursor chemicals which are subject to additional control by other regulations.

Highly toxic chemicals are defined as chemicals with high acute toxicity (usually GHS Acute Toxicity Category 1). Those chemicals can be lethal even in very small quantities. In China, highly toxic chemicals are mainly regulated by the following administrative regulations:

- Regulations on Safe Management of Hazardous Chemicals (2011) – State Council Decree 591;
- Catalogue of Hazardous Chemicals (2015);
- The Measures for the Administration of Licenses for the Purchase and Road Transportation of Highly Toxic Chemicals in China (2005) – Order 77 of the Ministry of Public Security (MPS).

The above regulations establish a much tighter regulatory regime for highly toxic chemicals than regular hazardous chemicals in China and set additional requirements on the storage, purchase and sales of highly toxic chemicals.

At one time MPS maintained a separate List of Highly Toxic Chemicals. This list has recently been incorporated into the Catalogue of Hazardous Chemicals (2015).

There are currently 148 highly toxic chemicals in the Catalogue of Hazardous Chemicals (2015). The Catalogue may be searched by Chinese name or CAS#.

Unlike China MEP order 7 which focuses on the registration of new substances, SAWS's order 53 focuses on chemical products which include both substances and mixtures. A product requires registration if:

- It is listed in the Catalogue of Hazardous Chemicals; or;
- It is not listed but identified as hazardous based on available data.

For a chemical product with unknown hazards (a chemical outside of the Catalogue), hazard identification needs to be conducted by qualified institutes as required by SAWS's order 60 for physico-chemical identification and classification. If the product is identified as hazardous, registration will be required.

All chemicals meeting GHS hazard classification (excluding certain hazard categories such as acute toxicity 5) will require registrations regardless of the volume produced or imported.

The following information for each hazardous product needs to be submitted online to the local HazChem registration office which conducts preliminary review and passes complete registration materials to the NRCC of SAWS based in Qingdao City of Shandong Province.

- Legal entity information;
- Classification and labeling(China GHS);
- Physical-chemical properties;
- Main uses;
- Hazard properties;
- Safety requirement for storage, use and transport;
- Emergency responses (24h emergency contact number required);
- Chinese GHS SDS and labels required.

The registration certificate is valid for 3 years and can be renewed 3 months prior to certificate's expiry date.

China REACH was issued in Jan 2010 and came into force on 15 Oct 2010. This regulation is similar in many respects to EU REACH. China REACH requires that manufacturers and importers submit new substance notifications and obtain approvals from the Solid Waste and Chemical Management Center (SCC) prior to production or importation. A foreign exporter may appoint a local Chinese agent (Only Representative) to submit new substance notifications.

The notification requirement not only applies to the new substance on its own, in preparation or articles intended to be released, but also applies to new substances used as ingredients or intermediates for pharmaceuticals, pesticides, cosmetics, food additives and feed additives, etc.

There are four types of notifications under China REACH which depend on the use and volume of a new substance. In general, with the exception of polymers of low concern which require only a simplified notification; substances produced or imported at or above 1 ton/year require regular notification. For lower volume substances the following applies: (1) scientific research or testing purposes only, scientific research record, simplified notification; (2) isolated intermediate, special conditions, simplified notification; (3) polymer of low concern, general conditions; and (4) regular new substance, regular notification.

For simplified notification under general conditions and regular notification, some eco-toxicology studies must be done locally in MEP-approved labs.

IECSC is not a static inventory. Generally, new substances will be added into IECSC only after 5 years since the date of the first commencement of manufacturing or importation. Whether hazardous new chemicals substances will be added onto IECSC depends on the review of a technical committee. New substances that have gone through simplified notification or scientific research record are not added into IECSC.

Upon obtaining a China REACH registration certificate, companies must fulfill post-notification obligations based on the category of management stated on the certificate. New substances are categorized as general new chemical substances or hazardous new chemical substances based on their hazard properties. Hazardous new chemical substances that are classified as persistent and bioaccumulative or are classified as harmful to ecological environment and human health will be further designated as priority hazardous new chemical substances for environmental management and are then subject to additional post-notification requirements.

There are some substantial differences between China REACH and EU REACH as follows:

China and EU REACH		
Characteristic	China REACH	EU REACH
Scope	All new substances regardless of volume produced or imported	New and existing substances produced or imported $\geq$ 1/tonne/year
Polymers	Notification of polymers	Polymers are largely exempt
Ecotoxicology Studies	Must be performed by local Chinese laboratories	No restriction on where testing is performed
Risk Assessments	Must be done on all substances $\geq$ 1 ton/year	Must be done on all substances $\geq$ 10 tonne/year
QSAR	Supporting information only	Accepted in lieu of some testing
Joint Submission	Optional	Mandatory
SVHC List	Not applicable yet	Yes
Articles	Out of scope	In scope

There is no China SVHC list yet. However, there is a Chinese version of REACH restricted substances list.

### ***B16.2. Scope of Chemicals Addressed***

IECSC and China REACH capture all chemicals on the Chinese market, including polymers, regardless of the volume they are produced or imported.

The following substances are exempt from China REACH.

- Chemical substances subject to other existing laws and regulations (pharmaceuticals, pesticides, cosmetics, food additives, etc.);
- Naturally occurring substances;
- Impurities (content of a single impurity  $<$ 10%w/w, total content of all impurities  $<$ 20%w/w), waste or by-products;
- Special categories such as glass, cement, alloys, non-isolated intermediates (\*), articles.

\*On-site isolated intermediate is regarded as non-isolated intermediate in China and thus exempt.

### ***B16.3. Ease of Access and Use of Chemical Information***

A major impediment to using IECSC and the Catalogue of Hazardous Chemicals is that they are not generally available in English. Both may be downloaded and searched by Chinese chemical name or CAS#. No English language help is available for conducting the searches.

**B16.4. Breadth and Depth of EHS Information Available**

There is no English language EHS information available from either IECSC or the Catalogue of Hazardous Chemicals.

**B16.5. Quality of the Underlying EHS Information**

Not applicable.

**B16.6. Procedures for Updating the Database with New Information**

IECSC is updated with new chemicals only 5 years after the commencement of manufacture or import. Moreover, the availability of publicly accessible updated IECSC or Catalogue of Hazardous Chemicals is at the discretion of MEE and SAWS, respectively.

**B17. Asean-Japan Chemical Safety Database (AJCSD)**

The information presented below represents a summary of key information available from the Asean-Japan Chemical Safety Database (AJCSD). More detailed information about AJCSD may be found at their website.

**B17.1. Overview/Description**

The AJCSD is a free, public online database that provides users with regulatory information on a hundred thousand chemicals in ASEAN and Japan. Participating member countries include: Brunei, Cambodia, Indonesia, Japan, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam. The AJCSD contains regulatory information on chemical substances provided directly by the governments of ASEAN countries, hazard and risk information from Japan, GHS Classification results from Japan, Malaysia and Myanmar, and sample SDSs in local language(s). Japan's NITE is the operator of the AJCSD which began operations in April of 2016. NITE sees the database as a way of promoting gradual harmonization in the region. They emphasize that the database is for reference only, and should not be used as a substitute for regulatory requirements.

**B17.2. Scope of Chemicals Addressed**

The focus is on industrial chemicals; however, this is not further described and users should examine the scope of chemicals addressed by each of the countries that is participating in the AJCSD for clarification.

**B17.3. Ease of Access and Use of Chemical Information**

AJCSD is publicly accessible and is free of charge to use. There is an English language user's manual available to assist with searches.

There are three ways to search at the AJCSD, Search (Multilingual\*), Advanced Search (English only), and Substance Lists (English only). Users can search by CAS# or chemical name in English. Advanced

searches may be conducted with multiple keywords, each separated by a space. They may also be conducted by molecular formula.

\*Burmese, English, Indonesian, Japanese, Khmer, Lao, Malay, Standard Thai or Vietnamese.

#### ***B17.4. Breadth and Depth of EHS Information Available***

Searches of AJCSD can yield the following information:

- Names, CAS#, and structural formulae for chemical substances;
- Sample safety data sheets (SDSs);
- GHS classification results from Japan, Malaysia and Myanmar; and
- hazardous and risk assessment results from Japan.

How each participating country regulates a particular substance or group of substances can also be searched for comparison purposes.

#### ***B17.5. Quality of Underlying EHS Information***

The AJCSD provides reliable data published by international authorities. However, NITE notes that Information or data is provided on an “as is” and “as available” basis. The operator and the participating countries make every effort to ensure, but do not guarantee, the accuracy or completeness of the information or data. Since the hazard and risk information derives from the Japan CHRIP database, users have assurance that this information has been compiled by experts and has undergone peer-review.

#### ***B17.6. Procedures for Updating the Database with New Information***

The AJCSD contains information for a lot of substances. The quality of the database is ensured by regular updates performed once every two months, and by a continual verification process.

### ***B18. US National Library of Medicine TOXNET Database***

Presented below is a summary of EHS information on industrial chemicals that is available from US National Library of Medicine TOXNET Database. For more detailed information, the reader should consult directly with their website. The reader should also be aware that several of the most important data sources contributing information to the TOXNET database (e.g., USEPA IRIS, etc.) are reviewed in greater detail in other sections of this report.

#### ***B18.1. Overview/Description***

TOXNET® (TOXicology Data NETwork) is a group of databases covering chemicals and drugs, diseases and the environment, environmental health, occupational safety and health, poisoning, risk assessment and regulations, and toxicology. It is managed by the Toxicology and Environmental Health Information Program in the Division of Specialized Information Services of the National Library of Medicine.

TOXNET may be used to find:

- Specific chemicals, mixtures, and products
- Chemical nomenclature
- Chemicals that may be associated with a disease, condition or symptom
- Chemicals associated with consumer products, occupations, hobbies, and more
- Special toxic effects of chemicals in humans and/or animals
- Citations from the scientific literature

TOXNET provides links to PubMed®, NLM's free web interface to the world's biomedical literature, and to additional sources of toxicological information.

Specific databases that can be searched through TOXNET include:

### **B18.1.1. Chemical Nomenclature and Structure**

ChemIDplus®

ChemIDplus contains over 400,000 chemical records. More than 300,000 of those records include chemical structures. ChemIDplus is searchable by Name, Synonym, CAS Registry Number, Molecular Formula, Classification Code, Locator Code, Structure, and/or Physical properties. Enhanced structure display is available in ChemIDplus Advanced.

### **B18.1.2. Toxicology Data**

Toxicological information may be found in the following databases:

CCRIS (Chemical Carcinogenesis Research Information System)

CCRIS is developed and maintained by the National Cancer Institute (NCI). It contains over 9,000 chemical records with carcinogenicity, mutagenicity, tumor promotion, and tumor inhibition test results. Data are derived from studies cited in primary journals, current awareness tools, NCI reports, and other special sources. Test results have been reviewed by experts in carcinogenesis and mutagenesis.

CCRIS provides historical information from the years 1985 - 2011. It is no longer updated.

CPDB (Carcinogenic Potency Database)

CPDB provides standardized analyses of the results of 6540 chronic, long-term animal cancer tests conducted since the 1950s and reported in the general published literature or by the National Cancer Institute and the National Toxicology Program. This database was developed at the University of California, Berkeley, and Lawrence Berkeley Laboratory.

CPDB provides historical information from the years 1980 - 2011. It is no longer updated.

CTD (Comparative Toxicogenomics Database)

CTD contains manually curated data describing cross-species chemical-gene/protein interactions and chemical- and gene-disease relationships. The results provide insight into the molecular mechanisms underlying variable susceptibility and environmentally influenced diseases. These data will also provide insights into complex chemical-gene and protein interaction networks. CTD is developed with funding from the National Institutes of Environmental Health Sciences (NIEHS) at North Carolina State University (NCSSU). The database is updated several times a year.

#### GENE-TOX (Genetic Toxicology)

GENE-TOX was created by the U.S. Environmental Protection Agency (EPA) and has genetic toxicology test results on over 3,200 chemicals. Selected literature was reviewed by scientific experts for each of the test systems under evaluation.

GENE-TOX provides historical information from the years 1991-1998. It is no longer updated.

#### HSDB® (Hazardous Substances Data Bank)

HSDB provides toxicity data for over 5,800 potentially hazardous chemicals. It also has information on emergency handling procedures, industrial hygiene, environmental fate, human exposure, detection methods, and regulatory requirements. The data are fully referenced and reviewed by a Scientific Review Panel.

#### Haz-Map®

Haz-Map is an occupational health database designed for health and safety professionals and for consumers seeking information about the health effects of exposure to chemicals and biological agents. The database is a "map" of workplace hazards to help you prevent occupational diseases. Haz-Map links jobs, hazardous tasks with occupational diseases and their symptoms, and other non-occupational diseases such as hobbies.

#### Household Products Database

The Household Products Database has information on the potential health effects of chemicals contained in common products used inside and around the home. Information is also available for some industrial grade products. Products can be searched by brand name, product type, manufacturer, ingredient/chemical name, and by health effects. The record for each product shows the ingredients as reported by the manufacturer. For many products, a link to the manufacturer's Safety Data Sheet (formerly Material Safety Data Sheet) is provided which includes more information such as handling, disposal, and health effects.

#### IRIS (Integrated Risk Information System)

IRIS, developed by the U.S. Environmental Protection Agency (EPA), is a human health assessment program that evaluates information on health effects (cancer and non-cancer) that may result from exposure to environmental contaminants, and which is subsequently compiled into a database. Reviewed by EPA scientists and representing EPA consensus, IRIS covers over 550 chemicals.

#### ITER (International Toxicity Estimates for Risk)

ITER provides health risk values and cancer classifications from authoritative groups worldwide for chemicals of environmental concern. It presents risk data in a tabular format for easy comparison between organizations, and includes synopses explaining data variations where they exist. ITER also has links to source documentation and more details. It is compiled by Toxicology Excellence for Risk Assessment (TERA).

#### LactMed® (Drugs and Lactation)

LactMed is a database of over 1,000 drugs and other chemicals to which breastfeeding mothers may be exposed. It includes information on the levels of such substances in breast milk and infant blood, and the possible adverse effects in the nursing infant. Suggested therapeutic alternatives to those drugs are provided, where appropriate. All data are derived from the scientific literature and fully referenced.

Data are organized into substance-specific records, which provide a summary of the pertinent reported information and include links to other NLM databases. Supplemental links to breastfeeding resources from credible organizations are also provided. LactMed is updated monthly.

#### TRI (Toxics Release Inventory)

TRI is a set of publicly available databases containing information on releases of specific toxic chemicals and their management as waste, as reported annually to the EPA by U.S. industrial and federal facilities. This inventory was established under the Emergency Planning and Community Right to Know Act of 1986 (EPCRA). TRI's data, beginning with the 1987 reporting year, covers air, water, land, and underground injection releases, as well as transfers to waste sites. In agreement with the Pollution Prevention Act of 1990, source reduction and recycling data is also included in TRI.

#### TOXMAP®

TOXMAP is a Geographic Information System (GIS) using maps of the United States to show the amount and location of toxic chemicals released into the environment. Data is derived from the EPA's Toxics Release Inventory (TRI), which provides information on the releases of toxic chemicals into the environment as reported annually by industrial facilities around the United States. TOXMAP also contains information from the EPA's Superfund Program.

### **B18.1.3. Toxicology Literature**

#### TOXLINE®

TOXLINE provides bibliographic information (1840s to present) covering the biochemical, pharmacological, physiological, and toxicological effects of drugs and other chemicals. It contains over 5 million references, most with abstracts, indexing terms, and Chemical Abstracts Service (CAS) Registry Numbers. The toxicology subset of MEDLINE®/PubMed is part of TOXLINE. TOXLINE also contains references from specialized journals, government reports, meeting abstracts, and other relevant collections of toxicology literature.

#### DART® (Developmental and Reproductive Toxicology Database)

DART contains references to reproductive and developmental toxicology literature. DART is created from a search profile run against PubMed. DART previously contained additional citations from various sources that no longer exist, and from journals which are now indexed by Medline.

### ***B18.2. Scope of Chemicals Addressed***

The scope of TOXNET is very broad and includes chemicals in commerce, chemical contaminants found in the environment, biological agents, drugs, pesticides, biocides, diseases, genes and proteins.

### ***B18.3. Ease of Access and Use of Chemical Information***

TOXNET is easily accessed and searched. Individual databases may be searched one at a time or multiple databases may be searched simultaneously using single or multiple keywords, chemical name or CAS#. There is an abundance of help with search strategies available. TOXNET may even be searched from mobile devices. Detailed training and guidance are available for those wishing to search TOXNET by visiting TOXNET and Beyond Training Class Schedule and Workbook for a class schedule and to download the TOXNET manual.

#### ***B18.4. Breadth and Depth of EHS Information Available***

The breadth and depth of EHS information available from TOXNET varies considerably based on the contributing data source and substance being queried. Generalizing somewhat, extensive EHS data are available for pesticides, biocides, high volume chemicals and those chemicals that have been produced and used for longer durations and have been subject to more intensive government agency scrutiny based on their uses/exposures and suspected hazard properties.

Raw data measuring the properties of chemicals (physical chemical properties, environmental fate and behavior, eco-toxicity, and mammalian toxicology) from a full range of tests and models (e.g., Quantitative Structure Activity Relationships (QSAR), computational toxicology methods, etc.) are available, as well as robust summaries of those data, hazard and exposure characterizations and risk assessments.

A clear advantage of TOXNET is that it can provide the user with rapid access to the full gamut of EHS information that is available on a particular substance from multiple sources.

#### ***B18.5. Quality of the Underlying EHS Information***

The data and information stored in each participating data source are the responsibility of the data owner. The National Library of Medicine cannot guarantee the correctness of the data, and provides explicit warnings that it cannot be held responsible or liable for errors.

TOXNET does provide brief descriptions of the sources and the peer review the data has undergone for each data source. Most sources have some procedures in place to assure the quality and reliability of the information they rely upon for making chemical safety assessments; however, users of the information should confirm the robustness of those procedures by checking with the relevant sources.

#### ***B18.6. Procedures for Updating the Database with New Information***

TOXNET databases are updated when new information becomes available. New data is checked for at least once a week. Users can refer to the TOXNET Databases Size Report to see if a specific database has been updated. Users should note that some databases are no longer updated and are maintained as historical resources.

### ***B19. GoodGuide***

Presented below is a summary of EHS information on industrial chemicals that is available from GoodGuide. [For more detailed information, the reader should consult directly with their website.](#)

#### ***B19.1. Overview/Description***

GoodGuide was launched approximately 10 years ago. Its stated mission is to provide consumers with the information they need to make better shopping decisions. GoodGuide believes that as more

consumers choose products that contain ingredients with fewer health concerns, retailers and manufacturers face compelling incentives to make and sell better products.

To fulfill their mission, GoodGuide combines manufacturer-provided information about product ingredients with authoritative information on the health effects of chemicals. They rate products so that consumers can have instant access to credible information about products that would be very difficult for anyone to develop on their own. GoodGuide employs a team of scientific experts in product and chemical information and have been engaged in this project for ten years. According to GoodGuide they have grown to become the web's most comprehensive and credible resource for information about the impact of consumer products on human health. More than 1 million consumers use GoodGuide's website and mobile apps every month to help decode product labels, research ingredients, and make more informed decisions about the products they purchase.

**With GoodGuide, users can:**

- Use their ratings to quickly identify the highest rated products on the market.
- Find out whether a product contains ingredients with health concerns.
- Rely on their science expertise to interpret complex information about the potential health effects of different chemicals.
- Get advice while shopping by using the GoodGuide iOS App, Product Scanner for Android, or the mobile website.

**International Users**

Though GoodGuide's product ratings currently cover U.S. based products, similar versions of the same product are available in many countries. Persons who live outside of the U.S. can still use the website as thousands of consumers currently do, but will need make sure to compare the ingredient lists for differences.

**GoodGuide Ratings**

The GoodGuide Rating was developed using methodologies that are grounded in the sciences of informatics and health risk assessment. Products are scored from a low of 0 to a high of 10. The higher the rating, the better the product from a health perspective.

Note that GoodGuide maintains complete control over its rating system — brands do not have any influence over the ratings they assign to their products.

GoodGuide uses “ontologies,” or structural frameworks for organizing information, to define “what matters” when assessing the health performance of a product or company. The major issues covered are summarized in their ratings overview. GoodGuide's issue framework is derived from current standards of practice in the scientific domains relevant to assessing health impacts. For example, they track issues that mirror the standard output of chemical risk assessments or nutritional evaluations. Their reliance on the informatics systems that have been developed by scientific, regulatory or other authorities to address specific issues ensures that their system provides science-based ratings and can take advantage of standardized information generation.

For each issue, GoodGuide identify a set of “indicators” that provide evidence about how a product performs on that issue. Product-level indicators are based on attributes of a product related to its potential health impacts (e.g., the level of health concern about the ingredients of a personal care product).

Data availability is one of the most important criteria for selecting indicators. In order to ensure they have comparable information available for rating products, they require that indicator information is publicly available for the majority of rated products. Data availability influences GoodGuide's rating system in two important ways:

- In many cases, data availability considerations require GoodGuide to rely on “screening-level” indicators rather than “data-intensive” indicators. In a world of perfect information, for example, product health ratings would be based on detailed health risk assessments that combine information about the health hazards of ingredients with data characterizing consumer exposure to those chemicals. Unfortunately, these data are almost never made available by manufacturers, so GoodGuide utilizes more readily ascertainable hazard indicators (e.g., the number of ingredients of health concern in a product).
- Because the pervasive lack of transparency about product attributes undermines the public's ability to evaluate performance, GoodGuide has created a number of indicators that track data availability and product impact ratings. At the product level, Data Adequacy indicators track whether the specific data elements that are needed to assess a product's health impact are public. GoodGuide penalize personal care or household chemical products missing complete ingredient lists in their scoring system because these products lack the data needed to assess chemical safety.

At the product-level, the GoodGuide ratings system is designed to support comparisons of products within a product category (e.g., after shave, body wash and cleansers, candy, etc.). The evaluative framework used to assess personal care products contains a different set of issues and indicators than the framework used to assess food products - the former focuses on characterizing the health impacts of ingredients, while the latter focuses on characterizing the nutritional value of products.

GoodGuide rolls-up indicator scores into issue-specific groups (e.g., human health impacts, ingredient disclosure) to assign ratings. All issues and indicators are not equal. In order to generate a rating that accurately reflects the relative importance of different issues or indicators, they apply weights to issues and utilize different aggregation algorithms.

GoodGuide's rating frameworks define what is known as a “value tree” in multi-attribute utility theory. Each specific set of indicators, sub-issues or major issues are hierarchically organized into “nodes.” For each node, they specify the weights or aggregation algorithm used to compile scores from the constituents of that node.

Aggregation algorithms are used throughout their ratings system to combine sets of scores. Available methods include:

- Maximum (select the highest score in a set). This is generally used in positive nodes that include certification indicators because this value promotes the most positive signal about an issue, without dilution due to inaction or no data on other indicators relevant to the same issue.
- Minimum (select the lowest score in a set). This is generally used in negative nodes that include Hazard or Restriction indicators because this value promotes the most negative signal about an issue, without dilution by positive values on other indicators relevant to the same issue.

- Mean (calculate the average of all scores in a set). This is generally used when aggregating scores from a set of positive and negative sub-nodes in order to allow real world signals (from either quantitative metrics or compliance counts) to influence a score in either a positive or negative direction.
- Preferred (select score from top available indicator in a rank ordered set of indicators). This is used in nodes where data sources or indicators have been rank ordered based on quality or relevance to an issue. It promotes the score from the best available source or indicator.
- Matrix (apply a custom calculation to a set of indicators). This is used in product-level ratings when a set of indicators have to be combined using domain-specific rules to correctly characterize an issue. Prominent examples include the scoring rules applied to rate food products on their nutritional value; personal care products on their potential human health impact; and attribution of extra credit for product performance.

Value judgments are unavoidable in rating systems, and GoodGuide's is no exception. Even the most scientifically grounded assessment requires value judgments about the relative importance of various issues and types of evidence, as well as the treatment of data gaps. GoodGuide acknowledge that users can disagree over the relative weight given to different health hazards as there is no objective, correct solution to the problem of how to aggregate such disparate concerns.

More detail is provided below for the methodology GoodGuide uses to score Personal Care and Household Chemical Products.

GoodGuide counts the number of ingredients in each product that are categorized as low, medium or high health concern. They then factor in other negative information (such as regulatory restrictions) and any available positive information (such as third-party certifications) to assign product ratings.

To rate a personal care or household chemical product, GoodGuide considers the following attributes:

- A health hazard rating based on the number of product ingredients categorized as low, medium or high health concern;
- Indicators that the product exhibits other negative aspects (e.g., does the product contain ingredients that have been banned or subjected to regulatory restrictions);
- Indicators that the product is among the best on the market in its category (e.g., has the product been certified as safe or healthy by a credible third-party);
- Indicators of data gaps that preclude evaluation of the product (e.g., no or inadequate disclosure of product ingredients).

In order to identify ingredients of health concern, GoodGuide utilize the science of health hazard assessment and rely on lists of chemicals labeled hazardous by various authoritative organizations. GoodGuide tracks whether chemicals are recognized or suspected of causing any of twelve major types of human health problems, ranging from cancer to endocrine toxicity to skin or eye toxicity. They combine this hazard data with chemical potency, human detection frequency and toxicity testing information, in order to assign ingredients to four levels of health concern: none, low, medium and high.

An ingredient raises no health concern if:

- It is not on any of GoodGuide's lists of toxic chemicals which cause suspected or recognized health effects;

- It has not been detected in human tissue or urine; It is not a high production volume chemical that lacks safety data.
- An ingredient raises a low level of health concern if:
- It exhibits two or less suspected health effects; and/or
- It has a relatively low toxic potency for inhalation and ingestion exposures; and/or
- It is only occasionally detected in human tissue or urine; and/or
- It lacks at least half of the six basic toxicity tests required to assess chemical safety.

An ingredient raises a medium level of health concern if:

- It exhibits three or more suspected health effects; and/or
- It has a relatively moderate toxic potency for inhalation and ingestion exposures; and/or
- It is regularly detected in human tissue or urine.

An ingredient raises a high level of health concern if:

- It exhibits one or more recognized health effects; and/or
- It has a relatively high toxic potency for inhalation and ingestion exposures; and/or
- It is frequently detected in human tissue or urine.

Chemicals are identified as recognized toxicants based on hazard identification efforts of authoritative national and international scientific and regulatory agencies.

To date, such efforts have been focused on only a few types of toxicity. GoodGuide utilizes California's Proposition 65 lists of chemicals in order to identify recognized carcinogens, reproductive toxicants, and developmental toxicants. Chemicals are listed on Proposition 65 following a scientific peer review process and regulatory rule-making, which incorporates the hazard identification efforts of a variety of other authoritative bodies, including the International Agency for Research on Cancer and the National Toxicology Program. Hence, a substantial weight of toxicological or epidemiological evidence supports the decision to list a chemical as a recognized health hazard under Proposition 65. Stakeholders that believe a chemical does not cause a recognized health effect have the opportunity to argue that the evidence does not support identifying the chemical as a hazard. If a chemical is listed under Proposition 65, such arguments failed to convince neutral scientific and regulatory experts. GoodGuide also relies on a peer-reviewed article in the medical journal *Lancet* to identify recognized neurotoxicants.

Chemicals are identified as suspected toxicants based on reports in the scientific or regulatory literature, or on information abstracted from major toxicological databases.

Lists of suspected toxicants are linked to twelve health effects. Suspected toxicants possess evidence that they can cause specific adverse health effects. However, no authoritative hazard identification process is currently conducted by regulatory agencies or scientific organizations for these health effects. It is important to consider a chemical on a "suspected" list as a preliminary indication that the chemical may cause this effect, rather than a definitive finding that it does. In order to identify suspected toxicants, information is abstracted from the principal toxicology text books (such as Casarett and Doull's *Toxicology*), medical journal articles, regulatory actions, and international chemical hazard resources (such as the European Union). The weight of toxicological or epidemiological evidence supporting suspect hazard identification can vary significantly between chemicals. For example, evidence from two different laboratory species indicates that acetonitrile can cause cardiovascular toxicity. In contrast, overwhelming evidence indicates that carbon monoxide causes cardiovascular toxicity in humans. These disparate data lead to designation as a "suspected" toxicant as an

authoritative agency has yet to compile lists of cardiovascular toxicants. Identifications developed by regulatory agencies or scientific references often undergo peer review, but an administrative process that allows for debate over and conclusive resolution to the toxicity designation of a chemical has yet to be put in place.

GoodGuide separates ingredients into two categories — “ingredients of health concern” and “controversial ingredients.” Only the former contribute to a product’s rating.

A chemical must be identified as a potential health hazard by a GoodGuide-approved authoritative source (e.g., a regulatory agency like USEPA or a scientific group like the National Toxicology Program) in order to be labeled an ingredient of concern. This system ensures that our ratings are based on the best available scientific evidence. GoodGuide labels chemicals as “controversial” ingredients if they have not been identified as hazardous by authoritative sources, but are the subject of current debate regarding potential adverse effects. “Controversial” chemical designations do not contribute to the product rating because the evidence of hazard is inconclusive, however they are flagged in the event a consumer wants to avoid such chemicals.

**Health Hazard Rating:**

Based on a count of ingredients of health concern.

**Other Negative Aspect Rating:**

Products that contain an ingredient that is banned from a category by regulatory agencies in the U.S., Canada, Japan or the European Union rate 0. Products that contain an ingredient that is being targeted for elimination by regulatory agencies also rate 0.

Ratings for products that contain an ingredient that is subject to regulatory restrictions in a category are capped at 8 unless the product label or its manufacturer provides data documenting that the product is in compliance with the applicable restriction.

**Product Management Rating:**

Products that are certified as safe or healthy by a credible third-party (e.g., USEPA Design for the Environment) rate 10. If the relevant certification involves a comprehensive evaluation and approval of a product’s formulation, those ingredients’ contribution to a product’s Health Hazard Rating will also be suppressed.

GoodGuide adjusts a product’s health rating if information is missing that is required to evaluate its potential impact.

Their health hazard evaluation requires a complete list of a product’s ingredients (with sufficient detail about chemical identity to allow ingredients to be checked against hazard lists) and information about the percent composition of a product (to characterize potential exposures and evaluate compliance with regulatory restrictions). Unfortunately, manufacturers are generally not required to provide both of these types of information for most consumer products.

For household chemical products, there is no current regulatory requirement that companies disclose full ingredient lists. For personal care products, ingredient disclosure is required, although it may include generic ingredient names that are not specific enough to support hazard evaluation. To create an incentive for full ingredient disclosure, GoodGuide caps a product’s score if it lacks complete ingredient

data or lists generic names that do not support chemical-specific evaluations. The caps applied are described as follows:

Caps applied by GoodGuide

Rating Cap	Amount of Ingredient Information Available
0	No information available
4	Some ingredient information available, but list includes generic categories potentially containing high or medium health concern ingredients
6	List includes generic fragrance, without further information
8	Some ingredient information available, but list includes generic categories potentially containing low health concern ingredients
10	All ingredients disclosed, including the constituents of generics like fragrance; or all ingredients reviewed and approved as part of a third-party certification

For household chemical products and most personal care products (with the exception of sunscreens), there is no current regulatory requirement that companies disclose percent composition data. This precludes evaluating whether a product is a potentially significant source of exposure to a chemical (e.g., presence of an ingredient at less than 0.1% of a formulation is unlikely to pose a risk, while presence of that ingredient at 10% of a formulation could be a significant source of human exposure). The absence of percent composition data also complicates the evaluation of whether a product is in compliance with applicable regulatory restrictions. Both regulatory agencies and trade associations manage the potential health risks of products by defining thresholds below which an ingredient is deemed safe as used (e.g., use of an ingredient is acceptable provided that it does not exceed 5% of a product's formulation). Unless a product label discloses the percent composition data required to evaluate compliance, GoodGuide caps a product's rating at 8 if it contains ingredients that have been restricted by regulatory agencies or trade associations.

GoodGuide increases a product's health rating if information indicates that an ingredient does not pose a health or regulatory concern as it is used in a product. This adjustment has the effect of minimizing the contribution of that ingredient to the product's health rating. Such adjustments are indicated in the "Product Ingredient List" section of GoodGuide product pages with a "Safe Use Exception" icon and an explanation of the basis for suppressing an ingredient.

Ratings may be adjusted for the following reasons:

- An authoritative third-party (such as USEPA's Safer Choice program) reviewed a product and approved its formulation.

- An authoritative third-party (such as a regulatory agency) reviewed the ingredient and determined that its use in a certain type of product (e.g., rinse-off hair products) does not result in significant exposure or health risk.
- Percent composition data indicate the level of the ingredient is below the most stringent regulatory or trade association threshold level that defines safe use; the applicable threshold is not the subject of substantial critique in regard to its health protectiveness; and the ingredient is not authoritatively linked to a health endpoint expected to pose low dose risk.

GoodGuide scientists collect data on consumer products and chemical ingredients from a variety of sources. Product ingredient lists are obtained from manufacturers, either by referencing company websites or from the manufacturer directly. Health effect information is obtained from authoritative scientific and regulatory sources. GoodGuide assesses the quality and credibility of each contributing data source. They use industry-standard identification and cross-referencing systems to facilitate matching data from external sources (e.g., chemical CAS numbers are used to connect information about product ingredients with chemical health effects).

GoodGuide states that it strives to be the most reliable source of information about the potential health effects of consumer products. They focus on ensuring they have correct and complete ingredient lists for a product, which may not always be available on manufacturer websites. They claim to have systems that allow product manufacturers to provide ingredient information directly to GoodGuide, because they are in the best position to know exactly what is in their products. Each GoodGuide product page notes the source of the ingredient data — Provided by the brand. Rated by GoodGuide.

### ***B19.2. Scope of Chemicals Addressed***

GoodGuide focuses on rating everyday household consumer products bought either from offline or online retail outlets like supermarkets or e-commerce sites. Their core product categories are personal care, household chemical and food products.

GoodGuide's goal is to rate the products that comprise the top 80% of current sales in a category, plus innovative products that are marketed as being healthy. GoodGuide use a variety of sources to define their catalogue of available products, identify relevant brands and companies and collect information about product attributes required for their ratings system.

To identify, track and organize relationships between products, brands, companies, and product categories, GoodGuide follows informatics standards used to organize consumer product and corporate information. For example, they use standard UPC codes to identify unique products. They can then link their product records to retailer-specific product identifiers as well as respond to bar code scans from mobile users. GoodGuide supplements this with a custom classification system to organize products into categories, because there is no standardized method for grouping products into consumer-relevant product categories.

### ***B19.3. Ease of Access and Use of Chemical Information***

GoodGuide may be searched in any number of ways:

- By product category (i.e., Personal Care, Household, Food, Babies and Kids)
- By subcategory (e.g., after shave, body washes and cleansers)

- By keywords, including chemical name and CAS#

Indexes are also available to facilitate searches by Category, Company, Brand, Product and Ingredients. There is no search guide available from their website.

GoodGuide also provides mobile apps that make it easy for consumers to search from their phones or other electronic devices. The GoodGuide iOS App and Android Product Scanner are free.

Users may download the GoodGuide App from the iTunes App Store or the GoodGuide Product Scanner from the Google Play store.

#### ***B19.4. Breadth and Depth of EHS Information Available***

GoodGuide's product pages provide consumers with key data used to rate products (e.g., a product's ingredient list or its available certifications). However, their ratings reflect a complex assessment algorithm that uses an extensive amount of data (e.g., health effects and regulatory lists) that is difficult to republish or even consistently cite via URL in a usable and easy to maintain fashion. Thus, GoodGuide typically does not provide access to the entire set of data used to determine health concern levels assigned to ingredients, or to rate the nutritional value of a food product.

A search of information on chemical ingredients will yield GoodGuide's rating of health concerns (high, medium, low or none); a listing of health hazard statements, the product category in which it is found as an ingredient and specific brand name of products that contain it.

#### ***B19.5. Quality of the Underlying EHS Information***

GoodGuide currently acquires data from over 1,000 different sources, including scientific institutions, governmental agencies, commercial data aggregators, non-governmental organizations, media outlets and corporations. Product-level information is typically obtained from the manufacturer's website or from product labels.

GoodGuide states that they strive to be the most reliable source of information on consumer products. They employ quality assurance and quality control (QA/QC) processes to ensure that the highest standards of data integrity are met and maintained. GoodGuide assesses the quality and credibility of each contributing data source based on the source's data collection process, public reputation and reviews received by experts in relevant fields. Additionally, their information architecture uses industry-standard identification and cross-referencing systems (e.g., using chemical CAS numbers to connect information about ingredients) to facilitate matching data from external sources. Their QA/QC protocols include procedures to proactively minimize data errors, resolve potential data issues, and ensure timely updates of sources.

Anyone who believes that a GoodGuide rating is incorrect or based on inaccurate data is encouraged to report the issue to them for investigation. GoodGuide does not charge any fees for investigating or correcting errors. Upon written request, they can treat submissions as confidential information. To report an error, an email can be sent to their team at [GoodGuideHelp@ul.com](mailto:GoodGuideHelp@ul.com).

GoodGuide’s science team will review complaints and any provided documentation and inform complainants about our determination in a timely manner. Error reports are classified into one of the following:

- **Raw Data Error:** If a user provides evidence indicating that GoodGuide contains incorrect information about a product's identity or attributes (e.g., incorrect product-brand relationship, missing product ingredients, etc.), GoodGuide will attempt to confirm the accuracy of proposed corrections using publicly available sources. If a user proposes alternate, more up-to-date information for consideration in rating a product on any given indicator, GoodGuide will review whether their current data is misleading in the light of the new information provided. In the event that GoodGuide determines a correction or update is warranted, they will proceed to integrate the resulting rating change into their services during their next scheduled database push. If incorrect or out-of-date data materially impacts the rating assigned to a product, GoodGuide will temporarily suspend publishing that entity's record until its score can be publicly updated.
- **Scoring Methodology Dispute:** If a user raises concerns regarding GoodGuide’s rating methodology (e.g., maintaining that an ingredient should have a different level of health concern or takes issue with the scoring rules we use), they will consider a user’s feedback in the context of overall stakeholder feedback on the GoodGuide rating system. GoodGuide do not implement custom modifications specific to a product to their rating methodologies.. They regularly review and enhance our methodologies in response to user feedback and new scientific or regulatory developments.
- In many cases, data that would be relevant for a thorough assessment of an important attribute is unavailable for a product. This may be because GoodGuide has not yet identified a credible data source for a given issue or topic. Or it may be that the data are not publicly available because companies have not disclosed critical information. GoodGuide is working collaboratively with key stakeholders around the world, including government agencies, non-profit organizations, private research agencies, and companies to promote the quantity and quality of disclosure of important data to the public. If users are aware of data sources that have not yet included in GoodGuide that would improve their product coverage, contact GoodGuide to nominate these sources for evaluation.

### ***B19.6. Procedures for Updating the Database with New Information***

The age of data used by GoodGuide varies by source. Their stated goal is to refresh product-level information at least once every 18 months.

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