Study on Selection of Risk Management Options

Final Report Version 2

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Authors	Tom Persich Graham Pattle Imogen Shapland Daniel Vencovsky
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Disclaimer

The views and propositions expressed herein are, unless otherwise stated, those of Risk & Policy Analysts and do not necessarily represent any official view of the Nickel Institute or any other organisation mentioned in this report.

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List of Abbreviations and Acronyms

ACCC	Australian Competition and Consumer Commission
ACVM	Agricultural Compounds and Veterinary Medicines
AICIS	Australian Industrial Chemicals Introduction Scheme
AICS	Australian Inventory of Chemical Substances
AQS	Air Quality System
CCPSA	Canada Consumer Product Safety Act
CDR	Chemical Data Reporting
CDX	Central Data Exchange
CEPA	Canadian Environmental Protection Act
CG	Canada Gazette
CICAD	Concise International Chemical Assessment Documents
CLP	Classification, Labelling and Packaging
CMP	Chemicals Management Plan
CMR	Carcinogenic, Mutagenic or Reprotoxic
DSL	Domestic Substances List
ECCC	Environment and Climate Change Canada
ECHA	European Chemicals Agency
ED	Endocrine Disrupting
EEWG	Environmental Expert Working Group
EFSA	European Food Safety Authority
ELoC	Equivalent Level of Concern
EPI	Estimation Programs Interface
EU	European Union
FDA	Food and Drugs Act
FRCaST	Flexible Reassessment Categorisation Screening Tool

GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HHEWG	Human Health Expert Working Group
HPV	High Production Volume
HSDB	Hazardous Substances Data Bank
HSNO	Hazardous Substances and New Organisms
HSWA	Health and Safety at Work Act
IARC	International Agency for Research on Cancer
IMAP	Inventory Multi-tiered Assessment and Prioritisation
INCI	International Nomenclature of Cosmetic Ingredients
IPCS	International Program on Chemical Safety
IRAP	Identification of Risk Assessment Priorities
IRS	Integrated Regulatory Strategy
MOE	Margin of Exposure
MSCA	Member State Competent Authority
NASA	National Aeronautics and Space Administration
NDSL	Non-Domestic Substances List
NEI	National Emission Inventory
NI	Nickel Institute
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NITE	National Institute of Technology and Evaluation
NSN	New Substances Notification
NZ EPA	New Zealand Environmental Protection Authority
OECD	Organisation for Economic Co-operation and Development
OELV	Occupational Exposure Limit Value
OSHA	Occupational Safety and Health Administration
PACT	Public Activities Coordination Tool

PBT	Persistent, Bioaccumulative and Toxic
PCPA	Pest Control Products Act
PEC	Priority Existing Chemicals
PESS	Potentially Exposed or Susceptible Subpopulations
PMN	Premanufacture Notice
POP	Persistent Organic Pollutant
QSAR	Quantitative Structure–Activity Relationship
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RIAS	Regulatory Impact Analysis Statement
RiME+	Risk Management and Evaluation
RMI	Risk Management Initiative
RMO	Risk Management Option
RMOA	Risk Management Option Analysis
RPA	Risk and Policy Analysts
SPIN	Substances in Preparations in Nordic Countries
SVHC	Substance of Very High Concern
TIMES	Tissue Metabolism Simulator
TOPKAT	Toxicity Prediction by Komputer Assisted Technology
TSCA	Toxic Substances Control Act
TRI	Toxic Release Inventory
UBA	Federal Environmental Agency (Germany)
US EPA	United States Environmental Protection Agency
WHS	Worker Health and Safety

1 Introduction

A risk management option analysis (RMOA) is a tool that helps authorities decide whether (and which) further regulatory activities are required to manage risk from a given substance. An RMOA can conclude that a specific regulatory action is necessary, but it may also decide that no regulatory action is warranted.

In the European Union (EU), RMOA was introduced in 2013 under the 2020 SVHC Roadmap, which commits EU authorities to have all relevant substances of very high concern (SVHCs) included in the Candidate List by 2020. In 2018, it was renamed Regulatory Management Option Analysis. Currently, RMOA falls within the context of the European Chemical Agency's (ECHA) Integrated Regulatory Strategy (IRS) (ECHA, 2019), which has been implemented since 2016, and continues the work started under the SVHC Roadmap. Specifically, ECHA's IRS aims to:

- Efficiently select substances or groups of substances that raise potential concern. The information needed to assess their safety is generated so that any remaining concerns can be addressed through the most suitable regulatory risk management measures;
- Ensure appropriate and timely intervention by all actors – ECHA, Member States, the European Commission and industry; and
- Provide confidence among stakeholders that registrants meet REACH information requirements, promoting improved communication on safe use in the supply chain.

As noted, an RMOA can conclude that regulatory risk management is required at EU level for a substance, or that no regulatory action is required. The instruments that can be used to address a concern include a REACH restriction, inclusion on the Candidate List, harmonised classification and labelling or another measure, such as an Occupational Exposure Limit under EU Occupational Safety and Health legislation.

RMOA considers both a substance's hazard and exposure, and therefore constitutes a risk-based approach to assessing a chemical's potential harm to human health and the environment. In the EU, RMOA is technically voluntary, as it is not part of the processes defined in the REACH regulation. Any Member State, ECHA or the European Commission can conduct an RMOA, which begins with the selection of a substance, assessment of its hazards and uses, documentation of applicable Risk Management Options (RMOs), and concludes with recommendations for any further necessary regulatory measures. An RMOA represents the position of the Member State and its recommendations may not be followed. It is then the responsibility of the Risk Management and Evaluation (RiME+) platform to discuss the RMOA conclusions and coordinate further risk management action.

Building on its positive experiences gained in relation to the EU RMOA process, the Nickel Institute (NI) contracted Risk & Policy Analysts Ltd (RPA) to undertake an assessment to explore how a select (but non-exhaustive) number of non-EU jurisdictions with fully developed and multifaceted chemicals management systems assess whether risk management measures are required, and if so, which options are most appropriate. The scope of the assessment (which has involved a detailed review of available literature and telephone interviews with the relevant authorities) includes how substances are selected, and how elements of hazard, exposure and risk assessment are used alongside any other decision-making factors in determining the option(s) to be implemented. The overall objective of the exercise is to identify the strengths associated with the systems in place and to identify examples of best practice. The situation within the EU has also been revisited.

2 Aims and Approach

2.1 Overview

The overall exercise has been structured on the following tasks:

- Desk research;
- Consultation;
- Overview of the RMOA-style approaches;
- Summary of key findings; and
- Identification of best practise.

The approach undertaken in relation to each of these tasks is outlined below.

It is also noteworthy that the exercise has been broken down into two phases. The first phase considered the core analysis of the selected jurisdictions (Australia, Canada, New Zealand, and USA), as well as overarching analysis at the EU level (i.e. based on discussions with ECHA). In the second phase, additional emphasis was given to the current situation within the EU, with a number of Member State Competent Authority (MSCA) interviews held (with the German, Swedish and Dutch authorities). Follow-up with the UK was also deemed appropriate in the context of the country's contribution to the RMOA process, but also considering the UK's withdrawal from the EU[1].

It is noted that the selection of non-EU jurisdictions falling within the scope of this exercise was confirmed during the project kick-off meeting. Factors considered included a preference to assess the situation in jurisdictions that already have established practices in place over jurisdictions that have recently revised their chemicals legislation and are currently transitioning into a new system. Practicalities relating to the availability of documentation in languages spoken by RPA staff members were also taken into consideration, in addition to other factors such as the availability of documentation informed by preliminary research.

For the additional EU MSCA interviews, the participants were chosen based on their apparent level of activity in the RMOA process over recent years. More specifically, a comparative assessment on the status of ECHA's RMOA list[2] between late 2017 and late 2019 suggested that the number of substances assessed / number of substance assessments completed was highest for the German, Dutch and Swedish authorities.

2.2 Desk research

Given the complex nature of chemicals management systems and the need to assess divergent regulatory regimes in multiple jurisdictions, significant emphasis was given to preliminary desk-based research. The aim of this activity was to gain an important initial (high-level) understanding of the regulatory regimes in place, identify key issues, and identify stakeholders in the countries within scope of the study. These activities would help to ensure that the documentation and strategy for consultation activities was effective and appropriately focused.

[1] In this regard, it is noteworthy that the UK approach has been discussed within the context (and under the headings) of the EU assessment given the historic contributions of the UK to the EU RMOA process and also given that, at the time of interview with the UK authorities, the UK remained within the EU.

[2] See https://echa.europa.eu/rmoa.

Desk-based research was structured around topics covered in a draft set of consultation questions, with research predominately focused on the websites of the organisations responsible for conducting risk assessments in their respective jurisdictions (i.e. ECHA in the EU, National Industrial Chemicals Notification and Assessment Scheme (NICNAS) in Australia, the New Zealand Environmental Protection Authority (NZ EPA), the United States Environmental Protection Agency (US EPA) and Health Canada / Environment and Climate Change Canada (ECCC) – see Table 2-1), published guidance and methodology documents, legislative text, and reviews of risk assessment frameworks.

Table 2-1: Example of sources utilised to assist desk-based research	
Country	**Source**
United States of America	https://www.epa.gov
Canada	https://www.canada.ca/en/health-canada
Australia	https://www.environment.gov.au
	https://www.nicnas.gov.au
New Zealand	https://www.epa.govt.nz
	https://www.worksafe.govt.nz
	https://www.mfe.govt.nz/consultations

Published journal articles and information provided by the NI were also used as supporting material, such as the NZ EPA consultation document 'Hazardous Substance Assessments: Improving Decision Making' and the NI's submitted comments on this document, the NI's 'EU Risk/Regulatory Management Option Analyses (RMOAs) from an industry perspective' presentation, and the EU RMOA template document.

2.3 Consultation

2.3.1. Approach to consultation activities

In relation to the consultation activities, instead of a detailed questionnaire being disseminated to consultees for completion, pre-prepared questions were presented to the authorities as briefing documents in advance of telephone interviews to be arranged by RPA.

It was agreed that there was a preference for running the consultation in this manner as hosting telephone interviews (rather than requesting questionnaire responses) would likely stimulate better participation, a more open dialogue and allow for additional avenues to be explored as appropriate.

2.3.2. Identifying appropriate contacts and arranging interviews

Extensive efforts were made to identify key contacts and arrange interviews with each of the relevant authorities. For the first phase, all authorities were sent initial invitation emails on 23 October 2019 (with the exception of ECHA who were initially contacted on 11 October 2019). For the second phase, similar invitations were distributed between 22 December 2019 and 3 January 2020. A supporting covering letter was also provided by the NI. The telephone interviews were eventually scheduled with key contacts, as follows:

First phase:

- US EPA: 8 November 2019;

- ECHA: 13 November 2019;
- NICNAS: 21 November 2019;
- Health Canada; Environment and Climate Change Canada: 25 November 2019; and
- NZ EPA: 26 November 2019.

Second phase:

- Environment Agency (UK): 31 January 2020;
- BAuA (DE): 3 February 2020;
- RIVM (NL): 3 February 2020; and
- KEMI (SE): 5 February 2020.

2.4 Overview of the RMO selection approaches

Desk-based research and consultation activities have allowed for the production of a detailed overview of the different RMO selection approaches in the relevant jurisdictions, including, inter alia, information on the following:

- Substance identification and selection;
- Internal and external working arrangements and procedures (including approach to consultation, involvement of key stakeholders e.g. risk management experts etc.);
- Information sources used (including to assess hazard and risk);
- Typical timescales;
- Level of collaboration between authorities, industry and other interested parties;
- Risk assessment content;
- Decision-making factors;
- Communication of decisions; and
- Possible improvements.

The study team has also used this information to identify similarities and differences between the approaches, and where possible, identify any reasons for key divergences.

2.5 Identification of best practice

To determine what constitutes best practice, the study team has used its expertise to assess the strengths of each assessment process, as well as utilised any relevant published feedback, peer reviews, reports and position papers. Participants have also been invited to comment on the perceived strengths, weaknesses and areas in need of improvement of their risk assessment procedures.

2.6 Organisation of this report

The remainder of this report has been organised as follows:

- **Section 3** presents information gained from both desk-based research and consultation activities in each of the relevant jurisdictions assessed within the scope of the project;
- **Section 4** presents a summary of key findings;
- **Section 5** provides the identification of best practice examples; and
- **Section 6** presents conclusions and recommendations.

3 Selected Jurisdictions – Summaries

3.1 Australia

3.1.1 Summary of national chemicals legislation

The main piece of chemicals legislation in Australia is the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which aims to protect people at work, the public, and the environment from the harmful effects of industrial chemicals, through the mandatory notification and assessment of these chemicals. This is achieved through the assessment of all new industrial chemicals that are entering Australia for the first time and priority existing chemicals that are already in use in Australia.

NICNAS requires new industrial chemicals not listed on the Australian Inventory of Chemical Substances (AICS) to be notified and assessed prior to their introduction (manufacture or import) to Australia, while the human health and environmental impacts of existing industrial chemicals listed on the AICS are assessed through the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

NICNAS is currently being reformed by the newly published Industrial Chemicals Act, which introduces a new regulatory scheme known as the Australian Industrial Chemicals Introduction Scheme (AICIS). Under AICIS, manufacturers or importers introducing new industrial chemicals are required to categorise the introduction into one of three categories, based on the level of risk to human health and the environment, each of which impose different regulatory requirements. Introductions posing a medium or high risk are required to undergo a chemical assessment which can take up to 90 days and result in either the granting of an assessment certificate, granting of an assessment certificate with recommendations for risk management measures and/or conditions of introduction, or refusal of an assessment certificate (Australian Government Department of Health, 2019).

The IMAP framework was established by NICNAS to accelerate the assessment of existing chemicals on the AICS. IMAP is a scientific and risk-based model designed to match assessment effort with the effects of chemicals on human health and the environment. It consists of three tiers, with the level of assessment increasing with each tier. The framework was developed through consultation with community, industry, government, and expert groups, and with consideration of various international approaches to risk assessment (Australian Government Department of Health, 2013).

3.1.2 Existence of an RMOA process

Existence of an RMOA

A direct equivalent to the EU RMOA system does not exist in Australia. However, the Australian legislation includes provisions that resemble the RMOA process, including substance selection, risk assessment, and selection of the most appropriate regulatory management tool. However, these procedures are a part of a more general, and largely automatic, chemicals management legislative framework that is designed to address all hazardous substances in a consistent manner, rather than to provide a tool for ad-hoc assessments or managing regulatory complexity or overlap.

Guidance documents/binding procedures

There are no binding procedures, but guidance on the assessment methodologies used for new and existing chemicals are available on the NICNAS website (Australian Government Department of Health, 2018a).

Publication of risk assessment findings

The outcomes of the Stage 1 screenings, which includes recommendations for risk management measures, are published in batches on the NICNAS website. The timing of the assessment publications aligns with the publication of the *Chemical Gazette* (Australian Government Department of Health, 2013).

Responsible bodies

NICNAS are responsible for the assessment process. Under a service agreement with NICNAS, officers from the Department of Health carry out occupational health and safety and public health assessments, and officers from the Department of the Environment and Energy conduct environmental assessments (Australian Government Department of Health, 2018b).

3.1.3 Substance selection

The IMAP framework is being implemented in stages, with Stage One having commenced in 2012. The list of Stage One chemicals consists of around 3,000 existing chemicals on the AICS, which were identified based on characteristics agreed through consultation with community, industry and governmental stakeholders as priorities for early consideration. Priority was given to:

- Chemicals for which NICNAS already holds exposure information;
- Chemicals identified as a concern, or for which regulatory action has been taken overseas; and
- Chemicals detected in international studies analysing chemicals present in the blood in babies' umbilical cords.

Table 3-1 below details the sources used to identify chemicals meeting each priority characteristic (Australian Government Department of Health, 2013).

Table 3-1: Prioritisation characteristics

Priority characteristic	Information sources
Chemicals for which NICNAS holds exposure data	• Chemicals reported in the NICNAS 2006 High Volume Chemical Survey • Chemicals on the NICNAS Candidate List • Chemicals for which NICNAS holds data as a result of various other information gathering activities or technical projects
Chemicals identified as a concern for which action has been taken overseas	• Chemicals assessed as part of the Canadian Challenge program • Chemicals assessed as part of the Canadian Petroleum Sector Stream Approach • Chemicals classified as Carcinogenic, Mutagenic or Reprotoxic (CMR) • International Nomenclature of Cosmetic Ingredients (INCI) listed chemicals, listed on Annex II of the Cosmetic Regulation EC No 1223/2009 (banned)

Table 3-1: Prioritisation characteristics	
Priority characteristic	**Information sources**
	• INCI listed chemicals listed on Annex III and V of the Cosmetic Regulation EC No 1223/2009 (restricted) • Chemicals with US EPA Action Plans • Chemicals included in the EU REACH Substances of Very High Concern Candidate List • Chemicals listed in Annex XVII of EU REACH Regulation 2006 • OECD perfluorinated chemicals
Chemicals detected in international studies analysing chemicals present in the blood in babies' umbilical cords	• Chemicals detected in umbilical cord blood in a study conducted by the Environmental Working Group • Chemicals detected in umbilical cord blood in a study conducted for Greenpeace and World Wildlife Fund UK by TNO

In order to gain efficiencies, NICNAS included additional chemicals into groups of chemicals that were already being assessed as part of Stage One. Therefore, by the end of December 2015, 416 additional chemicals were included in the Stage One list (Australian Government Department of Health, 2013).

Substances can also be prioritised for assessment if there is significant public interest around a chemical, or group of chemicals. If NICNAS becomes aware that there are concerns with regard to a chemical, or group of chemicals, then it/they may be assessed on that basis. Parabens are an example of a group of chemicals which have been prioritised by NICNAS via such means.

The assessment of Stage One chemicals began in July 2012, and in 2016, as Stage One was concluding, a review of the IMAP framework was conducted. The review made recommendations on the most efficient and effective approach to the assessment and prioritisation of the remainder of chemicals on the AICS . Following Stage One, chemicals will be prioritised for assessment using different criteria, which will be implemented as part of the new regulatory scheme known as the AICIS that commences on 1 July 2020. NICNAS are currently consulting on this new approach.

As part of the 2016 review, it was suggested that a greater number of lists of chemicals of concern developed by international regulatory agencies could be considered as inputs for prioritisation. Examples include the Japanese list of Class I Specified Chemical Substances and the Canadian Toxic Substances List. Feedback also supported the use of domestic indicators of concern, such as industry or consumer adverse event reports, to prioritise chemicals (Australian Government Department of Health, 2016).

3.1.4 Hazard and risk assessment

Information sources

According to Australian Government Department of Health (2013), information used in IMAP assessments was derived from a range of sources including:

- Internal databases and previous NICNAS assessments;
- Classification information/international lists of chemicals;
- International assessments and databases;
- Predictive models;
- Literature reviews;

- External peer reviews; and
- Public comment periods and targeted calls for information.

The IMAP framework was developed to maximise the use of data from overseas regulators, which was vital to many of the IMAP assessments. REACH registration dossiers were the major source of information on chemicals, as they were used in 75% of assessments. Data was obtained from various other international reports and databases, such as:

- The Canadian Categorisation of the Domestic Substances List and various Canadian assessments;
- EU REACH dossiers and various EU reports;
- Scientific Opinions on Cosmetic Substances by European Commission Committees;
- OECD assessments, eChemPortal database and QSAR Application Toolbox;
- Various US EPA reports;
- National Toxicology Program (NTP) reports;
- The US National Library of Medicine Hazardous Substances Data Bank (HSDB);
- The Substances in Preparations in Nordic Countries (SPIN) database;
- International Program on Chemical Safety (IPCS) publications; and
- International Agency for Research on Cancer (IARC) reports.

Information used from these sources included chemical identity, composition, potential groupings, chemical hazard and exposure information, use restrictions, risk assessment outcomes and approaches as well as identification of potential concerns. A range of international sources were used, as international risk assessments covering all factors prescribed in Australian chemical legislation were less readily available. Considerable resource effort and expert judgement were required to determine the relevance of international data within the Australian context (Australian Government Department of Health, 2013).

The application of expert judgement to form AICS-specific groupings, so that data for one chemical could be used to assess chemicals with no data, maximised the utility of international information. For example, the formation of AICS-specific groupings for azo dyes and petroleum stream chemicals allowed Canadian assessment data for 132 chemicals to be utilised in the assessment of 902 Stage One chemicals (Australian Government Department of Health, 2013). Information on the rationale for grouping chemicals is contained in the full assessment reports. Groupings may be based on similarities in physico-chemical properties, structural and functional properties, toxicity, and end-uses.

NICNAS holds exposure information for around 1,300 chemicals, with Australian use and/or volume information only available for one third of Stage One chemicals. To address this problem, the IMAP framework was developed to utilise surrogate information, such as from overseas sources, or conservative default values for the remaining chemicals where actual or surrogate information is not available. NICNAS has reviewed over 20 potential data sources that can be used to determine surrogate use, including international lists reporting chemical use, information from international assessment reports, literature searches, and dossiers (Australian Government Department of Health, 2013). Surrogate volume information is not used, except for in the assessment of cosmetics, as volumes used in industries can be very different from country to country.

To fill in gaps in available hazard data, predictive models were also used. During the development of IMAP, a comprehensive QSAR strategy that simultaneously used different mechanistic and statistical models was established in consultation with experts. To identify human health hazards,

the OECD QSAR Toolbox, OASIS-TIMES models, and TOPKAT were used. To identify environmental health hazards, the OECD QSAR Toolbox, OASIS's POPs and CATALOGIC models, and the US EPA Estimation Programs Interface (EPI) Suite were used (Australian Government Department of Health, 2013).

In the majority of cases, the information gathered by NICNAS from these sources was sufficient to complete an assessment and make any relevant recommendations, without the need to seek more information from stakeholders. However, sometimes it was necessary to seek information directly from manufacturers and importers. Strategies used to gain access to additional data to those held by NICNAS or available publicly included general and targeted voluntary calls for information and the opportunity to provide public comment on all assessments. During Stage One, use and/or volume information was provided for 350 chemicals, including 89 chemicals for which NICNAS previously held no data (Australian Government Department of Health, 2013).

Approach

The IMAP framework features a three-tiered assessment process where a chemical's hazardous properties, and the nature and extent of its use (i.e. exposure), are considered to characterise risk. The Tier I assessment is a high throughput approach, which uses data that is publicly available, held by NICNAS, or readily generated using QSAR modelling, which can be efficiently applied to all chemicals on the AICS to assess health effects, environmental effects, and exposure indicator criteria. As well as having an assessment aspect, Tier I assessments also have a prioritisation role by identifying chemicals that are expected to be of no concern, and those that require further assessment at Tier II. Tier II assessments are more in-depth and evaluate risk information on a substance-by-substance or chemical category-by-category basis, and make recommendations on regulatory controls to safely use chemicals. An outcome of a Tier II assessment can also be the identification of no unreasonable risk, through refinement of the risk characterisation, or that further assessment is required under Tier III (Australian Government Department of Health, 2013).

Risks are assessed using well established, internationally accepted methodology. Most Tier I, Tier II and Tier III assessments cover some, or all of, the following elements:

- Hazard identification;
- Hazard assessment, incorporating hazard identification and hazard characterisation (dose-response relationship);
- Exposure assessment; and
- Risk characterisation, where hazard and exposure assessments are integrated.

Human health and environmental assessments use a variety of different tools and approaches. One of the key tools for Tier I assessments is the prioritisation matrix, which characterises risks for workers and the public based on potential human health hazard and potential for exposure. The matrix features hazard and exposure bands. The hazard bands represent severities of hazard indicators, and the exposure bands represent different exposure scores, which are calculated by multiplying a chemical's volume with a use multiplier. The use multiplier is a weighting system that reflects the estimated fraction of the total introduced chemical that is available for exposure. All known uses for a chemical are sorted into five broad categories: cosmetic, domestic, commercial, site-limited and non-industrial, and allocated a use multiplier (Australian Government Department of Health, 2013).

Environmental assessments are conducted according to the guidelines and principles of the "*Environmental risk assessment guidance manual for industrial chemicals"* (Australian

Environment Agency, 2009). PBT chemicals are considered to be of inherently high concern and are prioritised for environmental assessment at Tier II (Australian Government Department of Health, 2013).

Two expert working groups, the Environmental Expert Working Group (EEWG) and the Human Health Expert Working Group (HHEWG), were established by NICNAS to develop scientific criteria for environmental and human health hazard endpoints respectively that would be used in assessments to identify chemicals of concern from the Stage One list. The HHEWG agreed on a hierarchy of hazard indicators, which placed greatest weighting on carcinogenicity, genotoxicity and reproductive/developmental toxicity (including neurotoxicity and endocrine disruption). The criteria for human health and environmental indicators were based on international classification frameworks and labelling schemes, in order to maximise the utilisation of international data (Australian Government Department of Health, 2013).

For Tier I assessments, dose-response relationships are not considered. Dose-response relationships are considered in the higher tiers of assessment, where consultation would be used to obtain the necessary exposure information.

Tier II assessments are conducted on a case-by-case basis and are based on a weight-of-evidence approach, taking into account scientific judgement, knowledge of the mechanism of action of effects, and recognition of the inherent uncertainty in extrapolating animal data to humans. The greater the uncertainty, the more precautionary NICNAS are in their assessment and recommendation of controls (Australian Government Department of Health, 2018c).

Tier III assessments are conducted if there is a specific concern which could not be resolved during a Tier II assessment, requiring more complex analysis of the collected data or additional information to be obtained to better refine the risk characterisation. For example, tris(2-carboxyethyl)phosphine (TCEP) warranted a Tier III assessment to determine if mouthing of products containing TCEP, such as children's toys, is a significant exposure route in Australian infants and toddlers and if this exposure route poses a significant risk for human health (NICNAS, 2017).

Working arrangements and procedures

Under a service agreement with NICNAS, officers from the Department of Health perform occupational health and safety and public health assessments, while officers from the Department of the Environment and Energy conduct environmental impact assessments (Australian Government Department of Health, 2018b). For assessments of food contact materials other agencies are usually consulted. In the majority of other cases, other government agencies are not consulted.

All IMAP assessments have a six to eight-week public comment period after the draft assessment report has been published, to allow stakeholders to provide information on assessments, such as hazard and exposure information. Unless any comments are received, the draft report is considered to be the final report. All comments are reviewed, and the responses are published on the NICNAS website.

3.1.5 Selection and assessment of Risk Management Options

Scope

There are three main pieces of legislation under which public health risk management options are established. These are:

- The Model WHS Laws that aim to protect the health and safety of workers, for which SafeWork Australia are responsible. Risk management options include Codes of Practice, exposure standards, and GHS classification;
- The Therapeutic Goods Act 1989, under which substances can be scheduled to allow restrictions and conditions to be placed on their supply to the public; and
- The Competition and Consumer Act 2010, which is enforced by the Australian Competition and Consumer Commission (ACCC) and covers product safety and labelling. Risk management options can include restrictions or bans on certain products exceeding safe concentration limits of hazardous chemicals.

There is no overlap between the legislations, so when a risk is identified it is clear what risk management approach needs to be taken. Currently, risk management recommendations have been made for about 3,250 chemicals.

Information sources

The level of regulation applied to a substance by overseas regulators is considered when selecting risk management options. Harmonisation with the level of regulation applied by international authorities can be a valid way to overcome problems with setting Australian health-based limits, due to lack of data in determining dose-response relationships.

Decision-making factors

When selecting risk management options, proportionality is a key aspect as the level of recommended risk management must be proportionate to risk. Risk managers will also take socio-economic information, availability of suitable alternatives, efficiency, and the use-scenarios into consideration as part of their process of implementation.

3.1.6 Administrative aspects

Timescales

On average, a medium complexity assessment will take around 16 days, while a more complex assessment will take 42 days.

Costs

In terms of staffing cost, a human health assessment would involve 19-23 people and an environmental assessment would involve around 10 people.

Previously the average staffing level dedicated to the operation of the Existing Chemicals Program, which includes undertaking Priority Existing Chemicals (PEC) and IMAP assessments for both human health and the environment, was 19.6 in 2012-13 and 25.4 in 2014-15, and was projected as 29.5 in 2015-16 (Australian Government Department of Health, 2016).

Strengths and weaknesses

Feedback from the Stage One assessments suggested that environmental risk management recommendations are one of the areas with most potential for improvement. Current recommendations were observed to be broad and mainly process-based (i.e. prioritised for further assessment under IMAP), and are not easily translated into tangible or practical risk management actions across the various jurisdictions. A reason for this is that there is no national framework for the streamlined uptake of environmental risk management recommendations (Australian Government Department of Health, 2016).

Many assessments were hindered by the lack of chemical use and exposure information in Australia and a lack of Australian environmental concentration data. Linking IMAP to a scheme for gathering concentration data would improve the strength of risk management recommendations, and more detailed information on actual existing uses would mean existing end uses could be better targeted (Australian Government Department of Health, 2016).

Another suggested improvement was better communication of chemicals prior to chemicals undergoing assessment to allow industry to better support assessment reviews, and enable horizon scanning and an understanding of the potential impacts on their supply chains early on in the process. Due to the large number of assessments published at once, feedback indicated that there was limited availability for industry stakeholders to review and provide public comment. It was suggested by stakeholders that the public consultation period be extended to 3 months and an alert system put in place to notify when chemicals have been selected for assessment (Australian Government Department of Health, 2016).

Another improvement highlighted through consultation with NICNAS, was the recommendation of safer alternatives.

One of the strengths of the IMAP framework, is that it has allowed NICNAS to produce quality reports while accelerating their chemical assessment programme. The impact that NICNAS has been able to achieve with its chemical assessment programme is also a major strength. Currently, over 20,500 human health and/or environment assessments have been completed and 14,162 unique chemicals have been assessed, which has resulted in NICNAS being able to publish over 4,000 risk management recommendations for 3,250 chemicals.

The flexibility of IMAP has also meant that NICNAS has been able to respond immediately to concerns and move to risk management very quickly. Moving forwards, it is important to have a future framework which remains dynamic and flexible so as to respond to emerging issues. New data, additional hazard sources and criteria, and stakeholder requirements will emerge and need to be integrated into the framework (Australian Government Department of Health, 2016).

3.2 Canada

3.2.1 Summary of national chemicals legislation

The Canadian Environmental Protection Act (CEPA) 1999 is the main federal chemical control law in Canada and sets out the framework to govern the assessment and management of new and existing chemical substances.

Under CEPA, the Federal Minister of Health and the Federal Minister of the Environment are responsible for conducting risk assessments of existing substances in commerce in Canada, which are those listed on the DSL, and new substances proposed for introduction to Canada, to determine whether they present a risk to human health or the environment. Prior to any new substances being introduced to Canada, they must undergo a human health and ecological risk assessment, a process which begins with a New Substances Notification (NSN).

For new substances which are not on the Domestic Substances List (DSL), manufacturers and importers must submit a NSN dossier to Environment Canada and Climate Change (ECCC) if their tonnage is above 0.1t per year. New substances not on the DSL but on the Non-Domestic Substances List (NDSL) require NSN if their volume is above 1t per year (Government of Canada, 2004, 2005).

Parts 5 and 6 of CEPA are the two main legislative tools used to prevent and reduce the release of substances that are harmful to people and the environment. There are a number of sections in Part 5 under which assessments can be undertaken (Government of Canada, 2016a). These include:

- Assessment of Substances and Activities New to Canada (Section 83 and Section 108);
- Screening Assessments (Section 74);
- Reviews of decisions of other jurisdictions (Section 75);
- Priority Substances List Assessments (Section 76); and
- Other assessments (Section 68).

Previously, Canada assessed and managed environmental and health risks from chemicals through the Priority Substances Assessment Program and the New Substances Program. More recently, the majority of risk assessment work is conducted under the Chemicals Management Plan (CMP), which is a Government of Canada initiative for reducing risks posed by all new and existing chemicals substances. Under the CMP around 4,300 substances were prioritised for assessment based on categorisation of around 23,000 existing substances on the DSL. In addition to DSL categorisation, substances are prioritised for assessment through the Identification of Risk Assessment Priorities (IRAP), which is an approach to identify chemicals of potential concern though a number of mechanisms.

CEPA is the cornerstone of the Canadian approach to the management of hazardous chemicals and provides the framework for risk assessment and consideration of RMOs. However, measures to manage chemical risks can be adopted under other “best placed” legislation, such as the Canada Consumer Product Safety Act, the Food & Drugs Act, the Pest Control Products Act, and the Fisheries Act.

3.2.2 Existence of an RMOA process

Existence of an RMOA

A direct equivalent to the EU RMOA system does not exist in Canada. However, the Canadian legislation includes provisions that resemble the RMOA process, including substance selection, risk assessment and selection of the most appropriate regulatory management tool. While there is an overarching framework and process for risk assessment and risk management of substances, risk management options are considered uniquely for the substance, or group of substances, being targeted.

Guidance documents/binding procedures

There are procedures under the CMP for carrying out risk assessments and selecting the most appropriate risk management option. The overall framework is outlined on the website of the Government of Canada and in government documents. In addition, the Risk Assessment Toolbox has been developed to identify the different risk assessment approaches that can be taken to address substances under the Chemicals Management Plan (CMP) (see Figure 3-1 below). It consists of three approaches, with Type 1 and 2 typically used to address multiple, dissimilar substances within a single document in order to gain efficiencies, and Type 3 typically used to address substances individually or in groups, based on chemical or functional similarities, using a standard risk assessment approach. The Type 3 approach is split into three levels based on the complexity of the assessment required. Both hazard and exposure are considered for all three types of approach. An example of a Type 1 approach would be referral of an assessment to a better-placed and more appropriate federal risk management program (Government of Canada, 2016a).

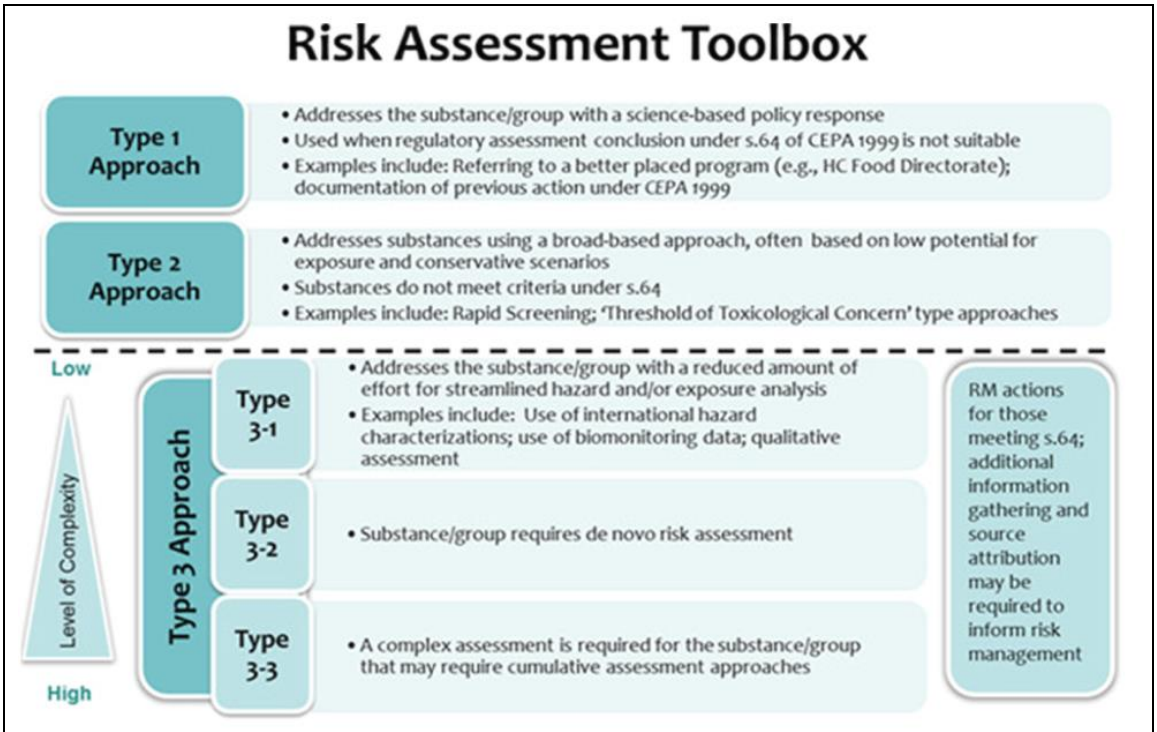

Figure 3-1: Approaches to Risk Assessment
Source: Government of Canada (2016a)

Publication of risk assessment findings

A summary of the scientific considerations and proposed measures from the assessments or reviews conducted under section 74, section 75 and section 76 must be published in the Canada Gazette for a 60-day public comment period. Following the public comment period, the final decision must be published in the Canada Gazette, including a summary of the risk assessment, the proposed measure and, in the case of a substance recommended for addition to Schedule 1 (Toxic Substances List), a statement indicating the proposed risk management instrument that will be developed, which is either a regulation or another instrument.

As well as being published in the Canada Gazette, draft and final assessments are also made available via the Government of Canada's Chemical Substances website. Associated reports, consultation documents, as well as tables summarising public comments received and the government's response to them, are also published (Government of Canada, 2016b).

Responsible bodies

Risk assessments for both new and existing substances are conducted by the Federal Minister of Health and the Federal Minister of the Environment (Government of Canada, 2019b).

3.2.3 Substance selection

Prioritisation activities are based on a set of guiding principles and considerations. There are seven mechanisms for prioritisation of substances for risk assessment (and, consequently, for potential regulatory action). One of the main means of selecting substances as priorities for risk assessment was through Categorisation of the DSL. 4,300 substances were identified through Categorisation as requiring a screening assessment. In addition, NSNs are another primary means of selection, with 400-500 being received annually. Other mechanisms for prioritisation include international hazard classifications or risk assessments, toxicity data submitted under Section 70 of CEPA 1999, information from the New Substances program and other relevant Government of Canada program areas, research and monitoring data, and quantities of substances in commerce domestically and internationally. An example of a substance identified through these additional mechanisms is polychlorinated naphthalenes, which were assessed and subsequently managed following their nomination to Annex I of the Protocol on Persistent Organic Pollutants under the United Nations Economic Commission for Europe (UNECE) Convention on Long Range Transboundary Air Pollution (LRTAP)[3]. Recently, a state of the science assessment on lead was developed in response to a request from the Federal-Provincial-Territorial Committee on Health and the Environment. All these mechanisms feed into the IRAP approach which results in a decision being taken to either initiate a risk assessment, collect further information/data, or conclude that no further investigation is required (Environment Canada and Health Canada, 2014).

Under the CMP, the aim was to review all of the 4,300 substances identified through categorisation, and a target of 500 risk assessments per year has been set. 3,800 substances have undergone risk assessment to date and all 4,300 substances are due to have been reviewed by 2021 (although this does not mean that regulatory action to address any identified risks will have been selected and/or implemented by that date).

The risk assessments of the 4,300 substances were split into three different phases:

- CMP Phase 1 (from 2006 to 2011): ~1100 substances

[3] See http://chm.pops.int/Portals/0/download.aspx?d=UNEP-POPS-COP.7-SC-7-14.English.PDF.

- CMP Phase 2 (from 2011 to 2016): ~ 1650 substances
- CMP Phase 3 (from 2016 to 2021): ~ 1550 substances

CMP Phase 1 included high priority substances which were reviewed on a substance-by-substance basis, CMP Phase 2 included medium priorities and involved grouping of substances to capture similarities and create synergies, while CMP Phase 3 included all other remaining substances.

3.2.4 Hazard and risk assessment

Decisions on whether or not risk management measures are needed are based on the assessment of the risk posed by a substance, which considers both the hazardous properties of the substance and the nature and extent of the exposure, which subsequently feed into decisions on whether or not (and which) risk management measures are needed. A range of information is considered in an assessment, including chemical properties, quantities manufactured in or imported into Canada, releases to and concentrations in the environment, environmental fate and behaviour, hazards, and nature of exposure (Government of Canada, 2019b).

Information sources

According to Government of Canada (2017), ECCC and Health Canada collect scientific data (e.g. toxicological studies) and commercial activity information (e.g. substance use and quantities) from a variety of published and unpublished sources and mechanisms, which may include:

- Publicly available information – an extensive literature search is conducted to collect critical studies published in peer reviewed scientific journals on properties, hazard and exposure to substances, as well as obtaining information through sources such as databases, trade journals, and safety data sheets. ECCC and Health Canada monitor publicly available information sources that relate to data collection (including from Statistics Canada), risk assessment and risk management initiatives undertaken on substances by other agencies;
- Information submitted by interested stakeholders and associations:
  - Inventory updates;
  - Voluntary information gathering;
  - Mandatory information gathering – Section 71 Mandatory Surveys, Section 70 submissions, Section 46 National Pollutant Release Inventory annual reports, etc., allow the Government of Canada to collect information from industry and other individuals regarding their activities with substances, as well as other available toxicological information that informs assessment;
  - New substances provisions – For new substances, industry is required to provide specific information to the New Substances Program as required by the New Substances Notification Regulations under CEPA 1999;
- ECCC and Health Canada research, monitoring and surveillance – generates new data on the potential exposures and hazards of chemical substances;
- Information from federal programs – Information on substances is available through other programs within the federal government. Some programs have their own respective databases that provide pertinent information on substances which can inform CMP activities; and
- Other regulatory jurisdictions – Information is also available in other jurisdictions, including other provincial/territorial government departments, which could be shared through agreements. For example, the US EPA, ECHA, and NICNAS can often provide information that informs risk assessment.

Approach

Risk assessments differentiate between the different substance uses whenever possible. In risk assessments, a weight of evidence approach and precaution are applied. Risk assessments can be either quantitative or qualitative depending on data and information available. Exposure can be either measured (e.g. environmental monitoring or human biomonitoring studies) or estimated based on predictive computer models. In the absence of data, conservative assumptions that are protective of human health and the environment can be used. Qualitative assessments are relied on when available information indicates that exposure is minimal or when data is limited (Government of Canada, 2019a).

First established in 2013 to provide expertise on scientific considerations during CMP delivery, the CMP Science Committee provides guidance to the Government of Canada on how to increase the quality, consistency and transparency of communicating uncertainty in risk assessments to facilitate informed decisions and risk management (Government of Canada, 2014).

Working arrangements and procedures

ECCC and Health Canada are responsible for the assessment of chemicals, but experts and other stakeholders are involved throughout the risk assessment process. The assessment reports undergo external peer review and/or consultation involving experts from government, academia, industry, and non-governmental organizations. Draft screening assessments are subject to a 60-day public comment period (Government of Canada, 2019b).

3.2.5 Selection and assessment of Risk Management Options

Scope

CEPA is the most important legislation available to the federal government for managing toxic substances, but risk management tools other than those under CEPA are also available. ECCC and Health Canada have a commitment to consider a range of risk management tools and to recognise jurisdictional roles when developing a risk management strategy under CEPA. When developing a Risk Management Strategy, ECCC and Health Canada identify the sectors that pose the greatest risk to the environment and human health and a risk management objective is then identified for those sectors. Once an objective has been set, the risk management tools and instruments that could achieve the objective are selected (Government of Canada, 2016d).

Currently under the CMP, more than 100 risk management actions (including regulatory and non-regulatory measures) have been put in place to address toxic substances for which risk has been identified after risk assessment. According to Government of Canada (n.d.), possible Risk Management Initiatives (RMIs) that can be considered to address risk include:

- Regulatory measures – pollution prevention plans, environmental emergency plans, environmental quality objectives and guidelines, release guidelines, significant new activity notices; chemical regulation (e.g. prohibition, restriction, substance concentration limits, release limits, concentration limits in products);
- Voluntary approaches – Environmental Performance Agreements, Memoranda of Understanding;
- Market-based instruments – financial incentives and subsidies, environmental charges and taxes;

- Joint federal/provincial/territorial initiatives – Canada-wide standards, guidelines, codes of practice;
- Provincial/territorial Acts – regulations, permits, licensing; and
- Other federal acts – e.g. Fisheries Act, Pest Control Products Act (PCPA), Hazardous Products Act, Canadian Consumer Product Safety Act (CCPSA), Food and Drugs Act (FDA).

As noted in Treasury Board of Canada Secretariat 2007*:*

> *"In addition to establishing regulation making powers, the Canadian Environmental Protection Act provides authority for the use of economic instruments, environmental quality objectives, guidelines and codes of practice, administrative and equivalency agreements, pollution prevention plans, environmental emergency plans, information-gathering notices, national pollutant release inventory, alternative compliance measures known as environmental protection alternative measures, and environmental protection compliance orders".*

The Two-Year Rolling Risk Management Activities and Consultations Schedule (Government of Canada, 2019c) provides information on risk management activities scheduled to occur during the next two years for substances managed under the Chemicals Management Plan, including opportunities for stakeholder consultations and engagement.

The Two-year Rolling Information Gathering Plan (Government of Canada, 2018a) provides stakeholders with an overview of potential upcoming information gathering activities. This includes the time periods during which mandatory surveys (section 71 Notices) may be published and when the planned voluntary data gathering outreach will begin. Information gathering initiatives are timed to inform priority-setting, risk assessment and risk management activities. Public consultation activities are announced on the Government of Canada website (for example see the consultation on the proposed risk management options for the phase-out of lead wheel weights) (Government of Canada, 2017a).

Approach

Whilst the screening assessment is being done, risk management is also considered, so the Risk Management Scope and Approach Document identifies potential options for risk management. Risk management scope documents are published at the same time as draft screening assessments and outline the Government of Canada's early thinking on risk management. If the final screening assessment maintains the toxic conclusion, the risk management approach document is published and outlines in more detail the Government of Canada's plan for risk management. Both the draft screening assessment and the risk management approach provide an opportunity for stakeholders to provide feedback and information to inform the path forward (Government of Canada, 2016d).

The Risk Management Scope and Approach documents are ordered into eight sections:

1. **Context**;
2. **Issue** – includes draft screening assessment conclusion and proposed recommendation under CEPA;
3. **Proposed risk management** – includes risk management objectives and options being considered, as well as any information gaps;
4. **Background** – includes general information on the substance and its current uses and sectors;

5. **Exposure sources and identified risk** – includes how Canadians may be exposed and the critical health effects, and vulnerable populations;
6. **Risk management considerations** – includes assessment of alternatives and socio-economic information;
7. **Overview of existing risk management** – details the Canadian and international risk management context; and
8. **Next steps** – details a public comment period and timing of actions.

Information sources

Information collected in the framework of public consultation activities, such as input on information gaps, technical considerations and socio-economic impacts, is taken into account when deciding on the most appropriate RMI.

Decision-making factors

To identify the most appropriate risk management instruments (mandatory or voluntary), a multi-dimensional but consistent and systematic approach is followed. Environment Canada's Qualitative Screening of Management Tools (QSMT) is a method for considering the most appropriate risk management instrument or mix of instruments. The QSMT comprises questions and sub-questions under five broad criteria (environmental effectiveness, economic efficiency, distributional impact, political and public acceptability and jurisdictional compatibility, and trade and investment obligations) with a qualitative assessment (i.e. high, medium, low) conducted for each (Government of Canada, 2007). Information on the sources of risk, and process guidance such as the Government of Canada's "*Cabinet Directive on Regulation*" (Government of Canada, 2018b), are taken into account.

The key decision-making factors include:

- Effectiveness and efficiency;
- Proportionality to the degree and type of risk;
- Costs and benefits (potential positive and negative economic, environmental, health, safety, security and social impacts on Canadians, businesses (with specific focus on small businesses), and government of the proposed RMI);
- Distributional impacts (how the positive and negative impacts may be distributed across various affected population groups including gender-based analysis, parties, economic sectors, and regions of Canada);
- Acceptability;
- Compliance with international obligations relating to human health, the environment, and trade; and
- Other jurisdictions (consider accepting as equivalent the regulation of other countries, provided they achieve the intended regulatory objective).

3.2.6 Administrative aspects

Timescales

Review of the 4,300 substances that were prioritised through Categorisation is planned for completion by the end of 2021, but not all risk management initiatives will have been taken by then. Consultation is carried out at several stages of the process and this can add to the timescales. The estimated time it takes to develop a risk management instrument, (i.e. from when

a final screening assessment is published in the Canada Gazette (CG) to when a RM instrument is published in CG Part II) is about 3.5 – 4 years. The time it takes for the entire process including risk assessment to be completed generally exceeds 4 years.

Costs

Consultation with ECCC and Health Canada indicates that no cost data or estimates are available for chemical risk assessments of individual substances. Costs associated with implementation of non-regulatory risk management instruments are not available. Costs associated with the implementation of specific regulations are outlined quantitatively if data is available and/or qualitatively in the Regulatory Impact Analysis Statement (RIAS) that is published in conjunction with each regulation. The RIAS includes an assessment of the cost of increased administrative burden imposed on businesses by a regulation.

Strengths and weaknesses

Consultation with the Canadian authorities revealed that data gaps are one of the major challenges for the majority of chemical substances that must be assessed. Although CEPA provides for data gathering authorities, submissions of data by industry are largely voluntary, and industry often has concerns regarding the use of their confidential business information. Data generation/data development is also an expensive undertaking. The uncertainty created by data gaps exist not only on the scientific side of risk assessments, but also on the economic side, leading to uncertainty in regard to valuation of costs and benefits of regulatory measures to reduce or eliminate chemical risks on the environment and/or human health.

One of the weaknesses identified in the 2018 Commissioner for the Environment and Sustainable Development Audit was that ECCC and Health Canada do not have a long-term, systematic approach to evaluate how effective their actions are in controlling toxic substances. It was recommended that this involve setting measurable objectives, monitoring the achievement of these objectives, and setting timelines for completion. ECCC are in the process of collaborating with Health Canada to develop a performance measurement strategy for chemicals management. Substance-based performance measurement evaluations are currently being piloted on four substances (Office of the Auditor General of Canada, 2018).

Strengths of the CMP include providing a predictable and transparent regulatory environment for chemicals, supporting coordination among federal statutes, and engaging stakeholders on proposed assessment conclusions and risk management approaches.

3.3 New Zealand

3.3.1 Summary of national chemicals legislation

The Hazardous Substances and New Organisms (HSNO) Act is the main chemical law in New Zealand intended to prevent or manage the risk that hazardous substances and new organisms may pose to human health and the environment. Under the HSNO Act, hazardous substances cannot be manufactured or imported without approval from the Environmental Protection Authority (EPA). The approval process for a hazardous substance incorporates controls into the substance approval in place to manage the risks resulting from its use. The controls assigned to hazardous substances vary, depending on the hazard classification of a substance and on the type of hazard involved. Each substance has a basic set of controls, known as prescribed controls, based on their hazard classification, as well as additional controls that are more risk-based in their nature. In general, the more highly hazardous substances have more stringent controls (Hazardous Substances and New Organisms Act, 1996).

A substance must be put through the approval process when they are new to New Zealand, are used in a new way, when changes are made to formulations, or when new risks are identified for older hazardous substances. New substances are assessed as part of the approval process, while the chemical reassessment programme is in place to review hazardous substances already approved in New Zealand.

3.3.2 Existence of an RMOA process

A direct equivalent to the EU RMOA system does not exist in New Zealand, however there are two areas of similarity:

1. 'Routine' risk management of substances through assessment/reassessment and approval processes; and
2. Reassessment candidate selection for NZ EPA-driven reviews of substance approvals.

Some procedures under the HSNO Act could resemble an RMOA. The application processes for approval or reassessment of hazardous substances involve a risk assessment and then risk management options (controls/rules) can be introduced (although it is considered that 'controls' in New Zealand have a broader meaning than Risk Management Options within the EU RMOA and that most are 'prescribed controls', i.e. triggered by hazard classification alone). Some prescribed controls apply to every substance in any quantity, which include preparation and maintenance of an inventory of all used and stored hazardous substances, SDS, worker training, emergency preparation, container labelling, and provision of PPE. Additional controls apply once specific threshold quantities are exceeding, such as certified handlers, emergency response plans, secondary containment systems, and workplace signage. Examples of hazard specific prescribed controls include a controlled substance licence, and restriction of use to workplaces. Other controls that are more risk based in nature may be applied as additional controls, or variations to the prescribed controls (WorkSafe, 2019).

Outside of NZ EPA's application processes, there are a number of other processes that involve RMOA-type considerations, for example as part of emerging issue screening and reassessment candidate prioritisation. There may also be similarities in the activities of other regulatory authorities in New Zealand as they have similar frameworks to manage other risks not covered by the HSNO Act (e.g. the Agricultural Compounds and Veterinary Medicines (ACVM) Group at the

Ministry for Primary Industries, who manage the ACVM Act, which looks at food safety, residues and efficacy concerns.

Guidance documents/binding procedures

High-level guidance is provided by the 'Risk Assessment Methodology for Hazardous Substances' consultation document (Environmental Protection Authority, 2018b), and the HSNO Act and the HSNO Methodology Order specifies key considerations that decision-makers must take into account when making a decision on an application (Hazardous Substances and New Organisation (Methodology) Order, 1998).

Publication of risk assessment findings

Decisions on completed applications (new approvals and reassessments) are published on the NZ EPA website, as well as outcomes of the reassessment screening/prioritisation processes. It should be noted that, under the HSNO regime, it is possible to rely on self-assignment to existing approvals. The NZ EPA does not receive or publish information if this occurs.

Responsible bodies

The NZ EPA is responsible for processing applications under the HSNO Act. While applicants may provide some analysis and proposed management options in their applications (noting that this may be external applicants or the NZ EPA in the case of some reassessments), the assessment of applications is carried out by the staff of the NZ EPA, with the statutory decision-making power undertaken by various NZ EPA decision makers. As mentioned above, it is possible to self-assign to an existing approval. It is the responsibility of the importer or manufacturer of a hazardous substance to ensure that the hazardous substance in question is appropriately approved.

3.3.3 Substance selection

In 2018, the NZ EPA developed the Flexible Reassessment Categorisation Screening Tool (FRCaST) to identify high-priority substances for review. FRCaST is a risk-based screening tool that uses a qualitative approach to determine a score for the different uses of each substance, based on hazards and exposures associated with each use. Once chemicals have been through the screening process, they are categorised into risk-driven Priority Groups (A – F) based on their highest individual score. Groups A and B make up the Priority Chemicals List, which forms the basis of the NZ EPA's reassessments work plan. An initial list of Chemicals of Interest that would undergo FRCaST screening was developed from lists of chemicals developed by major regulatory bodies in Europe, Norway, Canada, Australia and the USA for action in their jurisdictions (e.g. Candidate List, REACH Annex XVII, CEPA Priority Chemicals List, TSCA Work Plan) (Environmental Protection Authority, 2018a).

FRCaST has a similar approach to screening as that used in Australia (IMAP) and the USA, by taking into account use patterns and exposures, and giving key consideration to a number of specific chemical properties, such as persistence and bioaccumulation. The NZ EPA can also include chemicals that have significant levels of public, media or political interest as a way to identify screening targets for FRCaST (Environmental Protection Authority, 2018a). It is likely that particular issues of this nature will be considered in NZ EPA's Emerging Issue channel, which is expected to contribute to the Reassessment Work Plan. Ordinarily, the NZ EPA would consider domestic use products which pose a carcinogenic, mutagenic or reproductive toxicity hazard, and which have a realistic/likely exposure pathway, as a significant issue warranting further investigation.

FRCaST is one way that the NZ EPA identify substances for reassessment. The NZ EPA are currently working on a process to screen and prioritise emerging issues, with the intention of providing another route onto the Reassessment Work Plan. The first key stage is to 'triage' the emerging issue to determine whether any regulatory action is necessary. The second stage of the process would then probe more deeply the options for management of the concern, which could ultimately require a reassessment or amendment of the approval, or management of the risk through other non-statutory approaches. Consideration of overseas regulatory activity will also be included in this new process, but the level of concern arising from any given issue needs to be sufficiently great to be proposed for inclusion on the Reassessment Work Plan.

As well as reassessments initiated by the NZ EPA's Chief Executive, anyone can apply to the NZ EPA for a reassessment (Ministry for the Environment, 2019).

3.3.4 Hazard and risk assessment

Information sources

The information required for the FRCaST screening process was obtained from internal databases, approval documentation for hazardous substances, product labels, and publicly available databases of other international regulators (e.g. ECHA, European Food Safety Authority (EFSA), NICNAS, US EPA, and ECCC datasets). ECHA's registered substances database and NICNAS's Public Inventory have been particularly useful to the NZ EPA to gain information on how industrial chemicals are used commercially, as information on use volumes and application rates in New Zealand are largely unavailable. In the approval and reassessment processes, exposure information is most often determined quantitatively through modelling. Study data are also used for hazard classification, as well as to determine exposure endpoints, along with monitoring results (Environmental Protection Authority, 2018a).

Dose-response information is determined from analysis of relevant study reports. Study data allows appropriate effect levels to be determined, which are then used to determine how significant a predicted exposure is. Generally, the NZ EPA uses study data and uses No Observable Adverse Effect Levels (or less often Lowest Observable Adverse Effect Levels) and then assumes a threshold approach. Nevertheless, approaches such as use of the Benchmark Dose methodology is available as an alternative.

Approach

High-level guidance is provided by "Risk Assessment Methodology for Hazardous Substances" consultation document (Environmental Protection Authority, 2018b), which details how to address the risk, cost and benefit of using new hazardous substances in New Zealand. The document is intended to be used flexibly as each substance should be assessed in a way that is tailored to its proposed use and type of hazard, but there are five key steps in the recommended risk assessment process:

- Step 1 – Hazard Identification;
- Step 2 – Conceptual Model;
- Step 3 – Risk Assessment;
- Step 4 – Benefit Assessment; and
- Step 5 – Risk Management.

Step 1 involves classifying a substance's level of hazard. The system used in New Zealand to classify hazards is described in the NZ EPA's Hazardous Substances (Classification) Notice 2017. The thresholds and classification categories reflect those used in the GHS in order to make chemical management consistent globally.

Step 2 is the development of a conceptual model to gather information to understand how, when and where people and the environment can be exposed to the hazard. The conceptual model lays out the approaches that will be taken in the risk assessment.

Step 3 is the risk assessment, which needs to cover the whole life cycle of a substance, including manufacture, import, transport, storage, use, and disposal. The NZ EPA consider that there are three parts to analysing the risk from hazardous substances: the source of the hazardous substance; the pathways through which exposure occurs; and the receptor, which are the people or part of the environment that could be exposed to the substance. These three elements need to be connected for there to be a risk.

The exposure assessment component can be approached using either qualitative or quantitative assessment. A qualitative assessment, whether conducted by a scientist employed by the NZ EPA or an applicant, uses professional knowledge and judgement on the type of hazardous substance and how it is used. A quantitative assessment uses equations and models to calculate how large the potential exposure from the new substance would be. Substances can have more than one exposure pathway and multiple uses, so conceptual models must be broad and generic.

Where possible the NZ EPA rely on quantitative assessment of risk, but the current methodology is primarily focused on assessment of plant protection products. For other types of substances and uses it may not be possible or appropriate to use quantitative assessment. The NZ EPA would then undertake qualitative assessment, to determine a level of risk by estimating magnitude and likelihood of effects. The risk assessment undertaken is specific to different uses of a substance, which leads to a composite picture of risk being developed.

Step 4 is an evaluation of the positive effects of a hazardous substance. During reassessments, the NZ EPA seek comments from the public and industry to better understand the benefits of a substance and the consequences if the substance is withdrawn or its availability is restricted. The nature of this evaluation may be quantitative, qualitative or a combination of both.

Step 5 involves reaching a decision on the level of risk management, if any, that is required for a hazardous substance to be used as safely as possible.

Working arrangements and procedures

Industry and stakeholders are engaged at various points throughout the processes for approval, or reassessment. For reassessments, the EPA undertakes a Call for Information, which is intended to gather useful information about the use of a substance. At this point of the process, no proposals have been made by the EPA regarding possible risk management options.

If an application for approval or a reassessment application is formally received (i.e. the starting point of the statutory process), then the application is publicly notified for submissions. Any party may make a submission in writing and a public hearing may also be held if any submitters request to be heard. The hearing is an opportunity to present a submission directly to the decision makers.

3.3.5 Selection and assessment of Risk Management Options

Scope

In New Zealand, risk management options take the form of controls, which are restrictions or conditions that state how a hazardous substance can and cannot be used. The NZ EPA can also withhold or revoke approval for manufacture or import in New Zealand. Examples of risk management controls are limits on where a substance can be used, maximum concentrations or amounts in products, and handling conditions. There is a framework of controls prescribed under the HSNO Act 1996 and requirements prescribed under the Health and Safety at Work Act 2015, to ensure that they are applied consistently across all hazardous substances in use, and appropriate to the level of risk.

The NZ EPA makes best effort to align their risk management efforts with other authorities, but separate assessments are made by different authorities as they are intended to manage different risks. This means that management of different risks is mainly carried out independently. However, legislation requires that restrictions imposed under other legislation are considered when determining appropriate risk management options to be imposed through the HSNO Act approval process.

Approach

NZ EPA-initiated reassessments (i.e. risk assessment and RMO selection) are often carried out for a group of related substances. Examples include groups of organophosphate and carbamate substances, antifouling paints, and groups of substances with the same active ingredient. Group Standards are also used as an approval mechanism and risk management tool, which cover groups of substances with common attributes and uses.

Selection of RMOs differentiates between the different uses of substance, and reflects who is at risk, whether that be workers, consumers, or the environment.

Decision-making factors

When approving a hazardous substance, prescribed controls are applied based on its hazard classification. Decision-makers have the ability to expand on these by adding additional controls to manage identified risks, or alternatively by subtracting from the prescribed controls. Decisions on whether to do this will consider whether it is necessary to realise the beneficial effects of substance use, the relative effectiveness and cost effectiveness, and the likelihood that controls will achieve their intended purpose.

Furthermore, the HSNO Methodology Order states that the decision-maker must consider the degree of scientific or technical uncertainty associated with the assessment, and the effects on costs, benefits and effectiveness of making controls more or less restrictive (Hazardous Substances and New Organisation (Methodology) Order, 1998).

In addition, consideration of the impact of hazardous substances on Māori culture and traditions is written into legislation. The 'Incorporating Māori perspectives into decision making' protocol is used to aid the EPA to incorporate Māori perspectives (*mātauranga Māori)* appropriately into decision making (Environmental Protection Authority, n.d.).

Working arrangements and procedures

The NZ EPA is responsible for the assessment and reassessment of substances for approval under the HSNO Act, with input from WorkSafe New Zealand. WorkSafe New Zealand does not have any decision-making function under the HSNO Act, nor do they have their own approval process for hazardous substances. The HSNO decision makers (NZ EPA) are required to give 'particular regard' to input from WorkSafe. The NZ EPA cannot obligate WorkSafe to develop or implement any risk mitigation measures outside of the Health and Safety at Work Act (HSWA), but WorkSafe have the discretion and ability to develop non-standard controls through their own processes.

3.3.6 Administrative aspects

Timescales

For any reassessment, the statutory process is 100 working days, but this does not include pre-application work, such as proposal development. It is not possible to give an exact start to finish time for a reassessment as this is impacted by the size and complexity of a reassessment. However, it can be expected that a reassessment may take between 1 and 3 years to complete. For external applications the assessment work is carried out within the statutory period, so the timeframe is approximately 100 working days.

Costs

The NZ EPA absorbs the costs of NZ EPA-initiated reassessments, and these can vary largely due to the size and complexity of a reassessment. For external applications, a full reassessment costs NZ$30,000 and a modified reassessment costs NZ$12,650.

Strengths and weaknesses

For external applications, the regulatory process could be modified so that it is not the application which is the subject of the consultation, rather the application and the NZ EPA's assessment and proposal. That would allow submissions to be made on the NZ EPA proposals, which is not possible currently, and would better align with the approach that is taken for NZ EPA-initiated reassessments. In the latter, the NZ EPA produces an application that includes its assessment and proposals, which can be subsequently updated to take into account information received through submissions.

In consultation with the NZ EPA, it was highlighted that a strength of the reassessment process is the Call for Information, which is a key step in NZ EPA-initiated reassessments. This information gathering step is instrumental in obtaining new information which helps the NZ EPA understand how a substance is used.

3.4 United States of America

3.4.1 Summary of national chemicals legislation

The Toxic Substances Control Act (TSCA) is the United States' main law that regulates the introduction of new chemicals and the distribution and use of existing chemicals. Existing chemicals are listed in the TSCA Inventory of Chemical Substances, while those not listed in the Inventory are considered new substances. TSCA is administered by the United States Environmental Protection Agency (US EPA), which has the authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances.

TSCA requires the US EPA to evaluate the safety of existing chemicals via a three-stage process: risk prioritisation, risk evaluation, and risk management. The first step is prioritisation of existing chemicals, in which the US EPA designates chemical substances as either high-priority or low-priority after a risk-based screening process. The second step is the risk evaluation phase, which determines whether or not a chemical substance presents an unreasonable risk to health or the environment. The final step is risk management, under which the US EPA places regulatory controls on chemicals substances posing an unreasonable risk (US EPA, 2017b).

The framework for risk evaluations involves the following stages: planning and scoping; problem formulation (includes conceptual model and analysis plan); risk assessment (includes exposure assessment and effects assessment); and lastly risk characterisation. The US EPA intends to apply systematic review principles in the development of risk evaluations under TSCA to produce transparent, reproducible and scientifically credible risk evaluations. Risk evaluations can be initiated by the US EPA, or manufacturers of a chemical substance can request an US EPA-conducted risk evaluation (US EPA, 2017a).

3.4.2 Substance selection

The Frank R. Lautenberg Chemical Safety for the 21st Century Act was enacted on 22nd June 2016. Within 180 days, the US EPA was required to identify the first 10 high-priority substances from the 2014 Update to the TSCA Work Plan for Chemical Assessments to undergo risk evaluations. This was a unique request by Congress to get the Initial Risk Evaluations program underway. Of these 10 substances, there are six draft risk evaluations currently published.

Following this, the US EPA identified an additional 20 high-priority substances under the Prioritisation process of the Administrative Procedures Act. Following two 90-day comment periods, the substances entered the risk evaluation phase by December 2019. Once a risk evaluation has been completed on a high-priority substance, the US EPA must begin a new risk evaluation, meaning there will always be at least 20 risk evaluations ongoing at any one time (US EPA, 2019b). The law requires that at least half of all US EPA-initiated risk evaluations be drawn from the 2014 Update to the TSCA Work Plan and that the US EPA also give preference to Work Plan chemicals with the following characteristics:

- Persistence and bioaccumulation scores of three;
- Known human carcinogens; or
- High acute or chronic toxicity.

Aside from these statutory preferences and requirements, US EPA has discretion to determine which chemicals to prioritise. To support a proposed priority designation, US EPA (2019) will

screen the chemical substance under its conditions of use against certain criteria specified in TSCA section 6(b)(1)(A) by reviewing the reasonably available information with respect to:

- Hazard and exposure potential of the chemical substance;
- Persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations;
- Storage near significant sources of drinking water;
- Conditions of use or significant changes in the conditions of use of the chemical substance; and
- Volume or significant changes in the volume of the chemical substance manufactured or processed.

Prioritisation is typically a nine to 12-month process where the US EPA identifies high-priority chemicals that they conclude (without consideration of cost factors) as presenting an unreasonable risk to human health and the environment based on hazard and exposure routes or conditions of use.

Substances can undergo risk evaluations by either US EPA or manufacturer-initiated risk evaluations, both of which follow the same process. A manufacturer may request a risk evaluation for conditions of use that are of interest to the manufacturer. Manufacturers must submit a request for a risk evaluation using US EPA's Central Data Exchange (CDX). A request must include the following information: the manufacturer name and contact information, chemical identity, conditions of use of interest and all information necessary for US EPA to conduct the risk evaluation on the conditions of use of interest (e.g. hazard, exposure, potentially exposed or susceptible subpopulations), among other information (US EPA, 2019d). The US EPA granted the first two manufacturer requests for risk evaluation on 2nd December 2019 for disodecyl phthalate (DIDP) and diisononyl phthalate (DINP), two chemicals used in plastic production.

3.4.3 Hazard and risk assessment

TSCA implements a risk-based system, so in the risk evaluation process, both hazard and exposure are considered concurrently. The US EPA are required to look at all the evidence available on hazard and exposure. They conduct risk assessments independently of other regulators but review any available information and the regulatory decisions of overseas authorities to inform the decision-making process.

Information sources

Information sources for exposure scoring include:

- US EPA databases and information collected under TSCA regulatory instruments, such as Premanufacture Notice (PMN) Database, High Production Volume (HPV) Challenge, Submissions, Toxic Release Inventory (TRI), EPA National Emission Inventory (NEI) Database, and US EPA National Air Quality System (AQS);
- Information from international organisations, such as the OECD's eChemPortal and Screening Information Assessment Profiles and Reports, and the Japanese National Institute of Technology and Evaluation (NITE), IPCS Concise International Chemical Assessment Documents (CICADs) and IARC Monographs;
- State level authorities, such as German Federal Environmental Agency (UBA) survey on chemicals in indoor air; and

- Academic institutions, such as the National Library of Medicine Hazardous Substances Databank.

The exposure score is a combination of three scores: Use Type, General Population and Environmental Exposure and Release Score. The Release Score is based on the US EPA's TRI data (which includes annual volumes of chemicals released to the environment, and/or managed through recycling, energy recovery and treatment) for chemicals subject to TRI reporting, or for non-TRI chemicals, the Release Score is calculated using a method involving Chemical Data Reporting (CDR) data, which includes production volume, number of sites and type of use. When there is no exposure data or a quantitative proxy, modelling is used. The US EPA use a variety of models to predict what the exposure to humans and the environment will be. The US EPA always arrive at a quantitative estimate of exposure. While a chemical's production volume, use type, and number of manufacturing, processing, and industrial use sites do not provide exposure data, they can be used as an indicator of potential releases and resulting potential exposures (US EPA Office of Pollution Prevention and Toxics, 2012).

Approach

In each risk evaluation under TSCA section 6(b), the US EPA determines whether a chemical substance presents an unreasonable risk of injury to health or the environment, under the conditions of use. The determination does not consider costs or other non-risk factors. Unreasonable risk is determined by considering risk-related factors such as human health and environmental effects and exposures, populations exposed including any potentially exposed or susceptible subpopulations (PESS), nature and severity of hazard, and uncertainties. A risk is deemed unreasonable by comparing estimated risk with risk benchmarks. For non-cancer endpoints, a value less than the margin of exposure (MOE) benchmark is used to indicate potential unreasonable risk, while for cancer endpoints a value greater than the risk benchmark (the lifetime cancer risk value ranges from 1 in 1,000,000 to 1 in 10,000) is used to indicate potential unreasonable risk. For environmental endpoints, the US EPA considers a risk quotient greater than 1 to indicate potential unreasonable risk (US EPA, 2019a).

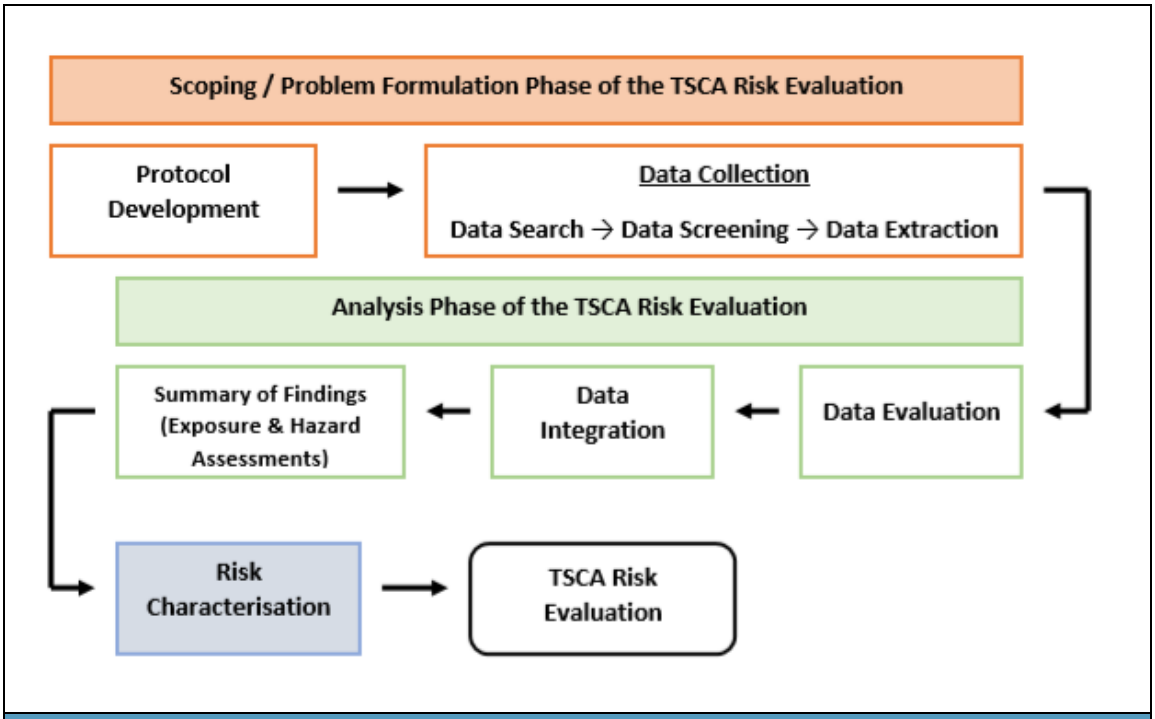

Figure 3-2: Hazard and risk assessment diagram
Source: RPA diagram

A conceptual model and analysis plan are required for each risk evaluation, which present the proposed approach for the risk evaluation. These are produced during the problem formulation stage of the systematic review. It is expected that the systematic review principles and general processes will be similar across all risk evaluations, although methods, approaches and criteria will be tailored where necessary to meet the assessment needs of each risk evaluation. The US EPA (2017a) framework for assessing risk involves the following stages:

- Planning and scoping;
- Problem formulation (includes conceptual model and analysis plan);
- Risk assessment for human health and the environment under conditions of use:
  - Exposure assessment
    - Environmental exposure
    - Populations exposed, potentially exposed or susceptible subpopulations
  - Effects assessment
    - Hazard identification (nature of the hazard and irreversibility)
    - Dose-response assessment
  - Uncertainties; and
- Risk characterisation.

Planning and scoping identify the level of assessment appropriate for the needs of the risk manager and the role that risk information plays in the decision. Information gathered during planning and scoping is used during problem formulation to develop a conceptual model and analysis plan. The assessment step builds on the conceptual model and implements the analysis plan (US EPA, 2016a, 2016c).

The data collection, data evaluation, and data integration stage of the systematic review process are used to develop the exposure and hazard assessments. As risk is a function of exposure and hazard, the exposure and hazard assessments are combined to support the integrative risk characterisation, which ultimately supports the risk determination (US EPA, 2018).

During the data evaluation stage, US EPA assesses the quality of the data sources using the evaluation strategies and criteria described in the Application of Systematic Review in TSCA Risk Evaluations. US EPA evaluates the quality of all data sources that pass full text screening. Each data source receives an overall confidence rating of high, medium, low or unacceptable. Data integration includes analysis, synthesis and integration of information from the data evaluation. The US EPA considers quality, consistency, relevance, coherence and biological plausibility to make final conclusions regarding the weight of the scientific evidence. Data integration involves transparently discussing the significant issues, strengths and limitations as well as the uncertainties of the reasonably available information and the major points of interpretation (US EPA, 2018).

In the exposure assessment, exposure is characterised, quantitatively or qualitatively, for relevant routes and pathways, frequency and duration, and populations and life stages. The effects assessment firstly involves hazard identification, which requires identification, evaluation, and synthesis or information to describe the health effects of a chemical, or group of chemicals (US EPA, 2017a). The exposure potential in the Use Type categories are based on a chemical's presence and characteristics of use in consumer, commercial, or industrial products. Chemicals in widely used consumer products with high exposure potential are ranked as high, chemicals in more narrowly used consumer products and a lower likelihood of exposure are ranked as medium, and commercially used chemicals are ranked as low. Chemicals with no commercial use are unranked (US EPA Office of Pollution Prevention and Toxics, 2012).

The Release Score for non-TRI chemicals factors in industrial and downstream processing uses and commercial and consumer uses. Each use is assigned a ranking of high, medium or low based on their potential to result in release. The uses were ranked by the US EPA using expert judgement, generic scenarios, and previous experience with new and existing chemical assessment. The types of studies that may be used include human clinical or epidemiological studies, in vivo or in vitro laboratory animal studies, or mechanistic or kinetic studies. Secondly, it involves a dose-response assessment which may be developed using a combination of data, science policy decisions, and models (US EPA Office of Pollution Prevention and Toxics, 2012).

Risk characterisation is the final, integrative step of risk assessment. This step integrates exposure assessment and effects assessment into quantitative and qualitative estimates of risk for the evaluated population(s) (US EPA, 2017a).

The US EPA intends to apply systematic review principles in the development of risk evaluations under TSCA. Integrating systematic review principles into the TSCA risk evaluation process is critical to develop transparent, reproducible and scientifically credible risk evaluations.

Working arrangements and procedures

The US EPA strives to be as transparent as possible and meet with stakeholders regularly, particularly to clarify data. There are also four comment periods: two in prioritisation, one in scoping, and one in risk evaluation. Furthermore, at any time during the process, stakeholders can contact the US EPA to set up a meeting if they have new data or data is not known or available to the US EPA.

3.4.4 Selection and assessment of Risk Management Options

Scope

The US EPA (2019c) take one or more of the following key RMOs to the extent that the chemical substance no longer presents an unreasonable risk under Section 6(a) of TSCA:

- Prohibit or otherwise restrict manufacture, processing, or distribution in commerce;
- Prohibit or otherwise restrict for a particular use or above a set concentration;
- Require minimum warnings and instructions with respect to use, distribution in commerce, or disposal;
- Require recordkeeping or testing;
- Prohibit or regulate any manner or method of commercial use;
- Prohibit or regulate any manner or method of disposal; and/or
- Direct manufacturers or processors to give notice of the unreasonable risk to distributors and replace or repurchase products if required.

Sections 6(c), 6(d), and 6(g) lay out the other legal requirements for risk management. If it can be concluded that a substance with unreasonable risk is best regulated under another piece of legislation (such as the Occupational Safety and Health Administration (OSHA) Act), a substance's risk findings can be referred to other federal agencies. For example, if the Office of Air at US EPA is addressing a chemical, then the chemical would likely not be evaluated or regulated under TSCA, as it is considered to be adequately regulated by another legislation.

Approach

Workers, consumers and the environment are all considered in the risk evaluation and the selection of risk management measures. A variety of approaches can be taken which allow some uses to continue while banning the use of the chemical in other uses. For example, the PBT rule allowed certain uses to continue and the methylene chloride rule banned the substance in consumer use.

Information sources

The views of industry and other stakeholders are heard and considered but they are not involved in the decision-making process. Information from overseas regulators is considered but the US EPA makes independent risk management recommendations. The US EPA also look at State regulation of chemicals particularly the State of California and OSHA's actions.

Decision-making factors

The US EPA selects the risk management option which gives the highest confidence that a risk is addressed. There is a legal requirement to act whenever 'unreasonable risk' is identified. Risk management considers risk assessment information (scientific factors) and other factors as follows (US EPA, 2017c):

- Economic factors: the cost of risks and benefits of reducing a chemical, risk mitigation, remediation and the distributional effects;
- Laws and legal decisions define the basis for the Agency's risk assessments, management decisions, and, in some instances, the schedule, level or methods for risk reduction;

- Social factors: income level, ethnic background, community values, land use, zoning, healthcare availability, lifestyle, and psychological condition of the affected populations;
- Technological factors: the feasibility, impacts, and the range of RMOs;
- Political factors are based on the interactions among branches of the Federal government, with other Federal, state, and local government entities, and even with foreign governments; these may range from practices defined by Agency policy and political administrations through inquiries from members of Congress, special interest groups, or concerned citizens; and
- Public values reflect the broad attitudes of society about environmental risks and risk management.

The availability of technically and economically feasible alternatives is also considered. Manufacturers, chemical users and other experts can supply information on the availability of alternatives.

Working arrangements and procedures

Once a proposed rule is cleared by the US EPA, it goes through an inter-agency process and is sent to various government departments in the United States (e.g. Office of Management and Budget Review, Department of Defence, Department of Energy, Department of Homeland Security, Department of Labour, National Aeronautics and Space Administration (NASA), OSHA) to give them an opportunity to comment, which can be influential on the final rule. This process usually takes 60 days, but in some cases it can take longer.

3.4.5 Administrative aspects

Timescales

Prioritisation takes typically nine to 12 months which includes two 90-day comment periods (Chemical Watch, 2017). The risk evaluation process takes three years with a possible 6-month extension. It is expected that efficiency gains will be made as more risk evaluations are conducted. The risk management process takes two years: one year to propose the measures and one year to finalise them. The Statute allows for two more years if additional information is required. Once a proposed rule is cleared, the inter-agency approval process typically takes 60 days or longer.

Costs

The US EPA science team is about 100 people working on various types of reviews for both new and existing chemicals. This is supplemented by contractors, and sometimes experts from the US EPA's Office of Research and Development. The US EPA receives two-year appropriated funds to carry out the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Under the Act, the US EPA is authorised to collect users' fees (up to $25 million annually) from chemical manufacturers and processors. Fees collected will defray costs for new chemical reviews and a range of TSCA implementation activities for existing chemicals (US EPA, 2016b).

Strengths and weaknesses

As yet, it is difficult to know the strengths and weaknesses of the programme given that only six risk evaluations have been completed. However, the risk-based system, where hazard and exposure are considered concurrently could be seen as an example of good practice.

3.5 European Union and the United Kingdom

3.5.1 Overview

Summary of chemicals legislation

EU legislation provides a number of options for dealing with risk from hazardous chemicals, including several RMOs under REACH and OSH legislation.

Authorisation and restriction are the two key instruments established under Regulation (EC) No 1907/2006 (REACH) to manage risk from hazardous chemicals (Oekopol & RPA, 2017).

A restriction involves a universal or targeted ban or limit on the marketing and use of a substance or group of substances. The basis for this is a dossier elaborated either by a MSCA or ECHA, which finds that there is an unacceptable level of risk from the substance in question. One or all applications of the substance can be covered. A restriction can also cover the presence of the substance in articles or its presence as a constituent of another substance, its manufacture in the EU, as well as imports (Oekopol & RPA, 2017).

An authorisation involves a general ban on the use of a substance in the EU with the possibility of authorising continued use. This follows on from a substance being identified as a Substance of SVHC and included in Annex XIV of REACH (The Authorisation List). The authorisation instrument provides individual companies with the option of applying for authorisation for specific uses (with a defined review period) (Oekopol & RPA, 2017).

In cases where a risk arises from occupational exposures, it can also be controlled under EU OSH legislation and binding Occupational Exposure Limit Values (BOELVs) under the Carcinogens and Mutagens Directive (Directive 2004/37/EC) and Chemical Agents Directive (Directive 98/24/EC) can ensure a common maximum exposure limit in the entire EU.

RMOs under other EU legislation that can be used to manage risk include: harmonised classification and labelling under the Classification, Labelling and Packaging (CLP) Regulation; permit conditions based on Best Available Techniques (BAT) under the Industrial Emissions Directive; Environmental Quality Standards (EQS) under the Water Framework Directive (WFD); and concentration limits in consumer products, such as those enforced under the Toy Safety Directive (TSD).

Existence of an RMOA process

An RMOA process is in existence in the EU. RMOAs are discussion documents, their conclusions do not necessarily have to lead to the recommended RMO or can even lead to another RMOA being carried out by a different Member State that comes to a different conclusion.

It was suggested by ECHA during consultation that some of the advantages of RMOAs include predictability towards the industry, transparency, consistency and avoidance of duplication of activity (e.g. two Member States working on the same issue). It was further stated that RMOAs can also facilitate discussion and exchange of views between Member States (and ECHA) and the development of common views and understanding. Whilst it is recognised that the RMOA process has contributed to the enhancement of predictability/transparency/consistency of chemicals management in the EU, it needs to be recognised that there are significant aspects of divergence at Member State level with regard to how RMOAs are undertaken and this has implications for the degree to which these benefits are being achieved in practice.

For example, although the public activities coordination tool (PACT) sets out the substances for which RMOAs are planned, together with the timeline and the responsible MSCA. Due to the absence of a universally applicable guidance document, it is not known ahead of time what information the authority will take into account and what procedures will be followed for the assessment, thus limiting predictability/transparency. Similarly, although there is basic consistency in terms of the scope and structure of the RMOA, there is no consensus on more specific analytical aspects of the assessment, meaning that there is some potential for Member States coming to different conclusions even where the substances and circumstances are similar.

To highlight such areas of divergence, some of the key findings from RPA's inputs to the 2017 study relating to the implementation of the EU RMOA process have been summarised at a high-level, in the remainder of this section (Oekopol & RPA, 2017).

These activities were based on discussions with MSCAs responsible for the vast majority of RMOAs which were either completed or were 'under development' at the time (as according to the ECHA public activities coordination tool in early 2017) (Oekopol & RPA, 2017)[4]. Following this overview, findings from a fresh series of interviews with the German, Swedish, Netherlands and UK authorities, carried out within the scope of this exercise (as noted in Section 2.1) are provided.

Guidance documents/binding procedures

A template has been developed to encourage a consistent way of presenting the RMOA and its conclusions. It should be noted that this is a template and not a guidance document and thus does not set out the approaches to be followed. In addition, its use is voluntary, and Member States are free to structure their RMOAs in any way they deem fit. The template is not a publicly available but the published RMOAs provide a good indication of the contents of the template.

Publication of RMOA results

It is up to the Member States to decide whether they want to publish only the conclusions or the whole RMOA document.

Responsible bodies

ECHA and EU Member States are responsible for RMOAs.

Substance selection

The selection of substances that undergo RMOA is driven by the interests of the individual Member States. It is often about national priorities, such as concerns over certain consumer uses, national interest regarding a particular substance or if the Member State has performed previous work in relation to a substance.

The common screening approach considered available information for substances in the REACH registration dossiers and other databases to identify substances for further regulatory action being either generation of data (compliance check, substance evaluation), RMOA or harmonised

[4] These were Denmark, France, The Netherlands, Germany and Sweden. It was also agreed that two additional authorities with less experience of the process would be contacted (Ireland and Bulgaria). At the time, the Irish authorities had completed one RMOA and had three ongoing and the Bulgarian authorities were very new to the process with one assessment under development. Therefore, it was believed that consultations with these authorities would provide a good variation in experience level as well as a suitable geographical spread.

classification and labelling. Since 2017, ECHA have begun grouping structurally similar substances (under the integrated regulatory strategy' (ECHA, 2019)), to ensure that they are treated in a consistent manner. This practice intensified in 2018 which allowed for better identification of regulatory measures.

ECHA is currently in the process of mapping the 'chemical universe' which includes over 21,000 REACH registered substances, into five pools based on the regulatory actions in place, initiated or considered for them. This is a planning and monitoring tool that helps Member States and EU authorities focus on substances of (potential) concern and identify appropriate regulatory actions, where needed. ECHA's goal is to conclude by the end of 2020 for all substances registered over 100 tonnes per year whether they are: a priority for regulatory risk management; currently of low priority for further regulatory action; or more data is needed for a judgement to be made. Potential regulatory actions need to be determined for nearly 19,000 chemicals, while 1,871 chemicals are deemed to be of high priority for assessment, or which data needs to be generated for 1,544 and for 327 risk management is under consideration (ECHA, 2019).

ECHA are aware that some Member States have systems in place to monitor overseas regulatory action, but this is not a predeterminant for substance selection. There would need to be an issue with a substance inside the EU, for it to proceed to an RMOA.

Hazard and risk assessment

Information sources

REACH registration dossiers and harmonized classifications are the main sources of hazard information. In the absence of a harmonized classification, Classification, Labelling and Packaging (CLP) notifications are considered. There are few instances in the context of RMOA where there is limited hazard information, since substances undergo RMOA because there is a known or suspected hazard (Oekopol & RPA, 2017). It was noted by ECHA that registration dossiers could be updated in a timelier manner. Details on uses (e.g. use description, tonnage per use information) is often missing.

Generally, the lead registrant for a substance is also the key point of contact and it was observed that informing a registrant of the RMOA process (or even just the addition of the substance to the PACT tool) often led to a registration dossier update (Oekopol & RPA, 2017).

Other sources of information can be used, too. Several MSCAs stated that industry has been eager to be involved in the RMOA process and had contacted them as a result of the RMOA activities being publicised on ECHA's PACT tool. However, the degree to which data from consultations was used varied significantly between Member States. Several authorities carried out either targeted or public consultation activities with a range of stakeholders whilst for others, no formal consultation activities existed (Oekopol & RPA, 2017).

Some Member States use outcomes from non-EU regulators in the hazard assessment.

Approach

RMOAs strive to consider risk when determining whether regulatory action is warranted; however, a full, quantitative or monetised assessment of human health or environmental effects is typically not provided. A combination of hazard information and use pattern is the main way of approximating risk and provide an indication for need of regulatory measures. It is very rare to have a full, quantitative, risk assessment and most often a proxy is used.

Working arrangements and procedures

This differs from case to case, depending on practice in MS and circumstances of the specific case.

The size of the MSCA appears to affect internal working arrangements. Large MSCAs may involve several separate specialised units, whereas smaller MSCAs tend to dedicate smaller teams to the process. In terms of written process and procedure, internal working arrangements also vary significantly between MSCAs; some MSCAs have a more formal drafting process while others work on a case by case basis (Oekopol & RPA, 2017).

Often industry is consulted, but on occasion stakeholders are not involved as sometimes there is a short time period for an RMOA to be completed due to political or other pressures. Some Member States may consult before, some after, others may even run a public consultation. In general, Member States will try to consult with the industry when elaborating an RMOA.

An established expert group for discussing endocrine disrupting (ED) and PBT properties comprising of members from Member States, the Commission and stakeholders facilitates the exchange of information and discussion in regular meetings. Several meetings are held each year.

Selection and assessment of Risk Management Options

An interview with ECHA suggests that all RMOAs consider all potential RMOs. Proportionality of action is considered and how realistic and achievable it is to implement. The type of hazard does not determine which RMO is selected. Therefore, the same hazard (i.e. Carc. 1B) may be regulated under different frameworks for different substances. Feasibility is then considered within the framework of the follow-up action (e.g. restriction, authorisation, OEL etc.).

Information at the Member State level suggests that the final decision with regard to follow-up activities is based on the concerns surrounding a substance and the range of options available for decreasing the risk associated with a substance. Multiple authorities 'consider the whole picture' that include a multitude of different factors (Oekopol & RPA, 2017). However, the approach is not entirely consistent between the different Member States.

Administrative aspects

Timescales

Past RMOAs have taken anywhere between 2 months to 2 years. This is of course dependent on the complexity of the individual cases (Oekopol & RPA, 2017), but this is not the only factor. Since RMOA is voluntary and does not have specific deadlines, it is often a stop-start process that is interspersed with periods of inactivity. Therefore, the timeframe of an RMOA is often more of a reflection of resource availability and workload, rather than the complexity of a substance assessment.

Of course, by necessity the allocated resources to RMOA activities will affect the depth to which the analyses can be undertaken (Oekopol & RPA, 2017).

Costs

In the Oekpol & RPA (2017) study, several MSCAs indicated that the number of RMOAs they were undertaking had decreased in recent years due to the resource intensive nature of performing a full RMOA. Multiple MSCAs stated that they were happy with the current process but that substances under consideration were becoming more complex and data were more limited than

in previous RMOAs (i.e. those substances considered the 'low hanging fruit' have already been assessed). In terms of plans for the future, several MSCAs indicated that enhanced collaboration with other MSCAs would be beneficial. Several MSCAs also highlighted that a substance grouping approach is likely to become more prominent. There were also some calls for RMOAs to remain reasonably concise and focused as they were becoming increasingly more comprehensive (Oekopol & RPA, 2017).

ECHA do not conduct many RMOAs themselves anymore, and instead undertake a more supportive role, which involves laying the groundwork and improving / streamlining the RMOA system. ECHA are mainly involved in activities such as the grouping of structurally similar substances requiring RMOA and identifying gaps in the substance screening / selection process. The cost to the Member State is unknown but depends on the time taken on literature searches, consultation, phone calls etc. There is no funding by ECHA available for Member States.

Strengths and weaknesses

It was suggested by ECHA that there is a high level of transparency throughout the RMOA process which is achieved through PACT where up-to-date information on the RMOA (and other) activities planned, ongoing or completed by ECHA and/or MSCAs, is published. Whilst it is recognised that PACT has created transparency in terms of awareness of the relevant substances that are (or are expected) to undergo an RMOA, it should also be recognised that there are significant aspects of divergence at Member State level with regard to how RMOAs are undertaken and this has implications for the degree to which transparency is achieved in specific cases. This is particularly significant since there are no binding/universally applicable approaches or guidance documents setting out the preferred approaches for specific analytical aspects of an RMOA.

It was noted by ECHA that establishing the correct level of information required is challenging. RMOAs should not comprise of lengthy documents / reports with unnecessary information. Reports should contain the appropriate level of information for a decision on the most appropriate follow-up action to be made with a more detailed assessment of the impacts of the RMO being provided in the run-up to the adoption of the RMO.

In the 2017 study, a number of MSCA's suggested that cooperation between Member States could be improved and also indicated a preference for more grouping activities (Oekopol & RPA, 2017). This approach is not being more extensively implemented.

3.5.2 Germany

Substance selection

Currently, Member States take the results of ECHA's screening and use this to select substances for RMOA, which is the approach towards substance selection taken by BAuA.

The national priorities used to select substances from ECHA's screening include:

- PFAS substances;
- Substances for which previous work has been undertaken by BAuA (e.g. borates);
- Substances indicated by third parties (e.g. enforcement authorities, employer's liability insurances (Berufsgenossenschaften)); and
- Substances indicated by monitoring studies (human biomonitoring and environmental monitoring) as being of potential concern.

There is little political or public pressure surrounding substance selection. Overseas regulatory action also has little influence, but once a substance has been selected, the German authorities (BAuA, Federal Institute for Risk Assessment (BfR) or the Environment Agency (UBA)) look at what is being done on a substance in other jurisdictions. BAuA only look at publicly available information from other jurisdictions as there is no internal information sharing between BAuA and non-EU authorities.

Information sources

The main information sources used in the development of RMOAs are REACH registration dossiers and chemical safety reports. To obtain information that is not available in registration dossiers, such as information from downstream users (i.e. information on their uses and exposure, alternatives, and socio-economic impacts of regulation), BAuA hosts a public consultation for each RMOA on the BAuA REACH helpdesk website. This usually lasts for 2 months, after which BAuA invites all participants to a face-to-face meeting, in order to further discuss their contributions and get any clarification on their comments.

For the consultation, BAuA puts together open questions and sends these to industry. BAuA has a standard questionnaire which they adapt from case to case. If BAuA does not have lots of existing information, the questions they ask industry are high level, but most of the time they try to be as specific as possible, as from experience, the more specific the questions the better the information received.

The consultation is not just Germany-focused, but is widespread, with feedback being received from companies all across the EU. When the consultation starts, BAuA informs all the registrants, sector-specific organisations, industry associations, as well as downstream users, who they try to reach by inviting those that have notified the substance under harmonised classification and labelling. When BAuA first began performing RMOAs, they shared the concern expressed by other Member States, such as the UK, that public consultation would cause unnecessary alarm in the supply chain. However, as with the SVHC Roadmap, ECHA had decided to publish information on RMOAs in the PACT anyway, BAuA decided to address this more proactively and engage industry and the supply chain through consultation and start a dialogue to give them the possibility of getting in touch and discussing their concerns.

If there are any uncertainties arising from lack of data, BAuA explains their nature and seeks to demonstrate why, despite the uncertainties, a particular follow-up is suitable.

Hazard and risk assessment

BAuA believes that an RMOA should not encompass a full risk assessment, as it should be more of a qualitative discussion of findings rather than a quantitative risk assessment. The qualitative assessment does not differentiate between individual substance uses. An indication of risk would, for example, be high tonnages and widespread uses.

Working arrangements

In terms of working on REACH, the German authorities have a coordinating unit (BAuA Division 5, Federal Office for Chemicals (BfC), which is the designated German competent authority for REACH) and several assessment units. Division 4 at BAuA deals with worker safety and BfR deals with consumer aspects, as well as toxicology aspects of REACH, while the UBA deals with ecotoxicity and all environmental aspects.

There are four or five meetings held each year between the different departments. Within these meetings, priorities and work plans are discussed and progress with substances that all parties have an interest in is sought, although this is not always possible. In such cases it is decided to carry out targeted assessments (e.g. look at environmental aspects only).

BAuA has a formal drafting process in place and tries to stick to this as much as possible, but sometimes there are case specific aspects which require some flexibility in the process. BAuA is of the opinion that, due to the voluntary nature of RMOA, it should be as flexible as possible. The ECHA template is useful for guidance, but it is not always fit for purpose. For example, when BAuA work with groups of substances, an additional section is required to justify the basis for the substance grouping, as this is currently not included in the template. Another example is if there is a specific concern for the workplace, BAuA needs to add a section to explain the advantages and disadvantages of regulatory action under REACH compared with regulatory action under occupational safety and health legislation.

BAuA undertakes a written consultation, and for certain specific cases they bring RMOAs forward at the RiME+ meetings. Whilst the consultation process is useful to share concerns before the regulatory process starts, it can on occasion be difficult to get detailed feedback, with only certain Member States providing comments.

The German authorities continue to collaborate with other Member States, which usually involves allocating the environmental assessment and human health assessment separately to each Member State, as this is the easiest way to operate.

Selection of RMOs

BAuA considers RMOs under REACH and those outside of REACH (i.e. occupational safety and health legislation, Water Framework Directive (WFD)). The main factors BAuA considers when selecting the most appropriate follow-up activity include:

- Hazard type (i.e. does the substance meet SVHC criteria (CMR, PBT, vPvB, ED or ELoC substances));
- Substance uses (i.e. consumer, professional, industrial use; intermediate uses; uses with emissions to the environment);
- Existing regulation; and
- Socio-economic information (i.e. how many companies will be affected and in what manner).

Availability of alternatives is also considered but it is not a major factor. In future, BAuA believes it could be beneficial to factor in overseas regulatory action, when applicable. From experience, BAuA has found that emissions can occur from use of mixtures and substances containing the hazardous substance as an impurity or constituent, so this also needs to be considered when selecting the most appropriate follow-up activity.

Administrative aspects

BAuA typically completes an RMOA in nine months, but this can range from six to twelve months. The speed of the assessment process has increased in the last few years as BAuA has gained experience and established working processes.

The main factors influencing the timeframe is waiting for data and translation of information, which can cause an RMOA to remain open for two to three years. The availability of resource also

has an impact, as sometimes there is competing work of greater priority, which can increase the timeframe. However, once an RMOA has been initiated, BAuA aims to finalise it with the resources available.

Populating the RMOA with the necessary information does not take long. Most of the time is spent circulating the document for consultation to ensure everyone has the opportunity to input, and in reaching a conclusion, as there are a lot of aspects that need to be considered in order to ensure the right decision is reached.

Strengths and weaknesses

BAuA has a very positive experience with consultation activities, which have provided valuable exposure information, monitoring data, and measurements from workplaces. However, consultation activities only reach industry using the substances of concern being targeted, and do not reach those using the alternatives, which makes it difficult to obtain information on the availability of alternatives.

Consultation activities could be more valuable if feedback was provided from a greater number of Member States, and input was received from other non-industry stakeholders.

3.5.3 Sweden

Substance selection

In autumn 2019, KEMI developed a more systematic way of prioritising substances for RMOA, which consists of an internal prioritisation system combining information on hazard type and total EU registered volumes and uses, with internally derived priorities, which include:

- Substances posing a risk for which regulatory action is required;
- Substances found in drinkable water; and
- Substances or endpoints that KEMI has previous experience working with.

The output of the system is a prioritisation index, from which the substances with the highest prioritisation are selected for RMOA, as long as the required expertise is available. Government interest in a substance, or group of substances, would also constitute a high internal priority when selecting substances.

KEMI has a list of substances identified as candidates for RMOA, that have been run through the system. KEMI usually starts with substances that have the hazard profile of a potential SVHC substance, as there is general agreement that substances with these properties should be substituted, if possible. However, on a case-by-case basis it is possible to target other issues and concerns.

Substances for which there is overseas regulatory action may be included on the screening list, but they are considered along with EU exposure, as there must be an EU issue surrounding a substance.

Reprotoxic substances are one of the concerns previously targeted by KEMI as these are harmful to unborn children. Reprotoxic substances have been targeted because KEMI were commissioned by the Swedish government about 10 years ago to focus on chemicals impacting the everyday lives of Swedish citizens. Other substances of national concern are PFAS substances, and for a long

time, certain metals such as lead and cadmium. Grouping of substances is a new direction being taken by the Swedish government as it is seen as being of increasing importance.

Information sources

The main information source used in the development of RMOAs is REACH registration dossiers. KEMI also frequently considers information in the Swedish Product Register, which is kept up to date as it is compulsory to report substances and mixtures placed on the market to the Register. If KEMI can see an increasing trend of substance use in the Register, this indicates that the substance is of importance and worth investigating further.

KEMI are of the opinion that all the information needed to complete an RMOA should be in the registration dossiers and this is the message they try to communicate to industry. If industry want KEMI to base their conclusions on correct data, then it is their responsibility to ensure their registrations are kept up to date.

KEMI do not hold a public consultation, but they have been approached by industry on several occasions, and in these instances, they have been willing to accept a dialogue with industry during preparation of the RMOA. For the majority of RMOAs, KEMI are not approached, albeit that it is public knowledge an RMOA is being performed. Sometimes a lack of good quality data can make it difficult to conclude whether there is a risk surrounding a substance. Information on alternatives is also frequently lacking as only industry tend to have this data. While it may be possible to obtain this data, it can be a lengthy process which may delay actions, and there are limits to how much time and resource can and should be spent on an RMOA.

Hazard and risk assessment

For the majority of RMOAs, KEMI performs a qualitative assessment. In a few instances, a quantitative assessment has been used but this has not led to any robust conclusions.

KEMI considers all substance uses during a risk assessment and are most concerned with widespread professional uses and consumer uses, rather than industrial uses where the exposure and release is more contained and easier to control.

Working arrangements

Substances are assessed on a case-by-case basis and the majority of the work is undertaken within a specific KEMI unit. KEMI makes use of the annotated ECHA template, although it can be used freely, and it is not rigid in nature. Given the voluntary nature of RMOAs, KEMI finds that some flexibility regarding the structure and format is required, so long as the RMOA remains fit for purpose and easy to read by other MSCAs. On occasion different headings are used to improve readability, while sometimes there are methodological aspects that need to be considered (e.g. investigation of impurities), which require some deviation from the template.

KEMI makes use of a checklist developed by ECHA, which highlights aspects that need consideration and provides guidance on structuring information in the RMOA. The checklist is aimed at generating a more thorough discussion on the consequences of taking regulatory risk management action.

KEMI always shares a full draft RMOA during written consultation with other Member States. The document is placed on the S-CIRCABC platform for a 3-week comment period. Generally, around three to five Members States provide comments, with some Member States being more active than others, while some Member States never provide comments. Depending on the comments received, KEMI may make changes before they finalise the RMOA, but there is no requirement for consensus between Member States.

Prior to finalising an RMOA, it can be brought forward to a RiME+ meeting, which are used by KEMI for discussion on preliminary findings, for approximately one in ten RMOAs. Discussions at RiME+ meetings are focused on more general issues (e.g. issue of impurities), rather than on specific substances and RMOAs.

On a case-by-case basis KEMI may circulate an RMOA amongst Swedish government authorities, but this is not normally the case.

Selection of RMOs

The main factors KEMI consider when selecting the most appropriate follow-up activity include:

- Hazard type (i.e. does the substance meet SVHC criteria (CMR, PBT, vPvB, ED and ELoC substances);
- Substance uses; and
- Effectiveness and appropriateness of a regulatory framework for managing the concern.

Socio-economic information and availability of alternatives are considered if this information is available. The level of consideration depends upon the follow-up activity being proposed (i.e. to a lesser extent if the follow-up is harmonised classification, and to a greater extent if the follow-up is restriction). Some assessments have also taken RMOs outside of REACH into account, meaning that an agency separate to KEMI would need to follow-up on specific issues. However, in practise this type of follow-up activity from a separate agency is uncertain as they may have different priorities. For this reason, KEMI tends to stick with forming REACH recommendations, which they can actively follow up on.

Administrative aspects

KEMI typically complete an RMOA in 20 to 30 full time working days. The main factor influencing this timeframe are:

- Complexity;
- Competing work tasks;
- Involvement of other Member States; and
- Interpretation of an intrinsic property and whether involvement of an expert group is needed.

The average cost of completing an RMOA is 275,000 SEK (€26,000) but this can range from 20,000 SEK to 1,000,000 SEK (€1,900 – €95,000). Collaboration with other Member States often takes longer and costs more than non-collaborative RMOAs. These are most efficient in terms of time and cost when the collaborating Member States have a similar organisational structure and there is a clear separation of tasks.

Strengths and weaknesses

KEMI finds that the consultation process and sharing RMOAs with other Member States is a particular strength.

3.5.4 The Netherlands

Substance selection

Bureau REACH[5] has primarily been using ECHA's Integrated Regulatory Strategy as the main route for identifying substances and substance groups requiring further action under REACH. ECHA performs an IT screening based on shortlisting criteria and then brings forward a list of substances to Member States for further manual screening.

In additional, Bureau REACH has a project on new and emerging risks, which mines information from various internet and literature sources, and signals obtained through enforcement and poison centres, as these are becoming an increasingly important element in the Netherlands' national selection procedures.

Substances currently being brought forward as candidates for RMOA are becoming more complex and are requiring more work in terms of substance evaluation and their classification and labelling.

National priorities influencing selection of substances includes:

- Substances produced in the Netherlands (i.e. substances with Dutch registrants);
- Substances found in the environment or in Dutch citizens; and
- Substances used in significant amounts with possible concerns for workers.

Bureau REACH considers any substance which has a concern for human health or the environment in the Netherlands as a priority. Previously, Bureau REACH had been particularly interested in skin sensitisers and Article 57(f) substances (i.e. ELoC substances). PFAS substances are also currently high on the political and public agenda. Bureau REACH produces a list of substances and substance groups, which are important to follow up on, that is then discussed with the Ministry to decide which substances are of highest priority, and it is at this stage that political and public pressure are also considered.

Bureau REACH follow overseas regulatory action, and this can trigger or emphasise concern, but an RMOA has not currently been initiated purely on the basis of overseas regulatory action.

Information sources

The main information source used in the development of RMOAs is REACH registration dossiers as these should contain the most up to date information on hazard and exposure. However, Bureau REACH also look at internet sources and academic studies to find additional information, such as possible substance uses.

When starting an RMOA, Bureau REACH always notifies the registrant and informs the Ministry, who organise further downstream communication through contacting sector-specific

[5] Within the Netherlands the competent authority (the Ministry of Infrastructure and the Environment – MINIEM) delegates RMOA work to Bureau REACH, a part of RIVM. Bureau REACH is responsible for the coordination of the RMOA work and produces draft RMOA documents which are discussed with MINIEM.

organisations. Bureau REACH does not hold a public consultation but if they have further questions they actively consult the registrants to clarify certain uses and exposure concerns. From experience, registrants are very collaborative, but sometimes they do not always understand each other, and it can be difficult to get clarity on a particular issue. Due to the time pressure involved in performing an RMOA, Bureau REACH cannot always wait to receive all the information industry are able to provide.

Where there are uncertainties due to data gaps in the risk assessment, which usually concern use and exposure, a precautionary approach is adopted. Bureau REACH are open to precluding that no regulatory follow up is needed when uses are sufficiently contained, but frequently this cannot be concluded due to insufficient evidence through lack of information.

Hazard and risk assessment

In the Netherlands, RMOA is seen as primarily a hazard evaluation, with the risk assessment as a secondary step.

Working arrangements

Bureau REACH has thorough and established processes for conducting RMOAs and for dividing up the work. Experts from two or three RIVM units write the hazard and exposure sections of the RMOA based on information found in the registration dossiers and through screening of additional scientific literature. The experts are often contracted for RMOA work and most have already been involved for a long time in screening dossiers. Bureau REACH typically involves one expert for the human health assessment, one for the environmental assessment, and one for the exposure assessment. Bureau REACH then prepares the full draft RMOA, in which a first scoping of RMOs is performed. This is then discussed with the other Bureau REACH coordinators (i.e. those responsible for authorisation, restriction, and CLP). If substance uses extend to cosmetic and biocide applications then Bureau REACH involve discussions with the relevant authorities to understand what they might need in terms of further regulatory measures under REACH, or to see if they are already taking up these concerns themselves. When drafting an RMOA, Bureau REACH uses the ECHA template as much as possible.

Bureau REACH always consults with other Member States in the last stage of the RMOA process. There is a written consultation process where all Member States are invited to comment. Bureau REACH also make use of the RiME+ meetings for the opportunity to have a face-to-face discussion on certain substances or substance groups posing particular challenges, or for which there are certain methodological issues of interest. There is no obligation to consult others, but it is regarded as best practice to do so. There is an informal control mechanism to make sure those RMOAs, for which an oral discussion would be beneficial, are brought forward to the RiME+ meetings.

Selection of Risk Management Options

Bureau REACH begin by scoping the concern and then finding which regulations may act on that scope. Bureau REACH assesses the extent to which further regulation under REACH would support any existing regulation, and the impact of any regulation under REACH.

Bureau REACH differentiates between different uses by considering which uses would warrant restriction or authorisation, and which would be more appropriately regulated under other legislative frameworks.

The main factors Bureau REACH considers when selecting the most appropriate follow-up activity include:

- Proportionality (i.e. the recommended follow-up should address the concern and not much more);
- Timeliness;
- Efficiency; and
- Effectiveness (i.e. the recommended follow-up should not regulate elements that are better regulated in another regulatory framework).

Socio-economic information is always considered in some way, but this is mostly at the level of type of uses, production volume, number of registrants and downstream user sectors, and availability of alternatives. Assessment of alternatives is always difficult because there are no databases on alternatives, and it can be challenging to get this information from academia and industry.

Bureau REACH has begun a project, which is expected to be delivered in April 2020, to investigate how to make the evaluation of socio-economic elements more systematic and get a better understanding on the type of arguments that can be included to decide on the most appropriate RMO. Bureau REACH are also looking to what extent they are not using socio-economic information which is easily assessible that could add to the decision-making process in the RMOA, which will hopefully add to the strength of discussion.

If it is concluded that further action under other legislation is needed, Bureau REACH passes the findings back to their Ministry who can then consult with the other Ministries responsible for the relevant legislation. However, there is no established process in place to make sure that they follow-up on this. There is also the issue that the priority Bureau REACH attaches to the concern may not be equal to that given to the concern by the other Ministries.

Administrative aspects

Bureau REACH has the target of completing each RMOA within one year, but where the assessment is highly complex or has lost priority, it can end up being shelved and taking longer. In future, the aim is to reduce the timeframe to six months to a year. On average around 60 hours are needed to complete an RMOA.

The main factors influencing the timeframe are:

- Interaction with other actors in the supply chain, and the back and forth of information exchange;
- Generation of information by industry;
- Availability of resources; and
- Assessments which fall between different regulatory frameworks.

The first two months of an RMOA are always the most efficient but Bureau REACH can then spend one to two years checking to see if there is still more insight to be gained which may lead to a different conclusion. Often the initial conclusion reached after the two months is maintained.

Collaboration with other Member States works best where this is clear division of the workload, such as allocation of the human health assessment and environmental assessment to individual

Member States. While the overall time spent on collaborative RMOAs is longer, the time spent by each Member State is less than if they were performing the whole RMOA themselves.

Strengths and weaknesses

A strength of the RMOA process is that is serves as a good discussion point and is effective at scoping concern and possible regulatory actions. One of the drawbacks of the process is that it can be time consuming to consult with all actors and allow everyone to have their input, but on the other hand it gives some assurance and confidence that the right decision is reached.

3.5.5 United Kingdom

Substance selection

The Environment Agency select substances from a series of evaluations performed under REACH. Primarily, these are substance evaluations, which follow a formal process, but some assessments are voluntary and are outside of the formal REACH process. An example of an informal evaluation, would be the evaluation of Dechlorane Plus, which the Environment Agency had particular interest in. The UK do not begin an RMOA until a risk is identified in the conclusion of an evaluation.

Many of the substances the UK has selected for RMOA are those which have been of historic interest. Prior to REACH, the Environment Agency produced a series of reports, mainly under the Dangerous Substances Directive, on various types of products and this work has been the main source of candidate substances for evaluation under REACH. It is expected that in future, the Environment Agency will place greater emphasis on substances detected in environmental monitoring.

The UK also have an interest in substitutes or potential substitutes of chemicals that have come under risk management. One such example is Dechlorane Plus, an alternative to decaBDE that was nominated as a POP and restricted under REACH, and the UK were aware that there may be similar concerns surrounding the substance.

The Environment Agency work jointly with the HSE on RMOAs, with the Environment Agency being responsible for the environmental assessment and the HSE being responsible for the human health assessment. Due to this organisational set up and the limited resources and time at hand, a balance needs to be struck between the environmental priorities and human health priorities of substances selected for RMOA.

There is very little political and public pressure on the Environment Agency's selection of substances, but in the first few years following the UKs withdrawal from the European Union, there is expected to be increased external scrutiny from industry, the Chemical Stakeholder Forum, and NGOs as to why the UK are picking certain substances.

Overseas regulatory action is not a primary consideration for substance selection as other jurisdictions have different legislation and regulatory drivers, which can lead to different conclusions regarding chemical risk. However, when beginning an evaluation, it is standard practice to take a global perspective and see if other authorities are looking into the same chemical.

Information sources

The main information source used in the development of RMOAs is chemical safety reports, in addition to which, academic literature, monitoring data, and the findings of the substance evaluation are also used. Information from outside the EU is considered if it exists, although its relevance needs careful assessment.

If additional information is required, the UK have the option to arrange a Call for Evidence through ECHA in order to reach out to industry. The Environment Agency also invites the registrants to participate in a dialogue during the preparation of an RMOA, to get their input and provide them with prior warning. These dialogues are seen as highly valuable as registrants are generally very cooperative and provide useful information, such as the availability of alternatives and potential barriers to substitution. During the dialogue with industry and registrants, the UK prefer to have a face-to-face conversation if possible, but often the companies they are dealing with are not UK based, in which case they hold a telephone conversation.

Despite the various information sources used, there are often some data gaps remaining, which tend to relate to socio-economic information and article imports. The UK does not have information on quantities of imported articles, the level of release from articles, and the types of articles releasing substances. Hence, there is no way to know the quantities of substances imported. This has historically been an issue and it is likely to continue into the future.

The UK does not want to disturb supply chains inadvertently. Therefore, they tend not to have detailed conversations with downstream users or their trade associations during the RMOA stage. For this reason, the UK also does not carry out public consultation as part of the development of an RMOA.

The UK has had conversations with overseas regulatory authorities to obtain information. This has primary been with the Canadian regulatory authorities as they are among the most active regulators that the UK has dealt with. These include *ad hoc* exchanges of documents and information.

Hazard and risk assessment

The UK only begins an RMOA if they have already identified a risk, and therefore a risk assessment has already been performed. This would be either a deterministic PEC/PNEC assessment, or a qualitative assessment for PBT and vPvB concerns where a risk is assumed if there is environmental emission. In relation to ED substances, the UK believes that a quantitative risk assessment can be used, which is a potential area of divergence from the EU moving forwards, as the EU generally assumes that ED substances pose a non-threshold concern.

When performing a risk assessment, the UK tries to prioritise substance uses which pose the greatest risk. As an example, a UK RMOA indicated wash-off personal care products were by far the biggest source of emissions of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5), and therefore a REACH restriction should target these end uses. Emissions from other sources posed less of a concern so the UK recommended that industry monitor these emissions to see how the environment was responding, and then implement more stringent measures if required.

Working arrangements

The risk management team in the Environment Agency consists of three specialists, with a counterpart team in the HSE. The Environment Agency perform the majority of the work if there is an environmental concern and the HSE perform most of the work if there is a human health concern, with the Environment Agency only being brought in if there are substitutes with properties that would have an environmental concern, or the risk arises because of human exposure via the environment.

When drafting an RMOA, the UK adopts a basic template which alters slightly for each substance depending on the amount of information available. The UK tries to be as comprehensive as possible but if there is no information on a section then this is stated clearly.

UK RMOAs are typically long documents as they try to remain objective and present all the evidence before making a decision. The UK aims to make their effort proportionate to the level of concern posed by a substance. There is also the need to strike a balance over the level of detail to include in an RMOA as they should be easy to read and understand, while still providing enough detail to transparently justify the recommended follow-up action. Therefore, the UK like to publish full RMOAs for public transparency purposes.

RMOAs are also circulated widely throughout UK government for consultation (e.g. policy teams at Defra, devolved administration governments and their environmental regulators, cosmetics regulator, etc.). The views expressed are taken into account before the RMOA is circulated at a RiME+ meeting to try and get a harmonised UK view before it is presented to the EU.

Selection of Risk Management Options

The primary follow-ups recommended are restriction and authorisation, but the UK also looks at other legislation such as the WFD, Environmental Quality Standards (EQS), and RoHS. The main factors the Environment Agency considers when selecting the most appropriate follow-up activity include:

- Hazard type;
- Substance use and industry size (i.e. if a substance has many uses an authorisation route would potentially generate a high workload for ECHA and its committees if substitution is not likely to be straightforward);
- Scale of article importation (i.e. if this is a significant source of exposure, authorisation is not an effective option);
- Enforceability (i.e. analytical methods need to be available to enforce the measures); and
- Alternatives (i.e. if alternatives are not readily available then restriction might not be a suitable option)

Usually there is very little socio-economic information available at the outset. If the UK has been working on a chemical for a long time (e.g. MCCPs) then some information might have been collected already, but this is an exception. If an authorisation route is chosen, it is up to the applicants to supply socio-economic information, but if a restriction route is chosen, the Environment Agency and the HSE would have to specifically collect relevant data from the registrants and their supply chains. Socio-economic information is therefore not needed to make a decision about which route to go down, but is useful if it is available.

The Environment Agency always needs to get policy approval from Defra before proposing formal risk management action that may arise from an RMOA.

Administrative aspects

The typical timeframe for an RMOA is three to nine months, with a couple of months being spent on drafting the RMOA and a further few months spent on the consultation. The main factors influencing the timeframe are:

- The amount of information available;
- Timings of the data gathering activities; and
- The level of uncertainty (i.e. more time may be required to reduce these with consultation or a Call for Evidence).

All the work is performed internally, meaning there are only staff costs, although these are not recorded.

Strengths and weaknesses

The Environmental Agency finds the ECHA template to be a very useful tool for providing guidance on what aspects need to be considered.

Industry engagement with the RMOA process could be improved, as while it often proves very valuable, it is sometimes limited. An example is the Dechlorane Plus RMOA, where one of the two major suppliers provided detailed information about their supply chain, whereas the other supplier did not respond. In the ECHA Call for Evidence only a couple of large companies responded.

Another weakness is the voluntary nature of the RMOA process, which leads to a lot of variability in the quality of RMOAs. Greater consistency could be achieved if the RMOA was a formal requirement that had to be agreed by consensus between Members States.

4 Summary of Key Findings

4.1 Existence of RMOA

A direct equivalent to the EU RMOA system does not exist in any of the non-EU jurisdictions examined in this study. However, the four non-EU systems all include features that resemble some elements of the RMOA process.

The **Australian and Canadian** systems include relevant elements with regard to substance selection, risk assessment and selection of the most appropriate regulatory management tool. However, these procedures are a part of a more general, and largely automatic, chemicals management legislative framework that is designed to address all hazardous substances in a consistent manner rather than to provide a tool for ad-hoc assessments or manage regulatory complexity or overlap.

In **Australia**, NICNAS are responsible for the assessment process. Under a service agreement with NICNAS, officers from the Department of Health carry out occupational health and safety and public health assessments, and officers from the Department of the Environment and Energy conduct environmental assessments. The outcome of the screening process includes recommendations for risk management measures which are published on the NICNAS website.

In **Canada**, the process of risk assessment also includes consideration of the most appropriate risk management tool which can be drawn from a variety of legislative and non-legislative instruments. The final decision is published in the Canada Gazette, including a summary of the assessment, the proposed measure and, in the case of a substance recommended for addition to Schedule 1 (Toxic Substances List), a statement indicating the manner in which a proposed regulation or instrument will be developed.

In **New Zealand**, there are two areas of similarity to an RMOA:

1. 'Routine' risk management of substances through assessment/reassessment and approval processes; and
2. Reassessment candidate selection for NZ EPA-driven reviews of substance approvals.

Some procedures under the HSNO Act could resemble an RMOA. The application processes for approval or reassessment of hazardous substances involves a risk assessment and then risk management options (controls/rules) can be introduced (although it is considered that 'controls' in New Zealand have a broader meaning than Risk Management Options within the EU RMOA and that most are 'prescribed controls', i.e. triggered by hazard classification alone). Other controls that are more risk-driven in nature may be applied as additional controls, or variations to the prescribed controls.

The **US** system also includes features that resemble an RMOA. For example, a range of different tools can be used to manage risk, including TSCA or OSHA.

In the **EU**, an RMOA process is in existence with examples of the possible RMOs including, REACH authorisation, restriction, and OSH legislation (including OELVs). RMOA in the EU is a voluntary process where the authority responsible for the specific assessment is free to choose the most appropriate approach to the assessment and reporting. A voluntary template has been developed to encourage a consistent way of presenting the results of the RMOA.

In general, **all the study countries** provide a high degree of transparency and publish documents relating to risk assessments and risk management decisions. In the **EU**, due to the voluntary nature of the RMOA process, it is up to the Member States to decide whether they want to publish only the conclusions or the whole RMOA document.

4.2 Substance selection

The **New Zealand** system differed from the other study countries as it was the only one to have a specifically developed screening tool for selecting substances for reassessment, while **Australia**, **Canada** and the **US** selected substances based on certain prioritisation criteria. Some of the common characteristics were PBT chemicals; probable or known carcinogens; and chemicals of potential concern to babies and children.

Across all the study countries, there was no single pathway or mechanism for selecting substances for assessment. In New Zealand and the US, risk assessments could be requested for a substance by external stakeholders. Public concern around a substance was also a means of prioritising substances for assessment in New Zealand and Australia.

All of the study countries considered information from a wide range of sources in their selection of substances, which included information from domestic regulatory activities and initiatives, and regulatory action and concern of overseas authorities.

The number of substances being prioritised for assessment differed widely across the study countries. Australia and Canada both have a tiered risk assessment system, which feature a high-throughput approach to screening chemicals. Australia has screened around 3,000 chemicals, while Canada has screened over 4,000 chemicals and has an annual target to complete 500 risk assessments. This is in contrast to the US system, where the US EPA had an initial work plan of 10 chemicals to undergo risk evaluation and has the target of conducting at least 20 risk evaluations at any one time. New Zealand has screened around 800 substances and has a list of 40 high priority substances for assessment. In the EU, ECHA is currently mapping the 'chemical universe' which includes over 21,000 REACH registered substances, into five pools based on the regulatory actions in place, initiated or considered for them. ECHA's goal is to conclude by the end of 2020 for all substances registered over 100 tonnes per year whether they are: a priority for regulatory risk management; currently of low priority for further regulatory action; or more data is needed for a judgement to be made. The aim is to draw these conclusions for the remaining registered substances by the end of 2027.

In the individual **EU Member States**, one of the primary sources for selecting substances or substance groups for RMOA is the results of ECHA's IT screening performed as part of their Integrated Regulatory Strategy, with Germany and the Netherlands both citing this as their starting point for substance selection.

Both the Netherlands and Sweden have additional means of selecting substances. KEMI have developed an internal prioritisation system combing information on hazard type and total EU registered volumes and uses, with internally derived priorities, while Bureau REACH have developed a system for identifying new and emerging risks, which mines information from various internet and literature sources, and signals obtained through enforcement and poison centres.

All Member States mentioned the use of national priorities as the main factors for selecting substances to undergo an RMOA, across which some similarities and common concerns were shared by Member States. Some common concerns were PFAS substances, which were considered

to be of high importance to Sweden, Germany and the Netherlands, and substances indicated by human biomonitoring and environmental monitoring as being of potential concern, which were a priority for both Germany and the Netherlands, and in future it is also expected to be a priority in the UK. In Germany, and especially the UK, substances of historic interest and who which work had previously been conducted by their national competent authorities were of high priority. In the UK this was how the majority of substances to undergo RMOA were selected.

Political and public pressure was also a factor in selection, but the extent to which is was considered varied widely across the Member States. In Sweden, political interest in a substance was seen to be a high internal priority when selecting substances, whereas in Germany and the UK there was very little political and public pressure. However, it is expected that this may change in the UK during the first few years following the UKs withdrawal from the European Union, as there is expected to be increased external scrutiny from industry, the Chemical Stakeholder Forum, and NGOs as to why the UK are picking certain substances.

Overseas regulatory action was considered by all Member States in the study, but it was not a primary consideration and RMOAs have not been initiated purely on this basis. This is because other jurisdictions have different legislation and regulatory drivers, which can lead to different conclusions regarding chemical risk, and so there must be an EU issue surrounding the substance for it to be selected for RMOA.

4.3 Information sources

In the individual **EU Member States**, the main information source used during the development of RMOAs was cited as REACH registration dossiers by Sweden, Germany and the Netherlands, with Germany also citing chemical safety reports as a primary source, along with the UK.

In addition to these, Sweden consider information on substances and mixtures placed on the market contained in the Swedish Product Register. The UK obtain further information from academic literature, monitoring data, and the findings of substance evaluations, while the Netherlands also utilise academic literature and internet sources.

It was mentioned by KEMI that they are of the opinion that all the necessary information should be found in the registration dossiers as these should be kept up to date with the correct data. Consequently, Sweden do not hold a public consultation, but they do however accept a dialogue with industry if they are approached. The Netherlands and the UK take a more proactive stance and actively engage with registrants. Bureau REACH notify registrants if their substances are undergoing an RMOA and consult with them to clarify certain uses and exposure concerns. The Environment Agency invites registrants to participate in a dialogue during the preparation of an RMOA, to get their input and provide them with prior warning of potential upcoming regulation.

Germany are the only Member State in the study who hold a public consultation. These are hosted for each RMOA on the BAuA REACH helpdesk website. They usually last for 2 months, after which all participants are invited to a face-to-face meeting, in order to further discuss their contributions and get any clarification on their comments. The consultation is not just Germany focused, but is widespread, with feedback being received from companies all across the EU. When the consultation starts, BAuA inform all the registrants, sector specific organisations, industry associations, and they try to reach downstream users by inviting those that have notified the substance under harmonised classification and labelling.

One of the reasons cited for not conducting a public consultation was the concern that this would cause unnecessary alarm and disruption in the supply chain, but BAuA decided to deal with this by engaging with industry and the supply chain to give them the possibility of getting in touch and discussing their concerns. Industry consultation and dialogues with registrants were generally seen by the Member States as being positive and highly valuable, with registrants being very cooperative and providing useful information.

Germany and the UK have both used information from overseas regulatory authorities. In the UK this has been more collaborative and has involved exchanges of documents following conversations, mainly with the Canadian authorities, while in Germany there is no internal information sharing as BAuA only look at what is publicly available. Any information outside the UK requires careful assessment of its relevance.

It was mentioned by Sweden and the Netherlands that limited resources and the time pressures involved in performing an RMOA, mean that not all information that industry are able to provide is used because there can be lengthy delays due to information provision.

4.4 Hazard and risk assessment

All countries featured a risk characterisation where hazard and exposure are considered together. The approach taken by Australia and Canada were similar as they both feature a tiered system, with the first tier having a high-throughput, and the complexity and rigour of assessment increasing with each tier. EU RMOAs strive to consider risk but a full, quantitative or monetised assessment of human health or environmental effects is rarely provided. A combination of hazard information and use pattern is the main way of approximating risk and providing an indication for need of regulatory measures in the EU.

In carrying out hazard and risk assessments, all the study countries drew information on hazard and exposure from a range of sources, such as internal databases, approval documentation, product labels, monitoring and study data, stakeholder engagement and public consultation, databases of overseas regulators, predictive models, and external peer review. It was mentioned by both the Australian and New Zealand authorities that a lack of information of domestic substances use and volumes is a key challenge to many assessments. In Australia and New Zealand this was lacking for the majority of screened substances, and so databases of overseas regulators, such as ECHA's database of registered substances has been very useful in providing a better understanding on how substances are used commercially.

Throughout the risk assessment process, stakeholder engagement was a key component in all the study countries. In general, EU Member States will try to consult with the industry when elaborating an RMOA. However, the degree to which data from consultations was used varied significantly between Member States. Several authorities carried out either targeted or public consultation activities with a range of stakeholders whilst for others, no formal consultation activities existed. All non-EU countries had a public consultation period for assessments, with any comments and information received being taken into consideration before the final conclusion of each risk assessment. In addition to public consultations, in New Zealand, stakeholders can request a public hearing in order to present a submission directly to the decision makers. The US EPA holds four comment periods: two in the prioritisation stage, one in the scoping phase, and one in the risk evaluation stage. Furthermore, at any time during the process, stakeholders can contact the US EPA to set up a meeting if they have new data or data is not known or available to the US EPA. General and targeted voluntary calls for information to stakeholders were found to be a source of valuable information for risk assessments. In Australia these provided use and/or

volume information for 350 chemicals, including 89 chemicals for which NICNAS previously held no data.

In all the study countries substances were grouped together to gain efficiencies in assessment of hazard and risk.

In **Australia**, NICNAS included additional chemicals into groups of chemicals that were already being assessed as part of IMAP Stage One. This resulted in 416 extra chemicals being included in the Stage One list by the end of December 2015. Internationally accepted approaches to grouping chemicals and read-across between chemicals based on similar characteristics (e.g. physico-chemical properties) through the application of QSAR tools were used to reach conclusions on the toxicity profile of certain chemicals. OECD guidance and expert judgement were used to formulate AICS-specific groupings. Several factors are considered when grouping chemicals, including similarity of chemical structures, similarity in toxicological structures, and use/volume and exposure patterns. Additional grouping criteria, such as 'likelihood of no industrial use' were used for chemicals with extremely limited hazard and/or exposure data.

The **US** EPA has use categories, which several uses fall under, to group similar exposure patterns. As an example, there is a group of seven phthalates that have been grouped together during prioritisation and risk evaluation since they have similar functionalities.

In **New Zealand**, EPA-initiated risk assessments are often carried out for a group of related substances. Examples include groups of organophosphate and carbamate substances, antifouling paints, and groups of substances with the same active ingredient.

In **Canada**, the second and third phases of the Chemicals Management Plan involved grouping of substances prioritised for assessment, in order to capture similarities and create synergies.

Collectively, the **EU Member States** in this study are of the opinion that RMOAs should not constitute a full risk assessment, with a qualitative assessment being favoured over a quantitative risk assessment. There are a few instances where KEMI have performed a quantitative assessment, but they did not result in any robust conclusions. The UK perform quantitative risk assessments were a PEC/PNEC value can be determined, and for ED substances, which is a potential area of divergence from the rest of the EU, as they generally assume that ED substances pose a non-threshold concern. In the Netherlands, an RMOA is primarily seen as a hazard evaluation, with the risk assessment as a secondary step.

Sweden, the UK and the Netherlands all differentiate between different substance uses in the risk assessment, with Germany being the only Member State in the study to not differentiate between individual uses. Bureau REACH differentiate between different uses by considering which uses would warrant restriction or authorisation and which would be more appropriately regulated under other legislative frameworks, and Sweden and the UK prioritise those substance uses posing the greatest risk, which for KEMI are widespread professional uses and consumer uses.

4.5 Working arrangements

In the individual **EU Member States**, RMOAs are generally performed by small teams of specialists working in specific assessment units, with the human health and environmental assessments conducted by separate units. For example, in the UK the human health assessment is carried out by the HSE and the environmental assessment is carried out by the Environmental Agency, while in German. Division 4 at BAuA and the BfR deal with human health aspects and the UBA deals with all environmental aspects.

All the Member States in the study conducted a written consultation where other Member States are invited to comment on the draft RMOA. A common issue voiced was the difficulty in getting detailed feedback, with typically the same three to five Member States providing comments. It was also expressed by Sweden and the UK that amendments in light of any feedback are not compulsory as there is no requirement for consensus; so this can mean that the Member State who drafted the RMOA retains their position.

In addition, all Members States mentioned use of RiME+ meetings as a means of consultation. Generally, these were used in instances where the was disagreement between commenting Member States, if substances or substance groups were particularly challenging, or if there were broader methodological aspects to discuss, such as investigation of impurities. Bureau REACH mentioned that although there is no obligation to consult with other Member States, it is regarded as best practice to do so. There is an informal control mechanism to make sure those RMOAs, for which an oral discussion would be beneficial, are brought forward to the RiME+ meetings.

Sweden, Germany and the Netherlands all make use of the ECHA template as much as possible while the UK adopt a basic template which alters slightly for each substance depending on the amount of information available. Both Sweden and Germany reported that alterations are required to the template, such as the use of different headings or additional sections. Examples of aspects requiring deviation from the template include justification for substance grouping, certain methodological issues of interest, such as investigation of impurities, and discussion of advantages and disadvantages of regulatory action under REACH compared with regulatory action under other legislation. Due to the voluntary nature of RMOA, flexibility regarding the structure and format were seen as important by KEMI and BAuA, provided RMOAs remain fit for purpose and easy to read by other Member States.

4.6 Selection of RMOs

In **Australia**, there are three main pieces of legislation under which public health risk management options are established. These are:

- The Model WHS Laws that aim to protect the health and safety of workers, for which SafeWork Australia are responsible. Risk management options include Codes of Practice, exposure standards, and GHS classification;
- The Therapeutic Goods Act 1989, under which substances can be scheduled to allow restrictions and conditions to be placed on their supply to the public; and
- The Competition and Consumer Act 2010, which is enforced by the ACCC and covered product safety and labelling. Risk management options can include restrictions or bans on certain products exceeding safe concentration limits of hazardous chemicals.

There is no overlap between these laws, so when a risk is identified it is clear what risk management approach needs to be taken. Currently, risk management recommendations have been made for about 3,250 chemicals.

When selecting risk management options, proportionality is a key aspect as the level of recommended risk management must be proportionate to risk. Risk managers will also take socio-economic information, availability of suitable alternatives, efficiency, and the use-scenarios into consideration as part of their process of implementation.

In **Canada**, RMOs can be split into four groups:

- Voluntary approaches – standards, codes of practice;

- Joint federal provincial/territorial/Canada-wide standards;
- Market-based instruments - financial incentives; and
- Regulatory measures – pollution prevention, chemical regulation.

To identify the most appropriate risk management instruments (mandatory or voluntary), a multi-dimensional but consistent and systematic approach is followed. Information on the sources of risk, and process guidance such as the Government of Canada's 'Cabinet Directive on Regulation, 2018', are taken into account.

The key decision-making factors include:

- Effectiveness and efficiency;
- Distributional impacts;
- Acceptability;
- Other jurisdictions; and
- Trade & investment.

In **New Zealand**, risk management options take the form of controls, which are restrictions or conditions that state how a hazardous substance can and cannot be used. The NZ EPA can also withhold or revoke approval for manufacture or import in New Zealand. Examples of risk management controls are limits on where a substance can be used, maximum concentrations or amounts in products, and handling conditions. The NZ EPA make best effort to align their risk management efforts with other authorities, but separate assessments are made by different authorities as they are intended to manage different risks. This means that management of different risk is mainly carried out independently. However, legislation requires that restrictions imposed under other legislation are considered when determining whether regulatory action by the NZ EPA is necessary or urgent.

Selection of RMOs differentiates between the different substance uses, and reflects who is at risk, whether that be workers, consumers, or the environment.

Decisions on whether to do this will consider whether it is necessary to realise beneficial effects, the relative effectiveness and cost effectiveness, and the likelihood that controls will achieve their intended purpose. Furthermore, the HSNO Methodology Order states that decision-maker must consider the degree of scientific or technical uncertainty associated with the assessment, and the effects on costs, benefits and effectiveness of making controls more or less restrictive.

In the **USA**, one of more RMOs are selected to the extent that a chemical substance no longer represents an unreasonable risk. The key RMOs that can be adopted by the US EPA are outlined in Section 6(a) of TSCA. If it is concluded that another legislation is better placed to manage a substance with unreasonable risk (e.g. OSHA Act), then the chemical is not likely to be regulated under TSCA. The US EPA selects the risk management option which gives the highest confidence that a risk is addressed. Risk management considers risk assessment information (scientific factors) and other factors, such as economic factors, social factors, technological factors, political factors, and public values. The availability of technically and economically feasible alternatives is also considered.

In the **EU**, all RMOAs consider all potential RMOs. Proportionality of action and achievability and feasibility of implementation are considered. RMO selection is not determined by hazard type, meaning the same hazard (i.e. Carc. 1B) may be regulated under different frameworks for different substances. At the Member State level, multiple authorities 'consider the whole picture' that

include a multitude of different factors. However, the approach is not entirely consistent between the different Member States.

In the individual **EU Member States**, the most cited factors that are considered when selecting the most appropriate follow-up activity include: hazard type, substance uses, effectiveness and socio-economic information. Other factors mentioned were proportionality, timeliness, efficiency, appropriateness, enforceability, and the level of existing regulation. On the basis of our study, a consideration unique to the UK is the scale of article importation.

Socio-economic information and availability of alternatives were considered by all Member States, but the extent to which they were considered varied, and was dependent on the availability of this information. For UK RMOAs there is often very little socio-economic information available, the only exception being if they have been working on a chemical for a long time. Bureau REACH have begun to look to what extent they are not using socio-economic information that is easily assessible, and are also investigating how to make the evaluation of socio-economic elements more systematic. The UK were the only Member State in the study to mention the availability of alternatives as a main consideration. It is difficult to conduct as assessment of alternatives because there are no databases on alternatives, and it can be challenging to get this information from academia and industry.

When selecting RMOs, all Members States considered both regulatory measures under and outside of REACH. One of the issues with recommending action under regulatory frameworks outside of REACH, is that the authorities responsible for these may not attach the same level of concern to a substance as the REACH competent authorities, meaning there is a degree of uncertainty with this approach.

4.7 Administrative aspects

Timescales

In **New Zealand**, for external applications the assessment work is carried out in approximately five to six months and for reassessments the statutory process takes 100 working days excluding pre-application work such as proposal development and overall it can be expected to take between one and three years to complete.

In a similar fashion, in **Canada**, decision on regulatory action and its implementation typically takes around 3.5 years. However, consultation is carried out at several stages of the process and this can add to the timescales. The 4,300 substances prioritised through Categorisation before 2006 are planned to all be reviewed by the end of 2021 but not all risk management initiatives will have been taken by then.

In the **US**, the process takes much longer although efficiency gains may be made as the EPA become more familiar with the system. Prioritisation typically takes 9 to 12 months, the risk evaluation process takes three years with a possible 6-month extension and the risk management process takes two years (one year to propose the measures and one year to finalise them). Once a proposed rule is cleared, the inter-agency approval process typically takes 60 days or longer. Overall, the process could take up to 6 years and 8 months.

In contrast, in **Australia**, to complete a medium complexity assessment, it takes around 16 days, while a more complex assessment takes 42 days.

In the **EU**, the timeframe of an RMOA is more of a reflection on resource availability and workload, rather than the complexity of a substance assessment as is the case in the other countries. RMOAs have taken anywhere between 2 months to 2 years. Since the RMOA is voluntary and does not have specific deadlines, it is often a stop-start process.

The typical timeframe for completing an RMOA varied widely across the **EU Member States**. KEMI had the shortest timeframe as on average RMOAs are completed in 20-30 full time working days, while the Netherlands aim to complete an RMOA within one year, which was the longest timeframe mentioned in this study. However, within this period, only 60 hours are spent on average by Bureau REACH. Germany typically complete an RMOA in nine months, but this can range from six to twelve months, and the UK timeframe ranges from three to nine months.

The most common factors influencing the timeframes were availability of resources due to competing work tasks, involvement of other Member States and stakeholders, and timing of information gathering and provision. The level of complexity and uncertainty surrounding the assessment, and assessments falling between different regulatory frameworks, also increase the timeframe. In Germany, RMOAs can remain open for two to three years due to some of these factors. Collaboration with other Member States is most effective when there is a clear division of the workload, such as allocation of the human health assessment and environmental assessment to individual Member States. Although the overall time spent on collaborative RMOAs is longer, less time is spent by each Member State than if they were performing the whole RMOA themselves.

According to both Germany and the Netherlands, the majority of time on an RMOA is spent circulating the document for consultation to allow all actors to have an input, and finetuning the initial conclusion, which is often reached in the first one or two months.

Costs

In **New Zealand**, the EPA absorbs the costs of EPA-initiated reassessments, and these can vary largely due to the size and complexity of a reassessment. A full reassessment costs NZ$30,000 and a modified reassessment costs NZ$12,650.

In the **US**, the EPA receives two-year appropriated funds to carry out the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Under the Act, the Agency is authorised to collect user fees (up to $25 million annually) from chemical manufacturers and processors. Fees collected will defray costs for new chemical reviews and a range of TSCA implementation activities for existing chemicals. The US EPA science team is about 100 people working on various types of reviews for both new and existing chemicals. This is supplemented by contractors, and sometimes experts from the US EPA's Office of Research and Development.

In **Australia** the staffing cost is lower. A human health assessment would involve 19-23 people and an environmental assessment would involve around ten people. The average staffing level dedicated to the operation of the Existing Chemicals Program, which includes undertaking PEC and IMAP assessments for both human health and the environment, was projected as 29.5 in 2015-16.

In **Canada** there is no cost data or estimates available. At the broad **EU** level the costs are also unknown because ECHA do not conduct many RMOAs themselves anymore. Of the **EU Member States** interviewed, cost information could only be provided by Sweden, who on average spend 275,000 SEK (€26,000) on an assessment - but this can range from 20,000 SEK to 1,000,000 SEK (€1,900 - €95,000).

4.7 Comparison Tables

Table 4-1: Comparison table of RMOA systems in the EU, Australia, Canada, New Zealand, and the United States					
RMOA Aspect	**EU**	**Australia**	**Canada**	**New Zealand**	**United States**
Substance selection					
Specific software tool	**No**	**No**	**No**	**Yes** – FRCaST	**No**
Who proposes / selects substances?	Common screening, mapping of chemicals universe, grouping by ECHA, MSs agree to carry out RMOAs	NICNAS	ECCC and Health Canada	Any stakeholder or NZ EPA	Any manufacturer or US EPA
Use of overseas data	**No** – Substance selection for RMOA is triggered by issues in the EU	**Yes** – International chemicals of concern lists considered during selection	**Yes** – International chemicals of concern lists considered during selection	**Yes** – International chemicals of concern lists considered during selection	**Yes** – Information from international organisations considered during selection
Particular selection criteria highlighted by consultees (not exhaustive)	National priorities, such as concerns over certain consumer uses, national interest with regard to a particular substance	Chemicals with exposure data Overseas chemicals of concern Chemicals found in blood of babies' umbilical cords	Persistence, bioaccumulative, inherently toxic, or substances with greatest exposure	Persistence, bioaccumulative, endocrine disruption, and domestic use are given extra weight	PBT, carcinogenicity, neurotoxicity, concern or exposure to children, and detection in biomonitoring programs
No. of screened substances	21,000 substances have undergone a mass IT screening phase. A list of 200-300 substances of potential concern are generated from the common screening	3,000	4,300	800	Unknown

Table 4-1: Comparison table of RMOA systems in the EU, Australia, Canada, New Zealand, and the United States					
RMOA Aspect	**EU**	**Australia**	**Canada**	**New Zealand**	**United States**
	approach each year though automated and manual screening				
Is public / political / consumer concern considered?	These are sometimes used by Member States to select substances for RMOA, but the priority attached to them varies across Member States	Significant level of public concern can be a cause for selection	Public nominations of substances for assessment can be made through the IRAP process.	Significant levels of public, media or political interest can be screening inputs	The US EPA considers public comments and tries to balance competing interests objectively
Hazard and Risk Assessment					
What information sources are used?	REACH registration dossiers, CLH, CLP, other sources, including consultation	Internal databases; previous NICNAS assessments; overseas assessments and databases; predictive models; literature reviews; peer reviews; and stakeholders	Internal databases, ECCC and Health Canada research, monitoring and surveillance; scientific journals; SDS; overseas assessments and databases; predictive models; and stakeholders	Internal databases; approval documentation; product labels; overseas assessments and databases; and stakeholders	Internal databases; overseas assessments and databases; information from State level authorities; academic institutions; and stakeholders
Is national use / volume information available?	**Yes** – from REACH	**Yes** – Australian use and volume information is available for around 1,300 substances	**Yes** – Manufacture and import quantities are obtained for many substances through CEPA S.71 surveys	**No** – New Zealand use and volume information is largely unavailable. Exposure information is most often determined quantitatively through modelling	**Yes** – National information is used on production volume, use types, and number of manufacturing / use sites

Table 4-1: Comparison table of RMOA systems in the EU, Australia, Canada, New Zealand, and the United States					
RMOA Aspect	**EU**	**Australia**	**Canada**	**New Zealand**	**United States**
Are dose-response relationships considered?	**No*** – For the vast majority of RMOAs dose-response is not considered. Risk is often approximated, or a proxy is used	**Yes** – Not considered for Tier I assessments, but is considered for higher Tiers, where consultation is used to obtain necessary information	**Yes** – study data on dose-response relationships are considered in the risk assessment	**Yes** – Study data combined with NOAELs and LOAEL are used in a threshold approach	**Yes** – The hazard assessment has two components: the hazard identification and the dose-response assessment. Study data is used to obtain dose-response relationships
Is there differentiation between uses?	**Yes**	--	**Yes** – Risk assessments differentiate between the different uses whenever possible	**Yes** – Risk assessments are specific to each use	**Yes** – All conditions of use are included in a risk evaluation
Level of stakeholder engagement	Varies widely between Member States/RMOAs	A 6 to 8-week public comment period is held on all draft assessments	A 60-day public comment period is held on draft screening assessments. Assessment reports undergo external peer review and/or consultation involving government, academia, industry, and NGOs	A public comment period, public hearings on request, and a "Call for Information" all provide opportunity for stakeholders to make submissions.	Four public comment periods: two in prioritization, one in scoping, and one on publication of the draft risk evaluation. At any time stakeholders can contact the US EPA to set up a meeting
Are substances grouped during risk assessment (albeit grouping criteria may differ across the study countries)?	**Yes** – increased grouping is a recent development	**Yes** – AICS-specific groupings were formed based on similarities in physico-chemical properties, structural and functional properties, toxicity, and end-uses	**Yes** – Substances grouped to capture similarities and create synergies	**Yes** – Related substances are grouped during reassessments and Group Standards are used for new assessments	**Yes** – Substances are grouped during prioritisation and, in the risk assessment, use categories group similar exposure patterns.

Table 4-1: Comparison table of RMOA systems in the EU, Australia, Canada, New Zealand, and the United States					
RMOA Aspect	**EU**	**Australia**	**Canada**	**New Zealand**	**United States**
RMO assessment & selection					
Is overseas regulatory action considered?	This is widely considered by Member States, but is not a primary consideration.	**Yes** – Harmonisation with the level of regulation applied overseas can be an option if an Australian health-based limit cannot be set	**Yes** – Harmonisation with the level of regulation applied overseas can be an option if it achieves the Canadian regulatory objective	**Yes** – Overseas regulation is considered in new substance assessments. It will also be considered in the NZ EPA's Emerging Issue process which is under development	**Yes** – Overseas regulation is considered but the US EPA makes independent risk management recommendations
What decision-making factors are considered?	Differs across Member States. Factors include: Hazard type, substance uses, effectiveness, and socio-economic information, availability of alternatives, proportionality, timeliness, enforceability, efficiency, appropriateness, and level of existing regulation	Proportionality; socio-economic information; availability of alternatives; efficiency; and use-scenarios	Proportionality; socio-economic information; distributional impacts; effectiveness; efficiency; acceptability; regulation in other jurisdictions; and compliance with international obligations	Effectiveness; socio-economic information; appropriateness; level of uncertainty; and impact of Māori culture and traditions	Effectiveness; socio-economic information; and availability of alternatives
Is there regulatory overlap?	**Yes**	**No** – There is no overlap between legislations, so when a risk is identified it is clear what risk management approach needs to be taken	**Yes*** – Type 1 approaches to assessment can involve referral to a better-placed and more appropriate federal risk management program	**Yes***	**No*** – If it can be concluded that a substance with unreasonable risk is best regulated under another piece of legislation (e.g. OSHA Act), risk management can be

Table 4-1: Comparison table of RMOA systems in the EU, Australia, Canada, New Zealand, and the United States					
RMOA Aspect	**EU**	**Australia**	**Canada**	**New Zealand**	**United States**
					referred to other agencies
Administrative aspects					
Published guidance	An unpublished template document, and checklist providing guidance of aspects to consider, are available to MSCAs	Risk assessment methodologies available on NICNAS website	Procedures for risk assessment and selection of risk management options available on the Government of Canada Chemical Substances website	Risk assessment methodology available on NZ EPA website. This include 5 recommended risk management steps (see pg. 24)	Guidance on conducting risk evaluations is available on the US EPA website
Publication of findings	Summary or full RMOA published on ECHA website	Risk assessment findings and risk management recommendations available on NICNAS website	Draft and final assessments available on Health Canada website and in the Canada Gazette	Assessment and reassessment outcomes available on NZ EPA website	Final risk evaluations available on US EPA website and in the Federal Register
Responsible bodies	ECHA and MSCAs	NICNAS	ECCC and Health Canada	NZ EPA	US EPA
Typical timescales	2 months – 2 years	Medium complexity assessment = 16 days High complexity assessment = 42 days	Selection and implementation of RMOs = 3.5 years	New substance assessments = 100 days Reassessments = 1-3 years	Risk assessment = 3 years Selection of RMOs = 2 years
*Based on limited information. Further consultation would be needed to confirm RPA's assumptions					

Table 4-2: Comparison of RMOA approaches in Sweden, Germany, the UK, and the Netherlands				
RMOA Aspect	**Sweden**	**Germany**	**UK**	**Netherlands**
Substance Selection				
How are substances selected?	Systematic prioritisation tool	ECHA IT screening	Substance evaluations performed under REACH	ECHA IT screening
Who proposes / selects substances?	KEMI	BAuA, UBA & BfR	Environment Agency & HSE	Bureau REACH
What are the national priorities for selection?	Substances posing a risk for which regulatory action is required (i.e. PFAS, reprotoxic substances, some metals) Substances found in drinkable water Substances or endpoints that KEMI has previous experience working with	PFAS substances Substances for which previous work has been undertaken by BAuA Substances indicated by third parties Substances indicated by monitoring studies	Substances of historic interest Substitutes or potential substitutes of chemicals under risk management	Substances produced in the Netherlands (i.e. substances with Dutch registrants) Substances found in the environment or in Dutch citizens Substances used in significant amounts with possible concerns for workers
Is political and public pressure considered?	**Yes** – Government interest constitutes a high internal priority	**No** – Little political or public pressure on substance selection	**No** – Little political or public pressure on substance selection	**Yes** – Political and public priorities are discussed with the Ministry
Is overseas regulatory action considered?	Substances subject to overseas regulatory action are considered but there must be an EU issue surrounding the substance	Overseas regulatory action has little influence	Overseas regulatory action has little influence	Overseas regulatory action can influence selection
Information Sources				
What are the main information sources?	REACH registration dossiers Swedish Product Register Dialogue with industry	REACH registration dossiers Chemical safety reports Public consultation	Chemical safety reports Monitoring data Scientific literature Dialogue with industry and registrants	REACH registration dossiers Internet sources Scientific literature Dialogue with registrants

Table 4-2: Comparison of RMOA approaches in Sweden, Germany, the UK, and the Netherlands				
RMOA Aspect	**Sweden**	**Germany**	**UK**	**Netherlands**
Is a public consultation performed?	**No**	**Yes** – BAuA hosts a public consultation for 2 months	**No**	**No**
Is there a dialogue with registrants?	**Yes** – KEMI accepts a dialogue with industry if approached	**Yes** – BAuA has a dialogue with industry as a follow-up to the public consultation	**Yes** – Registrants are invited to participate in a dialogue during the preparation of an RMOA. The UK also has the option to arrange a Call for Evidence through ECHA in order to reach out to industry	**Yes** – Bureau REACH notifies registrants when starting a RMOA
Is information from overseas authorities used?	**No**	**Yes** – BAUA looks at publicly available information from other jurisdictions	**Yes** – Information from overseas is used with careful assessment of its relevance. The UK has obtained information from the Canadian regulatory authorities	**No**
Hazard and Risk Assessment				
Is a quantitative risk assessment performed?	**Yes** – On occasion but this has not led to any robust conclusions. Primarily a qualitative assessment is performed	**No** – Risk assessments are qualitative discussions of findings	**Yes** – Risk assessments can be quantitative (e.g. PEC/PNEC assessment) or qualitative (e.g. PBT and vPvB concerns where a risk is assumed if there is environmental emission)	**No** – Risk assessments involve a qualitative scoping of concern
Does the risk assessment differentiate between substance uses?	**Yes** – KEMI considers all substance uses during a risk assessment and are most concerned with widespread professional uses and consumer uses	**No**	**Yes** – The UK differentiates between high and low risk substance uses	**Yes** – Bureau REACH considers which uses would warrant restriction or authorisation, and which would be more appropriately regulated under other legislative frameworks

Table 4-2: Comparison of RMOA approaches in Sweden, Germany, the UK, and the Netherlands				
RMOA Aspect	**Sweden**	**Germany**	**UK**	**Netherlands**
Working arrangements				
Is the ECHA template used?	**Yes** – KEMI use the ECHA template with some flexibility and deviation if this is required	**Yes** – BAuA use the ECHA template with some flexibility and deviation if this is required	**No** – The UK adopts a basic template which alters slightly for each substance depending on the amount of information available. However, it finds the ECHA template to be a very useful tool for providing guidance on what aspects need to be considered	**Yes** – Bureau REACH use the ECHA template as much as possible
Is there a written consultation with other Member States?	**Yes**	**Yes**	**Yes**	**Yes**
Are RMOAs presented to RiME+ meetings?	**Yes** – Approximately one in ten RMOAs are presented at RiME+ meetings	**Yes** – For specific cases RMOAs are presented at RiME+ meetings	**Yes**	**Yes** – RMOAs posing particular challenges, or for which there are certain methodological issues of interest, are presented at RiME+ meetings
Are RMOAs circulated amongst national government authorities?	**Yes** – On a case-by-case basis KEMI may circulate an RMOA amongst Swedish government authorities	**Yes** – Ministries are informed before an RMOA is concluded	**Yes** – This is performed before an RMOA is circulated at a RiME+ meeting	Unknown
Selection of RMOs				
What are the main factors influencing RMO selection?	Hazard type Substance uses Effectiveness and appropriateness	Hazard type Substance uses Existing regulation Socio-economic information	Hazard type Substance uses Industry size (e.g. many and diverse uses may lead to high workload for ECHA committees if Authorisation was selected) Scale of article importation Enforceability Alternatives	Proportionality Timeliness Efficiency Effectiveness

Table 4-2: Comparison of RMOA approaches in Sweden, Germany, the UK, and the Netherlands				
RMOA Aspect	**Sweden**	**Germany**	**UK**	**Netherlands**
Is socio-economic information and availability of alternatives considered?	**Yes** – Socio-economic information and availability of alternatives are considered if this information is available. The level of consideration depends upon the follow-up activity being proposed	**Yes** – Availability of alternatives is considered but it is not a major factor	**Yes** – However there is usually very little socio-economic information available	**Yes** – Socio-economic information is always considered in some way, but this is mostly at the level of type of uses, production volume, number of registrants and downstream user sectors, and availability of alternatives
Are RMOs outside of REACH considered?	**Yes** – However, recommended follow-ups under REACH are preferred as this is considered to be a more certain approach	**Yes** – e.g. occupational safety and health legislation, Water Framework Directive	**Yes** – e.g. Water Framework Directive, Environmental Quality Standards, RoHS	**Yes** – However, recommended follow-ups under REACH are preferred as this is considered to be a more certain approach
Administrative aspects				
Typical timeframe	20 – 30 working days	6 – 12 months	3 – 9 months	Within 1 year
What are the factors affecting the timeframe?	Complexity Competing work tasks Involvement of other Member States Interpretation of intrinsic property	Waiting for data and translation of information	Amount of information available Timings of the data gathering activities Level of uncertainty	Involvement of other stakeholders Timings of data gathering activities Availability of resource Assessments falling between different regulatory frameworks
What are the costs associated with a RMOA?	Approx. €1,900 – €95,000 Approx. €26,000 on average	Not available	Staffing costs only	Not available

5 Best Practice

During the consultation activities, the participants were invited to comment on the perceived strengths, weaknesses and areas in need of improvement of their risk assessment procedures, which, alongside study team judgement, were also used to inform what constitutes 'best practice'[6]:

- **Australia:** One notable example of good practice in Australia is the IMAP framework. It allows the utilisation of overseas data accelerating their chemical assessment programme and allowing NICNAS to produce quality reports. The impact that NICNAS has been able to achieve with its chemical assessment programme is one of the major strengths. Currently, over 20,500 human health and/or environment assessments have been completed and 14,162 unique chemicals have been assessed. NICNAS has been able to publish over 4,000 risk management recommendations for 3,250 chemicals. Indeed, from our sample, available information suggests that Australia may have the shortest timeframe and lowest costs for their assessments.

  The flexibility of IMAP has also meant that NICNAS has been able to respond immediately to concerns and move to risk management very quickly.

- **Canada:** The organised system of lists in Canada is a strong example of good practice. It ensures that all new substances are investigated by requiring a NSN. Furthermore, the 23,000 existing substances on the DSL continue to be investigated by incorporating new scientific and overseas knowledge through IRAP, a cyclical two-year process. Finally, there are strict deadlines such as the 4,300 substances prioritised from the DSL through Categorisation, which are planned to all be reviewed by the end of 2021.

- **New Zealand:** In New Zealand, the specific screening tool (FRCaST), which allows rapid screening of chemicals, was identified as a particular strength. It allows screenings to be re-run if new information arises and gives each substance a quantitative score which allows disparate chemicals to be compared. Notably, it has been peer reviewed by Canadian (ECCC) and Australian (NICNAS) authorities and judged to be fit for purpose.

  Secondly, NZ EPA-initiated reassessments (i.e. risk assessment and RMO selection) are often carried out for a group of related substances (although this can also be the case in other jurisdictions, e.g. in Canada). Examples include groups of organophosphate and carbamate substances, antifouling paints, and groups of substances with the same active ingredient. Group Standards are also used as an approval mechanism and risk management tool, which cover groups of substances with common attributes and uses.

  Furthermore, the HSNO Methodology Order states that decision-maker must consider the degree of scientific or technical uncertainty associated with the assessment, and the effects on costs, benefits and effectiveness of making controls more or less restrictive.

[6] When considering 'best practice' examples, it should also be borne in mind (as highlighted within the study conclusions, below) that whilst there are some similarities between the different systems (the four non-EU systems all include features that resemble some elements of the RMOA process, and there are some common elements and themes in each country's approach towards risk assessment and selection of risk management options) there was also a significant amount of disparity observed, meaning that direct comparison was not possible or pragmatic.

- **United States of America:** It is noted that the US EPA has a high level of structured stakeholder engagement with four comment periods: two in prioritisation, one in scoping and one in risk evaluation and regular meetings to clarify data. In addition, at any time in the process, stakeholders can contact the US EPA to set up a meeting if they have new data or data is not known or available to the US EPA.

- **European Union:** In the context of regulatory complexity and partially overlapping RMOs, RMOAs provide a useful tool for determining which, if any, of the different RMOs should be further considered. Its existence thus contributes to increased predictability, transparency, and consistency, although there are notable aspects of divergence at Member State level.

    - **Sweden:** KEMI has developed a systematic system for prioritising substances for RMOA, which combines information on hazard type and total EU registered volumes and uses, with internally derived priorities. KEMI also has access to a comprehensive database of substances and mixtures placed on the Swedish market, which can indicate increasing trends in substance use that may be a cause for concern.

    - **Germany:** Germany is the only Member State in this study to conduct a public consultation. This consultation is not just focused on Germany, but it aims to reach relevant companies across the EU. BAuA also informs all the registrants, sector specific organisations, industry associations, and they try to reach downstream users by inviting those that have notified the substance under harmonised classification and labelling.

    - **The Netherlands:** Bureau REACH has begun a project on identifying new and emerging risks, which combines information from various internet and literature sources with signals obtained through enforcement and poison centres. Bureau REACH have also begun a separate project investigating how to make the evaluation of socio-economic elements more systematic as well as the extent to which they are not using socio-economic information which is easily assessible.

    - **United Kingdom**[7]: According to consultation with the Environment Agency, UK RMOAs are typically detailed documents as they try to remain objective and present all the evidence before making a decision at the end. The UK also publishes full RMOAs, rather than just the conclusions, in order to increase public transparency. Of the Member States in this study, the UK were alone in circulating each RMOA to the national government for consultation, in order to obtain a harmonised UK view before it was presented.

[7] It is reiterated that within this study, the UK approach has been discussed within the context (and under the headings) of the EU assessment given the historic contributions of the UK to the EU RMOA process and also given that, at the time of interview with the UK authorities, the UK was still within the EU. At the present time (i.e. in the context of the current transition period and ongoing EU and UK negotiations) certainty as to the future direction of the UK RMOA process cannot be provided.

6 Conclusions

This study has found that a direct equivalent to the EU RMOA system does not exist in any of the non-EU jurisdictions included within scope. However, the four non-EU systems all include features that resemble some elements of the RMOA process, and there are some common elements and themes in each country's approach towards risk assessment and selection of risk management options. Examples include:

- **Similarities in priority characteristics for substance selection** (i.e. emphasis on PBTs, known and probable carcinogens, and chemicals of potential concern to babies and children);
- **Use of overseas data** (the majority of authorities take into consideration international chemicals of concern lists and activities of separate jurisdictions during substance selection - also as an efficient means of overcoming data gaps);
- **Emphasis on stakeholder engagement** (utilised as a means to clarifying and confirming existing data, providing valuable additional information on use and exposure to fill in data gaps, and to increase transparency. All authorities interviewed clearly welcomed the input of stakeholders and had systems in place to allow for this);
- **The integrated consideration of overlapping legislation when considering risk management options** (this was seen as important for many from the proportionality perspective and it also ties in with the emphasis on stakeholder engagement);
- **Grouping of chemicals undergoing assessment** (used effectively to improve the helpfulness of overseas data, to overcome data gaps, and to improve efficiency of the risk assessment process. All authorities interviewed acknowledged the usefulness of/necessity for substance grouping); and
- **Flexibility** (i.e. the ability for jurisdictions to incorporate new data that may become available).

Whilst there are some similarities there was also a significant amount of disparity observed between the different systems, meaning that direct comparison was not possible or pragmatic. This may in part reflect the differences in the overall chemical regulatory framework of each country that are often complex and involve various authorities and government departments, and which a risk assessment system must integrate into. In light of this it seems that there is no 'one size fits all' approach to risk assessment and what may work in one country may not work in others. In some jurisdictions there is no regulatory overlap, so when a risk is identified it is clear under what regulatory framework a risk will be managed, while in other jurisdictions some regulatory overlap exists, meaning there needs to be a decision-making process to determine which regulatory framework should be used to manage certain risks. In cases of the latter, an overarching process similar to that of an RMOA may be of particular relevance to ensure all possible risk management instruments are evaluated and the best policy choice is adopted.

Approaches towards risk assessment are also determined by the objectives and priorities of the national authorities. For example, in Australia, NICNAS has focussed on accelerating their chemical assessment programme meaning they have a high throughput approach, whereas the US EPA has adopted a particularly rigorous and systematic approach and has completed fewer risk assessments.

This study has highlighted that there are some unique strengths and areas of best practice within each risk assessment system, which should be more widely promoted in order to facilitate learning amongst jurisdictions.

Investigation of the RMOA process in individual EU Members States and the United Kingdom has reinforced the findings from the consultation with the EU at the broad level and the non-EU jurisdictions, in that there is no single gold standard approach that can be followed by all jurisdictions. There are many similarities in the approaches taken by the Member States, such as the use of REACH registration dossiers, the consultation process, and preference for qualitative risk assessments, as well as some common challenges, such as the lack of socio-economic information. The differences observed between the Member States are partly due to the voluntary nature of RMOAs, which means some flexibility in the format and approach is expected. Similarly to the non-EU jurisdictions, there were some individual strengths of each RMOA approach, from which some elements of best practice were identified amongst the Member States.

It is hoped that this study and its findings will stimulate useful discussions and provide a beneficial comparative assessment of the systems in place as well as useful insights to countries developing their own chemical management regimes.

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Risk & Policy Analysts Limited
Farthing Green House, 1 Beccles Road
Loddon, Norfolk, NR14 6LT, United Kingdom

Tel: +44 1508 528465
Fax: +44 1508 520758
E-mail: post@rpaltd.co.uk
Website: www.rpaltd.co.uk