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Report of the OECD Workshop on Sharing Information about New Industrial Chemicals Assessment

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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REPORT OF THE OECD WORKSHOP ON SHARING INFORMATION ABOUT NEW INDUSTRIAL CHEMICALS ASSESSMENT

Environment Directorate

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This Workshop report was produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC).

This publication is available electronically, at no charge.

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The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

Foreword

This document contains the report of the OECD Workshop on Sharing Information about New Industrial Chemicals Assessment. The Workshop, led by the governments of Australia and Germany, took place at OECD headquarters in Paris on 5-6 February 1996. Included in this report are the Workshop's Conclusions and Recommendations, as well as a summary of discussions, case studies, and perspectives on the sharing of information presented at the Workshop. Background material and the results of a survey of existing notification schemes for new industrial chemicals are also included.

Potential notifiers of new industrial chemicals under the various schemes described in this report are advised to contact the competent authority in the relevant country to discuss details of how to make a notification.

Derestriction of this document was recommended by the OECD's Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals. It is published on the responsibility of the Secretary-General of the OECD.

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Executive Summary

Objectives

New industrial chemicals notification and assessment schemes have been established in the majority of OECD Member countries, creating a variety of notification and assessment requirements and the potential for sharing assessment information. An OECD Workshop was held on 5-6 February 1996 to discuss ways of making it easier to share information about new industrial chemicals, given the differences that exist.

The Workshop confirmed that the objectives of sharing information were to:

- improve capacities for reducing risks to human health and the environment;
- optimise the use of resources for gathering information and assessing new industrial chemicals, both in government and in industry, by reducing any unnecessary duplication;
- avoid unnecessary animal testing;
- remove potential barriers to innovation consistent with needs for confidentiality;
- facilitate trade and sustainable economic growth;
- increase international co-operation between national authorities, especially at a regional level; and
- enable more harmonized approaches to the notification and assessment of new industrial chemicals to be developed.

Summary of the Workshop

Several major notification and assessment schemes for new industrial chemicals were identified by the Workshop, namely those of Australia, Canada, Japan, the United States and the European Union. Information on these schemes, obtained by means of a questionnaire, was discussed and augmented by presentations. These schemes are described in Annex 2 of this document, along with those of New Zealand and Switzerland.

The Workshop confirmed that while there were a number of important differences between the schemes, there was scope for further information sharing to help meet the objectives described above.

The Workshop noted a number of existing co-operative notification and assessment activities. In particular:

- co-operation between the Member States of the European Union and extension to the European Economic Area;
- the pilot Australian/German exchange programme;
- the well developed arrangements for co-operation between the United States and Canada (the so-called " Four Corners Program"); and
- the work of the OECD Pesticides Forum on developing ways to exchange assessment reports, including confidential information

.

Representatives of industry supported information sharing where industry wished to make notifications to multiple authorities or to share data with a second notifier. However, there were concerns about disclosure of confidential business information which could result in competitive disadvantage to the original notifier. Representatives of governments supported information sharing to reduce duplication of effort.

Government representatives and BIAC (the Business and Industry Advisory Committee to the OECD) expressed their willingness to explore ways to facilitate the use of existing publicly available information about new industrial chemicals to better effect.

The Workshop heard from a multi-national notifier who underlined the diversity between the schemes, resulting in the potential for duplication of effort. Examples were provided of emerging notification schemes in countries both inside and outside the OECD, which introduced an even greater diversity of notification and assessment requirements. Representatives of governments, industry and international organisations also considered ways of extending co-operation on request, in order to assist OECD and non-OECD countries in developing any new notification and assessment schemes in a compatible fashion. In particular, Mexico requested assistance from both industry and government in developing its own scheme.

Notification and assessment schemes differ in terms of the information available to the public. The issue of public access to information as a means of ensuring confidence in national and international for assessing new industrial chemicals was raised. However, some participants noted that there could be additional resource implications if reports were prepared.

Conclusions

1. Authorities involved in notification and assessment schemes need to have a good appreciation of the assessment methodologies, legislative requirements and procedures followed in other schemes before the full benefits of sharing information can be realised. A better understanding of the degree of overlaps in notification and assessment would also be useful.

2. Achievement of the objectives would be assisted by tackling the issues in a staged manner. An extension of the pilot projects would assist in a greater understanding of assessment procedures. Sharing information on the hazards could lead to acceptance of the conclusions of another authority's hazard assessment, particularly where harmonized hazard classification criteria are used. It was agreed that because risk assessments are subject to

local exposure scenarios and other factors, moves to accept risk assessments would be more difficult.

3. Industry stated that confidentiality was not a barrier to the exchange of information, provided that it remained in control of access to the information. Government still saw that there may be issues which need to be explored in this area, for example government to government exchanges. However, the confidentiality issues which had arisen from the pilot programmes were able to be managed and confidentiality provisions had not hindered the progress of these pilots (Germany/Australia and US/Canada).

4. Pilot schemes designed to encourage sharing of information between countries were considered useful approaches, to be continued with the participation of other parties.

5. A survey planned in the OECD Pesticide Programme on national CBI [Confidential Business Information] regulations and procedures for the release of pesticides data review reports to other countries and the public may also be useful for industrial chemicals. The possibility of a combined survey could be considered, keeping the difference between pesticides and industrial chemicals in mind.

Recommendations and Follow-up Work

1. New pilot projects should be encouraged, while existing pilots should be continued and expanded to facilitate exchange of information and progress should be reviewed at a subsequent OECD forum within two years.

2. Successful sharing of information should provide industry with opportunities to reduce testing costs, assessment fees, and time to market.

3. Notifiers should encourage the sharing of notification and assessment information by indicating to authorities a willingness to explore data sharing arrangements, such as that within the Canadian scheme and as already exists between EU Member States.

4. There should be continuing efforts to harmonize assessment methodologies so as to increase the usefulness of information that is exchanged, as part of the commitment to Chapter 19 of Agenda 21.

5. The Workshop papers should be published as an OECD General Distribution document, in order to share information about the key notification and assessment schemes.

6. Consideration should be given to including a section on CBI regulations which apply to industrial chemicals within the proposed survey for pesticides, in order to save resources in conducting the survey.

7. Given the emergence of new notification and assessment schemes in OECD and non-OECD countries, the extension of co-operation to countries developing new schemes should be further considered by governments, industry and international organisations (e.g. by encouraging the development of schemes compatible with existing ones).

The Conclusions and Recommendations of the Workshop were presented in February 1996 to the 24th Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals in Combined Session with the Pesticide Forum.

The Joint Meeting agreed to a number of follow-up actions to the Workshop, focusing initially on further development of material presented at the Workshop in order to provide guidance for the establishment of pilot projects and mechanisms to enable existing sources of information about new industrial chemicals to be used more effectively.

The Co-ordination Group on Sharing Information about New Industrial Chemicals was then organised in order to propose action and provide a focal point for work in this area. Regular progress reports will be provided to the Risk Assessment Advisory Board (RAAB) and, when necessary, to the Joint Meeting.

List of Acronyms

AICS	Australian Inventory of Chemical Substances
BIAC	Business and Industry Advisory Committee to the OECD
CA	Competent Authority
CAS	Chemical Abstracts Service
CBI	Confidential Business Information
CEC	Commercial Evaluation Category
CEPA	Canadian Environmental Protection Act
DSL	Domestic Substances List (Canada)
EC	European Communities, or European Commission
ECB	European Chemicals Bureau
EEA	European Economic Area
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ERMA	Environmental Risk Management Authority (New Zealand)
EU	European Union
FOEFL	Federal Office of Environment, Forests and Landscape (Switzerland)
HSNO	Hazardous Substances and New Organisms (Act) (New Zealand)
IUPAC	International Union of Pure and Applied Chemistry
LVC	Low Volume Category
LVE	Low Volume Exemption
LOREX	Low Release/Low Exposure Exemption
MHW	Ministry of Health and Welfare (Japan)
MITI	Ministry of International Trade and Industry (Japan)
ML	Ministry of Labour (Japan)
MSDS	Material Safety Data Sheet
NICNAS	National Industrial Chemical Notification and Assessment Scheme (Australia)
NDSL	Non-Domestic Substances List (Canada)
NOC	Notice of Commencement
PMN	Pre-Manufacture Notice
PLC	Polymers of Low Concern
SNIF	Summary Notification Interchange Format
SNUN	Significant New Use Notice
SNUR	Significant New Use Rule
TSCA	Toxic Substances Control Act (United States)
UNCED	United Nations Conference on Environment and Development
UVCB	Unknown or Variable Composition, Complex reaction products, Biological material

Introduction

Chapter 19 of UNCED's Agenda 21 describes the blueprint for action to ensure the environmentally sound management of chemicals. Sharing information about chemical assessments is of fundamental importance to Agenda 21, making possible strengthened national capabilities through better use of existing information.

The special characteristics of new industrial chemicals include: a strong emphasis on commercial confidentiality, their relation to the innovation programmes of particular companies, the limited public information on these chemicals, the short time frames for their assessment, and the large numbers being introduced into commerce. These characteristics are recognised in the legislative frameworks of the assessment schemes of individual countries. Therefore, they are also relevant to the ways in which information on new industrial chemicals notification and assessments can be shared between countries.

Sharing information about chemical assessments is vital for the environmentally sound management of chemicals. Consistent with its work on the harmonization of test data requirements and testing guidelines, the OECD Environmental Health and Safety Programme continues to provide an important forum in which Member countries can share experiences with the notification and assessment of new industrial chemicals and identify mechanisms for sharing, and maximising the use of, the assessment information generated. Better use of existing information is expected to reduce the possibility of duplicative assessment work and animal testing, increase the potential for harmonized assessment methodologies and policies, and help overcome any barriers to innovation and trade.

Sharing information about new industrial chemicals notification and assessments from other countries requires a good understanding of the similarities and differences of schemes operating in those countries, and of the information obtained during the assessment process.

In June 1995, the 23rd Joint Meeting of the OECD's Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals agreed to an Australian proposal to hold a Workshop to explore these areas.

Objectives

The objectives of the Workshop were to:

- discuss, and raise awareness of, existing information about new industrial chemicals notification and assessments;
- identify and explore ways of removing any barriers to the use of existing information for purposes of reducing duplicative assessment work;
- identify what mechanisms are needed to facilitate exchange of information on notification and on hazard and risk assessment of new industrial chemicals; and
- formulate strategies to encourage the sharing of information.

Overview of the Workshop

The Workshop was attended by about 50 participants from governments, industry and international organisations (see the list of participants in **Annex 1**). **Mr Warwick Pearse** (Australia) and **Dr Reiner Arndt** (Germany) co-chaired the Workshop and **Ms Lesley Onyon** (Australia) and **Mr Bob Woodward** (UK) were the rapporteurs.

Mr Rob Visser, Head of the OECD Environmental Health and Safety Division opened the Workshop.

Mr Visser explained that it was timely for the OECD to look at the possibilities for sharing information about new industrial chemical notification and assessments, in order to build on work completed over the last 15 to 20 years on harmonizing testing guidelines and assessment methodologies. The number of new industrial chemicals assessed each year is substantial and possibly increasing. The number of countries carrying out pre-manufacture or pre-marketing assessments on new chemicals is higher than before and is expected to increase in future. There is the likelihood of duplication of assessments because many chemicals are being notified in more than one country.

Dr Arndt, Chairman of the first half of the Workshop, outlined the Workshop's objectives and noted that duplication of assessments can be harmful to governments by using scarce resources unnecessarily, and to industry by increasing the costs of introducing new chemicals. Sharing information about assessments can reduce such duplication without affecting the sovereignty of individual governments to make decisions regarding the protection of their people and the environment.

He pointed to the consideration or introduction of cost recovery mechanisms by a number of governments for assessment work, and the emergence of notification and assessment schemes in newly industrialised countries or countries with growing economies, as providing new and important pressures for sharing information and harmonizing requirements as far as possible.

Summary of Presentations and Discussion

Main Features of Existing Schemes

Annex 2 provides a summary of the key features of selected notification schemes. Representatives of Australia, Canada, Japan, the United States and the EU presented summaries of their schemes at the Workshop and highlighted important issues in relation to information sharing. Also described in this annex are the schemes of New Zealand and Switzerland, as provided by those countries.

Mr Warwick Pearse (Australia) introduced the Australian scheme, which began operations in 1990 to assess the risks to occupational health and safety, the environment and public health due to both new and existing industrial chemicals. The Australian scheme operates on a cost recovery basis, with application fees being charged to industry. Its information requirements are compatible with those of similar schemes in other countries, and there are legislative arrangements for accepting less data for low-risk chemicals and for using assessment reports from other countries. The publication of assessment reports provided a good vehicle for sharing information with other authorities.

The Canadian scheme for new industrial chemicals, introduced by **Mr John Buccini** (Environment Canada), has been in operation since July 1994. Hazards for both public health and the environment are evaluated. The Canadian scheme made significant use of information developed for regulatory purposes outside Canada, and opportunities for information sharing were being actively considered. The relevant Canadian legislation has provisions for sharing information between foreign governments.

The European Union scheme, built on developments in several European countries in the 1970s, provided an example of 15 countries already sharing information about new industrial chemical assessments, with other countries soon to join. **Mr Andrew Fasey** (DG XI of the European Commission) explained that the structured and detailed format for undertaking an assessment of the hazard, and hence assignment of a standard hazard label, followed by a risk assessment incorporating exposure data, facilitated information sharing between EU competent authorities. Some EU competent authorities had moved to implement cost recovery for some of the assessment work. Two main inventories or lists of "existing" and of notified/assessed substances (EINECS and ELINCS, respectively), along with an ELINCS-derived list of dangerous substances (Annex I), provided a way of finding out the status of a particular chemical in the EU. Four hundred notifications are made per year in the EU. Confidentiality, language and resources can be identified as three of the key issues that would need to be considered carefully in any international efforts to share information.

The two Japanese schemes were introduced by **Mr Kazuhiro Kenmotsu** (Ministry of Health and Welfare) and **Ms Kazuyo Ofuchi** (Ministry of Labour).

The Chemical Substances Control Law was established in 1973 with the main purpose of examining new chemical substances with persistence, bioaccumulation and toxicity for the environment with a view to either prohibiting manufacture and import (Class 1) or setting conditions of use (Class 2). It is estimated that 70-80 per cent of the substances examined were locally manufactured.

The Industrial Safety and Health Law, which came into effect in 1979, was established mainly to prevent occupational cancer and so principally dealt with mutagenicity and carcinogenicity screening information. Over 80 per cent of tested compounds were manufactured in Japan. The name of the chemical and mutagenicity results were not confidential.

The United States scheme was introduced by **Mr Charles Auer** (US EPA). The Toxic Substances Control Act has been in effect since 1979. Fees are payable for pre-manufacturing notifications. A large number of notifications (over 2500) are made each year, and approximately half enter commerce. Approximately 30 per cent of notifications originated outside the US. Confidential business information created high costs for the administration of the US scheme and limited the amount of information which could be shared. Also, because the US relies on a risk management approach to assessment, the level of information required by authorities in other countries might impose additional costs on the US administration.

Information on hazard assessment could have the greatest potential for sharing, compared with exposure assessment, which may or may not be useful depending on the proposed use in another country. The agreement between the US EPA and Environment Canada/Health Canada for sharing information will be effective soon, an example of the commitment and interest to share information on new industrial chemical assessments (see later in this section and **Annex 3**).

Discussions on the presented schemes emphasised that, in order to identify opportunities for greater sharing of information about new industrial chemicals notifications and assessments, a good understanding of the similarities and differences of schemes operating in other countries and the information arising from the assessment process is needed.

Survey to Identify Possibilities for Sharing Information on New Industrial Chemicals

In preparation for the Workshop, a questionnaire survey was undertaken to identify possibilities for sharing information about new industrial chemicals notification and assessment.

Replies to the questionnaire were received from a majority of EU countries (Austria, Belgium, Denmark, Germany, Ireland, the Netherlands, Spain, Sweden, the UK); from Norway, which is preparing to adopt the EU system; and from Australia, Canada, Japan, New Zealand, Switzerland and the United States.

The European Commission played a co-ordinating role for the EU Member States, and a consolidated EU response has been presented for ease of comparison. However, it should be noted that individual EU countries have some special characteristics additional to the features of the EU scheme.

An overview of the responses to the questionnaire is given in **Annex 4**, with detailed summary tables in **Annex 5**. **Ms Lesley Onyon** (Australia) introduced the findings.

The questionnaire (**Annex 6**) was designed to help with the planning and conduct of the Workshop by identifying existing sources and types of information on new chemical notifications and assessments and finding out about current and potential mechanisms for sharing information between countries, including existing co-operative work.

The questionnaire requested information about the scope of each scheme's assessments of new chemicals: for example, risks for occupational health, public health and the environment, and whether these assessments were conducted prior to manufacture or prior to marketing. Basic differences in scope may have an important bearing on the availability of information for sharing. For example, in the United States' pre-manufacturing scheme, approximately 50 per cent of notified chemicals are never placed on the market. Including such notification in an information exchange mechanism could be burdensome, with little cost benefit.

The questionnaire did not explore the extent or detail of each country's legislation for industrial chemicals, which can vary in the definition of industrial use, the volume cut-off, data requirements for different categories, and the definitions which trigger notifications of special categories such as polymers. While such detailed information is vital for the development of harmonized assessments and for the use of other countries' assessments, emphasis was given to identifying the types of information that could be shared.

Similarly, the questionnaire did not directly address the systems and procedures that individual countries use to keep track of their notification and assessment data. These mechanisms, especially those for keeping track of multiple notifications, could provide useful models for a wider scheme of sharing information about chemicals assessed in different countries. For example, in the EU mechanisms have been established to encourage data sharing between notifiers.

Learning successful sharing of full assessment information from these existing mechanisms would probably need to involve both government and the original notifier in authorising information transfer.

Types of Information Available for Sharing

The survey revealed that the types of information available vary from country to country. Most countries appear to have arrangements for prospective notifiers to find out if a chemical has been notified previously. However, tools to enable cross-referencing between schemes do not appear to be well developed.

In order to examine the types of information that might be available, a stepwise approach was taken in the questionnaire to find out how much information was available at each stage of the assessment process and to whom it was available. The categories of information considered most important were the initial fact of notification and assessment, and the outcomes of the assessment.

While assessment reports are not routinely published, every scheme has some way of documenting its assessment process. Countries have formalised this to a greater or lesser extent and make different levels of information available to different groups. Various types of information are publicly available, ranging from notices of regulatory action to inclusion on an Inventory to denote that an assessment has been made. In the EU, information on the chemical's hazard classification is included in a list of notified chemical substances (ELINCS).

National Inventories are common forms of information associated with a country's notification and assessment scheme. They have the potential to be made more useful from the point of view of sharing information.

Possible barriers to sharing include confidentiality provisions (especially where these mask the identity of chemicals), differences between schemes in notification requirements and outcomes, and differences in the way chemicals are identified, particularly the way complex chemicals are named.

Confidentiality

In the 1980s the OECD undertook a significant amount of work on confidentiality, as this was seen as the factor most often limiting the exchange of information between countries. Two OECD Council Recommendations set out a number of principles to govern the exchange of confidential data and information on chemicals between countries, and a list of Non-confidential Data on Chemicals was established (**Annex 7**).

Notwithstanding this work, responses to the questionnaire mentioned confidentiality time and again as a key barrier to greater sharing of new chemicals assessment information. (This may partly be due to the mistaken idea that "data sharing" routinely requires the exchange of actual test data.)

While the commercial value of information about new industrial chemicals (and the need to restrict access and use by competing commercial interests) are obvious, the precise barriers to enabling greater sharing of information need further investigation.

Identification of the notified chemical appears to have a central role in preserving commercial confidentiality in most countries. A number of mechanisms appear to have been developed which may further act to diminish the information available to be shared.

Case Studies and Perspectives on Sharing Information

An Industry Perspective

Mr Dave Vosvenieks (Zeneca Pharmaceuticals, UK) outlined the stages involved in notifying a "new" chemical on an international basis. The regulatory requirements and Inventory status were identified at an early stage to enable appropriate test data to be generated. The differences between existing schemes, such as test data requirements and study protocols, were highlighted. Some schemes enabled waivers of some requirements, while others did not. The need for considerable knowledge, and interpretation, of regulatory requirements in order to ensure compliance and the entry of the chemical into the market was emphasised.

For many companies, research and development activities would focus on developing new product opportunities and technology on the basis of traditional chemistry and, where possible, by exploiting "existing" rather than "new" chemicals. In this regard, industry was concerned that Inventories should be as harmonized as possible.

Generally, industry worked to get a mutually acceptable test data package for all the countries where it wished to market. However, it still had to create a different package for each regulatory authority, highlighting the considerable potential for harmonization of requirements in future. With new schemes being developed, and suggestions that schemes be harmonized, industry had concerns about the possibility of an unworkable hybrid being established which would capture the most severe of all the data requirements.

A number of situations in which information was already being shared and exchanged were noted, such as to support research and development programmes, to aid commercial agreements between supplier and user, and to meet product stewardship obligations. Information is generally provided on a *"need to know – need to have"* basis and is usually subject to secrecy agreements between interested parties to protect commercial interest, especially the investment in research and development, and to avoid "know-how" being made available to competitors. Information getting into the hands of a competitor could give valuable clues to the marketing process and make a difference to the ultimate success of being first to market the new chemical.

Industry's main goal was first to get harmonization of assessment requirements around the world, in order to enable acceptance of any given notification dossier. It was strongly suggested that the control mechanism for sharing assessment information should reside firmly with the notifier to protect commercially confidential information. Sharing of hazard information should be given a higher priority than the sharing of risk assessment information, which could be considered a longer term goal.

Ms Karon Armstrong (3M Toxicology Services International) provided an overview of emerging schemes for new industrial chemicals, principally in the Asia-Pacific Region, and pointed to the enormous diversity in requirements.

The OECD Pesticide Forum and Exchange of Data Reviews

Mr Teruyoshi Hayamizu (OECD Secretariat) introduced the work of the OECD Pesticide Forum on the sharing of pesticide assessments. This work was initiated as a step towards the mutual use and acceptance of pesticide assessments between countries in order to ease the burden of re-registration. A pilot study to compare pesticide data reviews was carried out (see Environment Monograph No. 108, *Final Report of the OECD Pilot Project to Compare Pesticide Data Reviews*, OECD, Paris, 1995) and an ad hoc system for exchanging review reports established.

The pilot study investigated several key aspects, such as structure, content, degree of transparency, the original data sets reviewed, hazard levels, and final hazard characterisation of the pesticide. The main outcome of this study was that mutual use of pesticide data review reports among countries, and co-operation in re-registration, could begin straight away in spite of the existence of some differences.

Other recommendations which are emerging call for:

(1) harmonization of the way industry submits its data to governments, and of the structure and content of governments' data review reports;

(2) countries' beginning, if they wish, to exchange data review reports; and

(3) the establishment of a data base of countries' pesticides review schedules and lists of the review reports they have available.

Problems concerning confidentiality and proprietary rights were not heard about during the pilot project, but they might need to be addressed or clarified so that the exchange of pesticide data reports could proceed smoothly. A survey was therefore proposed concerning national CBI regulations and procedures for the release of pesticide data review reports to other countries and the public.

Since the completion of the pilot project in October 1994, 128 pesticide data review reports (or similar documents) are known to have been exchanged between countries and a further 122 have been requested. A number of practical solutions were being considered by the Pesticide Forum to facilitate information sharing while protecting CBI.

Sharing of New Chemicals Information in the EU

Mr Gerald Vollmer (European Chemicals Bureau) introduced the EU system as one which demonstrated the possibilities for greater information sharing on new industrial chemicals. Anchored within a larger system of harmonization, the countries involved have had to develop comprehensive systems to maintain good communication and consistency. Procedures for undertaking an assessment of the hazard, assignment of a standard hazard label, followed by a risk assessment incorporating exposure data, had been developed, which facilitated information sharing.

A new chemical notified and placed on the EU market by an EU manufacturer or EU-based importer does not need to be notified in all Member States. Risk assessments are made available to the competent authorities of all EU Member States and summaries of notification data are also shared.

Article 15 of Council Directive 92/32/EEC provides for notifiers to share data about new industrial chemicals to avoid renotification of the same substance and to avoid duplicating testing on vertebrate animals. Essentially, the legislative arrangements ensure that prospective notifiers ask the relevant competent authority in the Member State within which they intend to notify whether or not the substance has already been notified and the name and address of the first notifier. The first notifier and the prospective notifier are then required to take all reasonable steps to reach an agreement on the sharing of information.

Modern information tools for making notifications, such as the electronic Summary Notification Interchange Format (SNIF), facilitate transfer to and from competent authorities and better information management

The US-Canada Four Corners Agreement

Mr John Buccini (Environment Canada) outlined the significant development of an agreement between US EPA and the Canadian government on the international sharing of information on new chemicals. This agreement, commonly known as the "Four Corners Agreement" because it was negotiated among officials from the US and Canadian governments and representatives from US and Canadian industry groups, will establish a two-year pilot aimed at reducing the time it takes for US-approved new industrial chemicals to enter the Canadian market.

Any chemical not listed on the Domestic Substances List is considered new to Canada. Environment Canada also recognises certain chemicals in international commerce. Assessment of these chemicals is subject to a reduced set of assessment requirements. Chemicals are included on the Non-Domestic Substances List (the NDSL) once a year, but with a five-year waiting period to allow the accumulation of information based on use.

Canadian and US chemical industries had expressed their belief that the five-year waiting period is too restrictive and wished to explore ways by which chemicals added to the TSCA Inventory (which have been notified and assessed in the US) could be placed on the Canadian NDSL in less than five years, including use of information used by the US EPA's New Chemicals Program.

The pilot project has been designed to encourage voluntary sharing of information while protecting confidentiality. The proposed administrative procedures (see **Annex 3**) include:

- The Canadian notifier (an agent for the US PMN filer) makes an application for addition of a TSCA substance to the NDSL, providing relevant information to the EPA's prior assessment.

- Environment Canada acknowledges the request and copies US EPA and the US notifier.

- The Canadian notifier requests the US notifier to authorise the US EPA to send Environment Canada the US EPA Review Notes and waiver CBI.

- The US notifier complies with this request.

- US EPA sends Review Notes to Environment Canada.

- Environment Canada/Health Canada decide to add the chemical to the NDSL, or identify elements for which testing is required, and inform the Canadian notifier and US EPA of this decision.

- Environment Canada sends US EPA the Environment Canada/Health Canada assessment and any subsequent health and safety data generated.

The "Four Corners " agreement is informal and would be evaluated after one year. If the process works, the medium-term goal would be an intergovernmental exchange on a more formal basis.

The Australian-German Pilot Exchange Programme

Mr Joe Rundle (Hoechst Australia Ltd) outlined an Australian-German pilot project which was initiated to explore arrangements and the circumstances which would provide for the acceptance of overseas assessments under Australian legislation, with the objective of reducing the time to undertake the assessment and, ultimately, assessment fees. This was seen as particularly important given Australia's position as a predominant importer of non-commodity chemicals which have been researched, developed, manufactured and marketed in major chemical markets such as Japan, the United States and the EU.

Hoechst AG and Hoechst Australia, together with competent authorities in Australia and Germany, established the arrangements for the pilot, which included:

- Hoechst AG to provide Hoechst Australia the European risk assessment for the chemical, made available to the German company on request under German legislation;

- Hoechst Australia to notify the chemical to NICNAS in Australia, providing the European risk assessment and supporting data package;

- Australian NICNAS authority to conduct risk assessment, based on the European risk assessment, supplemented by additional information form German authorities as necessary;

- Australian NICNAS to inform German authorities regarding the outcome of the risk assessment.

The pilot is still continuing and would benefit from wider participation of other companies. Several positive aspects have already been observed. There are general similarities in format/content between the EU and Australian assessment reports, including hazard identification, exposure assessment, and characterisation of risks to humans (workers and the public) and to the environment.

Summary of Discussion

Mr Warwick Pearse (Worksafe Australia) chaired the latter part of the Workshop. Participants discussed barriers to greater information sharing and mechanisms for enabling greater sharing of information in future.

The Workshop confirmed that the objectives of sharing information were to:

- improve capacities for reducing risks to human health and the environment;

- optimise the use of resources for gathering information and assessing new industrial chemicals, both in government and in industry, by reducing any unnecessary duplication;

- avoid unnecessary animal testing;

- remove potential barriers to innovation, consistent with needs for confidentiality;

- facilitate trade and sustainable economic growth;

- increase international co-operation between national authorities, especially at a regional level; and

- enable more harmonized approaches to the notification and assessment of new industrial chemicals to be developed.

The Workshop also confirmed that while there were a number of important differences between the schemes, much information was already being shared. However, there was scope for further information to be shared to help meet the above objectives. Further work would be necessary to determine the degree of overlaps in notification and assessment between the different schemes.

Representatives of industry supported the sharing of information where industry wished to make notifications to multiple authorities or to share data with a second notifier. However, there were concerns about disclosure of confidential business information which could result in competitive disadvantage to the original notifier. Representatives of governments supported the sharing of information to reduce duplication of effort.

Government representatives and BIAC (the Business and Industry Advisory Committee to the OECD) expressed their willingness to explore ways to facilitate the use of existing publicly available information about new industrial chemicals to better effect.

The Workshop heard from a multi-national notifier who underlined the diversity between the schemes, resulting in the potential for duplication of effort. Examples were provided of emerging notification schemes in countries both inside and outside the OECD, which introduced even greater diversity in notification and assessment requirements. Representatives of governments, industry and international organisations also considered ways of extending co-operation on request, to assist OECD and non-OECD countries in developing any new notification and assessment schemes in a compatible fashion. In particular, Mexico requested assistance from both industry and government in developing its own scheme.

Notification and assessment schemes differ in terms of the information available to the public. The issue of public access to information as a means of ensuring confidence in national and international for assessing new industrial chemicals was raised. However, some participants noted that there could be additional resource implications if reports were prepared.

Conclusions[1]

Participants agreed to the following conclusions:

1. Authorities involved in notification and assessment schemes need to have a good appreciation of the assessment methodologies, legislative requirements and procedures followed in other schemes before the full benefits of sharing information can be realised. A better understanding of the degree of overlaps in notification and assessment would also be useful.

2. Achievement of the objectives would be assisted by tackling the issues in a staged manner. An extension of the pilot projects would assist in a greater understanding of assessment procedures. Sharing information on the hazards could lead to acceptance of the conclusions of another authority's hazard assessment, particularly where harmonized hazard classification criteria are used. It was agreed that because risk assessments are subject to local exposure scenarios and other factors, moves to accept risk assessments would be more difficult.

[1] These Conclusions are the same as those in the Executive Summary of this document.

3. Industry stated that confidentiality was not a barrier to the exchange of information, provided that it remained in control of access to the information. Government still saw that there may be issues which need to be explored in this area, for example government to government exchanges. However, the confidentiality issues which had arisen from the pilot programmes were able to be managed and confidentiality provisions had not hindered the progress of these pilots (Germany/Australia and US/Canada).

4. Pilot schemes designed to encourage sharing of information between countries were considered useful approaches, to be continued with the participation of other parties.

5. A survey planned in the OECD Pesticide Programme on national CBI [Confidential Business Information] regulations and procedures for the release of pesticides data review reports to other countries and the public may also be useful for industrial chemicals. The possibility of a combined survey could be considered, keeping the difference between pesticides and industrial chemicals in mind.

Recommendations and Follow-up Work[2]

Participants also agreed to the following recommendations on the future work related to the promotion of information exchange on new industrial chemicals assessment:

1. New pilot projects should be encouraged, while existing pilots should be continued and expanded to facilitate exchange of information and progress should be reviewed at a subsequent OECD forum within two years.

2. Successful sharing of information should provide industry with opportunities to reduce testing costs, assessment fees, and time to market.

3. Notifiers should encourage the sharing of notification and assessment information by indicating to authorities a willingness to explore data sharing arrangements, such as that within the Canadian scheme and as already exists between EU Member States.

4. There should be continuing efforts to harmonize assessment methodologies so as to increase the usefulness of information that is exchanged, as part of the commitment to Chapter 19 of Agenda 21.

5. The Workshop papers should be published as an OECD General Distribution document, in order to share information about the key notification and assessment schemes.

6. Consideration should be given to including a section on CBI regulations which apply to industrial chemicals within the proposed survey for pesticides, in order to save resources in conducting the survey.

7. Given the emergence of new notification and assessment schemes in OECD and non-OECD countries, the extension of co-operation to countries developing new schemes should be further considered by governments, industry and international organisations (e.g. by encouraging the development of schemes compatible with existing ones).

[2] The Recommendations and Follow-up Work are also the same as those in the Executive Summary.

The Conclusions and Recommendations of the Workshop were presented in February 1996 to the 24th Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals in Combined Session with the Pesticides Forum.

The Joint Meeting agreed to a number of follow-up actions to the Workshop, focusing initially on further development of material presented at the Workshop in order to provide guidance for the establishment of pilot projects and mechanisms to enable existing sources of information about new industrial chemicals to be used more effectively.

The Co-ordination Group on Sharing Information about New Industrial Chemicals (see **Annex 8**) was then organised in order to propose action and provide a focal point for work in this area. Regular progress reports will be provided to the Risk Assessment Advisory Board (RAAB) and, when necessary, to the Joint Meeting.

Acknowledgments

The OECD gratefully acknowledges the assistance of Australia in the preparation of Workshop materials, in particular the work done by Ms Lesley Onyon, Ms Rosemary Sager and Ms Suzanne Burling. Also acknowledged is the leadership of the co-chairs of the workshop, Dr Reiner Arndt (Germany) and Mr Warwick Pearse (Australia).

ANNEX 1

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ANNEX 2

SUMMARIES OF SELECTED NOTIFICATION SCHEMES

AUSTRALIA
CANADA
JAPAN (MHW/MITI)
JAPAN (ML)
NEW ZEALAND (NEW SCHEME)
SWITZERLAND
UNITED STATES
EUROPEAN UNION

NOTE: The descriptions in this annex are summaries, and appropriate legislation overrides anything in them. Potential notifiers of new industrial chemicals under the various schemes described in this annex are advised to contact the competent authority in the relevant country to discuss details of how to make a notification.

SUMMARY OF AUSTRALIAN NEW CHEMICAL NOTIFICATION SCHEME

NAME OF LEGISLATION: Industrial Chemicals (Notification and Assessment) Act 1989, as amended.

Industrial Chemicals (Notification and Assessment) Regulations and Amendments

MAIN POINT OF CONTACT: Mr Warwick PEARSE
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1. BACKGROUND TO SCHEME

The Industrial Chemicals (Notification and Assessment) Act 1989 is Commonwealth legislation which came into force on 17 July 1990, and the operation of its scheme is the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). It covers the introduction into Australia, by import or manufacture, of new industrial chemicals. The Act also covers the assessment of selected existing industrial chemicals and has provision for participation in international chemical control schemes such as Prior Informed Consent.

Several categories of chemical exist for the purposes of assessment; some of these were created after the scheme commenced, in response to the needs of industry. The first new chemicals were assessed in 1991, and up until June 1995 there had been a total of 432 assessments: 69 standard and 147 limited notifications, 161 in the commercial evaluation category (CEC), 43 in the low volume category (LVC), and 12 polymers of low concern (PLC).

2. DATA REQUIREMENTS

The Australian scheme has varying data requirements for different classes of notifiable industrial chemicals. In general more data is required if the quantity is greater, the chemical is not site-limited, and the class of the chemical is more likely to be hazardous. The exact requirements for data can be varied depending on availability and the characteristics of the chemical.

No notification is needed for chemicals covered by other schemes (agricultural and veterinary chemicals, food additives, therapeutic agents), those which are imported only as

articles, radioactive chemicals, and mixtures which are not UVCB substances. All of the above are outside the scope of the scheme. Within the scope of the scheme but also exempt from notification are reaction intermediates, incidentally produced chemicals, naturally occurring chemicals obtained by limited extraction procedures, existing synthetic polymers with only changes in the monomer ratio or containing <2% of new monomers or reactants, and chemicals for research, development and analytical use at a rate of no more than 50kg per year.

A full package of data, similar to the pre-marketing data set of the OECD, is required for a standard notification, and this includes information on toxicity, ecotoxicity and biodegradability/bioaccumulation.

The least amount of data is required for notifications which include the categories of commercial evaluation, low volume chemicals, and synthetic polymers of low concern. All of these, however, require basic identification, use, volume and exposure data, a summary of the effects on public health, occupational health and safety, and the environment, and the provision of material safety data sheets and labels.

The legislation has provision for approval of overseas schemes which meet Australian requirements and have reports available on notified chemicals. No overseas scheme has yet been accredited.

Concessions on data requirements can also be made at the Director's discretion if a chemical is listed on a recognised Foreign Inventory.

3. SCOPE OF ASSESSMENTS

All data submitted is reviewed in order to assess the chemical's likely effect on the areas of concern: public health, occupational health and the environment. Three government agencies co-operate in carrying out this assessment, with the overall assessment being made by the Director.

4. HAZARD AND RISK ASSESSMENT

Since the first chemicals were assessed in 1991, hazard and risk have been estimated qualitatively. Now all chemicals are classified according to approved criteria for classifying hazardous substances, in a system similar to that of the EU.

5. ACTIONS RESULTING FROM NOTIFICATION AND ASSESSMENT

All assessments (other than those for categories such as commercial evaluation, which are handled via a permit system) result in a published report covering all areas of the assessment. Some areas, e.g. identification data or details of the use, can be exempted from publication on the request of the notifier. The report includes recommendations on the conditions under which the chemical should be used.

The chemical cannot be introduced into Australia until it has been assessed and a certificate issued. There is a statutory period of 90 days allowed for assessment, which may be extended if extra information is required.

The Chemicals Gazette, published monthly, is the official communications channel of NICNAS. As well as summary reports on assessed chemicals, it has listings of chemicals introduced by permit, information on the Australian Inventory of Chemical Substances (AICS), notices about existing chemicals, and general information about the scheme and related matters.

6. FURTHER TESTING

A secondary notification is required if any one of a number of circumstances change after the initial assessment. These include a significant new use or change of use which is likely to increase the risk to health or the environment, a significant increase in production, and new information on the hazardous properties of the chemical. Special conditions for secondary notification can also be set at the time of assessment.

7. INVENTORIES

A chemical is added to the Australian Inventory of Chemical Substance (AICS) five years after assessment. This inventory also carries existing chemicals which have not been assessed and which are eligible to be on the Inventory because they were in use in Australia between 1977 and 1990.

Both new and existing chemicals can, on request, be placed on the confidential section of AICS, which is not published. Continuation on the confidential section is not automatic, and for assessed chemicals it can occur for a maximum of 11 years after assessment, after which they must be transferred to the main section of AICS.

8. CONFIDENTIALITY OF DATA

As already mentioned, notifiers can apply to have identifying or other information excluded from the public report of the assessment, and the Director can allow this if it would be desirable to protect commercial interests and the public interest is not harmed. Certain types of information, based on the OECD's list of non-confidential information, cannot be withheld from publication.

Where a chemical is listed on the confidential section of AICS, information on its listing can be obtained by bona fide enquiry by those wishing to introduce the chemical themselves.

9. INFORMATION SOURCES

There are several public sources of information on NICNAS:

- "The Australian Inventory of Chemical Substances" (AICS), Volumes 1 and 2, 1992

- "Chemical Gazette," Commonwealth of Australia Gazette, published monthly.

- Annual Reports, "The Operation of the Industrial Chemicals (Notification and Assessment) Act 1989". Latest edition is 1994-5.

- "Handbook for Notifiers," National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Contains AICS on microfiche and the legislation, as well as detailed guidance.

SUMMARY OF CANADIAN NEW SUBSTANCE NOTIFICATION SCHEME

CHEMICALS AND POLYMERS

NAME OF LEGISLATION: Canadian Environmental Protection Act
New Substance Notification Regulations
Part II: Chemicals and Polymers

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1. BACKGROUND TO SCHEME

The Canadian Environmental Protection Act (CEPA) is the primary legislative instrument in Canada for Environmental Protection. Part II of the Act concerns the introduction, by import or manufacture, of new substances into Canada through a requirement for a pre-import or pre-manufacture notification and assessment. The legislation came into force in July 1994.

2. DATA REQUIREMENTS

There are several categories of notification depending on the projected risk (exposure), with tiered information requirements according to the category: Transitionals, Research and Development, Product Development, Export only, and Site limited reaction intermediates. The tiered information requirements are based on (1) the volume of the chemical or polymer, (2) the condition under which it will be used, e.g. site limited intermediate, or (3) presence on the Non Domestic Substance List. Polymers also have reduced reporting requirements when they meet the criteria for low concern polymers. Transitional substances are those that were imported or manufactured in the interval between the development of a domestic inventory, the Domestic Substance List (DSL), and the coming into force date.

Substances on the DSL and naturally occurring substances that have not been processed are not notifiable. Materials in wastes, impurities in chemicals, or incidental reaction products resulting from use are not notifiable. Other substances that are not subject to the

CEPA notification are substances that are part of a finished article, provided that the ingredients cannot be separated by normal physical means. Constituents that could be separated such as volatile solvents, aerosols or chemicals in mixtures are notifiable.

Substances intended for uses regulated by other federal Acts which provide for an assessment of toxic, as defined by CEPA, are exempt from the CEPA notification requirements for those uses.

The technical data fall into four categories: identification of the chemical, human health data, physical chemical properties, and environmental toxicity data. The data can be supplied in three forms: test data, surrogate data, or requests for waiver of information requirements. Surrogate data is non-test, and may be either calculated or “read across” data.

The information required varies with the potential risk, increasing according to the quantity of substance involved, or based on the potential for release into the environment. The full data package, similar to the pre-marketing data set of the OECD, is required for substances that do not qualify for the reduced requirements.

Where the information requested is either not relevant to the assessment of toxic, or it is not technically feasible to perform the test, or information is provided that the chemical/polymer will be used in a manner that will satisfactorily protect the environment and human health, the notifier can apply for a waiver. The notifier must provide information to substantiate the claim for a waiver. Waivers require Ministerial approval and must be published in the Canada Gazette. The application for a waiver must accompany the notification and is evaluated first. If the waiver request is rejected, the notifier is informed, and the evaluation will not start until the information is supplied.

3. SCOPE OF ASSESSMENTS

The general requirements of the regulations are:

- provision of sufficient information for an environmental and health evaluation;

- pre-manufacture/pre-import notification and submission of data;

- the notifier is responsible for the provision of the data.

The areas of concern are public health and the environment. Both Health Canada and Environment Canada assess the substance. The final action is taken by the Minister of the Environment.

Since July 1, 1994, 430 New Substances Notifications were accepted, 230 preliminary data packages for chemicals, 50 complete packages for chemicals and 180 for polymers. Of these four substance evaluations resulted in a conclusion of suspicion of toxic under CEPA. For the period 1987-1994 notification packages for 5000 transitional substances have been received, approximately 50% chemicals and 50% polymers.

4. HAZARD AND RISK ASSESSMENT

All substances are evaluated and a qualitative estimate of hazard is made. Chemicals are not classified according to a classification scheme for hazard.

5. ACTIONS RESULTING FROM NOTIFICATION AND ASSESSMENT

The assessment can have one of three results:

- Substance is toxic, or a suspicion of toxicity:
    - prohibit import or manufacture
    - impose conditions on import or manufacture

- Suspicion of toxicity:
    - request additional information

- No suspicion of toxicity:
    - addition to the DSL when the quantity exceeds trigger.

Prohibition of import or manufacture is effected through an order in Council ordering a prohibition for two years, during which time a regulation must be developed for control of the chemical. After two years the prohibition order lapses. If the assessment results in a conclusion of “toxic”, or a suspicion of toxic and no additional information is requested, then control measures may be instituted. These are referred to as conditions in the Act (Section 29). Additional data may be requested of the notifier to confirm or reject a suspicion of toxicity. If the finding is not suspicion of toxic, and no other conditions have been applied, then the chemical is eligible for listing on the DSL.

The basis of a CEPA assessment is the definition of toxic found in the Act. “CEPA toxic” is defined as follows: does or may pose an unacceptable risk to human health or the environment, and conditions must be imposed on the entry or exposure. It is noteworthy that under CEPA a conclusion of “suspicion of toxic” is sufficient for regulatory action. The information requested in the regulations is required to answer questions relating to human health and the environment. As indicated above, information on proposed use is intended as a surrogate for exposure data.

6. FURTHER TESTING

A suspicion of toxicity will trigger a request for additional information on the specific issue, or issues, that give rise to the suspicion of toxicity. The Act only permits this action once per notification. The assessment is stopped until the additional information is received, at which time an additional period of time equivalent to the assessment period for the original notification is allowed. If the additional information does not resolve the suspicion, or confirms it, the chemical is treated as “toxic”. If the information resolves the concern, the chemical is treated as non-toxic.

7. INVENTORIES

The statutory instrument that defines “new” for the Canadian Environmental Protection Act is the Domestic Substance List (DSL). The DSL was published in the Canada Gazette in May 1994. The unique identifier for all chemicals and polymers in the DSL is the CAS number. The DSL contains about 23,000. Conditions for addition of a chemical to the DSL are that: the assessment is completed and there is no suspicion of toxicity or conditions on import manufacture or use applied, and the trigger volume has been reached. The DSL is updated on a regular basis and the eligible chemicals added. The actual process requires Ministerial approval since this is an amendment to a statutory legal instrument.

Environment Canada recognised that there were chemicals in international commerce, but not in Canada, and so developed the Non-Domestic Substance List (NDSL). The NDSL was developed from the TSCA Inventory, and is a list of those chemicals in the 1985 TSCA Inventory not put on the DSL. The NDSL is updated with the addition of chemicals that have been on the TSCA inventory for five years. In 1995, the NDSL was updated with chemicals that were on the TSCA inventory between 1985 and 1990. Chemicals that appeared on the TSCA inventory in 1991 will be added to the NDSL in 1996.

8. CONFIDENTIALITY OF DATA

Section 31 of the Act provides for the use of a “masked name” for a chemical when it is listed on the DSL and NDSL, or in the Canada Gazette, and Section 19 provides for some submitted information to be treated as confidential. Confidentiality must be claimed in writing at the time the notification is submitted. All information not claimed as confidential will be considered as non-confidential and may be released without further action.

In addition, Sections 20 and 24 of the Act identify information for which confidentiality may not be claimed. This information is generally summary in nature and relates to health.

Regulations detailing the process for obtaining a masked name have been published in the Canada Gazette on April 6, 1994.

9. INFORMATION SOURCES

- Guidelines for New Substance Notification under CEPA
- DSL
- NDSL
- Environmental Protection Act; New Substance Notification Regulations

SUMMARY OF JAPANESE NEW CHEMICAL NOTIFICATION SCHEME

MHW/MITI SCHEME

NAME OF LEGISLATION: The Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances

MAIN POINTS OF CONTACT: Mr Kohsaku UCHIDA
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Mr Bunro SHIOZAWA
Director, Chemical Products Safety Division
Ministry of International Trade and Industry
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1. AN OUTLINE OF THE LAW CONCERNING THE EXAMINATION AND REGULATION OF MANUFACTURE, ETC. OF CHEMICAL SUBSTANCES (CHEMICAL SUBSTANCES CONTROL LAW)

The Chemical Substances Control Law was established in 1973 to prevent environmental pollution and hazards to human health by chemical substances used for various purposes. The impetus for its enactment was the problem of environmental pollution caused by PCB (polychlorinated biphenyl) in the late 1960s. It provided for examination of new chemical substances which have similar properties to PCB (low biodegradability, high bioaccumulation and chronic toxicity) as Class I Specified Chemical Substances, and in fact prohibited the manufacture and import of such substances.

Then the Law was amended in 1986, which introduced the system designating Designated Chemical Substances and Class II Specified Chemical Substances, originating out of the necessity to regulate the substances having the properties of low bioaccumulation, but low biodegradability and chronic toxicity, depending on the degree of persistence in the environment.

With regard to Class II Specified Chemical Substances and Designated Chemical Substances, efforts are being made to reduce the accumulation of these substances in the

environment through examination of the conditions of production, import and use of these substances, and through guidance given to the companies using these substances.

Purposes of the Chemical Substances Control Law (Article 1):

This Law, in order to prevent pollution of the environment by chemical substances which have persistence and which may possibly be harmful to human health, has as its purpose the establishment of a system of examination to determine, before the manufacture or import of new chemical substances, whether such substances have persistence or other such properties, and the implementation of necessary regulations, in the manufacture, import, use, etc. of chemical substances according to their properties, etc.

2. EXAMINATION OF NEW CHEMICAL SUBSTANCES

Any new chemical substance is examined for safety with respect to its biodegradability, bioaccumulation and chronic toxicity based on a notification submitted from companies before it is manufactured or imported.

3. DATA REQUIREMENTS

Our scheme on the Chemical Substances Control Law requires the result of a biodegradability test of any new chemical substance by microorganisMs If a new chemical substance is biodegradable, no further tests are required. In case of low biodegradability, results of testing on the degree of the bioaccumulation in the body of fish, 28-day repeated dose toxicity test in mammalian species, mutagenicity test based on reverse mutagenicity test based on reverse mutation assay in bacteria, and chromosomal aberration test in cultured mammalian cells are required.

4. REGULATION OF CLASS I SPECIFIED CHEMICAL SUBSTANCES

Designation of chemical substances having low biodegradability, high bioaccumulation and chronic toxicity by Cabinet Order, and Enforcement of regulation concerning permission for manufacture or import and restriction of use. (Heretofore, there have been no cases of permission for manufacture or import.)

5. REGULATION OF DESIGNATED CHEMICAL SUBSTANCES AND CLASS II SPECIFIED CHEMICAL SUBSTANCES

Chemical substances having low biodegradability, low bioaccumulation and suspected chronic toxicity are identified as Designated Chemical Substances; reporting of the quantities of manufacture, import and shipment, quantitative assessment of environmental pollution and harm to the human based upon the reported quantities and additional tests on chronic toxicity.

Any substances determined as having chronic toxicity as the result of additional studies were designated as Class II Specified Chemical Substances by Cabinet Order, requiring regulation such as affixed labelling and publication of technical guidelines, reporting of the intended quantities for manufacture, import or delivery, and ordering, as required, alteration of the manufacturing or import quantity.

6. PUBLIC ANNOUNCEMENT

After the examination and classification of a new chemical substance, the name of the chemical substance and the category of the substance, such as Designated Chemical Substance or non-regulated chemical substance, are announced.

7. RECOGNITION OF NEW CHEMICAL SUBSTANCES IN LOW VOLUME

For any chemical substance whose total volume of manufacture or import is 1 ton or less a year throughout the nation, recognition is based on reports submitted by the companies, and manufacture and import of the substance are approved.

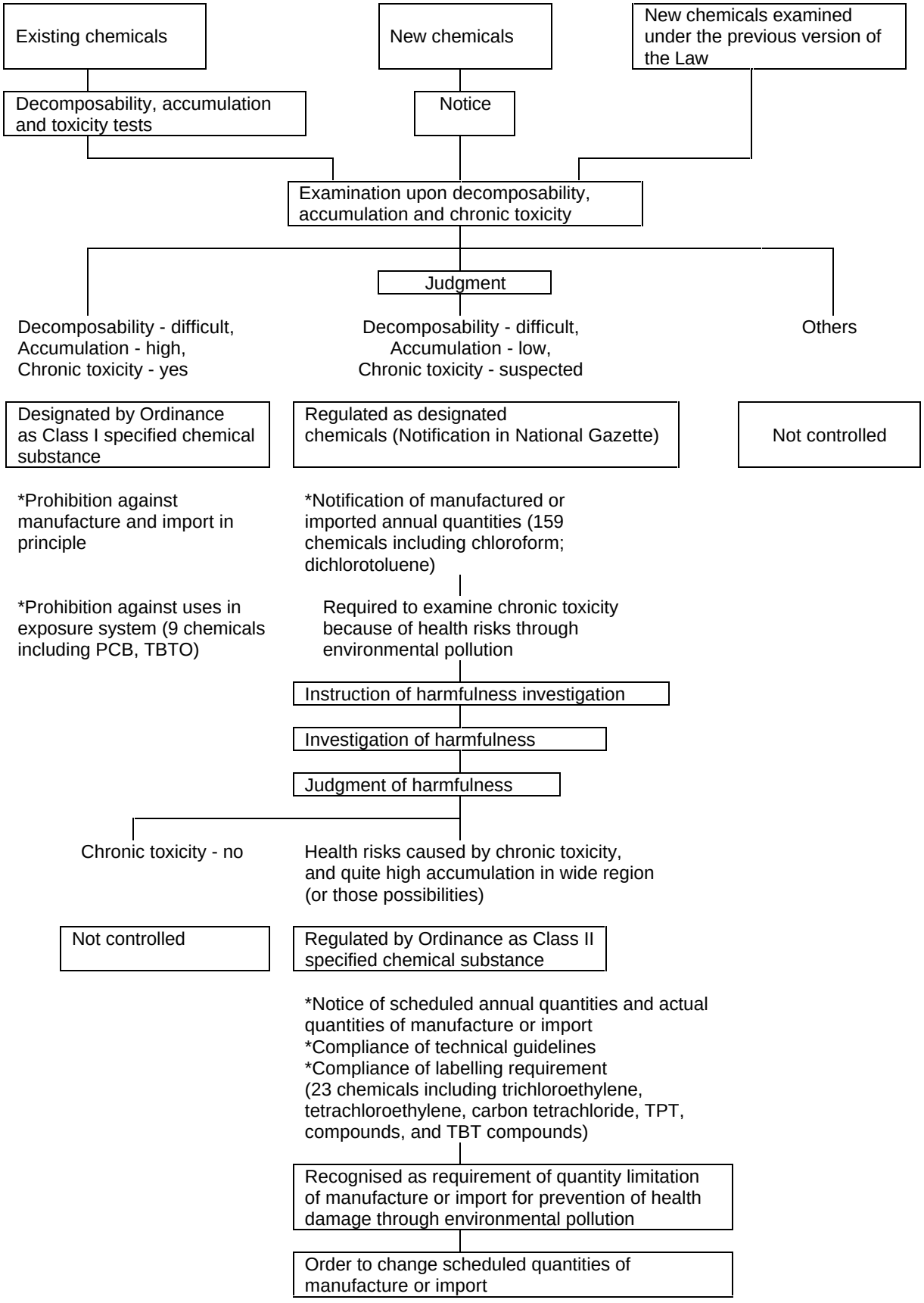
8. PROMOTION OF THE GOOD LABORATORY PRACTICE (GLP) SYSTEM

To promote mutual acceptance of test data among the Member countries of the OECD, compliance with OECD GLP standards was recommended at the OECD in 1981 as the standards testing facilities should comply with.

9. PROMOTION OF INSPECTION FOR SAFETY OF EXISTING CHEMICAL SUBSTANCES

For about 20,000 chemical substances already actually manufactured or imported at the time of enactment of the Chemical Substances Control Law (existing chemical substances), the Government has been performing inspection for safety of existing chemical substances and designating Class I Specified Chemical Substances, Class II Specified Chemical Substances or Designated Chemical Substances, as required.

Systematic Chart of the Law Concerning Examination and Regulation of Manufacture, etc. of Chemical Substances (Those in Parentheses Designated as of November 1995)



Recent PMN in JAPAN

Year	Number of Notification	Biodegradable	Polymer	Toxicity date		Unable to Judge
				(No Regulation)	(Designated)	
1987	57	23	16	9	3	6
1988	147	37	45	43	14	8
1989	242	33	97	68	6	38
1990	272	33	84	98	26	31
1991	269	49	73	75	42	30
1992	276	43	73	94	39	27
1993	229	27	48	98	41	15
1994	227	31	52	82	39	23

Recent LVE in JAPAN

Year	1987	1988	1989	1990	1991	1992	1993	1994
Manufacture	3111	3722	4188	4772	5089	5202	5303	5529
Import	1532	1795	2024	2028	2066	1994	2039	1995
Total	4643	5517	6212	6800	7155	7196	7432	7524

PMN: Pre-Marketing Notification

LVE: Low Volume Exemption

SUMMARY OF JAPANESE NEW CHEMICAL SUBSTANCE NOTIFICATION

MINISTRY OF LABOUR SCHEME

NAME OF REGULATION: Industrial Safety and Health Law 1977, as amended

MAIN POINT OF CONTACT: Ms Kazuyo OFUCHI
Chief Official,
Chemical Substance Investigation Division
Industrial Safety and Health Department
Labour Standards Bureau
Ministry of Labour
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1. BACKGROUND TO SCHEME

According to the Industrial Safety and Health Law, manufacturers/importers should investigate the toxicity of new chemicals and notify those chemicals to the Labour Minister prior to production/import of the substances. And manufacturers/importers should take measures of worker's protection from new chemicals based on the result of investigation.

The first new chemical was notified in 1979, 7686 chemicals were notified by the end of 1995, and 157 chemicals among these have been classified as a strong mutagen.

2. DATA REQUIREMENTS

The result of mutagenic test ("Bacterial Reverse Mutation Test") is needed to notify new chemicals if the amount of production/importing exceeds 100kg per year at one site.

The law is applied not only to industrial chemicals but also medicines, pesticides and other use of chemicals, including intermediate and chemical waste.

"New chemical" is defined as a "chemical other than existing chemicals" and "existing chemicals" are defined as follows:

(1) elements
(2) chemicals obtained as natural resources
(3) radioactive chemicals
(4) chemicals which had been produced or imported by June 29, 1979, whose names were made public by the Labour Minister thereafter.

Some kinds of “new chemicals” which consist of existing chemicals alone are considered as existing chemicals:

(1) molecular compounds, etc.;
   a. molecular compounds
   b. hydrates
   c. inclusion compounds
   d. salts made from organic acid or organic base
   e. onium salts
   f. double salts

(2) block polymers and graft polymers which are made from existing polymers

(3) polymers which are made from existing monomers and meet some conditions

3. SCOPE OF ASSESSMENT

All data submitted is reviewed by experts in order to assess the chemical’s harmfulness in regard to occupational health.

4. HAZARD AND RISK ASSESSMENT

All chemicals notified are classified as mutagen (strong or weak) or not a mutagen by the Assessment Committee.

5. ACTIONS RESULTING FROM NOTIFICATION AND ASSESSMENT

The Director-General of the Labour Standards Bureau of the Ministry of Labour announces officially the names of chemicals which are classified as strong mutagens and issues guidelines on measures to take against such chemicals.

The outline of the guidelines is as follows.

(1) The employer should take measures to reduce his workers’ exposure to the mutagenic substances.

(2) The employer should measure the air concentration of the mutagenic substances at the workplaces.

(3) The employer should give his workers hygienic education about the mutagenic substances.

(4) The employer should make labels and MSDSs for the mutagenic substances.

(5) The employer should keep the work records concerning the mutagenic substances.

6. FURTHER TESTING

For the notification of new chemicals, a “Bacterial Reverse Mutation Test” is needed. If the test result is classified as mutagenic, an “In Vitro Mammalian Chromosome Aberration Test” is requested as further testing from the notifier.

7. INVENTORIES

Every notified chemical is announced officially in the official gazette within one year of the notification of the chemical, and the new chemical comes into the group of existing chemicals just after the announcement.

20,298 chemicals were listed as existing chemicals before the notification system started on June 30, 1979, and thereafter 6,892 chemicals were announced as new chemicals by December 1995.

8. CONFIDENTIALITY OF DATA

The name of every new chemical is announced by the official gazette. If the chemical is a strong mutagen, only the result of classification by the Assessment Committee is announced by the Director-General of the Labour Standards Bureau of the Ministry of Labour. All other related information on new chemicals is kept confidential.

9. INFORMATION SOURCES

There are several public sources of information on the notification system, but they are written only in Japanese.

SUMMARY OF NEW ZEALAND "NEW" SCHEME

REQUIREMENTS RELATING TO NOTIFICATION AND ASSESSMENT IN THE HAZARDOUS SUBSTANCES AND NEW ORGANISMS LEGISLATION

NAME OF LEGISLATION

Hazardous Substances and New Organisms Act 1996

MAIN POINT OF CONTACT

When the scheme is operational, the point of contact will be the Environmental Risk Management Authority (ERMA).

In the meantime, inquiries should be directed to Dr S R Vaughan, Project Manager HSNO Reform, Ministry for the Environment, PO Box 10-362, Wellington, New Zealand.

1. BACKGROUND TO SCHEME

The Hazardous Substances and New Organisms (HSNO) Act, which integrates management of all hazardous substances into a single framework, was passed on 23 May 1996. However, the HSNO Act will not come into effect until the associated regulations have been prepared, which is expected to take a further 12-15 months.

The HSNO Act provides a single modern piece of legislation that focuses on the management of adverse effects of hazardous substances and new organisMs

The HSNO Act replaces the following existing Acts:

- Explosives Act 1957;
- Dangerous Goods Act 1971;
- Toxic Substances Act 1979; and
- much of the Pesticides Act 1979 and some of the Animal Remedies Act 1967

The HSNO Act imposes a general duty on every person who imports, possesses or uses a hazardous substance or new organism to comply with requirements or controls set in regulation. Such controls will address each aspect of the lifecycle that the substance presents a risk, including storing, transporting, using, and disposal.

For substances which are controlled or approved under existing legislation, the Act includes transitional provisions that provide:

a) that substances subject to existing legislation be approved substances under the HSNO Act; and

b) for the existing controls on such substances to be carried over.

During the transition period, these existing controls will be progressively translated over into controls under the HSNO Act.

2. PROHIBITION OF IMPORT OR MANUFACTURE OTHERWISE THAN IN ACCORDANCE WITH THE HSNO ACT

When the Act is in force, no hazardous substance shall be imported or manufactured otherwise than in accordance with an approval issued under the HSNO Act. Approvals are issued as the result of an approved application.

3. DEFINITION OF A HAZARDOUS SUBSTANCE

A hazardous substance is any substance with one or more of the following intrinsic properties:

- explosiveness;
- flammability;
- a capacity to oxidise;
- corrosiveness;
- toxicity (including chronic toxicity);
- ecotoxicity, with or without bioaccumulation; or
- which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any one or more of the properties mentioned above.

The level of each hazardous property will need to be above a threshold to be defined in regulations. Where appropriate, threshold levels will be based on internationally recognised measures and will be expressed so that it can readily be determined whether a substance will be covered by the legislation.

The definition of a substance in the Act allows that a “substance” can include any mixture with a range of percentages of the elements or compounds making up the “substance”.

4. INFORMATION TO BE SUPPLIED WITH APPLICATIONS FOR ASSESSMENT

For hazardous substances the HSNO Act requires that information be provided on:

- the unequivocal identification of the substance and its properties;
- all the possible adverse effects of the substance on the environment;
- the intended uses of the substance throughout its lifecycle;
- methods of disposal of the substance;
- all occasions where the substance has been considered by the government of any prescribed state, country or organisation and the results of such consideration.

5. CONFIDENTIAL INFORMATION WILL BE PROTECTED

The HSNO Act provides a public process for assessment of hazardous substances. The public process requires that sufficient information is provided to the public about effects on people and the environment to enable them to comment on the adverse effects of the substance while ensuring that commercially sensitive information can be protected.

6. EFFECTS-BASED

The HSNO Act is effects-based legislation. Substances will be classified or scheduled according to the degree of adverse effect (e.g. toxicity) that such substances present, and the degree of controls that will be imposed on substances will be proportional to such effects.

7. INTERIM REQUIREMENTS FOR NOTIFICATION, ETC.

A number of existing legislative requirements relating to notification of substances will be repealed when the HSNO Act comes into effect, and replaced by a requirement to apply for assessment under HSNO. Such requirements include those relating to notification of toxic substances, registering of pesticides and animal remedies, and the licensing of explosives.

Substances that are lawfully present in New Zealand on the date that the HSNO Act comes into force will be subject to the Transitional Provisions.

8. EXCLUSIONS

Radioactive substances, which continue to be controlled under the Radiation Protection Act 1965;

Ozone depleting substances which are controlled under the Ozone Layer Protection Act 1990.

The HSNO Act also does not cover UNRTDG division 6.2 (infectious substances), as these are organisMs

9. INVENTORIES

A register of approved substances will be available to the public.

10. FOLLOW-UP TO NOTIFICATION

The applicant must inform the ERMA of any changes to the information supplied for assessment relevant to the adverse effects, quantity or use to which the substance is to be put. Significant changes may trigger reassessment.

11. INFORMATION SOURCES

- Hazardous Substances and New Organisms Act 1996
- Proposals for Regulations Under the Hazardous Substances and New Organisms Bill
- Guide to the Hazardous Substances and New Organisms Act (in preparation).

SUMMARY OF THE SWISS NEW CHEMICAL NOTIFICATION SCHEME

NAME OF LEGISLATION: Federal law relating to the protection of the environment, 1983

Ordinance relating to environmentally hazardous substances, 1986

MAIN POINT OF CONTACT: Andreas WEBER
Head of Section on Substances Hazardous to the Environment
Federal Office for Environment, Forests and Landscape
Hallwylstrasse 4
CH-3003 Bern

Tel: +41-31 322 68 59
Fax: +41-31 324 79 78

1. BACKGROUND TO SCHEME

The notification scheme is based on the Federal Law Relating to the Protection of the Environment and the Ordinance Relating to Environmentally Hazardous Substances. It came into force on 1 January 1988 and covers the assessment of the environmental impact. The Federal Office for Environment, Forests and Landscape (FOFEL) is the competent authority for the notification of new substances under this notification scheme.

For the assessment of occupational and public health a separate notification is needed. The requirements are laid down in accordance with the Law Relating to
Toxic Substances and are decided by the Federal Office of Public Health. However, this scheme does not distinguish between new and existing substances and includes preparations as well. It is not discussed in detail in this summary.

Between 1988 and the end of 1995, about 500 first notifications of new substances have been received from manufacturers and importers. About 30% of these substances are produced in Switzerland.

2. DATA REQUIREMENTS

A substance is subjected to notification for environmental impact assessment if:

- it is placed on the Swiss market either on its own as a substance or as a component in a preparation or article, and

- it is not on the European Inventory of Existing Commercial Chemical Substances (EINECS), or

- it is not contained in the second edition, 1985, of the register of toxic substances (Toxic List 1) issued by the Federal Office of Public Health, or

- it cannot be shown to have been supplied on the Swiss market in a total quantity exceeding 500 kg during the period 1975 to 1984, or

- it is not covered by one of the exemptions mentioned below.

Substances are exempted from notification if:

a) they are subject to a marketing permit (agricultural pesticides, wood preservatives, antifoulings, additives used in animal feeding stuffs);

b) they are mixed exclusively with foodstuffs as preservatives or additives or in order to improve the nutritional value;

c) they are used exclusively in pharmaceutical products;

d) they are higher polymerizates, polycondensates or polyadducts containing in combined form less than 2% of their weight of any monomer considered to be a new substance or made up exclusively of the elements carbon, hydrogen, oxygen and nitrogen;

e) they are supplied to another manufacturer solely as intermediate products for further chemical conversion;

f) they are supplied only in small quantities and for a short period to selected parties in order to determine their properties, to examine possible applications or to test production processes.

The test requirements for notification are based on the OECD Minimum Pre-marketing set of Data and are equal for all new substances independently of the quantity put on the market. Individual items from the minimum list of data may, however, be omitted when valid reasons are given. A low consumption combined with special applications or disposal methods which strongly reduce the possibility of an environmental contamination may be an acceptable reason for the omission of certain data.

Data on human health aspects are not included in the data requirements. However, they are necessary for the notification based on the Law Relating to Toxic Substances.

3. ENVIRONMENTAL HAZARD AND RISK ASSESSMENT

Environmental hazard and risk assessments are carried out by the notifier and the notification must be accompanied by an environmental impact report. In the assessments he has to show that handling in accordance with the information on the label, the instruction for use and material safety data sheet cannot present a hazard to the environment nor to persons indirectly through the environment.

A notifier must reassess a substance if it is supplied for other purposes or in considerably larger quantities than predicted at the time of notification. A new assessment will be necessary as well when differences in type and amount of impurities occur.

4. ACTIONS RESULTING FROM NOTIFICATION

The FOFEL has the obligation to check the completeness and consistency of the notification dossier as well as the correctness of the assessment and the proposed risk and safety phrases. In case of disagreement, the Federal Office can in particular demand:

- revision of the assessment;
- revision of risk and safety phrases;
- additional information (including tests) required for revision of the assessment;

5. INVENTORIES

Notified new substances will be added to the inventory of notified new substances as soon as the notification is received. The inventory includes information on trade names and intended uses of the substances as well as the names of the first notifiers. The inventory is kept by FOFEL.

Substances (new and existing) and preparations within the scope of the law on toxic substances are included in the so-called list on toxic substances and preparations. This list includes information on toxicity classification and is published once a year by the Federal Office of Public Health.

6. CONFIDENTIALITY

All information is treated as confidential for which preservation of secrecy is deemed to be worthy of protection. A notifier can indicate which information he requires to be kept secret. In particular, the manufacturer's interest in preserving business and trade secrecy can be deemed to be worthy of protection, However, information contained in the material safety data sheet is in no case confidential.

7. OUTLOOK

According to a decision of the Federal Council of June 1993, the existing differences between EU and Swiss legislation shall be eliminated. This harmonization includes requirements regarding notification of new substances, classification and labelling, and material safety data sheets.

The Federal Law Relating to the Protection of the Environment has been revised recently, and the Federal Law on Trade in Toxic Substances is actually in revision. Once the revision is completed, harmonization of details will become possible at the level of the Ordinances.

A full integration into the EU notification scheme is intended as soon as the harmonization of the legal basis is completed.

8. INFORMATION SOURCES

- Ordinance Relating to Environmentally Hazardous Substances 1986;
- Notification form with explanatory notes;
- *Anmeldung von Stoffen nach Umweltschutzgesetz - Wegleitung für Hersteller und Importeure* (d/f only).

SUMMARY OF THE UNITED STATES' NEW CHEMICAL NOTIFICATION SCHEME

NAME OF LEGISLATION: Toxic Substances Control Act

MAIN POINT OF CONTACT: Mr Paul CAMPANELLA
Chief, New Chemicals Branch
US EPA OPPT
401 M Street SW
Washington DC 20460
USA

Tel: 202-260-3948
Fax: 202-260-8168

1. BACKGROUND TO SCHEME

The Toxic Substances Control Act (TSCA) (15 U.S.C. 2601) was enacted in October 1976 and took effect January 1, 1977. The notification and assessment system for new chemicals came into operation on July 1, 1979.

Section 5 (15 U.S.C. 2604) of TSCA governs the introduction of new industrial chemicals. TSCA §3(9) defines a "new chemical substance" as any chemical substance not included on the TSCA Inventory of Existing Chemical Substances maintained pursuant to §8(b).

The areas assessed are occupational health and safety, environmental effects and public health.

2. NOTIFICATION AND ASSESSMENT

A manufacturer must submit a Pre-Manufacture Notice (PMN) to EPA at least 90 days before commencing non-exempt commercial manufacture of a new chemical. Section 5(e) of TSCA authorises EPA to regulate via a unilateral administrative order issued at least 45 days before the end of the 90-day period. However, virtually all of the over 600 §5(e) Orders that EPA has issued have been bilateral Consent Orders signed by the manufacturer wherein, among other things, the manufacturer waives its rights to receive the Order by that deadline. Instead, EPA must issue the Order before the expiration of the 90-day review period. Additionally, under §5(c) of TSCA, EPA can "for good cause" unilaterally "extend" the review period for an additional 90 days and, under 40 CFR 720.75(b), EPA can, with the manufacturer's consent, "suspend" the review period.

New chemical substances submitted as PMNs are added to the Inventory only after the 90-day review period expires and the manufacturer submits a Notice of Commencement (NOC) to EPA within 30 days of commencing non-exempt commercial manufacture. However,

the program's experience shows that approximately 50% of PMN substances never commence commercial manufacture.

There are a number of exemptions from full notification which do not go onto the TSCA Inventory, i.e. low volume ((10,000 kg/year), research and development, test marketing, low release/low exposure, and polymer. The polymer exemption does not include a new polymer with monomer(s) not on the TSCA Inventory.

Complex mixtures are differentiated by considering each combination of substances to be either 1) a mixture, composed of two or more well-defined chemical substances to be listed separately; 2) a reaction product, to be listed as a single chemical substance using one name that collectively describes the products, or, failing that, the reactants used to make the products.

TSCA §5(a) (2) also requires 90-day advance notice before manufacture or import of any chemical substance (new or existing) for any activity that EPA designates by rule as constituting a "significant new use". Such a rule is called a Significant New Use Rule (SNUR).

There were 2645 §5 notices submitted from 1/10/93 to 30/9/94.

The US is required to publish a receipt of notice in the Federal Register and make available a public copy of each notice (that does not contain confidential information) along with any health and safety studies which cannot be claimed to be confidential. It also publishes receipt of Test Marketing Exemption Applications in the Federal Register, as well as the decision to grant or deny these applications. Notice of Commencement information is also published periodically in the Federal Register.

No formal public dossier is compiled. Because of constraints with confidentiality, informal program reports are retained in in-house confidential files. These informal reports consist of assessments undergone by chemicals under the various program disciplines such as chemistry, toxicology, occupational and environmental exposure, risk assessment, economic assessment, and risk management.

Information may be available to other governments only if the notifier waives Confidential Business Information (CBI) rights and there is a formal/informal agreement between governments. Information available to the original notifier is decided on a case-by-case basis in a company meeting.

3. DATA REQUIREMENTS

Information required to be provided by the notifier includes: CAS number, chemical name, structural and molecular formulae, trade name, spectral analysis, and nature and proportion of impurities. After the assessment process the information is stored in confidential files and databases.

Name and chemical structure are considered the two types of information most useful to identify a chemical.

No test data is required to be produced for notification; however, if test data had been produced prior to notification and is "reasonably ascertainable", then it must be submitted with the notification. When testing is recommended under a consent order or under a ban, then the neat form is recommended.

4. ACTIONS RESULTING FROM NOTIFICATION AND ASSESSMENT

The TSCA §5 New Chemicals Program is not considered a registration program, but rather a screening program in which certain chemicals are regulated and others are not. Informally, within EPA, the chemicals that are not regulated are called "drops". Under §5(e), EPA may regulate via an administrative order those chemicals for which there is insufficient information and either: (a) the substance may present unreasonable risk to human health or the environment (the "risk-based" finding under §5(e) (1) (A) (ii) (I)), or (b) the substance will be produced in substantial quantities and there may be substantial human exposure or environmental release (the "exposure-based" finding under §5(e) (1) (A) (ii) (II)). Risk-based Orders usually require: development of toxicity, fate or other test data; human exposure and/or environmental release controls; and a hazard communication program including MSDS, labels and worker training. Exposure-based Orders usually require only development of toxicity, fate or other test data, and, if that data indicates a risk, inclusion of that information in an MSDS.

The Orders apply only to the manufacturer that submitted the PMN, whereas a §5(a) (2) SNUR applies to all manufacturers and processors of the same chemical. Therefore, to extend the requirements of the §5(e) Order, EPA generally follows the risk-based Orders with a SNUR that essentially imposes the same requirements on other manufacturers and processors. For example, the SNUR can define as a "significant new use" handling the substance without gloves, goggles, respirators, MSDS, labels, worker training and the development of test data. Anyone intending to use the substance for a "significant new use" must submit a significant new use notice (SNUN) 90 days before doing so, and, if appropriate, EPA can respond by issuing a §5(e) Order that may impose additional requirements on the SNUN submitter.

5. CONFIDENTIALITY

Information claimed by the first notifier as Confidential Business Information (CBI) under TSCA §14, 40 CFR Part 2, and 40 CFR 720, Subpart E is protected. All of the information required to be submitted to the EPA under TSCA may be confidential except any health and safety studies. A second notifier will be informed if the substance is on the Inventory and if there are any restrictions under a SNUR.

The public may only access "sanitised" documents which have the confidential information removed. The submitter must provide the sanitised version of the notification. Assessments are considered internal deliberative documents which are not part of the public record, although the Public Docket for SNURs does contain certain sanitised Agency assessments.

6. SHARING OF INFORMATION

The US does not apply concessions to chemicals which have been assessed in other countries or use their assessments. However, if a chemical identity had not been claimed confidential for a chemical substance, then there could be an informal exchange of information.

An agreement exists between the US EPA and Environment Canada/Health Canada for sharing information. There are reduced notification requirements in Canada if a new chemical which does not exist on their Domestic Substances List (DSL) appears on the TSCA Inventory. However, a five-year interval exists before additions to TSCA are eligible for

inclusion on the Non-Domestic Substances List (NDSL), in order to allow the accumulation of information.

7. INVENTORIES

The US chemicals inventory is the TSCA Chemical Substances Inventory. Its purpose is to define whether a substance is new or existing and thus whether or not a PMN is required.

The Inventory was created in 1979 by requiring manufacturers/importers to report chemical substances manufactured or imported during 1977. Optionally, processors could report anything currently being processed at the time. Subsequently, manufacturers (importers) were allowed to report for substances manufactured/imported from 1975 to 1979.

Chemicals are added to the Inventory only after the 90-day review period expires and the manufacturer submits a Notice of Commencement (NOC) to EPA within 30 days of commencing non-exempt commercial manufacture. The fact that an assessment has occurred is not noted on the Inventory, but it is assumed to have occurred.

Listing on the Inventory is affected by confidentiality provisions. EPA maintains two versions of its TSCA Inventory, one confidential, one non-confidential. Persons wishing to determine whether a substance is listed on the confidential Inventory must, pursuant to 40 CFR 720.25, demonstrate to EPA a *bona fide* intent to manufacture or import the chemical substance for commercial purposes.

Chemicals listed on the non-confidential TSCA Inventory are available for purchase on tape and PC diskette through the National Technical Information Service (NTIS), and are updated every six months. A paper copy can be purchased through the US Government Printing Office (GPO). The Chemicals Abstract Service (CAS) publishes and sells a CD-Rom version of the non-confidential TSCA Inventory. Online commercial services are also available through several vendors. Finally, the Agency will do searches but only upon receipt of a complete intent to manufacture.

SUMMARY OF EUROPEAN UNION (EU) NEW CHEMICAL NOTIFICATION SCHEME

NAME OF LEGISLATION: Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, as amended (7th Amendment to Directive 92/32/EEC)

MAIN POINT OF CONTACT:

Mr G. CORCELLE
DG XLE.2
BU-5 02/04
Rue de la Loi 200
B-1049 Brussels
BELGIUM

Tel: (+32-2) 296.87.49
Fax: (+32-2) 296.69.95

1. BACKGROUND TO SCHEME

1. In the 1970s many EC Member States started to introduce notification schemes for new substances prior to these substances being placed on the market. The purpose of these schemes was to undertake an *a priori* assessment of a new substance before it was marketed, thereby allowing any necessary measures to be taken to protect man (consumers and workers) and the environment from exposure to unacceptable risks. However, one consequence of the introduction of divergent national procedures was the distortion of the EC single market because chemical manufacturers/ importers were subject to different requirements in the different Member States. Furthermore, information submitted on a substance in one Member State was not communicated to other Member States whereas the substance itself could, as internal borders began to disappear, quite easily be transported and used across the Community. In these circumstances the most effective course of action was to establish a harmonized EC-wide system of notification whereby the same procedures would be applied across the Member States and wherein the information collected would be exchanged between all national authorities.

2. The EC-wide scheme for the notification of new substances was introduced as part of the 6th amendment to Directive 67/548/EEC concerned with the classification, packaging, and labelling of dangerous substances. As the name of the Directive indicates, it contains, in addition to the rules for the notification of new chemicals, detailed rules for the classification, packaging and labelling of all dangerous substances. The 6th amendment (Directive 79/831/EEC) was adopted in September 1979 and was in force in all Member States in September 1981.

3. In the light of more than ten years' experience in implementing the 6th amendment, a 7th amendment to Directive 67/548/EEC (Directive 92/32/EEC) was adopted on 30 April 1992 (O.J.L 154 of 5.6.92). The 7th amendment became effective as from the beginning of November 1993 in all Member States.

4. As of 12 December 1995, the total number of notifications made in the EU system was 2865 (covering 1440 different substances). Of these, 140 were reduced notifications (< 1 tonne), 16 were polymers notifications, 60 were at level 1 (100 tonnes), five at level 2 (1000 tonnes), and 160 notifications included a risk assessment.

2. DATA REQUIREMENTS

1. A substance is subject to notification if:

   (I) It is placed on the EU market either on its own as a substance or in a preparation, and

   (ii) It is not on the European Inventory of Existing Commercial Chemical Substances (EINECS),[3] and

   (iii) It is not covered by one of the exemptions granted under the Directive.

2. The following substances are exempted from the harmonized EU notification procedures:

   - cosmetic products as such, and as they are made available to the final user;
   - additives and substances for exclusive use in animal feeding stuffs;
   - substances used exclusively as additives or as flavourings in foodstuffs;
   - active ingredients used exclusively in medicinal products for human or veterinary use. This does not include chemical intermediates; substances for exclusive use in plant protection products and which are subject to the evaluation procedures foreseen under Article 6 of Directive 91/414/EEC.

3. In addition to those substances which are exempted from the notification procedure, the Directive identifies further categories of substances which are considered as being notified and hence not subject to the harmonized EU notification procedures, although certain limited information may be required:

   - polymers (with the exception of those which contain in combined from 2% or more of any substance which is not on EINECS);
   - substances placed on the EU market in quantities of less than 10 kg per one year per manufacturer;
   - substances for scientific research and development;

[3] EINECS is an inventory containing over 100,000 entries of substances which were on the EU market before 18 September 1981, the date of entry into force of the EEC notification procedure.

- substances for process-oriented research and development.

4. The essential contents of a notification dossier for a new substance include:

   - a technical dossier, describing the intrinsic properties of the substance, the extent of which varies with the quantity of the substance to be placed on the market. A special technical dossier is necessary for notifiable polymers;

   - a proposal for the classification and labelling of the substance;

   - for substances classified as dangerous, a proposal for a safety data sheet.

   The notification may also include, at the request/discretion of the notifier:

   - a provisional risk assessment carried out by the notifier;

   - a request to be exempted for one year from the data-sharing requirements imposed by the Directive.

5. The information to be provided on intrinsic properties is dependent upon the amounts which will be marketed annually across the EU: more than one tonne per annum; Less than one tonne but greater than 100kg; and less than 100kg but greater than 10 kg. The testing packages corresponding to these marketing levels are laid down in Annexes VII A, B and C to the Directive respectively. A separate testing package for notifiable polymers is laid down in Annex VII D of the Directive (O.J.L 294 of 30.11.93).

3. CONFIDENTIALITY

1. Some of the data submitted in the notification dossier may be regarded as being confidential business information, the release of which to competitors may have a prejudicial economic impact on the notifier. The Directive recognises the importance of the issue, allowing notifiers to claim, with justification, certain information as confidential. For the purposes of the EU notification system 'confidential' means restricted to the Member State Competent Authorities (CAs) and the Commission.

2. However, in the interests of transparency and public right of access to information of relevance for environmental protection, notifiers are not allowed to claim confidentiality for the following pieces of information:

   - the trade name of the substance;

   - the name of the manufacturer and the notifier;

   - physico-chemical data concerning the substance;

   - the possible ways of rendering the substance harmless;

   - the summary results of the toxicological and ecotoxicological tests;

   - if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;

- recommended methods and precautions for handling, storage and transport of thesubstance as well as the emergency measures in case of accidental spillage or injury to persons;
- the information contained in the safety data sheet;

- in the case of dangerous substances, analytical methods that make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

4. RISK ASSESSMENT

1. The Directive requires CAs receiving a notification dossier to carry out a risk assessment. Risk assessment involves a comparison of the likely concentrations of the substance to which the environment, workers or consumers will be exposed and the concentrations of the substance which are capable of eliciting negative effects. The risk assessment is carried out by the CAs according to a series of general principles laid down in Commission Directive 93/67/EEC (O.J.L 227 of 8.9.93) and supported by a 'Technical Guidance Document'.

2. The Commission Directive recognises four potential administrative actions from the risk assessments carried out by the CAs:

   - the substance is of no immediate concern and need not be considered again until further information is made available;

   - the substance is of concern and the CA shall decide whether information is required for revision of the assessment but shall defer a request for that information until the quantity placed on the market reaches the next tonnage threshold;

   - the substance is of concern and further information shall be requested immediately;

   - the substance is of concern and the CA shall immediately make recommendations for risk reduction (i.e. measures which would enable the risks for man and/or the environment in connection with the marketing of the substance to be lessened. They may include: modifications to the classification, packaging and labelling; modifications to the safety data sheet; modifications to the recommended methods and precautions or emergency measure; advice to the relevant control authorities to consider appropriate measures for the protection of man and/or the environment).

In the event that any of the last three conclusions is possible, it is expected that the CA will enter into a dialogue with the notifier in order to confirm or remove these concerns.

5. INVENTORIES

1. Each year the Commission publishes a list of the new substances notified under the Directive (ELINCS - European List of Notified Chemical Substances). However, there are various possibilities for the way substances are identified in this list:

- For new substances which are not classified as dangerous according to the Directive the substance may, at the request of the CA, be included in ELINCS in the form of its trade name alone. Normally, inclusion by trade name will only last for three years but if the CA can provide evidence that disclosure of the full IUPAC name would reveal information concerning commercial exploitation or manufacture, the substance can be included in ELINCS under the trade name for as long as the CA sees fit;

- Substances which are classified as dangerous according to the Directive are normally identified in ELINCS according to their UPAC name and their trade name. However, the CAs can request that they be temporarily included in ELINCS under their trade name alone until such time as the substance is introduced into Annex I of the Directive, at which time the IUPAC name will be added.

6. FOLLOW-UP TO NOTIFICATION

1. The notifier must inform the relevant CA of any changes to the information included in the notification and of any new data of which they may become aware and which are relevant to the risk assessment of the substance. In addition to this general requirement, the Directive also foresees specific trigger points initiating a formal requirement for the submission of additional data; these trigger points are linked to the tonnages of the notified substance which are placed on the market.

2. The CAs may also require the notifier to provide additional information at any time irrespective of whether the production triggers have been attained or not; this is especially true of substances which are identified by the risk assessment procedure as being of potentially high/very high risk. In these cases the notifier can expect to be requested for further data as an immediate follow-up to the submission of the notification dossier.

3. The testing requirements for up to 1 tonne per annum (5 tonnes cumulative) are clearly set out in the Directive (Annexes VII A, B, C - 'base set' and 'reduced notifications'). At 10 tonnes per annum (50 tonnes cumulative) the authorities review the dossier and a request for further testing is entirely discretionary. At 100 tonnes per annum (500 tonnes cumulative) the notifier is obliged to carry out a supplementary testing package according to the schedule set out in Annex VIII of the Directive - level 1. However, while it is obligatory to carry out further testing at this point, it is possible for the notifier to justify why a given test/study would not be appropriate or an alternative test/study would be preferable. Similarly, when marketed quantities reach 1000 tonnes per annum (5000 tonnes cumulative) notifiers are again required to carry out a supplementary testing package according to the schedule set out in Annex VIII of the Directive - level 2.

4. As with the information submitted in the original notification, the data submitted as part of the supplementary testing package is exchanged between the Competent Authorities and the Commission. On the basis of the additional information submitted, the risk assessment of the substance is reviewed as well as the original classification and labelling.

ANNEX 3

FOUR CORNERS AGREEMENT BETWEEN US EPA AND THE CANADIAN GOVERNMENT ON INTERNATIONAL SHARING OF INFORMATION ON NEW CHEMICALS

FOUR CORNERS AGREEMENT BETWEEN EPA AND THE CANADIAN GOVERNMENT ON INTERNATIONAL SHARING OF INFORMATION ON NEW CHEMICALS

(MARCH 29, 1996)

PREAMBLE:

Sharing information about chemicals assessments is a priority issue arising from the UN Conference on Environment and Development (UNCED) (June 1992, Rio de Janeiro). Better use of existing information and mechanisms for information exchange are vital parts of Agenda 21, Chapter 19, which provides the blueprint for action to ensure the environmentally sound management of chemicals. The Organisation for Economic Co-operation and Development (OECD) recently initiated efforts to encourage the sharing of assessments and, as part of that effort, this agreement between Canada and the U.S. provides one model for achieving this goal.

On July 1, 1994 the New Substances Notification regulations of the Canadian Environmental Protection Act (CEPA) came into force. Under these regulations, the manufacture or importation into Canada of chemicals and polymers that are new to Canada require notification and submission of information sufficient to make an initial assessment of environmental and human safety. Any chemical not listed on the CEPA Domestic Substances List (DSL) is considered new to Canada. Chemicals that appear on the TSCA Inventory of 1985, but are not on the DSL form the basis of a second list, the Non Domestic Substance List (NDSL), for which there are reduced information requirements. CEPA provides for the NDSL to be amended yearly by including the annual additions to the TSCA Inventory, but with a 5-year interval to permit the accumulation of information based on actual use of the chemical. Thus, the 1991 additions to TSCA are eligible for inclusion on the NDSL in 1996.

Canadian and American chemical industries have expressed their belief that the 5-year waiting period is too restrictive and wish to explore ways by which additions to the TSCA Inventory could be moved onto the NDSL in less than 5 years. In theory, if the information used by the U.S. EPA's New Chemicals Program to make a decision regarding a chemical was made available to decision makers in charge of Canada's New Substances Notification Program, the process by which a chemical was added to the NDSL might be expedited.

Consultations between the U.S. Environmental Protection Agency, Environment Canada, Canadian Chemical Producers' Association, and the Chemical Manufacturing Association have resulted in an agreement in principle on a Pilot Project for sharing information about new industrial chemicals between the U.S. and Canadian governments. We believe this procedure will encourage voluntary sharing of information, protect the confidentiality of any information between countries, and provide industry with opportunities to reduce testing costs, assessment fees and time to market.

This pilot project will proceed for two years from the effective date at which time all parties involved will evaluate the costs and benefits of the pilot, suggest modifications and

make recommendations as to whether the program should continue. The proposed administrative procedure is attached.

The start of the pilot project will come into effect two (2) weeks following the signature of both parties:

V. Shantora
Director General
Toxics Pollution Prevention Directorate
Environment Canada
Canada

William H. Sanders, III, Director
Office of Pollution Prevention
and Toxics
Environmental Protection Agency
United States of America

Proposed Administrative Procedure for Data Sharing on Chemicals Listed on the TSCA Inventory but not on the CEPA NDSL, for the Purpose of Permitting Early Listing of those Chemicals on the NDSL Prior to the Expiry of the Stipulated Five-Year Period:

STEP 1: The CEPA notifier (an agent for the US PMN filer) makes an application to Environment Canada for addition of a TSCA substance to Non Domestic Substance List (NDSL).

The application must include:

a. The original TSCA PMN and PMN number

b. The US TSCA Notice of Commencement (NOC)

c. Any TSCA 5(e), or 8(e) compliance documentation

d. Any US generated Letters of Concern (LOCs)

e. All new data, of any kind, on the chemical for which the notification is submitted generated since the original PMN was filed (which if it had been available would have been required to be submitted to US EPA with PMN), and as per CEPA Schedules 1 or 11 (chemicals) or Schedules VI or VII (polymers) notification requirements

f. CEPA notifier and US PMN filer provide authorization allowing Environment Canada and Health Canada to discuss submissions fully with US EPA and exchange information as warranted with US EPA.

STEP 2: Environment Canada acknowledges receipt of the request and identifies the information submitted. Environment Canada copies the US EPA and the US PMN filer (identified in #1).

STEP 3: The CEPA notifier requests the US PMN filer to authorise the US EPA to send Environment Canada the US EPA Review Notes.

STEP 4: The US PMN filer:

a. Requests the US EPA to send Review Notes to Environment Canada

b. Provides authorisation for the US EPA to direct reviews to Environment Canada and discuss reviews of particular PMN submissions with Environment Canada staff

c. Includes acknowledgment letter from Environment Canada (STEP 2) and additional information generated since the filing of the PMN (STEP 1.e. new data) with the request package

STEP 5: US EPA sends Review Notes to Environment Canada.

STEP 6: Environment Canada and Health Canada make one of two decisions regarding addition to NDSL. In instances where the decision is 1) to add the chemical to the NDSL, Environment Canada and Health Canada will advise the notifier of the addition, and 2) in instances where a chemical will not be added to the NDSL, Environment Canada and Health Canada will identify data elements for which testing will be required of the notifier.

STEP 7: Environment Canada informs CEPA notifier and the US EPA of decision. In addition, Environment Canada provides the US EPA with the Environment Canada/Health Canada assessment.

STEP 8: Environment Canada sends the US EPA all subsequent health and safety data generated after the receipt of the CEPA application referenced in STEP 1.

CONDITIONS

1. This is a case by case procedure. Either party may, without restriction, determine that particular PMN submissions are not appropriate for this procedure.

2. The TSCA PMN# is the main reference identifier for all requests, files and correspondence. Environment Canada will also assign a CE identifier number to the application received from the CEPA notifier.

3. The process is voluntary and not subject to rigorous timeliness for implementation, although all parties recognise the need for a timely and efficient process.

4. Resource requirements cannot be estimated until the process is functional. Excessive resource requirements may result in re-examination of the process.

5. Frequent refusal by any party to abide by the informal agreement would result in a re-examination of the process.

6. Confidential Business Information in EPA PMNs submitted to Environment Canada and Health Canada through this agreement would be protected under Canadian law.

7. This informal agreement between EPA, Environment Canada and Health Canada will be operational for an initial 2-year trial period which will include a review of the value of the program after 1 year to determine if the trial period should be extended. Industry input will also be sought at this time. If the process works, the medium term goal would be for an intergovernmental exchange on a more formal basis.

ACTION ITEM DIAGRAM

	CEPA NOTIFIER	US PMN FILER	ENVIRONMENT CANADA	US EPA
STEP 1.	Submits Application to Environment Canada (see address below) New Substance Div. Environment Canada Ottawa, Ontario K1AOH3	Cosigns Authorisation With CEPA Notifier		
STEP 2.			Sends Acknowledgement letter to CEPA Notifier with CE# .cc to US PMN filer .cc to US EPA (see address below) Document Control Office/7407 Office of Pollution Prevention and Toxics US EPA 401 M St. SW G-099 Washington, DC 20460	Opens Docket
STEP 3.	Requests US PMN Filer to Authorise US EPA to Send Review Notes to Environment Canada			
STEP 4.		.Authorises US EPA to Send Review Notes to Environment Canada .Submits Any New Data to US EPA		
STEP 5.				US EPA Sends Review Notes to Environ-ment Canada
STEP 6.			Makes Decision re Addition to NDSL	
STEP 7.			Informs CEPA Notifier & US EPA of Decision	
STEP 8.			Subsequent New Data Sent to US EPA	

Pilot for Sharing New Chemicals Information
Between United States and Canada

Dear Sir/Madam:

Below is the documentation/and or data being sent to Environment Canada by the CEPA modifier and PMN filer as part of a pilot project in shared hazard data and risk assessments between the United States and Canada:

Signiture and Title of
Authorised Official _____Date_____

Company Name _____

Compay Address _____

_____

_____

Subject chemical substance identifier:	PMN #
Items Included:	
1. US TSCA PMN	
2. US TSCA Notice of Commencement (NOC)	
3. Any TSCA 5(e) or §8(e) Compliance Documentation	
4. Any US Generated Letters of Concern (LOCs)	
5. All New Data on the Chemical Generated since the Original PMN was Filed	
6. Authorisation by Both CEPA Notifier and US PMN Filer Allowing Environment Canada and Health Canada to Discuss Submissions and Exchange Information with US EPA	

Address: New Substance Div.
Environment Canada
Ottawa, Ontario K1AOH3

Pilot for Sharing New Chemicals Information
Between United States and Canada

Dear Sir/Madam:

Below is the documentation/and or data being sent to the US EPA by the PMN filer as part of a pilot project in shared hazard data and risk assessments between the United States and Canada:

Signiture and Title of
Authorised Official _____Date_____

Company Name _____

Compay Address _____

_____

_____

Subject chemical substance identifiers:	CE # PMN #
Items Included:	
1. PMN Filer's Authorisation Letter Allowing US EPA to Send/Discuss CBI re PMN Submission with EC	
2. Copy of EC Acknowledgment Letter	
3. Data Generated Since PMN Submission	
4. Other	

ANNEX 4

OVERVIEW OF RESPONSES TO THE SURVEY

TO IDENTIFY POSSIBILITIES FOR SHARING INFORMATION ABOUT NEW INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT

Introduction

In October 1995, a questionnaire (Annex 6) was circulated to OECD Member countries to gather background information about the systems of new industrial chemical notification and assessment for each country.

The questionnaire was designed to help with the planning and conduct of the Workshop by identifying existing sources and types of information on new industrial chemical notification and assessments and finding out about current and potential mechanisms for sharing information between countries, including existing co-operative work.

The results of the questionnaire survey have been collected together in tabular form in Annex 5.

This annex (Annex 4) is intended to give an overview of the responses to each of the questions.

Information is organised in the following sections.

A: General Information about Notification and Assessment Schemes
B: Types of Information for sharing on New industrial Chemicals
C: Inter-Country Co-operation
D: Identification of Industrial Chemicals Being Notified and Assessed
E: Outcomes from Notification and Assessment
F: Inventory or List of Chemicals

Summaries of the new industrial chemical schemes of Australia, Canada, Japan, New Zealand, the United States and the European Union are given in Annex 2. Notifiers intending to make notification to any of the schemes included in this publication are however advised to make direct contact with the specific scheme to discuss and identify particular notification requirements.

OVERVIEW OF RESPONSES TO QUESTIONNAIRE

A) General information about notification and assessment schemes

Table 1: Questions 1 & 10

Do you have legislation covering the introduction of new industrial chemicals and when did your notification and assessment system for new chemicals come into operation?

All responding countries have current legislation. The earliest (Japan's MHW/MITI scheme) commenced operation in 1973 and the most recent (Canadian) commenced in 1994.

In the European Union, the appropriate Council Directive is enacted into the legislation of Member States. Specific legislation of responding EU countries is given in a footnote to the table. The application of the EU scheme will extend to the non-EU countries Norway, Iceland and Liechtenstein through their membership in the European Economic Area.

Both New Zealand and Switzerland are currently changing their legislative arrangements. New Zealand is introducing an integrated system for controlling all hazardous substances and Switzerland is harmonizing its system with that of the EU.

Table 2: Question 2

What areas are assessed?

The assessment schemes of Australia, the US and the EU cover occupational health and safety, public health and environmental effects. The Swiss scheme assesses environmental effects only, while Canada covers public health and environmental effects but not OHS. Japan's ML scheme covers OHS, and its MITI/MHW scheme covers public health and environmental pollution related to persistent chemicals with potential adverse health effects.

Table 3: Question 3

When are new chemicals required to be notified/assessed?

For substances that meet the definition of "new industrial chemical", which can vary from country to country, the majority of countries require notification and assessment prior to manufacture or import into that country. The EU Member States assess prior to marketing.

Table 4: Question 4

How are the terms "new chemical" and "existing chemical" defined in your system?

Within the definitions of substances covered by each country's scheme, new chemicals are most commonly distinguished from existing ones by not being included on that country's list or inventory.

Table 5: Question 5

Is a formal written assessment produced and, if so, what is its format?

Countries vary in whether or not a formal assessment is produced at all, irrespective of whether it is public or confidential. Where reports are prepared, the areas covered include environmental and health assessments (Australia, Canada) and risk assessment (EU, Switzerland). In the US no formal public dossier is compiled, but informal reports are retained on in-house confidential files. The EU risk assessment is prepared in accordance with the principles laid down in Directive 93/67/EEC and following the Technical Guidance Document for the Risk Assessment of New Substances.

Table 6: Question 6

When a new chemical is notified/assessed, is data required on the pure chemical or the commercial grade as marketed?

Countries are fairly evenly divided on whether they require data on the pure chemical or the commercial grade as marketed. Canada, Japan and the US focus on the pure chemical, whereas Australia and the EU focus on the commercial grade as marketed. The EU system specifies that all testing is carried out on the substance as it is produced, including impurities and any additives for maintaining stability.

Table 7: Questions 7 & 8

Under what circumstances are chemicals notified more than once and does the assessment process vary when this happens?

In all countries, chemicals have the potential to be notified more than once. Circumstances include when there is a second company introducing before listing on an Inventory or announcement or if there is a significant use. In a number of countries arrangements are in place to enable sharing of data (e.g. Canada and the EU) and avoid duplication of assessment. Canada and the EU stated that assessment would only be repeated if additional information was provided.

Table 8: Question 9

If new chemicals can be notified more than once in your system, is the commercial advantage of the first notifier protected in any way?

In situations where chemicals are notified more than once the commercial advantage of the first notifier is usually protected in some way. The entire notification process must usually be repeated by a second notifier indefinitely (Switzerland), in the period preceding full listing on the inventory (5 years) (Australia, Canada, Japan [ML]), or for a set period (EU).

In the US information claimed by the first notifiers as Confidential Business Information (CBI) is protected. In the EU an exemption from data sharing is given for a maximum of one year otherwise. Notifiers are free to reach a commercial agreement on the sharing of data.

Table 9: Question 11

Approximately how many chemicals are notified/assessed per year?

The number of chemicals notified/assessed per year varies between countries, from 60 for Switzerland up to 2465 for the US.

B) Types of information for sharing on new industrial chemicals

Table 10: Questions 12 & 13

Is the information about "Fact that specific chemical has been notified" accessible and to whom is it available?

The fact that a substance has been notified is accessible in all countries, although the specific chemical identity is often confidential. Different mechanisms are used to convey this information e.g. in the US a PMN is published in the Federal Register at the outset of the notification, whereas in the EU the substances which have been assessed are listed in ELINCS. In some cases unique notification numbers are used to overcome confidentiality restrictions.

Table 11: **Questions 12 & 13**

Is the information –"Fact that assessment has taken place" accessible and to whom is it available?

The fact that an assessment has taken place is accessible in the majority of countries. Various barriers to accessing this information exist in several countries. The question is not relevant to the current New Zealand system, where assessment does not occur. Confidentiality of the specific chemical identification is an important factor limiting access to this information.

Table 12: **Questions 12 & 13**

Is the information – "Identification of notifying company" accessible and to whom is it available?

The identification of the notifying company is available in approximately half the surveyed countries. In others it is considered confidential or can be so. In the EU it is not routinely published but not considered confidential.

Table 13: **Questions 12 & 13**

Is the information – "Type of assessment that has been done" accessible and to whom is it available?

In some countries different requirements exist for chemicals introduced in low volume or specific uses. The type or extent of assessment carried out for each chemical is accessible by governments in Australia, Japan (ML), Switzerland and the EU, and publicly available in Australia, Japan (ML) and Switzerland..

Table 14: **Questions 12 & 13**

Is the information – "Approval or rejection" accessible and to whom is it available?

Most countries do not use the terms "approval" or "rejection" in relation to new industrial chemicals assessment and they vary in the type of controls or conditions which are applied. Some schemes focus on providing information, others on controls for the chemical in question.

Table 15: **Questions 12 & 13**

Is the information "Hazard classification" accessible and to whom is it available?

The hazard classification of the substance is publicly available information in the majority of countries.

Table 16: **Questions 12 & 13**

Is the information –"Control action" accessible and to whom is it available?

The control action taken as a result of notification and assessment is publicly available in the majority of countries. In the EU it can only be released beyond competent authorities and the Commission with the notifier's approval.

Table 17: **Questions 12 & 13**

Is the information – "Further testing" accessible and to whom is it available?

The requirement for further testing is a possible outcome in most countries, and is publicly accessible in a number of countries including Japan (MHW/MITI), Switzerland and the US (in a SNUR notice).

Table 18: **Questions 12 & 13**

Is the information – "Availability of approved MSDS" accessible and to whom is it available?

The MSDS is associated with the assessment process in several countries, but its preparation is usually the responsibility of the notifier.

Table 19: **Questions 12 & 13**

Is the information – "Copy of assessment report" accessible and to whom is it available?

It is not common to be able to access a copy of the assessment report, and a formal report is often not published. Exceptions to this are in Australia and the EU (among competent authorities).

Table 20: **Questions 12 & 13**

Is the information –"Copy of data submitted accessible" and to whom is it available?

Data submitted during the course of the assessment is not commonly released. In the US, sanitised health and safety studies are released; the data in the EU is available to other EU competent authorities and the European Commission.

Questions 12 & 13

Is the any other information accessible and to whom is it available?

In the EU, the Trade Name, EU number and IUPAC name (if the chemical is classed as dangerous) are published.

Table 21: **Questions 14 & 15**

What information on new chemicals would be useful to have publicly available and, if this was done, do you foresee any problems with confidentiality?

A range of information was considered by countries to be potentially useful to share more widely, including specific identity, use, hazard classification and safety data, toxicity and eco-toxicity, MSDS and physico-chemical properties. Most countries envisaged confidentiality problems with the release of some of the desired information particularly information that notifiers considered linked their company to a specific chemical. Ownership of test data is often claimed.

C) Inter-country co-operation

Table 22: **Question 16**

Are there any concessions for notification/assessment in your legislation if a new chemical has previously been in use in another country?

Most countries do not currently provide concessions for companies notifying chemicals in more than one country. The exceptions are the formal arrangements between EU countries and Canadian concessions (via their NDSL) for chemicals on the US TSCA Inventory. The Australian legislation has provisions for such arrangements but are dependent on access to an assessment report from the other country or on recognised overseas inventories where substantial use experience is available.

Table 23: **Question 17**

Are there ways in which you make use of the assessments of another country?

The use of other assessment information from other countries varies greatly between countries, ranging from use of published information in the literature, information on the status on overseas inventories, to formal and routine exchange of risk assessments and notification data between EU countries. With the exception of the EU and pilot-exchange programs between Australia and Germany and Canada-US there is little exchange of assessments.

Table 24: **Question 18**

Do you have any comparative statistics on the origin of the chemicals being notified and assessed in your country?

Formal statistics supplied by the EU and Switzerland indicate that these countries, the US and Japan are large producers of new chemicals. Some other countries do not hold detailed statistics, but are aware of the ratio of imported and locally produced new chemicals among their notifications.

Table: 25 **Question 19**

If you have an existing co-operative system with other countries on sharing/exchanging information, please describe how it works.

The major existing co-operative scheme for sharing and exchanging information is between EU countries. Canada and the US have developed an information-sharing pilot scheme and Australia has a pilot scheme with Germany.

D) Identification of industrial chemicals being notified or assessed

Table 26: **Question 20**

What information must be provided by the notifier and where is that information reported/stored after the notification process?

– "Chemical Abstracts Service (CAS) Number"

Chemical Abstracts Service (CAS) numbers are used in one way or another by all countries as a form of identification. The notifier is required to supply them in most schemes, and they are commonly reported on inventories if not confidential. In the EU, CAS numbers are included in Annex 1 to Directive 67/548/EEC if classification is agreed at community level.

Table 27: Question 20

What information must be provided by the notifier and where is that information reported/stored after the notification process?

– "Chemical name"

The chemical name is also an important identifier in all schemes. It is required to be supplied by the notifier (sometimes specifically the CAS or IUPAC form), is used in internal reports in all countries, and may also be used in published data such as inventories, official gazettes and classification lists, if not claimed confidential by the notifier.

Table 28: Question 20

What information must be provided by the notifier and where is that information reported/stored after the notification process?

– "Structural formula"

Structural formulae are required from notifiers (if available) by all countries except New Zealand. They are included on the inventories of both Japanese schemes, on the EU Annex 1 if classified as dangerous, and in Australia's report unless confidential.

Table 29: Question 20

What information must be provided by the notifier and where is that information reported/stored after the notification process?

– "Molecular formula"

The molecular formula must be supplied by notifiers in all countries except Canada and New Zealand. It is publicly available in Australia, Japan (MHW/MITI) and the United States, if not claimed confidential.

Table 30: Question 20

What information must be provided by the notifier and where is that information reported/stored after the notification process?

– "Unique notification number for your country"

Other unique notification numbers are assigned in some but not all countries as administrative aids. They are reported in the official gazettes of Australia and both Japanese schemes and included in the European List of Notified (New) Chemical Substances (ELINCS).

Table 31: **Question 20**

What information must be provided by the notifier and where is that information reported/stored after the notification process?

– "Trade name"

The trade name must be supplied by the notifier in all schemes except that of Japan (MHW/MITI). It is reported in the inventories of the EU and Switzerland and in Australia's Chemical Gazette and published report.

Table 32: **Question 20**

What information must be provided by the notifier and where is that information reported/stored after the notification process?

– "Spectral analysis"

Spectral analysis is required from notifiers in several countries but is not published in any. Spectral data are crucial for proving compositional identity, as is required for data sharing to be agreed.

Table 33: **Question 20**

What information must be provided by the notifier and where is that information reported/stored after the notification process?

– "Nature and proportion of impurities"

The nature and proportion of impurities must be supplied by notifiers in all countries except New Zealand, but is only publicly available in Australia (if not considered by notifiers to be confidential).

Table 34: **Question 20**

What information must be provided by the notifier and where is that information reported/stored after the notification process?

– "Other"

The following types of information associated with identification were mentioned in responses: classification and labeling proposal (New Zealand, EU), use of the chemical (Japan), appearance, quantity to be introduced and (for Canada) information prescribed in regulation.

Table 35: Question 21

Which of the types of identification information do you use most commonly to pinpoint the identity of a chemical?

The CAS number, chemical name and structural formulae are considered the most crucial to the identification of a chemical. Molecular formulae, trade name and unique identification number were also mentioned in responses, but less frequently.

Table 36: Question 22

Are there any circumstances when any of this information is treated as confidential? Please indicate which items may be confidential.

The schemes have differing rules on items of identification information which can be exempted from release. In some countries all identifying information (US) or all but the trade name (Australia, Switzerland) can be kept confidential in some circumstances. In the EU and Canada there are some restrictions on withholding or masking the chemical name. The Japanese schemes allow little information to be withheld. The situation is more complex in New Zealand because it covers preparations as well as chemicals.

Table 37: Question 23

How do you identify complex mixtures and differentiate between one complex mixture and another?

The main approach taken to the issue of complex mixtures is to identify and characterise individual chemicals if possible, and otherwise to describe the mixture via the main components or via the starting products and manufacturing process. The Chemical Abstracts Service (CAS) rules are mentioned as being influential in Canada and the US. In the EU, difficult cases can be referred to the European Chemicals Bureau (ECB).

E) Outcomes from notification and assessment

Table 38: Question 24

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

– "Approval or rejection"

The terms "approval" or "rejection" are not used to characterise the regulatory outcome of the new industrial chemical notification and assessment scheme surveyed. For example, the US TSCA New Chemicals Program was characterised as a screening program in which some chemicals are regulated and others not, rather than a registration program under which chemicals are approved. Inventory listing most often signals fulfilment of the regulatory requirements.

Table 39: Question 24

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

– "Request for further information from the notifier"

Further information may be requested from the notifier in most countries. However, only in the US is this done publicly, in the form of a Significant New Use Rule (SNUR) Notice.

Table 40: Question 24

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

– "Specific control on the chemical"

Specific controls may be recommended or applied in all schemes as an outcome of the assessment, except in Japan (MHW/MIT). Such an outcome is made public in Australia, Canada, Japan (ML) and the US.

Table 41: **Question 24**

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

– "Hazard classification of the chemical"

Hazard classification is a possible outcome in many countries and is published in Australia, Japan and the EU.

Table 42: **Question 24**

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

–"Risk assessment"

Risk assessments are possible outcomes in all countries except Japan, but are only published by Australia. Several countries report the outcome of the risk assessment in internal reports. In the EU, risk assessments are shared among competent authorities and referred to appropriate regulatory authorities for action.

Table 43: **Question 24**

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

– "Production of an agreed Material Safety Data Sheet (MSDS)"

MSDS are provided as part of the notification and assessment information by companies in many countries. They may be a formally agreed outcome of assessment in Australia, New Zealand, Switzerland and the US.

Table 44: **Question 24**

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

– "Requirement for follow-up or secondary notification"

Follow-up or secondary notification is a possibility in all countries except Japan. In Canada, this is required under control options or if any new information on toxicity is reported. In the EU, secondary notification may be required as a result of risk assessment or as a higher tonnage is reached. In the US and Australia, secondary notification requirements may be published.

Table 45: Question 25

Is the public availability of the outcome of notification/assessment affected by confidentiality provisions?

In most countries the availability of the outcome of the notification and assessment is not directly affected by confidentiality provisions, but may be indirectly affected through the confidentiality of identity or other information related to the notification and by the fact that assessment reports are not published.

Table 46: Question 26

Is a Material Safety Data Sheet (MSDS) or label required to be submitted along with the notification?

An MSDS is required to be submitted in Australia, Canada and Switzerland, but is compulsory in the EU only for chemicals classified as hazardous. Labels are only required in Australia and the EU. In the US, the supply of both items is encouraged but is not compulsory.

Table 47: Questions 27 & 28

Do you have a formal definition of "hazard" and "risk" and are they clearly distinguished in your assessment process?

Most countries consider that "hazard" and "risk" are distinguished in the assessment process. The EU and Australia (health hazard) and Canada ("toxic") have definitions in their new chemicals legislation.

F) Inventory or list of chemicals

Table 48: Questions 29 & 30

Do you have an inventory of chemicals and if so what is it called?

All responding countries have an inventory of chemicals. The EU Member States use the common EINECS and ELINCS inventories, but some also have national inventories.

Table 49: Question 31

What is the purpose of your inventory?

The most common purpose of inventories is to distinguish new from existing chemicals and to make it clear which chemicals must be notified.

Table 50: Question 32

How can your chemicals inventory be accessed?

Many inventories are available as publications or on CD-ROM and other computer media, e.g. tape and PC diskette, on-line services.

Table 51: Question 33

When are new chemicals added to your inventory after assessment?

All countries have different time periods or provisions before a chemical may be added onto the inventory. Most are added periodically. For example, the US adds a chemical after the manufacturer has issued a Notice of Commencement to the EPA. In the EU, chemicals are not added to EINECS following assessment but to a separate ELINCS Inventory.

Table 52: Questions 34 & 35

For new chemicals which are assessed, is the fact that assessment has occurred noted on the inventory? Is listing on the inventory affected by confidentiality provisions?

The fact that an assessment has occurred is noted on the Canadian DSL and on the Japanese inventories. Inclusion of a new chemical on the US TSCA inventory, the Australian AIC, and ELINCS indicates that the chemical has been assessed. Listing is affected by confidentiality provisions in all countries except Japan and New Zealand.

ANNEX 5

TABULATED SUMMARY OF THE SURVEY TO IDENTIFY POSSIBILITIES FOR SHARING INFORMATION ABOUT NEW INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT

A) GENERAL INFORMATION

TABLE 1:

Questions 1 and 10
Do you have legislation covering the introduction of new industrial chemicals and when did your notification and assessment system for new chemicals come into operation?

Country	Name of current legislation	Date system began operation
Australia	Industrial Chemicals (Notification and Assessment Act) 1989 as amended.[1]	17/7/90
Canada	Canadian Environmental Protection Act (New Substances Notification Regulations) (Statute 1/6/88 and Regulations 1/7/94)	1/7/94
Japan (ML)	Industrial Safety and Health Law (1/7/77)	30/6/79
Japan (MHW/MITI)	Law Concerning the Examination and Regulation of Manufacture etc. of Chemical Substances (16/10/73)	16/10/73
New Zealand[4]	Toxic Substances Act 1979	1/8/83
Switzerland[5]	Ordinance relating to Environmentally Hazardous Substances (9/6/86)	1/1/88
United States	The Toxic Substances Control Act (TSCA) 15 USC 2601(October 1976) Section 5.	1/7/79
European Union[2]	Council Directive 92/32/EEC amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification packaging and labeling of dangerous substances.[3]	18/9/81

PLEASE NOTE THAT FOOTNOTES FOR THIS TABLE ARE ON FOLLOWING PAGE

FOOTNOTES FOR TABLE 1.

1 Most recent amendment made in 1992.

2 Norway, Liechtenstein and Iceland will become part of the EU system through their membership of the European Economic Area once they have introduced appropriate legislation.

3 The European Directive is enacted by the legislation of each Member State; e.g.:

Denmark	Statutory Order No. 831 on Notification of New Substances (15/10/93)
Germany	Gesetz zum Schutz vor gefährlichen Stoffen (Chemikaliengesetz - ChemG) (1/8/94)
Ireland	S.1 77 of 1994 (7/4/94)
Netherlands	Chemical Substances Act (1985)
Spain	R.D. 363/95 Notification on New Chemical, Classification, Packing, and Labeling of Dangerous Substances (5/6/95)
Sweden	The National Chemicals Inspectorate Regulations on New Chemical Substances (1/1/95)
UK	The Notification of New Substances Regulations 1993

4 New Zealand is in the process of introducing new legislation that will significantly change the arrangements for the control of chemicals. The Hazardous Substances and New Organisms (HSNO) Act, which integrates management of all hazardous substances into a single framework, was passed on 23 May 1996. However, the HSNO Act will not come into effect until the associated regulations have been prepared, which is expected to take 12-15 months. The summary of the NZ scheme included in Annex 2 of this document refers to the new scheme, and not to the one on which the survey replies are based.

5 Switzerland will implement changes to this legislation and to the separate Law Relating to Toxic Substances, aimed at harmonizing its scheme with that of the EU.

TABLE 2:

Question 2
What areas are assessed?

Country	Occupational health & safety	Environmental effects	Public health	Other
Australia	Yes	Yes	Yes	No
Canada	No	Yes	Yes	No
Japan (ML)	Yes	No	No	No
Japan (MHW/MITI)	No	No	Yes	Yes Environmental pollution[1]
New Zealand[3]	No	No	No	No
Switzerland	No[2]	Yes	No[2]	No
United States	Yes	Yes	Yes	No
European Union	Yes	Yes	Yes	No

1 Environmental pollution by chemical substances which have persistence and may be harmful to human health.

2 Assessment of chemicals for occupational and public health in Switzerland is under the Federal Law on the Trade in Toxic Substances, which is not covered in this document. New and Existing Chemicals are not distinguished under this law, preparations are included, and there is no requirement to produce assessment reports.

3 In general assessment not carried out, but extra information on e.g. toxicity can be requested if necessary.

TABLE 3:

Question 3

When are new industrial chemicals required to be notified and assessed?

Country	When is notification/assessment required for a new industrial chemical?
Australia	Prior to manufacture or import.
Canada	Prior to manufacture or import.
Japan (ML)	Prior to manufacture or import.
Japan (MHW/MITI)	Prior to manufacture or import.
New Zealand[2]	Prior to manufacture, preparation, packing or import of a toxic substance bearing a name (chemical, common or trade name) that has not previously been distributed in New Zealand.
Switzerland	Before supplying them as substances or as components of a product or article. Some exemptions are food additives, pharmaceuticals, intermediates, substances for research, and higher polymers.
United States	Prior to manufacture.[1]
European Union	Prior to being placed on the EU market (including import) in quantities >10 kg/ year.

1 A pre-manufacture notice (PMN) must be submitted 90 days before commencing commercial manufacture. The EPA can extend the review period a further 90 days.

2 This covers new product names and new formulations as well as new chemicals.

TABLE 4:

Question 4
How are the terms "new chemical" and "existing chemical" defined in your system?

Country	Definition of “new” chemicals and “existing” chemicals
Australia	Existing chemicals are those on the Australian Inventory of Chemical Substances (AICS) (i.e. those in use in Australia between 1/12/77 and 16/7/90). New chemicals are defined as those not listed on the AICS.
Canada	New substances are those not included on the Domestic Substances List (DSL). A chemical substance is not defined. Rather it is a substance not meeting the definitions of polymer or product of biotechnology. All three classes of substance require notification (biotechnology pending).
Japan (ML)	Existing chemicals are “elements, chemicals obtained as natural resources, radioactive chemicals and those produced or imported by 29/6/79 and whose names have been made public by the Labour Minister”. New chemicals are defined as “chemicals other than existing chemicals”.
Japan (MHW/MITI)	Existing chemicals are those manufactured or imported by 16/10/73 and made public by the Minister of International Trade and Industry. New chemicals are those which are not existing chemical substances. New polymers made from existing monomers are new chemical substances.
New Zealand	These terms are not specifically used, as the legislation refers to whether or not a particular chemical/product has previously been distributed under a particular description.
Switzerland	Existing substances appear on the "Toxic List 1" of 1985 or EINECS, or have been supplied in quantities > 500 kg from 1975 to 1985. All others are new.
United States	A new chemical substance is any chemical not included on the TSCA Inventory of Chemical Substances. New chemical substances submitted as PMN's are added to the Inventory only after the 90-day review period expires and the manufacturer submits a Notice of Commencement (NOC) to EPA.
European Union	Existing chemicals are those listed on EINECS (i.e. those on the EC market between 1/1/71 and 18/9/81). New chemical substances are those not listed on EINECS. New polymers contain >2% weight of a new monomer.

TABLE 5:

Question 5

Is a formal written assessment produced and if so what is its format?

Country	Format of written assessment
Australia	A set format including chemical identity, properties, purity, use, occupational, public and environmental exposure, toxicology, environmental hazard and effects, public and OH&S effects, recommendations and MSDS.
Canada	Contains an environmental assessment prepared by Environment Canada and a human health evaluation prepared by Health Canada. The report indicates data and other factors used in the evaluation and the decision taken with respect to a suspicion of "toxicity", as the latter term is defined in the legislation.
Japan (ML)	No formal written assessment is produced.
Japan (MHW/MITI)	No formal written assessment is produced.
New Zealand	No.
Switzerland	Produced by notifier according to the Guide to self-supervision. Main points covered are identification of emission sources and environmentally relevant substance properties (hazard assessment) and calculation of PEC/PNEC ratio (risk assessment).
United States	No formal public dossier is compiled. Informal reports are retained on in-house confidential files. These informal reports assess chemistry, toxicology, occupational and environmental exposure, risk assessment, economic assessment and risk management.
European Union	A risk assessment is carried out on notified new substances and in accordance with the principles laid down in Directive 93/67/EEC, and following the Technical Guidance Document for the Risk Assessment of New Substances the RA is copied to the Competent Authorities (CAs) in other EU Member States as chapter 7 of the “Summary Notification Interchange Format” (SNIF)

TABLE 6:

Question 6

When a new chemical is notified/assessed, is data required on the pure chemical or the commercial grade as marketed?

Country	Pure chemical	Commercial grade as marketed	Other
Australia	No	Yes	No
Canada	Yes	No	No
Japan (ML)	Yes	No	No
Japan (MHW/MITI)	Yes[1]	Yes[2]	No
New Zealand[5]	Yes	Yes	Formulation
Switzerland	No	Yes	No
United States	Yes[3]	No	No
European Union	No	Yes[4]	No

1 MITI requires decomposability test and accumulation test on the pure chemical.

2 The commercial grade is accepted by the MHW for toxicity testing.

3 No test data is required to be produced, but when testing is recommended under a consent order or ban, the pure form is recommended.

4 All testing is carried out on the substance as it is produced including impurities and any additives necessary for maintaining the stability of the substance minus any separable solvents which may be removed.

5 Assessment is not carried out; the information required for notification may include the pure or commercial chemical, or the formulation mixture, depending on what is being notified.

TABLE 7:

Questions 7 and 8

Under what circumstances are chemicals notified more than once and does the assessment process vary when this happens?

Country	Under what circumstances and how is the assessment process varied?
Australia	A new chemical is not listed on AICS until 5 years after the issue of an assessment certificate. Other manufacturers or importers are also required to notify the chemical to introduce it during this period. Process does not vary, although first notifier may allow access to submitted data. Legislative changes are being considered to enable the sharing of data.
Canada	All substances not listed on the DSL must be notified, irrespective of whether the chemical has previously been notified. A substance is added to DSL if: i) a full data package is provided ii) assessment has not resulted in conditions being published in the Canada Gazette iii) a prescribed volume of manufacture has been exceeded. A substance is reassessed if new information is provided in the package or the evaluator determines new considerations apply. Notifiers may elect to share data.
Japan (ML)	In the case where a chemical is notified but the name has not been announced. For example, if the amount produced or imported is < 100 kg/ year, it would not be announced and notification would be required. No variation in assessment.
Japan (MHW/MITI)	In the case of another notifier submitting a notification before the name of the chemical has been announced for the first notification. No variation in assessment.
New Zealand	This occurs frequently because of the nature of the legislation, where different names of a chemical, different formulations, and different suppliers all trigger notification. No variation in process.
Switzerland	When the substance is supplied by more than one company, each has to notify. There is an exemption if one company is designated as sole representative. No variation in assessment process.
United States	TSCA requires 90-day advance notice before manufacture or import of a chemical, new or existing, for any activity that the EPA designates as a "significant new use" (SNUR - Significant New Use Rule). No variation in assessment process.
European Union	i) If the substance is manufactured and placed on the market in the EU by more than one EU manufacturer. ii) If the substance is imported into the EU by more than one importer (not covered by the “sole representative” facility). The risk assessment would only be repeated if additional information was provided. Mechanisms exist for data sharing between notifiers.

TABLE 8:

Question 9

If new chemicals can be notified more than once in your system, is the commercial advantage of the first notifier protected in any way?

Country	How is the commercial advantage of the first notifier protected when the substance is notified more than once?
Australia	The effect of the Act is to give the holder of an assessment certificate an exclusive right for five years to manufacture or import the chemical. Subsequent persons wishing to introduce the chemical in that time must also submit a full data package.
Canada	Until listing on the DSL, requirements are the same for all notifiers. The notifier responsible for the DSL listing obtains no special advantage for doing so. May request listing under "masked" name; however, strict criteria apply for acceptance.
Japan (ML)	Until the name of the chemical has been made public by the Labour Minister, requirements are the same for all notifiers.
Japan (MHW/MITI)	No protection.
New Zealand	No protection for industrial chemicals, although there is for pesticides. This is less important in a system that has notification but not assessment.
Switzerland	A second notifier must provide a full data set unless the first notifier permits use of their data.
United States	Information claimed by the first notifier as Confidential Business Information(CBI) is protected. A second notifier will be informed if the substance is on the Inventory and if there are any restrictions under a Significant New Use Rule (SNUR).
European Union	The first notifier may request that the disclosure of the company's name and address to potential notifiers for the purpose of data sharing be exempted for a maximum period of one year. Notifiers are free to reach a commercial agreement on the "sharing of data" (Article 15 of Directive 92/32/EEC)

TABLE 9:

Question 11

Approximately how many chemicals are notified/assessed per year?

Country	Approximate number of notifications/assessments
Australia	168 (for 1994-95) 26 Standard, 47 Limited, 7 Polymers of low concern, 60 Commercial Evaluation and 28 Low Volume
Canada	300-400
Japan (ML)	600
Japan (MHW/MITI)	250
New Zealand	Usually 200, but high at present in anticipation of new system being introduced (currently 2000+)
Switzerland	Approximately 60 per year. Total from 1988 to 1995 is about 500.
United States	2645 chemicals from 1/10/93 to 30/9/94. 2185 Pre-manufacture notifications, 299 Low Volume, 17 Test Market exemptions and 144 Polymer exemptions.
European Union	400 (Total EU notifications)

B) TYPES OF INFORMATION FOR SHARING ON NEW INDUSTRIAL CHEMICALS

Please note: N/A indicates "not applicable"

TABLE 10:

Questions 12 and 13
Is the information accessible and to whom is it available?

"Fact that specific chemical has been notified"

Country	Accessible	By other governments	By original notifier only	By prospective notifiers	By others (public)	Barriers to sharing
Australia	✔	✔	No	✔	✔	Chemical identity may be concealed
Canada	✔	✔	No	✔[1]	✔	Only accessible when 1) added to the DSL or 2) action is taken
Japan (ML)	✔	✔	No	✔	✔	Not accessible before the name is announced (about 1 year)
Japan (MHW/MITI)	✔	✔	No	✔	✔	Not accessible before the name is announced
New Zealand[4]	✔	✔	No	No	No	Accessibility of information
Switzerland	✔	✔	No	✔	✔	Chemical identity may be concealed
United States	✔[3]	✔[3]	No	✔[3]	✔[3]	Only accessible if notifier waives CBI rights
European Union	✔	✔	No	✔	(✔[2])	Confidential information available only to EU competent authorities

PLEASE NOTE THAT THE FOOTNOTES FOR THIS TABLE ARE ON THE FOLLOWING PAGE

1 In Canada notifiers must elect if they want to share information.

2 Trade name and IUPAC name.

3 The PMN published in the Federal Register makes some information available, including the generic chemical name (if the specific name is confidential), volume and company name.

4 In effect, the only information routinely available is the classification

TABLE 11:

Questions 12 and 13
Is the information accessible and to whom is it available?

"Fact that assessment has taken place"

Country	Accessible	By other governments	By original notifier only	By prospective notifiers	By others (public)	Barriers to sharing
Australia	✔	✔	No	✔	✔	None
Canada	✔	✔	No	✔	✔	Only accessible when 1) added to the DSL or 2) action is taken
Japan (ML)	✔	✔	No	✔	✔	None
Japan (MHW/MITI)	✔	✔	No	✔	✔	Not accessible before the name is announced
New Zealand	N/A for industrial chemicals	N/A	N/A	N/A	N/A	N/A
Switzerland	✔	✔	No	✔	✔	None
United States	✔	No[#]	✔	No	No	[#]Only accessible if notifier waives CBI rights
European Union	✔	✔	No	✔	✔	Confidential information available only to EU competent authorities

TABLE 12:

Questions 12 and 13
Is the information accessible and to whom is it available?

"Identification of notifying company"

Country	Accessible	By other governments	By original notifier only	By prospective notifiers	By others (public)	Barriers to sharing
Australia	✔	✔	No	✔	✔	The company must be identified but identity of the chemical may be concealed
Canada	No	No	No	No	No	Confidential
Japan (ML)	No	No	No	No	No	No comments
Japan (MHW/MITI)	No	No	No	No	No	No comments
New Zealand	No	No	No	No	No	Confidentiality
Switzerland	✔	✔	No	✔	✔	None
United States	✔[1]	✔[1]	No	✔[1]	✔[1]	Only accessible if notifier waives CBI rights
European Union	✔	✔	No	✔	(✔)	Not routinely published but not considered confidential.

1 The identification of the notifying company is published in the Federal Register with the PMN (if not confidential).

TABLE 13:

Questions 12 and 13
Is the information accessible and to whom is it available?

"Type of assessment that has been done"

Country	Accessible	By other governments	By original notifier only	By prospective notifiers	By others (public)	Barriers to sharing
Australia	✔	✔	No	✔	✔	None
Canada	No	No	No	No	No	Substance specific assessment is confidential. General information on the assessment process is public.
Japan (ML)	✔	✔	No	✔	✔	None
Japan (MHW/MITI)	No	No	No	No	No	No comments
New Zealand	N/A	N/A	N/A	N/A	N/A	N/A
Switzerland	✔	✔	No	✔	✔	None
United States	N/A[1]	N/A	N/A	N/A	N/A	N/A
European Union	✔	✔	No	✔	No	Confidential information available only to EU competent authorities

1 The type of assessment does not vary, only the degree to which the chemical is assessed. PMNs and Test Market Exemptions (TME) are published in the Federal Register, but Low Volume Exemptions (LVE) and Low Release/Low Exposure Exemptions (LOREX) are not published.

TABLE 14:

Questions 12 and 13
Is the information accessible and to whom is it available?

"Approval or rejection"

Country	Accessible	By other governments	By original notifier only	By prospective notifiers	By others (public)	Barriers to sharing
Australia	N/A[1]	N/A	N/A	N/A	N/A	N/A
Canada	N/A[1]	N/A	N/A	N/A	N/A	N/A
Japan (ML)	N/A	N/A	N/A	N/A	N/A	N/A
Japan (MHW/MITI)	N/A[2]	N/A	N/A	N/A	N/A	N/A
New Zealand	N/A	N/A	N/A	N/A	N/A	N/A
Switzerland	✔	✔	No	✔	✔	None
United States	N/A[3]	N/A	N/A	N/A	N/A	N/A
European Union	N/A	N/A	N/A	N/A	N/A	N/A

1 There is no formal rejection, only approval under specific conditions.

2 There is no formal rejection or approval.

3 There is no formal rejection, only approval with negotiated controls under a § 5(e) Order.

TABLE 15:

Questions 12 and 13
Is the information accessible and to whom is it available?

"Hazard classification"

Country	Accessible	By other governments	By original notifier only	By prospective notifiers	By others (public)	Barriers to sharing
Australia	✔	✔	No	✔	✔	None
Canada	N/A	N/A	N/A	N/A	N/A	N/A
Japan (ML)	✔	✔	No	✔	✔	None
Japan (MHW/MITI)	✔	✔	No	✔	✔	None
New Zealand	✔	✔	No	No?	No?	None?
Switzerland	✔	✔	No	✔	✔	None
United States	✔	✔	No	No	No	Only accessible if notifier waives CBI rights
European Union	✔	✔	No	✔	✔	None

TABLE 16:

Questions 12 and 13
Is the information accessible and to whom is it available?

"Control action"

Country	Accessible	By other governments	By original notifier only	By prospective notifiers	By others (public)	Barriers to sharing
Australia	✔	✔	No	✔	✔	None
Canada	✔	✔	No	✔	✔	None
Japan (ML)	✔	✔	No	✔	✔	None
Japan (MHW/MITI)	✔	✔	No	✔	✔	None
New Zealand	✔	✔	No	No?	No?	None?
Switzerland	✔	✔	No	✔	✔	None
United States	✔	✔[1]	No	✔[1]	✔[1]	Only accessible if notifier waives CBI rights
European Union	✔	✔	No	No	No	Can only be released beyond the CAs and the Commission with the notifiers approval.

1 The nature of the controls resulting from a § 5(e) Order may be released if requested, while those resulting from a SNUR is public information.

TABLE 17:

Questions 12 and 13
Is the information accessible and to whom is it available?

"Further testing"

Country	Accessible	By other governments	By original notifier only	By prospective notifiers	By others (public)	Barriers to sharing
Australia	N/A	N/A	N/A	N/A	N/A	No comments
Canada	✔	No	✔	No	No	Confidentiality
Japan (ML)	No	No	No	No	No	No comments
Japan (MHW/MITI)	✔	✔	No	✔	✔	None
New Zealand	N/A	N/A	N/A	N/A	N/A	N/A
Switzerland	✔	✔	No	✔	✔	None
United States	✔[1]	✔	No	✔	✔	Only accessible if notifier waives CBI rights
European Union	✔	✔	No	No	No	Can only be released beyond the CAs and the Commission with the notifiers approval.

1 Further testing requirements are made public in a SNUR notice, and further testing resulting from risk-based orders and exposure-based orders are also public (a sanitised version).

TABLE 18:

Questions 12 and 13
Is the information accessible and to whom is it available?

"Availability of approved MSDS"

Country	Accessible	By other governments	By original notifier only	By prospective notifiers	By others (public)	Barriers to sharing
Australia	✔	✔	No	✔	✔	None
Canada	N/A	N/A	N/A	N/A	N/A	N/A
Japan (ML)	No	No	No	No	No	No comments
Japan (MHW/MITI)	No	No	No	No	No	No comments
New Zealand[2]	✔	✔	No	No	No	Accessibility of information
Switzerland	✔	✔	No	✔	✔	None
United States	✔[1]	✔	No	✔	✔	MSDS is the responsibility of the notifier
European Union	No	No	✔	No	No	MSDS is the responsibility of the notifier and is not approved by the CAs.

1 Often a condition of approval of a PMN includes modifications to the MSDS.

2 Preparation of an MSDS is optional.

TABLE 19:

Questions 12 and 13
Is the information accessible and to whom is it available?

"Copy of assessment report"

Country	Accessible	By other governments	By original notifier only	By prospective notifiers	By others (public)	Barriers to sharing
Australia	✔	✔[1]	No	✔[1]	✔[1]	None
Canada	No	No	No	No	No	Confidentiality
Japan (ML)	No	No	No	No	No	No comments
Japan (MHW/MITI)	No	No	No	No	No	No comments
New Zealand	N/A	N/A	N/A	N/A	N/A	N/A
Switzerland	No	No	No	No	No	Report is written by the notifier. No obligation to provide to third parties.
United States	No	No	No	No	No	Not available even if claimed non-confidential information
European Union[2]	✔	✔	No	✔	No	Can only be released beyond the CAs and the Commission with the notifiers approval.

1 Three reports are prepared. The Assessment report contains confidential information and is available to the notifier only. The Full Public Report and Summary Report do not contain confidential information and are available to the public and prospective notifiers.

2 In Germany and the Netherlands non-confidential assessment information is available.

TABLE 20:

Questions 12 and 13
Is the information accessible and to whom is it available?

"Copy of data submitted"

Country	Accessible	By other governments	By original notifier only	By prospective notifiers	By others (public)	Barriers to sharing
Australia	No	No	✔	No	No	Confidentiality
Canada	No	No	No	No	No	Confidentiality
Japan (ML)	No	No	No	No	No	No comments
Japan (MHW/MITI)	No	No	No	No	No	No comments
New Zealand	N/A	N/A	N/A	N/A	N/A	N/A
Switzerland	No	No	✔	No	No	Confidentiality
United States	✔ Sanitized health and safety studies only	✔	No	✔	✔	Confidentiality: § 8(e) makes some information available
European Union	✔	✔	No	No	No	Can only be released beyond the CAs and the Commission with the notifiers approval.

Questions 12 and 13
Is the information accessible and to whom is it available?

"Other"

In the European Union, the trade name, EU number and IUPAC name (if the chemical is classed as dangerous) are published.

TABLE 21:

Questions 14 and 15

What information on new chemicals would be useful to have publicly available and if this was done, do you foresee any problems with confidentiality?

Country	Information useful to have publicly available	Problems with confidentiality
Australia	MSDS, CAS number, physico-chemical properties, hazard classification, use pattern	Yes
Canada	Chemical identity, use profile, assessment decision, action taken and data support for action taken and assessment decisions	Yes. Notifiers consider much of the information provided and the link of a chemical to their company to be confidential. They often claim ownership of test data.
Japan (ML)	General information and toxicity data	None
Japan (MHW/MITI)	All the information notified	Trade secrets
New Zealand	Hazards of the chemicals and first aid and safety instructions relating to the formulated product. Precautions to protect the environment e.g. no discharge to waterways	None if confidential information such as composition was not divulged
Norway	That information required in the EU Directive.	No experience in this area
Switzerland	Trade name, chemical name, structural formula, MSDS, hazard classification, control action and assessment report	Confidentiality of chemical name, structural formula and the assessment report
United States	All the information mentioned in Q12	Yes, under the current US law
European Union (Member States' views)	Classification and labeling, MSDS, risk assessment (non-confidential), recommendations for safe use, chemical identity, trade name, notification number, physico-chemical and eco-toxicological properties, recommendations.	Yes. Industry is concerned with confidentiality and in some cases think that even ELINCS contains commercially valuable information. Chemical identity, especially for substances not classified.

C) INTER-COUNTRY CO-OPERATION

TABLE 22:

Question 16

Are there any concessions for notification/assessment in your legislation if a new chemical has previously been in use in another country?

Country	What concessions are available for new chemicals that have been used in another country?
Australia	A foreign scheme may be declared as an "Approved Foreign Scheme" by the Minister if certain criteria are met. Also, some information requirements may be waived when a chemical is listed on a "Recognised Overseas Inventory". The Director must be satisfied that the exempt information is sufficient to meet the requirements of the Australian scheme.
Canada	The Non-Domestic Substances List (NDSL) identifies substances for which information requirements are reduced, although notification is still required. This is primarily related to the US TSCA Inventory.
Japan (ML)	There are no concessions.
Japan (MHW/MITI)	There are no concessions.
New Zealand	There are no concessions.
Switzerland	There are no concessions.
United States	No concessions at this time.
European Union	A new chemical notified and placed on the EU market by an EU manufacturer or EU-based importer does not need to be notified in other Member States.

TABLE 23:

Question 17

Are there ways in which you make use of the assessments of another country?

Country	Ways of making use of assessments of other countries
Australia	Australia has an informal agreement with the German assessment authorities to compare requirements for information used in the assessment of new chemicals (since early 1995).
Canada	Using public information. The notification history in the US (PMN) is determined, including type of controls. ELINCS status is also checked. See also Table 22.
Japan (ML)	Assessments of other countries may be used with the approval of the assessments committee.
Japan (MHW/MITI)	Do not make use of assessments of other countries
New Zealand	Not for industrial chemicals/products, but there is for pesticides
Switzerland	Do not make use of assessments of other countries
United States	Not at this time. However, if a chemical identity had not been claimed confidential, then there could be an informal exchange of information.
European Union	Risk assessments are made available to the CA's of all EU Member States and summaries of notification data are also shared.

TABLE 24:

Question 18

Do you have any comparative statistics on the origin of the chemicals being notified and assessed in your country?

Country	Do you have comparative statistics?	Details
Australia	No	Only have general information on chemicals - Imported: > 90% Locally manufactured:< 10% Most chemicals believed to originate in Europe, Japan or North America.
Canada	Yes (not supplied)	Do have accurate information on whether the substance is manufactured in or imported into Canada. Also have general information for country of origin of import (i.e. US, Europe, Japan, others).
Japan (ML)	Yes	1979-1994: Locally manufactured 86%, imported 14%
Japan (MHW/MITI)	No	
New Zealand	Statistics not readily available	
Norway	No	
Switzerland	Yes	From 1/1/88 to 19/9/95: Switzerland: 35%, Japan: 29%, EU: 24%, US: 9%, Others: 3%
United States	Yes	Collect information on the origin of chemicals but do not currently have statistics.
European Union	Yes. Most EU members also have national statistics (only supplied by Germany)	1983-1992, origin of those notified in the EU: Switzerland: 38%, Japan: 23%, US: 12%, Germany: 12%, UK: 6%, France: 2%, Netherlands: 2%, others: 5%.

TABLE 25:

Question 19

If you have an existing co-operative system with other countries on sharing/exchanging information, please describe how it works.

Country	Description of existing co-operative systems with other countries
Australia	Currently do not have a co-operative system with other countries. However, a German-Australian pilot is being tested.
Canada	An information-sharing plan between US EPA and Environment Canada is under development. Assessment reports will also be shared when the industry providing the information provides authorisation.
Japan (ML)	Do not have a co-operative system with other countries.
Japan (MHW/MITI)	Do not have a co-operative system with other countries.
New Zealand	Participates in the CIEP with respect to industrial chemicals and pesticides, which provides much useful information.
Norway	Co-operation with the European Communities according to the EEA agreement. The same procedures are practised by the EU countries and will be introduced in Norway when the Directives are implemented there.
Switzerland	Do not have a co-operative system with other countries.
United States	An agreement for sharing information exists between the US EPA and Environment Canada/Health Canada.
European Union	There is a harmonized notification system for all EU Member States, and countries are subject to EEA once appropriate legislation is in place. The Member State receiving a notification and conducting a risk assessment circulates a summary of the notification on the SNIF to the European Commission, which then copies the SNIF to all EU Member State CA's.

D) IDENTIFICATION OF INDUSTRIAL CHEMICALS BEING NOTIFIED OR ASSESSED

TABLE 26:

Question 20

What information must be provided and where is the information reported/stored after the notification process?

"Chemical Abstracts Service (CAS) Number"

Country	Notifier must supply	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	✔[1]	✔	✔[2]	✔[2]	✔[2] Chemical Gazette
Canada	✔[1]	✔	No	✔[3]	No
Japan (ML)	No	No	No	✔	No
Japan (MHW/MITI)	No	No	No	✔	No
New Zealand	✔	✔[7]	No	No	No
Switzerland	✔	✔	No	No	No
United States	✔[1]	✔	No	✔[2]	No
European Union	✔	✔[4]	No	✔[5]	✔[6] Annex I

1 If available.

2 If not confidential.

3 If the substance is not listed with a masked name.

4 This report is available to all competent authorities of the EU.

5 Is reported on EINECS only (not ELINCS).

6 Included in Annex I to Directive 67/548/EEC if classification is agreed at the community level.

7 Is recorded internally on file, and computerised database is being developed.

TABLE 27:

Question 20

What information must be provided and where is the information reported/stored after the notification process?

"Chemical Name"

Country	Notifier must supply	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	✔ CAS or IUPAC	✔	✔[1]	✔	✔[1] Chemical Gazette
Canada	✔ CAS or IUPAC	✔	No	✔ CAS - English IUPAC - French	No
Japan (ML)	✔ IUPAC	No	No	✔	✔ Official Gazette
Japan (MHW/MITI)	✔ IUPAC	✔	No	✔	✔ Official Gazette
New Zealand	✔ Chemical and common name	✔[4]	No	No	No
Switzerland	✔ Any internationally accepted	✔	No	No	No
United States	✔	✔	✔[1] Federal Register	✔[1]	No
European Union	✔ CAS or IUPAC	✔	No	✔	✔[3] Annex I

1 If not confidential.

2 Only if classified as hazardous to health.

3 Included in Annex I to Directive 67/548/EEC if classified.

4 Recorded internally on file, and computerised database is being developed.

TABLE 28:

Question 20

What information must be provided and where is the information reported/stored after the notification process?

"Structural Formula"

Country	Notifier must supply	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	✔[1]	✔	✔[2]	No	No
Canada	✔	✔	No	No	No
Japan (ML)	✔	No	No	✔	No
Japan (MHW/MITI)	✔	✔	No	✔	No
New Zealand	No	No	No	No	No
Switzerland	✔	✔	No	No	No
United States	✔	✔	No	No	No
European Union	✔	✔	No	No	✔[3] Annex I

1 If available.

2 If not confidential.

3 On Annex I to Directive 67/548/EEC if classified.

TABLE 29:

Question 20

What information must be provided and where is the information reported/stored after the notification process?

"Molecular Formula"

Country	Notifier must supply	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	✔[1]	✔	✔[2]	✔	✔[2] Chemical Gazette
Canada	No	No	No	No	No
Japan (ML)	✔	No	No	No	No
Japan (MHW/MITI)	✔	✔	No	✔	No
New Zealand	No	No	No	No	No
Switzerland	✔	✔	No	No	No
United States	✔	✔	No	✔[2]	No
European Union	✔	✔	No	No	No

1 If available.

2 If not confidential.

TABLE 30:

Question 20

What information must be provided and where is the information reported/stored after the notification process?

"Unique notification number for your country"

Country	Notifier must supply	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	No	✔	✔	No	✔ Chemical Gazette
Canada	No	✔	No	No	No
Japan (ML)	No	No	No	✔	✔ Official Gazette
Japan (MHW/MITI)	No	No	No	✔	✔ Official Gazette
New Zealand	No	No	No	No	No
Switzerland	No	✔	No	No	No
United States	No	No	No	No	No
European Union	No	✔	No	✔[1]	No

1 ELINCS - European List of New Notified Substances

TABLE 31

Question 20

What information must be provided and where is the information reported/stored after the notification process?

"Trade Name"

Country	Notifier must supply	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	✔	✔	✔	No	✔ Chemical Gazette
Canada	✔	✔	No	No	No
Japan (ML)	✔	No	No	No	No
Japan (MHW/MITI)	No	No	No	No	No
New Zealand	✔	✔[1]	No	No	No
Switzerland	✔	✔	No	✔	No
United States	✔	✔	No	No	No
European Union	✔	✔	No	✔	No

1 Recorded internally in file, and computerised database is being developed.

TABLE 32:

Question 20

What information must be provided and where is the information reported/stored after the notification process?

"Spectral Analysis"

Country	Notifier must supply	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	✔	✔	No	No	No
Canada	✔[1]	✔	No	No	No
Japan (ML)	No	No	No	No	No
Japan (MHW/MITI)	No	No	No	No	No
New Zealand	No	No	No	No	No
Switzerland	✔	No	No	No	No
United States	✔[2]	✔	No	No	No
European Union	✔	✔	No	No	No

1 Not required in all notifications.

2 Only required if available.

TABLE 33:

Question 20

What information must be provided and where is the information reported/stored after the notification process?

"Nature and Proportion of Impurities"

Country	Notifier must supply	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	✔	✔	✔[1]	No	No
Canada	✔	✔	No	No	No
Japan (ML)	✔	No	No	No	No
Japan (MHW/MITI)	✔	✔	No	No	No
New Zealand	No	No	No	No	No
Switzerland	✔	No	No	No	No
United States	✔	✔	No	No	No
European Union	✔	✔	No	No	No

1 If not confidential.

TABLE 34:

Question 20

What information must be provided and where is the information reported/stored after the notification process?

"Other"

Country	Notifier must supply	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	Volume Appearance	✔ ✔	✔[1] ✔	No No	No No
Canada	Information prescribed in regulation	No	No	No	No
Japan (ML)	Use	No	No	No	No
Japan (MHW/MITI)					
New Zealand	Classification	✔[4]			
Switzerland					
United States					
European Union	Classification and labeling proposal	✔	No	✔[2]	✔[3] Annex I

1 May be confidential.

2 ELINCS - European List of New Notified Substances.

3 On Annex I to Directive 67/548/EEC if classified.

4 Recorded internally on file, and computerised database being developed.

TABLE 35:

Question 21

Which of the types of identification information do you use most commonly to pinpoint the identity of a chemical?

Type of identification	Country
CAS number	Australia, Austria, Canada, Germany, Ireland, Netherlands, New Zealand, Sweden, Switzerland
Chemical name	Canada, Ireland, Japan,[1] Norway, Sweden, Switzerland, New Zealand, US
Structural formula	Australia, Germany, Japan,[1] Netherlands, Norway, Switzerland, UK, US
Molecular formula	UK
Unique notification number	Austria, Netherlands[#]
Trade name	Netherlands[#]
Spectral analysis	
Nature and proportion of impurities	
Other	

1 The Japanese responses were the same.

The Netherlands proposes using unique notification number together with trade name.

TABLE 36:

Question 22

Are there any circumstances when any of this information is treated as confidential? Please indicate which items may be confidential.

Country	Which items of identification information may be considered confidential?
Australia	CAS number, chemical name, impurities, structural formula, molecular formula, volume of chemical.
Canada	A notifier is entitled To request confidential treatment for any data. Confidentiality requests for chemical name and CAS number are subject to strict criteria. The number of "masked" names on the DSL is limited. Other requests are usually accepted.
Japan (ML)	Trade name and nature and proportion of impurities.
Japan (MHW/MITI)	Nature and proportion of impurities.
New Zealand	Chemical identity of mixtures and composition. Trade names also for some companies
Switzerland	All but the trade name.
United States	All information submitted except health and safety studies may be confidential.
European Union	A notifier may request confidentiality for any part of a notification with a full justification except for the Trade Name which has restrictions on its use in lieu of the correct chemical name. If a chemical is listed on Annex 1, its chemical name must be published. If listed on ELINCS and not classified, the chemical name may be withheld from publication for 3 years or at the competent authority's discretion.

TABLE 37:

QUESTION 23

How do you identify complex mixtures and differentiate between one complex mixture and another?

Country	How are complex mixtures identified?
Australia	Classified as UVCB (Unknown or Variable Composition, Complex reaction products, Biological material). Other mixtures differentiated by CAS numbers (if available).
Canada	Approach to complex mixtures is the same as that of the US EPA (and the CAS approaches to the naming of such substances).
Japan (ML)	Consider one complex to be the same as another if the species of the components are the same.
Japan (MHW/MITI)	The IUPAC name is required for notification, and mixtures should be notified with all names of the components. If the components are not known, then the mixture can be notified with the manufacturing process.
New Zealand	Not applicable, as New Zealand system requires notification of formulations rather than chemicals, so most/all notifications would be complex mixtures.
Norway	Spectral data analysis.
Switzerland	The concentrations of the main components
United States	Each combination of substances is considered to be either: 1) a mixture, composed of two or more well-defined chemical substances to be listed separately; 2) a reaction product, to be listed as a single chemical substance, using one name that collectively describes the products, or, failing that, the reactants used to make the products.
European Union	By defining the quantity of the main components, describing the manufacturing process or difficult cases can be referred to the EC's European Chemicals Bureau.

E) OUTCOMES FROM NOTIFICATION AND ASSESSMENT

TABLE 38:

Question 24

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

"Approval or Rejection"

Country	Possible outcome	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	No[1]	No	No	✔[1]	No
Canada	No[2]	No	No	✔[2]	✔[2] Canada Gazette
Japan (ML)	No	No	No	No	No
Japan (MHW/MITI)	No	No	No	No	No
New Zealand	✔[4]	No	No	No	No
Switzerland	✔	✔	No	No	No
United States	No[3]	No	No	✔[1]	No
European Union	No	No	No	No	No

1 Listing on the inventory indicates that the chemical has been approved.

2 There is no formal "approval or rejection", but approval is indicated by listing on the DSL and rejection is indicated by controls applied.

3 The TSCA New Chemicals Program is not a registration program, but rather a screening program in which some chemicals are regulated and others are not. Chemicals that are not regulated are called "drops". Section 5(e) control Orders apply only to the manufacturer that submitted the PMN. A "Significant New Use Rule" applies to all manufacturers and processors of the same chemical.

4 In New Zealand rejection is a possible but rare outcome.

TABLE 39:

Question 24

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

"Request for further information from the notifier"

Country	Possible outcome	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	✔	No	No	No	No
Canada	✔	✔	No	No	No
Japan (ML)	No	No	No	No	No
Japan (MHW/MITI)	No	No	No	No	No
New Zealand	✔	No	No	No	No
Switzerland	✔	✔	No	No	No
United States	✔	✔	✔[1]	No	No
European Union	✔	✔	No	No	No

1 The US does not have a published “report” but does publish requests for further information in the form of SNUR notices and § 5(e) Orders in the Federal Register.

TABLE 40:

Question 24

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

"Specific control on the chemical"

Country	Possible outcome	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	✔	✔	✔	No	No
Canada	✔	✔	No	No	✔ Canada Gazette
Japan (ML)	✔	✔	No	No	✔[1]
Japan (MHW/MITI)	No	No	No	No	No
New Zealand	✔[4]	No	No	No	No
Switzerland	✔	✔	No	No	No
United States	✔	✔	✔[3]	No	No
European Union	✔[2]	✔	No	No	No

1 Recommendation by Labour Minister.

2 Only after referring to other EU legislation following risk assessment.

3 Controls are not published in reports, but in SNUR notices and § 5(e) Orders in the Federal Register.

4 In New Zealand this is a possible but rare outcome.

TABLE 41:

Question 24

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

"Hazard classification of the chemical"

Country	Possible outcome	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	✔	✔	✔	No	No
Canada	No	No	No	No	No
Japan (ML)	✔	✔	No	No	No
Japan (MHW/MITI)	✔	✔	No	No	✔ Official Gazette
New Zealand[1]	✔	✔	No	No	No
Switzerland	✔	✔	No	No	No
United States	✔	✔	No	No	No
European Union	✔	✔	No	✔	✔ Annex I

1 In addition, if the product contains a scheduled chemical, labeling requirements must be followed.

TABLE 42:

Question 24

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

"Risk assessment"

Country	Possible outcome	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	✔	✔	✔	No	No
Canada	✔	✔	No	No	✔ Canada Gazette[1]
Japan (ML)	No	No	No	No	No
Japan (MHW/MITI)	No	No	No	No	No
New Zealand	✔[2]	No	No	No	No
Switzerland	✔	✔	No	No	No
United States	✔	✔	No	No	No
European Union	✔	✔	No	No	Refer to appropriate regulatory authority

1 If controls are applied.

2 In New Zealand this is a possible but rare outcome.

TABLE 43:

Question 24

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

"Production of an agreed material safety data sheet (MSDS)"

Country	Possible outcome	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	✔	✔	✔	No	No
Canada	N/A	N/A	N/A	N/A	N/A
Japan (ML)	No	No	No	No	No
Japan (MHW/MITI)	No	No	No	No	No
New Zealand	✔	No	No	No	No
Switzerland	✔	✔	No	No	No
United States	✔	✔	No	No	No
European Union	No	No	No	No	No

TABLE 44:

Question 24

What are the possible regulatory outcomes and where is the information on those outcomes reported/stored after the notification process?

"Requirement for follow-up or secondary notification"

Country	Possible outcome	Reported in internal report	Reported in published report	Reported on inventory	Other
Australia	✔	✔	✔	No	No
Canada	✔[1]	✔	No	No	✔ Canada Gazette
Japan (ML)	No	No	No	No	No
Japan (MHW/MITI)	No	No	No	No	No
New Zealand	✔[4]	No	No	No	No
Switzerland	✔	✔	No	No	No
United States	✔	✔	✔[3]	No answer	No answer
European Union	✔[2]	✔	No	No	No

1 i) A control option would be to limit manufacture/import to a specific use (substance not placed on DSL).

.

ii) Legislation requires any new information on toxicity to be reported.

2 As a result of the risk assessment or as a higher tonnage threshold is reached.

3 Secondary notification requirements may be published in a notice in the Federal Register (e.g. an Exposure-based Order may require further information at certain volumes).

4 In New Zealand this is a possible but rare outcome.

TABLE 45:

Question 25

Is the public availability of the outcome of notification/assessment affected by confidentiality provisions?

Country	Yes/No	Comments
Australia	No	The outcome of notification/assessment in the form of the Published Report is publicly available, irrespective of confidentiality provisions. Certain data cannot be claimed as confidential, including control measures to reduce exposure.
Canada	No	The "outcome" of the final assessment is public information. If the substance name is "masked", only partial information on substance identity is known. The assessment report, describing the basis of decision making, is confidential.
Japan (ML)	No	
Japan (MHW/MITI)	No	
New Zealand	Yes	Composition details for mixtures may be withheld. Some companies have considered trade names confidential.
Switzerland	No	
United States	Yes	The public may only access "sanitised" documents which have the confidential information removed. The submitter must provide the sanitised version of the notification. Assessments are considered internal deliberative documents which are not part of the public record, although the Public Docket for SNURs does contain certain sanitised Agency assessments.
European Union	Yes	Only the non-confidential data of a notification can be publicly available. In the Netherlands the notifier prepares a non-confidential version. Germany comments that risk assessment is not published but is available on request to non-EU authorities.

TABLE 46:

Question 26

Is a Material Safety Data Sheet (MSDS) or label required to be submitted along with the notification?

Country	Material Safety Data Sheet (MSDS)	Label
Australia	Yes	Yes
Canada	Yes (if one exists)	No
Japan (ML)	No	No
Japan (MHW/MITI)	No	No
New Zealand	No	No
Switzerland	Yes	No
United States	Not required but encouraged. The MSDS is often provided.	Not required but encouraged
European Union	Yes (a proposed MSDS is required if the substance is classified as hazardous)	Yes (a proposal for classification and labeling)

TABLE 47:

Questions 27 and 28

Do you have a formal definition of "hazard" and "risk" and are they clearly distinguished in your assessment process?

Country	Formal definition of "hazard" and "risk"	Are they distinguishable in the assessment process?
Australia	Yes, for health hazard	Yes
Canada	No (legislation defines "toxic", tends to be risk orientated)	Yes
Japan (ML)	No	Yes
Japan (MHW/MITI)	No	N/A
New Zealand	No	N/A
Switzerland	No	Yes
United States	No. Not in the Statute or regulations but the US EPA has definitions for regulatory purposes.	Yes
European Union	Yes (see Directive 93/67/EEC).	Yes

The Netherlands has definite ideas about "hazard identification" and "risk characterisation", set out in the questionnaire and in the covering letter.

F) INVENTORY OR LIST OF CHEMICALS

TABLE 48:

Questions 29 and 30
Do you have an inventory of chemicals and if so what is it called?

Country	Inventory?	Name of Inventory
Australia	Yes	Australian Inventory of Chemical Substances (AICS)[1]
Canada	Yes	Domestic Substances List (DSL)[2]
Japan (ML)	Yes	Chemical substances under the Industrial Safety and Health Law
Japan (MHW/MITI)	Yes	Chemical substances under the law concerning the Examination and Regulation of Manufacture etc. of Chemical Substances
New Zealand	Yes	Notification of Toxic Substances Database
Switzerland[3]	Yes	Inventory of Notified New Substances List on Toxic substances and preparations (Giftlisten 1, 2 and 3)
United States	Yes	The TSCA Chemical Substances Inventory
European Union	Yes[4]	EINECS - European Inventory of Existing Commercial Chemical Substances (O.J. C146A Vol. 33 15 June 1990). ELINCS - European List of Notified Chemical Substances (O.J. C361 Vol. 37, 17 December 1994 latest edition, updated annually). EU New Chemicals Database[5]

1 There are two sections to the AICS: confidential and non-confidential.

2 Canada also has a Non-Domestic Substances List which identifies substances for which information requirements are reduced. Is linked to the US TSCA inventory.

3 New substances notified in Switzerland are added to two lists. The List on Toxic Substances also contains existing chemicals and preparations..

4 Some EU Member States have national inventories also. The Netherlands has a National Database which includes all the data of the EU notified substances but does not have an official national published inventory. Austria has the *Chemikalienregister*.

5 Used for internal purposes between Competent Authorities.

TABLE 49:

Question 31
What is the purpose of your inventory?

Country	What is the purpose of the chemicals inventory?
Australia	To distinguish between new and existing industrial chemicals.
Canada	Identifies those substances which do not require notification (some substances e.g. pesticides, drugs, are addressed by their own legislation and are excluded from notification).
Japan (ML)	For manufacturers and importers to check if a chemical is existing or not.
Japan (MHW/MITI)	To determine if a chemical is existing or has been announced as a new chemical.
New Zealand	To identify the chemicals and products used in New Zealand and their composition, together with the details of the importers, manufacturers and distributors, so that hazards identified with particular chemicals can be addressed.
Switzerland	The List on Toxic Substances includes information on substances and preparations and toxicity classification. Used as a working instrument for Information Centres on Toxics. The List of Notified New Substances includes information on trade names, intended uses of the substance, and names of first notifiers.
United States	The inventory defines whether a substance is new or existing and thus whether a Pre-Manufacture Notice (PMN) is required.
European Union	EINECS lists existing substances, i.e. those placed on the market between 1971 and 1981, and is essential to identify a new substance. ELINCS lists new notified substances and is essential to inform the public and potential notifiers of already notified substances.

TABLE 50:

Question 32
How can your chemicals inventory be accessed?

Country	How can the inventory be accessed?
Australia	Microfiche, hard copy (book, 2 volumes)
Canada	Hard copy (Canada Publishing Group), CD-Rom (CCInfo disk, CAS surveyor)
Japan (ML)	Sold as a publication
Japan (MHW/MITI)	Sold as a publication
New Zealand	Currently only manually, but a computer database is being developed
Switzerland	The List on Toxic Substances is available from EDMZ, CH-3000 Bern, and is published once a year by the Federal Office of Public Health. The List of Notified New Substances is an internal list of the Federal Office of Environment, Forests and Landscape, but information can be given on request.
United States	Chemicals listed on the non-confidential TSCA Inventory are available for purchase on tape and PC diskette, in a paper copy, on CD-Rom and through on-line commercial services. The Agency will do searches, but only on receipt of a complete intent to manufacture.
European Union	Both inventories are published in the "Official Journal of the European Communities". EINECS is also on CD-Rom.

TABLE 51:

Question 33

When are new chemicals added to your inventory after assessment?

Country	When are new chemicals added to the inventory?
Australia	The chemicals are not added to the inventory for five years. They are published in the Chemical Gazette with a Summary Report. A list of notified and assessed chemicals is published annually.
Canada	1) After the information package is provided and assessed 2) No conditions placed on the chemical 3) When a prescribed volume is exceeded Addition to the inventory follows relatively quickly afterwards.
Japan (ML)	Are added periodically.
Japan (MHW/MITI)	Are added periodically.
New Zealand	Products are added after notification (no assessment done).
Switzerland	Added before marketing to the List on Toxic Substances, but only when within the scope of the law on toxic substances. Added to FOEFL's internal List of Notified New Substances after notification.
United States	New chemicals are added to the Inventory only after the 90-day review period expires and the manufacturer submits a Notice of Commencement (NOC) to the EPA within 30 days of commencing manufacture.
European Union	ELINCS is updated annually.

TABLE 52:

Questions 34 and 35

For new chemicals which are assessed, is the fact that assessment has occurred noted on the inventory? Is listing on the inventory affected by confidentiality provisions?

Country	Is assessment noted on the inventory?	Is listing affected by confidentiality provisions?
Australia	No	Yes
Canada	Yes	Yes. In some cases a masked name may be used if a claim is made for confidentiality of the chemical name.
Japan (ML)	Yes	No
Japan (MHW/MITI)	Yes	No
New Zealand	N/A	No
Switzerland	No	Yes
United States	No. However, it is assumed to have occurred.	Yes. EPA maintains a confidential and a non-confidential version of the Inventory. Those wishing to determine whether a substance is listed as confidential must demonstrate a *bona fide* intent to manufacture or import the chemical.
European Union	No. Every chemical added to ELINCS must have been assessed.	Yes. ELINCS only includes limited information (non-confidential). But if listed in Annex I the IUPAC name must be given.

G) SUMMARY TABLES

TABLE A:

Types of information for sharing

Information publicly accessible

Country	Chemical notified and assessed	Notifying company	Approval or rejection	Hazard classification and control action	Further testing	MSDS	Assessment report	Data submitted
Australia	✔[#]	✔[#]	N/A	✔	No	✔	✔[5]	No
Canada	✔[#]	No	N/A	✔[2]	No	N/A	No	No
Japan (ML)	✔[#]	No	N/A	✔	No	No	No	No
Japan (MHW/MITI)	✔[#]	No	N/A	✔	✔	No	No	No
New Zealand	No	No	No	No	No	No	N/A	No
Switzerland	✔[1]	✔[1]	✔[1]	✔[1]	✔[1]	✔	No	No
United States	✔[#]	✔[#]	N/A	✔[#]	✔[#]	✔[4]	No	✔[6]
European Union	✔[#]	✔	N/A	✔[3]	No	✔[4]	No	No

PLEASE NOTE THAT FOOTNOTES FOR THIS TABLE ARE ON THE FOLLOWING PAGE

#	Barriers to availability exist.
1	The information is not published, but can be provided on request from the FOEFL.
2	Control action only, hazard classification not applicable.
3	Hazard classification only, control actions are confidential.
4	Available from notifier.
5	The internal assessment report is not available, but a Full Public Report and Summary Report with the confidential information removed are.
6	Sanitized health and safety studies only.

TABLE B:

Identification of chemicals being notified or assessed

Information publicly accessible

Country	CAS number	Chemical name	Structural formula	Molecular formula	Notification number	Trade name	Spectral analysis	Impurities	Other
Australia	✔[#]	✔[#]	✔[#]	✔	✔[1]	✔[1]	No	✔[#]	✔ Volume[#] Appearance
Canada	✔[#]	✔	No	No	No	No	No	No	No
Japan (ML)	✔	✔	✔	No	✔	No	No	No	No
Japan (MHW/MITI)	✔	✔	✔	✔	✔	No	No	No	No
New Zealand	No	No	No	No	No	No	No	No	No
Switzerland	No	No	No	No	No	✔	No	No	No
United States	✔[#]	✔[#]	No	✔[#]	No	No	No	No	No
European Union	✔ Annex 1	✔	No	No	✔	✔	No	No	✔ Classification and labeling

If not confidential.
1 In published report but not on the inventory.

TABLE C:

Outcomes from notification and assessment

Information publicly accessible

Country	Approval or rejection	Request for further information	Specific control on the chemical	Hazard classification	Risk assessment	MSDS	Secondary notification
Australia	N/A	No	✔	✔	✔	✔	✔
Canada	N/A	No	✔	N/A	✔	No	✔
Japan (ML)	N/A	No	✔	No	No	No	No
Japan (MHW/MITI)	N/A	No	No	No	No	No	No
New Zealand	No	No	No	No	No	No	No
Switzerland	✔[1]	✔[1]	✔[1]	✔[1]	No	✔	✔[1]
United States	N/A	✔	✔	No	No	No	✔
European Union	N/A	No	No	✔	No	No	No

1 The information is not published, but can be provided on request from the FOEFL.

TABLE D:

Types of information for sharing

Who can access the information?

Type of information	Assessment has taken place	Notifying company	Type of assessment	Approval or rejection	Hazard classification	Control action	Further testing	MSDS	Copy of assessment report	Copy of data submitted
Australia	G, P, O	G, P, O	G, P, O	N/A	G, P, O	G, P, O	Not available	G, P, O	G, P, O[2]	N
Canada	G, P, O	Not available	Not available	N/A	N/A	G, P, O	N	N/A	Not available	Not available
Japan (ML)	G, P, O	Not available	G, P, O	N/A	G, P, O	G, P, O	Not available	Not available	Not available	Not available
Japan (MHW/MITI)	G, P, O	Not available	Not available	N/A	G, P, O	G, P, O	G, P, O	Not available	Not available	Not available
New Zealand	G[4 ,5]	Not available	N/A	Not available	G	G	Not available	G[5]	N/A	Not available
Switzerland	G, P, O	G, P, O	G, P, O	G, P, O	G, P, O	G, P, O	G, P, O	G, P, O	Not available	N
United States	N	G, P, O	N/A	N/A	G	G, P, O	G, P, O	G, P, O	Not available	G, P, O[3]
European Union	G, P, O	G, P, O	G, P	N/A	G, P, O	G[1]	G[1]	N	G[1]	G[1]

G: Accessible by other governments
N: Accessible by original notifier only
O: Accessible by others (public)
P: Accessible by prospective notifiers
N/A: Not applicable

1 Available to EU governments only
2 May only access those reports without confidential data
3 Only sanitised health and safety studies
4 This applies to notification only, as assessment is not carried out
5 Accessibility of information is barrier to access

ANNEX 6

QUESTIONNAIRE TO IDENTIFY POSSIBILITIES FOR SHARING INFORMATION ABOUT NEW INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT

QUESTIONNAIRE

NAME OF COUNTRY:

NAME OF ORGANISATION:
NAME OF PERSON COMPLETING QUESTIONNAIRE:
FAX NUMBER:

NAME OF CONTACT PERSON TO WHOM WE CAN SEND ONE-PAGE SUMMARY OF YOUR COUNTRY'S SCHEME FOR COMMENT:
FAX NUMBER:

A) GENERAL INFORMATION

The purpose of this section is to find out some general information about each country's system of notification/assessment for new industrial chemicals.

1) Do you have legislation covering the introduction of new industrial chemicals?

☐ Yes ☐ No

If so, please give: Name of the legislation:
Date of legislation:

2) What areas are assessed?

☐ Occupational health & safety
☐ Environmental effects
☐ Public health
☐ Other, give details

3) When are new industrial chemicals required to be notified and assessed?

_____

_____

_____

4) How are the terms "new chemical" and "existing chemical" defined in your system? (e.g. in some countries new polymers made from existing monomers are not notified as new chemicals) _____

_____

_____

5) Is a formal written assessment produced? ☐ Yes ☐ No

If so, what is its format ?

_____

_____

_____

6) When a new chemical is notified/assessed, is data required on:

☐ Pure chemical ☐ Commercial grade as marketed

☐

Other, please give details_____

_____

_____

7) Under what circumstances are chemicals notified more than once?_____

_____

_____

8) Does the assessment process vary when this happens? _____

_____

_____

9) If new chemicals can be notified more than once in your system, is the commercial advantage of the first notifier protected in any way? _____

_____

_____

10) When did your notification/assessment system for new chemicals come into operation?

_____

_____

11) Approximately how many chemicals are notified/assessed per year?_____

_____

B) TYPES OF INFORMATION FOR SHARING ON NEW INDUSTRIAL CHEMICALS

The purpose of this section is to identify the types of information on a new chemical notification/assessment that could be useful to others.

12) The table below lists some of the types of information which could be shared on new industrial chemicals. For each item please indicate:

i) Which information held by your country could others could currently access?

ii) If you consider there are barriers to sharing any of the listed information, could you please identify them?

.

TYPES OF INFORMATION THAT COULD BE SHARED ON NEW INDUSTRIAL CHEMICALS

TYPE OF INFORMATION	ABLE TO BE ACCESSED? (PLEASE TICK)	BARRIERS TO SHARING THIS INFORMATION
Fact that specific chemical has been notified		
Fact that assessment has taken place		
Identification of notifying company		
Type of assessment that has been done		
OUTCOME OF ASSESSMENT		
Approval/rejection		
Hazard classification		
Control action		
Further testing		
Availability of approved MSDS		
Copy of assessment report		
Copy of data submitted		
Other (please specify)		

13) For the types of information in the previous table that have been ticked, please indicate if they are available to:

- ☐ other governments
- ☐ only the original notifier
- ☐ prospective notifiers
- ☐ others

14) What information on new chemicals would it be useful to have publicly available?

_____
_____
_____

15) If this was done, do you foresee any problems with confidentiality?

_____
_____
_____

C) INTER-COUNTRY COOPERATION

The purpose of this section is to find out if there are any formal or informal links with the schemes of other countries.

16) Are there any concessions for notification/assessment in your legislation if a new chemical has previously been in use in another country? _____
_____
_____
_____

17) Are there any ways in which you make use of the assessments of another country?

_____
_____
_____
_____

18) Do you have (or are you aware of) any comparative statistics on the origin of the chemicals being notified and assessed in your country?

_____
_____
_____
_____

19) If you have an existing cooperative system with other countries on sharing/exchanging information, please describe how it works.

_____
_____
_____
_____

D) IDENTIFICATION OF INDUSTRIAL CHEMICALS BEING NOTIFIED OR ASSESSED

The purpose of this section is to find out how industrial chemicals are identified in your notification and assessment scheme.

20) The following table asks:

i) What information on the identity of a chemical is required to be provided when a new chemical is notified?

ii) Where is that information reported/stored after the notification process?

Please fill in the table as it applies to your country's procedures.

		PLEASE TICK WHERE EACH TYPE OF INFORMATION IS REPORTED AFTER THE NOTIFICATION PROCESS			
TYPE OF IDENTIFICATION INFORMATION	**PLEASE TICK IF NOTIFIER MUST SUPPLY THIS INFORMATION**	**REPORTED IN INTERNAL REPORT**	**REPORTED IN PUBLISHED REPORT**	**REPORTED ON INVENTORY**	**OTHER (PLEASE SPECIFY)**
Chemical Abstracts Service (CAS) number					
chemical name (please specify what nomenclature is required, e.g. IUPAC, as for CAS registry)					
structural formula					
molecular formula					
unique notification number for your country					
trade name					

(contined next page)

TYPE OF IDENTIFICATION INFORMATION	PLEASE TICK IF NOTIFIER MUST SUPPLY THIS INFOR-MATION	REPORTED IN INTERNAL REPORT	REPORTED IN PUBLISHED REPORT	REPORTED ON INVENTORY	OTHER (PLEASE SPECIFY)
spectral analysis					
nature and proportion of impurities					
other (please specify)					

21) Which of the above types of identification information do you use most commonly to pinpoint the identity of a chemical? Highlight the <u>two</u> you consider most useful.

_____
_____
_____
_____

22) Are there any circumstances when any of this information is treated as confidential?

Yes ☐
No ☐

If so, please indicate below which items of information may be confidential.

_____
_____
_____
_____
_____

23) How do you identify complex mixtures, and differentiate between one complex mixture and another?

_____
_____
_____

E) OUTCOMES FROM NOTIFICATION AND ASSESSMENT

The purpose of this section is to look at the possible results of notification/ assessment and how the results are recorded.

24) The following table asks:

i) What are the possible regulatory outcomes or endpoints of the process when a new chemical is notified?

ii) Where is information on those outcomes reported/stored after the notification process?

Please fill in the table as it applies to your country's procedures.

		PLEASE TICK WHERE EACH TYPE OF INFORMATION IS REPORTED AFTER THE NOTIFICATION PROCESS			
TYPE OF OUTCOME	**PLEASE TICK IF THIS IS A POSSIBLE OUTCOME IN YOUR SYSTEM**	**REPORTED IN INTERNAL REPORT**	**REPORTED IN PUBLISHED REPORT**	**REPORTED IN INVENTORY**	**OTHER (PLEASE SPECIFY)**
Approval or rejection					
Request for further information from notifier					
Specific control on the chemical					
Hazard classification of chemical					
Risk assessment					
Production of an agreed Material Safety Data Sheet (MSDS)					
Requirement for follow-up or *secondary notification					
Other (please specify)					

*** Notifier becomes aware of a significant change in circumstances, e.g. new use, significant increase in the quantity of chemical imported or manufactured, new information on potentially hazardous properties of the chemical.**

Please add details of any other outcomes of notification/assessment.

25) Is the public availability of the outcome of notification/assessment affected by confidentiality provisions? _____
_____
_____
_____

26) Is a Material Safety Data Sheet or Label required to be submitted along with the notification?

Material Safety Data Sheet: ☐ Yes
☐ No

Label: ☐ Yes
☐ No

27) Do you have a formal definition of “hazard” and “risk”?

Yes ☐
No ☐

28) Are “hazard” and “risk” clearly distinguished in your assessment process?

Yes ☐
No ☐

F) INVENTORY OR LIST OF CHEMICALS

The purpose of this section is to find out about inventories and lists of chemicals.

29) Do you have an inventory of chemicals?

Yes ☐
No ☐

30) If so, what is it called? _____
_____
_____
_____

31) What is its purpose? _____
_____
_____
_____

32) How can it be accessed? _____
_____
_____
_____

33) Are new chemicals added to this inventory after assessment?

Yes ☐
No ☐

If yes, when are they added? _____
_____
_____
_____

If no, are they listed elsewhere? Please describe. _____
_____
_____
_____

34) For new chemicals which are assessed, is the fact that assessment has occurred noted on the inventory.

Yes ☐
No ☐

35) Is listing on the inventory affected by confidentiality provisions?

Yes ☐
No ☐

THANK YOU FOR CONTRIBUTING TOWARDS THE PLANNING OF THE WORKSHOP BY COMPLETING THIS QUESTIONNAIRE.

ANNEX 7

EXTRACTS FROM THE OECD COUNCIL RECOMMENDATIONS ON THE EXCHANGE OF CONFIDENTIAL DATA ON CHEMICALS AND THE LIST OF NON-CONFIDENTIAL DATA ON CHEMICALS

OECD COUNCIL RECOMMENDATION C(83)97(FINAL)
Concerning the Exchange of Confidential Data on Chemicals
(adopted on 26 July 1983)*

APPENDIX

SUGGESTED PRINCIPLES TO GOVERN THE EXCHANGE OF CONFIDENTIAL DATA AND INFORMATION ON CHEMICALS BETWEEN MEMBER COUNTRIES (EXTRACT)

1. The exchange of confidential information on chemicals between the competent authorities of countries is intended solely to facilitate the hazard assessment of chemicals and the protection of man and the environment.

2. A country having received information in response to a request must in no circumstances use such information for any purpose other than the assessment of hazards of chemicals and the protection of man and the environment.

3. A country, whenever requesting information about a chemical, must substantiate the need for the information, on the grounds that:

a) The chemical is present or is shortly to be marketed in its territory; and

b) The information is necessary for the assessment of its hazards and the protection of man and the environment.

4. A country requesting information

a) must abide by the decision made by the transmitting country in respect of the confidential nature of the information;

b) must treat the transmitted information with at least the same degree of confidentiality as is practiced in the country from which the information has been requested;

c) may make the information available to national, regional or local authorities only when necessary for purposes of hazard assessment of chemicals or protection of man and the environment and only when such authorities are able to guarantee the same level of confidential treatment;

d) shall not transmit the information received to any other country.

5. The requesting country shall not ask for the transmission of confidential information which it does not have the authority to collect and use under its legislation or in the normal course of its administration.

6. The solicited country should consult with the person who submitted the requested confidential data before transmitting them.

*Australia abstained

OECD COUNCIL RECOMMENDATION C(83)98(Final)
Concerning the OECD List of Non-Confidential Data on Chemicals*

(adopted on 26 July 1983)*

The Council,

Having regard to Articles 2 a), 2 b), 2 d), 3, and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14th December 1960;

Having regard to the Recommendation of the Council of 7th July 1977, Establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [C(77)97(Final)];

Having regard to the Decision of the Council of 21st September 1978, concerning a Special Programme on the Control of Chemicals and the Programme of Work established therein and the extension of the duration of the Programme by the Council of 12th May 1981 [C(78)127(Final) and C/M(81)7(Final), Item 86];

Having regard to the Decision of the Council of 12th May 1981, concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final)] and Addendum 1 to that Decision [C/M(82)22(Final), Item 215] ;

Having regard to the Decision of the Council of 8th December 1982, concerning the Minimum Pre-marketing Set of Data in the Assessment of Chemicals [C(82)196(Final)];

Having regard to the Recommendation of the Council of 26th July 1983, concerning the Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals [C(83)96(Final)];

Having regard to the conclusions of the First High-Level Meeting of the Chemicals Group of May 1980, concerning the confidentiality of data [ENV/CHEM/HLM/80.M/1];

Having regard to the conclusions of the Second High-Level Meeting of the Chemicals Group of November 1982, on non-confidential data [ENV/CHEM/HLM/M/82.1];

Considering the need to avoid unnecessary duplication of effort in developing data on chemicals, to make better use of existing data, to utilise more effectively scarce specialist manpower and test facilities, and to reduce the number of animals used in testing;

Considering the need of governments to inform the public and the need to disclose certain data related to the assessment of chemicals or to other purposes connected with the protection of man and the environment;

* Australia abstained

On the proposal of the Second High-Level Meeting of the Chemicals Group, endorsed by the Environment Committee;

1. RECOMMENDS that Member countries, for purposes of assessment and for other uses relating to protection of man and the environment, facilitate the disclosure and exchange of data belonging to the OECD List of Non-Confidential Data, set out in the Appendix hereto, which is an integral part of this Recommendation, and other data which may be deemed by the Member country concerned to be non-confidential.

2. INSTRUCTS the Environment Committee and the Management Committee of the Special Programme on the Control of Chemicals to review actions taken by Member countries in pursuance of this Recommendation and report thereon to the Council.

APPENDIX

THE OECD LIST OF NON-CONFIDENTIAL DATA ON CHEMICALS

Certain data, of value for hazard assessment of chemicals and for other purposes connected with the protection of man and the environment, may be termed non-confidential.

In this context, "non-confidential" means that no restrictions should be put on the exchange of the data between governments nor on the disclosure of such data to the public. Proprietary Rights to data are not affected by the non-confidential status of such data. Data should be exchanged between governments on request and not as a matter of routine.

The following list is not restrictive. It is recognised, on the contrary, that in some circumstances there may be other data which are considered non-confidential both by the government and the submitter and that if these are useful for hazard assessment of chemicals, they should also be exchanged. The list below is inspired by the OECD Minimum Pre-marketing Set of Data, but is not meant to be restricted to information on new chemicals. Non-confidentiality, as defined above, applies to all chemicals.

- trade name(s) or name(s) commonly used (in the United States of America, trade names or names commonly used may mean a generic name of a chemical substance);

- general data on uses (the uses need to be described only broadly, like: closed or open system, agriculture, domestic use, etc.);

- safe handling precautions to be observed in the manufacture, storage, transport and use of the chemical;

- recommended methods for disposal and elimination;

- safety measures in case of an accident;

- physical and chemical data with the exception of data revealing the chemicals identity (e.g. spectra). If the physical and chemical data make it possible to deduce therefrom the chemical identity only ranges of values need be given;

- summaries of health, safety, and environmental data including precise figures and interpretations. (The submitter of the health, safety, and environmental data should participate in the preparation of the summaries.)

ANNEX 8

MEMBERS OF THE CO-ORDINATION GROUP ON SHARING INFORMATION ABOUT NEW INDUSTRIAL CHEMICALS

Mr Warwick PEARSE	Worksafe Australia	Australia
Mr John BUCCINI	Environment Canada	Canada
Mr Reiner ARNDT	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA)	Germany
Ms Cristina CORTINAS DE NAVA	Ministry of Social Development	Mexico
Mr Paul HAYES	Health and Safety Executive	United Kingdom
Mr Charles AUER	Environmental Protection Agency	United States
Mr James WILLIS	IRPTC	UNEP
Ms Elizabeth SURKOVIC	UK Chemicals Industries Association	BIAC