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Findings of a Review of Performance Measurement of Chemicals Management Systems

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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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Foreword

This document focuses on the measurement of performance of chemical management systems. It contains a report drafted by Canada and discussed by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

The overall conclusions of the analysis by Canada, on comparing the current performance measurement frameworks for chemical management programmes includes the following:

1. There is no common and accepted terminology regarding performance measurement. There is a wide variety of terms used to measure performance: output indicators, impact indicators, result indicators, process indicators, outcome indicators, essential elements and core activity areas.
2. There is no common approach in terms of the level where performance is being measured. For example, if performance is measured at the level of outputs, outcomes or impacts.
3. No single performance measurement model would fit all of the chemical management programmes.

Based on this, there is an opportunity to establish general terminology and indicators that could be applied to measuring the performance of chemicals management systems. This could include the analysis of which indicators can best be measured with available information, and which provide the most meaningful insight into the performance of a chemicals management system and lead to the development of best practices.

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

1. Performance Measurement of Chemicals Management Systems

1.1. Introduction

Performance measurement[1] is a management approach to continuously monitor and report a program's progress and accomplishments, using pre-selected indicators to be measured so that programs can be assessed in terms of their economy, efficiency and effectiveness. By establishing program measures, departments or organisations can gauge whether their program is meeting their goals and objectives. Measurement data can be used to identify/flag areas of increasing or decreasing performance that may warrant further investigation or evaluation. Program evaluations assess whether the program is meeting those performance measures but also look at why they are or are not meeting them[2].

The Treasury Board Secretariat of Canada[3] defines a performance measurement strategy as a results-based management tool that is used to guide the selection, development and ongoing use of performance measures.

One of the challenges internationally is that there does not appear to be standardised or accepted terms for chemicals management performance measurement. This can lead to confusion when the performance measurement frameworks across international/national programs are compared or analysed.

[1] See http://www.epa.gov/evaluate/program-evaluation-and-performance-measurement-epa.

[2] See http://www.epa.gov/evaluate. For Canadian documents on program evaluation see http://www.tbs-sct.gc.ca/hgw-cgf/oversight-surveillance/ae-ve/cee/index-eng.asp.

[3] See http://www.tbs-sct.gc.ca/hgw-cgf/oversight-surveillance/ae-ve/cee/dpms-esmr/dpms-esmrpr-eng.asp.

2. Brief summary of the five examples examined regarding performance measurement frameworks

2.1. Canada's Chemicals Management Plan

Launched in 2006, the Chemicals Management Plan (CMP)[4] enables the Government of Canada to protect human health and the environment by addressing substances of concern in Canada. Lead departments are Health Canada (HC) and Environment and Climate Change Canada (ECCC). It is a science-based approach that includes the following key activities:

- Research
- Information collection
- Risk Assessment
- Monitoring/Surveillance
- Stakeholder Engagement & Risk Communication
- Risk Management
- Compliance and enforcement

Canada's Chemicals Management Plan (CMP) performance measurement framework evaluates the ongoing relevance, success and effectiveness of the actions taken to manage risks from toxic substances. In order to measure if the CMP objectives have been met, the performance measurement framework comprises immediate and intermediate outcomes for each of the five key activities of the Plan. The immediate and intermediate outcomes contribute to the overall final outcome. Each level of reporting has its own performance indicator associated with it. Below is an example of an "intermediate outcome" of the activity "risk management".

Table 1.1 Example of Intermediate Outcome under CMP

Intermediate Outcome	(Activity) Risk management actions reduce the potential for exposure to harmful substances	(Intermediate Outcome) Exposure concentration or release levels for a selected group of chemicals in humans, the environment, food, and consumer products.

In addition to the Chemicals Management Plan (CMP) performance measurement framework, Canada has substance-based and instrument-based performance measurements. Substance-based performance measurement considers performance of all final risk management instruments applied to a chemical substance and relevant data or

[4] See https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/departmental-performance-reports/2015-2016-supplementary-information-tables/page-4-horizontal-initiatives.html.

indicators of exposure to the environment or human health. Instrument-based performance measurement evaluates the effectiveness of an individual instrument in meeting the specific risk management objectives that were set out when the risk management tool was designed.

2.2. Australian Regulatory Information

The overarching policy principles of chemical regulation and management in Australia are to protect human health and the environment.

The regulation of chemicals and chemicals products in Australia takes into account the following general uses. Each of the groups of chemical uses is regulated within a separate legal and regulatory framework.

At the Commonwealth level, the chief relevant authorities comprise:

- Agricultural and veterinary chemicals – regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA)
- Chemicals for therapeutic use – regulated by the Therapeutic Goods Administration (TGA)
- Food ingredients and additives – regulated by Food Standards Australia and New Zealand (FSANZ)
- Gene technology and genetically modified organisms – regulated by the Office of the Gene Technology Regulator (OGTR)
- Industrial chemicals (including cosmetic ingredients) – regulated by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
- Workplace and worker health and safety (including GHS) – standards established by Safe Work Australia
- Transport of dangerous goods – regulated by the National Transport Commission Australia
- Consumer welfare and product safety – regulated by the Australian Competition and Consumer Commission (ACCC)

Implementation of management requirements is largely within the remit of state and territory authorities.

Indicators of regulator performance are related to the specific legislation of each regulator, their regulatory posture and the regulatory priorities of the government. The Australian Government has two primary mechanisms to measure the performance of chemical regulators at the Commonwealth level. These are the Australian Regulator Performance Framework and the Portfolio Budget Statements.

2.2.1. The Australian Regulator Performance Framework

This framework allows regulators to report objectively on the outcomes of their efforts to administer regulation fairly, effectively and efficiently. It will also be a useful tool for regulators to identify opportunities for improvement and better target their resources for

greater impact. The Framework assists in highlighting where improvement of regulatory frameworks could reduce compliance costs[5].

To articulate the Government's overarching expectations of regulator performance, the Framework comprises of six outcomes-based key performance indicators (KPIs)[6]:

- KPI 1 - Regulators do not unnecessarily impede the efficient operation of regulated entities.
- KPI 2 - Communication with regulated entities is clear, targeted and effective.
- KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed.
- KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated.
- KPI 5 - Regulators are open and transparent in their dealings with regulated entities.
- KPI 6 - Regulators actively contribute to the continuous improvement of regulatory frameworks.

The measures of good regulatory performance in the framework outline the principles that should be used to guide assessment of regulator performance against the KPIs. These measures are not an exhaustive list and there is flexibility provided in the Framework for measures to be tailored for individual regulators and their role, specific tasks and legislative environment.

2.2.2. The Health Portfolio Budget Statement (PBS)

The Health Portfolio Budget Statements (PBSs)[7] set out agreed performance criteria against which performance is assessed. The outcomes are published through the Australian Department of Health's Annual Report[8].

The outcome relating to chemicals management is 'Protecting people and the environment by assessing the risks of industrial chemicals and providing information to promote their safe use'. To address this outcome NICNAS reports on a number of criteria including:

- Proportion of NICNAS risk management recommendations considered by Commonwealth and State and Territory risk management agencies and accepted to promote safer use of industrial chemicals.
- Proportion of known importers and manufacturers of industrial chemicals registered with NICNAS, to promote awareness among the regulated community of their legal obligations.
- Proportion of NICNAS risk assessments completed within statutory timeframes to minimise regulatory burden on businesses.

[5] See: http://cuttingredtape.gov.au/sites/default/files/files/Regulator_Performance_Framework2.pdf.

[6] See: http://cuttingredtape.gov.au/resources/rpf/kpis.

[7] See:https://www.health.gov.au/internet/budget/publishing.nsf/Content/2017-2018_Health_PBS_sup4/$File/2017-18_Health_PBS_Complete.pdf.

[8] See: http://www.health.gov.au/internet/main/publishing.nsf/content/annual+reports-3.

2.3. European Union - Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

REACH[9] provisions entered into force in 2007 and aim to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. This is done by the four processes of REACH, namely the registration, evaluation, authorisation and restriction of chemicals. The REACH Regulation places responsibility on industry to manage the risks from chemicals and to provide safety information on the substances. Manufacturers and importers are required to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database in the European Chemicals Agency (ECHA).

In 2006, before REACH entered into force, a methodology was established to monitor the effectiveness of REACH as regards to risk reduction and improvement of the quality of data available for the assessment of chemicals. Two indicators were developed with a set of 237 substances that can be considered representative of the chemicals available in the EU market:

- a Risk Score, which indicates the risk posed by a substance; and
- a Quality Score, which indicates the quality of the data available to assess the risk associated with a substance.

The EC (2017) Reach Baseline study[10] aimed to monitor the effectiveness of REACH over 10 years regarding risk reduction and improvement in the quality of data available for the assessment of chemicals. This study showed a clear increase in the quality of data over time and a decline in the Risk Scores which resulted from a decline in the chemical exposure estimates and/ or increase in toxicity estimates.

2.4. Strategic Approach to International Chemicals management (SAICM)

SAICM was adopted in 2006 at the First International Conference on Chemicals Management (ICCM1). It is a policy framework to promote chemical safety around the world. Reporting on SAICM implementation is a key in assessing progress towards the achievement of the 2020 goal. The 2020 goal is that chemicals should be used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment. In order to measure the implementation of SAICM, a set of 20 indicators is used by all stakeholders in reporting progress on the sound management of chemicals. A baseline report, which covers the period of 2006-2008, was published in 2012[11]. The report contained results of an analysis of readily available information on strategic approach

[9] See: http://ec.europa.eu/environment/chemicals/reach/reach_en.htm.

[10] See: http://ec.europa.eu/mwg-internal/de5fs23hu73ds/progress?id=O_uiCJpyyc5XKwy3SNMmKlXK6_i__hoYD6I93T8Obh8,&dl.

[11] See SAICM/ICCM.3/INF/5: http://www.saicm.org/Portals/12/Documents/reporting/ICCM3_INF_5_%20baseline%20report.pdf

implementation. Two progress reports have been published (2009-2010 and 2011-2013)[12,13].

2.5. Organisation for Economic Cooperation and Development study on indicators used for environmental compliance

Mazur, E. (2010)[14] analysed the experience of ten OECD countries [Australia, Belgium (Flanders), Canada, the Netherlands, Switzerland, the United Kingdom (England and Wales) and the United States, with additional inputs from Denmark, Ireland and Poland] in the design and implementation of quantitative indicators used to assess the outcomes of environmental enforcement authorities' efforts to ensure compliance with pollution prevention and control regulations.

The report considers the following six types of intermediate and final outcome performance measures, including compliance rates as well as indicators of improved environmental management practices and reduced risk.

- Compliance rates
- Measures of recidivism and duration of non-compliance
- Pollution release indicators
- Indicators of improved environmental management practices and reduced risk
- Measures of effectiveness of individual compliance assurance instruments
- Environmental quality (final outcome) indicators

[12] See SAICM/ICCM.3/INF/6 http://www.saicm.org/Portals/12/Documents/reporting/ICCM_3_INF6_first%20progress%20report_Final.pdf.

[13] See SAICM/OEWG.2/INF/4 http://www.saicm.org/Portals/12/Documents/reporting/k1403579-eowg2-inf4-second-progress-report.pdf.

[14] See http://www.oecd-ilibrary.org/environment/outcome-performance-measures-of-environmental-compliance-assurance_5kmd9j75cf44-en.

3. Outcomes measured in performance measurement frameworks

In comparing the current performance measurement frameworks for chemicals management programmes, it is noticeable that they do not measure outcome at the same level.

For example, in a European Commission study[15] on the calculation of the benefits of chemicals legislation on human health and the environment, indicators were defined at three different levels of objectives: output indicators, results indicators and impact indicators. Output indicators are related to the deliverables that the legislation is expected to produce and aim to measure the specific actions of the legislative mechanisms (operational objectives). Result indicators measure the immediate effects of the legislation on the direct recipients (specific objectives) and have therefore been defined in terms of changes in exposure to chemical substances. Finally, impact indicators measure the ultimate consequences of the legislation beyond its direct interaction with recipients. This has been interpreted as moving from changes in exposures to changes in effects, either in terms of chemical related diseases or chemical related impacts on environmental ecosystems and biota.

Some countries, such as Australia, measure results at the regulatory level, namely, the government level using key performance indicators (KPIs). While others, like Canada, measure their results at the program, substance and instrument levels using a logic model approach with immediate, intermediate and final outcomes and associated performance indicators.

It should be noted that countries/organizations have processes in place to periodically review their performance measurement outcomes.

3.1. Ultimate Outcomes

Despite the fact that not all countries or organizations studied measure their outcomes at the same level, protecting human and the environment is a common goal. To demonstrate this alignment, below are examples of how each country or organisation expresses their ultimate/final outcome. There are significant similarities across programs that could be a good starting point for comparing outcomes.

[15] See : http://ec.europa.eu/environment/chemicals/reach/pdf/study_final_report.pdf.

Table 3.1. Ultimate Outcomes of Chemical Management Programmes

Country/Organization	Ultimate Outcome
Strategic Approach to International Chemicals management (SAICM)	"chemicals should be used and produced in way that lead to minimization of significant adverse effects on human health and the environment"
Canada's Chemicals Management Plan	"reduced threats to health and the environment from harmful substances"
Australian Regulatory Performance Framework	"the protection of the Australian people and the environment by finding out the risks to occupational health and safety, to public health and to the environment that could be associated with the importation, manufacture or use of the chemicals"
European Union REACH	"improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances"
Japan's Chemicals Substances Control Law (CSCL)	"the purpose of the Act is to prevent environmental pollution by chemical substances that poses a risk of impairing human health or of interfering with the population and/or growth of flora and fauna"
New Zealand's Chemical Regime	"the purpose of the chemicals regime is to protect people and the environment from harm"

3.2. Intermediate Outcome

As mentioned above, not all countries and organizations studied measure intermediate outcomes. Two examples of intermediate outcomes are Canada and those identified in the OECD report on indicators used for environmental compliance. Intermediate outcomes can be a useful tool to measure progress towards ultimate outcomes which may be more difficult to measure.

Table 3.2. Examples of Intermediate Outcomes

Country/Organization	Intermediate Outcomes
Canada's Chemicals Management Plan	"Canadians and stakeholders groups understand information on the risks and safe use of substances of concern" "targeted industry conforms or complies with requirements or risk management measures, taking voluntary or enforced action to protect Canadians and the Environment"
OECD Countries – Environmental enforcement to ensure compliance with pollution prevention and control regulations	"compliance rates" "measures of recidivism and duration of non-compliance" "pollution release indicators" "indicators of improved environmental management practices and reduced risk" "measures of effectiveness of individual compliance assurance instruments"

3.3. Direct/Process Outcomes

Direct/Process outcomes are found in almost every performance measurement framework as they often are the result of operational process, therefore, easy to identify and measure. Below are examples of direct/process outcomes.

Table 3.3. Examples of Direct/Process Outcomes

Country/Organization	Direct/Process Outcome
SAICM	"risk reduction" "knowledge and information" "governance" "capacity building and technical cooperation" "fight against illegal international traffic"
Canada's Chemicals Management Plan	"knowledge, information and data on substances of concern is made available to HC and EC recipients (or other stakeholders) to inform risk management; risk communication and stakeholder engagement; research; risk assessment; monitoring and surveillance; and international activities"
Australian Regulatory Information	KPI 1 - Regulators do not unnecessarily impede the efficient operation of regulated entities; KPI 2 - Communication with regulated entities is clear, targeted and effective; KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed; KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated; KPI 5 - Regulators are open and transparent in their dealings with regulated entities; and KPI 6 - Regulators actively contribute to the continuous improvement of regulatory frameworks.

3.4. Indicators used to measures the outcomes in the Performance Measurement Framework (PMF)

For each level where results are measured, a performance indicator is used. The performance indicator allows to measure progress towards the outcome. Direct/process outcome indicators usually measure a delivered output. Below are examples of direct/process outcome indicators:

Table 3.4. Examples of Performance Indicators used for Direct/Process Outcomes

Country/Organization	Direct/Process Outcome – Performance indicators
SAICM	"number of countries (and organizations) implementing agreed chemicals management tools" "number of countries (and organizations) providing information according to internationally harmonized standards" "number of countries (and organizations) engaged in regional cooperation on issues relating to the sound management of chemicals"
Canada's Chemicals Management Plan	"percentage of research activity milestones met in accordance with annual research for new substances" "percentage (and number) of the 4,363 priority existing substances assessed by March 31, 2021" "percentage of new substance notifications received that are assessed within legislated timelines prescribe in the New Substance Notification Regulations (NSNR) or within established service standards"
UNEP Framework for effectiveness evaluation and on the use of the elements and indicators	"number of parties with regulatory and assessment schemes for new pesticides and/or new industrial chemicals" "number of parties that have promoted the adoption of best available techniques and best environmental practices for priority source categories" "Number of parties with measures in place to manage wastes in an environmentally sound manner"

4. Data collected to support performance measurement

Various approaches have been used to collect information on performance indicators.

SAICM used an internet-based questionnaire to collect data. The questionnaire contained a mixture of mandatory and optional questions on each of the 20 indicators. It also includes specific advice on the data to be collected on each indicator and general guidance.

Australia used information from the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to collect evidence against the Key Performance Indicators (KPIs). NICNAS populates a database that is used to 'report' on its performance. As part of the reform of NICNAS, new tools/databases to conduct audits and monitor and measure performance are being developed. NICNAS prepares quarterly and annual reports of all program activities as a tool for measuring performance.

In Canada, under the Chemicals Management Plan (CMP), data are collected against predetermine indicators linked to output and outcomes. They are periodically collected using a template.

Other countries, like Japan, New Zealand and Switzerland used either basic statistics about chemicals, monitoring data, or exposure measurement.

The next section includes case studies of three different approaches that have been taken to measure progress against outcomes. Each study emphasizes a different aspect of performance measurement. All four approaches provide a unique perspective on the performance of chemicals management systems.

4.1. Data collection case study 1: REACH Baseline Study – 10 Years Update Monitoring REACH with the Risk and Quality Indicator System

The REACH Baseline Study aims to monitor the effectiveness of REACH in regards to risk reduction and improvement of the quality of data available for the assessment of chemicals. In 2006, before REACH entered into force, a methodology was established to derive the following indicator values for a set of 237 reference substances that can be considered representative of the chemicals available in the EU market:

- a Risk Score, which indicates the risk[16] posed by a substance; and
- a Quality Score, which indicates the quality of the data available to assess the risk associated with a substance.

After 5 years, the assessment was repeated for the substances which had been registered by August 2011. The 5 Years Update (5YU) allowed to detect changes in the nominal risk of the reference substances and in the quality of their data, which are likely to be due to the first registration phase (by 30 November 2010). The 5YU (EUROSTAT 2012) contributed to the REACH review in 2012.

[16] "Risk" in the context of the REACH Baseline Study means a value derived from the evaluation of toxicity data and exposure data according to the methodology of the REACH Baseline Study. Therefore, it is not a risk that has been measured at specific places, but a calculated risk derived from a statistical evaluation. We call this calculated risk "nominal" risk.

The 10 Years Update (10YU) analyses changes in the Risk Scores and Quality Scores based on registrations until September 2015, including registrations from the second registration phase (by May 2013) as well as updates from dossiers registered previously. In close cooperation with the European Chemicals Agency (ECHA), confidential data from the relevant registration dossiers were assessed for this purpose. In addition, the 10YU analyses some impacts of substance evaluation, dossier evaluation and additional measures of ECHA.

The 10YU was conducted using the same methodology developed for the assessments at baseline and in the 5YU. The key elements of the Risk and Quality Indicator system consist of an element assessing the nominal risk, and an element assessing the quality of the underlying data.

As a result, for each substance a Risk Score (RS) and a Quality Score (QS) is calculated.

- The Risk Score is calculated based on an estimate of the exposure and on an estimate of the toxicity. The fraction of these two estimates is the Risk Characterisation Ratio (RCR). In an additional step, the Risk Score is calculated by multiplying the RCR by an approximation of the size of the population potentially exposed (Population Risk Modifier, PRM). The Risk Score Risk Scores can range by several orders of magnitude. Lower values indicate lower risks.
- The total Quality Score (QStotal) consists of two elements: a score for the quality of the toxicity estimate (QStox) and a score for the quality of the exposure estimate (QSexp). QStotal can range between 1 (best quality) and 100 (worst quality). Lower values indicate better quality.

The Risk Scores and Quality Scores are calculated for four impact areas: impacts on workers, on the environment, on consumers and impacts on human health via the environment. The values obtained should not be compared between impact areas.

Conclusions:

1. The results of the 10 Years Update show a clear increase in the quality of the data.
2. The results of the 10 Years Update show a clear decrease in the Risk Characterisation Ratios and the Risk Scores when compared with the situation at baseline.

Overall, the improvement in quality (decline in Quality Scores) appears to be a direct consequence of REACH while the decline in Risk Scores and RCRs is caused by a decline in exposure estimates and/or an increase in toxicity estimates. The impact of these two factors differs between the impact areas. With the toxicity of a substance being an inherent property, the main effect of REACH in relation to the toxicity estimates is the improvement of the data, on which these are based.

Overall, the evaluations show that the implementation of the REACH Regulation leads to lower Risk Scores for the environment and improved quality of the underlying data in the 10YU when compared with the pre-REACH baseline. It is observed that the toxicity estimate is of importance and that REACH appears to lead to an "improved toxicity", i.e. the eco-toxicity dataset for many substances has been improved leading to higher toxicity estimates. The Quality Score of the toxicity assessment is similar between the consumers and the environment impact area.

Among the 94 substances registered at the time of this evaluation, specific data on exposure for humans via environment is reported for 39 of them and 4 substances include measured data. The data for the other substances are calculated by modelling. The aggregated Risk Scores (for 94 substances) are lower in the 10YU than at baseline. This shift is mainly explained by the decrease of the exposure level, while for the 5YU the decrease of Risk Scores was due to the improvement of data availability for toxicity leading to higher DNELs.

While an increase in the Derived No Effect Levels (DNEL) is also observed in the 10YU, the decline in the exposure estimates has a much more pronounced effect on the decline of the Risk Scores. This is somewhat surprising, since the exposure estimates for the impact area environment (predicted concentrations in water) do not change much for High Production Volume chemicals[17] (HPV) and Medium Production Volume chemicals[18] (MPV) chemicals. However, the exposure estimates for the impact area humans via the environment are also influenced by predicted concentrations in other compartments (e.g. soil) and the partitioning behavior between compartments. The partitioning is largely modelled on the basis of log Kow values and the software used for modelling (EUSES) employs some outdated algorithms for predicting concentrations in food from log Kow. For example, the concentration in root crops is considerably overestimated at high log Kow values (RIVM[19], 2014, Undeman and McLachlin[20], 2011). The decline in exposure estimates in the 10YU may therefore be a consequence of declining log Kow values, which are more often based on reliable experimental data in the 10YU than they were at baseline.

4.2. Data collection case study 2: SAICM Baseline Study 2006-2008

In the SAICM baseline study reports of 2006-2008, baseline is defined as a measurement, calculation, or location used as a basis for comparison. The underpinning rationale for establishing a baseline in the context of a chemicals management programme is to set the frame for monitoring progress in the achievement of objectives over time, by providing a snapshot of the situation before adoption of the chemicals management programme. In order to measure progress in implementation of the programme, the baseline is compared with similar information obtained by a periodic review of progress. Such review aims at providing a picture of the measure and activities undertaken during the given period. To ensure the comparability of data, the baseline and subsequent progress should ideally be measured using the same modalities and presented in the same unit.

[17] Reference substances for the REACH Baseline Study with an estimated tonnage band per manufacturer at baseline of more than 1 000 tonnes/year.

[18] Reference substances for the REACH Baseline Study with an estimated tonnage band per manufacturer at baseline between 100 and 1 000 tonnes /year.

[19] RIVM, National Institute of Public Health and the Environment (2014): Identification and preliminary analysis of update needs for EUSES. CONTRACT NO. ECHA/2014/253. van de Meent, D., Quik, J., Traas, T., Bilthoven, The Netherlands. https://echa.europa.eu/documents/10162/13630/echa_2014_253_euses_report_en.pdf.

[20] Undeman, E.; McLachlan, M.S. (2011): Assessing model uncertainty of bioaccumulation models by combining chemical space visualization with a process-based diagnostic approach. Environmental Science & Technology, 45, 8429-8436.

SAICM has established a baseline to measure progress towards the implementation of the Strategic Approach. To establish the baseline, data were collected, covering the period of 2006 to 2008, using readily available sources of information and data. The baseline assessment therefore covers the first three years of implementation of the Strategic Approach, instead of providing a snapshot of the situation before its adoption. Since the baseline has been established, two progress reports were published, in 2009-2010 and 2011-2013. The reports showed a considerable level of activity in relation to the adopted indicators and highlight some area where additional efforts may be beneficial in future. Positive progress from baseline is demonstrated.

4.3. Data collection case study 3: Australian Regulatory Information collected using voluntary approaches

How is evidence collected?

The examples of output or activity-based evidence provided in the Australian Framework are not exhaustive and are provided as a guide only. Using the suggested examples of evidence is not mandatory. Application of the Framework is flexible to minimize burden, including by using existing processes, where possible, for data collection and analysis. Reviewers should adapt approaches for particular groups, such as small business, to ensure that the collection of evidence does not create an unnecessary burden.

The data collected may be used as evidence for assessing multiple KPIs. However, a range of evidence from different sources should be used to ensure adequate assessment of the regulator's performance against each KPI. Assessment against the Framework should be comprehensive, accounting for all regulatory functions of the regulator and their interactions with stakeholders while undertaking these functions. The evidence base should include opportunities for a full range of stakeholders to contribute to the assessment through, for example, business surveys, interviews, focus groups or feedback mechanisms.

When determining what evidence is to be used, reviewers should test its suitability with their relevant department(s) and Ministerial Advisory Councils (MACs), or other approved stakeholder consultation mechanisms to ensure the proposed evidence provides a valid measurement of performance. Evidence metrics must be agreed with the responsible Minister prior to the review commencing and must be made publicly available.

5. Summary of similarities and differences between performance measurement approaches and what they are measuring

In comparing the current performance measurement frameworks for chemicals management programmes, there are a series of points to be made.

5.1. Differences in terminology lead to challenges in comparing approaches

First, there is a wide variety of factors which these frameworks measure and these includes: goals, outcomes, indicators, outputs, activities, and impacts. In fact the wide variety of terminology includes: output indicators, impact indicators, result indicators, process indicators, outcome indicators, essential elements and core activity areas. This lends confusion to doing a comparison as these individual factors do not appear to be defined or if they have been defined there is variation across organizations and countries. In addition, there is no common approach in terms of the level where performance is being measured. For example, if performance is measured at the level of outputs, outcomes or impacts.

Canada's intermediate outcomes are focussed around the risks associated with substances harmful to health and the environment, the understanding of society regarding these risks and industry understanding its obligations to take the appropriate action to protect people and the environment. These types of middle level factors in a performance measurement framework appear to be consistent across the regulatory regimes of many countries and could be the best type of factors to measure. The tiered indicators of the European Commission are another good example of a range of indicators although some are very specific for their regulatory regime. Overall, it would appear that the more general outcomes could be modified for many countries and could serve as a best practice in terms of generalized performance measurement frameworks.

5.2. How successful has each approach been in measuring impact?

Another question to ask is regarding the degree of success at measuring the impact of a programme on human health and the environment. The best example is the recent work of the European Commission (2017) in reporting on the REACH programme. This study showed a clear increase in the quality of data over time but a decline in the Risk Scores which resulted from a decline in the chemical exposure estimates and/ or increase in toxicity estimates. Showing improvement in the quality of data used in chemical assessment is another important step towards building confidence in any process that could aim to accept assessment information from other countries or outside agencies.

A further question to pose would be: do the factors mentioned above (e.g. Canada's intermediate outcomes or those of the European Commission's Reach programme) at the intermediate outcome level appear to be the most impactful factors? The answer to that question would be yes as these outcomes focus around the health and environmental impacts of chemicals, the exposure data is being collected internationally (e.g. for the subset of persistent organic pollutants) and the quality of related data as noted by the EC (2017) REACH programme which indicates the increase in the quality of related data.

5.3. Considering socioeconomic considerations in evaluating performance

Some of the performance measurement frameworks take into account the socioeconomic considerations when considering chemicals management programmes. In recent studies and workshops at the OECD (http://www.oecd.org/chemicalsafety/risk-management/sacame.htm) the various aspects of cost benefit analysis for chemicals management has been discussed. Quantifying the costs and benefits of regulating the risks related to chemicals is a special aspect of performance measurement and chemicals management. The OECD reports note that for chemicals legislation, result indicators can be interpreted in terms of changes in chemical exposures and the best measure would be changes of exposure to chemicals, as measured by changes in concentrations of chemicals in human and/or animal tissues. A related measure would be changes of concentrations of chemicals in environmental media.

5.4. Tools for performance measurement and benchmarking

As described in the case studies above, there are a number of tools to assist in performance measurement and benchmarking. This includes the usefulness of the European Commission's industrial toxicity classes, Australia's development of new tools and data bases to monitor and measure performance and Canada's data collection being linked to outputs and outcomes for chemicals management. In addition the standardization of performance measurement terminology as used by the Canadian Treasury Board Secretariat would be a useful tool to consider.

6. Potential areas of work that could be developed to improve performance measurement.

Simple indicators of progress in the performance measurement frameworks for chemicals management should be considered as well as baselines from which performance can be measured.

The development and definitions of accepted terms for performance measurement would be useful to ensure it can be possible to compare the performance measurement components across regulatory regimes involving chemicals management of different countries.

The Canadian concept of a logic model with definitions of its various components could be considered as a starting point for a discussion on the international harmonization of performance measurement terms.

With regard to chemicals legislation which is monitored using a performance measurement framework, work on result indicators appears to be limited although important for measurement. For instance result indicators can be interpreted in terms of changes in chemical exposures and the best measure would be changes of exposure to chemicals, as measured by changes in concentrations of chemicals in human and/or animal tissues. This work should be expanded.

In terms of quantifying regulatory efficacy, retrospective analysis, drawing from information from performance measurement practice, provides for an opportunity to learn to inform future regulations/policies. Also, this analysis helps to identify key uncertainties that are the most substantial to address in future regulatory/policy design (employing a Value of Information (VOI) approach).