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PRELIMINARY ANALYSIS OF POLICY DRIVERS INFLUENCING DECISION MAKING IN CHEMICALS MANAGEMENT

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PRELIMINARY ANALYSIS OF POLICY DRIVERS INFLUENCING DECISION MAKING IN CHEMICALS MANAGEMENT

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

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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FOREWORD

The OECD Joint Meeting of the Chemicals Committee and the Working Parting on Chemicals, Pesticides and Biotechnology conducted two preliminary scoping studies on policy drivers influencing decision making in chemicals management. Based on submissions provided by member countries, the analysis outlines experiences that can assist member countries in developing efficient and effective regulatory regimes. These include experiences regarding transitioning to a new chemical management regime and the (re)assessment of historical chemical approvals/notifications; and comparing policy objectives of different countries' chemical management regimes. This preliminary analysis also aids members in identifying opportunities for future collaborative work and may be of interest and use to partner countries.

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Introduction

1. The OECD Joint Meeting of the Chemicals Committee and the Working Parting on Chemicals, Pesticides and Biotechnology conducted two preliminary scoping studies on policy drivers influencing decision making in chemicals management:

- experiences regarding transitioning to a new chemical management regime and the (re)assessment of historical chemical approvals/notifications; and

- comparing policy objectives of different countries' chemical management regimes, and identifying commonalities and differences (in light of how this may assist with increased regulatory alignment between countries).

2. Several member countries contributed descriptions of national/regional experiences and this document, prepared by New Zealand, presents the submissions provided by New Zealand, Australia, the European Commission (EC), United States, Canada and Japan regarding their chemical management regimes. It includes two case studies consisting of a preliminary comparative analysis of these submissions and additional information provided by the jurisdictions during the writing of the document. The submissions provided by the member countries can be found in the appendices to this paper. The Joint Meeting considered that this preliminary analysis may be of interest and use to partner countries.

Outcome of the scoping study

Case Study One - Experiences regarding transitioning to a new chemical management regime and the (re)assessment of historical chemical approvals/notifications

3. Five of the submissions from member countries shared experiences of transitioning through chemical management regimes, with a particular focus on approaches used to ensure existing chemicals are subject to current risk management mechanisms.

Drivers for change

4. By and large the drivers for changing how existing chemicals are examined were consistent:

- a large number of existing chemicals (ranging from 20,000 chemicals through to 100,000 substances) had not been subject to current risk assessment practices;

- information gaps regarding the properties of many existing chemicals hampered risk assessments and management, and subsequently these chemicals may not have been appropriately risk managed;

- the slow rate at which these chemicals were being examined - approximately 5-10 per year; and

- to increase innovation and promote competitiveness. In some cases regulation was seen as a major factor in shaping the innovation behaviour of firms in the chemical industry and there was also a desire to promote the competitiveness of the chemical industry and encourage innovation, in particular by supporting the development of safer chemicals.

Table 1. Number of Existing Chemicals Covered by Legislation and Number Assessed

Jurisdiction	Existing chemicals covered by legislation (approximately)	Number of existing chemicals assessed through previous regimes
Australia	36,000	180 over 20 years (9 assessments per year)
Canada	23,000	69 over 10 years (6.9 assessments per year)
New Zealand	70,000 (includes chemicals and chemical products)	35 over 6 years (5.8 assessments per year)
EU	100,000	330 over 30 years (11 assessments per year)
Japan	28,000	over 40 years: approx. 560 for biodegradation; approx. 1,020 for bioaccumulation, approx. 1,000 for human toxicity; and approx. 600 for eco-toxicity

5. These drivers largely became apparent in the 2000s, after the implementation of new chemical legislation in the late 1980s-90s. Regulators became aware that a new approach was needed as the rate of examination of existing chemicals, as illustrated in the table above, was not sufficient. It was apparent in some member countries that the international goal of sound management of chemicals by 2020 could not be met if they applied existing processes and that policy or regulatory amendments were required.

Policy Responses

6. The submissions illustrate that there have been different policy responses to these issues. While some of the desired outcomes vary slightly, there are lessons to be drawn from the various approaches, which could inform other countries examining their chemical management frameworks.

7. The amount of work and accessing the resources needed to manage large numbers of existing chemicals that haven't been subject to systematic risk assessment is an underlying thread. In particular, Canada, and more recently Australia, the EU and Japan, employed a prioritised risk assessment approach. New Zealand employed an approach which attempted to manage the risk of substances according to their nature, type or circumstances of use.

8. New Zealand assigned modern risk management measures on a grouping basis (through hazard classification and area of use) to many chemicals rather than undertake a process of reassessing individual chemicals. The mechanism (termed a 'Group Standard') deems a specific range of chemicals to be approved where the range is restricted to specific hazard classifications (based on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)) and their area of use. The Group Standards do not cover all GHS classification, and exclude explosives, pesticides and some of the severe hazard classifications. Assessment of individual chemicals is only needed for chemicals outside of Group Standards. New Zealand's risk assessment approach to these individual chemicals, until the last two years, did not focus on significantly increasing the number of risk assessments of chemicals. However, as detailed below, recently New Zealand has also found synergies in reassessing chemicals in groups.

Increased prioritisation and efficiency of risk assessment

9. With regard to Australia, Canada, Japan and the EU, the approach has been to improve the ability with which regulators are able to prioritise and assess existing chemicals. This has included a systematic approach to chemical assessment, where timelines for assessments have been accelerated. Being responsive to the needs of industry, the community and government, and encouraging stakeholder and public participation has also been a focus.

10. At the core of the policy response is a focused prioritisation exercise to determine which, when and how chemicals are to be assessed. The driver for the prioritisation is twofold: to ensure efforts are focused on higher risk chemicals in the first instance (increased effectiveness); and to ensure assessment techniques are commensurate with the risks being examined (increased efficiency).

Table 2. Prioritisation Techniques Illustrated in the Canadian, Australian, EU and Japanese Submissions

In **Australia,** 3,000 chemicals were identified by stakeholders as having particular characteristics warranting early consideration ('Stage One Chemicals'- examined within four years). These characteristics are:

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

These chemicals then go through a tiered process, which consists of the following:

- Chemicals are first exposed to a high-level, high-throughput assessment (Tier I);
- Tier I chemicals that indicate potential for concern undergo a chemical by chemical evaluation (Tier II); and
- Chemicals requiring further assessment are prioritised for an in-depth chemical assessment (Tier III).

In **Canada,** 4,300 chemicals had been identified as requiring further assessment. These had been identified through a *Categorization* exercise, which focused on identifying chemicals that were:

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

To address these chemicals, the Chemical Management Plan (CMP) was created in 2006. These 4,300 were then divided into three groups of priorities for action between 2006 and 2020 (CMP1, 2 and 3). Within CMP1, several initiatives were created:

- *The Challenge* focused on approximately 200 substances identified as high priority for action;
- *The Rapid Screening Approach* was applied to potential lower risk substances that were unlikely, given

current evidence, to be harmful to the environment or human health; and • *The Petroleum Sector Stream Approach* included approximately 160 substances to be addressed in a sectoral approach.
In the **EU,** manufacturers and importers are required to collect or generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures to control these risks. REACH adopted the approach of having manufacturers and importers carry out the risk assessment of all identified uses of their chemicals rather than having each operator in the supply chain do this because the manufacturing industry have better competencies to conduct risk assessment than most downstream users. To ensure that they meet these obligations, as well as for transparency reasons, manufacturers and importers are required to prepare a registration dossier and submit it to authorities. Initial registration responsibilities were triggered for substances that: • are manufactured or imported in larger volumes; or • are very toxic to aquatic organisms and manufactured or imported in certain volumes; or • are classified as Carcinogenic, Mutagenic or Toxic to Reproduction and manufactured or imported in certain volumes. In addition to this process, there is a programme to address substances of very high concern, so that these can be subject to authorisation procedures and promote substitution. Those chemicals are identified as: • CMRs (substances that are carcinogenic, mutagenic or toxic for reproduction); • PBTs (substances that are Persistent, Bioaccumulative or Toxic for the Environment); • vPvBs (substances that are very Persistent and very Bioaccumulative); and • substances of equivalent concern (such as endocrine disruptors or respiratory sensitisers).
In **Japan**, the first round of annual notification of manufacture/import of chemicals was conducted in 2011. Based on the notified information, Priority Assessment Chemical Substances (PACS) were designated in 2012, to which more PACS are being added every year. (The first set of PACS was designated in 2011 based on the information of former Type 2 and/or Type 3 Monitoring Chemical Substances, which were already available under the previous law). • Chemical substances manufactured or imported in an amount of 1 tonne or more per year by a company are notified to the authority. In case of mixtures, chemical substances each of which makes up 10% or more by weight are requested to be notified. • The amount of chemical substances manufactured or imported is notified. In addition, the use of each chemical substance is notified according to approximately 50 use categories. • Screening assessments are conducted by the authority. A hazard class is assigned based on hazard information regarding human health and aquatic species. An exposure class is assigned based on the amount of total national discharge which is estimated from information notified by manufacturers/importers. These 2 factors are used as the 2 axes of a “risk matrix” in which the risk of each chemical is ranked “High”, “Medium”, or “Low”. 8,000 chemicals which are manufactured and imported at more than 10 tonnes per year

have been considered in the screening assessment process in 2013.

- Chemicals ranked "High" are designated as PACS. Chemicals ranked "Medium" may be designated as PACS as a result of expert judgement. 160 chemical substances have been designated as PACS in 2011-2013.

Reassigning risk management measures to existing chemicals

11. With regard to the New Zealand submission, Group Standards were introduced to assign modern risk management measures to existing substances that had been regulated through previous regimes. Under New Zealand law all hazardous substances must be approved before they can be imported or manufactured so formal approval of all chemicals in use was needed when the current law came into force. Group Standards allowed for a range of substances with similar properties and uses to be approved together. New Zealand's Group Standard approach has proved effective at assigning risk management measures to existing chemicals.

12. Within New Zealand's Group Standard mechanism, higher risk substances are assigned more stringent risk management measures, and vice versa. The Group Standard mechanism has not been used for some substances as the regulator considered that these, usually higher risk substances, should be managed under individual approvals. Explosives, pesticides, wood preservatives and chemicals toxic to vertebrates fit within this category, and remain individually approved for use and assigned risk management measures.

13. In New Zealand chemicals in use that are already legally approved for use can be assessed (often termed a reassessment[1]) and the reassessment may result in the approval being removed or in changes to the rules governing use of the chemical. Historically, New Zealand reassessments have been targeted at individual substances where evidence suggests there is a need to reconsider the approval or rules relating the chemicals' uses. More recently New Zealand has reassessed a number of approvals in conjunction with each other.

14. The New Zealand reassessment process follows the same process and cost recovery rules as assessments of new chemicals and can be a time consuming and resource-heavy process. Reassessments can by undertaken in response to user or industry application or through a programme of regulator initiated reassessments. The process for assessing new chemicals and for the reassessment of existing chemicals places responsibility on applicants to provide information and contribute processing costs.

15. However, there is less incentive on industry to seek reassessments of existing chemicals where the likely result is additional restrictions or prohibition on use. Where an industry no longer needs a chemical there is no need for them to seek approval before they stop using it unless they are replacing it with an entirely new, unapproved chemical. Consequently the cost of reassessing existing chemicals

[1]The reassessment process enables the regulator to re-examine whether a substance can be imported, manufactured or used in New Zealand. It involves assessing all effects of a specified substance - both positive and adverse effects. Where the negative effects of a substance outweigh the positive effects, the regulator may remove the approval to import, manufacture or use the substance, or to restrict its use. Reassessments can be triggered through new information relating to the effects of the substance, new alternatives with improved beneficial or reduced adverse effects, or significant changes in use.

typically falls on government. This means that there are generally higher legislative requirements imposed on new chemicals, along with the costs that fall on applicants. This is acknowledged as incentivising the continued use of existing chemicals as opposed to developing or importing safer and/or more effective alternatives.

16. The resources available for reassessments are limited so the number being undertaken has been constrained. A priority list of 20 substances for review was prepared in 2008 and these have been completed. In addition, reassessments started in 2012 and completed in 2013 covered two groupings of related substances. The groupings were antifouling paints (a use grouping) and organophosphate pesticides (a grouping of use and similar chemical structure), and enabled the individual approvals of an additional 35 chemical actives to be reassessed.

17. This linked reassessment of similar substances leads to savings in gathering information on use and in monitoring impacts of chemical use. The grouping also enables consideration of possible substitution between chemicals as a result of changing rules on use. Grouping reassessments has enabled New Zealand to complete a larger number of substance reassessments and the experience suggests that there are advantages in the Group Standards approach for managing the higher hazard substances. New Zealand has not undertaken an in-depth priority setting exercise.

18. A grouping approach is also underway for Canada's CMP2. A key initiative is the Substance Groupings approach, whereby 500 substances are being addressed under nine substance groupings. The groupings were identified based on structural or functional similarities and were assembled based on considerations related to assessment efficiencies, management efficiencies, the ability to support informed substitution decisions, timing of international actions and stakeholder engagement.

19. With respect to the EU, although substances are registered on an individual basis, there are opportunities to cluster similar substances together in terms of work planning to create efficiencies as they proceed through substance evaluation or restriction and authorisation steps. However, decisions are made on an individual substance basis.

Table 3. Illustration of Number of Chemicals Assessed or Registered Through the New Regimes

Jurisdiction	Number of existing chemicals assessed through new regime
Australia	1,808[2] chemicals assessed in first two years (3,000 to be assessed over four years)
Canada	1,100 assessed over first four years (4,300 to be assessed over 14 years)
New Zealand	48 individual substances assessed over two years
EC	By January 2014, 12,276 unique substances had been registered with ECHA
Japan	8,000 substances considered in the screening

[2] This figure includes additional chemicals not included on the Stage One list of 3000 chemicals proposed to be assessed over the four years, but subsequently identified as members of chemical groups under assessment.

	assessment process over three years

Increased role and commitment of industry

20. Underpinning the efforts for increased efficiency is the increased role and commitment of industry in generating and providing data. The EU approach has made the industry manufacturing (or importing) chemicals responsible for generating and assessing data, and assessing risks of intended uses. Canada has successfully engaged industry resources to generate necessary data to ensure government decisions are well informed. The costs of the Australian government reassessments are met by a pool of funds which is levied from chemical users.

Table 4. Division of Responsibility for Assessment and Associated Costs

Jurisdiction	**Who is responsible for generating and providing data on hazard assessments?**	**Who is responsible for generating and providing data on the use of substances?**	**Who is responsible for assessing substances?**	**Who is responsible for paying assessment costs?**
Australia	*New Chemicals* Industry (manufacturers or importers) are responsible for generating and providing data for hazard assessment of new chemicals. *Existing Chemicals* For chemicals declared as Priority Existing Chemicals (PECs), relevant persons may be compelled to supply information required for the PEC assessment. For all other existing chemicals, the regulator is responsible for collecting data. Information from industry can be provided on a voluntary basis.	*New Chemicals* Industry (manufacturers or importers, sometimes using information provided by their customers) are responsible for providing data on the intended use of new chemicals. *Existing Chemicals* Same as for hazard data.	*New Chemicals* The government (through NICNAS) is responsible for assessing new chemicals, except those eligible for exemptions (which require self-assessment by industry against criteria set by Government). *Existing Chemicals* Regulator is responsible for assessing existing substances.	The full costs of administration of NICNAS are currently recovered from the regulated industry in accordance with the Australian Government *Cost Recovery Guidelines.* *New Chemicals* Cost recovered from assessment fees. *Existing Chemicals* Cost recovered from registration fees.

Canada	*New Chemicals* Industry is responsible for providing data. *Existing Chemicals* Regulator gathers existing hazard data and has authority to request data generation by industry. Also, industry provides data on hand.	Industry is responsible for providing data. Regulator also generates and gathers data.	Regulator is responsible for assessing new and existing substances.	For new substances, industry pays a notification fee contributing to some cost recovery, however Regulator is responsible for assessment and maintenance of schedules. Regulator bears cost of existing substances assessments.
New Zealand	*New Chemicals* Industry is responsible for providing data on new chemicals (as applicant for a chemical's approval). *Existing Chemicals* Regulator is implicitly responsible for providing data on existing chemicals (as applicant for a reassessment is usually the regulator).	*New Chemicals* Industry is responsible for providing data on new chemicals (as applicant for a chemical's approval). *Existing Chemicals* Regulator is implicitly responsible for providing data on existing chemicals (as applicant for a reassessment is usually the regulator).	Regulator is responsible for assessing new and existing substances.	Both industry and regulator are responsible for assessment costs of new substances (partially cost recovered – fixed charges that recover less than 20% of the cost of decision making). Regulator is responsible for assessment costs for Group Standards (as applicant is usually the regulator) unless there is an external applicant in which case cost recovery as for a new substance. Regulator is implicitly responsible for reassessment costs for existing substances (as applicant is usually the regulator) unless there is an external applicant in which case cost recovery as for a

				new substance.
EC	Industry	Industry	Industry Authorities perform compliance checks and further risk assessment for chemicals for which further risk management measures may be warranted.	Industry
Japan	*New Chemicals* Manufacturers or importers are responsible for providing data for hazard assessments of new chemicals. *Existing chemicals* At the stage of initial screening assessment, hazard assessments of existing chemicals for designating PACSs are conducted by using available data from literature and/or reports submitted by manufacturers or importers. At the stage of detailed risk assessment of PACSs, if necessary, regulator can require manufacturers or importers to provide data of existing chemicals and cover all cost for generation.	Manufacturers or importers are responsible for generating and providing data on the use of new and existing substances.	Regulator is responsible for assessing new and existing substances.	*New chemicals* Regulator is responsible for covering cost for assessment of new chemicals (e.g. cost for arranging expert committees). *Existing chemicals* Regulator is responsible for covering cost for assessment of existing chemicals (e.g. cost for arranging expert committees).

United States[3]	*New Chemicals* For chemicals to be introduced into commerce ("new chemicals"), industry is responsible for providing available data, and under certain circumstances may be responsible for developing new data. *Existing Chemicals* For chemicals already in commerce ("existing chemicals"), the US EPA compiles and assesses data on chemicals of concern. The data sources may include publicly available materials, and/or materials required to be reported or EPA may use rulemaking to compel the generation of data where certain exposure- or risk-based findings are made.	*New Chemicals* Information on uses must be provided as part of pre-manufacture notification. *Existing Chemicals* For existing chemicals that meet certain production thresholds, use information to the extent known or reasonably ascertainable must be provided every 4 years by manufacturers (including importers) and can be otherwise required from manufacturers and processors via rule-making. Testing of chemicals by manufacturers and processors can be required on a chemical specific-basis where certain risk findings are made by the EPA.	The Agency is responsible for the assessments of all "new" chemicals and "existing" chemicals that the US EPA decides to assess.	The resources used to assess new and existing chemicals come out of the US EPA's budget.

Conclusions

21. As an increasing number of member countries are planning or in the process of improving efforts to assess the risks of existing chemicals, the above case study illustrates several different approaches used.

[3] Although the United States did not provide a submission for this case study, this information from the United States is included in the table to provide an additional example

22. While there are differences to how these have been undertaken, interestingly there does appear to be a developing convergence of approaches in some areas, but differences remain in others. Commonalities include a desire to provide information to the public, to further involve the chemical industry in the process and to use the regulatory regime to reduce use of dangerous chemicals and promote the use of safer alternatives.

23. Priorities for assessment - Australia, Japan and Canada developed lists of chemicals for further assessment through a formal process. New Zealand has used a more limited priority list of existing chemicals for reassessment by the government. The EU REACH programme set deadlines for the registration of different chemicals, but the requirement is that all chemicals above 1 tonne should be registered and special attention should be given to long-term and chronic effects at the higher tonnages. There are strong similarities between the Canadian and Australian approaches.

24. Grouping of chemicals for assessment and/or risk management - New Zealand's approach to reassessing groups of individual substances has created efficiencies in data collection and analysis as well as improving consideration of substitution between chemicals. Canada's on-going Substance Groupings Initiative is likely to draw comparisons with New Zealand's recent reassessment of groups of substances. Australia is also assessing groups of chemicals, in order to gain more efficiency.

25. Industry responsibility and resourcing - All countries seek industry involvement but there are some contrasts. The EU makes industry responsible or generating data and undertaking risk assessment of chemicals currently in use and uses an industry fee to further assess high priority chemicals. It has established deadlines for this. Canada has engaged industry in developing data for the assessment of chemicals that are a priority. Australia, on the other hand, uses an industry fee to fund government's development of assessments. New Zealand is a contrast in that assessment of existing chemicals is undertaken through an applications process where costs of developing the application are met by the applicant and the costs of processing the application are partly met by the applicant. The bulk of assessment of existing substances in New Zealand is done with a government agency as the applicant. In the case of Japan, industry is responsible for submitting information on manufacturing/import amount and categorised uses of chemicals annually. The government authorities conduct screening risk assessment in order to select chemicals to be further assessed on a priority basis. Then, industry is asked to submit hazard data, if needed, for the detailed risk assessment of prioritised chemicals, which is conducted by the government. No fees are paid by the industry for assessment, although they cover the cost of generating data that is required to be submitted.

26. Experience in some countries seems to indicate that putting increased responsibility on industry increases the efficiency of the assessment process. As pointed out by the EU, industry is well placed to conduct risk assessments. Increased data has led to better decisions being made resulting in more appropriate risk management measures. Increased information and clear obligations on users of chemicals of concern have encouraged substitution of those chemicals. Canada noted that increasing efficiencies for government through a greater rate of assessments per year has been possible through an acceptance of uncertainty with risk assessment conclusions (along with strategies to mitigate risks through research, monitoring and surveillance, information collection and stakeholder consultation).

27. On the other hand, Japan's experience indicates that there are other aspects that need to be considered. In Japan the government is responsible for the risk assessment through collecting information from industry in a step wise manner, and this approach has been found to provide an effective and efficient risk assessment system for existing chemicals. It also reduces the burden on industry for preparing necessary notification which is especially beneficial for small and medium size companies which have lower resources than large companies.

28. The regulatory approaches are still evolving. The Australian system is to be reviewed in 2015/16, with recommendations expected on the most efficient and effective approach for the assessment of the remaining existing chemicals.

29. In moving towards the international goal of sound management of chemicals by 2020, this analysis demonstrates that a number of jurisdictions are heading in this direction via different approaches. Comments illustrating increased substitution of chemicals of concern and the assigning of more appropriate risk management measures signal that new approaches are encouraging the production and use of chemicals in ways that minimise significant adverse impacts on human health and the environment.

Case Study Two- Comparing policy objectives of different countries' chemical management regimes, and identifying commonalities and differences

30. Due to the nature of the submissions on policy objectives, there is limited ability to draw detailed conclusions. While the following summary gives some insight into some of the objectives, there are likely to be further objectives underpinning regimes not mentioned here. The following aims to highlight the primary objectives of the relevant regimes.

United States policy objectives for chemical reform

- Principle No. 1: Chemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment.
- Principle No. 2: Manufacturers should provide the United States Environmental Protection Agency (US EPA) with the necessary information to conclude that new and existing chemicals are safe and do not endanger public health or the environment.
- Principle No. 3: Risk management decisions should take into account sensitive sub-populations, cost, availability of substitutes and other relevant considerations.
- Principle No. 4: Manufacturers and the US EPA should assess and act on priority chemicals, both existing and new, in a timely manner.
- Principle No. 5: Green chemistry should be encouraged and provisions assuring transparency and public access to information should be strengthened.
- Principle No. 6: The US EPA should be given a sustained source of funding for implementation.

New Zealand's chemical regime policy objectives

- The purpose of the chemicals regime is to protect people and the environment from harm.
- Risk assessment is intended to inform decisions on approval (required for all hazardous substances before they can made or imported into New Zealand) and on rules regulating storage and use of the substances. Note that hazardous substances can be a chemical or a formulated mixture or product.
- The assessment of chemicals is based on a risk assessment, which includes a requirement to assess

monetary and non-monetary costs and benefits.

- The applications process for new chemicals and for the reassessment of existing approvals places responsibility on applicants to provide information and contribute to application processing costs.
- Caution must be taken into account in managing the adverse effects of a chemical where there is scientific uncertainty about those effects.
- Chemical assessment decisions must give specific regard to Māori perspectives, the indigenous New Zealand population.

Australian policy objectives (as stated in legislation)

A national system of notification and assessment of industrial chemicals for the purposes of:

- aiding in 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;
- providing information, and making recommendations, about the chemicals to Commonwealth, State and Territory bodies with responsibilities for the regulation of industrial chemicals; giving effect to Australia's obligations under international agreements relating to the regulation of chemicals;
- collecting statistics in relation to the chemicals; and
- being a system under which information about the properties and effects of the chemicals is obtained from importers and manufacturers of the chemicals;

National standards for cosmetics imported into, or manufactured in, Australia and the enforcement of those standards.

EU policy objectives of the new chemical management system

- Protection of human health and the environment.
- Maintenance and enhancement of the competitiveness of the EU chemical industry.
- Prevent fragmentation of the internal market.
- Increased transparency.
- Integration with international efforts.
- Promotion of non-animal testing.

Conformity with EU international obligations under the WTO.

Purpose of Japan's Chemical Substances Control Law (CSCL) (as stated in the law)

The purpose of this Act is to establish a system for evaluating the properties of new chemical substances before their manufacture or import and for implementing necessary regulations with respect to the manufacture, import, use of chemical substances, with due consideration to their properties, in order 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.

31. As is illustrated in the above tables, there are a number of commonalities between the policy objectives as provided in the member country submissions.

32. As expected, protecting human health and the environment is a primary objective of all regimes. Also represented in all cases is that industry should be responsible for providing information into chemical assessment programs.

33. However, as described in the first case study, the level of industry responsibility for conducting risk assessment varies between countries. In the case of Japan, the government authorities basically have responsibility for risk assessment, in contrast with EU-REACH in which industry is responsible for assessing the risk of their chemicals as part of the registration process.

34. Other points of difference are also readily identifiable. Giving regard to Māori perspectives is a key component identified in the New Zealand case, and a parallel concept is not referred to elsewhere. The EU case notes the promotion of non-animal testing, also not referred to in others.

APPENDIX 1- AUSTRALIAN SUBMISSION [2013]

Policy drivers influencing decision making in the management of industrial chemicals: Australian Government case study

Industrial Chemicals Regulation in Australia

1. Australia is a federation with the Commonwealth (Australian) Government and six state governments, namely New South Wales (NSW), Queensland (Qld), South Australia (SA), Tasmania (Tas.), Victoria (Vic.) and Western Australia (WA). Each state has its own state Constitution, which divides the state's government into the same divisions of legislature, executive, and judiciary as the Australian Government. The six state parliaments are permitted to pass laws related to any matter that is not controlled by the Commonwealth under Section 51 of the Australian Constitution. There are ten Australian territories outside the borders of the states. Two mainland territories, The Australian Capital Territory (ACT) and The Northern Territory (NT) and one offshore territory, Norfolk Island, have been granted a limited right of self-government by the Australian Government. In these territories, a range of governmental matters are handled by a locally-elected parliament. Seven other territories are governed by Commonwealth law, usually through an Australian Government-appointed Administrator.[4] A third tier of local government also operates within Australia at the local, provincial level with powers derived from the relevant state government.

2. In terms of the Australian chemicals regulatory framework, it similarly operates across three levels of government; Commonwealth, state and territory and local government. Commonwealth responsibilities primarily relate to chemicals assessment with chemical risk management powers residing with the state and territory governments. A guide to the breakdown of responsibilities is provided below.

Level of Government	Regulatory Responsibility
Commonwealth	• Registration (companies introducing industrial chemicals, including cosmetics) • Hazard and risk assessment of chemicals (including chemicals in products and mixtures) • Setting standards for chemicals and chemical products • Implements international agreements and regulates international trade • Transport of dangerous goods by road, rail, sea and air

[4] http://australia.gov.au/about-australia/our-government/state-and-territory-government

State and territory	• Risk management of chemical safety including: a) Protection of public health b) Work health and safety c) Transport (by road and rail) and storage of dangerous goods d) Environmental protection (e.g. emissions and disposal)
Local	• Planning and waste disposal (from powers given to local governments by the relevant state or territory)

Challenges for Australia

3. Regulating the chemicals industry in Australia is the collective responsibility of over 19 agencies at Commonwealth level, 34 agencies at state and territory level and also includes local government involvement. There are over 140 acts and regulations impacting on the industry at the combined Commonwealth, state and territory levels. Chemicals regulation has been an ongoing focus of regulatory reform in Australia, and reforms are continuing in an effort to reduce regulatory fragmentation and complexity.

Cross- agency and cross-jurisdictional regulatory responsibly

4. At the Commonwealth level the rationale determining which agency has regulatory responsibility is linked to the intended use of the chemical or chemical product. For example, agricultural and veterinary chemicals, including pesticides, are regulated within the Agriculture portfolio, whereas food and food additives, therapeutic goods for human use, and industrial chemicals (which are defined by exclusion as those chemicals that do not have one of these other uses) are regulated within the Health portfolio. Further controls apply for use, transport and release of chemicals which are usually covered by the Employment, Transport and Environment portfolios respectively.

5. While risk assessment is conducted at the Commonwealth level, risk management through the enforcement of regulatory controls is predominantly the responsibility of state and territory jurisdictions. For example, state and territory environmental protection authorities monitor the emission or disposal of chemicals where a Commonwealth assessment decision has identified hazardous properties related to that chemical. In some areas of regulation, operational decisions made by state and territory risk management agencies has led to inconsistent regulations on the same chemicals/products when used in different jurisdictions. Further, the implementation of new controls based on the outcomes of Commonwealth assessments is often delayed and inconsistent, leading to uncertainty for businesses and weakening Australia's national risk management coverage. Stakeholders have been critical of previous reform efforts recognising limited success in dealing with these systemic problems associated with the Australian chemicals regulatory framework.

Australian Chemicals Regime Policy Objectives

6. The policy objectives for the notification and assessment of industrial chemicals are stated in the *Industrial Chemicals Notification and Assessment Act (1989)*. The objects of this Act are to provide for:

1. a national system of notification and assessment of industrial chemicals for the purposes of:

- aiding in 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; and

- providing information, and making recommendations, about the chemicals to Commonwealth, State and Territory bodies with responsibilities for the regulation of industrial chemicals; and

- giving effect to Australia's obligations under international agreements relating to the regulation of chemicals; and

- collecting statistics in relation to the chemicals;

- being a system under which information about the properties and effects of the chemicals is obtained from importers and manufacturers of the chemicals; and

2. national standards for cosmetics imported into, or manufactured in, Australia and the enforcement of those standards.

Ongoing policy considerations

7. In addition the policy objectives provided in the legislation the Commonwealth Government, in conjunction with state and territory governments, has been undertaking ongoing medium term reform processes to deliver more efficient and effective policy objectives for chemicals regulation. Since 2009, efforts have largely focussed on:

- Work Health and Safety – Reforms have achieved the adoption of the GHS system for industrial chemicals in all state and territory jurisdictions. Reforms have also created national regulations for the management of major hazard facilities have also been developed.

- Poisons scheduling – These reforms are concerned with the consistency across jurisdictions of regulatory controls on scheduled poisons to protect public health.

- Chemical of security concern – These reforms have aimed to raise awareness and vigilance around the use of security sensitive chemicals and precursors to homemade explosives.

Transitioning to a new chemicals management regime and the (re)assessment of historical chemical approvals/notifications

8. Industry has argued that relaxing Australia's pre-market risk assessment requirement for lower hazard chemicals, coupled with an increased focus on post-market compliance monitoring and acceptance of international assessments would assist business and encourage the introduction of innovative and safer chemicals. Community and worker representatives have argued that the large number of unassessed chemicals currently in industrial use is unacceptable, and that greater effort should be placed on assessing and managing the risks of these chemicals.

9. When the *Industrial Chemicals (Notification and Assessment) Act 1989* (ICNA Act) was enacted, approximately 38,000 industrial chemicals in commercial use at the time were nominated for inclusion in

the Australian Inventory of Chemical Substances (AICS) (as 'existing chemicals'). From the period of 1989 to 2008, about 180 existing chemicals, together with around 2,000 chemicals new to Australia were assessed by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The high number of unassessed existing chemicals mirrored the situation in many other developed countries where systematic approaches to chemical assessment were relatively new.

10. Under the ICNA Act, NICNAS prioritises the assessment of existing industrial chemicals based on concerns about their possible adverse impacts on people and the environment. A Priority Existing Chemical (PEC) is an industrial chemical that has been identified as requiring an assessment because there are reasonable grounds to suspect that the manufacture, handling, storage, use or disposal of the chemical gives rise, or may give rise, to a risk of adverse health and/or environmental effects.

11. A PEC assessment results in a report and recommendations for risk management. Tailored or focused preliminary assessments are also undertaken, in lieu of an immediate full hazard and risk assessment, targeting particular issues relevant to an existing chemical.

12. As part of the reform of the NICNAS Existing Chemicals Program and in line with initiatives being taken to improve the assessment of chemicals used in industrial processes across the world, it was agreed to implement a new accelerated assessment program which will be more flexible, transparent and responsive to the needs of industry, the community and government.

Policy Response – Accelerated assessment of existing industrial chemicals using innovative methodology

Inventory Multi-tiered Assessment and Prioritisation (IMAP)

13. In 2012, NICNAS implemented a new framework known as Inventory Multi-tiered Assessment and Prioritisation (IMAP) for the assessment of chemicals on the Australian Inventory of Chemical Substances (AICS): see Box 1.

Box 1 - The Australian Inventory of Chemical Substances

The Australian Inventory of Chemical Substances (AICS) lists the industrial chemicals that are currently available for use in Australia. It is therefore used to distinguish 'new' from 'existing' industrial chemicals — that is, chemicals not on the AICS are deemed 'new chemicals'.

Some chemicals may only be available for specific or conditional use and this is detailed in the AICS. The AICS is a list of chemical identity data and does not contain information on toxicity, manufacturers or importers. When the AICS was established, all industrial chemicals already in commercial use in Australia from 1 January 1977 to 28 February 1990 were included as 'grandparented' chemicals. This included approximately 36,000 non-confidential chemicals, with 2,500 in the Trade Name section and 1,000 in the Confidential section of the AICS.

Objectives

14. The objectives of the IMAP framework are the identification and rapid assessment of existing chemicals of concern, leading to enhancements in chemical safety information flow and chemicals management. The IMAP framework provides a more flexible and transparent approach to the assessment of the large number of chemicals on the national inventory and is responsive to the needs of industry, community and governments.

15. The IMAP process arose from recommendations from an independent review of the NICNAS Existing Chemicals Program and a subsequent review conducted by the Productivity Commission which is the Australian Government's research and advisory body on economic issues. The new framework aims to provide more timely information about the hazards and risks associated with industrial chemical use and identifies those chemicals which:

- Pose no unreasonable risk to human health or the environment (Tier I assessment); or
- Require risk management measures to be instituted for safe use (Tier II assessment); or
- Require more in-depth (Tier III) assessment to fully determine their impact on human health and/or the environment.

16. Where chemicals have been identified as requiring further risk management measures, recommendations are made for the safe use of chemicals in the areas of:

- Public health;
- Worker health and safety; and
- Environmental health.

17. The new IMAP framework is being implemented in a staged manner. During the first stage of implementation, approximately 3,000 chemicals that met characteristics that stakeholders identified as priorities for early consideration are being examined through application of at least Tiers I and/or II of the framework. The chemicals in this first group to be assessed were identified as "Stage One Chemicals". This first stage will take four years to complete (finishing in 2015-16).

18. The Stage One Chemicals were selected for assessment based on the following:

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

Progress to date

19. Under the ICNA Act, costs for the operation of NICNAS are recovered from industry. All costs are recovered via new chemicals assessment fees and registration fees. The costs for the IMAP programme are included in this cost recovery arrangement (through registration fees).

20. NICNAS commenced the assessment of Stage One Chemicals in 2012-13. By the end of 2013-14 NICNAS had conducted 2408 human health and/or environment assessments for a total of 1808 chemicals. Tier II assessments resulted in 929 recommendations to improve worker health and safety; 209 recommendations to protect public risk from the use of these chemicals; 84 were referred to the Australian Competition and Consumer Commission (ACCC) in light of concern about the safety of consumer products containing these chemicals; 78 required a more in depth (Tier III) assessment.

Review and Evaluation of Stage One Chemical Assessments

21. Stage One of the IMAP program will conclude with a review of the framework in the fourth year of operation (2015-16). This review is expected to make recommendations on the most efficient and effective approach for the assessment and prioritisation of the remaining high number of existing chemicals on the AICS.

APPENDIX 2 - CANADIAN SUBMISSION [OCTOBER, 2013, AMENDED JANUARY, 2014]

Sharing Canada's Experience in Implementing its Chemicals Management Plan (CMP)

Introduction

1. In Canada, municipalities, the provinces and territories, and the federal government each have roles in protecting Canadians and their environment against risks from chemical substances. The federal government makes laws and develops guidelines and objectives that apply across Canada, conducts scientific research on human health and environmental issues, and collaborates with other countries on the assessment and effective management of chemicals. The Government of Canada leads a range of activities to promote a life cycle approach to the sound management of chemicals: ecological and human health assessments, and risk management where warranted, supported by research, monitoring and surveillance. Canada's approach strives to be transparent – and all stakeholders – including industry, academia, health and environmental organizations, Aboriginal organizations, community groups, and other non-government organizations are given opportunities to provide input.

Regime leading up to the Chemicals Management Plan

2. Over the past 25 years the key legislation covering industrial chemicals in Canada has been the *Canadian Environmental Protection Act (CEPA)*. It was first promulgated in 1988 and renewed in 1999 and provides the regulatory framework and process for the risk assessment and management of existing and new substances in Canada. The Priority Substances Assessment Program was the first systematic chemicals assessment program identified under CEPA 1988 whereby chemical substances were identified on a priority basis by a Ministerial appointed panel of experts, added to a Priority Substances List and then evaluated through a risk assessment to determine whether they were harmful to Canadians or the environment. The government was mandated by law to carry out and complete the risk assessments within a period of five years. The Priority Substances Assessment Program included two Priority Substances Lists (PSL), the PSL1, dating from 1989, and the PSL2, dating from 1995, covering 44 and 25 substances respectively over a combined ten year period.

3. In 1994, the Domestic Substances List (DSL) was established, identifying an inventory of existing substances that were reported to be in use or commerce in Canada from 1984-1986. With the establishment of the DSL, Canada also developed a set of regulations effectively launching the New Substances Program, which required every new substance made in Canada, or imported from other countries, to be assessed for potential risks to human health and the environment before being allowed on the Canadian market.

4. When the *Canadian Environmental Protection Act* was updated in 1999 (CEPA 1999), it introduced new tools and approaches to address pollution prevention and chemicals management within Canada. A key initiative within the legislation was a mandatory provision requiring the Government to review all of the substances on the DSL (23,000 substances) to determine whether they had certain characteristics indicating that the government should further assess the risk associated with their continued use in Canada. Canada completed this exercise, called Categorization, in 2006, identifying 4300 that the legislation then required to be further assessed.

Drivers for Change

5. As the Categorization process came to a close, Canada required a new plan of action to address the results. A number of factors indicated that the PSL approach was no longer tenable. It was apparent

that the international goal of the sound management of chemicals by 2020 could not be met if Canada applied the 5 year time frame of the PSL assessments to address each of the 4,300 substances identified for further assessment under Categorization. The proposed process, the Chemicals Management Plan, included greater transparency, and a greater role for industry and other stakeholders to participate. This approach received a broad spectrum of support, further enabling its implementation. Looking at domestic drivers, along with other activities that were underway internationally (REACH, HPV Program etc.) it developed a new, revolutionary approach that would be launched.

The Launch of Canada's Chemicals Management Plan (CMP)

6. The Government of Canada created the Chemicals Management Plan (CMP) in 2006 to protect human health and the environment by assessing chemicals used in Canada and by taking action on chemicals found to be harmful. Delivered jointly by Environment Canada and Health Canada, and through partnership and engagement with stakeholders, activities under the CMP help to protect Canadians and their environment from harmful effects of chemical substances.

7. The CMP accelerated timelines to assess environmental and human health risks posed by chemical substances, and develop and implement prevention, reduction, elimination and management measures to reduce these risks by using the most appropriate management tools among a full suite of federal laws.

8. Under the CMP, information is gathered on substances in use in Canada; assessments and, when necessary, risk management is conducted on these substances through regulatory and non-regulatory activities; the public is informed of any known risks; and the public and stakeholders are encouraged to participate. The government also engages in research, monitoring and surveillance, and participates in international activities.

9. The *Canadian Environmental Protection Act, 1999* is the main tool used to manage harmful substances in Canada. Other acts may also be used where they are best placed to do so, such as the *Canada Consumer Product Safety Act*, the *Food & Drugs Act* and the *Pest Control Products Act*. A further tool for managing substances, introduced under the CMP was the new application of a regulatory instrument, previously reserved for new substances, applied against existing substances of concern, requiring industry to notify the government if they wish to use the substances in question (a Significant New Activity – SNAc – notice). The application of this existing tool, normally reserved for new substances, to the existing substances regime, demonstrated an evolution in Canada's approach in effectively and efficiently managing chemical substances in Canada.

10. Under the CMP, the 4,300 existing substances requiring further assessment have been divided into three groups of priorities for action between 2006 and 2020, so that the government could take accelerated and measured action on chemicals of greatest potential concern. During the first phase (2006-2011), 1,100 chemicals were addressed, around 1,500 are being addressed in the second phase (2011 – 2016) and approximately 1,700 are planned to be targeted for the third phase (2016 – 2020).

New Substances

11. Under its New Substances Program, the Government of Canada is responsible for administering the New Substances Notification Regulations (Chemicals and Polymers) and the New Substances Notification Regulations (Organisms) of CEPA, 1999. These regulations were created to ensure that any new substance (chemical, polymer or animate product of biotechnology) is subject to an assessment of potential risk to human health and/or the environment, and any appropriate control measures are taken.

Under this program, the Government of Canada typically receives and evaluates approximately 450 notifications per year and takes action on 15 to 20 substances.

12. When a company or individual plans to import or manufacture a new substance, it must first submit a notification package. The data requirements and associated assessment period depend on the type of substance and quantities that the companies intend to import or manufacture. When the assessment identifies that a new substance may pose a risk to human health or the environment, CEPA 1999 empowers the Government of Canada to intervene prior to or during the earliest stages of its introduction into Canada. This ability to act early makes the New Substances program a unique and essential component of the federal management of toxic substances.

CMP: Phase One

13. The first phase of the Chemicals Management Plan (CMP1) involved several important initiatives, built on a base of strong science, including the Challenge for high priority substances, the Rapid Screening of lower priority substances, an approach for substances in the Petroleum Sector, establishment of key stakeholder initiatives, an update of the DSL Inventory as well as taking action on substances, with potential high hazard characteristics, deemed not to be in Canadian commerce.

- *The Challenge* initiative focused on about 200 high-priority substances which were divided up into 12 batches. Each batch included mandatory information gathering, publication of draft assessments for public comment and final assessment decisions were published with appropriate risk management approaches as required.

- *The Rapid Screening Approach* was applied to approximately 1100 substances which were identified as potential lower risk substances that were unlikely, given current evidence, to be harmful to the environment or human health. Government scientists expected that the substances, while meeting the categorization criteria, were not likely to pose a risk in the amounts at which they are found. An accelerated screening approach applied conservative scenarios to determine whether further assessment was necessary.

- *The Petroleum Sector Stream Approach* included approximately 160 substances identified as priorities for action through Categorization and were grouped to be addressed in a sectoral approach. A large portion of high priority petroleum substances are used or manufactured during petroleum refining or bitumen / heavy crude oil upgrading activities.

- Stakeholder bodies were also established, including the Stakeholder Advisory Council with the mandate to provide input on the implementation of the CMP. The Challenge Advisory Panel was established to review the application of precaution and weight of evidence in risk assessments and to provide third-party advice on approaches developed for risk assessments under the Challenge

14. Under the CMP1 the Government of Canada was successful in taking decisive action to address substances of high concern, and reassured Canadians about substances that were of little concern. Canada demonstrated its commitment to assessing all of the substances that have been identified through categorization via successive rounds of assessment and, where necessary, taking action to manage risks. Continuously improved information on the uses and effects of chemical substances through mandatory information collection helped establish future rounds of priorities moving beyond CMP1. During CMP1, it was also recognized that managing chemicals safely relied on strong stewardship from Canadian industry. The federal government also worked to ensure that information about chemical substances (hazards and practices for safe management) was available to Canadians through a central website for the CMP.

15. As of November, 2013, the Government of Canada has either proposed or published a final risk management instrument for 38 of the 42 substances concluded toxic under the "Challenge" process. Under the *Canadian Environmental Protection Act*, 1999, the instruments to be used include, but are not limited to: Environmental Performance Agreements, Significant New Activity (SNAc) Orders, Codes of Practice and Guidelines, Pollution Prevention Plans, and Regulations. Other actions are also being taken under the *Canada Consumer Product Safety Act* and the *Food and Drug Act*.

CMP: Phase Two

16. Canada renewed the Chemicals Management Plan in 2010-2011, for a further 5 years, with an updated approach, building upon lessons learned under the first phase of the CMP, and a continued commitment to strong science to start to address the remaining priorities. Key initiatives under the second phase include a groupings approach, whereby 500 substances are being addressed under 9 substance groupings. Canada is also undergoing an update of the list of substances in Canadian Commerce (Domestic Substances List – DSL) as well as further rapid screening initiative for substances identified as no longer being in commerce, or used in low volumes, under the inventory updates. Stakeholder bodies were also modified, with the Challenge Advisory Body, being replaced with the CMP Science Committee to provide independent expertise on scientific considerations.

Lessons Learned

17. In reflecting upon seven years of implementation of the CMP, there are some key observations that can be shared from the Canadian experience.

Public Timelines and Transparency

18. The first key element that proved beneficial and successful was the clear, public timelines and openness and transparency in the decision making process. While very challenging at the time, given the shift in volume of assessment work and numbers of substances to assess, timelines were adhered to, establishing confidence in the program from stakeholders as well as demonstrating effectiveness in delivering on the timelines.

Stakeholder Engagement

19. The support and buy-in gained from engagement of stakeholders which required the commitment of resources, illustrates the benefits of working in a respectful manner with all stakeholders, and proved overwhelmingly important to the integrity of the program. One highlight was a joint letter of support received from both industry and non-governmental organizations to Ministers in which they indicated the importance of the program and the need to continue the work, received in the lead up to CMP2, which effectively aided in its launch.

Integration across the Federal Government

20. Given that there are shared authorities related to chemicals management within the federal government in Canada, the desire to work together and achieve successful outcomes has been paramount to the success of the program. Horizontal program management can add additional challenges to an already complex and demanding regulatory regime. However, the benefit of an integrated approach has outweighed these challenges, and a system designed for effective communication and continuous improvements is essential.

Information Management / Information Technology Challenges

21. An additional challenge experienced in Canada, and one that has been shared in other national or regional chemicals regimes is one of Information Management / Information Technology. The need to develop systems that support the maintenance of scientific information in a structured way within a regulatory regime can be challenging. This is an area where Canada continues to work on improvements internally, as well as within international forums, such as the OECD, where member countries can learn, and share experiences. As an example of this, programs have undertaken successful pilot testing of IUCLID, and are working towards a more fulsome implementation. Development and implementation of IM Tools will lead to improved productivity to advance CMP 2 and 3 results as efficiently as possible.

Working Internationally

22. Given the global nature of chemicals management and the strong collaborative work being done in international forums, there is a desire to share the workload, maximize efficiencies, and avoid duplication. In participating in this, however, it has been essential to ensure balance and capacity for delivering upon domestic commitments. From the perspective of risk assessment, Canada has benefitted from work in international forums such as the OECD as well as through bilateral relationships in the form of securing additional data and information, peer reviewing assessments, development of technical approaches and guidance as well as sharing experiences in program implementation. One challenge we have experienced is that countries (and sometimes international organizations) often have different timelines and schedules for working on chemicals and this can hinder the ability to fully realize the benefits of cooperation. Further, there are often difficulties in sharing information which has been designated as confidential. Finally, with regards to chemicals, Canada is largely an import market with relatively limited manufacturing of chemicals so the need for industry stakeholders to ensure there are inter-linkages to international operations and company headquarters is essential to ensuring Canadian companies can provide regulators with the information necessary to inform the chemicals management processes in place.

Additional Challenges

Need for Cultural Change

23. When the Chemicals Management Plan was introduced in 2006, it was accompanied by a large number of significant changes in order to meet the challenge of addressing all 4,300 substances by 2020. These included changes to the way chemical substances were addressed in Canada, changes to the role of industry, changes in internal governance and organization, and changes to methodologies and approaches. The ability to work in an environment of 'learning by doing" and deriving solutions that fit the needs was an essential element. In order to do this, it took internal expertise and willingness to find solutions, but additionally, it took buy-in from senior management as well as stakeholders to ensure the CMP was a success.

Efficiency: Evolution of day-to-day business

24. Key to the success of the CMP has been an acceptance of uncertainty in moving forward with risk assessment conclusions, along with an extensive strategy to mitigate risks through research, monitoring and surveillance, information collection and stakeholder consultation. Prior to the CMP, an average of less than 10 risk assessments of existing substances were completed annually, with some assessments taking more than 10 years to conclude. To attain the goal of addressing all 4,300 substances by 2020, this rate needed to increase by a factor of 30, to 300 per year, with only a modest increase in risk

assessment staff. In order to do this, risk assessment conclusions had to be made with the best available information, but less certainty than would have been accepted under the previous regime.

25. In addition to requiring a paradigm shift in expectations surrounding certainty among those working on the CMP, this required a strategy to validate the decisions made This strategy included a coordinated research program to inform future risk assessment, risk management actions and monitoring and surveillance efforts; an enhanced monitoring and surveillance program (environmental and biomonitoring) to detect, measure and characterize environmental change; and the updating of the domestic substances list to support timely and strategic risk assessment of remaining priorities as well as to confirm which substances are in commerce in Canada. Public comment periods and the engagement of stakeholder bodies further worked to ensure that the assessment conclusions made, and the risk management strategies, were sound.

26. This systematic approach enabled Canada to implement the current program of work and provided the mechanisms to revisit decisions made ensuring that government made the appropriate decisions based on sound science along with the information held at the time. Where the science evolved and new or additional information was brought forward by stakeholders, risk assessments were updated, taking into consideration this new information, and changing the assessment conclusion where warranted. This continual evolution represented a strong commitment by government in working with stakeholders and ensuring the appropriate decisions were made.

27. Once a substance has been assessed, and it has been determined that risk management is necessary, choosing a tool or, more importantly, the appropriate mix of tools, involves selecting the tools that are most likely to achieve the public policy objective pursued on a sustained basis and at an acceptable cost. A standardized framework is used for selecting tools which ensures that risk managers systematically consider all available options to identify tools that are appropriate to the level of risk. The use of a standardized framework is mandated by the Canadian Cabinet Directive on Streamlining Regulation as it increases transparency, efficiency, and coherence of regulatory decisions.

28. The Government of Canada used Environment Canada's Instrument Choice Framework as a guide to the development of the Treasury Board Document "Assessing, Selecting and Implementing Instruments for Government Action" used to help other departments initiate Instrument Choice.

Changes in Role of Industry and other Stakeholders

29. One of the key principles of the Chemicals Management Plan is the increased role for stakeholders, especially the regulated community. Additional to the predictable, ongoing opportunities to provide input on draft assessments, industry has been challenged to provide data for the assessments undertaken. Stakeholder bodies were also set up, notably the Stakeholder Advisory Council, with the mandate to provide input on the implementation of the CMP from a stakeholder perspective. Under the first phase of the CMP, the government indicated that it was predisposed to determine that the high priority substances were harmful (based on the information the government had collected and reviewed through Categorization) – in the absence of further information from industry. This impetus successfully engaged industry to generate the necessary data, which informed the assessment process. This engagement of industry was sustained under the second phase of the CMP through regular meetings with Canada's Industry Coordinating Group, as well as through the ongoing transparency and predictability of the program in soliciting input at regular intervals.

Chemicals Management in Canada Moving Forward

30. In living through an evolution of chemicals management in Canada, and continuously advancing, it is important to recognize the importance of the successes realized, as well as the challenges encountered, and having a systematic design or construct that can enable solutions to be found. Moving forward, it is critical to ensure Canada works with others, while continuing to advance its domestic work and agenda with its international partners as the chemical industry is increasingly more and more global with drivers coming from many different sources, and affecting regulatory authorities in many of the same ways. The openness, transparency, and goodwill in communicating successes along with challenges will hopefully assist others and oneself in the goal of constantly improving.

APPENDIX 3 - UNITED STATES SUBMISSION [DECEMBER, 2013]

Policy Objectives Case Study: US EPA's Principles for the Reform of Chemical Management Law

1. Passed initially in 1976, the Toxic Substance Control Act (TSCA) grants the US EPA jurisdiction over chemicals manufactured, processed, or distributed in the United States. While TSCA represented an important step forward at the time of its passage, TSCA is now the only major US environmental statute that has not been reauthorized since its initial passage.

2. Over the years, TSCA has not only fallen behind the industry it is intended to regulate, but has also proven an inadequate tool for the protection against chemicals risks that the public expects. In the 37 years since TSCA was passed, much has changed in both the US and in the greater scientific and regulatory community - we have developed a better understanding of the environmental impacts, exposure pathways, and health effects some chemicals can have – especially on children.

3. In the US there is broad agreement that TSCA should be modernized and strengthened; over the past few years a series of ongoing discussions have begun within Congress about what an update to US chemicals law should look like.

4. It is against this backdrop that the Administration announced its Essential Principles for Reform of Chemicals Management Legislation. While the US EPA remains committed to using the tools available under existing law, these Principles present Administration goals for updated legislation that would give the EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals. The remainder of this case study outlines these principles, or policy objectives, released in 2009 and that the Administration believes are crucial to updating and strengthening the US chemicals regime.

5. The US EPA should have authority to establish and use safety standards based on sound science, using risk-based criteria protective of human health and the environment. Chemical manufacturers should be responsible for providing the EPA with sufficient information for the EPA to evaluate chemicals against these safety standards and conclude that new and existing chemicals are safe and do not endanger public health or the environment, including sensitive subpopulations. Where manufacturers do not provide such data, the EPA should have the authority to quickly and efficiently require testing or other relevant information from manufacturers. This authority should extend to chemicals previously assessed should a change potentially affecting risk occur (e.g. increased production volume, new uses, or the emergence of new information on potential hazard or exposures). The EPA should have the authority to take into account sensitive subpopulations (e.g. children), economic and social costs and benefits, availability of substitutes, and equity concerns in its risk management decisions. The EPA should also be able to prioritize existing chemicals for safety reviews based on risk and exposure considerations, and conduct those reviews in a timely manner, with enforceable and practicable deadlines applicable to both the EPA and the industry.

6. The US EPA should encourage the design of safer and more sustainable chemicals, processes, and products through research, education, recognition, and other means. Stricter requirements for a manufacturer's claim of Confidential Business Information (CBI) should be set to discourage unwarranted CBI claims, and data relevant to health and safety should not be permitted to be claimed or otherwise treated as CBI. The EPA should be able to share CBI data with other governments (local, state, and foreign), with the necessary protections, when necessary to protect public health and safety. Finally, implementation of a reformed chemicals management law should be adequately and consistently funded,

with manufacturers of chemicals supporting the cost of implementation, so that the safety goals of the law may be reached, and public confidence in chemical safety review is maintained.

APPENDIX 4 - NEW ZEALAND SUBMISSION [SEPTEMBER, 2013, AMENDED JANUARY, 2015]

Experiences regarding transitioning to a new chemical management regime and the (re)assessment of historical chemical approvals/notifications

1. New Zealand, like many other countries, has developed a new chemical management regime in the last 20 years. Under the former regime, substances were notified, not assessed, and only very limited controls were in place to manage their effects. The new Hazardous Substances and New Organisms Act 1996 regime for chemicals was implemented in 2006. The Act requires that all chemicals have an approval to ensure the appropriate controls are assigned to that chemical. This meant that over 70,000 hazardous substances (chemicals and chemical products) that were notified through the former regime were required to be assessed under the new regime. Additionally, as part of requiring all substances to have an approval, the new regime also introduced a 'one-size-fits-all' approach to the management of all types of substances, regardless of where they are used (for example, industrial chemicals, agrichemicals, and chemical products for consumer use).

2. The process for assessing new chemicals and for the reassessment of existing chemicals places responsibility on applicants to provide information and contribute processing costs. The costs of assessments of new substances are partially cost recovered through fixed charges to applicants that recover less than 20% of the cost of decision making. The same charges apply to reassessment where the regulator is not the applicant. Responsibilities for providing data on chemicals and in meeting costs under the New Zealand regulatory regime are outlined below.

	Who is responsible for generating and providing data on hazard assessments?	**Who is responsible for generating and providing data on the use of substances?**	**Who is responsible for assessing substances?**	**Who is responsible for paying assessment costs?**
New Zealand	*New Chemicals* Industry is responsible for providing data on new chemicals (as applicant for a chemical's approval) *Existing Chemicals* Regulator is implicitly responsible for providing data on existing chemicals (as applicant for a reassessment is usually the regulator)	*New Chemicals* Industry is responsible for providing data on new chemicals (as applicant for a chemical's approval) *Existing Chemicals* The regulator is implicitly responsible for providing data on existing chemicals (as applicant for a reassessment is	Regulator is responsible for assessing new and existing substances	Both industry and regulator are responsible for assessment costs of new substances (partially cost recovered – fixed charges that recover less than 20% of the cost of decision making). Regulator is responsible for assessment costs for Group Standards (as applicant is usually the regulator) unless there is an external

		usually the regulator)		applicant in which case cost recovery as for a new substance. Regulator is implicitly responsible for reassessment costs for existing substances (as applicant is usually the regulator) unless there is an external applicant in which case cost recovery as for a new substance.

3. After 5 years of preparation for implementation, inefficiencies associated with the new regime were identified (which were likely amplified by the relatively small size of New Zealand industry and the businesses within it), and a policy response was required. These inefficiencies were:

- a time consuming and costly approval process for the transfer of existing notified substances into the new approval regime;
- a complicated and costly approval process for low risk substances (non-proportionate to the risk being managed), which doesn't encourage the substitution of high risk substances;
- individual approvals for similar products resulting in unnecessary work for applicant and the regulator; and
- difficult processes for reassessment of substances, which involves reassessment of each approval in isolation, when changes may be needed to the approval and the controls imposed by the approval.

Objectives for policy response:

4. New Zealand sought to remove redundancies and costs from the hazardous substance approval process and management system where they do not add to the objective of the regime - 'protection of the environment, and the health and safety of people and communities'. This includes enabling improved economic wellbeing through reducing barriers to the introduction of new low risk hazardous substances.

Policy response: A 'Group Standard' mechanism, where:

5. The legislation was amended in 2005 to provide a 'Group Standard' mechanism which approved groups of substances. Under this mechanism substances are grouped and controls set for the group rather than for individual substances (this has some similarities to the 'control banding' approach but had a different design purpose). An application, and an approval from the regulator, is not necessary in order for new qualifying substances to be added to the group.

6. Group Standards cover substances with specific hazard classifications (based on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)) and within defined areas of use. This includes offering similar benefits and posing similar risks. Accordingly the risks posed by substances within a group can be managed by one set of controls. A Group Standard can exclude specific substances of similar nature or type that pose a significantly greater risk.

7. In the legislation, before Group Standards can be used the regulator must be satisfied they are an efficient and effective way of managing the risks of the substances. The controls in the Group Standard stand in place of regulations that might otherwise apply if there were individual approvals.

8. The controls are legally enforceable and are generally intended to set prescriptive controls (rather than performance based requirements as set out in legislation).

9. Group Standards shifts the cost of an 'approval' from the applicant to the Government (although as the new regime only cost recovers around 20% for individual approvals, there are still savings to Government through the Group Standard mechanism as there are significantly less applications for individual substances to be considered).

10. Chemical importers or manufacturers self-assign substances to the relevant Group Standard based on whether the hazard properties of the substance and its uses fall within scope of the Group Standard. The regulator is only notified when the substance contains a component not previously notified. As long as this fits within the scope of the Group Standard, there is no requirement for an application for approval.

11. Approximately 200 Group Standards were established to aid the transfer of existing substances in 2006, and around ten have been established since. The Group Standard mechanism has not been used for some substances as the regulator considered that these, usually higher risk substances, should be managed under individual approvals. Explosives, pesticides, wood preservatives and chemicals toxic to vertebrates fit within this category, and remain individually approved for use and assigned risk management measures.

12. The experience suggests that there would be advantages in the Group Standards mechanism for managing the higher hazard substances. Before this mechanism can be used proposed amendments to the legislation would need to be enacted as the only grounds for removing individual substance approvals are the grounds for no longer permitting the substance in New Zealand. Replacement of the approval by a more recent Group Standard is not currently grounds for removal of individual approvals. Where substances are subject to both Group Standards and to individual approvals users have to option of using the controls specified in either so introducing Groups Standards without being able to remove individual approvals would mean the regulatory regime would have many duplicate instruments, all of which would need to be amended to effect any future changes to rules governing the use of a particular chemical.

Reassessments

13. In New Zealand chemicals in use that are already legally approved for use can be assessed (often termed a reassessment[5]) and the reassessment may result in the approval being removed or in changes to the rules governing use of the chemical. Changes to Group Standards also require reassessment if new restrictions are to be placed on substances within the scope of the Group Standard.

[5] The reassessment process enables the regulator to re-examine whether a substance can be imported, manufactured or used in New Zealand. It involves assessing all effects of a specified substance - both positive and adverse effects. Where the negative effects of a substance outweigh the positive effects, the regulator may remove the approval to import, manufacture or use the substance, or to restrict its use. Reassessments can be triggered through new information relating to the effects of the substance, new alternatives with improved beneficial or reduced adverse effects, or significant changes in use.

14. Historically, New Zealand reassessments have been targeted at individual substances where evidence suggests there is a need to reconsider the approval or rules relating the chemicals' uses. More recently, learning from the experience with Group Standards, New Zealand has reassessed a number of approvals for individual substances in conjunction with each other.

15. The New Zealand reassessment process follows the same process and cost recovery rules as assessments of new chemicals and can be a time consuming and resource-heavy process. Reassessments can by undertaken in response to user or industry application or through a programme of regulator initiated reassessments. There is less incentive on industry to seek reassessments of existing chemicals where the likely result is additional restrictions or prohibition on use. Where an enterprise no longer needs a chemical there is no need for them to seek approval before they stop using it. If enterprises are replacing an existing substance with an entirely new, unapproved chemical then any application is for the new chemical. Consequently the cost of reassessing existing chemicals typically falls on government. This is acknowledged as incentivising the continued use of existing chemicals as opposed to developing or importing safer and/or more effective alternatives.

16. The resources available for reassessments are limited so the number being undertaken has been constrained. Initially all reassessments were undertaken in isolation. While a priority list of 20 substances for review was prepared in 2008, New Zealand has not undertaken an in-depth priority setting exercise. The reassessment of the last of 20 substances in the 2008 priority list was completed in early 2014.

17. Reassessments covering two groupings of related substances, antifouling paints and organophosphate pesticides, were started in 2012 and completed in 2013/14. This enabled the individual approvals of an additional 35 chemical actives to be reassessed in the two groups. With other single substance reassessments New Zealand was able to reassess a total of 48 individual substance approvals in two years from June 2012 to June 2014. Without any grouping of reassessment New Zealand was only able to reassess 35 substance approvals between 2006 and June 2012.

18. This grouping of reassessments of similar substances leads to savings in gathering information on use and in monitoring impacts of chemical use. The grouping also enables consideration of possible substitution between chemicals as a result of changing rules on use.

19. In addition to reassessments of individual substances New Zealand has also revised its Group Standard for Cosmetic Products. The revisions have been to adopt regulatory changes relating to cosmetics made in other jurisdictions, especially the EU.

Outcomes/lessons learnt from experience:

20. Did the development of the Group Standard mechanism meet its objective, and what lessons have been learnt?

Reduced costs and efficiencies

21. The Group Standard mechanism reduced costs to government and industry associated with the application and decision making process. For substances that fit within the scope of a Group Standard, the mechanism removed the majority of costs for industry associated with the application process. While government remains responsible for developing Group Standards, the mechanism has reduced the need, and subsequent costs to government and applicants, for undertaking individual substance assessments.

22. The Group Standard mechanism was also successful in removing inefficiencies associated with requiring assessments for substances where similar substances were already approved. The ability to group

substances according to type or nature removed the need to assess each substance individually regardless of what substances of a similar nature already existed on the market.

23. Even where Group Standards have not been used New Zealand has found that the grouping of individual substance reassessments by areas of use has led to savings in gathering information on use and in monitoring impacts of chemical use. The grouping also enabled consideration of possible substitution between chemicals as a result of changing rules on use. These savings have enabled New Zealand to increase the number of substances being reassessed.

Setting of risk based controls

24. The ability to develop more efficient or effective controls, or controls based on use, was originally observed as a feature of the Group Standard mechanism. On reflection there have been operational challenges in achieving this. Controls for individual approvals are linked to the substance's hazard classification, and these are linked to highly technical, performance-based controls set out in regulations. Where a chemical has an individual approval the Group Standard is an alternative mechanism for compliance.

25. The complexity of the resulting multiple authorisations, and the form in which Group Standards have been developed, has proven difficult for users, especially small and medium size companies, to understand and implement. While not required by legislation, the majority of Group Standards have been developed according to hazard classifications and to similar circumstances of use, and controls are largely linked to the technical regulations (this linking back to regulations is due in large part to the timing constraints associated with implementation of the Group Standard mechanism- a 6 month period in 2006 in which to create and implement 200 Group Standards).

26. Given these operational timeframes, pointing controls back to regulations may have been efficient from a government perspective. However this has prevented the regulator from better assessing and testing the needs of different chemical user groups, and therefore the workability and practicality of Group Standard controls. More specifically, it did not enable the development of prescriptive, but more understandable, controls based on use, where controls are more informed by particular user groups (particularly industry groups characterised by small and medium size companies). This has impacted upon the effectiveness of the mechanism. While there is an ability to revisit these Group Standards and individual approvals without legislative change and consider how controls could be better aligned to industry needs, this does require substantial operational resources for the regulator.

Substitution of high risk substances

27. Similar to the outcome associated with setting of risk based controls, the Group Standard mechanism as implemented also fails to take a holistic approach to the substitution of high risk substances. While Group Standards do exclude some of the highest hazard category substances, in their current form, once a chemical is included in the Group Standard it is treated the same as other chemicals falling under the same group (unless there are specific conditions). The Cosmetic Products Group Standard includes many specific conditions on different substances. Many of the others, however, do not currently encourage the substitution of higher risk substances (e.g. contaminants of emerging concern) by lower risk chemicals under the same Group Standard. Despite this, the experience suggests that there would be advantages in the Group Standards mechanism for managing the higher hazard substances. However, before this approach can be used proposed amendments to the legislation would need to be enacted to enable replacement of existing individual approvals by appropriate Group Standards.

Comparing policy objectives of different countries' chemical management regimes, and identifying commonalities and differences

28. Historically, OECD member countries have found it comparatively easy to agree at a high level what the desirable outcomes for chemical management should be i.e. protecting human health and the environment by promoting chemical safety. There has also been agreement that increased alignment between countries is of value, and member countries have been able to work together and align processes for lower tier technical issues, as illustrated through the Joint Meeting's work on Test Guidelines and Principles of Good Laboratory Practices.

29. However, less progress has been made with regard to alignment between member countries at the regulatory decision making level e.g. mutual acceptance of chemical assessment decisions. While the OECD is working to progress this through programmes such as the OECD Cooperative Chemicals Assessment Programme, there has been limited detailed work to examine the differing policy objectives of member countries' chemical regimes and how these may impact, either positively or negatively, on the ability for increased cooperation between member countries in regulatory decision making.

30. Policy objectives in this context refer to the key factors that underpin chemical assessment decision-making processes within member countries. An improved understanding of policy objectives is considered necessary should member countries work towards progressing regulatory alignment.

31. As a brief illustration, among New Zealand's chemical regime policy objectives are the following:

- The purpose of the chemicals regime is to protect people and the environment from harm.
- Risk assessment is intended to inform decisions on approval (required for all hazardous substances before they can made or imported into New Zealand) and on rules regulating storage and use of the substances. Note that hazardous substances can be a chemical or a formulated mixture or product.
- The assessment of chemicals is based on a risk assessment, which includes a requirement to assess monetary and non-monetary costs and benefits.
- The applications process for new chemicals and for the reassessment of existing approvals places responsibility on applicants to provide information and contribute to costs of processing the application.
- Caution must be taken into account in managing the adverse effects of a chemical where there is scientific uncertainty about those effects.
- Chemical assessment decisions must give specific regard to Māori perspectives, the indigenous New Zealand population.

32. A comparison of member countries' policy objectives regarding chemicals management is likely to reveal commonalities and differences that could be used to identify opportunities for increased collaboration in regulatory decision making for managing chemicals.

APPENDIX 5 - EUROPEAN COMMISSION SUBMISSION [JANUARY, 2014]

WORKING DOCUMENT[6] - Policy Objectives and Choices When Developing REACH

Introduction

1. Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) was adopted on 18 December 2006 after an 8 year political process. In developing the legislative proposal the European Commission implemented a stepwise process of first reviewing the existing legislation, carrying out a number of public and stakeholder consultations and performing an impact assessment to understand the costs and the benefits of the proposal.

2. This document sets out a number of the main policy drivers in the development of REACH. In discussing this development it distinguishes between the early discussions leading to the Commission's proposal for REACH of 2003 (hereafter referred to as 'the REACH proposal') and the later discussions of that proposal by the Council and the European Parliament leading to the adoption of REACH[7] in 2006. This document is not a comprehensive analysis but provides an insight to some of the main drivers and the process for developing REACH as a replacement of the previously existing legislation.

The Process

3. In the EU the European Commission has the 'right of initiative', that is it is the only institution that may propose legislation. The Council, made up of the Member States, and the European Parliament, made up of directly elected representatives, constitute the legislator and negotiate and then adopt the laws proposed by the Commission.

4. Often a legislative proposal from the Commission is preceded by policy debates and definition of preliminary positions in the other institutions. These take the form of Council Conclusions when the Council articulates a policy view and of Resolutions or ‘Own Initiative reports’ when it’s the European Parliament.

5. The discussions leading up to the development of the REACH proposal can crudely be categorised of two types, the policy level and the technical level. Both fed in to the development of REACH and both significantly interacted as the discussions progressed. The next two sections set out these two debates in order to identify the main policy drivers of the REACH debate and the available evidence.

[6] This document reflects the views of certain Commission Officials who were involved in the development of REACH. The intention of the document is to provide input to the discussion of the OECD Joint Meeting on policy drivers. It does not necessarily reflect the official views of the European Commission.

[7] When the text refers simply to 'REACH' and not the 'REACH proposal' it is to be understood as the legal text adopted in 2006.

The Policy Debate

Overview

6. The policy debate is well documented (e.g. the Commission Website[8] or the Lowell Centre for Sustainable Production[9] have links to many relevant original documents). A succinct chronology with the main events of the policy discussions leading to the REACH proposal and to REACH is:

- 1998 April: Informal Environment Council in Chester, UK, expresses concerns about the lack of progress made under the existing chemicals regulation and the lack of information on existing chemicals. The Commission responds by proposing to develop a report on the functioning of the chemicals legislation.

- 1998 November: Commission publishes a report[10] on the functioning of the four main current chemicals regulatory instruments. This report identified the main weaknesses of the operation of the current legislation and provides recommendations of how to resolve some of them;

- 1998 December: The European Council welcomes the report and concludes that an integrated and coherent approach to chemicals management is needed, particularly dealing with the risk assessment and risk management inefficiencies;

- 1999 February: Commission organises a stakeholder debate entitled "Industrial Chemicals: Burden of the Past, Challenge for the Future."

- 1999 June: the Environment Council asks the Commission to write a White Paper setting out a new approach to chemicals regulation and setting out a number of the main elements.

- 2001 February: the Commission publishes the White Paper setting out a strategy for a new chemicals policy and describing the main elements of a future legislation that was to become REACH.

- 2001 April: European Commission holds a stakeholder debate on the White Paper.

- 2001 June: Council Conclusions supporting the Commission's proposal for a new chemicals policy.

- 2001 November: European Parliament votes on resolution on the White Paper, supporting the Commission's proposal for a new chemicals policy.

- Late 2001 to early 2002: Technical working groups on REACH, organized by the Commission with contributions from Member State Authorities, industry and stakeholders.

- 2003 May: Internet consultation on a draft legal REACH text.

[8] http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/white-paper/background/

[9] http://www.chemicalspolicy.org/archives.reach.timeline.php

[10] SEC(1998) 1986 final. Commission Working Document. Report on the Operation of Directive 67/548/EEC, Directive 88/379/EEC, Regulation (EC) 793/93 and Directive 76/769/EEC.

- 2003 October: The Commission's proposal for REACH (revising the draft legal text which was subject to public consultation based on the comments received) is published by the European Commission, with an extended impact assessment. The legislative process starts.

- 2005 November: First reading in the European Parliament.

- 2005 December: Political agreement in the Council.

- During 2006: Second Reading and trialogues, where Council, the European Parliament and the Commission negotiate the final legal text based on the first reading outcome in the European Parliament and the Political Agreement in the Council.

- 2006 December: REACH adopted by the European Parliament and the Council.

7. Although the political and technical discussions continued (and still continue) after 2006, the scope of this paper does not extend to after December 2006. This paper therefore also does not discuss the policy drivers, the evidence base and the policy response that led to the creation of the European Chemicals Agency, nor the lessons learned from its start-up.

Background

8. The reason for the REACH policy debate was the slow progress of risk assessment and risk management under the Existing Substances Regulation (ESR – Regulation (EEC) No 793/93). The policy driver through-out was therefore the need to speed up the risk assessment and risk management of existing chemicals, but as the discussions progressed, other drivers and conditions were identified.

9. In line with the initial policy dissatisfaction with the progress of ESR in the late 1990's was the publication of two technical studies (by the US EPA[11] in 1998 and the European Commission's JRC in 1999[12]) showing that basic data necessary to carry out a screening level initial risk assessment was only publicly available for a minority of chemicals (less than 20%) and that this situation mirrored what the US National Academy of Sciences had estimated to be the case in the 1980s. This added another, albeit related, policy driver, namely the need to obtain the necessary data for existing substances to even enable the risk assessment and risk management of existing chemicals to take place.

10. The lack of data and the difficulty for authorities to continue being responsible for the risk assessment and risk management of existing substances triggered the conclusion that, in line with the 'polluter pays principle[13]' (or 'extended producer responsibility' as its often referred to), it should be the responsibility of industry to test their chemicals, risk assess and risk management them and for authorities to focus on those risks which industry cannot manage or does not manage appropriately. It was this link, dubbed 'reversal of burden of proof' which drove much of the design of REACH.

11. Though environment and health concerns related to the marketing and use of existing chemicals were the initial driver of the policy debate, that debate was also shaped by the general EU policy objectives of ensuring a level playing field in the EU (preserving the internal market), ensuring the competitiveness of the EU industry and fostering innovation, being non-discriminatory internationally (respecting WTO) and promoting non animal test methods (promoting animal welfare).

[11] http://www.epa.gov/hpv/pubs/general/hazchem.htm

[12] http://chemicalspolicy.net/downloads/DataAvailabilityEUHPV.pdf

[13] http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm

Policy Issues, Evidence Base and Policy Response – Up to 2001

12. The policy issues which emerged at the level of the Council and European Parliament during 1998 and 1999 can be summarised as:

1. The (then) current approach to chemicals regulation is too slow and places undue burden on authorities to risk assess and risk manage chemicals.

2. There was a significant information gap regarding the properties of existing chemicals hampering the risk assessment and risk management of existing chemicals.

13. The evidence base produced in 1998 and 1999 can be summarised as follows:

- Less than 20% of existing substances have publicly available the minimum data needed to carry out a screening level initial assessment of the hazard properties.

- The progress in assessing existing substances was too slow and too resource intensive, with a summary of the output set out in the following table[14]:

Instrument	Years in Force	Output	Type of Output	Average Output per Year
Dir 67/548 (New Substances)	29 years	8,000	Notifications of New Substances	275
Reg 793/93	15 years	138	Comprehensive Risk Assessment Reports	9
Reg 793/93	15 years	92	Risk Reduction Strategies	6
Dir 76/769	32 years	ca. 100[15]	Restricted Substances	3
Dir 67/548 (Classification and Labelling)	41 years	7,900	Complete Harmonised Classifications	190

14. It is relevant to note that for the work under Regulation (EEC) No 793/93, where the progress was deemed insufficient, but also for all the work under Directive 67/548/EEC, there was a significant learning curve. Hence towards the end of the programmes the output was considerably higher than the average, with it being in the earlier years considerably less than the average.

[14] European Commission (2008). The European Chemicals Bureau: an overview of 15 years' experience in EU chemicals legislation. EUR 23301 EN – 2008. Available under: http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/5316/1/ecb%2015%20years%20report%202.pdf

[15] This number covers group entries which in themselves could cover many substances.

15. The policy response developed between 1999 and 2001 and published in a Commission White Paper in 2001[16] was to establish a new chemicals policy fundamentally changing the approach to chemicals management by merging the approaches to new and existing substances and by reversing the burden of proof, so as to oblige industry to demonstrate safety of the chemicals they market and setting 7 policy objectives which the new chemical management system should adhere to:

1. **Protection of human health and the environment.**

   - This objective was in itself to be met by introducing REACH, which would merge the new and existing chemicals schemes to one unified system allowing existing substances to be phased in. REACH should revise the new substances system of Directive 67/548/EEC, to become more effective and efficient and the revised obligations be extended to existing substances. The requirements, including the testing requirements, of REACH should depend on the proven or suspected hazardous properties, uses, exposure and volumes of chemicals produced or imported. All chemicals above 1 tonne should be registered and special attention should be given to long-term and chronic effects at the higher tonnages. In doing so REACH should:

   - ***Set deadlines***: A step-wise approach should be implemented to address the 'burden of the past' and hence to develop adequate knowledge for existing substances that industry wishes to continue marketing.

   - ***Make industry responsible for safety***: The responsibility for generating and assessing data and assessing risks of the intended uses should be shifted to industry.

   - ***Extend the responsibility along the supply chain***: Manufacturers, importers and down-stream users should be responsible for all the aspects of the safety of their products and should provide information on use and exposure for the assessment of chemicals.

   - ***Authorise substances of very high concern***: Substances with certain hazardous properties that give rise to very high concern should be given use-specific permission before they can be used. Evidence demonstrating that the specific use only presents a negligible risk or, in other cases, that the use is acceptable taking into account socio-economic benefits, lack of 'safer' chemicals for the same task and measures minimising the exposure of consumers, workers, the general public and the environment will be considered before granting an authorisation. Uses which do not give rise to concern may be subject to general exemptions from the authorisation procedure.

   - ***Substitution of hazardous chemicals***: REACH should also encourage substitution of dangerous by less dangerous substances where suitable alternatives are available and introduce an authorisation system for the substances of very high concern (SVHCs).

   - The technical basis for implementing this in REACH was developed during the technical discussions leading up to the Commission's proposal for a Regulation on REACH in 2003 (see section 2.2).

[16] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0088:FIN:EN:PDF

2. Maintenance and enhancement of the competitiveness of the EU chemical industry.

- Regulation was seen as major factor in shaping the innovation behaviour of firms in the chemical industry. REACH should therefore promote the competitiveness of the chemical industry and encourage innovation, by in particular supporting the development of safer chemicals.

- In comparison with the old 'divided' system, the new unified system would make it easier to develop and market new innovative chemicals whilst making it more difficult to market existing chemicals. Combining this with a regulatory system which promotes the use of less dangerous substances was seen as a means to enhance EU competitiveness and innovation in the chemicals sector.

- Already in 2001 the policy decision was taken to implement this objective by increasing the thresholds for registration of new substances (from 10 kilogrammes to 1 tonne), to extend the conditions for derogation from registration for research and development and finally enable test data to be used and submitted in a more flexible way.

- It was also seen to be necessary to take into account the costs and resource implications for industry. The time schedule for phasing in existing substances, together with the increased testing thresholds for new substances and a more flexible approach to generating test data, should limit the costs for industry to the absolute minimum needed.

3. Prevent fragmentation of the internal market.

- REACH aims at fully harmonising the chemicals legislation at Union level. This was implemented by choosing a regulation based on the EC Treaty provision on harmonisation of legislation as the legal form of REACH, which ensures uniform application in all Member States; by establishing a central agency to do much of the scientific and technical work and by establishing detailed rules for allowing marketing and use of substances in the EU.

4. Increased transparency.

- REACH aims at giving consumers and companies access to information on chemicals to enable them to make informed decisions about the substances that they buy or use. This was implemented by establishing extensive obligations to communicate in the supply chain, to ensure publication of much of the information collected by the European Chemicals Agency (ECHA) and finally by giving consumers rights to know about certain substances contained in articles they buy.

5. Integration with international efforts.

- REACH should contribute to meeting the WSSD 2020 goal, build on the ICCA HPV and OECD SIDS Programme and assist developing counties by generating and making available information on existing substances.

- This was implemented by increasing efforts at UN and OECD. At UN increased efforts were made to finalise the development of the GHS system for classification and labelling. At OECD increased efforts were made to develop IT tools and guidance documents for authorities and industry on REACH implementation which in turn were directly used by

ECHA in REACH and by implementing to a large extent the OECD Existing Chemicals Programme into REACH.

6. Promotion of non-animal testing.

- The REACH testing requirements should be met as far as practicable through use of existing non-animal test methods and measures to increase testing thresholds and more flexible test regimes which limit the need for testing.

- This was implemented by establishing an obligation on registrants to systematically collect all available information and only when this information was insufficient to fulfil an information requirement should a test be proposed. Furthermore most testing involving animals needs approval by ECHA and the legal possibilities to use alternative methods to fill information gaps (e.g. through read across) was introduced.

- Separately the Commission committed to encourage the development of new non-animal test methods.

7. Conformity with EU international obligations under the WTO

- REACH should not create any unnecessary barriers to trade and should not discriminate against imported substances and products. This was implemented by ensuring that importers and EU manufactures have the same obligations as regards substances and mixtures under REACH and checking that the specific provisions for articles were conform with WTO.

Policy Issues, Evidence Base and Policy Response – 2001 to 2003

16. The Commission developed its proposal for REACH between 2001 and 2003 using the White Paper of 2001 and further input

17. The policy issues which emerged at the level of the Council and European Parliament during 2001 and 2003 mainly concerned:

1. The REACH proposal must be workable;

2. The costs of the REACH proposal must be manageable.

18. The evidence base to consider workability was (among others) collected through a series of Commission Working Groups held towards the end of 2001 and the beginning of 2002 attended by Member States and a wide range of stakeholders to discuss the implementation of a number of the topics in the White Paper and through a public consultation held in 2003 of the building blocks of the REACH proposal. Some of the specific technical issues are discussed in greater detail in Section 2.2.

19. The evidence base for the impact assessment was initially developed by the Commission and discussed in an open process led by the Commission[17], bringing additional information and resulting in an extended impact assessment[18]. The policy response was to adapt the building blocks of the REACH proposal along the following lines:

[17] http://ec.europa.eu/environment/chemicals/reach/background/i_a_en.htm

[18] http://ec.europa.eu/environment/chemicals/reach/pdf/background/eia_se_2003_1171.pdf

- Substantial simplification of the requirements to be met by manufacturers and importers in relation to Chemical Safety Assessments and Chemical Safety Reports, and a much reduced burden for downstream users;

- No registration or evaluation for polymers;

- Lighter registration for substances produced between 1 – 10 tonnes, with reduced testing requirements and no need to complete Chemical Safety Assessments or Chemical Safety Reports;

- A reinforced authorisation system, introducing a specific requirement for applicants to present a substitution plan in cases where authorisations are being granted on socioeconomic grounds;

- Streamlined administration of REACH, giving the proposed chemicals agency more responsibility in the areas of registration, evaluation and data-sharing;

- Greater legal certainty was provided through clarification of the requirements for the duty of care, the treatment of confidential data, exemptions for research and development and sanctions while still protecting health and the environment; and

- A more practical formula was introduced for determining when substances in articles need to be registered or notified to the authorities.

Policy Issues, Evidence Base and Policy Response – 2003 to 2006

20. From 2003 to 2006 the policy discussions took place in the European Parliament and the Council through the legislative procedure discussing the REACH proposal.

21. The Policy Issues relevant to the legislative process from 2003 to 2006 leading to the adoption of REACH in 2006 were similar to those relevant to the development of the Commission's proposal but were either further developed or discussed because the assessment and solution developed by the Commission was not (completely) shared by the legislator. The Evidence Base was significant. For example 36 impact assessments of REACH or specific parts of it on society and business were developed by Member States' and were discussed at a Workshop held in The Hague 25-27 October 2004. France developed an impact assessment regarding the Agency and the UK regarding avoidance of duplicate testing.

22. The policy response was to adapt the REACH proposal along the following lines:

23. From 2003 to 2005:

- Scope: the interface with other legislation and the removing of POPs from the scope of REACH;

- Lighter registration for substances produced between 1 – 10 tonnes, in particular for existing substances;

- The structure and functioning of Evaluation was altered, in particular moving the responsibility of evaluating compliance from the Member States to the Agency;

- Strengthening the data sharing requirements by making it obligatory and strengthening aspects aiming at avoiding duplicate testing where possible;

- Further practicality issues were addressed for the obligations regarding substances in articles.

In 2006:

- The main discussion in 2006 centred around Authorisation and in particular when and how substitution of substances of very high concern should be implemented;

- Further issues concerning the duty of care, data sharing, confidentiality, information to consumers and animal testing were discussed and changes in the legal provisions made.

24. In parallel to the policy discussions the Commission organised three technical discussion fora to discuss the technical implementation of the agreements reached between Parliament and Council and to prepare for eventual implementation:

- Commission Working Group: the Commission set up a working group of Member States and stakeholders (including a representative from non-EU Member States) to discuss the technical implementation of REACH;

- REACH Implementation Projects: the Commission set up a working group of Member States and stakeholders (including a representatives from non-EU Member States) to develop technical guidance documents for implementation of REACH;

- Strategic Partnerships: the Commission set up partnerships with industry to test specific elements of REACH.

The Technical Input Debate

Overview

25. At technical level there was a multiplicity of fora where aspects related to the new chemicals policy were presented and debated. Again these fora interacted and fed into one another's debate and into the debate at policy level to an extent that cannot possibly be covered in this paper.

Assessing the Functioning of the Legislation

26. Already from 1996 the Competent Authorities for Regulation (EEC) No 793/93 starting discussing how to increase efficiencies and meet within the regulatory limits of Regulation (EEC) No 793/93 the emerging new policy demands. Building on these activities the Commission developed in 1998 a detailed report on the functioning of the 4 main instruments governing the (then) chemicals management in the EU. The report's main conclusions were:

1. There was a need to address technical issues identified in the operation of all instruments;

2. There was a need to address the lack of resources available to implement the legislation;

3. There was a need to address the lack of available information on existing chemicals and the burden of proof being on authorities and not on industry;

4. There was a need to accelerate and rationalise the restrictions process;

5. Ensure that the precautionary principle is given full consideration;

27. Dedicated workshops where held in 1999 and 2000 to see how the deficiencies identified in the Commission Report could be implemented in the then existing legislation and thereby contribute to meeting the new policy demands. The recommendations developed fed into the White Paper (in 2001) and the Commission Proposal for REACH (in 2003).

28. An example of a Member State initiative to provide technical input to the policy debate was a Dutch report produced in 2002 by the RIVM[19]. The two main conclusions were that (1) "*a priori* knowledge on possible risks of priority substances is […] poor" and (2) "For a great number of chemicals, additional testing was […] needed [invoking] questions about the completeness of the current base-set [of information requirements]".

Technical Development of Certain Issues

29. The technical discussion on the feasibility of implementing the reversal of burden of proof was based on industry's activities in the late 1990s. Under the previous legislation it was clear that industry could take the responsibility for developing test data using OECD and EU test methods and there had also been some examples where industry developed risk assessments for new chemicals. The ICCA HPV initiative, which had its origin in the US HPV Challenge Programme (later renamed) was a model for how international hazard assessments could be done. The reviews of the SIARs and SIDS dossiers originating from ICCA and submitted to OECD showed that the industry could develop hazard assessments which resulted in international agreement. Hence implementing fully a reversal of burden of proof would require 'only' the moving of the requirement to carry out the exposure assessment to industry, laying the bases to REACH's Chemical Safety Report. The principle feasibility of requiring industry to do this was discussed and concluded in a workshop in 2001, although the discussions on the practical feasibility continued.

30. The REACH approach to having manufacturers and importers carry out the risk assessment of all (identified) uses rather than oblige each operator in the supply chain to do this, came from the observation that the manufacturing industry (and by extension importers) have better competences to conduct risk assessment than most downstream users. Finally building the whole REACH implementation on OECD agreed approaches, including the SIAR, would ensure maximum alignment with international activities, maximum utility from existing work and benefit those companies who had volunteered within the OECD.

31. The much higher legislative requirements for new chemicals staggered innovation and the low legislative requirements on existing chemicals promoted continued use of existing chemicals rather than finding innovative new chemicals solutions. Equalising the demands should therefore reduce the incentive to continue using existing chemicals and should increase the incentive to develop and use innovative new chemicals, thus promoting innovation and hence competitiveness. The discussion of this assessment in turn led to an extension of the exemptions under REACH regarding Research and Development, Process Oriented Research and Development.

The Result

32. The REACH Regulation was adopted in 2006, establishing the European Chemicals Agency in 2007 and its main operational provisions entering into force in 2008. In 2012 the Commission carried out a

[19] http://www.rmri.ro/EU_2850/Downloads/RIVM_report_601504002.pdf

comprehensive review of REACH[20] based on evidence collected through the reports prepared by ECHA and Member States and evidence the Commission itself has collected which concluded that REACH functions well and delivers on all objectives that at present can be assessed. Some key findings are:

Regarding Human Health and Environment

- Increased information is resulting in changes in classification, with the majority becoming more stringent. The quality of the information available for risk assessment has already improved if compared with the pre-REACH situation.

- Increased information in the supply chain and improved safety data sheets is resulting in more appropriate risk management measures, thus contributing to the observed reduction in nominal risk, and has benefited end-users, such as article producers.

- Increased obligations on SVHC through the Candidate listing and Authorisation provisions have led to increased moves towards the substitution of those substances through the supply chain.

- Many registration dossiers have been found to be non-compliant, including with regard to substance identity, as reported by ECHA.

- Insufficient assessments by registrants of persistent, bioaccumulative and toxic (PBT) and very persistent, and very bioaccumulative (vPvB) properties, as reported by ECHA.

- Problems with regard to the content and format of the extended safety data sheet, as reported by industry.

Internal Market

- From 1999 to 2009 the EU chemical industry grew slightly higher than the average rate for all manufacturing sectors, and has largely recovered from the crisis of 2008. The industry generates a positive trade balance and is particularly well-performing in high margin sectors of specialty chemicals.

- In 2003, when REACH was proposed, the EU was the world's largest chemicals market with approximately 30 % of the global chemicals sales. Today it amounts to about 21 %, with China now being the largest chemicals market. However, the EU chemicals industry remains the world's largest exporter and its turnover has increased in absolute terms.

- The internal market is a key driver for growth and competitiveness for the chemicals industry and REACH has further harmonised it. The industry acknowledges the positive economic effects for their business even if some barriers remain.

- The cost of REACH registration has discouraged some companies from competing on certain substances' markets, which in these cases have increased market concentration and prices. A potential positive effect is that greater specialization amongst chemical suppliers and new

[20] http://ec.europa.eu/environment/chemicals/reach/review_2012_en.htm

business models (like chemical leasing) may increase safety. The need to restructure some supply chains opens opportunities which, due to financial and organizational constraints, SMEs are less likely to exploit unless properly supported.

- The registration has impacted also downstream users who are, in general, less aware of their role in REACH. Given that great majority of downstream users are SMEs, they should be a focus in improving the implementation of REACH.

- It is believed that a significant number of SMEs are unaware about their role and obligations related to REACH, and those who are aware, may have a false impression of the exact scope of their duties. The Commission's concern over the impact of REACH on SMEs is reinforced by the recent survey showing that REACH is considered by SMEs as one of the 10 most burdensome pieces of EU legislation.

Innovation

- REACH aims to enhance innovation. Communication in the supply chain provides chemical companies with new information about their customers and their needs. Many companies state a positive impact of that information on innovation. Information generated for the registrations provide inspiration for the innovative use of existing substances.

- REACH has had a positive impact on research into new substances, due to generally equal treatment of new and phase-in substances. The number of registrations of new substances has increased in line with the expectations before REACH was adopted.

- Another innovation incentive in REACH is the product and process orientated research and development (PPORD) exemption from registration. This has been welcomed by the industry in general, but only few SMEs have used PPORD so far.

- REACH fulfils its objective with regard to innovation even if, for example, a gap in R&D intensity in comparison to the US and Japan still exists and pressures from the emerging economies are increasing.

33. Some needs for adjustments have therefore been identified, but balanced against the interest of ensuring legislative stability and predictability, the Commission concluded that there is no need to propose any changes to the enacting terms of REACH. Within the current framework, however, there is a need to reduce the impact of REACH on SMEs. There are also many other opportunities for further improvement of the functioning of REACH by optimizing the implementation at all levels. Some key recommendations are:

- The report makes recommendations to improve REACH implementation. These include improving the quality of registration dossiers, encouraging companies to enhance the use of safety data sheets as a central risk management tool, and addressing issues related to the transparency of cost sharing within the Substance Information Exchange Forums (SIEFs).

- The report recommends reducing the financial and administrative burden on SMEs in order to ensure the proportionality of legislation and to assist them to fulfil all their REACH obligations. The Commission will look into greater fee reductions to SMEs.

- There are no major overlaps with other EU legislation.

- Considerable efforts to develop alternative methods to animal testing have been made and will continue: since 2007, the Commission has made available € 330 million to fund research in this area.

- Enforcement could be improved. As this is the responsibility of the Member States, the report recommends to Member States to reinforce coordination among them.

- Although the report identifies a need for some adjustments to the legislation, the Commission wants to ensure legislative stability and predictability for European businesses. No changes to REACH's main terms are proposed at present.

34. Since the review was published further information has been collected further supporting the difficulties SMEs have, both in understanding their role and their obligations under REACH. It is also noteworthy that turnover in EU chemical's industry continues to increase in absolute terms, however production (in volume) remains below the peak of 2007, and has actually decreased in 2012 and 2013.

APPENDIX 6 – JAPANESE SUBMISSION [MARCH, 2014]

Amendment of the Chemical Substances Control Law[21]

Purpose of the amendment

(1) At the time of the amendment, public interest in safety and security had increased, and so had public concern over chemical substances. At the global level, an agreement was reached at the World Summit on Sustainable Development to minimise adverse effects of chemicals on human health and the environment. Since then, the situation concerning control of chemical substances had changed substantially, as seen in Europe, where a new regulation on chemical substances entered into force in 2008.

(2) The Act on the Evaluation of Chemical Substances and Regulation of their Manufacture, etc. (hereinafter the "Chemical Substances Control Law") has imposed strict pre-marketing evaluation of chemical substances that were introduced on the market from 1973 onward (*i.e.* after the enactment of the Chemical Substances Control Law). On the other hand, the government, on its own, has been conducting risk assessment of chemical substances that had been on the market before the enactment of the Chemical Substances Control Law (hereinafter "existing chemical substances") and has taken regulatory measures under the Chemical Substances Control Law as needed. However, not all of the existing chemical substances have been assessed yet.

(3) Therefore, there was a need to steadily implement risk assessment and to further enhance strict control of chemical substances in Japan by obliging manufactures and importers of the existing chemical substances to notify the amount of chemicals they have handled in each fiscal year and by requiring them to submit toxicity information as needed. In addition, the government aims to allow related ministries to share increased amounts of information gathered under the amended Chemical Substances Control Law and enforce more effective regulations on chemical substances pursuant to relevant laws and ordinances.

(4) Another purpose of the amendment is to eliminate international inconsistencies and construct a rational evaluation and regulation system in Japan. Although additional substances are expected to be listed under the Stockholm Convention on Persistent Organic Pollutants, corresponding provisions concerning the uses permitted exceptionally under the convention are not provided for in the Chemical Substances Control Law, which domestically implements the convention.[22]

Summary of the amendment

(1) Introduction of a comprehensive control system that covers existing chemical substances

[21] This document summarises the basic concept and contents of the amendment of Chemical Substances Control Law (CSCL) of Japan in 2009, which included conceptual changes on the approach for assessing risk of existing chemicals. Detailed information of the law and background of its amendment is downloadable from: http://www.meti.go.jp/policy/chemical_management/english/cscl/about.html

[22] This part of the amendment aimed to incorporate some exemptions for using PFOS which was listed on the Annex B (Restriction) of the Stockholm Convention. Before the amendment, such exemptions for use did not structurally exist in the Chemical Substances Control Law.

(a) Companies that have manufactured or imported any chemical substance, including existing ones, equal to or in excess of the specified amounts (1 tonne) are newly obliged to notify quantity and other information (*e.g.* uses) for every fiscal year.

(b) Chemical substances which the government identifies, from the content of their notifications and available knowledge of their hazardous properties, as having higher priority in risk assessment shall be designated as Priority Assessment Chemical Substances (PACS).

(c) Manufacturers and importers of those PACS may be required to submit information on hazardous properties and companies handling them may be required to report their use.

(d) Among the PACS, substances which raise concerns about adverse effects on humans or the environment through information gathering and risk assessment shall be subject to regulations on manufacture and use as "Specified Chemical Substances," as in the existing law.

(e) In addition to "chemical substances which are persistent in the environment," which have been under control, "chemical substances which are not persistent in the environment" are regulated in the amended law.

(2) Appropriate control on chemical substances in the supply chain

To prevent environmental pollution by the Specified Chemical Substances and products containing them, the amended Chemical Substances Control Law requires companies handling them to adhere to specific handling standards and obliges them to label them as needed for transactions.

(3) Rationalisation of evaluation and regulation systems in light of international trends

The government eliminates international inconsistencies in its regulations, for example, by reviewing regulations on Class I Specified Chemical Substances in order to permit the exceptional use of substances listed under the Stockholm Convention under strict control.