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SERIES ON TESTING AND ASSESSMENT
NO. 314

INTERNATIONAL BEST PRACTICES FOR IDENTIFICATION OF PRIORITIES WITHIN CHEMICALS MANAGEMENT SYSTEMS

IOMC
INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS
A cooperative agreement among FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD

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ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT
Paris 2019

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FOREWORD

OECD member countries collaborate in developing and harmonising methods for assessing risk to human health and the environment, including methodologies for hazard and exposure assessment. This document is intended to provide an overview and analysis of approaches used across countries for prioritising chemicals for risk assessment and/or risk management, and to identify commonalities, differences, lessons learned, best practices and areas for improvement.

The development of this document was led by Health Canada and reviewed by the OECD Working Party on Hazard Assessment (WPHA) and Working Party on Exposure Assessment (WPEA).

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

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1. Executive Summary

This document captures and examines schemes used internationally for prioritising chemicals for risk assessment and/or risk management, and identifies commonalities, differences, lessons learned and areas for improvement. Based on this analysis in offers guiding principles and best practices to consider within prioritisation schemes.

Based on the information collected, some findings are not unexpected. For example, most prioritisation schemes commonly select substances based on existing inventories of chemicals known to be in commerce and that the legislation of respective jurisdictions drives the design of, and the parameters around, most prioritisation schemes. The lack of availability of exposure or hazard data is the most common issue encountered during prioritisation. However, prioritisation schemes differ in how they handle data poor chemicals, with some schemes applying worst-case assumptions whilst others apply best-case assumptions. Further, some schemes suspend the prioritisation process completely for chemicals lacking either quality hazard or exposure data; that is, they do not proceed with prioritisation for these chemicals. On this issue, the document concludes that, as best practice, prioritisation decisions should be risk-based and a lack of data should not be sufficient reason to deprioritise a chemical. At the same time it is noted that some risk management measures stem directly from a hazard based approach (e.g. harmonized classification and labelling).

Other important best practices and common areas for development identified include using a common data platform to facilitate data sharing (e.g., IUCLID), increased sharing of results and rationales, collaboration on the development of new approach methodologies and tools/approaches for improving the prioritisation process, including the use of automation to improve efficiencies, and a comparison of international chemical inventories.

2. Introduction/Background

A method to identify priorities for risk assessment and/or risk management is crucial to all chemicals management systems. The degree to which countries collect information on substances; monitor for emerging risks; and integrate newly acquired information into decisions about the assessment and management of chemicals and polymers, including the prioritisation of substances for future risk assessments, or risk management, is highly variable from country to country. Some countries use one-time, highly complex and rigid processes which identify large numbers of priorities, whereas others use on-going, more flexible processes.

Scientific information and regulatory actions on chemicals continue to evolve, as does the use of chemicals. As a result, it is important for countries to continue to enhance the ways in which they incorporate new scientific knowledge into their prioritisation schemes. Increasing collaboration with other regulatory and international agencies will expedite improvements and help to identify or avoid common areas of weakness. This will enable countries to be better positioned to recognise concerns, to track emerging issues and to prioritise substances requiring further work, such as information gathering, data generation or risk assessment.

This document captures and examines the existing prioritisation schemes, or those being developed, to identify commonalities and differences in the approaches being used, lessons learned and areas for improvement. Dissemination of this information will also help to increase transparency in the process of identifying new priorities, which will be highly useful to countries looking to improve and expand their current prioritisation schemes, or in the development of new schemes. It is anticipated that this work will also support broader objectives related to data and knowledge sharing, which strengthens priority-setting exercises. Ultimately this is expected to enhance collaboration in sharing and utilising outcomes of prioritisation activities, sharing and coordination of (pre-) assessment planning as relevant, as well as sharing of (pre-) assessment outcomes.

To gather information on how prioritisation is conducted internationally a survey was designed and sent out to members of the OECD Working Party on Hazard Assessment (WPHA) and Working Party on Exposure Assessment (WPEA). Twenty-five responses were received from nine countries/regions. Summaries of these responses can be found in Annex A. The responses were used to inform the analysis discussed in this report.

3. Analysis of key commonalities and differences

3.1. Development of prioritisation schemes

The majority of the prioritisation schemes identified in this report are driven by legislation from the country or region of origin. Legislative differences will often dictate the population(s) (i.e., general population, consumers and workers) or types of substances considered within the prioritisation schemes. Legislation may also impact the consultation processes used, the ability to generate data and the frequency of reviews. These legislative parameters limit the ability for many elements of these schemes to be closely aligned or to be easily modified to increase harmonisation between countries.

For the development of prioritisation schemes, it is common practice to have some form of consultation. Usually stakeholders, government partners and scientific review panels are consulted, through in-person meetings or written commenting periods. Most organisations also choose to publish the approach to prioritisation and the results of the process so that it is available to all stakeholders.

It is common for prioritisation schemes to select substances based on an existing inventory of chemicals known to be in commerce in a specific country/region. Most of the inventories used are specific to the organisation or country. For example, many of the Canadian schemes focus on substances on the Domestic Substances List (DSL) and a number of European organisations use substances registered under Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations.

Some form of pre-prioritisation is also inherently included in the majority of approaches. Generally pre-prioritisation is a by-product of the information being selected for use in the scheme (i.e., the defined scope) and may result from the general tendency for chemicals to be sorted or excluded based on a number of factors. These include data availability, volume in commerce and other refinements to the original candidate list to reduce the scope of the candidates for the prioritisation process. Some of the different ways in which pre-prioritisation occurs in various schemes includes pre-screening substances to exclude specific types of substances, using pre-prioritised feeder lists (e.g., using lists of substances with pre-determined hazard classifications) and selection or categorisation of substances prior to prioritisation. Some approaches require a substance to be registered in a specific programme like REACH; others require a certain type of exposure to be considered.

Most organisations have complementary mechanisms in place to identify priorities that do not specifically meet the standard requirements of the scheme being used. Some consider outcomes of assessments from other jurisdictions, either national or international. For example the Canadian Drinking Water Chemicals Prioritisation process can include emerging issues raised by other federal departments, stakeholders or provinces/territories. The New Zealand Environmental Protection Agency has a work stream looking at actions taken in overseas jurisdictions which can result in additional chemicals being prioritised or reassessed. Other schemes allow the addition of chemicals through governmental

nomination processes. In the USA, congress has the ability to amend the Toxic Substances Control Act (TSCA) to include or exclude specific chemicals, and in Finland the government and ministerial initiatives are also taken into account in identifying priorities.

A few schemes adopt the actual risk management actions taken in other jurisdictions, not just in terms of prioritisation (i.e., trusted-regulator approach), while most use the results of others' actions to prioritise assessment activities. Multi-national organisations such as the European Chemicals Agency (ECHA) implementing REACH are dependent on gathering data/ knowledge from other organisations/ jurisdictions. For schemes such as IRAP (Identification of Risk Assessment Priorities) in Canada, identifying classifications and risk assessment decisions developed in other countries is a major factor in the prioritisation process.

3.2. Consideration of data used for prioritisation

About half of the schemes require a minimum data set before considering a chemical for prioritisation, however what is considered to be the minimum data set is highly variable. In the absence of this minimum data the various schemes have different methods of proceeding. In some instances worst-case assumptions are applied, others take the opposite approach and in the absence of data best-case assumptions are applied. Other approaches define the substances outcome as "uncertain" and do not conduct prioritisation on the chemical.

Data generation for the acquisition of information on hazard and exposure properties to inform the prioritisation process is not common. Physical-chemical properties are taken into consideration by many schemes. Some examples that are considered are biodegradability, persistence and solubility. Only a minority of the schemes (6/25) reported generating some required data and in most of these cases the data generation is required by the chemical manufacturer or processer. Some of the information generated is available to the public, but more commonly the results remain internal to the organisations for which it was generated. In the case of categorisation of the Canadian DSL, toxicity studies were commissioned for some endpoints to specifically generate de novo data for prioritisation. About half of the schemes incorporate information from New Approach Methodologies (NAMs), including a number of approaches highlighting the incorporation of (Q)SAR and/or predicted data. For example, NORMAN (EU) and the NICNAS Inventory Multi-tiered Assessment and Prioritisation (IMAP) will apply (quantitative) structure-activity relationships ((Q)SAR)) and read across models when there are gaps in experimental data. Other NAM data considered includes results from ToxCast, or read-across between analogue substances.

More frequently, the prioritisation schemes are based on available data. These data are collected from an array of different sources to inform the prioritisation decisions. Both hazard and exposure data were commonly reported to be collected from publicly available information sources, including peer reviewed scientific literature, grey literature and chemical databases such as the ECHA/REACH dissemination database. Many organisations also use internal reports and data which in some cases are confidential and not available to the public, such as data submitted directly by industry.

Almost all schemes (i.e., 21 of 25) consider data quality in the context of prioritisation and those that do not indicated that data quality would be considered only at the assessment stage. In some cases, even though data quality is considered, lower quality data may be accepted when better data are not available. For the majority of schemes that do consider data quality, it is usually the evaluators of a particular substance that ensure quality data are being used. Two schemes use Klimisch principles to assess data quality; others look for elements like the use of good laboratory practices (GLP) for study conduct.

For collecting and processing data, most organisations indicated that no specialised data mining software or databases are currently used. Many manually extract information from literature and databases and rely on tools such as standard spreadsheets and databases for data compilation. Multiple schemes also reported using IUCLID[1] for compiling hazard data or extracting data from dossiers prepared for REACH. For those that do have specialised tools for data mining or data processing, they vary between organisations. Some examples of programs used include: RISCTOX[2], ChemBioOffice[3], Risk21[4] and Cognos Analytics[5].

3.3. Process of prioritisation

As shown in Figure 1, the frequency in which prioritisation occurs is variable between the different schemes surveyed, but the majority of schemes are intended to be implemented more than once. Only five of the prioritisation schemes were designed for one-time use, performed in accordance with legislation. For example, Categorisation of the Canadian DSL had to be completed within seven years of Royal Assent of the Canadian Environmental Protection Act (CEPA) and RIVM's prioritisation scheme was performed on request of the Netherlands Food and Consumer Product Safety Authority in 2014-2015. The more common approach is to prioritise continually or at a set interval. On-going prioritisation allows for new information to be examined as it becomes available and appropriate action to be taken in a timely manner, including examination of nominations. Some advantages identified for an annual prioritisation process are that it allows for new information to be added through a formal and structured process. Other options reported included prioritisation on a sub-annual basis, every two years, every four years, performed on demand and prioritisation having occurred twice thus far. The driver for the choice of frequency was typically legislation.

[1] https://iuclid6.echa.europa.eu/

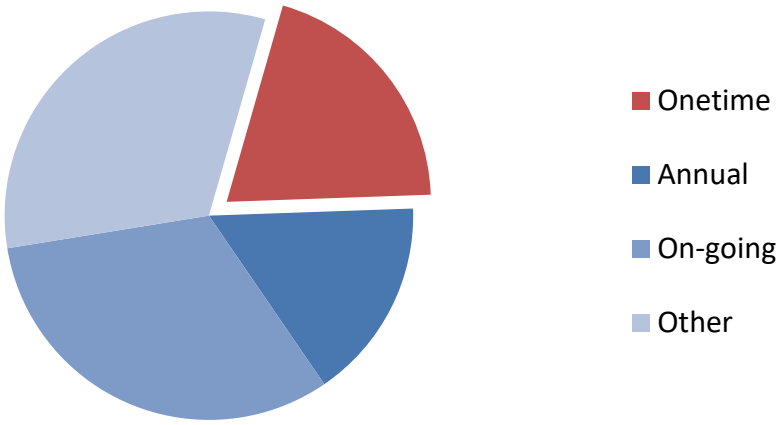
[2] https://risctox.istas.net/en/

[3] http://www.cambridgesoft.com/solutions/details/?fid=188

[4] https://risk21.org/

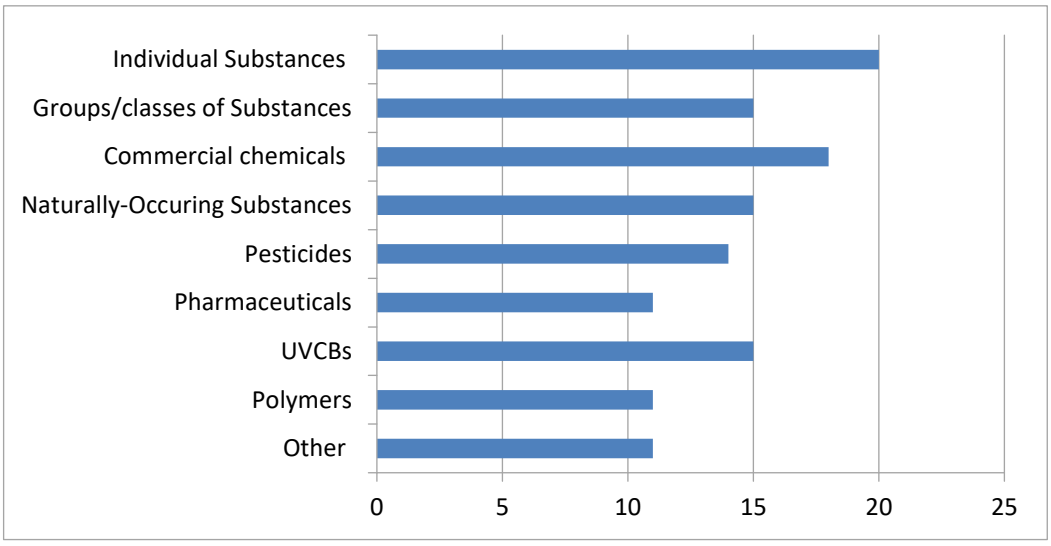
[5] https://www.ibm.com/products/cognos-analytics

Figure 1: Frequency of application of prioritisation schemes



Overall the majority of prioritisation schemes reviewed included a wide range of substances (see Figure 2), with differences in legislation driving certain inclusions or exclusions, like pharmaceuticals and pesticides. Most prioritisation schemes were reported to include individual substances and commercial chemicals. Of the schemes that include commercial chemicals, seven of them include a consideration of volume thresholds, which ranged from 1 t/year up to 1000 t/year. UVCBs, naturally occurring substances, groups/classes of substances and emerging issues are all included relatively frequently in prioritisation. Classes of substances are typically reported as being based on chemical or structural similarity and/or similar uses. The majority of schemes also prioritised substances with properties of potential concern, the most common being carcinogens, sensitisers, endocrine disruptors, Persistent/Bioaccumulative/Toxic substances (PBTs) and neurotoxicants.

Figure 2: Frequency of inclusion of major chemical categories in reported prioritisation schemes

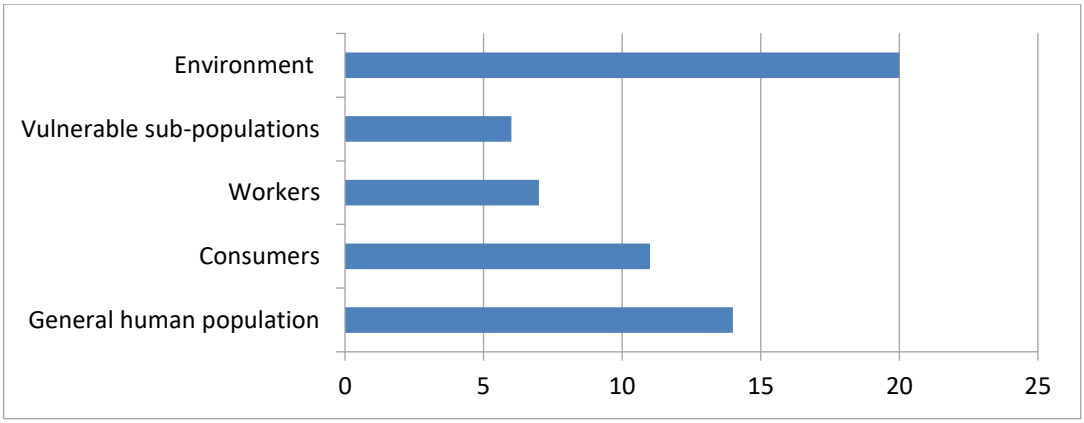


The various approaches have different requirements for chemicals that are excluded from prioritisation. Some exclude substances that do not meet a specific manufacture or import volume threshold. Other schemes have a more limited set of chemicals that they prioritise and therefore exclude most that do not meet the criteria. For example, the Canadian Ecological Risk Classification of Inorganic Substances was designed for the specific subset of remaining priority inorganic substances; as a result, all organic substances are excluded from this approach. A few schemes do not explicitly exclude substances; instead substances are ranked as lower priority or in categories that require specific actions, rather than excluding them.

Less than half the schemes allow for nominations from the public or other external parties. For those that do, nominations are received from a mix of governmental departments and organisations, in addition to taking into account public inquiries. In Canada, although public nominations are not formally requested, they are permitted under CEPA. The USA allows manufacturers to request that the EPA conduct a risk evaluation, as well the NZ EPA allows external parties to request that existing approvals of a particular substance be reviewed. In both the case of the US EPA and NZ EPA, this is a multi-step process requiring submission of required information to initiate the process. Only one scheme, used by the German Federal Institute for Occupational Safety and Health - Assessment Unit for Occupational Safety and Health, includes asking some external parties to nominate substances for screening on an annual basis.

As shown in Figure 3, the most common exposures considered in the reported prioritisation schemes are to the environment and the general human population. More specific sub-populations are less frequently considered, with more approaches choosing to exclude rather than include these categories. The vulnerable sub-population category has varying definitions depending on the approach; even different organisations within the same country have inconsistent definitions. Most commonly the term refers to infants, children, pregnant women and the elderly. This list can be expanded to include people with genetic polymorphisms, people with pre-existing disease conditions, those in close proximity to a source or activity and workers. Bystanders are listed as an “other” type of exposure considered in the categorisation of the German Work Program of the Committee on Hazardous Substances and Manual screening for Regulatory Actions.

Figure 3: Types of exposures considered in prioritisation



3.4. Prioritisation outcomes

A combination of hazard, exposure and risk factors were reported as the most common basis for prioritisation. In some circumstances, such as New Zealand's Flexible Reassessment Categorisation Screening Tool, hazard and exposure information is used to produce an overall risk score. In other cases, hazard, exposure and risk factors may all be considered as is deemed necessary, such as in the Canadian Indoor Air Contaminants Assessment Section (IACAS) approach. The use of only hazard-based criteria to inform prioritisation was reported infrequently and there were no indications of identification of priorities based solely on exposure.

Almost half of the prioritisation schemes reported using a quantitative scoring system to identify priorities. One commonly used system is to produce separate hazard and exposure scores which are then combined using a scoring matrix; the final score is then used to determine the priority of the substance.

The overall purpose for the prioritisation schemes was variable (see Figure 4). While a few schemes focused only on the identification of high priorities, the majority of schemes reported the goal of identifying both high and low priorities, with an equal number identifying the purpose being for risk assessment or for risk assessment and risk management. No schemes were identified that solely focused on the identification of low priorities. Some approaches also reported the use of prioritisation to identify high priorities for acquiring further data or for national monitoring programs.

Figure 4. Overall purpose of prioritisation schemes reported



4. Lessons learned

4.1. Key Strengths

Overall, organisations value simplicity, efficiency, flexibility and transparency in their prioritisation schemes. For those organisations with short mandated time frames to complete the prioritisation exercise, a relatively quick approach is essential. Simplicity is emphasised, so the process is not only straightforward to conduct and is less resource-intensive, but also so that it is easy to convey information to interested parties/stakeholders. This includes the use of clear criteria for making decisions, either a pass/fail or scoring system done manually or with the help of specialised software, which helps improve transparency and reproducibility of results. It is also considered beneficial when an approach is flexible and adaptable so that considerations can be modified or enhanced over time as science and methods evolve. For example, the European NORMAN scheme (see Appendix A) specifically indicates that the approach used can be easily adapted to different geological scales and different prioritisation objectives.

Some organisations identify the use of consultation and acquiring input from various sources to be considered a strength of their approach. For example, the Canadian Drinking Water Chemicals Prioritisation process gathers input from the different provinces and territories and the German Manual Screening for Regulatory Action scheme consults occupational safety experts and takes into account expertise from toxicologists, exposure experts and experts from legislation in the final prioritisation outcomes. Some organisations reported consulting with other organisations involved in conducting prioritisation to help enhance and improve their proposed schemes.

4.2. Weaknesses

Limitations in data availability and the quality of the data are the most common issues encountered during prioritisation. Developing methods to overcome this problem and deal with an insufficient amount of information on substances has been a challenge for most of the organisations. Organisations deal with lack of data in vastly different ways. Some assume worst-case assumptions, potentially prioritising substances for further work when not warranted, while others consider those substances as low priority, as there is no indication for concern. Data availability challenges can be exacerbated when schemes have short, strict time frames for review and identification of priorities. It is also mentioned that highly data intensive schemes are not practical to be used on a regular basis due to the resource-intensive nature of the work. Further, schemes that are highly specific for a certain subset of chemicals may not be easily applied to other substances or uses.

There are also a number of other weaknesses identified by organisations that are dependent on the specific approach used. One organisation indicated that the complexity of the prioritisation criteria being used in the scheme is its primary weakness, making it difficult to explain to management and stakeholders. Other weaknesses identified included the need to make decisions based on dated information that may have changed significantly over time and the use of rigid criteria that cannot easily be adapted as time and knowledge changes.

5. Guiding Principles and Best Practices

Although every prioritisation scheme is inherently different as it is developed to meet the specific needs and goals of the organisation conducting the prioritisation, analysis of the existing prioritisation schemes has identified a number of guiding principles that should be considered in the development of a new or updated scheme.

- Information used in the prioritisation process must be relevant and scientifically reliable. Processes for evaluating data quality and approaches for gathering data needed for prioritisation should be considered prior to development of the scheme.
- New prioritisation schemes should be developed in consultation with domestic and international experts.
- Data should be collected and stored in a common platform to facilitate sharing and use by others (e.g., by using IUCLID and robust study summaries). Available data and information from other domestic and international programs should be utilised to minimise duplication of effort and improve consistency.
- Prioritisation should be primarily risk-based, with greater priority assigned to substances for which there is information suggesting a potential concern for **both** exposure and hazard. However, lack of data should not be sufficient reason to deprioritise a substance. Data needed for prioritisation should be identified, with efforts made to gather that data whenever possible.
- Schemes should be flexible and adaptable to allow incorporation of new science and emerging issues over time.
- Prioritisation decisions should be based on clear criteria so decisions are transparent and reproducible.
- Proposed prioritisation decisions should be reviewed in the context of other domestic and international assessments or information-gathering activities that could provide an opportunity for efficiencies, collaboration and/or alignment.

6. Common areas for development

A number of common areas for further investigation or development were identified based on the analysis of the survey results.

It was acknowledged that there is a need to continue to improve sharing of data that can be used to inform priority setting. This includes:

- sharing of hazard and exposure data incorporated into the schemes, ideally in a common platform like IUCLID, to expand the breadth and diversity of available data;
- sharing of the methodologies developed for prioritisation; and
- sharing of the results of the prioritisation processes to allow for comparison of outcomes and identification of outliers between schemes.

There were also a number of areas identified where collaboration amongst OECD member and partner countries would be beneficial to help advance prioritisation efforts. This includes:

- collaboration on the incorporation of new approach methodologies into prioritisation schemes;
- collaboration on the use of machine learning approaches to improve efficiencies in data collection and analysis; and
- collaboration on the development of other specialised tools to help with the prioritisation process.

An area raised by multiple countries was the need to explore similarities and differences in national substance inventories, particularly regarding incongruently named substances (e.g., the same substance with different identifiers on different inventories). This would help prioritisation efforts by facilitating collaboration and sharing of data between countries, thereby improving consistency in decision making. This effort would also help facilitate grouping of similar substances to help fill data gaps and increase the efficiency of the prioritisation process.

Annex A. Summary of prioritisation processes based on country responses

Australia

Inventory Multi-tiered Assessment and Prioritisation (IMAP)

Organisation: National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

Web link: https://www.nicnas.gov.au/chemical-information/imap-assessments/what-is-imap

The purpose of IMAP is to accelerate the assessment of the large number of unassessed existing chemicals on the Australian Inventory of Chemical Substances (the Inventory). During Stage One of the process, predetermined criteria were used to select 3000 chemicals for assessment and prioritisation over a 4 year period. At the end of 4 years, Stage Two of IMAP has continued to use the same criteria for selecting further chemicals for assessment. In addition, chemicals that can be rapidly identified and assessed by using Stage One information and chemicals on the Inventory that pose a low risk to human health or the environment are being prioritised to provide information to the public. The scheme is focused on the identification of both low and high priorities for risk assessment and management and takes into consideration the general population, consumers, workers and the environment. Prioritisation deals with all chemicals on the Inventory with industrial uses that meet the selection criteria including commercial chemicals, polymers, UVCBs, individual substances and endocrine disrupting substances. Chemical groups, as defined on the basis of structural or hazard similarities or based on a similar use, are also included. Naturally-occurring substances and chemicals used exclusively as pharmaceuticals or pesticides are not considered in the prioritisation process.

Chemicals for prioritisation are taken from the Inventory and two distinct mechanisms were used to narrow the scope of applicability. Firstly, chemicals to be assessed in Stage One were identified based on three selection criteria, (i.e., chemicals for which NICNAS holds exposure data, chemicals identified as a concern for which action has been taken overseas and chemicals detected in international studies analysing chemicals present in the blood in babies' umbilical cords). The 3000 chemicals identified were then compared against human health hazard, environmental hazard and exposure criteria to determine those not expected to pose an unreasonable risk (Tier I), those considered to require regulatory controls for safe use (Tier II) and those requiring further assessment to determine their risk (Tier III). For chemicals that required Tier II assessment, factors considered in the timing of these assessments included potential grouping, impact on related assessments, potential risk management outcomes and availability of data. Further, while IMAP was implemented outside of the legislation, giving NICNAS some flexibility in identifying priorities, chemicals assessed by NICNAS under the legislation (new chemicals, Priority Existing Chemicals) could be prioritised for re-assessment if the risks have changed and risk management measures recommended in the previous

assessment do not apply anymore. The public or external parties are not able to nominate substances for prioritisation.

Risk is used as the basis for prioritisation and there is no minimum data set requirement for evaluating substances. Both hazard and exposure information is collected from a number of publically available, international sources with some data provided by industry for internal use. Internationally-accepted approaches such as grouping of chemicals or read-across between chemicals and the application of QSAR tools were routinely employed, where relevant, to reach a conclusion regarding the toxicity profile of a chemical. During IMAP Stage One, Australian use and/or volume data were only available for approximately one third of assessed chemicals so surrogate information, such as from overseas sources or conservative default values, was utilised for the remaining chemicals. In-house electronic data management systems were developed to document the decision making process and outcomes of prioritisation. During the development of IMAP, new approach methodologies including a comprehensive QSAR strategy that simultaneously used different mechanistic and statistical models was established in consultation with experts. In silico methods were also used to allow grouping and read-across of data however data were not generated de novo for prioritisation. Data quality is taken into consideration, although there is no formal approach.

For the development of the approach, stakeholders and technical experts were consulted. The criteria for the Stage One chemicals and prioritisation were also developed through consultation with stakeholders, including through the use of expert panels. Information explaining the approach, status and outcomes of the assessment process is published and updated on the website. All assessments had a public comment period during which information which had not been considered in the initial assessment could be provided. Overall, the strengths of this approach are that it combined both assessment and prioritisation, focused on chemicals for which no risk management was in place in Australia and allowed accelerated assessment and risk management for a large number of chemicals. On the other hand the selection criteria (used in Stage One) and the early identification of the 3000 chemicals impacted the ability to address potentially higher concern chemicals not on the list. Additionally, the parallel screening for human health and environment would have benefited from early synchronisation of activities and a more integrated approach to this stage of assessment would have enhanced the robustness of screening outcomes. Other outcomes and lessons learned are described in a review of IMAP[6]. Next steps will follow on from the Australian Government's decision to reform NICNAS. The reforms will introduce improved approaches to reviewing chemicals on the market through a more responsive and a flexible evaluation process and methods for the prioritisation and evaluation of industrial chemicals are being developed.

[6] https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-review-2016

Canada

Priority Substances List

Organisation: Environment and Climate Change Canada and Health Canada

Web link: N/A

The Canadian Priority Substances List (PSL) is an on-going prioritisation process driven by the Canadian Environmental Assessment Act (CEPA). There have been 2 lists to date: PSL1 and PSL2. Various lists (such as the National Pollutant Release Inventory) and reporting mechanisms were used to produce the first 2 PSLs. Pre-prioritisation involved the use of screening criteria, such as presence in the Canadian environment and either toxicity, bioaccumulation potential, or persistence in the environment, to narrow down an initial list. Other non-threshold factors that they considered included mortality, endocrine dysfunction, biomagnification and ecosystem problem indicators. The Panel also used principles to help guide discussions, confirm priorities and assist in the selection process. The seven principles were 1) National significance, 2) Impact on health or the environment, 3) Feasibility, 4) Context, 5) Substances (i.e., not limited to individual chemicals) 6) Prevention, improvement and remediation, and 7) Use of all available information. Nominations were received from national and international organisations, academia, industry interested groups and the public. An Expert Advisory Panel was responsible for reviewing all the nominations and taking data quality into consideration when developing the final lists.

This scheme identifies high priorities for assessment, considering exposure to the general human population, consumers and the environment. Commercial chemicals, UVCBs, naturally occurring substances, individual and classes of substances are all included in prioritisation. It also includes effluents, wastes and mixtures such as releases from smelters and refineries, and respirable particulate matter and road salts.

Overall the prioritisation scheme is risk based. Information on hazard criteria was gathered through public literature searches and international assessments along with inventory data. Exposure information was also gathered from publically available sources, through literature searches and inventory and monitoring data bases. All available information was considered during prioritisation, including phys-chem properties. The Expert Advisory Panel highlighted significant gaps in exposure information, especially in the domains of field data, impacts on populations and ecosystems, and exposure levels in the Canadian Environment. The Expert Advisory Panel comprised of a highly technical team had the ability to review and consider the quality of data being used.

There was consultation with the public and a Ministers Expert Advisory panel during development of the PSLs. The PSLs were published and are available to the public. Recommendations for the next steps were made by the Expert Advisory Panel for each assessment. One important note is that the prioritisation selection process was driven by those high profile and data rich substances that were identified by the department, panel members and the public. One weakness is that there are issues involving resources and data gaps. All substances added to the PSL must be assessed within 5 years to determine if there is risk to the environment or human health which requires risk management. Although the PSL nomination process is still in place, nominations for a third list are not being sought at this time.

Categorisation of the Canadian Domestic Substances List

Organisation: Environment and Climate Change Canada and Health Canada

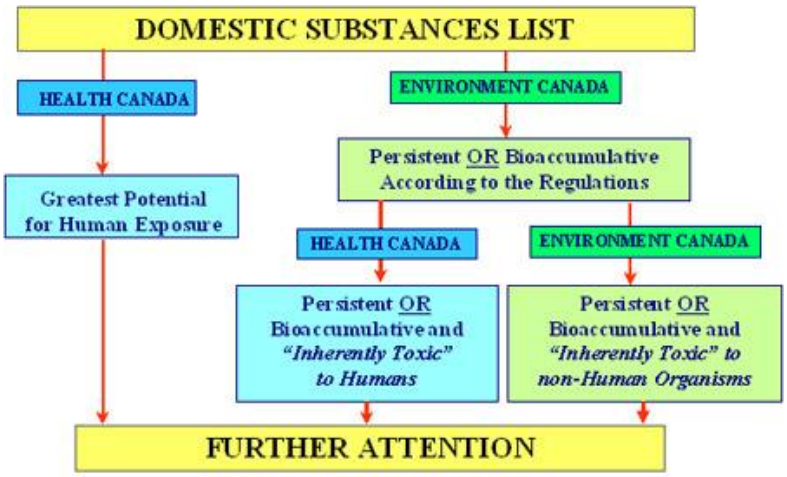
Web link: https://www.canada.ca/en/health-canada/services/chemical-substances/canada-approach-chemicals/categorization-chemical-substances.html

http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=5F213FA8-1&wsdoc=6FCF94B3-CD63-CE3A-4A08-7764E4B847C6

Categorisation of the Domestic Substances List (DSL) was developed in accordance with the Canadian Environmental Protection Act, 1999 (CEPA). Prioritisation was a one-time occurrence, as legislated by CEPA 1999. Categorisation of the DSL identified high priorities for risk assessment, taking into consideration exposures to the general human population, consumers and the environment. Categorisation decisions were made on a substance basis, with some decisions made on a substance class basis, and included commercial chemicals manufactured or imported in Canada at >100 kg/yr. It did not consider exposure to workers or vulnerable subpopulations. Substances not on the DSL in 2006, or substances that went through the new substances program were also not subject to categorisation.

Priorities were selected based on the criteria in Figure 5.

Figure 5. Criteria used to categorise the substance on the DSL



This prioritisation scheme is based on hazard and exposure. Hazard information was used to determine inherent toxicity (iT) for both the environment and human health. Exposure for human health was determined based on criteria for Greatest Potential for Exposure (GPE), taking into account the volumes and uses reported to be in commerce in Canada between 1984 and 1986. Environmental exposures were based on a substances persistence and bioaccumulation potential. In certain cases both hazard and exposure criteria were combined in prioritising a substance, which could be considered risk based. Hazard and exposure information was collected from a mix of publically available literature searches and international assessments. Stakeholders were also encouraged to submit data. In addition to gathering available information, some data was generated de

novo. For inorganic substances, there were two main toxicity testing studies conducted, to generated data specifically for prioritisation. In silico predictive modeling was incorporated into the scheme for organic substances, specifically for prediction of PBT and CMR endpoints. Substances with significant data gaps (e.g., no reporting of use or volume, or uncertain PBT estimates) were not prioritised for assessment.

Consultation of scientific review panels, stakeholders and the public were all conducted during the development of this approach. Final results were published online for public comment. The main strengths of this approach are that it prioritised an extremely large number of substances and identified the worst chemical hazards. The approach was consistently applied to the entire inventory of substances and the results are static, which led to a high degree of certainty when communicating priorities to stakeholders. Some of the weaknesses identified include limited data availability and dated inventory data which resulted in misidentification of priorities, rigid criteria that could not be modified with changes in scientific understanding, overlapping hazard properties and limited hazard domain coverage. Additionally, while consistency is listed as a strength, it can also be considered a weakness as it creates an obstacle to responding to scientific developments and new approaches. Most importantly, the lack of a true risk-based prioritisation resulted in identifying many substances as priorities that should not have been, and various rapid screening approaches were necessary to deal efficiently with those priorities once identified.

Next steps for the substances identified as priorities through categorisation include risk assessment by 2020. Those substances where the criteria were not met may be prioritised for further assessment through other mechanisms such as s. 68, s. 75, s. 76 or s. 83 of CEPA 1999.

Ecological Risk Classification Approach for Organic Substances

Organisation: Environment and Climate Change Canada

Web link: https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=A96E2E98-1

The Ecological Risk Classification (ERC) approach is a one-time re-prioritisation of organic substances that were originally prioritised in 2006 using the categorisation approach. This scheme focuses on the environment and identifies both high and low priorities for assessment. It includes individual substances and emerging issues according to evidence-driven rules for hazard and exposure classification. Organic chemicals are taken from the Canadian DSL.

Overall this is a risk-based quantitative approach that uses a risk matrix (a semi-quantitative scoring system) to identify priorities. Hazard and exposure data are generated de novo and/or collected from existing sources. Hazard information is obtained from in vitro, in silico and in vivo empirical studies and modelling sources. Exposure data are gathered from stakeholder surveys, including tonnage information, which is used to inform fate and exposure modelling. Some specialised tools are used for data generation, collection and processing, in addition to online databases.

For development of the scheme there was consultation with stakeholders, scientific peer review, a 60 day public consultation, as well as support from the chemicals management plan science committee. Results of the approach are shared via face-to-face stakeholder consultations and publication of results.

The main strengths of this scheme are that it uses an evidence based IATA approach that is not subject to the limitations of the previous prioritisation approach (categorisation) in that the criteria are more flexible and change be adjusted to adapt to increasing scientific understanding. Weaknesses of this approach involve uncertainties for hazard and exposure classification due to reliance on modelling.

Next steps are to further assess high priorities from the ERC approach. Identified low priorities are not assessed further, but those with a high hazard classification are tracked for changes in exposure that may change the result. A second version of ERC being developed seeks to reduce these uncertainties and improve on balanced accuracy of prioritisation results.

Ecological Risk Classification of Inorganic Substances

Organisation: Environment and Climate Change Canada

Web link: https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/science-approach-ecological-risk-classification-inorganic-substances.html

The Ecological Risk Classification of Inorganic Substances (ERC-I), was developed as a one-time approach one-time re-prioritisation of inorganic substances that were originally prioritised in 2006 using the categorisation approach. The prioritisation scheme identifies both high and low priorities for assessment, but only presents results for substances classified as low ecological concern with high tier, conservative approaches.

The prioritisation scheme uses a risk based approach. Predicted no effect concentrations (PNECs) were identified from previous domestic and/or international assessments, or from domestic and international environmental quality objectives with similar protection goals (e.g., not remediation targets). Literature searches were conducted in the absence of these. Conservative PNECs were derived using a species sensitivity distribution or an assessment factor approach based on the amount of available data (number of species represented, consistency in types of endpoints, etc.). Read-across was often necessary to fill data gaps. New PNECs were developed by conservative, high-tier approaches for the purposes of ERC-I only and are not promoted for other uses. For exposure data, only national information gathered from publically available sources were used for predictive modeling. Data was not generated de novo for prioritisation nor are New Approach Methodologies (NAMs) taken into consideration.

ERC-I was peer reviewed by a panel of academic experts and chemical toxicology consultants, it was also published for a 60-day public comment period. A strength of this approach is that it addresses substances of low ecological concern in an efficient manner while also identifying substances of high ecological concern that require a more detailed evaluation. One weakness identified is that the approach is highly data intensive and would not be easily applied on a regular basis or to other substances. Next, all the substances classified by ERC-I will be formally assessed as either toxic or not toxic. For substances classified as having low ecological concern, the results of ERC-I will be used to form the basis for the conclusion of future screening assessments.

Approach for the Identification of Risk Assessment Priorities

Organisation: Health Canada (HC) and Environment and Climate Change Canada

Web link: https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan/initiatives/identification-chemicals-polymers-risk-assessment-priorities.html

The Approach for the Identification of Risk Assessment Priorities (IRAP) is conducted on a cyclical basis, which to date has been annual, to review and identify new scientific information on a regular basis. IRAP focuses on substances listed on the Canadian DSL. There is no formal pre-prioritisation process, but the scope of the review is defined annually and may exclude certain classifications of substances (e.g., those already listed on CEPA schedule 1 or those already identified as priorities for assessment).

IRAP focuses on identifying high priorities for assessment using a risk-based approach, as well as identifying areas where data gaps exist and steps that can be taken to address them. IRAP considers the general human population, consumers, the environment and vulnerable subpopulations, via biomonitoring studies that look at groups such as northern communities or maternal/infant measures. IRAP collects data primarily on individual substances, but its relevance to a larger group is considered before outcomes are identified.

Hazard criteria used for IRAP focus on CMR and PBT. All hazard sources used by IRAP are publically available, except for information submitted under section 70 of CEPA. Exposure sources are taken from a mix of both internal and publically available literature and databases. For human health, exposure information is generally focused on uses and the potential for direct exposure to the population rather than focusing on volume thresholds. Biomonitoring data are also considered where available. New Approach Methodologies (NAMs) such as the models from the OECD toolbox are incorporated into the prioritisation process on an ad hoc basis.

Information on the IRAP process and results of each IRAP review are publically available online and shared with stakeholders. The IRAP approach is flexible and based on guiding principles and consideration that allow new data sources and mechanisms to be continually incorporated. Nominations and candidates from a number of mechanisms are integrated into a master data base. Overall it is simple to use and is not overly resource intensive to manage a large number of substances. Some areas that still need improvement include finding an effective way to conduct comprehensive searches of scientific literature to identify quality scientific data; and the implementation of a quantitative scoring system to enhance transparency and consistency in decision making.

Possible outcomes of IRAP include no further action, data gathering to inform future prioritisation, risk assessment, or further scoping/problem formulation.

Scoping and Prioritisation for the Indoor Air Contaminants Assessment Section

Organisation: Health Canada, Indoor Air Contaminant Assessment Section

Web link: N/A (internal document)

Scoping and Prioritisation for the Indoor Air Contaminants Assessment Section (IACAS) occurs every 2 years or as needed to allow forward planning with flexibility to take on new activities as necessary. This frequency allows for longer term vision of multi-year

projects. It identifies high and low priorities for both assessment and management. Individual substances, groups of substances defined as VOCs/semi-VOCs and other air pollutants (e.g., particulate matter) are included in prioritisation. The general human population and vulnerable subpopulations are considered for exposure. All vulnerable subpopulations identified in literature are also considered, these are mainly infants, children, pregnant women, those with genetic polymorphisms or pre-existing disease conditions and those with greater exposure due to proximity to a source or activity.

Substances considered for prioritisation come from those that have Residential Indoor Air Quality Guidelines or those registered as VOCs. Other substances can also be added during prioritisation. Although there is no formal pre-prioritisation process, possible issues are screened before prioritisation takes place. Input on prioritisation is also accepted from external parties; prioritisation is guided in part by trends in inquiries about air pollutants through email and phone.

This scheme cannot be identified as purely hazard, exposure or risk based, it is flexible and all three factors are considered as necessary for a holistic approach. A quantitative scoring system using the Risk 21 approach is currently under development. Hazard and exposure information are gathered from public resources including: peer reviewed scientific literature, grey literature, published internal, provincial and territorial risk assessments. Exposure information is also gathered from research produced by Heath Canada research teams in cooperation with partners as necessary. The team assigned to assess a particular chemical will also look at the hazard endpoints and quality of the study. All methodologies are considered in this prioritisation scheme including New Approach Methodologies (NAMs) such as in vitro assays and in silico analyses.

There was consultation with the Federal/Provincial/Territorial Indoor Air Committee during the development of the scheme. The results are compiled in guidance documents, which are then shared with partners and published on the Government of Canada website. This approach is flexible, holistic and comprehensive and addresses clearly defined exposure scenarios and risks. The process has been recently revised and has been built on Water and Air Quality Bureau best practices and has yet to identify weaknesses, as a result there are currently no lessons learned. For the next steps high priority chemicals will undergo full risk assessments and chemicals of lower priority will be addressed in other ways.

Prioritisation of the Revised in Commerce List

Organisation: Health Canada

Web link: https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan/initiatives/approach-prioritization-substances-revised-commerce-list.html

Prioritisation of the Revised in Commerce List (ICL) is an ongoing process, prioritisation was completed in 2016 but substances continue to be nominated for addition to the list and prioritised. However, the list will be closed to nominations in 2019. This initiative differentiates between substances which require further consideration (i.e., assessment) and those that do not. It takes into account exposure to the general human population, consumers, the environment and vulnerable subpopulations, specifically children. The process considers both individual substances and groups of substances which are defined

based on similar chemical structure. Microorganisms are also considered based on their taxonomical classification and use pattern.

Prioritisation is based on hazard criteria, exposure and risk. Hazard criteria used are CMR, PBT, TSCA categories of concern and endocrine disruption. Information is gathered from databases, assessments and literature that is mostly available to the public, with a limited number of internal sources. Exposure information is also gathered from various public sources, along with a few internal sources. Priorities are selected based on a weight of evidence in a precautionary manner. Phys-chem properties are also taken into consideration to determine the fate of chemicals in the environment for PBT predictions. One new approach methodology (NAM) used in this approach is QSAR predictions which were used to estimate inherent toxicity, bioaccumulation and persistence. Data quality is only taken into consideration at the assessment stage, not during the prioritisation process.

For development of the scheme, government partners, non-governmental organisations and industry representatives were consulted in face-to-face meetings and teleconferences. Information on the prioritisation process and results are published on the Health Canada website and stakeholders are kept informed through consultations, meetings, webinars and by email. This approach is precautionary in nature, simple to follow and consistent. At the same time it is possible that the approach is overly cautious, as it flags substances containing TSCA New Chemical Categories of Concern or those identified as CMR or PBT. Next those substances prioritised for further consideration will undergo robust evaluations.

Prioritisation of Nanoscale Forms of Substances on the Domestic Substances List

Organisation: Health Canada

Web link: https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/consultation-document-prioritization-approach-nanoscale.html

Prioritisation of Nanoscale Forms of Substances on the Domestic Substances List (DSL) was developed to enable Health Canada to explore the information available for exposure and human health of DSL nanomaterials for prioritisation and quantitative risk assessment, identify data gaps and to develop a strategy for filling those gaps. This process is on-going so that priorities may be updated as the field of nanotechnology evolves and incorporates additional DSL substances over time. This scheme identifies both high and low priorities for assessment as well as data gaps or "insufficient information" for assessment. Exposure to the general human population, consumers, the environment and vulnerable subpopulations (children) are taken into the consideration. Prioritisation includes both individual and groups of substances. Naturally occurring substances, pharmaceuticals and substances that are not nanoscale are not included in prioritisation.

The list of chemicals for prioritisation encompassed 53 substances that were identified to be in commerce in Canada in 2014 based on a survey of stakeholders. This group was narrowed down from an initial list of 206 substances based on a Canada-US Regulatory Cooperation Council initiative, stakeholder consultation and literature searches.

This is a risk-based scheme. Hazard criteria used includes CMR, endocrine disruption, repeated dose, acute toxicity, skin sensitisation, irritation and bulk substance toxicity. Exposure information relies on volume and use data. Priorities are selected based on weight of evidence in a precautionary manner, using a risk matrix with low, moderate and high bands for both exposure and hazard considerations. Information for hazard and exposure comes from a variety of domestic and international sources; many are publically available, while a small number are internal documents and databases. Particle size distribution, shape, surface modifying groups, dissolution rate and any structural alerts were considered at this stage for both exposure and hazard perspectives. In the absence of sufficient data, conservative worst case assumptions are applied. Data quality is only considered at the assessment stage and not during prioritisation. All available information on a nano form of a substance was used to determine both hazard and exposure priorities, this includes NAM data. However, if data from NAMs was the only information found then the substance was deemed a priority but with insufficient data to conduct an assessment.

There was initial consultation with government partners, NGOs, industry and academia representatives in face-to-face meetings and teleconferences. Stakeholders continue to be informed through further consultations, meetings, webinars and emails. The results of the process are also published on the Health Canada website. The main strengths of this approach are that it is precautionary in nature; it is simple to follow while still having incorporated key considerations for nanomaterials into a checklist for consistency. One weakness identified is that there are no mechanisms for overcoming a lack of information related to specific nanomaterials. As a result it means that a substance can be deemed as having "insufficient information to prioritise", although this is seen as favourable compared to assigning a low priority based on the absence of hazard or exposure data.

Next, all nanomaterials identified as being in-commerce in Canada will undergo risk assessment and management. A framework describing how the risk assessments are to be conducted will be published and the assessments will be made public as part of the Canadian Chemicals Management Program.

Proposed Regulatory Amendments for Environmental Risk Assessment of Medicinal Ingredients in Drugs

Organisation: PPIAD, HPFB, Health Canada

Web link: N/A

The Proposed Regulatory Amendments for Environmental Risk Assessment of Medicinal Ingredients in Drugs is currently in development under the Canadian Food and Drugs Act. The main driver is to address gaps in information needed to understand the long-term environmental and indirect human health impact of drugs. This is an ongoing process with the intent to trigger an environmental risk assessment of medicinal ingredients, when particular submissions types are made to Health Canada, but only in circumstances where there is a potential increase in the quantity of medicinal ingredient released to the environment. It considers exposure to the environment and indirect exposure of the general human population. This scheme also considers medicinal ingredients in drugs used for aquaculture, while excluding medical devices, radiopharmaceuticals, natural health products and cosmetics and medicinal ingredients used solely in disinfectants.

Veterinary drugs for non-food producing animals and veterinary health products and drugs required for timely access to lifesaving treatments are exempted from the process.

Substances listed on the Canadian Domestic Substances List (DSL) prior to the regulatory proposal coming into effect will be exempt from the requirements. Industry has the option to request a pre-submission meeting to discuss changes to the data requirements laid out in regulations. There is a minimum data set but the requirements vary with substance type and life-cycle stage.

Prioritisation of substances is based on exposure and hazard. Chronic ecotoxicity data was gathered from PhACT and MISTRA databases, neither of which are available to the public. Both databases contain comprehensive aquatic life data on pharmaceutical compounds from the peer reviewed literature. From these databases, NOECs were extracted for 88 active pharmaceutical ingredients. The results indicated that impacts on aquatic life were more likely above a predicted environmental concentration (PEC) of 0.1µg/L. Below this level, only a few types of substances were shown to have potential for adverse environmental impacts (categorical inclusions). Only substances with a PEC >0.1 ug/L or those that are categorically included would be identified for further assessment.

For development of this scheme there were multi-stakeholder consultations with industry and industry representatives during the beginning of the project (2006-2011) with additional consultation in 2018 as the project was revitalised. Results of risk assessments are publically available through product monographs or published in publically available databases. Results are also communicated personally with the notifiers. Some of the strengths of this approach are that it introduces more appropriate data requirements, it harmonises requirements with key international regulators (EU and US) and information is made available to the public. The main weakness is the complexity of the scheme, with many different triggers and exclusions/ exemptions, which makes it is difficult to explain to the public. Once in force, notifiers will be required to submit the required environmental risk assessment data to Health Canada as part of the regular drug submission process. Health Canada will use that data to conduct an environmental risk assessment of that medicinal ingredient and manage any potential risks where appropriate.

Drinking Water Chemicals Prioritisation Process

Organisation: Water and Air Quality Bureau, Health Canada

Web link: N/A

The Water and Air Quality Bureau of Health Canada works with the provinces and territories, along with other federal departments to deal with drinking water issues. The Drinking Water Chemicals Prioritisation Process occurs every 4 years. This frequency allows new science to be reviewed in a timely fashion to identify potential new contaminants and update existing guidelines for drinking water. The objective of the process is to allow forward planning of workload with flexibility to take on new activities as necessary. The comprehensive, systematic prioritisation process identifies the top 25-30 health-based priorities taking into account treatment and analytical considerations, as well as the priorities established by provinces and territories. The process takes into consideration whether or not a chemical is present in the environment based on monitoring data, or phys-chem properties that may impact exposure, such as solubility or

leaching potential. Exposures considered are relevant to the general human population along with vulnerable sub-populations, which are defined as infants, toddlers, children and pregnant women. Both individual substances and groups based on chemical similarities and structure are included.

The process starts with the list developed in the previous prioritisation process. Hazard criteria are gathered from national/ international assessments, peer reviewed literature, grey literature and published risk assessments, all of which are available publically. Exposure looks at occurrence and monitoring levels. Information is also taken from publically available primary references and national/international assessments. The Risk21[7] model is used to integrate hazard and exposure data using a scoring system of 1 (low), 2 (moderate) and 3 (high).

The provinces/territories and other federal departments that deal with drinking water issues (e.g., Environment and Climate Change Canada, Department of National Defence, National Research Council) were consulted for the development of the approach. Information is shared with provinces and territories throughout the process. Some of the key strengths of this approach are that it is a science based scheme, it receives input from provinces and territories, and provides a thorough, systematic review of hazard and exposure considerations, integrated by the Risk21 model. The use of the Risk21 model is considered a significant improvement from the previous exercise completed in 2014. The final priority list is established ranking chemicals from 1 to 25-30. Following the ranking, a 5-year work plan is established in collaboration with stakeholders and partners.

European Union

Trade Union Priority List for REACH

Organisation: European Environmental Bureau

Web link: https://www.etuc.org/en/trade-union-priority-list

The Trade Union Priority List for REACH authorisation is driven by REACH. Thus far the list has been reviewed twice due to changes in the classifications and other priority lists being updated. This scheme identifies high and low priorities for assessment. Commercial chemicals with high production volume (>1000T), pesticides, individual substances and groups are all included in prioritisation. CMRs, PBT, vPvB, POPs and substances liked with occupational diseases are also included in the Trade Union Priority list. It considers exposure to the general human population, workers and the environment.

All chemicals included in the process are High Production Volume Chemicals (HPVC) listed in European Chemical Substances Information System (ESIS) or covered by a Substance Information Exchange Forum (SIEF), all other chemicals are not taken into account. The European Risk Ranking Method (EURAM) for ranking HPVC by scores has been adapted to cover all chemicals considered to be substance of very high concern (SVHC). Points are attributed to various criteria and scores for each are additive, the most urgent SVHC to be included in the candidate list are the ones which accumulate criteria. The trade union priority list does rely on actions taken in other jurisdictions; many of the

[7] https://risk21.org/

lists used are regulatory lists. The European Trade Union Confederation (ETUC) believes that including the union listed chemicals in the REACH authorization list would reduce the incidence of chemical-related occupational disease/ For SVHC identification, the Trade Union Priority list takes into consideration additional inherent hazard properties not explicitly mentioned in REACH, but are considered to be of "equivalent level of concern".

Prioritisation is based on hazard, exposure and risk. Hazard criteria are CMRs (category 1A, 1B or 2), carcinogens (1, 2A or 2B), PBT substances, known and suspected endocrine disrupters and neurotoxic substances. Hazard information is gathered from a variety of international organisations where the data are publically available. The substances must be officially classified or listed in the different lists to be included. Exposure criteria include high production volume thresholds and workers exposure. Inventory volumes used for exposure information are also available to the public. Phys-chem properties are considered if they trigger classification under CLP regulation. The reliability of the different sources was scrutinised; sources deemed not reliable were discarded. The RISCTOX database was used for prioritisation. It provides information on substance classification, specific health risks, specific environmental risks, environmental and health-related regulations.

National and EU trade unions were consulted through email and workshops in development of the approach. The priority list was widely disseminated and presented to the EU authorities, including the European Parliament, Commission and chemicals Agency (ECHA). The process is based on a very reliable set of regulatory and scientific lists. It allows hazard properties to accumulate, increasing the chance that a substance will be prioritised. It also considers potential to cause occupational diseases an important criterion for prioritisation and the sources used to gather data are all publically available. The main weakness attributed to this scheme is resource constraints and as a result the list hasn't been updated frequently enough to keep up with changes to existing lists. Next, ETUC believes that including union-listed chemicals in the candidate list will allow professional users to get more information on their uses. If the substances are subsequently subject to restrictions, it would surely promote the development of safer alternatives and cut both the incidence of chemical-related occupational diseases and the attendant costs for the community, workers and industry itself.

Screening as part of the integrated regulatory strategy

Organisation: European Chemicals Agency (ECHA)

Web link: https://echa.europa.eu/echa-irs and https://echa.europa.eu/screening

Screening as part of the integrated regulatory strategy occurs on an annual basis, driven by REACH and CLP, however it is likely that it will eventually evolve so that it is a continuous process. This scheme identifies high and low priorities for assessment, management and data generation. Exposure to the general human population, consumers, workers and the environment are all considered, while vulnerable subpopulations are not. Individual substances and groups based on chemical similarity or similar uses are included. Polymers and Pesticides are not included in prioritisation.

No specific inventory is used for prioritisation; instead, substances are taken from live updates of chemicals in commerce. Overall, the prioritisation uses a sequence of steps where selection becomes increasingly narrow. There is also assessment of how 'good'

cases are for further data generation and/or assessment, if there is enough information and what potential regulatory hurdles there may be. This scheme uses global knowledge (using a commercial product, LOLI by ChemAdvisor), but does not use the "trusted regulator" approach.

Both internal and external sources are used to gather information on exposure and hazard. The IUCLID dossier submitted under REACH is the main source of both hazard and exposure data used and data analysis tools are partially based on IUCLID and partly customised. New approach methodologies such a ToxCast and QSAR predictions are incorporated into prioritisation and a minimum data set under REACH is defined per tonnage band. When submitted information is not sufficient for compliance this is seen as a data gap and prioritised for compliance check. To identify priorities a list of candidates is made, member states can volunteer to continue work based on preferences, available resources and regulatory relevance.

The strategy was developed with engagement from stakeholders (industry, member states and NGOs) and screening is developed and executed in collaboration with member states. Implementation and execution of prioritising substances is done by ECHA internally. There is currently no public list of chemicals being looked at, but registrants are informed that their chemical might be under scrutiny. Once it is clarified that a substance will be further worked on, information is published on the ECHA website. Some of the strengths identified for this approach are that ECHA has a starting point where all relevant chemicals have a base level of information and there is no distinction between existing and new chemicals. The main goal of this scheme is to identify potential substances of very high concern (SVHC). Some of the weaknesses acknowledged are that despite REACH requirements there are still significant knowledge gaps in the dossiers. Additional use or exposure data would be helpful for further prioritisation/de-prioritisation but the area is under development in terms of data and methods (e.g., improving supply chain communication, improving assessment approaches for articles). Depending on the need and level of priority, substances can be 'picked up' by different processes (e.g., evaluation, risk management options analysis, harmonised classification and labelling), which each have different time frames.

NORMAN Prioritisation framework

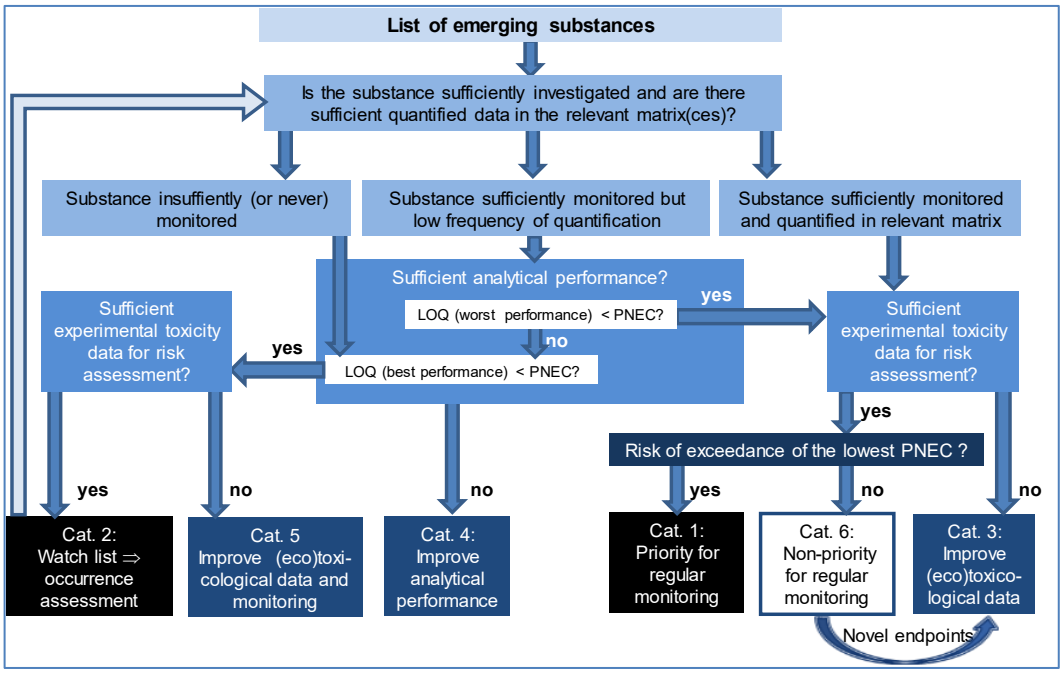
Organisation: NORMAN

Web link: https://www.norman-network.net/?q=node/126

The NORMAN Prioritisation framework for emerging substances was initially driven by the European Water Legislation, but has now been adapted for other purposes. The process has no set frequency and instead is performed on an on demand basis. This allows for updates as new information and datasets become available. The main objective of the NORMAN prioritisation scheme is to provide a rational approach to deal with the knowledge gaps associated with emerging substances. This scheme identifies high and low priorities for both assessment and management and is designed for environmental risk assessment purposes only and does not take into consideration human exposures. The NORMAN prioritisation scheme can be applied to any individual chemical substance but it is not appropriate for UVCBs or polymers, nor does it consider groups or classes of substances. There is no exclusion criteria, compounds are ranked as lower priority or in categories that require specific actions, rather than being excluded.

NORMAN uses the Suspect List Exchange database (SusDat) as the inventory for candidate compounds for prioritisation. SusDat is today a list of more than 40,000 compounds, collected by different NORMAN partners / labs as compounds of potential interest for environmental monitoring. New lists are regularly provided by various contributors. There is a categorisation step, where substances are placed into 1 of 6 categories based on the identified knowledge gaps and actions needed to fill them, and then each is prioritised separately. In the second stage, substances are ranked within each category, on the basis of their occurrence, hazard and risk indicators (see Figure 6).

Figure 6. NORMAN categorisation / prioritisation scheme



This approach is risk- based. Hazard criteria include ecotoxicity (PNEC), CMR classification, PBT/ vPvB classification and proven or suspected endocrine disruption. Hazard assessment is based on an internal database of ecotoxicity data used to derive Predicted No-Effect Concentrations (PNEC), as well as databases with published PNEC data. Exposure criteria are the frequency of quantification of the substance, concentration level and the number of countries/ sites in which the substance has been measured and found. Exposure information is related to environmental monitoring data. Raw monitoring data are regularly collected from both water authorities and research partners. Data collection is performed manually and transferred to collection templates before being uploaded to the dedicated NORMAN databases. High quality data are preferred to non-validated literature. Lower quality data can be used for preliminary assessment of substances, but minimum requirements must be fulfilled to upload the data to the NORMAN database. Some data are generated de novo and new approach methodologies are incorporated into the prioritisation scheme. PNECs are derived using QSAR and read across models for preliminary assessment of compounds, when experimental information is lacking. These substances will be allocated into the appropriate category to address the knowledge gap. In addition, phys-chem properties are taken into consideration and are

used as supporting parameters for the derivation of indicators used for the prioritisation process. Risk indicators are also applied; these are a risk ratio and frequency of exceedance of the PNEC. A quantitative scoring system is used to identify priorities, scores range from 0-1, but the algorithm used to calculate the final score differs depending on the category.

This process was developed in consultation with the NORMAN network, consisting of over 70 organisations. NORMAN creates facts sheets containing all relevant information on compounds that can be shared with stakeholders. The approach used is transparent and rational, it justifies the need to implement control measures or actions for different categories of emerging contaminants and takes into account knowledge gaps. The approach is flexible and can be adapted to different scales and target prioritisation objectives. The approach is unable to account for mixture effects and it's mainly a top-down approach. After prioritisation the results are shared with NORMAN members (research and governmental organisations) to take further actions.

Finland

Matrix for risk-based prioritisation

Organisation: Finnish Safety and Chemicals Agency

Web link: N/A

The purpose of the matrix for risk-based prioritisation scheme is to comply with legislation (e.g. REACH), support work programmes and improve the risk assessment of chemicals. Prioritisation processes based on ongoing hazard identification, including screening and public consultations on proposals to identify new substances of very high concern (SVHC), are conducted on a regular basis throughout the year. The scheme is focused on the identification of both low and high priorities for risk assessment and management and takes into consideration consumers and the environment. For hazards impacting human health, the prioritisation focuses on sensitisers and consumer chemicals, while persistent, bioaccumulative and toxic (PBT) or endocrine disrupting (ED) substances are prioritised for the environment. Workers and vulnerable population exposures are not considered in the prioritisation process. Additionally, chemicals not on the market in Finland are also excluded.

Chemicals for prioritisation are derived from authorities' work programs by using the prioritisation matrix, with no pre-prioritisation process included, however government programmes and ministerial initiatives on chemicals are taken into account. The public is not able to nominate substances for prioritisation, although governing ministries' requests involving external party interests are considered when available.

Hazard and exposure are used for the basis for prioritisation with scores given in a two-dimensional nine-field matrix. The matrix has two variables: strategic importance, for example regulatory and EU/national objectives, and effectiveness of risk management. The most effective tasks for improving chemical safety obtain the highest scores and are prioritised (i.e. SVHC identifications vs. dossier evaluation draft decisions). There is no minimum data set requirement to assign a score. Hazard information is collected from a number of publicly- and non-publicly available EU sources, while exposure information is from non-publicly available sources including REACH registration. Data submitted by Finnish chemical introducers for the national chemicals products register are used

however no data are generated de novo specifically for prioritisation. Data quality is taken into consideration with Klimisch principles followed at the preliminary evaluation step of prioritisation.

No external parties were consulted in the development of the approach. Information explaining the approaches and outcomes are published on the ECHA website and corporate stakeholders are provided with updates. Overall, the strength of this approach is that it helps allocate limited resources in the most efficient manner. Next steps include listing the substances in the Community rolling action plan (CoRAP) or risk management option analysis (RMOA). These processes take less than a year to complete but follow-up evaluation leading to proposals for risk management, such as restrictions or authorisations, usually take several years.

Germany

Manual Screening for Regulatory Action

Organisation: Federal Institute for Occupational Safety and Health

Web link: N/A

The Assessment Unit for Occupational Safety and Health within the German Federal Institute for Occupational Safety and Health is engaged in a prioritisation scheme to identify substances of potential concern under REACH. The purpose of the prioritisation is to fulfil the legislative requirements of Regulation (EC) No. 1907/2006 – REACH legislation. The prioritisation is updated annually in accordance with the annual update of the Community Rolling Action Plan under REACH. The prioritisation by the Institute addresses concerns with occupational (worker) exposures to chemicals. These include both individual chemicals as well as groups of chemicals that are related not necessarily chemically, but through their uses in specific occupational health and safety contexts. Substances are excluded if they are not registered under, or covered by REACH (e.g., plant protection products, pharmaceuticals), used at low annual tonnages, are intermediates or substances predominantly used in closed manufacturing systems or used predominantly in industrial settings without widespread uses registered under REACH.

Regulatory agencies, trade unions and insurance associations are invited annually to submit chemical substances and emerging issues for consideration. The Institute includes substances for prioritisation that are identified by other assessment units (environment and consumer) and federal consultative bodies, for example the German Committee on Hazardous Substances within the Federal Ministry of Labour and Social Affairs. Issues raised by these organisations as well as data on the prevalence of specific occupational-related diseases are considered when selecting substances for prioritisation. The institute also considers substances shortlisted by ECHA in the annual screening.

The prioritisation scheme is based on hazard, exposure and risk information. The highest priority criteria are sensitisation, CMR, dispersive uses, processes with potentially high worker exposure and the potential for necessary regulatory action. Data are obtained from publicly available sources such as the ECHA dissemination site and from confidential sources such as the chemical safety reports of lead REACH registrants. The Institute keeps its own internal database of substances which include those registered under REACH and substances for which occupational health and safety concerns have been raised. The minimum dataset for screening and for decisions regarding in-depth

assessment is the registration dossier under REACH. During pre-screening for the annual prioritisation, substances are identified and then sorted using filter criteria. The resulting substances are then subject to in-depth screening.

For prioritisation, stakeholders are invited to contribute information at early stages. Results from prioritisation are always made available to all stakeholders and interested parties. A key strength of the prioritisation process is use of a variety of expertise from toxicologists, exposure experts and experts in legislation. The process has been adapted and enhanced from knowledge of regulatory actions (under REACH and elsewhere) to make it more fit for purpose and to identify only those substances that are the highest priority for workplace safety. Success of the prioritisation process depends critically on data availability and quality. When a regulatory action under REACH (e.g., SVHC identification, restriction, substance evaluation, dossier evaluation, classification) is deemed necessary this process will be indicated and communicated to ECHA.

Work Program of the Committee on Hazardous Substances

Organisation: Committee on hazardous substances (AGS) (Ausschuss für Gefahrstoffe (AGS))

Web link: https://www.baua.de/DE/Aufgaben/Geschaeftsfuehrung-von-Ausschuessen/AGS/pdf/AGS-Arbeitsprogramm.pdf

The Committee on Hazardous Substances (Ausschuss für Gefahrstoffe (AGS)) has developed the Work Program of the Committee on Hazardous Substances, driven by the Hazardous Substances Ordinance. The prioritisation process occurs every 4 years, as determined by the length of the mandate committee. This approach identifies high priorities for management, considering exposure to workers and bystanders. It includes commercial chemicals, naturally occurring substances, individual substances as well as groups of substances classed based on their use as opposed to the substance family. This scheme also looks at carcinogens as emerging issues of concern.

There is no existing inventory of chemicals used for prioritisation; instead the work plan is created by analysing the voting members of the committee. The Ministry for Labour and Social Affairs (BMAS) wants to be advised and has to accept the work plan

Prioritisation is based on hazard criteria (e.g., carcinogens, mutagens) or overall risk. All sources used to gather hazard and exposure information are available, whether public or internal. Phys-chem properties are considered in this approach, if they lead to high risk for workers or bystander using such chemicals.

There was no consultation with other organisations or review panels in the development of the approach. Stakeholders are members of the committee; they vote and decide the work plan. The fact that stakeholders are involved in all steps of the work plan is seen as one of the key strengths of this approach. This can also be seen as a potential weakness: there are only few risk- or data-based criteria for purposes, often they depend on the (current) interests of the stakeholders. The work plan is to substantiate by project sketches, which describe the frame and implication of the further steps (working group, schedule, etc.). The project sketches have to be accepted by the committee.

Prioritisation for different REACH processes, assessments and regulatory measures

Organisation: Umweltbundesamt, UBA (German Environment Agency)

Web link: N/A

The German Environment Agency undertakes different environmental prioritisation for a variety of actions under REACH (e.g., SVHC identification, restrictions, authorisations, classification and labelling). The driver for prioritisation for environmental impacts is the REACH legislation. The prioritisation is updated annually in accordance with the annual update of the Community Rolling Action Plan under REACH. There are also prioritisation processes that occur within the Agency on an ongoing basis. Only environmental exposures are considered, which include freshwater, marine waters, sediments, soil and air. Prioritisation addresses individual chemicals as well as chemical groups. Endocrine disruptors, PBTs, Persistent/Mobile/Toxic substances (PMTs) are of particular concern. Only substances registered under REACH are included in prioritisation.

Chemicals for prioritisation are taken from the ECHA registration database and a manual screening of substances occurs as a pre-prioritisation step. Substances may be submitted for evaluation from a variety of sources including ECHA, other member states, other government departments, non-governmental organisations, as well as the public.

Prioritisation are conducted considering both hazard and exposure. Phys-chem properties are also considered. With regards to hazard, all types of data including data from new assessment approaches (e.g., SAR/QSAR predictions) are used. In general, hazard data without exposure information may be insufficient for prioritisation. The prioritisation use a qualitative rather than quantitative scoring approach and generally do not rely on or adopt actions taken by other jurisdictions. Data are obtained from publicly available sources such as the ECHA dissemination site, the scientific literature, and from partially confidential sources such as the ECHA registration database (IUCLID) and internal research reports. The Agency uses internal tools and databases for storing and analysing information on substances and regulatory actions (e.g., KnowSEC).

Consultation was conducted at the EU level during the development of the approach. Prioritisation are conducted transparently under REACH. Initial screening processes are internal but exchanges take place commonly with stakeholders during the processes. Data availability and quality are crucial. Substances may be difficult to prioritise, or de-prioritise, because of missing or low quality data. In general, a weakness of the approach is that dossier quality needs to be improved, particularly with respect to endocrine disruption and information on use and exposure. Substances are prioritised for a substance evaluation and listed on the CoRAP list, or they may be directly prioritised for further management/ regulatory measures.

Human medicinal products (HMP)

Organisation: Umweltbundesamt, UBA (German Environment Agency)

Web link: N/A

The German Environment Agency is undertaking an environmental prioritisation and review of active pharmaceutical ingredients (APIs) in human medicinal products

authorised before 2005. The drivers for prioritisation are data gaps for legacy products that contrast with the requirements of the European Medicines Agency Guideline on environmental risk assessment (ERA) of medicinal products for human use (EMEA/CHMP/SWP/4447/00). The prioritisation is to address around 1300 legacy APIs of environmental concern, only around 300 of which have available environmental risk assessments, and the lack of environmental effects and fate data for around 254 APIs detected in surface water and 94 APIs detected in ground water. Prioritisation is ongoing. Substances excluded from the prioritisation are those that are not environmentally relevant, including: herbal APIs, vitamins, electrolytes, amino acids, peptides, proteins, carbohydrates and lipids and naturally occurring compounds.

Substances for prioritisation are sourced from the German human medicinal products information system[8] and a separate internal database. Priority is given to data-poor substances and/or those included in national monitoring programs.

Hazard information is sourced mainly from publicly available assessment reports of national and EU-wide authorisations and an internal database containing validated endpoint data and confidential study reports. Exposure information is sourced from calculations based on indications and applied daily doses, internal national consumption data, data from national and EU-wide monitoring programs and a publicly accessible database of pharmaceuticals in the environment[9].The minimum data required for evaluating substances in the prioritisation are environmental exposure data. Overall, data are judged for relevance, reliability and validity. Prioritisation is hazard based (effects, PBT, CMR, endocrine activity) as well as exposure based (consumption). Phys-chem properties are also considered for prioritisation. Prioritisation does not use a quantitative scoring approach and does not rely on or adopt actions taken by other jurisdictions.

For development of this approach a concept poster was presented and discussed among environmental scientists at SETAC, a scientific conference in 2018. The results of prioritisation are shared with stakeholders and scientists including at international conferences. A strength of the prioritisation process is that it is a simplified approach based on existing experimental data and which groups substances into classes based on pharmacological mode of action and on application. Data gaps are a concern for prioritisation. For example, some substance classes based on pharmacological mode of action only contain a few APIs with environmental risk assessment data. Overall, environmental risk assessment data are available for only around 25% of APIs available nationally. Moreover, APIs detected in ground and surface water commonly lack environmental risk assessment data. The next step following prioritisation is implementing a review monograph program for the legacy human medicinal APIs.

Veterinary medicinal products (VMP)

Organisation: Umweltbundesamt, UBA (German Environment Agency)

Web link: N/A

[8] www.pharmnet-bund.de

[9] https://www.umweltbundesamt.de/en/database-pharmaceuticals-in-the-environment-0

The German Environment Agency is undertaking an environmental prioritisation and review of active pharmaceutical ingredients (APIs) in veterinary medicinal products authorised before 2005. The drivers for prioritisation are data gaps for these products that contrast with the requirements of the European Medicines Agency Guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL38 (CVMP/VICH/592/98 and CVMP/VICH/790/03). Eighty-four APIs used in veterinary medicinal products have been identified that require an in-depth environmental risk assessment. For ranking, these are grouped into classes using substance specific information. Prioritisation is ongoing. Substances excluded from the prioritisation are those that are not environmentally relevant (e.g., vitamins, electrolytes, amino acids, peptides, proteins and naturally occurring compounds). Also excluded are substances used in products for non-food animals and those with negligible environmental concentrations due to use in only small numbers of animals.

Substances for prioritisation are sourced from the German veterinary medicinal products information system[10] and a separate internal database. Pre-prioritisation screening is conducted on the basis of use in the German market. Further priority is given to data-poor substances and/or those included in national monitoring programs.

Prioritisation is hazard based (effects, PBT, endocrine activity) as well as exposure based (consumption and monitoring). Phys-chem properties are also considered for prioritisation. Prioritisation uses a quantitative scoring approach to rank substances into classes and does rely on data obtained from other jurisdictions (e.g., pesticides and biocides regulations). Hazard information is sourced mainly from publicly available assessment reports of national and EU-wide authorisations and an internal database containing validated endpoint data and confidential study reports. Exposure is calculated based on indications and applied daily doses, national consumption data for antimicrobials, data from national end EU-wide monitoring programs and a publicly accessible database of pharmaceuticals in the environment[11]. The minimum data required for evaluating substances in the prioritisation are environmental exposure data. Overall, data are judged for relevance, reliability and validity.

During the development of this approach a concept poster was presented and discussed at ICRAPHE conference in Paris, further discussion occurred at an internal workshop in Brussels. The results of prioritisation are implemented in veterinary pharmaceutical legislation and shared at international conferences with stakeholders. A strength of the prioritisation process is that it is a simplified transparent approach based on publicly available data. A concern for the prioritisation is the exclusion of veterinary medicinal products from non-food animals. The next step following prioritisation is implementing a review monograph program for the legacy veterinary APIs.

[10] www.pharmnet-bund.de

[11] https://www.umweltbundesamt.de/en/database-pharmaceuticals-in-the-environment-0).

POPs-related prioritisation projects

Organisation: Umweltbundesamt, UBA (German Environment Agency)

Web link: https://www.sciencedirect.com/science/article/pii/S1309104215304128

https://www.bmu.de/fileadmin/Daten_BMU/Pools/Forschungsdatenbank/fkz_3711_65_406_pops_bf.pdf

The German Environment Agency is undertaking two POPs-related prioritisation projects. The first is aimed at evaluating the data, methods and procedures used to identify current POPs and to develop a strategy for identifying new POPs. The second aims at identifying POPs candidates by applying the revised strategy. The driver for prioritisation is the large number of chemicals currently on the global market and the need to determine effectively the number of additional POPs that could require regulation. A one-time prioritisation was conducted on commercial chemicals > 100 tonnes/annum. It identifies high priorities for assessment and only environmental exposures were considered in prioritisation.

Substances for prioritisation were sourced from the ECHA pre-registration database and the ECHA dissemination website. There is a pre-prioritisation process included in the workflow. Prioritisation was based on hazard and production volume (high). Phys-chem properties were also considered for prioritisation with Epi Suite being used for estimations. Hazard information was sourced from the ECHA registration database, the ECHA dissemination site, publicly available literature and internal research reports. Prioritisation used a semi-quantitative scoring system which did not rely on, or adopt actions taken in other jurisdictions.

No consultation with other organisations or reviewers was used in development of this approach. A key strength of this prioritisation process is its transparency. A weakness was the use of pre-registration data to identify substances. Since many of the resulting priorities were never registered under REACH, no data became available for these.

Consumer exposure considerations for screening activities in different REACH processes

Organisation: German Federal Institute for Risk Assessment

Web link: N/A

The German Federal Institute for Risk Assessment conducts on-going prioritisation for the purposes of identifying both high and low priorities to inform assessment and management of risk for consumers, including bystanders and children. The driver for this prioritisation is REACH legislation (Regulation (EC) No 1907/2006) and it applies to commercial chemicals registered under REACH, including polymers, UVCBs and naturally-occurring substances. Substances not registered under REACH, intermediates, and substances and/or uses that are outside the scope of REACH regulation (e.g., plant protection products, biocides, cosmetics, food additives, pharmaceuticals, etc.) are excluded from the prioritisation process. Substances may be prioritised individually, or in groups. In the context of consumer exposure, grouping may involve substances with similar phys-chem properties or technical functions, but in addition groups can be generated based on characteristics related to the product, its use and other exposure factors (e.g., use frequency, purpose of activity, product design and location). On-going

prioritisation is conducted for nomination and for participation/scope-setting in regulatory processes (e.g., substance evaluation). The manual screening is performed on an annual basis for the purpose of updating the Community Rolling Action Plan (CoRAP) to indicate upcoming work for the next several years.

Prioritisation was based on overall risk of the substance, based on hazard classification and consumer exposure considerations. Prior to manual screening, the substances are sorted by filter criteria to narrow down the set of substances initially identified through the pre-screening process before being screened in depth. Hazard information is sourced from ECHA classifications and the ECHA dissemination site. Exposure information is gathered in the ECHA dissemination site, active REACH registration dossiers (CSRs of registrants, confidential data set on use and exposure in IUCLID), the database on the use of substances in products in Nordic countries (SPIN Database[12]), the Mintel Database[13], and publically-available literature. Phys-chem properties are used to estimate exposure potential in combination with the information on the product and/or the substances technical function.

No consultation with other organisations or reviewers was used in development of this approach. Consultation with internal experts from the areas of toxicology and risk management does occur during the final step of the prioritisation scheme. Only standard office software is used to conduct the work. A key strength of this prioritisation process is the EU-wide consideration of available information and consultation with experts during the process. An identified weakness of this scheme was the heavy reliance on the availability of data on substances in products, mixtures and articles. Substances that do not meet the standard requirements of this prioritisation scheme may still in identified as priorities through other parties (e.g., by ECHA, other member states or national assessment units), or from other activities outside REACH.

After the prioritisation is complete, the next step is for high and low priorities to be identified on a national level in consultation with other German assessment units (worker and environment). The results of the prioritisation process are made available publicly via substances lists for the public activity coordination tool (PACT) and CoRAP.

Japan

Priority Assessment Chemical Substances

Organisation: Ministry of Health, Labour and Welfare; Ministry of Economy, Trade and Industry; Ministry of the Environment

Web link: N/A

The three ministries have developed the prioritisation scheme under the Screening Assessment in Chemical Substances Control Law. The purpose is the selection of priorities linked to an annual mandated notification by industry of manufacturing quantities and other data. The scheme is focused on the identification of both low and high priorities for risk assessment and takes into consideration exposures to the general

[12] http://spin 2000.net

[13] http://www.mintel.com/

population and the environment. The prioritisation includes commercial chemicals, polymers, UVCBs, pesticides (unless covered by other regulations), naturally-occurring substances and individual substances but not pharmaceuticals, chemical groups or emerging chemicals of concern. Additionally, chemicals with a manufacturing and import volume of ≤10T per year, or estimated emission volume of ≤1T per year, are also excluded.

Chemicals for prioritisation are taken from lists of new and existing chemical substances that have been evaluated by the government. These lists are pre-prioritised before being included in the main prioritisation process. Chemicals estimated to be released to the environment at <10T per year are screened and classified into five exposure classes while those with an environmental release of >10T per year are designated as Priority Assessment Chemical Substances (PACS) if certain hazard and exposure criteria are met. Further, expert judgement using monitoring and pollutant release and transfer registers (PRTR) data are applied by the joint councils of the three ministries to identify priorities that do not meet the requirements of the prioritisation scheme.

Risk is used for the overall basis for prioritisation, with hazard and exposure criteria being combined to produce a priority rating. Chemicals are assigned to one of five hazard classes (based on quantified severity of effect) and one of six exposure classes (based on environmental release). A default hazard classification is assigned in the absence of test data for endpoints required under the Chemical Substance Control Law (CSCL). A priority of low, medium or high is assigned according to a risk matrix with cut-off criteria determined by simulation results of detailed risk evaluations. Hazard information is sourced from publications by national/international organisations, such as government agencies, while exposure information is based on industry-provided introduction volume for each usage classification combined with environmental release as calculated using published emission factors. The introduction quantities and exposure class are updated annually and are publicly available. No data mining software or specialised database is used in this process and data quality is taken into consideration using Klimisch principles and final review based on established reliability criteria.

For the development of the approach, the joint councils of the three ministries and the public were consulted. Information describing the process and results of the prioritisation is deliberated on by the council, which includes experts on chemical assessment and consumer and industry representatives and is published on the web. Overall, the strengths of this approach are that it is an efficient way to prioritise existing chemicals for environmental risk assessment. On the other hand it can be difficult to identify substances since the unit of some substances in the list of existing chemical substances are not appropriate as risk evaluation units and there are some reporting deficiencies with the current notification system. Next steps include amendment of the notification system, designation of high priority substances as PACS and multi-stage risk assessment of the priorities before risk management under the CSCL (if required).

Netherlands

Prioritisation tool for chemical substances in consumer products

Organisation: RIVM

Web link: https://www.rivm.nl/bibliotheek/rapporten/2015-0194.pdf

The purpose of this prioritisation tool was to comply with REACH and improve product safety at the request of the Netherlands Food and Consumer Product Safety Authority (NVWA) in the years 2014-2015. The scheme was focused on the identification of criteria for hazard and exposure. The prioritisation identified individual substances that were classified as carcinogenic, mutagenic or toxic for reproduction (CMR) and used in consumer products in high volume (> 100T) as registered in the REACH database over the period from June 2014 to March 2015. Only consumer exposures were considered.

Priorities were identified on the basis of risk. Using expert judgment, a score for exposure was established with regard to PC (Product Category) and AC (Article Category) codes used in REACH Hazard data came directly from REACH and was scored by quantifying the effect and the potency. No minimum data set was required for evaluating substances in prioritisation. No data mining software was used in this process and data quality was not considered.

There was no consultation in the development of the approach. Information explaining the approach is published on the RIVM website and a report was provided to the NVWA and other interested organisations. Overall, the strengths of this approach include its use of industry data on consumer products, incorporation of aggregate exposure, adaptability to different endpoints and ability to rank chemicals within specific single product categories. It could easily be repeated to reflect database updates and takes into account both hazard and exposure. On the other hand it is dependent on the accuracy of information submitted by industry in REACH registration dossiers (i.e. classification, derived no effect levels, selection of consumer use), was initially restricted to registered substances from June 2014 to March 2015 and is a screening tool where highly ranked substances need to undergo further assessment. The next step will be determined by the NVWA.

New Zealand

Flexible Reassessment Categorisation Screening Tool" (FRCaST)

Organisation: New Zealand Environmental Protection Authority

Web link: https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Reassessments-programme/FRCaST-Tool-Notes.pdf

The purpose of this prioritisation scheme is to update the 2010 priority list and have a scheme that is maintained live internally, with updates published regularly to help with stakeholder certainty. The scheme is focused on the identification of high priorities for risk assessment and takes into consideration the general population, workers and the environment. The prioritisation mainly deals with individual substances though grouping may occur on an ad hoc basis if a class is deemed sufficiently numerous and homogeneous. Pharmaceutical substances and vulnerable population exposures are not considered in the prioritisation process. Additionally, chemicals prohibited in New

Zealand under the Stockholm convention, chemicals deemed not used in the country, formulations and dilutions are also excluded.

Chemicals for prioritisation are taken from existing lists of substances which, for example, have been identified as concerns by other regulators or of public interest. Some of these feeder lists, are prioritised themselves before being included in the main prioritisation process. Further, there is a work stream dedicated to emerging issues and watching actions taken by overseas jurisdictions which can result in a chemical being added or reassessed. The public is not able to nominate substances for prioritisation, however, external parties are able to request that the NZ EPA review existing approvals of a particular hazardous substance.

Hazard, exposure and risk are all used for the basis for prioritisation, with hazard and exposure criteria being combined to produce a risk score. The risk score can then be modified depending on the scenario and /or emerging concerns (e.g., endocrine disrupting substances), with the final value then used to inform the ranking. Substances must have a hazard classification and a use pattern to return a score. In the absence of such data they assume a 'best case' scenario, or a most benign hazard for absence of end points. Both hazard and exposure information is collected from a number of publically available, international sources. No data mining software is used in this process and data are not generated de novo for prioritisation. Data quality is taken into consideration, although there is no formal approach. The most conservative endpoint is used. No specialised database is used for prioritisation.

For the development of the approach, international organisations with established processes were consulted. Information explaining the approach is published on the EPA website and emails to stakeholders provide them with updates. Overall, the strengths of this approach are that it is fast, not chemical specific and excel allows for scoring in real time and easy visualisation. It provides a fair analysis and takes into account both hazard and exposure. On the other hand it is difficult to account for hazards that don't fall into formal classifications or address substances that are data poor. Next steps include considering all high priority chemicals for reassessment, or other management within a few years.

United States

TSCA Chemical Prioritisation Process

Organisation: US EPA

Web link: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation

The principle driver for prioritisation is new legislation (the Frank R. Lautenberg Chemical Safety for the 21st Century Act) passed on June 22, 2016. The prioritisation process is continuous and ongoing based on a schedule that requires candidate selection, prioritisation and risk evaluation. The prioritisation process is completed within a nine to 12-month statutory timeframe, at the conclusion of which a risk evaluation may be initiated. Upon completion of a risk evaluation (within 3 to 3.5 years), EPA must designate at least one additional High-Priority chemical to take its place, thus ensuring that the EPA's risk evaluation queue always remains full. This process identifies both high and low priorities for assessment and considers the environment, the general population, consumers, workers and vulnerable subpopulations (such as infants, children,

pregnant women, workers or the elderly). This scheme includes individual substances, as well as groups of chemicals, defined as substances that are "similar in molecular structure in physical, chemical or biological properties, in use or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification." Exclusions to the prioritisation process are based on the exclusions in the TSCA definition of a "chemical substance" and thus from TSCA regulatory jurisdiction. TSCA specifically excludes:

- pesticides when manufactured, processed or distributed in commerce for use as a pesticide;
- tobacco or any tobacco product;
- any source material, special nuclear material, or by-product material as such terms are defined in the Atomic Energy Act of 1954 [nuclear materials];
- any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 [ammunition]
- any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug and Cosmetic Act) when manufactured, processed or distributed in commerce for use as a food, food additive, drug, cosmetic, or device

The prioritisation is focused on chemicals designated as "active" in 2018 reporting to the TSCA inventory. Additionally, it is required that 50% of all high priority designations be drawn from 2014 update of the TSCA work plan, until exhausted. A candidate selection process for prioritisation is being developed to assess data availability and other factors as needed before initiation of the prioritisation process. Chemical manufacturers are able to request that the EPA conduct a risk evaluation at any time by following correct procedures and submitting required information.

TSCA Chemical Prioritisation Process is a risk-based scheme. Legislatively, criteria and considerations are based on: (1) The chemical substance's hazard and exposure potential; (2) the chemical substance's persistence and bioaccumulation; (3) potentially exposed or susceptible subpopulations; (4) storage of the chemical substance near significant sources of drinking water; (5) the chemical substance's conditions of use or significant changes in conditions of use; and (6) the chemical substance's production volume or significant changes in production volume.

A quantitative scoring system is currently being developed for use in identifying priorities. Both public and internal sources are considered for hazard and exposure information. TSCA has the authority to require that chemical manufacturers/processers generate data to support prioritisation. The longer-term strategy for selecting candidate chemicals for prioritisation will integrate NAMs to fill gaps when traditional testing data are not available.

This approach provides stakeholders with notice of any prioritisation activity, as well as two opportunities for the public to submit relevant information or comments during the prioritisation step. Initiation formally begins the prioritisation process. At the initiation step, a chemical substance is formally announced to be initiated to the prioritisation process and the public is given a 90-day comment period to submit relevant information or comments. To support a proposed priority designation, the chemical substance is screened/reviewed under its conditions of use against certain criteria. At Proposal, a proposed designation is made (High/Low) and published with information, analysis and

basis used to make the designation. The public is given a 90-day comment period on the proposed designation and supporting materials. During the Final Designation step, a final designation is made considering public comments and published along with information analysis and basis used to support the designation.

Strengths of this approach include the strict timelines for the process and the criteria that are applied throughout which are consistent with previous prioritisation efforts as well as those used by other jurisdictions. Key challenges include data sufficiency and availability due to the short time frame required for screening. Chemicals deemed high priority will undergo risk evaluation and then if necessary risk management. Those that meet the definition of a low priority substance are taken out of consideration for further assessment at that time.