

New Chemical Notification Systems

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DRAFT



IOMC

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

***CHEMICAL MANAGEMENT
INSTRUMENTS***

***A RESOURCE FOR COUNTRIES
MAKING CHOICES***

MODULE TWO

***NEW CHEMICAL NOTIFICATION
SYSTEMS***

This publication is produced by UNITAR and UNEP within the framework of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC).

The **Inter-Organization Programme for the Sound Management of Chemicals (IOMC)** was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO, and OECD (Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen cooperation and increase coordination in the field of chemical safety. In January 1998, UNITAR formally joined the IOMC as a Participating Organization. The purpose of the IOMC is to promote coordination 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.

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About the Series...

This document is part of a series which provides countries with basic and practical information on various chemicals management instruments. The purpose of the series is not to prescribe nor advocate the use of specific chemicals instruments. Rather, the aim is to provide factual and practical information to assist countries in making well-informed choices about whether a specific instrument or approach would meet their needs and priorities and if so, how they might wish to go about implementing the instrument, drawing upon the approaches taken and real-life experiences gained by other countries.

In making use of the modules, countries are encouraged to consider questions such as:

- Would the instrument address an area of priority national/local interest or concern?
- Would the instrument fit well with other existing or planned aspects of the national chemicals management scheme?
- Could the instrument be feasibly implemented taking into consideration institutional and human capacities and existing infrastructures?
- Are there alternative instruments/measures that would achieve similar results but which would require less time and/or fewer resources?
- Given the experiences that other countries have had, how might this instrument be implemented in order to best meet national needs and circumstances?

The development of the series is being coordinated by UNEP Chemicals and UNITAR, with individual modules being prepared by interested governments and organizations, either individually or in small teams. A Technical Advisory Group has been formed to provide guidance and input on the overall development of the series and to review the draft modules prior to their publication. The development of the series is considered to be an ongoing process, with additional modules being prepared taking into account those topics which have emerged as of priority interest to countries which are in the process of strengthening their national chemicals management schemes.

Organizations and governments which may be interested in contributing to the further development of the series are encouraged to contact UNEP Chemicals and/or UNITAR.

FOREWORD

The policy instruments that a country selects for national chemical management can influence its ability to respond to concrete problems affecting its population and the quality of its environment. The selection of policy instruments also has practical and resource implications. Some instruments utilized as part of existing national chemicals management schemes are relatively sophisticated in terms of technical capacity and resource needs, while other approaches, though perhaps less comprehensive, may address priority concerns with fewer resources.

Much experience can be shared among countries about the merits of these various instruments, the resources needed and the issues and problems faced. Exploring and documenting experiences with these different approaches as implemented at the country level could provide a useful basis for decision making by other countries interested in selecting chemicals management policy instruments to address their individual circumstances. This could be particularly useful for those countries which are in the early stages of developing their chemicals management schemes and/or those which are faced with very limited resources.

In light of the above, UNEP and UNITAR have initiated a project to coordinate the development of a series of documents which will provide practical information on a range of chemicals management policy instruments, including the experiences and perspectives of those countries which have developed and implemented such instruments. The series is intended for decision makers concerned with chemicals management at the national level, particularly in developing and industrializing countries, and aims to enable informed choices by providing useful and objective information based on practical experiences. The document series is not intended to be prescriptive, and thus will not try to rank the different approaches or make recommendations.

The series of documents is expected to become an input to various capacity building programmes of international organizations and other actors involved in country-based chemicals management capacity building activities. Specifically, it is anticipated that part of the document series will be linked to the *UNITAR/IOMC Pilot Programme to Assist Countries in Implementing National Action Programmes for Integrated Chemicals Management*, in which Argentina, Ghana, Indonesia and Slovenia are participating.

Cooperation with Interested Partners

The experiences of individual countries and international organizations will be a key source of information for the instrument series, thus active and broad input will be crucial to the success of the project. UNEP-Chemicals and UNITAR are exploring with interested governments and organizations opportunities for a partnership approach for the development of specific modules. Through such partnerships, countries and/or organizations with a particular interest in one or several module topics would coordinate with UNEP-Chemicals and UNITAR in developing each module, including inviting input, through use of a questionnaire, from countries which have experience with the particular instrument. Input from developing and industrializing countries, including the four pilot countries participating in the UNITAR/IOMC Pilot Capacity Building Programme, will

also be important for ensuring that the document series is geared towards their priority needs.

Scope of the Project

The proposed series will cover a range of policy instruments used in the context of chemical management and decision-making, including regulatory and non-regulatory approaches.

Policy instruments considered for possible inclusion in the document series are, for example,

- inventories of existing chemicals
- Pollutant Release and Transfer Registers
- notification schemes for new chemicals
- registration schemes
- classification of chemicals
- packaging and labeling schemes
- product registers
- integrated pest management
- community/workers' right-to-know programmes
- pollution prevention/cleaner production
- life cycle assessment

The project will result in a series of peer-reviewed modules on specific chemicals management instruments. The individual modules are planned to be developed through a decentralized, partnership approach involving interested countries, bilateral assistance agencies and international organizations. An introductory document to facilitate the use of the modules and to provide guidance to assist countries in selecting among chemicals management policy instruments is also being considered. Overall UNEP and UNITAR will provide coordination for development of the series.

Module Content

Each module will be comprised of two sections. The first section will provide generic information on the instrument, including a general description of the instrument, its purpose and objectives, the services it can provide and related benefits, problems it may not be able to address and other limitations, and resources required for its implementation. A second section will describe the practical experiences and perspectives of countries that have applied the instrument. For selected countries, summary information will be provided on the use of the instrument in the context of national chemicals management, the results, benefits and drawbacks of the instrument from the country perspective, any special design features or adaptations of the instrument as implemented by the country, and national contact points for more information. A Technical Advisory Group of interested individuals from governments and other interested parties was established to guide the development of the resource series and to review draft modules. This advisory group comprises chemicals management experts from developed and developing countries, international/regional organizations and non-governmental groups/associations, with UNEP Chemicals and UNITAR providing the secretariat.

The Technical Advisory Group is requested to review and provide input into the list of chemicals management instruments to be addressed in the series and will be involved in designing the standard module format and sample questionnaire to be used in compiling the various modules. Once draft modules have been prepared, the experts review them to ensure that the information is accurate, objectively presented and relevant to the needs of target groups.

Acknowledgement

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1. Overview of the elements of a New Chemical Notification Scheme

"New Chemicals" are substances which have not previously been in commerce in a given country. Members countries of the Organization for Economic Cooperation and Development (OECD) as well as other countries (e.g., Philippines) implement, as a part of an overall program of chemical management, New Chemical Notification Systems (NCNSs) as a means to assess new chemicals and to decide if any actions are need to protect human health and the environment. NCNSs represent a "high level" environmental protection activity. Most countries develop and implement more basic chemical management programs before starting a NCNs. Examples of these more basic chemical management elements include programs to manage chemical accidents, "existing chemicals" (substances already in use in a given country), Pollutant Release and Transfer Registers (PRTRs) and so on. Thus, the general purpose of NCNSs is to gather information on the hazards, exposures, and risks of new chemicals and assist efforts to assess new chemicals hazards and risks as a component in an overall program to manage chemical risks.

NCNSs are a useful component of an overall program of chemical assessment and management. Among the benefits of NCNSs are the following:

- complement existing chemical management programs and can assist in managing existing chemical problems through encouraging the introduction of safer or "greener" new chemicals as substitutes for existing chemicals; for example to prevent new persistent bioaccumulative and toxic chemicals (PBTs) from coming onto the market.
- allow countries to anticipate and prevent the introduction of risky new chemicals. Depending on the circumstances, this can involve the development and introduction of new chemicals for the world or the introduction into additional countries of new chemicals already on the market in other countries.
- forces manufacturing countries to develop information on new chemicals that can be useful also to countries which only import new chemicals.

1.1 Basic Design of OECD NCNSs

All OECD NCNSs have certain elements in common:

- NCNSs are comprised of 3 components: Inventories; Notifications and Assessment Procedures; and Post-Notification Activities. Each of these is discussed in detail in sections that follow in the Toolbook;
- legal implementation involves national legislation, directive, decree, and/or regulation;
- "new chemicals" are distinguished from existing chemicals by use of an Inventory (a listing) of existing chemicals;

- NCNSs exclude certain chemicals from coverage (e.g.; drugs, pesticides, etc.) which are covered by other laws;
- chemical management decisions on new chemicals generally have a risk basis;
- NCNSs recognize and handle "Confidential Business Information" so as to protect commercial information;
- the focus of enforcement generally involves voluntary compliance because of the number of companies and chemicals involved.

While there are many similarities, there are also key differences among the NCNSs in OECD Members Countries:

- some require "premarket" notification while others rely on "premanufacture" notification (i.e., at an earlier stage of commercial development);
- some systems list polymers on their inventory and require notification on all polymers not on the inventory, other systems do not include polymers on their inventory but require notification of any polymers made with "new monomers" (ones not listed on the initial inventory);
- countries require differing amounts of test data with the notification ranging from full "base set" testing, less than base set testing, or no testing;
- some countries add new chemicals to their Inventory of existing chemicals following review, others maintain a separate listing of the new chemicals (thus they do not become "existing chemicals");
- some countries rely heavily on classification and labeling as the key element in risk management while other countries look to other means of controlling risks (use restrictions, controls on environmental releases, etc.)

1.2 Inventories

An "Inventory" is a list of the industrial chemicals in commerce in a country or region. Drugs, pesticides, etc., are generally not included on an Inventory unless they also have industrial uses; some Inventories do not include polymers. Inventories are the foundation of NCNSs in OECD Members countries as they are used to distinguished new and existing chemicals ("new chemicals" are those not on the Inventory). Some Inventories were created *de novo*, others were based on existing Inventories. While common to all OECD NCNSs, developing and maintaining an Inventory is technically difficult, presents logistical challenges, and is time consuming. The Toolbook reviews these aspects and discusses less complex alternatives. In developing or maintaining an Inventory it is important to establish a good working relationship with the chemical industry and its major trade associations in a given country or region.

1.3 Notification

A "notification" is the information provided to the government by a company intending

to commercialize the new chemical. Notification can be required prior to manufacture ("premanufacture" as in the US and Canada) or prior to marketing the new chemical ("premarketing" as in the EU).

The notification generally includes basic information on chemical identity (used to identify the substance and confirm new chemical status), use information, production volume, identity of the manufacturer, exposure information, and test data on the new chemical. Use and exposure information submission requirements can be general or specific and detailed. Production volume estimates generally cover the first several years after introduction. Many countries require that the notification includes a "base set" of testing. The test set can be similar to one recommended by the OECD (as is done in the EU and Canada) or be somewhat less detailed (Japan); alternatively, the notification requirement might not include any testing (US). Some countries allow exemption from full notification for certain chemicals. Examples of exemptions include polymers and low volume chemicals.

The initial notification must be updated in some countries if uses, volumes, etc. change. Other countries allow any use or volumes of production to occur after notification unless specific action is taken (e.g.; a Significant New Use Rule or SNUR in the US). Some systems (EU and Canada) require higher levels of testing as production volume increases.

All OECD NCNSs allow information to be claimed as "Confidential Business Information" or CBI. Such information must be handled carefully by the government authorities to ensure that only authorized individuals see the information.

Most countries impose fees on notifiers to help cover costs. Currently Canada does not impose fees on notifiers but is in the process of developing a cost recovery program.

1.4 Assessment

The topic of assessment is presented as a general overview in the Toolbook. The OECD has developed numerous detailed guidance documents as have Member Countries or other international organizations (IPCS). A number of these are noted in the Appendix to the assessment section.

Assessment requires technically trained assessors to evaluate the notification and develop recommendations. The assessment generally considers issues relating to chemical identity, human and environmental exposure, hazard (or toxicity), risk (hazard plus exposure), economics aspects (e.g., benefits of the new chemical), and other aspects.

Exposure assessment uses the information in the notification plus other relevant information to determine the nature and magnitude of potential exposure. The assessment, depending on the country, can include any or all of the following: workers, consumers, general population exposure (human exposure via the environment), environmental releases, environmental concentrations, and environmental fate. Some countries perform general exposure assessments while others conduct more detailed site-specific analyses.

Depending on the level of base set testing required, hazard assessment can focus on the

data submitted or consider other information (such as the use of Structure Activity Relationships (SAR) in the US to predict potential hazards).

The focus of the assessment in OECD Members Countries is to determine the hazards and risks presented by the new chemical. If unacceptable risks are identified through the Risk Assessment, control actions can be taken. These actions are generally termed Risk Management.

1.5 Post-Notification Activities

Risk management control actions are implemented and enforced post-notification. This generally includes record-keeping requirements imposed on the company to ensure that the control actions are followed. Risk management approaches vary among countries and can include classification and labeling, use restrictions, emission controls and other action up to, and including, bans.

Some systems require a notice once manufacture begins. This is termed a "Notice of Commencement" in the US. Some countries add the former new chemical to the Inventory and thus change the chemical's status to an existing chemical. Other countries maintain separate lists of new and existing chemicals.

As noted above, additional notifications can be required after the initial notification - this can be a standing requirement for all new chemicals (triggered by a change in use, increase in production , etc.) or be directed against selected new chemicals or uses (e.g., SNURs).

The general focus of enforcement efforts on new chemicals is to obtain improved voluntary compliance by companies. Thus, compliance assistance is provided to industry to improve the ability of companies to effectively meet new chemicals requirements. Countries also rely on inspections and investigations in some cases. Nevertheless, inspections are generally limited in numbers and thus it is not possible to rely solely on enforcement efforts. For this reason, voluntary compliance is a key goal. Trade associations can generally be helpful in working with government officials to improve compliance.

1.6 On-Going and Future Efforts Relating To Harmonization

Increased harmonization of OECD new chemical notification systems is a long-term goal of the OECD. There are several harmonization efforts underway. Through the OECD efforts are being made to share assessments between Germany and Australia as well as between the US and Canada. In 1996, the US and Canada entered into a pilot project whose goal is to demonstrate that information sharing saves resources - for industry and government - and that through US sharing of its assessment, new industrial chemicals can enter the Canadian market faster and with fewer test costs. The accord is commonly called the Four Corners Agreement because it was negotiated among officials from the US and Canadian governments and by representatives from US and Canadian industry. In addition, the US and the EA. are examining possible harmonization opportunities through the Trans Atlantic Business Dialogue. Thus efforts are underway to make the systems in different countries more alike, which can save resources of government and industry alike and make for increased efficiency in the overall process. Particular

opportunities for sharing and utilizing previous work will exist for chemicals which have been notified elsewhere but are introduced as new chemicals for a given country, rather than as new chemicals for the world.

1.7 References

1996 OECD Workshop

2. Inventories

***See Chemical Management Instruments, A resource for Countries Making Choices,
Module one: Chemical Inventories***

3. Notification Requirements

1 Brief Description

The purpose of the notification requirements is to obtain information that allows responsible authorities to make proper risk assessment and thus to protect the environment and human health against harmful effects of hazardous chemicals and formulations. Notification requirements are essential to identify these harmful effects, to avert them and to prevent their occurrence. The type and amount of information required for the notification of new chemicals depends on the NCNS and on the risk assessment approach used to assess this information. The information provided in the notification dossier is the basis for an assessment of potential risks. This section describes the link that exists between notification requirements and risk assessment approaches, whereas Section 4 describes different risk assessment systems.

1.1 Scope of Application

Limitations can be imposed on the chemicals requiring notification. New chemicals that have to be notified are new chemicals as such or that are ingredients of mixtures. Several countries exclude chemicals such as naturally occurring chemicals, chemicals that are contained within articles, incidental reaction products, products of end-use reactions, mixtures (but not components of mixtures), impurities, by-products and non-isolated intermediates.

Complete or partial exemptions from the comprehensive notification requirements can also be granted for substances with low associated risks or exposures, e.g. polymers, research and development chemicals, test marketing chemicals, chemicals that are manufactured or imported in small amounts (e.g. < 10 kg/yr) and chemicals that are expected to have low releases and low exposures, e.g. due to their uses.

Some NCNSs differentiate between chemical classes, i.e. polymers as defined by the OECD, biotechnology products and chemicals, to determine the specific notification requirements.

Chemicals that are already regulated under other legislations are also excluded. These include inter alia tobacco/tobacco products, nuclear materials, munitions, food/food additives, drugs, cosmetics and chemicals used solely as pesticide or drug formulations.

The industry, either the manufacturer or the importer, is responsible to notify new chemicals.

NCNSs require "pre-manufacture" or "pre-market" notifications. While pre-manufacture notifications are required only from the initial manufacturer, pre-market notifications required of each manufacturer/importer.

Normally, exported chemicals are excluded from NCNSs. However, some NCNSs require a reduced notification package before exportation of the new chemical. The amount and type of information requirements depend on the amount of substance to be exported ("pre export notification").

1.2 Required Information

Generally, NCNSs include some minimum amount of required administrative and technical information such as the identity of the chemical substance and the identity of the notifier. Required information enabling consideration of the risks that may be posed by the substance can include, among other items:

- information on impurities and by-products
- intended use of the chemical
- results of tests of the substance's effects on test animals
- physical-chemical properties of the substance
- manufacturing process description
- production volume
- mechanisms of waste disposal
- human exposure
- worker protection methods
- results of prior-conducted risk assessment

Pre-manufacture notification systems, such as the US system, require all available data on the chemical identity, production volume, by-products, use, environmental release, disposal practices, and human exposure, as well as all the existing health and environmental data in the possession of the notifier, parent company, or affiliates, and a description of any existing data known to or reasonably ascertained by the notifier are also required. There is no prescribed minimum amount of information requirements, or Minimum Premarket Data Set (MPDS), for each notification. After review of this information, submission of additional data is required when the information available about the notified chemical and similar chemicals is not sufficient to do the risk assessment.

This type of system is on the one hand less cost-intensive because information on chemicals can be obtained using structure-activity relationships to categorise chemicals and to determine whether to require additional information. On the other hand, the MPDS could enable the responsible authorities to have more certainty about potential problems associated with the use of a chemical and that there is a close relation with its risk assessment and that of other similar chemicals.

Other NCNSs require information, for example a full MPDS or a reduced data set, depending on the volume of a new chemical that is placed on the market or manufactured by the notifier of the chemical. A MPDS is, for example, requested in Europe, when a company manufactures or imports more than 1 000 kg/yr of a new chemical. It consists of physico-chemical studies, toxicological studies such as acute toxicity, repeated dose toxicity, mutagenicity tests, and ecotoxicological studies such as acute toxicity for fish and daphnia, growth-inhibitor test on algae, bacterial inhibition, degradation, and adsorption/desorption screening test. Additional information on the chemical identity, production volumes, proposed uses, recycling, disposal, recommended methods and precautions concerning handling, storing, transport, fire, etc., emergency measures and packaging are also required. It takes about one year to prepare such a set of data under the conditions of Good Laboratory Practice (GLP). Depending on the amount of the chemical placed on the market or manufactured, additional information is required. For

low volume chemicals a reduced data set is required. The minimum notification includes information on the identity of the substance and its physico-chemical properties.

The more cost- and time-intensive system allows for an extensive evaluation of the hazard of each new chemical. The request for further information is either associated with an increase of the amount of the chemical placed on the market or manufactured or with a justified suspicion that the substance is hazardous. Other exemptions apply when the reduced testing is scientifically not justifiable or technically not feasible.

Some NCNSs require information/tests depending on the chemical class, volume and use. A third approach could be to require a minimum data set and to request more information only if necessary for a risk assessment.

1.3 Corrections and New Information

Any notifier who has submitted information in support of a new chemical notification and later determines that the information is erroneous should immediately notify the authority of that fact and submit the necessary correction. This ensures that proper decisions with respect to the toxicity of the substance are based on correct information. Furthermore, subsequent to the notification of a new chemical, a notifier obtains new information on the chemical, the notifier should provide this information to the notification authority. The objective is to ensure that new information about chemicals which have already been considered is given to the notification authority so that it can be examined to determine whether regulatory decisions made in the notification process for those substances should be changed. If new information is obtained for a substance that has been added to the inventory of existing substances, a link with other regulatory mechanisms such as existing chemicals provisions is suitable. For NCNSs where pre-market notifications have to be submitted, any change or correction in the content of the dossier and all new information available has to be provided to the responsible authority.

1.4 Confidentiality

The responsible authority has to guarantee that it will treat data on new chemicals that have been accepted as Confidential Business Information (CBI) as such. Suitable measures have to be taken to ensure that data are protected appropriately. Certain exemptions from confidentiality exist, such as for the trade name of the notified substance and for the information contained in the safety data sheet. Should the new chemical be hazardous, suitable analytical methods enabling its detection in the environment and determination of direct exposure of humans to the chemical should not be kept confidential.

The name of the manufacturer and the notifier is kept confidential in some countries for a certain period of time. On certain inventories, the specific chemical identity may not be claimed as confidential if the chemical is classified (such as the ELINCS in the EA.).

If the identity of some reactants for the chemical synthesis, or of the chemical itself, is not known to the manufacturer, some countries agree to accept a letter of support from the supplier of the reactant, whose content will be held confidential.

1.5 Testing Requirements

To prepare the tests that are required under the NCNS, test methods published by the OECD, or in Europe by the European Commission, have to be used. These test methods should be well known by those institutes/laboratories that also have to comply with the principles of Good Laboratory Practice (GLP). The institute or laboratory doing the tests should provide a written declaration indicating that the tests have been performed in accordance with the principles of GLP. A prerequisite for the mutual acceptance of tests from a foreign testing institute depends on a mutual recognition of GLP schemes between countries.

Some NCNSs require that data be developed from the pure chemical, whereas others may accept data on the commercial grade chemical.

1.6 Reviewing Procedures

Responsible authorities review new chemical notifications within specific time frames that may vary from 5 to 90 days depending on the NCNS. In the first step the notification is reviewed to determine whether the dossier is complete, the data sets are valid, and the results are plausible. The second step is to assess the submitted data. This may be done using expertise from health, environment and occupational safety and health protection.

To facilitate the notification and review work, countries have introduced standardized forms and sometimes the notifier is obliged to provide diskettes.

After assessing the available data, a decision is taken whether further information or tests have to be requested to assess either the risk or the hazard of the new chemical (using one of the above mentioned approaches). If no further information is required the risk assessment is completed.

Notification authorities are normally either the national Departments of environment/labour/health or subordinated authorities/agencies.

1.7 Fees

Most NCNSs impose fees on notifiers. Fees differ from country to country and according to the volume of the dossier, which depends on volume of chemical to be manufactured or imported. Some NCNSs give a reduction if the notifier provides an adequate risk assessment or if the hard copy of the dossier is replaced by a diskette.

2 Aim and Objectives

Notification requirements are important to get the information necessary to facilitate the government assessment of whether intended activities surrounding the manufacture, processing, use, and disposal of the substance identified in the notification may pose an unreasonable risk for the human health or the environment, and whether the control measures proposed by the notifier can adequately reduce exposures and/or releases to enable positive conclusions regarding the identified risk. On the basis of this risk assessment those measures described in Section 5 on Post-Notification Activities (i.e. compulsory classification and labelling, limit values, bans and restrictions, etc.) can be applied.

The communication of risks and hazards can be done by the notification authorities by means of a publication addressed to the users of the new chemical or by the supplier on the Material Safety Data Sheet (MSDS) that is provided to users or as a label on the packaging of the chemical.

3 Linkages/relationship to other Instruments

The notification of new chemicals was introduced to fill a gap for commercial chemicals not addressed by other legislations on chemicals (e.g. on nuclear materials, food additives, drugs, cosmetics, pesticides, etc.). New chemicals falling under the jurisdiction of these other legislations are exempted from notification under NCNSs.

To define a new chemical one has to refer to an inventory of existing chemicals or to a list of chemicals that do not have to be notified, see also Section 2.

The set of information required in a notification forms the basis for a risk assessment on each notified chemical. Depending on the result of this assessment further measures to reduce the risk are possible. See Section 5.

4 Advantages and Potential Benefits

Over the years thousands of chemicals have been notified to different countries under different NCNSs. These notifications have allowed governments to perform risk assessments of these new chemicals and to take appropriate preventive actions to protect the environment and human health. The appendices describing specific countries experiences with NCNSs provide more specific information in that regard.

5 Limitations and Drawbacks

The general strategy of applying scrutiny to "new" chemicals through a notification-assessment-inventory system can lead to regulation of a new chemical and not of a similar chemical already on the market. This issue is sometimes referred to as "new chemical bias". The requirement to notify new chemicals, while existing chemicals can continue to be used, represents a differing standard the responsible authorities must meet before they can take regulatory actions. This apparent inequity is circumvented by a variety of approaches. Those can include voluntary agreements, alone or in combination with regulatory approaches; regional, federal, state and local partnerships; dissemination of risk management information to assist the selection of safer substitutes; emphasis on pollution prevention and innovative control technology to reduce exposure and environmental release; use of chemical emission data from an inventory on toxic releases to help address site-specific chemical concerns; refined risk assessment and cost/benefit analysis; and the challenge to industry to meet its own Product Stewardship and Responsible Care goals.

6 Resource Requirements

The preparation and review of new chemical notifications is burdensome for both notifiers and notification authorities. It also requires expertise in different fields such as chemistry, biology, toxicology, etc. See Appendices on specific countries experiences for more details.

7 Factors Affecting Effectiveness/Feasibility

Proper understanding of NCNSs by the regulated community is essential to ensure that appropriate information is provided with notification dossiers. This requires notifiers and government authorities to dedicate time and effort in establishing proper communication and in understanding what they are expecting from one another.

4. Assessment of Notifications

1 Brief description

As described in Section 3 and Appendix to Section 3, NCNSs include some minimum amount of required administrative and technical information.

Information provided in the notifications, often coupled with independent research by the reviewing and assessing group and with information which has been received by the notification authority on similar substances, is assessed for determining potential hazard to the environment and human health. Results of the hazard assessment are provided to the group responsible for risk management decisions (who may or may not be part of the group which assessed the hazard).

The determination whether a chemical may be harmful to the environment or human health consists of integrating the assessment of potential exposure of a chemical to humans and components of the environment with potential adverse effects on humans and the environment.

The following four steps are part of a risk assessment:

- *Hazard identification*: the identification of the adverse effects which a chemical has an inherent capacity to cause.
- *Dose (concentration) - response (effect) assessment*: the estimation of the relationship between dose, or level of exposure to a chemical, and the incidence and severity of an effect.
- *Exposure assessment*: the determination of the emissions, pathways and rates of movement of a chemical and its transformation or degradation in order to estimate the concentrations/doses to which human populations or environmental compartments are or may be exposed.
- *Risk characterization*: the estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a chemical, and may include risk estimation.

The result of a risk characterization can be the decision:

- that the risk can be sufficiently assessed and no further information is necessary, or
- that the chemical is of concern and further information is requested on the effects or the exposure or
- the chemical is of concern and risk management to reduce the risk is necessary.

2 Aim and objectives

The purpose of assessing the information submitted under NCNSs is to determine the hazards, exposures, and risks new chemicals may pose to the environment and human health and to understand these risks in order to take proper decisions so that levels of risk from chemicals use can be kept at an acceptable level relative to their benefits.

3 Linkages/Relationship to other Instruments

An assessment process works with the information provided in a notification, and provides quality information only if that required information is complete and useful. The mechanism of determining which chemicals must be notified is usually comparison of the chemical identity to a national inventory of substances in commerce; and there can be exclusions from scrutiny even for non-inventory substances (natural products, polymers meeting certain published criteria, food, tobacco, pesticides, products produced below a certain volume, substances used in research laboratories, nuclear materials, e.g.). Once assessment is complete, the result will be linked to mechanisms of chemical control (regulations, orders) and to entry of the substance onto the national inventory of substances in commerce.

4 Advantages and Potential Benefits

A NCNS of the type notification-assessment-inventory system ensures that a new chemical does not enter commerce without a thoughtful assessment of the potential hazard and risk it can represent and a consideration whether to restrict use or release. It does so at a time in the product development cycle when large amounts of resources have not been committed to building production facilities and when downstream markets are not dependent on a continued supply of the material, which means that a decision not to allow production to begin or to require safeguards will be minimally costly.

The assessment portion of the NCNS enables cost-effective protective decisions to be taken.

5 Limitations and drawbacks

None of the three systems detailed in this tool book (Canada, EU, US) is on a product-as-sold (mixture) basis. Each calls for assessment of notifications on a chemical basis. Assessment of notifications does not ensure that potential synergistic or additive effects will be considered (product-basis registration, however, would increase the complexity and cost of the system by many times).

6 Resource requirements

Specific resources used in assessment processes are discussed under the Appendix to Section 4. It is worth noting that many of the strategies used by developed countries for assessment of notifications depend on availability of a "critical mass" of resources - a minimum number of risk assessors, reviewers from several different academic disciplines are needed in the group, etc., and it would be expected to be particularly difficult to transfer these resource-dependent approaches to most developing countries on a short term basis. In many, even most cases, a substance being notified to a developing country will already have been through an assessment process in another country/ countries, and strategies enabling use of prior risk assessments are likely to be helpful.

7 Factors Affecting Effectiveness/Feasibility

In many ways the needs for a successful assessment process of notifications will be similar to any governmental regulatory work: adequacy of staff (number and qualifications for their work) and facilities are essential. The "critical mass" question is identified in subsection 4.6, above. As well, it is important to be able to provide a NCNS with stability. There is a learning curve and staff members' sense of history and response to similar chemicals in the past are important to success. It is crucial that the NCNS has the ability to compel that sufficient information be provided.

5. Post-Notification Activities

1 Brief Description of Post-notification Activities

Post-notification activities depend on the NCNS and are developed to ensure proper actions are taken by regulators and regulatees after the new chemical has been submitted and assessed. Options and alternatives include:

- No Post-notification activities

This is suitable only if the notification requirements are limited to minimal, essential information where the country plans to conduct little or no assessments of hazards, exposures, and risks.

- Imposition of Post-notification activities

This is suitable where the notification requirements are set out to conduct assessments that will determine the potential adverse effects of the new chemical on the environment and human health.

1.2 Types of Post-notification activities

Risk Management Actions

Where the authorities determine that the new chemical may pose an unreasonable risk to the environment or human health, it is important for the authorities to take appropriate control measures for protecting the environment and/or human health. Control measures can include:

- Permit commercialization of the substance subject to conditions such as: restricted uses, limited release in the environment, limited exposures, limited volumes, proper management of hazardous wastes and requirements that additional information be developed and submitted to the authorities before a set volume is produced.
- Ban commercialisation pending submission of additional information requested by the authorities in order to reach better conclusions concerning the toxicity of chemicals.
- Total ban.

Control measures can be imposed through a consent order or Significant New Use Rule or Activity which requires that new uses or activities of the chemicals be notified through the same new chemicals notification process.

New chemicals notification schemes being developed could rely on actions taken in other countries (e.g., classification and labeling decisions taken on EU notifications, actions taken by the U.S. or Canada etc.), augmented as needed by actions required in light of special circumstances. Actions taken in other countries should appear on MSDSs in recognition of regulatory requirements on the original manufacturer.

Notice of Commencement or Notice of Excess Quantity

Once a chemical has successfully been through the notification process, one of the inventory listing criteria may require that notifiers inform the authorities that commercial activities for the chemical have commenced. This can be done through notices of commencement, or notices of excess quantity if one of the listing criteria specifies regulatory trigger quantities. This ensures that the inventory is limited to chemicals for which there is genuine commercial activity in the country.

Addition of Chemicals on the Inventory

If the new chemicals notification scheme includes an inventory of existing chemicals, the authorities may choose to update this inventory by adding new chemicals that meet established listing criteria. This ensures that the inventory reflects the commercial chemicals activities of the country.

Record Keeping and Tracking

In order to keep track of all information and correspondence pertaining to new chemical notifications it is important to develop a tracking system. A computerized tracking system may be used to indicate the status of notifications as well as entering administrative and specific chemical information related to the notification package. A good filing system for keeping all the correspondence with the notifier and copies of the notification package is also essential.

Stewardship Agreement with Notifiers

Besides the compulsory use restrictions identified above, the authorities may enter into Stewardship agreements with importers and manufacturers to encourage appropriate safety precautions with new and existing chemicals. Often these special agreements will cover groups of chemicals, for some of which the authorities have the ability to compel certain restrictions and for some of which (generally because of prior placement on the inventory) it does not. These agreements can cover the basic elements which can be covered by rules, including restricted uses, limited release in the environment, limited exposures, limited volumes, proper management of hazardous wastes, and requirements that additional information be developed and submitted to the authorities before a set volume is produced.

Classification and labeling of dangerous goods

Based on the test data received with a notification and the use information, risk assessment for man (worker, consumer and environment) can be conducted by the notifier and the relevant notification authority to classify chemicals.

Classification is be the assignment of one or more categories of danger (explosive, toxic, carcinogenic, dangerous for the environment,...) based on the comparison of test data to established classification criteria. The classification can be the responsibility of the notifier and controlled by the notification authority. Self classification by industry can be replaced by a legally binding classification when the chemical is added to a list of dangerous chemicals. If a chemical or preparation is classified as dangerous a variety of follow up legislation could apply.

This classification exercise ensures that consumers and professional users are informed about the dangerous properties of chemicals through the use of danger symbols and safety phrases on container labels. During transport, internationally agreed labeling requirements are mandatory. In addition supplier of chemicals have to provide professional users with a Material Safety Data Sheet.

Classification and labeling procedures can be developed in parallel with the new chemicals notification scheme. Countries could use already established and recognized procedures or develop their own.

Publication of Information on New Chemicals

The notification authority should publish information such as: inventory updates, control measures imposed on new chemicals, and guidance on certain aspects of the notification scheme that are of general interest. Information may be communicated through official government publications or as information notes sent directly to the regulated community. This ensures some transparency and that industry is aware of new outcomes concerning the NCNS. Confidentiality issues must be taken into account with respect to the format of the published information.

1.3 Compliance and Enforcement Activities

Before implementing a NCNS it is important to consider its enforceability and to develop a proper compliance and enforcement strategy.

Measures to promote compliance include communication and publication of information, consultation with parties affected by the NCNS, technical assistance and technology development.

Enforcement activities include:

- inspection and monitoring to verify compliance with the law and control measures,
- investigations of violations,
- measures to compel compliance without resorting to formal court action, such as directions by inspectors, ticketing, fines and authorities orders,
- measures to compel compliance through court action, such as injunctions, prosecution, court orders upon conviction, and civil suit for recovery of costs,
- ensuring wide awareness of potential penalties for noncompliance.

Even though, inspection and monitoring is essential to ensure industry is complying with the NCNS, compliance and enforcement activities should also include efforts for obtaining voluntary compliance by industry. Self-policing through industry associations should be encouraged and supported. Commitment to the reporting program by trade/industry associations provides an endorsement in principle by the entire sector. Violations result in embarrassment and adverse publicity.

Associations can also assist by distributing program information to their membership and by providing names and addresses of new companies or companies of which the government is unaware. Such cooperation is in the best financial interests of companies

complying with the notification requirements since competitors are obtaining an advantage by not developing the required information packages.

Assurances of voluntary compliance signed by the Chief Executive Officer of a company may also be useful in encouraging compliance as they are intended to ensure the participation of the most senior management level in the program and non-compliance becomes a breach of personal commitment.

2 Aim and Objectives

Review and assessment of notifications sometimes result in conditions being imposed on the importation, manufacture, or use of new chemicals. The primary objective of the post-notification activities is to ensure that the notifier is implementing risk management actions required by the notification authority after the new chemical has been submitted and assessed. The field of application is those chemicals which have been notified, and may include those which have been placed in the Inventory and those which fall under an exemption. Another post-notification objective is to ensure the regulated community is complying with the NCNS.

3 Linkages/Relationship to other Instruments

Other regulatory mechanisms for chemicals management include controls on transport, storage, import and export, waste handling requirements, and occupational health and safety requirements (e.g., legislation on how to avoid major chemical accidents on safe handling and on the use of chemicals in the work place). These regulatory mechanisms are generally used on materials which have not been assessed under the new chemicals notification scheme; because they were existing chemicals at the time the initial inventory was developed. However, any chemical which has been assessed under the NCNS and been placed into commerce can later be controlled under these other regulatory mechanisms.

4 Advantages and Potential Benefits

Post-notification activities ensure that a new chemical does not enter commerce and is not added to the inventory before proper risk management actions are taken.

Compliance and enforcement activities by the notification authority will ensure that notifiers are aware of consequences they are facing if they are not complying with the law.

5 Limitations and Drawbacks

Proper risk management actions may be difficult where the notification information is limited and the assessment subject to relatively short prescribed regulatory deadlines. Where controls apply specifically to the notifier, the chemical is subject to re-evaluation if another notifier wants to import or manufacture the same chemical.

6 Resource requirements

Post-notification activities is the responsibility of assessors, enforcement officers and legal authorities. Assessors make recommendations to minimize the identified risk

associated with the chemical Enforcement officers ensure the proposed controls are enforceable and legal authorities ensure that controls fall within the legal scope of the NCNS. See Appendix to Section 5 for more details.

7 Factors Affecting Effectiveness/Feasibility

In order to take proper risk management actions it is crucial that the NCNS is designed in such a way that it requires notifiers to provide information allowing assessors to do a meaningful risk assessment. The NCNS and control options should be developed in an enforceable manner.

6. Resources and Infrastructure

1 Resource elements to be consider

- **Infrastructure**

- legal authority
- availability of laboratories performing testings (OECD tests guidelines in OECD country) according to GLP

- **Resources of Industry** (see Annex A)

- **Testing costs for notification**

- **Administrative Costs**

USEPA estimates the burden imposed on notifiers for notifying new chemicals as approximately 100 hours per submission.

- **Notification Fees**

- **Time delay before marketing due to**

- testing
- time for assessment by government

- **Resources of Government**

2 Notification Requirements

The preparation and review of new chemical notifications is burdensome for both notifiers and notification authorities. It also requires expertise in different fields such as chemistry, biology, toxicology, etc

2.1 Canada

It requires approximately 9 full time employees to process new chemical notifications before they are assessed. This includes processing and reviewing NCNS dossiers, waiver requests, masked names, and providing advice to industry. The estimated cost for these activities is approximately \$800,000 Canadian.

2.2 EU (Germany)

The management of the EA. Directive on notification of new chemicals and of the EA. regulation on risk assessment of existing chemicals in Germany is coordinated by the same authority: the notification authority in the Federal Institute for Occupational Safety and Health.

The four authorities or institutions that work at the procedure of notification and risk assessment of new and existing chemicals are:

- The Notification Authority, Federal Institute for Occupational Safety and Health
- The Federal Institute for Health Protection of Consumers and Veterinary Medicine
- The Federal Agency of Environment and
- The Division Hazardous Chemicals, Federal Institute for Occupational Safety and Health.

Qualified experts with a University or a technical college degree in the fields of chemistry, biology, toxicology and chemical engineering and technology are required for notification review and assessments. These experts not only work on notification review and assessments but also do scientific work associated the development of test methods.

2.3 US

3 Notification Assessments

It is worth noting that many of the strategies used by developed countries for assessment of notifications depend on availability of a "critical mass" of resources - a minimum number of risk assessors, reviewers from several different academic disciplines are needed in the group, etc., and it would be expected to be particularly difficult to transfer these resource-dependent approaches to most developing countries on a short term basis.

In many, even most cases, a substance being notified to a developing country will already have been through an assessment process in another country/ countries, and strategies enabling use of prior risk assessments are likely to be helpful.

- costs for notification system
- number and mix of technical personnel
- scientists- chemists, health and environmental hazard assessors, exposure assessors, risk assessors, risk managers, legal advisors, computing specialists
- number of administrative personnel
- necessary infrastructure (computer, fax, E-mail, access to databases)

3.1 Canada

The Canadian assessment procedure is more "generalist" in nature than the US EPA. In Canada, each notification is forwarded for separate assessments by Environment Canada and Health Canada. At Environment Canada, one individual is responsible for assessing all aspects such as physical/chemical properties, chemical structures, engineering processes, exposure and releases from an environmental perspective, as well as ecotoxicological data. At Health Canada, two individuals, a chemist and a biologist review each submission. The chemist addresses physical/chemical properties, chemical structures, engineering processes, exposure and release issues from a health perspective, while the biologist addresses mammalian toxicological information.

The Canadian assessment system has proven to be effective in identifying chemicals anticipated to pose a risk to human health or the environment and when necessary, in the implementation of specific controls. A generalist as opposed to a specialist evaluation procedure may be conducive to evaluating smaller numbers of assessments.

The assessment period ranges between 5 and 90 days, with the most frequent being 5 day and 45 day reviews. Canada reviews between 500-800 notifications per year.

The assessment of chemicals requires 11 full time employees. The annual cost is estimated to be \$1,000,000.

3.2 EU (Germany)

3.3 US

Approximately 75 people work in this regulatory effort for USEPA. The TSCA sets a 90-day period for the review of PMN notifications, exemptions are reviewed more quickly under regulations issued by the Agency. Roughly 2000 PMNs and other (exemption) submissions are reviewed in a year.

4 Post-Notification Activities

Post-notification activities are the responsibility of assessors, enforcement officers, and legal authorities. Assessors make recommendations to minimize the identified risk associated with the chemical Enforcement officers ensure the proposed controls are enforceable and legal authorities ensure that controls fall within the legal scope of the NCNS.

- number of compliance monitoring inspectors, GLP inspectors (expertise)
- necessary infrastructure

4.1 Canada

Control options (conditions) are proposed and developed by assessors. Then, enforcement officers provide input with respect to the enforceability of the conditions and legal authorities ensure that the conditions fall within the scope of CEPA.

The annual cost for the development of control options is approximately \$40,000 and requires the equivalent of 1 full time employee.

The annual cost for the maintenance of the DSL is approximately \$56,000 and requires the equivalent of 0.5 full time employee.

For compliance promotion the annual cost is approximately \$21,000.

4.2 EU (Germany)

4.3 US

Control options (conditions) are proposed and developed by regulatory staff which

require the equivalent of approximately 12 full-time employees. The cost for compliance monitoring and enforcement which includes compliance monitoring inspectors and GLP inspectors should also be included.

7. Frequently Asked Questions

GENERAL

1. How does a NCNS fit in an overall scheme of chemical management?

Member countries of the OECD implement, as part of an overall program of chemical management, New Chemical Notification Systems (NCNSs) as a means to assess new chemicals and to decide if any actions are needed to protect human health and the environment. NCNS represent a "high level" environmental protection activity. Most countries develop and implement more basic chemical management programs before starting a NCNS. Examples of these more basic chemical management elements include programs to manage chemical accidents, "existing chemicals" (substances already in use in a given country), Pollutant Release and Transfer Registers (PRTRs) and so on.

2. What is the value of NCNS for a chemical producing country?

NCNS are a useful component of an overall program of chemical assessment and management. NCNSs are of value to a chemical producing country because they: (1) complement existing chemical management programs and can assist in managing existing chemical problems through encouraging the introduction of safer or "greener" substitutes, (2) allow countries to anticipate and prevent the introduction of risky new chemicals; and (3) keep tabs on developing innovative technologies and market trends.

3. How can a country avoid becoming a dumping site for unwanted chemicals if it decides to function without a NCNS?

A country could develop a list of unwanted or special restriction chemicals and then set up a system to monitor imports of these chemicals. In the absence of such a system or a NCNS, it will be much more difficult to manage this issue since chemicals would be found after they have entered commerce in the country. International systems, like PIC and POPs, provide a starting point for lists of dangerous chemicals.

4. How might a country which does not develop or produce many new chemicals implement a NCNS?

A NCNS for such a country could focus on reviewing imports which are new to the country, although as the country's chemical industry develops it would eventually become necessary to implement a similar program for domestically produced new chemicals.

5. What are the drawbacks/limitations associated with NCNS?

Proper risk management is difficult, skilled staff are needed to evaluate notifications in a short period of time (i.e., 45 days in Canada, 90 days in US) so as not to unduly disrupt commerce. NCNS and industry apprehension about regulation can have a stifling effect on innovation of new chemical substances or technologies. Also, the information submitted in notifications, on which risk assessments are based, is often

preliminary. The actual use of a chemical may not follow what was proposed and therefore the risk assessment may not be an accurate prediction of the actual risk.

MANAGING NEW CHEMICAL NOTICES

1. What is involved in developing and running a program to assess new chemicals?

To develop a program to assess new chemicals, you need to determine the goals you want to achieve in your NCNS, then determine the information you need in order to reach your goals. Next determine the staff needed, according to your goals. Make sure you have the capacity to follow through. Make it enforceable. Make a system simple at the beginning but that can be easily expanded.

To run a program to assess new chemicals, the basic elements of the notification system must be defined: what information must be submitted and in what form; what the role of base set testing; what exemptions from notification will be permitted; etc. This is generally implemented via a law or directive. A system for receipt of the notices must be established, including provisions for handling confidential information. A team of skilled assessors must be assembled to review the information and recommend appropriate actions. Post notification activities must be instituted that will ensure that the notifier is implementing the risk management actions required by the notification authority. Lastly a proper compliance and enforcement strategy must be developed.

2. How can these costs be minimized?

Adopting an existing inventory will provide a major cost savings. Utilizing a phased implementation program to limit the number of notices received initially is another strategy (the number of notices could be limited through exclusions (polymers, on-site intermediates), production volume triggers, etc. Notifiers could be required to include information on previous notifications to other countries and a system to share these assessments could be developed between the involved countries. Also, notifications made under other systems could be accepted, perhaps with the requirement that aspects unique to your country (uses and exposure, special environment exposures) receive specific coverage in the notice.

3. When an attempt is made to use new chemical assessments from another country, how does one ensure that local risks are properly addressed and managed?

Much of the information contained in a hazard assessment is applicable broadly. There are exceptions, however, if your country has special environments (tropical or coral reef environments, for example). These might require additional focussed assessment. Exposures will differ from country to country, often dramatically, due to differences in the way the chemical is used or the protective equipment available. A country considering a NCNS would need to consider how it might obtain and evaluate the exposure information needed to tailor exposure assessments to the situation within the country.

4. How can I minimize the costs of implementing a NCNS?

Adopting an existing inventory will provide a major cost savings. Utilizing a phased implementation program to limit the number of notices received initially is another strategy, for example, the number of notices could be limited through exclusions (polymers, on-site intermediates) or production volume triggers, etc. Another strategy could be to accept notifications made under other systems, perhaps with the requirement that aspects unique to your country (uses and exposure, special environment exposures) receive specific coverage in the notice.

OTHER CHEMICAL MANAGEMENT OPTIONS TO ADDRESS HAZARDOUS CHEMICALS

1. Where does a NCNS fit into an overall program of chemical management?

A NCNS is a "high level" program which is generally implemented after a country has already put into place other chemical management programs, such as ones directed at chemical accidents, required use of Material Safety Data Sheets (MSDSs), Pollutant Release and Transfer Registers, and managing risks associated with chemicals that are covered by international agreements such as PIC, POPs, and the Montreal Protocol.

8. Options for New Chemical Notification Systems

8.1 Options for Inventories

As discussed above, the compilation and maintenance of inventories require a large effort, involving many skilled individuals. The magnitude of the effort will depend upon the size and level of industrialization of the economy. However, given the number of chemicals in commerce around the world, even the smallest of economies can be expected to have thousands of chemicals in use and manifold more products. Thus, decision makers should consider carefully their options for an inventory, including the following:

8.1.1 Operate without an inventory

Before deciding upon a chemical inventory or product register, countries may wish to consider carefully whether one is needed. Perhaps the chemical management problems in the country are so clear that an inventory is not required. Perhaps, if a country seeks to establish a new chemical review program, it can decide to trigger notification, not based upon whether the chemical or product is new to the country (which would require a national inventory), but instead whether it is new to those responsible for submitting such notifications (which would not). Alternatively, a regional (multi-country) inventory might allow countries to share the costs of development.

8.1.2 Use an existing inventory as a starting point

Several chemical inventories already exist, and instead of compiling a completely new one, it would be possible to start on the basis of one or more of the existing ones (e.g., US/EA./CD). Such an existing inventory compilation could be adopted by the country with the presumption that all listed chemicals are in commerce in that country. Alternatively, the country could publish the existing inventory compilation and seek submissions on only those chemicals not already listed. If a country starts with a large inventory, this should result in the submission of very few new chemical notifications, at least initially (and vice versa). The approach of adopting an existing inventory is best suited to chemical inventories intended primarily for defining existing chemicals for a new chemical review program. It would not provide information on who was importing and manufacturing what chemicals, and in what quantities, within the country; obtaining this information would require that companies report details concerning the commercial presence of specific chemicals in a country.

If such information is important for sound chemical management in the country, an existing inventory could still be used as the backbone for an inventory database, and additional substances or country specific production or use information could be gathered and be added to the inventory data base. A similar approach, in which another effort could be used as the starting point for a national database, could be considered for a national chemical register of pesticides or other product uses.

8.1.3 Use policy analyses and conclusions of others

If a new full inventory is called for by national circumstances, it still should be possible to save much effort by adopting many of the policies and approaches used by the inventory programs of other countries. Such an approach should cut down on the need for skilled labor in tackling new issues such as chemical identity, definitions, and inventory coverage. Resolving such issues has proven to be very difficult, technically complex, and extremely resource intensive in the countries which have done this work.

8.1.4 Use of thresholds or a narrower scope of coverage to meet national needs

While current national chemical inventories typically contain between 50,000 to 100,000 substances, relatively few are produced in large quantities. For example, the U.S. chemical inventory has greater than 75,000 chemicals on it with total production and imports in excess of 3 billion metric tons. However, only about 3,000 chemicals are reported as produced or imported in greater than 500 metric tonne quantities per year. Very few of these are chemicals that have entered commerce in the past decade and the percentage of total production accounted for by recently introduced chemicals is well below one percent.

The biggest environmental concerns and highest priorities for chemical management programmes are most likely to be associated with the relatively small number of materials produced or used in the greatest quantities. As a result, it may be possible to greatly reduce the resources needed to establish and maintain an inventory as part of a national sound chemical management programme through the use of minimum thresholds below which reporting is not required. In addition to production volume limitations, countries could also decide to exclude polymers from the inventory (the EA. used this approach), petroleum streams, or other groupings of chemicals which are judged to be of less interest to the country.

8.2 Options for New Chemical Notification System

8.2.1 Minimal Requirements

Implement a NCNS with notification requirements limited to minimal, essential information. This may focus on tracking new chemical introductions where the country plans to conduct little or no assessment of hazards, exposures, and risks. This could be an interim step of a more developed NCNS.

8.2.2 Requirements of Existing NCNS

Utilize in a relatively intact manner the notification requirements of an existing NCNS. The OECD's MPD/new chemical information recommendations would be used as one of the options under this item. Notification could use existing NCNSs as such, or could be conditional to prior notification and acceptance by another country (i.e., approaches which would take advantage of work already completed by other more experienced countries; chemical nomenclature issues may be particularly appropriate for handling under this approach). Notification could also be based only on relevant portions of existing NCNSs (e.g., focus on the intended commercial activities in the country). Specialized conditions (tropical environments, e.g.) might require notification of additional requirements.

8.2.3 Develop your own notification requirements.

This approach could be based in large or small part on other existing NCNS or involve de novo development of your own requirements.

This could be done in a step by step approach:

Step 1

Require notification of chemical identity, quantity, uses, available hazard information (postcard notification) for a period of time (3 to 5 years). Focus could be on all chemicals or potential problem chemicals such as:

- PIC chemicals (annex III, PIC Convention)
- Chemicals banned or severely restricted in one or more countries (art 5, 6 PIC Convention)
- Chemicals restricted in use in one or more countries (art 14 para 1 PIC Convention) or which are classified

require notification of new chemicals which are produced/imported above a higher volume than the inventory trigger (e.g. 10, 25 or 100 000 kg/year). This could include notification at a lower volume for problematic chemicals (as described above) to ensure that industry is aware of the hazards and risks, to harmonize if necessary the information available to industry and to alert government. This would assist capacity building with simple notifications and basic assessments. Based on the experience about the necessary and available resources and capabilities the decision about the further scope of the NCNS can be made.

Step 2

Once experience has been built, implement basic NCNS and continue to build capacities and expertise such as:

- testing facilities for chemicals including GLP
- test applicability of other countries notifications and assessments for your country

More complete notifications could be required if the chemical was not previously notified in other countries with a more sophisticated NCNS or the information on such a notification was not accessible. Reporting could include:

- Adequate specific chemical name (CAS or IUPAC)
- OECD base set testing
- Information on the outcome of notifications in other countries (establish arrangements with other governments to get copies of the notification dossier and assessment to avoid CBI procedures)
- MSDS
- Basic exposure information (OECD SIDS basic level)
- Information on use in special environments

- Information on benefits (e.g. safer, more sustainable, greater efficacy/effectiveness, energy efficiency, pollution prevention)
- Hazard and risk assessment by industry which is reviewed by another country (review agreement necessary between countries and notification requirement must include this review process to overcome CBI issues)
- For PBTs require product management plan to ensure adequate handling of releases and wastes (use POPs criteria for P and B)
- Develop concepts for compliance monitoring

Step 3

Refine NCNS:

- Add testing elements (reflecting specific environmental conditions or exposures)
- Do more refined assessments
- Use appropriate assessments from other countries
- Develop criteria for exemptions
- Implement compliance monitoring

Appendix

Country Experiences with Notification Requirements

1. Canada

1.1 Objective

The Canadian NCNS is using a pre-manufacture/pre-importation approach. Its main objective is to ensure that new chemicals are not introduced into Canada before they are assessed to determine their potential adverse effects on the environment or human health. Materials that are subject to the NCNS are "chemicals" as defined in the *Canadian Environmental Act* (CEPA), "new" for the purposes of CEPA and neither excluded nor exempted under CEPA or the NCNS.

New chemical notifications must contain all required administrative and technical data and must be provided by manufacturers or importers to Environment Canada by a prescribed date that precedes manufacture or import.

1.2 Process through which Notification Requirements were Developed/Implemented

The statutory powers for the development of notification regulations within CEPA allowed Environment Canada and Health Canada to establish a NCNS that had the flexibility recommended by a committee composed of representatives from Environment Canada and Health Canada, provincial governments, industry, non-governmental interest groups, and labour. The main regulatory features of the NCNS are: establishment of classes of chemicals; identification of administrative and information requirements; timing of notification prior to import or manufacture; requirements for Environment Canada and Health Canada to assess information within a set time; and specification of conditions, test procedures, and laboratory practices to be followed when developing test data.

1.3 Special Design Features or Adaptations

To meet the need for flexibility when dealing with certain classes of chemicals, information requirements are tiered. Consequently, chemicals are categorised on the basis of such factors as generic class (e.g., polymers, chemicals), volume of import/manufacture, or proposed use (e.g., research and development, export only). This system of tiered information requirements allows Environment Canada and Health Canada to match information requirements with anticipated concerns about quantities and characteristics of specific classes of chemicals, and to ensure suitable assessment of potential health and environmental hazards. It is the responsibility of Canadian importers and manufacturers to determine if their chemicals are notifiable under the NCNS and to provide all the prescribed information.

The Domestic Substances List (DSL) and Non-Domestic Substances List (NDSL) (see Section 2) are the basis of the NCNS. For the purposes of CEPA, the DSL which lists all chemicals existing in Canadian Commerce is the sole basis for determining whether a chemical is new. If a chemical is listed on the DSL it is not subject to the NCNS. If a chemical is not listed on the DSL it is subject to the NCNS unless the chemical is excluded or exempted under CEPA or the NCNS. The NDSL identifies chemicals existing in world commerce but not yet commercially available in Canada, i.e. new to Canada. Chemicals listed on the NDSL are subject to the NCNS unless they are

excluded or exempted under CEPA or the NCNS. Notification of chemicals on the NDSL, however, allows for less stringent reporting requirements than other new chemicals. Therefore, it is very important for importers and manufacturers to compare their chemicals with the DSL and NDSL prior to notification to Environment Canada.

Since the NCNS requires each importer or manufacturer of new chemicals to notify, multiple notifications for the same chemical are possible until the chemical is added to the DSL. In order to avoid multiple testing on the same chemical the NCNS includes a mechanism that allows notifiers of the same chemical to share information.

1.3.1 Scope and Features of the NCNS

The NCNS were developed as a safety net addressing new chemicals (not on the DSL) that are not excluded under CEPA or not covered under other Canadian legislations.

1.3.2 Exclusions under CEPA and the NCNS

As for the DSL (see Appendix to Section 2), CEPA imposes exclusions on the statutory definition of "chemical" for the purposes of the NCNS. Therefore the NCNS does not cover materials such as mixtures, manufactured items or articles, and animate matter or mixtures contained in effluents.

CEPA also establishes criteria for new chemicals that do not require notification. The following chemicals are not covered under the NCNS:

- Chemicals regulated by other federal legislation (note that chemicals manufactured or imported for use as a chemical precursor in the manufacture of chemicals regulated by these other federal legislation are subject to the NCNS)
- Transient reaction intermediates
- Impurities, contaminants and partially unreacted materials
- Incidental reaction chemicals

The NCNS also exempt chemicals such as:

- Chemicals carried through Canada
- Chemicals not exceeding the first regulatory trigger quantity
- Polymers subject to the two percent rule

1.3.3 Classification of Chemicals

For the purposes of the NCNS, new chemicals are grouped into three major classes: chemicals, polymers as defined by the OECD, and biotechnology products, each subject to their own specific information requirements.

1.3.4 Categories of Chemicals

Information requirements are less comprehensive for chemicals that fall under categories such as: Research and Development, Product Development, Export Only and Site-limited Intermediates. New chemicals that fall within any of these categories are assessed when notified, however, they are not added to the DSL after the assessment.

1.3.5 Information Requirements

The Canadian NCNS contains a series of Schedules indicating the information that must be provided by importers and manufacturers depending on the category of chemical and volume to be imported/manufactured. If the manufactured/imported volume does not exceed the minimum quantity prescribed by the Regulations, the chemical is not subject to notification.

In general the type of information that must be provided for full notification of new chemicals can be summarized as follows:

- Administrative information identifying the notifier, the type and category of chemical, importation/manufacture volume, and type of Schedule
- Chemical identity
- Physical-chemical properties
- Ecotoxicity data
- Health related toxicity data
- Manufacture, importation, use and disposal information
- All the information in the notifier's possession

For the least comprehensive information Schedules only items 1,2 and 7 are required. Therefore, before submitting a notification dossier to Environment Canada importers and manufacturers must determine the appropriate notification schedule and timing by determining:

- The type of chemical (e.g., chemical or polymer)
- Whether the chemical is listed on the NDSL (because those chemicals are subject to less stringent information schedules)
- Whether the chemical falls within any of the special categories
- An estimate of the yearly and cumulative import/manufacture volumes

Polymers of low concern which include polymers of high number-average molecular weight that have a limited percentage of low molecular weight components and that are chemically stable and do not contain certain reactive or cationic moieties are also subject to less comprehensive information requirements.

All the data required by the NCNS must be addressed by submission of test data, waiver requests or surrogate information. Waiver requests must be scientifically substantiated and may be submitted: if the information is not needed in order to determine whether the chemical is toxic; if a chemical is to be used for a prescribed purpose or manufactured at a location where, the person requesting the waiver is able to contain the chemical so as to satisfactorily protect the environment and human life; or if it is not, practicable or feasible to obtain the test data necessary to generate the information. Surrogate information available for a chemical similar to that being notified or obtained by means of Structure Activity Relationship (SAR or QSAR) may also be submitted if properly justified.

Any notifier who has submitted information in support of a new chemical notification and later determines that the information is erroneous must immediately notify the authority of that fact and submit the necessary correction. This ensures that proper decisions with

respect to the toxicity of the chemical are based on correct information. Furthermore, information generated after a notification that reasonably supports the conclusion that the chemical is toxic, or is capable of becoming toxic, must be provided immediately to Environment Canada.

1.3.6 Timing of Notifications

The timing of notification depends on the schedule of information required. Notifications must be provided within a prescribed time period in advance of the regulatory trigger quantity being exceeded. This time period varies from 5 to 90 days. For example a Schedule VI notification must be provided by the notifier at least 45 days prior exceeding 1000 kg/yr or an accumulated total of 5000 kg. This 45 day-period also represents the period of time allotted to the government to assess the chemical and take any action if the chemical is suspected of being toxic. Importation or manufacture of the new chemical can not begin until the prescribed time period has expired.

1.3.7 Confidential Information

Under CEPA, any person who provides information to the government in support of a new chemical notification may, at the same time, submit a written request that information be treated as confidential. This feature ensures that genuine confidential business information is protected from public disclosure. Under specific circumstances CEPA allows the government to release confidential information.

The NCNS also includes a mechanism that allows foreign supplier of chemicals to provide confidential information required to complete notifications submitted by their Canadian customer (the importer) directly to Environment Canada. This information is kept confidential from the Canadian notifier.

1.3.7.1 Confidential Chemical Identity Claims

Publication of a masked name is required under CEPA if publication of the actual identity of a chemical would result in the release of confidential business information. Therefore, when claiming confidentiality for chemical identity, the notifier must provide a proposed masked name developed in accordance with the Masked Name Regulations of CEPA. The intent of masking is to disguise, only to the extent necessary, the full identity of the chemical by substituting non-descriptive terms for distinctive parts of the name.

Such claims are not granted for purposes of confidential inventory listing if those chemicals are already included as non-confidential entries on other inventories such as TSCA, EINECS, EILINCS etc.

1.3.8 Test Procedures and Practices

The conditions and test procedures used for the development and reporting of test data must be consistent with the conditions and test procedures of the Organisation for Economic Cooperation and Development (OECD) "Guidelines for Testing of Chemicals" that are current at the time of testing.

The notifier must determine the appropriateness of the OECD method for the chemical

and any necessary modification should be made (including the use of an alternative method) to ensure the acceptability of test data. Any deviations from the OECD guidelines should be clearly noted and explained. The OECD Test Guidelines are not designed to serve as rigid test procedures appropriate for all chemicals, rather, they allow flexibility for expert judgement and adjustments to new developments. Therefore, credible alternative procedures are considered consistent with the spirit of the OECD guidelines.

1.3.9 Good Laboratory Practice

The laboratory practices used to develop test data for a new chemical notification must be consistent with the "Principles of Good Laboratory Practice" (GLP) set out by the OECD.

All factors (test procedures and results as well as adherence to OECD GLP) relative to the development of a specific data requirement in a notification are assessed by Environment Canada and Health Canada on a case-by-case basis. Such data must include the name and address of the head of the quality assurance unit of the testing laboratory. In addition, for data developed after the Regulations came into force and that employ a non-OECD GLP, provide a description of the GLP including quality control and quality assurance procedures and an indication of reference chemicals. In keeping with commitments to OECD, Environment Canada and Health Canada are currently developing a Canadian GLP program based on OECD GLP requirements.

1.4 Results and Benefits

During the first three years of the NCNS (July 1, 1994 to June 30, 1997) over 6300 New Chemical Notifications have been received and accepted for assessment. Out of those 6300 notifications 4800 were for transitional chemicals (imported into or manufactured in Canada between January 1, 1987 and June 30, 1994) and 1500 were for □new□ chemicals (imported or manufactured on or after July 1, 1994).

1.5. Limitations or Problems Faced

Initial unfamiliarity of notifiers with the details of the notification process has caused delays in the introduction of new chemicals. These delays should become less frequent as notifiers gain experience with the notification process.

1.6 Resource Requirements

It requires approximately 9 full time employee to process new chemical notifications before they go for assessment. This includes processing and reviewing NCNS dossiers, waiver requests and masked names and providing advice to industry. The estimated cost for these activities is approximately 800 000 Canadian dollars.

1.7 National Contact

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Canada

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e-mail: martin.sirois @ ec.gc.ca

1.8 Additional Sources of Information

Environment has prepared an information package on the NCNS. It includes documents such as the New Substances Notification Regulations, copies of the DSL, public advisory notes on the NCNS, information on how to obtain the □Guidelines on the notification and testing of new substances: chemicals and polymers etc...□

This information package can be obtained for free by contacting the information line at:

Tel: 819-953-7156
Fax: 819-953-7155

e-mail: nsn-infoline@ec.gc.ca

You can also visit our organization Web site at the following location:

http://www.doe.ca/cceb1/eng/cc_index.htm

For those interested in CEPA and its regulations, including the New Substances Notification Regulations, you can download them from the Justice Canada Web site at:

<http://canada.justice.gc.ca/FTP/EN/Regs/Chap/C/C-15.3/index.html>

2. *Germany*

Annotations:

The following is based on several EU-harmonized instruments from the viewpoint of Germany. To get a representative overview for the EU, the member states and the European Commission will be involved.

All the numbers that are used refer to the period of time from the introduction of notification duties/special instruments in the EU until 31 December 1997.

2.1 Objectives

Notification requirements are designed to protect the environment and human health from the harmful effects of hazardous "new" chemicals and formulations, in particular to identify them, avert them and prevent their occurrence.

2.2. Process through which Notification Requirements were Developed/Implemented

In 1982, the first comprehensive chemical law called "Chemicals Act" came into force which required the review of new chemicals. In the EU, commercial chemicals in commerce between January 1, 1971 and September 18, 1981 were listed in the European Inventory of Existing Commercial Chemical Substances (EINECS), without considering if they were hazardous (see also Section 2). Once on the Inventory, a chemical is considered an existing chemical. These chemicals are regulated in the EU Regulation 793/93/EEC on existing chemicals and have to be tested if they are on one of the priority lists of hazardous existing chemicals. Before these regulations came into force, there existed a voluntary agreement between industry and the German Government to test and assess existing chemicals with the highest expected risk.

The pre-market notification obligations imposed on industry according to the German Chemicals Act is based on Directive 67/548/EEC and refers only to new "commercial" chemicals. It does not apply to chemicals that are regulated by other legislation: tobacco products, cosmetic agents, pharmaceuticals that have to be authorized according to the Drugs Act, the Epizootic Diseases Act, as well as other pharmaceuticals, medical products within the scope of the Act on Medical Products, wastes for disposal, radioactive wastes, waste water, foodstuff, animal feedstuff, active chemicals in pharmaceuticals or medical products and to chemicals that are subject to an authorization procedure in accordance with the Plant Protection Act.

Due to the fact that there were data gaps identified for commercial chemicals that remained even though several laws on chemicals (e.g. on nuclear materials, food additives, drugs, cosmetics, pesticides etc.) were already in force, political and scientific discussions took place on the national and European level and led to the sixth 79/831/EEC and seventh amendment 92/32/EEC of Directive 67/548/EEC.

2.3 Special Design Features or Adaptations

For each new chemical a Minimum Pre-market Data Set (MPDS) has to be submitted by each importer or manufacturer. That means that multiple notifications of one new chemical by different importers can occur. To reduce the number of multiple notifications, the instrument of a sole representative, an institute or a company that can represent several importers of one new chemical, has been introduced. The amount of data and the point in time the data have to be submitted to the notification authority in the Institute for Occupational Safety and Health before the chemical is placed on the European market depend on the importation volume (either 30 days for annual amounts < 1000 kg or 60 days for larger amounts). Each notification is reviewed to determine whether the dossier is complete, the data sets are valid, and the results are plausible. A second step is to assess the submitted information. Experts from the following authorities are involved: the Federal Institute for Health Protection of Consumers and Veterinary Medicine, the Federal Agency of Environment and the Division Hazardous Chemicals in the Federal Institute for Occupational Safety and Health.

If the data sets provided to the notification authority are not complete and the documents do not permit adequate assessment of the chemical, the period of 30/60 days starts again after receiving the data requested from industry. Marketing can commence only when data are complete and the time period is over.

For chemicals placed on the market in amounts > 1000 kg/yr the following information has to be submitted:

- Chemical identity
- Information on manufacture, use, exposure etc.
- Hazardous effects during use
- Information on toxicokinetics
- The planned classification, packaging and labeling
- Recommendations on the precautions to be taken during use and emergency measures in the case of accidents
- The amount of the chemical that shall be placed on the market or imported per year
- Procedures for the proper disposal, possible re-use or other means of rendering the chemical harmless
- The results of testing on physical, chemical and physico-chemical properties, acute toxicity, screening for carcinogenic or mutagenic properties, irritant and corrosive properties, sensitizing properties, sub-acute toxicity, abiotic and biological degradation, toxicity in relation to water organisms after short-term exposure, inhibition of algae growth, bacterial inhibition and adsorption/desorption. The tests have to be performed under the condition of Good Laboratory Practice (GLP).

This information forms the basis for a comprehensive evaluation of the hazard of each new chemical. The request for further information either depends on the amount placed on the market (threshold amounts are 10 000 kg/yr or 50 000 kg accumulated, 100 000 kg/yr or 500 000 kg accumulated and 1 000 000 kg/yr or 5 000 000 kg accumulated) or is mandatory upon request when there is a justified suspicion that the chemical is hazardous. If the submission of test results is not necessary on the basis of available scientific facts or testing is technically not possible the relevant justification must be provided.

For a notification, fees are requested. The charge is 10 000 DM (5 100 \$) for a full notification and 2 500 to 6 000 DM (1 300 to 3100 \$) for a reduced notification. In particular cases (e.g. when a higher effort is needed) the fee can be doubled. It can be reduced when a diskette is submitted instead of the hard copy.

Any information provided in a notification has to be updated by the responsible notifier if changes occur or if erroneous information has been identified. Addressee of this new information is the notification authority which has to check whether decisions based on the initial information have to be revised.

The notification authority has to guarantee that information accepted as Confidential Business Information (CBI) is treated as such. Suitable measures that have been implemented in Germany include special manners of delivery and coding of data, safe cases for dossiers, admonition of personnel etc. According to the Chemicals Act, CBI shall not include the trade name of the chemical, the name of the manufacturer, physico-chemical properties, precautionary measures, disposal, evaluation of toxicological and ecotoxicological tests, the purity of the chemical and the content and identity of dangerous additives and impurities as far as they are necessary for the classification and labeling and information for the MSDS.

The enforcement of the Chemicals Act in Germany is the responsibility of the 16 Länder. They inspect companies and sales agents. Another aspect of enforcement activities for chemicals is done by customs.

Specific new hazardous chemicals, formulations or products which can be released in harmful manners or contain any such chemical or formulation can be banned or restricted by the German Federal Government. See Section 5 and Appendix to Section 5 for more details on risk management options.

Apart from the above harmonized EU instrument on notification requirements, specific legislation exists in each member state in those areas that are not fully EU harmonized (see item 2.3).

Besides the notification of new chemicals, limited announcements have to be submitted to the authority for chemicals that are exempted from notification requirements.

Since the latest change of the Chemicals Act in 1994 this applies to chemicals:

- which are introduced on the market exclusively for the purposes of process-orientated research and development for the maximum period of one year (period of time can be lengthened to a second year)
- that are very toxic, toxic or mutagenic and to chemicals toxic for reproduction that are either:
 - polymers exempted from notification because of their molecular and because they contain two per cent or less of a new chemical in their composition
 - chemicals placed on the European market in amounts not exceeding 100 kg per manufacturer per year exclusively for the purpose of scientific research and development
 - chemicals placed on the European market in annual quantities not

- exceeding 10 kg per manufacturer
- or that are site limited intermediates or that are only put into commerce outside the EU in quantities of at least 1 000 kg per annum.

457 of these limited announcements were submitted to the German authorities. Their content is - different to the notification dossiers - normally not shared within the EU.

To avoid duplication of testing of vertebrate animals, each German notifier is obliged to ask the notification authority whether he can refer to tests of others. If such tests exist, the notifier has to refer to them and to give a financial compensation. This requires the notifier to submit a request in advance of submitting the notification. In total 528 such letters were received since the Act was changed in 1994. In Germany, Nonfeasance is punished.

It is not mandatory to use test data of other member states of the EU.

2.4 Results and benefits

In the EU, until December 31, 1997, 2109 new chemicals (submitted in 3793 notifications) were notified and assessed. In Germany, a total of 659 chemicals (in 1009 notifications) were notified and assessed.

2.5. Limitations or problems faced

After having reached a threshold amount of e.g. 100 000 kg/yr or 1 000 000 kg/yr, industry is required to submit further tests on the new chemical. Due to the high costs associated with these additional tests, industry often tries to extend the deadline for submitting these tests for hazardous chemicals.

2.6 Resource Requirements

The management of the EU Directive on notification of new chemicals and of the EU regulation on risk assessment of existing chemicals in Germany is coordinated by the same authority: the notification authority in the Federal Institute for Occupational Safety and Health.

The four authorities or institutions that work at the procedure of notification and risk assessment of new and existing chemicals are:

- The Notification Authority, Federal Institute for Occupational Safety and Health
- The Federal Institute for Health Protection of Consumers and Veterinary Medicine
- The Federal Agency of Environment and
- The Division Hazardous Chemicals, Federal Institute for Occupational Safety and Health.

Qualified of experts with a University or a technical college degree in the fields of chemistry, biology, toxicology and chemical engineering and technology are required for notification review and assessments. These experts do not only work on notification review and assessments but also do scientific work associated to the development of test methods. Other fields of work are the regulation on chlorofluorocarbons and the export

/ import regulation.

2.7. National Contact Point

Federal Institute for Occupational Safety and Health
Notification Authority
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D - 44149 Dortmund

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homepage: <http://www.baua.de/amst>

– Additional Sources of Information

Technical Guidance Documents (TGD) in support of the Commission directive
93/67/EEC
on risk assessment for new notified substances and the Commission regulation (EC)
1488/94
on risk assessment for existing substances

3. *United States*

3.1 Objective

Notification requirements are designed to get EPA the information necessary to facilitate the review and assessment of whether intended activities surrounding the manufacture, processing, use, and disposal of the chemical identified in the notification may present an unreasonable risk to human health or the environment, and whether the control measures proposed by the notifier can adequately reduce exposures and/or releases to enable positive conclusions regarding risk.

The US statute, the Toxic Chemicals Control Act (TSCA), specifies the notification requirements for the submissions of new chemicals. These informatino requirements include: relevant existing information, additional information required by the USEPA if needed for the risk assessment, length of the review period, etc. Specific regulations have since been written which formalise the requirements for notification such as the form to be used and how to present the information.

The US imposes different notification requirements for entry into commerce under several exemptions/exclusions and for listing on the TSCA Chemicals Inventory (Inventory).

3.2 Process through which Notification Requirements were Developed/Implemented

When promulgated TSCA required that there be a NCNS for chemicals not already in commerce, and that information which can allow EPA to determine the potential risk of new chemicals be submitted with the notification. After implementation of the NCNS the Agency developed a form which called for the required information. Notification is required to be made with the §5 notification (pre-manufacture notification, PMN) form.

3.3 Special design features or adaptations

PMN submissions require all available data on:

- chemical identity
- production volume
- byproducts
- use
- environmental release
- disposal practices
- human exposure

as well as,

- all existing health and environmental data in the possession of the notifier, parent company, or affiliates, and
- a description of any existing data known to or reasonably ascertainable by the notifier.

If the identity of some reactants for chemical synthesis, or of the chemical itself, is confidential from the manufacturer, EPA has a mechanism to receive a letter of support from the source of the reactant, which will be held confidential. The NCNS requires submission of data when the information available about the chemical and similar chemicals is not adequate to make a determination of the potential risk.

The TSCA framework also contemplated that the Agency could exclude certain classes of chemicals from all or part of the notification requirements if it found that they were unlikely to pose an unreasonable risk. EPA has exempted new chemicals in several product categories from all or part of its NCNS reporting requirements because it has determined that they do not warrant review and assessment or require only a short review. These categories are:

- Chemicals manufactured in small quantities for research and development provided special procedural and record keeping requirements are met (no notification)
- 10 000 kilograms or less of the chemical will be manufactured or imported each year (Low Volume Exemption, LVE (notification and review, not placed on Inventory))
- The chemical is expected to have low releases and low exposures, LOREX under the specific requirements (notification and review, not placed on Inventory)
- The chemical is being manufactured or imported for test marketing, TME (notification and review, not placed on Inventory)
- The chemical is a polymer that meets certain specified criteria enabling it to be considered not chemically active or bioavailable (a year-end notification to the Agency that the exemption has been used is required)

The Agency uses the same form for notification of requests for LVE and LOREX as it does for other new chemicals. The TME notification is by letter describing intended test marketing and the polymer notification does not submit any information except that the manufacture has taken place.

Some new chemicals are excluded from TSCA jurisdiction: tobacco and certain tobacco products, nuclear materials, munitions, foods, food additives, drugs, cosmetics, and chemicals used solely as pesticides. These new chemicals fall under the jurisdiction of other federal legislation and are reviewed by other federal programs.

In addition, the following (though within the scope of the TSCA) are excluded from notification under certain conditions: naturally-occurring materials, products of incidental reactions, products of end-use reactions, mixtures (but not mixture components), impurities, byproducts, chemicals manufactured solely for export, non-isolated intermediates, and chemicals formed during the manufacture of an article. If needed, controls on these materials can be imposed under other provisions of the TSCA, which enables the government to place restrictions on the use of non-"new" chemicals, requires testing and submission of data on hazardous chemicals.

3.4 Results and Benefits

Historically, the USEPA has taken regulatory actions on less than a sixth of the new chemical notifications it has received (approximately 30 000 notifications have been received and reviewed during the life of the program). The rest have been allowed to go into commerce with no special requirements. These regulatory actions are covered in the Appendix to Section 5. The expected benefit of this work is appropriate care in use of the materials and avoidance of health impacts and environmental harm.

3.5 Limitations or Problems Faced

The USEPA will frequently regulate a new chemical and not a similar existing chemical. This issue is sometimes referred to in US as a "new chemical bias."

Before 1976, there was no comprehensive chemical legislation like TSCA to require the review and assessment of new chemicals. Under TSCA, chemicals in commerce between 1975-1977 were grand-fathered into the Inventory without considering if the chemicals were hazardous. Once on the Inventory, a chemical is considered an existing chemical and for the USEPA to control its use, a legal finding has to be made that the chemical will present an unreasonable risk to human health or the environment. This is a standard which requires EPA to have conclusive data on that particular chemical. By comparison, new chemicals can be regulated under TSCA prior to their introduction on the market based on whether they pose an unreasonable risk and this finding of risk can be based on data for structurally similar chemicals.

This is an apparent inequity between the USEPA regulation of new and existing chemicals. The Agency, however, uses a variety of approaches to reduce risks from existing chemicals that appear to pose problems. These approaches include voluntary agreements, alone or in combination with regulatory approaches; regional, federal, state and local partnerships,- dissemination of risk management information to assist the selection of safer substitutes; emphasis on pollution prevention and innovative control technology to reduce exposure and environmental release; use of chemical emission data from the Toxics Release Inventory (TRI) to help address site-specific chemical concerns; refined risk assessment and cost/benefit analysis; and the challenge to industry to meet its own Product Stewardship and Responsible Care goals.

A second limitation in the US program, reflected in its notification requirements, was its choice not to have a prescribed minimum amount of data with each notification, a Minimum Premarket Data Set (MPDS). An MPDS could enable the EPA to have more certainty pertaining to problems associated with the use of a chemical, and that there is good comparability between its risk assessment and that of different chemicals. On the other hand, an MPDS would impose costs which might be unnecessary for chemicals which are similar to chemicals for which there is adequate information. Instead of an MPDS, EPA uses structure-activity relationships to categorize chemicals and considers whether the Agency has adequate information about the category in determining whether to require additional information about a chemical.

3.6. Resource Requirements

USEPA estimates the burden imposed on notifiers for notifying new chemicals as approximately 100 hours per submission. USEPA has estimated its yearly cost in

assessing approximately 1600 notifications as \$4 million. This work is done by approximately 100 people in the office regulating new chemicals with some contract support.

3.7 National Contact

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U.S. Environmental Protection Agency
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3.8 Additional Sources of Information

The New Chemicals Program has developed an Internet Web Page, available at <http://www.epa.gov/opptintr/newchms>. A discussion of the notification requirements is available there.

Country Experiences with Assessment of Notification

1. Canada

1.1 Objective

As part of a pollution prevention management approach to toxic chemicals, the NCNS established under the *Canadian Environmental Protection Act (CEPA)* ensures that no new chemical is introduced into Canadian commerce before an assessment of its "toxicity" has been completed. Consequently, the purpose of the assessment process is to determine whether or not chemicals are suspected of being toxic as defined in CEPA. The determination whether a chemical meets the criteria to be "toxic" consists of integrating the assessment of potential exposure of a chemical to humans and components of the environment with potential adverse effects on humans and the environment.

1.2 Process through which Assessment of Notifications was developed/implemented

The *Canadian Environmental Protection Act (CEPA)*, promulgated on June 30, 1988, provides the Canadian government with authority to address pollution problems on land, in water, and through all layers of the atmosphere. As part of a "cradle to grave" management approach to toxic chemicals, the provisions for establishing a NCNS in CEPA are intended to ensure that no new chemical is introduced into Canadian commerce before an assessment of its toxicity has been completed. Toxicity, as defined in CEPA, refers to risk to human health or the environment. Features of the NCNS include criteria for identifying "new chemicals", a mechanism for assessing new chemicals, and when necessary, the enabling powers to implement specific controls.

The CEPA approach for the control of new chemicals is preventative and employs a pre-import or pre-manufacture assessment process. Chemicals suspected of being "toxic" may be controlled as necessary, including banning their import or manufacture. The assessment process is initiated when Environment Canada receives a so called New Chemical Notification (NSN) prepared by the company or individual that proposes to import or manufacture a new chemical. New chemical notifications must contain all required administrative and technical data and must be provided to Environment Canada by a prescribed date that precedes manufacture or import. Notification information is jointly assessed by the Departments of Environment and Health to determine the potential adverse effects of the chemical on the environment and human health. This assessment must be completed within a time specified by regulation. If the government takes no action before the end of this assessment time period, the notifier is free to import or manufacture the chemical.

1.3 Special Design Features or Adaptations

As described in Appendix to Section 3, The NCNS contains a series of Schedules indicating the information that must be provided by importers and manufacturers depending on the category of chemical and quantities to be imported/manufactured. The

assessment process is tiered based on the proposed manufacture or importation volume for the chemical. After a new chemical notification has been received, it is reviewed by Environment Canada Reviewers to determine if all the information prescribed by regulation has been submitted. If it is the case, the notification dossier is forwarded to Environment Canada and Health Canada assessors and the assessment process begins.

1.3.1 Overview of the Process

The assessment of new chemicals considers all the prescribed data endpoints provided by the notifier for the chemical as well as data on the chemical or surrogates that can be obtained from the literature, electronic data bases or mathematical models. In general the type of information that must be provided for full notification of new chemicals is:

- Administrative information identifying: the notifier, the type and category of chemical, importation/manufacture volume, and type of Schedule
- Chemical information identifying: Chemical identity, Physical-chemical properties, Ecotoxicity data, Health related Toxicity data, Manufacture, importation, use and disposal information, and all other information in the notifier's possession

The Environmental risk assessment includes:

Behaviour and fate

- Potential accumulation based on fate information
- Potential ecotoxicity based on effect concentrations to representative biota
- Determinations of concern concentrations based on the first two items and incorporating appropriate assessment (safety) factors

Exposure Assessment

Determination of predicted environmental concentrations for the environmental compartments (i.e., aquatic, terrestrial, and air) likely to be exposed to the chemical.

Risk Characterization

The potential for exposure to a chemical depends on the amount of chemical released into the environment and its environmental fate. The exposure assessment, therefore, consists of predicting the environmental concentrations (PEC) of a chemical from releases resulting from its production, processing uses, and disposal, and its environmental fate evaluated on the basis of intrinsic physical/chemical properties, environmental mobility, compartmentalization, and persistence. The subsequent ecological and human risk assessment is conducted using a quotient method comparing the concern concentration with predicted environmental concentrations for each environmental compartment at risk, comparing predicted concern concentrations and predicted environmental concentrations.

1.4 Results and benefits

The results of an NSN assessment include:

- An understanding of how a chemical is used by manufacturers, processors and consumers.
- An understanding of the impact of that chemical both to the public and to the environment.
- A determination of potential problems with use and disposal.
- A determination of problems with potential uses .
- An assessment of potential hazards prior to high scale use, marketing and investment of large sums of money.

Benefits include:

- Protecting both the public and the environment from exposure to potentially harmful chemicals.
- Assurance that releases to the environment are not of concern.
- Pro-active management of chemicals .
- Peace of mind to the public as all new chemicals are screened prior to use.
- Aids chemical industry in good stewardship of chemicals.
- Encourages self screening by industry thereby eliminating some chemicals that industry knows would not survive the scrutiny of an assessment process

1.5 Limitations or problems faced

Some of the difficulties include the limited amount of information available upon which an assessment must be based. Limited information can lead to the use of conservative assessment approaches.

In addition, companies have claimed that the requirement for up-front testing has discouraged the introduction of new chemicals.

1.6. Resource Requirements

The Canadian assessment procedure is more "generalist" in nature than the US EPA. In Canada, each notification is forwarded to separate assessments in Environment Canada and Health Canada. At Environment Canada, one individual is responsible for assessing all aspects such as physical/chemical properties, chemical structures, engineering processes, exposure and releases from an environmental perspective, as well as ecotoxicological data. At Health Canada, two individuals, a chemist and a biologist review each submission. The chemist addresses physical/chemical properties, chemical structures, engineering processes, exposure and release issues from a health perspective while the biologist addresses mammalian toxicological information.

The Canadian assessment system has proven to be effective in identifying chemicals anticipated to pose a risk to human health or the environment and when necessary, in the implementation of specific controls. A generalist as opposed to a specialist evaluation procedure may be conducive to evaluating smaller numbers of assessments.

Assessment period range between 5 and 90 days, with the most frequent being 5 day and 45 day reviews. We review between 500-800 notifications per year.

The assessment of chemicals require 11 full time employee and the annual cost is estimated to be \$1 000 000.

1.7 Canada National contact point

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1.8 Additional Sources of Information

Environment Canada is currently developing a document describing the assessment approach and process developed under the NCNS. This document should become publicly available in 1999. In the mean time you should contact the above contact person if you have any questions or require further information on the Canadian assessment process.

2. *Germany*

Annotation:

The answers are given on several EU-harmonized instruments from the viewpoint of Germany. To get a representative answer for the EU, the member states and the European Commission will be involved.

2.1. **Objective**

As described in Section 3, the objective of notifications is to protect the human health and the environment against harmful effects of hazardous new chemicals and formulations. Therefore, each notifier has to provide information which together with information gathered or estimated by the assessment authority allows to do the risk assessment. This information includes: toxicological tests, ecotoxicological tests, information on exposure during production, use and disposal information, and expected quantity to be marketed.

The notifier may submit a risk assessment proposal but the final responsibility lies with the assessment authority. The assessment provides an estimation of risk to man (consumer, worker) and the environment through direct or indirect exposure during the whole life cycle of the chemical (production, processing, storage, use, disposal or recovery).

2.2 **Process through which Assessment of Notifications was Developed/Implemented**

The notification requirement for new chemicals was first introduced by the modification of the European Labeling Directive 67/548/EEC as the sixth amendment 79/831/EEC. The seventh amendment 92/32/EEC requires the responsible authorities to prepare a risk assessment for each new chemical. Basic principles for the assessment are described in the Commission Directive 93/67/EEC. This EU legislation has been implemented via the German Chemicals Act. Additionally, the European Commission and the member states developed a Technical Guidance Document in support of the Directive 93/67/EEC that is not legally binding for industry, but which harmonizes the work of the responsible authorities of the member states.

2.3 **Special design features or adaptations**

The hazard identification is based on test results and includes the following effects:

- Toxicological effects:
 - acute toxicity
 - irritation (eye, skin)
 - corrosivity
 - sensitization
 - repeated dose toxicity

- mutagenicity
- carcinogenicity
- toxicity for reproduction

- Ecotoxicological effects:
 - aquatic toxicity
 - terrestrial toxicity
 - biodegradation
 - bioaccumulation

- Other effects:
 - explosivity
 - flammability
 - oxidizing potential

The comparison of the test results with criteria for classification as hazardous leads to the identification of a hazardous effect. In the dose/response assessment for each effect where appropriate, a NOAEL (no observed adverse effect level) is identified. The exposure assessment takes into account exposures that are reasonably foreseeable in the light of the available information about the life cycle of the chemical as such, in formulations (mixtures) or in products. The exposure to worker, consumer (direct, indirect via the environment), and for the environment compartments air, water and soil is estimated. It is based on:

- adequately measured exposure data
- the marketed quantity
- the form in which the chemical is marketed
- use categories and degree of containment during the use
- process data
- physico-chemical data
- likely pathways to the environment
- frequency and duration of exposure

The objective is to make a quantitative or qualitative estimate of the dose/concentration of the chemical to which man or environment are exposed, and to determine an exposure level or a PEC (predicted environment concentration). For effects for which there is an identified NOAEL, the risk characterization consists of a comparison between the exposure level or PEC with the NOAEL. If no NOAEL has been determined, an evaluation of the likelihood that the effect occurs for the estimated exposure level is performed. The result of a risk characterization can be the decision:

- that the risk can be sufficiently assessed and no further information is necessary, or
- that the chemical is of concern and further information is requested on the effects or the exposure or
- the chemical is of concern and risk management to reduce the risk is necessary.

Any proposal for risk reduction shall take into account that reducing the exposure of

certain human populations or environmental compartments may increase the exposure of others. In the EU the details and the methodology of risk assessment are harmonized and for this purpose described in extensive technical guidance documents (TGDs). The risk assessment is available to the notifier and other EU member states in a written report in an agreed format. The methods and the process of risk assessment are transparent as all background material is publicly available.

To improve the capacity for reducing risks to human health and the environment it has been decided to share data, especially risk assessments, with certain countries. In a trial phase the conditions for data sharing are tested.

While several EU member states offer a reduction of fees for a notification to a notifier who submitted a complete risk assessment, this is not done in Germany. The notifier can submit a risk assessment for his new chemical, however, the final risk assessment is solely the responsibility of the assessing authorities.

German industry has voluntarily agreed to assess the hazard of site limited intermediates that are not placed on the market which have been produced before 1990 for the first time and of wood preservatives.

2.4 Results and benefits

The obligation to do a risk assessment for each European notification of a new chemical guarantees that all the data available and provided by the notifier are regarded and used for the assessment of risks for man and the environment and may lead to post-notification activities. This is a prerequisite for a preventive approach to risk management of new chemicals in Germany and the EU.

The results can be exchanged with other interested parties. This exchange might save resources in other countries which accept parts or the complete risk assessment.

Data contained in the risk assessments are exchanged with the 16 provinces ("Länder"). Under the federal system of Germany they are responsible for compliance and enforcement of the Chemicals Act. They will store these data in existing data bases of the provinces (that inform e.g. fire services in case of emergencies about properties of hazardous chemicals) for further use.

2.5 Limitations or Problems Faced

To be able to exchange the risk assessments within the EU and with other interested countries (e.g. Australia) it is necessary to translate all the risk assessments that are prepared in German into English.

2.6 Resource requirements

The management of the EU Directive on notification of new chemicals and on the EU regulation on risk assessment of existing chemicals in Germany is coordinated by the same working unit: the Notification Authority in the Federal Institute for Occupational Safety and Health.

The four units or institutions responsible for the review that work at the procedure of notification and risk assessment of new and existing chemicals are:

- the Notification Authority, Federal Institute for Occupational Safety and Health,
- the Federal Institute for Health Protection of Consumers and Veterinary Medicine,
- the Federal Agency of Environment, and
- the Division Hazardous Chemicals, Federal Institute for Occupational Safety and Health.

Qualified experts with a University or a technical college degree in the fields of chemistry, biology, toxicology and chemical engineering and technology are required for notification review and assessments. These experts do not only work on notification review and assessments but also do scientific work associated to the development of test methods. Other fields of work are the regulation on chlorofluorocarbons and the export / import regulation.

2.7 National Contact Point

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2.8 Additional Sources of Information

3. *United States*

3.1 Objective

USEPA toxicologists, chemists, biochemists, engineers, and experts in other disciplines work together to predict the potential risks to the environment and human health from each new chemical. They rely on data submitted under the NCNS, other information available to the agency, and exposure and environmental release modeling. USEPA undertakes a case by case review of each notified chemical.

3.2 Process through which Assessment of Notifications was Developed/Implemented

The US Toxic Chemicals Control Act (TSCA) was enacted in 1976, and included provisions for developing and implementing a NCNS. USEPA personnel responsible for implementing TSCA developed regulations for this program within this broad outline: US notification to the Environmental Protection Agency (USEPA) required under the TSCA is called the Premanufacture Notice (PMN). Notifiers (PMN submitters) are required to submit all available data on chemical identity, production volume, byproducts, use, environmental release, disposal practices, and human exposure. Notifiers are also required to submit the following information with the PMN: all existing health and environmental data in the possession of the notifier, parent company, or affiliates, and a description of any other existing data known, to or reasonably ascertainable, by the notifier.

3.3 Special design features or adaptations

There is no defined base data set required for PMNs, and the TSCA does not require prior testing of new chemicals. Thus, the amount of information made available to reviewers by notifiers varies tremendously, with extensive information provided on the potential effects of some chemicals and limited information provided for others. Less than half of the PMN forms submitted include toxicological data. In these cases, USEPA scientists assess the chemical's structural similarity to chemicals for which toxicological data are available - called structure-activity relationship analysis (SAR) - to predict toxicity. However, when data available to the New Chemicals Program do not provide adequate information to make predictions of toxicity through SARs, or when there is expected to be high exposure to the chemical, submission of additional data will be required for new chemicals. When USEPA decides that information is inadequate, there can be a ban on manufacture, import, or processing of the chemical until the required data is submitted, or review of the PMN may be suspended until the needed data is made available to the Agency by the notifier.

The New Chemicals Program has tried to inform the regulated community of many of the principles of SAR, including issuance of a document called Chemical Categories which describes information often sought for chemicals of frequently-submitted types.

3.3.1 Description of Process

Notification and Early Review:

The notification is reviewed for completeness, and information about similar chemicals already known to the Agency is considered, along with any information which has been submitted by the notifier. If the chemical is not found on the TSCA Inventory under the submitted name, and the notification is complete, the chemical enters the early review process.

During the second week of the process, a chemistry review meeting is held in which agency scientists make an early assessment as to whether information is adequate to drop a chemical from further review, or further review is appropriate. The chemistry review meeting ensures that the chemical identity is fully characterized. The submitted name is reviewed for consistency with naming rules of the TSCA Inventory. Submitters of PMNs and exemption notices are required to provide the currently correct Chemical Abstract (CA) name for the chemical(s) identified in the notice, based on the Ninth Collective Index (9CI) of CA nomenclature rules and conventions, and consistent with listings for similar chemicals in the Inventory. If the chemical meets criteria which have been established for low risk polymers, it is dropped from further review.

Also in this period, the Structure-Activity Team (SAT) meeting considers potential analogs to the submitted chemical, and any test data which has been submitted with the notification. Environmental fate data is first discussed in this meeting, and necessary exposure reviews are identified.

Focus meeting:

Reports from the review process described above, as well as estimates of worker exposure and environmental release, are considered by the Focus committee. SAR is used to predict toxicity. This meeting takes place, in general, between day 15 and day 19 of the review period. If information is inadequate, and the Agency expects risk, or if the chemical is made in large quantities with exposure, the notifier is contacted and told that he/she needs to suspend review until additional information is provided, or a ban pending the submission of test data will be imposed.

The Focus meeting, in about 80% of cases, results in a decision to drop a chemical chemical from further consideration. A drop can be coupled with a "letter of concern" to the notifier, suggesting that precautions in use of the material would be prudent, or issuance of a "non 5(e) SNUR", a significant new use rule (SNUR) to control a potential use for the material which could be initiated in future but was not identified in the submission itself. Exemptions, which are permissions to manufacture under more restricted conditions than those resulting from PMNs, are granted or denied in the focus meeting:

- Test market exemptions (45-day review)
- Low volume exemptions (30-day review)
- Low release/low exposure exemptions (30-day review)

Some decisions on whether to restrict or control use of chemicals are taken in Focus meeting, when USEPA reviewers believe that risk can be controlled or additional testing

is necessary to understand a category of chemicals, and result in negotiation of orders based on exposure or risk. Frequently Focus decisions are based on the chemical falling into a category with which the program has had a good deal of experience over the years, and for which the decision to regulate has been delegated down to this point in the process. Better than 95% of chemicals have some sort of decision by the end of the Focus meeting. Regulatory outcomes of the Focus meeting can be:

- To drop the chemical from further review with no restrictions, or with issuance of a Letter of Concern.
- To allow manufacture and use by notifier under the terms of a Consent Order under TSCA (and issue a SNUR to control use by others). Frequently this will set limits on the amount which can be made without submission of additional information, or require that certain precautions be taken unless additional information is submitted, or requires that certain testing be completed and submitted before production exceeds a certain value.
- To issue a non-Consent Order SNUR, applicable to notifier and others, to allow restricted use.
- To require that identified testing be done before any manufacture, import, or use is initiated.

Standard Review

A decision can also be taken to undertake limited additional review or a "Standard Review" of a chemical. This is called standard even though less than 5% of cases continue on from Focus through this Standard Review process. "Standard Review" is for intensive assessment of chemicals for which the process leading to the Focus meeting has not yielded adequate certainty for a decision, frequently for chemicals not within the standard categories which have been developed by the Agency. This post-Focus process begins with a multi-disciplinary workplan meeting at day 23-29. Over roughly the next month, Agency professionals work up the hazard - exposure - risk assessment. There is a meeting between day 44 - 48 to review progress, one between day 57 - 61 to agree on the hazard - exposure - risk assessment followed by a decision meeting to choose regulatory action at day 79 - 82. Possible regulatory outcomes are the same as identified above for Focus, though they more frequently involve some sort of control because the chemicals tend to be of greater concern.

The assessment is completed by the 90th day after submission, however, the clock is frequently stopped, in the case of complicated or uncertain reviews, by agreement between the notifier and the Agency, to allow additional information to be generated and submitted.

3.4 Results and benefits

The US assessment system enables a thoughtful assessment of the potential hazard a chemical can represent and whether restrictions should be imposed on its use.

3.5 Limitations or problems faced

The US NCNS does not include a mechanism to reexamine chemicals already in commerce and chemicals that are in the Inventory. The US system does not require that

toxicological data be submitted with each chemical, so it makes judgment on new chemicals based on widely varying amounts of data.

3.6 Resource requirements

Approximately 75 people work in this regulatory effort for USEPA. The TSCA sets a 90-day period for the review of PMN notifications, exemptions are reviewed more quickly under regulations issued by the Agency. Roughly 2000 PMNs and other (exemption) submissions are reviewed in a year.

Risk assessments are done by toxicologists, chemists, economists, industrial hygienists, environmental fate experts, neurotoxicologists, etc., who prepare assessments of each chemical from the point of view of their disciplines and come together in a standard series of meetings to consider Agency action. It is generally that, because of its reliance on SAR, a relatively large staff is needed for the US program to function satisfactorily, regardless of the number of submissions: many of the functions require specialized training and it would not be practical to have staff handle tasks outside their areas of expertise. This suggests that a country attempting to duplicate the USA procedures for a smaller number of submissions would probably face a substantially higher cost for each submission reviewed.

3.7 National Contact Point

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3.8 Additional Sources of Information

Country Experiences with Post-notification Activities

1. Canada

1.1 Objective

Canadian assessors work together with enforcement officers and legal authorities to ensure that controls developed in a manner to protect the environment and human health are also enforceable.

1.2 Process through which Post-notification Activities were developed/implemented

Post-notification activities such as addition to chemicals on the inventory, notices of excess quantities, imposition of controls on chemicals and enforcement activities are part of the *Canadian Environmental Protection Act (CEPA)* which is the Act under which the NCNS was developed and implemented. CEPA includes special provisions that give authority to the government to address post-notification activities and enforce them.

1.3 Special Design Features or Adaptations

1.3.1 Description of Post-notification Activities

Risk Management Actions

When assessors of Environment Canada or Health Canada suspects that a chemical may be toxic, the following measures may be taken:

- Permit the manufacture or import of the chemical subject to specified conditions such as restricting the release of the chemical in the environment, restricting the quantities that may be imported or manufactured, restricting the use of the chemical.
- Ban the manufacture or import of the chemical.
- Ban the manufacture or import of the chemical until supplementary information or test results (not required by the NSN Regulations but necessary to determine whether or not the chemical is toxic) have been submitted to Environment Canada and assessed.

Currently, only chemicals that are not anticipated to pose a risk to the environment or human health, regardless of their use or quantity, are placed on the DSL without restrictions. Environment Canada is in the process of developing a Significant New Activity Condition (SNAC) approach which is similar to the SNUR concept of the USEPA. This SNAC concept will be implemented within the new CEPA and will allow to place chemicals on the DSL with specific restrictions.

Notice of Excess Quantity

After proceeding with the import or manufacture of the new chemical, notifiers must

advise Environment Canada when the manufactured or imported quantity exceeds the regulatory quantities. Notifiers must provide a notice of excess quantity within 30 days of exceeding the regulatory quantity.

Addition of Chemicals on the Inventory

When the period for assessment has expired, Environment Canada is obliged to place the chemical on the Domestic Chemicals List (DSL) if all of these criteria have been met:

- environment Canada has been provided with all the prescribed information,
- environment Canada is satisfied that the chemical has been imported, or manufactured in excess of the regulatory quantity, and
- no conditions (controls) have been imposed on the chemical

Publication of Information on New Chemicals

When a condition or prohibition is issued or modified, Environment Canada must publish a notice in the *Canada Gazette* describing the action and the chemical to which it applies. The name of the notifier is not included in this notice. Furthermore, if the publication of the chemical name would result in the release of confidential business information, a masked name is published.

Chemicals notified under the NCNS remain "new" chemicals, and thus notifiable for a second party, until they are published as a supplement to the DSL in the *Canada Gazette*.

Record Keeping and Tracking

Notifiers are using so called New Chemical Notification (NSN) forms in the preparation of a submission. These forms contain the following information:

- Notifier's name, address and telephone number
- Chemical Type (chemical, polymer)
- Specific Chemical Name and Chemical Abstract Services Registry Number
- Activity (manufacture or import)
- Anticipated quantity of exceedence of importation or manufacture
- Date of exceedence of importation or manufacture
- Schedule Number under which the chemical is notified

Environment Canada follows a standard operating procedure for the logging and tracking of all NSN submissions and other significant communications with industry.

All NSN submissions are assigned a unique NSN number. All information pertinent to a given NSN submission are maintained in that file (the initial submission, follow-up written correspondence, logs of telephone communications and notices of conditions or prohibitions imposed on the chemical following assessment).

An Oracle database containing the above information is maintained to track the status of NSN submissions (e.g., acknowledged, rejected, completed, controlled).

1.3.2 Compliance and Enforcement Activities

Whereas compliance promotion is the responsibility of program staff, enforcement activities are the responsibility of the Office of Enforcement. However, staff of the new chemicals program cooperate with the Office of Enforcement to develop a suitable compliance and enforcement strategy. Program staff also provide the Office of Enforcement with specific information on chemicals and companies in order to assist them in their duty. Program staff may also participate in on field inspections as experts of the NCNS to help inspectors.

1.4 Results and Benefits

Proper risk management ensures protection of the environment and human health. It also indicates to industry that chemicals which pose a risk to the environment or human health will be controlled, encouraging them to find more environmentally friendly chemicals. In Canada, about 10 chemicals are controlled each year. This corresponds to about 7% of the high volume (> 10 000 kg/yr) notifications.

1.5 Limitations or Problems Faced

In Canada, measures on new chemicals must be taken before the expiration of the assessment period which allows very short time to develop conditions. The development of enforceable conditions is not always straightforward.

1.6 Resource Requirements

Control options (conditions) are proposed and developed by assessors. Then, enforcement officers provide input with respect to the enforceability of the conditions and legal authorities ensure that the conditions fall within the scope of CEPA.

The annual cost for the development of control options is approximately \$40 000 and requires the equivalent of 1 full time employee.

The annual cost for the maintenance of the DSL is approximately \$56 000 and requires the equivalent of 0.5 full time employee.

For compliance promotion the annual cost is approximately \$21 000.

1.7 National Contact

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Canada

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Fax: 819-953-7155
e-mail: martin.sirois @ ec.gc.ca

1.8 Additional Sources of Information

The compliance and enforcement policy adopted by Environment Canada is available from the information line at:

Tel: 819-953-7156

Fax: 819-953-7155

e-mail: nsn-infoline@ec.gc.ca

The publications identifying chemicals that are suspected of being toxic along with control actions can also be obtained from the information line.

2. *Germany*

Annotations:

The answers are given on several EU-harmonized instruments from the viewpoint of Germany. To get a representative answer for the EU, the member states and the European Commission will be involved.

All the numbers that are used refer to the period of time from the introduction of notification duties/special instruments in the EU until the 31 December 1997.

2.1 Objective

In Germany, the EU Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labeling of hazardous chemicals (Labeling Directive, describing inter alia the rules for the notification of new chemicals) has been implemented into German law via the Chemicals Act. All the other member states also implemented the relevant EU legislation, so that post-notification measures are mainly the same.

2.2 Process Through which Post-notification Activities was developed/implemented

In the EU different tools have been developed to improve chemicals management over the years. They have been implemented inter alia via Directives 76/769/EEC (limiting marketing and use) and 91/155/EEC (safety data sheet).

2.3 Special Design Features or Adaptations

Based on the test data received with a notification and the use information an assessment of hazardous properties (classification) and on risk characterization for man (worker, consumer and environment) is done by the notifier and the relevant notification authority.

2.3.1 Description of Post-notification Activities

Risk Management Actions

Classification is the assignment of one or more of 14 categories of hazard (explosive, toxic, carcinogenic, dangerous for the environment ...) by comparing the test data and published classification criteria. The classification is the responsibility of the notifier and controlled by the notification authority. The self classification by industry is replaced by a legally binding classification when the chemical is added on an EU list of hazardous chemicals. For hazardous chemicals that are marketed in formulations (mixtures) the classification for the preparation has to be determined by the supplier using the concentration of hazardous chemicals and mandatory calculation methods specific for the categories of hazard or by testing the formulation.

In addition to the post-notification activities that follow directly from classification there

are other regulatory or non-regulatory measures based normally on the risk characterization of the hazardous chemical/formulation, i.e.:

- publication of non-confidential information of new chemicals,
- proposals for limit values for workplace exposure or emission limits/quality criteria for air, water, soil,
- proposals for bans or restrictions of use,
- proposals for safe management of hazardous waste,
- monitoring chemicals and the exposure of man and environment.

The authority can also require further testing or impose certain conditions for the marketing if there are reasons to suspect the chemical is hazardous. The notification authority can in these cases ban the introduction of the chemical on the market when a notifier does not comply with such a request.

Other legislation

If a chemical or formulation is classified as dangerous a variety of follow-up legislation applies automatically. Those include legislation for preventing major chemical accidents, safe handling and use at the workplace, safe storage for protecting man and the environment, use restrictions and bans of cancerogenic, mutagenic and reproductive toxic chemicals for consumer use are also in place.

Packaging and Labeling

The hazardous chemical/formulation has to be packaged in a way to prevent unintentional release. Certain hazard categories require child safe fastening and/or tactile warnings for the blind. During transport internationally agreed labeling requirements are mandatory.

Information

The supplier of the chemical has to provide the professional user with a Material Safety Data Sheet (according to Directive 91/155/EEC, amended by Directive 93/112/EEC). The consumer or professional user is informed about the hazardous properties by symbols of danger and safety phrases (labeling).

To inform the provinces about all the notifications that have been handed in, an information exchange between the notification authority and the "Länder" takes place.

Notice of Exceedence

When quantity limits have been exceeded notices have to be sent to the notification authority to determine whether further tests are required (volume of requested data depends on the volume of the chemical that is introduced on the European market, annual thresholds are 10 000 kg, 100 000 kg or 1 000 000 kg and cumulative volumes are 50 000 kg, 500 000 kg or 5 000 000 kg cumulative).

Addition on Inventory

While existing chemicals of the EU listed in EINECS (closed inventory of existing chemicals, see Section 2 and Appendix to Section 2) bear an EINECS number, new chemicals are assigned number that is called ELINCS number (European List of Notified Chemicals Chemicals), inter alia to simplify the identification. This number is used when adding chemicals on ELINCS. For those two kinds of EU numbers the term EEC number is used.

Record Keeping and Tracking

A database has been developed to keep track of all information on notified new chemicals within the German notification authority. To exchange data/risk assessments between the member states of the EU, the exchange software is standardized. One can choose the language of the corresponding country.

2.3.2 Compliance and Enforcement

Another activity is the compliance monitoring and enforcement in case of violations of chemicals legislation.

The control of compliance and monitoring functions are the responsibility of the 16 provinces ("Länder") due to the fact that Germany is a federal state. The provinces are supported by the customs authorities. In the EU projects were carried out to harmonize inter alia the monitoring of the EU Directive on the notification of new chemicals. German participates with representatives from the provinces and the responsible federal authority.

If necessary, the responsible "Länder" authorities can issue orders to eliminate established or to prevent future violations. Violations can be punished with fines up to imprisonment for a period up to five years.

Customs are explicitly required to control the compliance of industry with the Chemicals Act.

2.4 Results and benefits

As already mentioned in the Appendix to Section 2, 2109 new chemicals (in 3793 notifications) were evaluated. In Germany, 659 chemicals (in 1009 notifications) were processed in total, for 64 of those a discussion of potential bans/restrictions took place. In the whole EU three chemicals have been banned and 1184 of the notified chemicals had to be labeled due to their dangerous properties. 145 notified chemicals reached the annual threshold amount of 10 000 kg, 34 an annual volume of 100 000 kg (level 1) and 5 level 2, annual volume of 1 000 000 kg, so that further testing of these chemicals became necessary. In total in the EU 87 notifications reached level 1 and nine reached level 2.

For level 1 and 2 testing fees are required according to the number of tests asked for by the responsible authorities.

In Germany corrections/additional data were requested for 165 notifications within the deadline of 30/60 days (see Appendix to Section 2) which resulted in a delay of the

introduction of the chemical on the market.

528 inquiries of industry to determine whether tests of vertebrate animals do exist for a single new chemical were submitted in Germany. 163 of these inquiries led to a notification.

The notification authority requested further testing based on the assessment of risk for 72 chemicals. In two cases, the notification authority banned the marketing of a chemical due to failures to comply with such requests.

2.5 Limitations and Problems Faced

Due to the federal structure of the country, the control of compliance done by the provinces is facilitated by some coordination to achieve an equal treatment of companies.

While the notification authority receives all the notification information, the process-oriented research and development etc., the provinces are responsible for the monitoring have to be provided with all the data necessary for the inspection work. This is possible through an intensive exchange of data.

2.6 Resource requirements

The management of the EU Directive on notification of new chemicals and of the EU regulation on risk assessment of existing chemicals in Germany is coordinated by the same authority: the Notification Authority in the Federal Institute for Occupational Safety and Health.

The four authorities or institutions responsible for the review and risk assessment of new and existing chemicals are:

- the Notification Authority, Federal Institute for Occupational Safety and Health,
- the Federal Institute for Health Protection of Consumers and Veterinary Medicine,
- the Federal Agency of Environment, and
- the Division Hazardous Chemicals, Federal Institute for Occupational Safety and Health.

Qualified experts with a University or a technical college degree in the fields of chemistry, biology, toxicology and chemical engineering and technology are required for notification review and assessments. These experts do not only work on notification review and assessments but also do scientific work associated to the development of test methods. Other fields of work are the regulation on chlorofluorocarbons and the export / import regulation.

The Ministry of Environment is inter alia responsible for the chemicals legislation and for the supervision of the notification system. The provinces (Länder) with the assistance of the customs control the compliance with chemicals legislation.

2.7 National contact point

Federal Institute for Occupational Safety and Health

Notification Authority
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2.8 Additional Sources of Information

3. *United States*

3.1 Objective

US regulatory staff work together with enforcement, compliance, and legal staff to ensure that controls developed to protect human health and the environment are also enforceable.

3.2 Process through which Post-notification Activities were Developed/Implemented

Post-notification activities such as notices of commencement, addition of chemicals to the inventory, imposition of controls on chemicals through consent orders and SNURs, and enforcement activities are authorized under the Toxic Substances Control Act (TSCA), the statute under which the US NCNS was developed and implemented. TSCA includes special provisions that give authority to the government to address post-notification activities and enforce them.

3.3 Special Design Features or Adaptations

3.3.1 Description of Post-notification activities in USA

Risk Management Actions

When the Agency finds adequate likelihood that the risk posed by the new chemical may be unreasonable it requires appropriate control measures for protecting the environment or human health. Control measures can be imposed through a consent agreement with the notifier and/or through a "Significant New Use Rule" (SNUR) which requires that some uses of the chemical be notified (submission of a "Significant New Use Notice", SNUN) before they are initiated and enables Agency review of an intended new use through the same mechanism as that used for initial review of a new chemical.

Requirements imposed through consent order or SNUR include: restricted uses, import-only (no domestic manufacture), limited release in the environment, limited exposures, limited volumes, proper management of hazardous wastes, and requirements that additional information be developed and submitted to the Agency before a set volume is produced.

Notice of Commencement

Once a material has successfully been through the notification process, the notifier is required to inform the Agency that commercial activities for the chemical have commenced. Only after this "Notice of Commencement" is received is the material placed on the Inventory. This is to ensure that the Inventory is limited to chemicals for which there is genuine commercial activity in the country.

After notification and Notice of Commencement, EPA adds new chemicals to the Inventory.

3.3.2 Compliance and Enforcement Activities

Agency personnel inspect manufacturing facilities to determine whether control measures that have been imposed, such as limited release to the environment, limited production volumes, and use of personal protective equipment, are being complied with.

Agency personnel also monitor the submission of required studies to determine if they are submitted when production triggers are met.

Also, EPA enters into stewardship agreements with manufacturers and manufacturers' groups to encourage appropriate safety precautions with new and existing chemicals. Often these special agreements will cover groups of chemicals, for some of which the Agency has the ability to impose restrictions and for some of which (generally because of prior placement on the Inventory) it does not.

These agreements can cover the basic elements which can be covered by rules, including restricted uses, limited release in the environment, limited exposures, limited volumes, proper management of hazardous wastes, and agreements that additional information will be developed and submitted to the Agency for risk assessment.

3.4 Results and benefits

The US measures to promote compliance include several regulatory mechanisms: consent orders requiring compliance with protective measures ("§5(e) orders"), regulations requiring review by the Agency if certain activities are initiated (Significant New Use Rules, SNURs), regulations identifying activities which have not been found to be generally safe (□not to pose an unreasonable risk□), communication and publication of information, consultation with parties affected by the new chemicals notification scheme, technical assistance and technology development.

3.5 Limitations or problems faced

In the case of the chemicals covered by LVEs or LoREXs, the exemptions cover only one manufacturer, so even a material which is the subject of an exemption is subject to re-review if submitted by another intending maker.

3.6 Resource requirements

Control options (conditions) are proposed and developed by regulatory staff which require the equivalent of approximately 12 full-time employees. The cost for compliance monitoring and enforcement which includes compliance monitoring inspectors and GLP inspectors is *****.

3.7 National contact

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3.8 Additional Sources of Information

4 The Republic of Korea

1. BACKGROUND

1.1 What was the historical context?

In the beginning of 1980, rapid industrial development evolved specific interest in human health and environment effect caused by chemicals in Korea. At that time, only poisonous and deleterious substances based on its acute toxicity were mainly managed. So lawful instrument tool to manage chemicals considering acute toxicity as well as ecotoxicity was required. As a result, Toxic Chemicals Control Act was established in August 1, 1990, and it was amended in August 3, 1994 and then wholly amended in December 30, 1996.

1.2. What were the purpose/needs served?

The purpose of the Act is to prevent any harm caused by chemical substances to human health and the environment and to properly control hazardous chemicals so that everyone to live in a healthy and amenable environment.

1.3. Why was it done?

Before establishment of the Act, a number of new chemical substances were manufactured, imported and used without any notification or registration. So it was impossible to investigate the chemicals in the market and its related information to be a basic information for management. And chemicals likely to be hazardous were exposed to the public and environment without any regulation.

1.4. Which justification was the decisionmaker and which was the Implementer?

-

1.5. How long did it take?

Pre-requisite information is needed for proper chemical substance management. In Korea, it took about 7 years to investigate the chemicals in the market, collect them and develop existing chemical inventory.

2. Description

2.1. What was done?

The Act required a person who intend to manufacture or import a new chemical substance that is not listed in existing chemical inventory to submit related information-chemical identity, physico-chemical properties, use, environmental release, toxicological data and so on. The New Chemical Notification Section performed technical reviews and evaluated its hazard/risk to the human health and environment. As a result, it was classified as non-toxic chemicals, toxic chemicals and observational chemicals by its characteristics and managed it properly.

2.2. What was the scope and applicability?

This Act is applied to chemical substances except any of the following items that are managed by other law;

- Radioactive substances defined under the Atomic Energy Act
- Pharmaceutical products, quasi-pharmaceutical products and cosmetics defined under the Pharmaceutical Affairs Act
- Narcotics defined under the Narcotics Act
- Psychotropic drugs defined under Psychotropic Drugs Control Act
- Agricultural chemicals defined under the Agrochemicals Management Act

- Fertilizers defined under the Fertilizers Management Act
- Foods and Food Additives defined under the Food Sanitation Act
- Livestock feeds defined under the Livestock Feeds Management Act
- Explosives defined under the Gun, Sword and Gunpowder Control Act
- Toxic gases defined under the High-Pressured Gas Safety Control Act

and hazard evaluation exemption is applied to any of the following substances:

- Any chemicals whose annual import amount does not exceed 100kg
- Any chemical reagents in small packages to be directly used for tests, research or examinations
- Any chemicals imported as already contained in machines or equipment or chemicals imported together with the relevant machinery or equipment to be used for preliminary testing or operation
- Any solid chemicals imported in a finished form that consumers can directly use without additional processing (including chemicals used for stationery or painting)
- Any chemicals that have been designated as chemicals that do not require hazard evaluations in a Public Notice

2.3. What was the timing?

As said in 1.1, rapid industrial development emerged social caution to effect and risk caused by chemicals in the beginning of 1980. To prevent any accident by chemicals and minimize it, regulation of instrument tool to manage and control chemicals was needed.

3. ISSUES

3.1. What issues were faced?

To certificate new chemical manufactured or imported, we should investigate chemicals being circulated in the market, collect and register it and develop a existing chemical inventory. It required lots of time, expenses and manpower. And it was necessary to announce and recognize the Act to the public efficiently because it is mainly performed by chemical industry's voluntary determination to notify new chemicals.

3.2. How were they addressed?

A person who intend to manufacture or import a new chemical should submit notification dossier about the chemical to nation competent authority at least 60 days in advance. In the beginning of performance of the Act, discontents emerged from chemical industries. They alleged that the Act retard business activity and cause international commercial transaction problem.

4. EVOLUTION

4.1. What changes have been made over time?

In amendment of the Act, the following articles related New Chemical Notification Scheme were involved.

- The designation of observational chemicals
- The designation of testing and research institutes for issuance of test reports
- To concrete article related protection of submitted materials

4.2. Why?

-In case a chemical substance is likely to cause harm to human health and environment but is not possible to designate as toxic substance in short term's evaluation, it is classified as observational chemicals to assess the toxicity exactly and manage it properly

by assessing the effect on environment, manufacture, import and use pattern in time.

-As Korea became a member of OECD in 1996, the international harmonization of the regulations related new chemicals risk evaluation was required. Based on OECD level, the Act established the designation of testing and research institutes, that is Good Laboratory Practice-GLP, for issuance of the test report submitted. In addition, detailed matters necessary for protecting of submitted materials or data were prescribed in amended Act.

5. OPTIONS

5.1. What options were considered and dismissed?

It is possible to exempt from the submission of some test reports in case of polymer chemicals and chemicals which are designate and announced as being commercially circulated in foreign countries before the date of the enforcement(2 Feb. 1991), that is listed in at least two other foreign nation's existing chemical inventories.

5.2. Why?

Polymer notification and reduced notification are adopted for efficient assessment of a chemical based on its characteristics.

6. EFFECTIVENESS

6.1. How effective has the instrument been?

By assessing new chemical substances before they are manufacture or imported, the New Chemicals Notification instrument is actively carrying out the strategy to prevent or minimize any harm caused by chemical substances to human health and the environment. Enforcement of the Act enabled to designate the toxic chemical to be managed safely. Since 1991, the establishment of the Act, about 1000 new chemicals were notified and 67 substances of them were classified as toxic chemicals.

6.2. How can you determine its effectiveness?

The Act classifies toxic chemicals according to their physico-chemical or toxicological properties. It also specifies symbols and indications of danger for labelling as well as risk phrases, safety phrases and MSDS. So it can make safe and proper management for dangerous substance.

6.3. What conditions are important for its effectiveness?

7. COSTS

no information available

8. RECOMMENDATION

8.1. Would you recommend that developing and industrializing countries use this instrument?

yes

8.2. What lessons can they learn from your experiences with it?

Although the instrument requires lots of time, expenses, manpower to settle it, it can provide a kind of guidance for safe management of chemicals to the public.

10. VIEW OF REGULATE PARTIES IN THE COUNTRY ON THE

INSTRUMENT

positive

11. VIEW OF PUBLIC INTEREST ORGANIZATIONS ON THE INSTRUMENT

positive

12. CONTACT FOR MORE INFORMATION

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Acronym List

CA	Chemical Abstract
CAS	Chemical Abstracts Services
CBI	Confidential Business Information
CEPA	Canadian Environmental Protection Act
DSL	Domestic Substances List
ECOIN	European Communities Core Inventory
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EA.	European Union
FTE	Full Time Employee
GLP	Good Laboratory Practice
IOMC	Inter-Organization Programme for the Sound Management of Chemicals
IPCS	International Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Chemistry
IUR	Inventory Update Rule
LoREXs	Low Releases & Low Exposures
LVEs	Low Volume Exemption
MPDS	Minimum Pre-market Data Set
MSDS	Material Safety Data Sheet
NOAEL	No Observed Adverse Effect Level
NCNS	New Chemical Notification Systems
NDSL	Non- Domestic Substances List
NSN	New Substances Notifications
NSNR	New Substances Notification Regulations
OECD	Organization for Economic Cooperation and Development
PCBs	PolyChlorinated Biphenyls
PBTs	Persistent Bioaccumulative Toxics
PEC	Predicted Environment Concentration
PIC	Prior Informed Consent
PMN	Pre-Manufacturing Notification

POPS	Persistent Organic Pollutants
PRTRs	Pollutant Release and Transfer Registers
R&D	Research and Development
SAR	Structure-Activity Relationship
SAT	Structure-Activity Team
SIDS	Screening Information Data Set
SNA	Significant New Activity
SNAC	Significant New Activity Condition
SNUN	Significant New Use Notice
SNUR	Significant New Use Rule
TGDs	Technical Guidance Documents
TME	Test Marketing Exemption
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
USEPA	United States Environmental Protection Agency
UN	United Nations
UNEP	United Nations Environmental Programme
UNITAR	United Nations Institute for Training And Research
UVCB	Unknown or Variable composition Complex reaction products and
Biological	materials
9CI	Ninth Collective Index

ANNEX A

Notification Requirements and Assessment **and Securely Handling Confidential Business Information** **An Industry View**

**Presented to the Joint UNEP/OECD Workshop on
Notification and Assessment of New Industrial Chemicals
for the Latin American Region
Buenos Aires, Argentina
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Abstract

The purpose of this paper is to provide an industry view on New Substance Notification Requirements and Notification Assessment Approaches. To do this an industry proposal for notification requirements and assessment is provided. The paper also addresses the secure handling of Confidential Business Information. Again, an industry proposal is offered.

Notification Requirements and Assessment

From an industry perspective, the objective of an overall Chemical Management System is to protect people and the environment from unreasonable risks. New Substance Management can be one component of such a system. As discussed elsewhere, the first element of New Substance Management is often a Chemical Inventory, which is used to identify those substances that would be subject to the second element of New Substance Management -- New Substance Notifications.

To be clear, industry does not suggest that all countries should establish New Substance Notification programs. Industry proposes that chemical regulations be approached in a step-wise fashion. In many countries, there are other needs/other priorities which should be addressed before New Substance Notifications are even considered. However, if your country has thoroughly assessed its needs and has concluded that, in order to achieve its objectives, a New Substance Notification program is indicated, then industry has recommendations about how you should go about it.

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The purpose of New Substance Notifications is to provide government the opportunity:

- to consider the introduction into commerce of new chemical substances before it occurs,
- to intervene to prevent the commercialization of new substances which would pose unreasonable risks, or
- to propose risk management actions which would reduce those risks to acceptable levels.

In most cases, as I'll discuss later, we expect that such intervention will not be necessary.

Please notice I have not suggested either that industry should request, nor that government should grant, permission to commercialize a chemical or product. Neither have I suggested that a chemical should be registered or licensed for commercialization. In industry's view, these options are not a good utilization of either government or industry resources. Rather, New Substance Notifications announce to government industry's intention to commercialize a new substance and provide government a chance to intervene, if warranted, to ensure the risk posed by this commercialization will not be unreasonable.

What should a New Substance Notification include? Let me share some general thoughts before I discuss specific provisions.

First, a New Substance Notification should be simple and straightforward, but at the same time flexible. This combination can be difficult to achieve. For example, the Canadian system offers some important flexibility, but with over 20 different notification schedules, tiered notification requirements and volume tracking obligations, it is far from simple or straightforward. On the other hand, the EU system is very straightforward (one might even say prescriptive), but as it is implemented by some Competent Authorities, it lacks the flexibility that would best support the introduction of innovative new technologies.

Next, a New Substance Notification system should minimize unnecessary delays in introducing new substances into commerce. One way to achieve this is to avoid duplication, rework or any non-value-added work on the part of either the notifier or the regulatory authorities. For example, no information should be collected unless there is already an identified use for that information.

Finally, it is imperative that any New Substance Notification system protect Confidential Business Information. More about the topic of Confidential Business Information protection is included later in this paper. Relatedly, New Substance Notification systems should include a process for acquiring Confidential Business Information from 3rd parties -- that is, companies other than the notifier.

Industry also recommends that New Substance Notification systems not require notifications on mixtures, articles, substances which are only impurities or by-products, substances which are utilized for research and development purposes, and new polymers produced from monomers which are not "new" substances. These recommendations are consistent with industry's recommendations for what substances should be included in

the Chemical Inventory.

Industry recommends that a Chemical Inventory contain both a public portion and a confidential portion. If so, then a process must be established for searching the confidential portion of the Inventory to determine whether or not a substance is really “new” and must be the subject of a Notification. Such processes are currently in place in both the US and Canada, and industry recommends using these processes as the model for any new systems. In both cases, the party requesting a search of the Confidential portion of the Inventory must demonstrate a *bona fide* intent to manufacture or import the substance in order to justify the search.

Finally, as I mentioned earlier, industry believes that a New Substance Notification system should be just that -- a notification system, not a registration or licensing system. Thus, after the review period for the notification has been completed, unless the regulatory authority has raised an objection, the notifier should be free to initiate commercial activity with the substance without having to wait for an affirmative response from the authority.

The industry recommended approach for New Substance Notifications is somewhat different from any of the options you may have seen before. It is based on dividing the universe of new substances into two groups. The first group contains those substances which may be new in your country, but which can be found on either the US TSCA Inventory, the Canadian DSL, EU’s EINECS or EU’s ELINCS. I’ll refer to these substances as “new to the country”. It is certainly true that there are other Inventories in the world to which one could refer for the purpose of defining “new to the country” substances, but the ones I’ve mentioned are among the Inventories which are most widely recognized. The other group of “new” substances contains those substances which are both new in your country and also are not found on any of the reference inventories. I’ll refer to these substances as “new to the world”. The notification requirements and assessments would be different for these two groups of substances.

For “new to the country” substances, we recommend a very simple New Substance Notification. Such a notification would contain:

- the chemical identity of the substance (for example, the substance’ Chemical Abstract Registry Number, if one has been assigned), as well as an indication of which of the reference inventories the substance is on;
- a good quality, 16 section Material Safety Data Sheet;
- an estimate of the expected annual volume and expected use for the material; and
- a description of any bans or usage restrictions imposed by other countries.

This notification would be submitted 45 days prior to the new substance’ being placed on the market for a commercial purpose.

In order to establish which substances would be eligible for this type of notification, we recommend countries not establish a separate list of chemicals like the Canadian NDSL. Such a list, by its nature, is always out of date and requires significant resources to create and maintain. Instead, we recommend relying on the information contained in the notification, along with publicly available information from the original jurisdiction, to

confirm a substance is “new to the country”.

For substances which are “new to the world”, a more complete, but still simple, New Substance Notification is warranted. Such a notification would contain:

- the chemical identity of the substance and a material safety data sheet;
- an estimate of the expected volume and expected use for the material; and
- information required to adequately address the risk posed by the new substance. This information, which may include test data or other information, should be limited to that which is needed to address the risk posed by the substance. In this context, authorities should accept and utilize any scientifically sound information for this purpose.

This notification would be submitted 90 days prior to the substance’ being placed on the market for a commercial purpose.

I suggested that notifications on “new to the world” substances should contain only the information required to adequately address the risk posed by the substance. How would a notifier determine what information will be deemed adequate for this purpose by the regulatory authority? There are several ways. The best way is for the notifier and the authority to talk with each other prior to the submission of the notification. During such a consultation, the notifier could describe the substance and what is known about it at that point in time; the authority could outline the kinds of questions it has about the substance with respect to the risk it will pose; and they could jointly reach consensus about what information is needed to address those questions. Alternatively, or perhaps in addition, the authority could publish guidance about what information is generally useful in notifications, outlining the fundamental questions the authority will answer in addressing the risk posed by most substances. The last and least desirable option might be for the authority to publish a standard menu of information elements from which the notifier could pick those relevant to the new substance for inclusion in the notification.

Industry recommends that a fixed, mandatory list of tests for all notifications be avoided. Such inflexible lists are almost never “right” for any particular substance, either lacking relevant information for that substance or containing testing requirements that are not needed. Further, such lists tend to lead to a “check the box” implementation in which sound scientific thinking is supplanted by concern over whether all the entries in the list have been included in the notification. It is important to avoid the generation and collection of data which do not yield knowledge and understanding.

Now that I’ve outlined what industry thinks should be included in a notification, let me describe our recommendation for how the notifications should be assessed. I’ll begin by outlining the purpose of the Notification Assessment. It is two-fold. First, the assessment is intended to help authorities determine if the new substance is likely to pose an unreasonable risk to human health or the environment. If it is not, then the authorities need not take any action. Second, if the substance would pose an unreasonable risk, then the assessment helps identify risk management actions which the authority might implement in order to reduce the risk to acceptable levels so commercialization could proceed. Alternatively, the assessment could lead to the conclusion that no risk management action short of a prohibition would reduce the risk posed by the substance

to an acceptable level. However, this outcome is considered very unlikely.

In considering how assessments should be conducted in many countries -- especially those with economies in transition -- industry has predicated its recommendation on several assumptions. First, because of the nature of the global chemical industry, and the location of the largest members of this industry, we believe most New Substances will be imported into countries with economies in transition -- at least initially -- rather than being manufactured there for the first time. Further, most of these substances will already exist on one or more existing inventories and will not be of unique concern in subsequent countries. Finally, resource limitations are a fact of life in all countries, but they are especially acute in countries with economies in transition. As a result, it is imperative for authorities in these countries to focus their limited resources on substances which are most likely to be of concern. Attempting to take on too much, all at once, will lead inevitably to failure, as overly ambitious programs collapse under the weight of their required infrastructure. As a result, such systems will fail to provide to society any of the benefits which might otherwise be realized via more modest programs.

As I did earlier with the Notification Requirements, let me begin the discussion of industry's recommended approach to Notification Assessments with a few general remarks.

As I stated already, it is very important to focus the expenditure of resources -- both personnel and monetary resources -- toward those risks that have the greatest impact on human health and the environment. Based on experiences in other countries, new substances have not been major, or even measurable, sources of unreasonable risk. For example, of the over two thousand new substances notified in the EU, only three have been banned from commerce. This suggests that extensive efforts should not be aimed at reassessing substances which are simply "new to the country". As assessment capability develops over time, if warranted, assessments might be broadened. But at least initially, resources must be carefully aimed at those efforts which will yield the highest societal benefit.

Further, cooperation rather than confrontation will likely lead to a more successful program with a lower expenditure of resources. Consultation with industry can facilitate this process and enhance the acceptability of the outcomes.

Finally, in extending this spirit of cooperation, we recommend that if you create a Notification and Assessment System, you include among its design criteria a method for notifiers to determine the status of their notifications. Uncertainty is one of the key obstacles to orderly commercialization of new technologies and a major source of frustration for industry in dealing with regulatory authorities. Having a notification tracking system of some type helps to alleviate this uncertainty.

To build your confidence in the acceptability of avoiding large expenditures of resources to reassess substances which are not new elsewhere in the world, industry recommends that you initially invest effort in learning about the toxicity endpoints and exposure scenarios -- that is, the components of risk -- which are assessed in the US, Canada and the EU. We believe this will help you to feel comfortable in not starting from scratch with every new substance notified in your country. Workshops like this one are one way to enhance this understanding, but industry stands ready to assist you further as your

programs begin to take shape.

Finally, and most importantly, you should determine if there are any unique, local conditions or exposures which would cause you not to apply in your country the assessment conclusions reached elsewhere. We believe the default assumption -- that differences are not significant -- will apply most of the time, despite the obvious differences in climate and infrastructure which exist among nations. To determine if there are any rare occasions where this assumption fails in your country, we recommend that you convene an expert group, made up of experts from government, academia and industry, to develop screening criteria to indicate when more detailed assessments are warranted. These experts should focus on realistic exposure scenarios and their conclusions should be subject to broad-based peer review. These screening criteria should be developed before notification requirements are in effect. Increasingly sophisticated screening elements should be phased in over time only as the capability to process their output is built in your country.

Now, I'd like to offer specific recommendations on how to assess notifications on the two groups of substances I outlined before -- "new to the country" substances and "new to the world" substances.

For "new to the country" substances, assessment should begin by screening for known concerns. For example, determine if the substance has been subject to a regulatory action, such as a ban or severe restriction, in another country. This information would be contained in the notification we recommended. Next, identify unique, local concerns (if any) based on the screening criteria developed by the expert group for that purpose. If any such concern is identified, determine if a risk management action is needed to reduce the risk to an acceptable level. As previously noted, this outcome should be rare. If no unreasonable risks are identified, then take no action and allow the substance to be commercialized as planned. Alternatively, if a more detailed assessment is indicated, then consult with the notifier about the next steps to be undertaken.

For "new to the world" substances, begin with a screening process similar to that conducted for "new to the country" substances. Since the notification for a "new to the world" substance will contain additional information, based on the pre-notification consultation between the notifier and the regulatory authority, many of these assessments will still be straightforward. However, again, if a more detailed assessment is indicated, consult with the notifier about what kind of assessment is needed and what, if any, additional information will be required. As previously noted, such detailed assessments should be phased in over time as the capability to conduct them is built in the country. Based on the outcome of the risk assessment, determine if any risk management actions are needed to ensure that the risk posed by the new substance is not unreasonable. If there is no unreasonable risk identified, take no action and allow commercialization to take place.

Here are a few follow-up thoughts on assessing New Substance Notifications. First, it is unfortunate, but inevitable that there will be occasional disputes over the conclusions from the assessments. Among the other design criteria for a Notification/Assessment System, there should be a process to resolve such disputes in a fair and timely manner. However, if the system is transparent and the notifier is consulted in an appropriate way, the number of disputes will be minimized. Finally, let me emphasize the importance of

phasing in the notification requirements. Making requirements effective only after the capability is in place to efficiently handle them will greatly increase their effectiveness and will smooth the transition to their implementation. This will not be achieved over night. Under TSCA, US EPA has been working on their process for over 20 years and they are still refining and improving their screening and assessment approaches. This is true in other jurisdictions, as well.

Let me conclude this discussion with the following thoughts:

- Development of an effective and efficient notification, screening and assessment approach will take time. Don't try to rush it.
- Start screening for the most immediate concerns first, and focus the Notification Requirements on collecting information for this purpose.
- Build on what has been done in other countries, but don't try to duplicate or repeat their processes.
- Phase in additional, more sophisticated screening and assessment approaches over time, but only as the capability exists to manage the additional requirements.
- Finally, ensure the process is transparent to the regulated community. Uncertainty and confusion are the enemies of cooperation.

Securely Handling Confidential Business Information

As I mentioned earlier, any New Substance Notification System must have a means to properly and securely handle Confidential Business Information. Industry believes it has a right to expect that any Confidential Business Information it provides to government will be protected from unauthorized disclosure by the agency receiving it. So let's start this discussion by defining Confidential Business Information.

Confidential Business Information is any information developed or acquired by a business about a product or process, and its production, sale, or use thereof, which allows the business to obtain or retain business advantage from its right to such information. This is a fairly broad definition, but appropriately so. Confidential Business Information may encompass a broad range of information, which will be different for different companies in different situations. Let me offer you some specific examples.

Examples of the kind of information which may be considered confidential include:

- The identity of a chemical substance. The identity of chemicals substances cannot always be accurately reverse engineered by a competitor and companies cannot always rely upon patents to protect their proprietary chemicals so protecting identity can be crucial.
- The identity of the company which either manufactures or imports a substance. Sometimes company identity will not be confidential -- for example when a chemical supplier is seeking to generate new sales of a chemical. Other times, the company identity may be considered Confidential Business Information -- for example when a formulator imports and uses a substance which it believes to be the source of a particular competitive advantage for its product. Revealing the

company identity could tip off the competition to look for a new ingredient in the formulator's product.

- A description of the process by which the substance is made. This can reveal the chemical identity, or allow a competitor to estimate the cost of production of a substance.
- A variety of commercial information is often Confidential Business Information, including production, import and sales volume, customer lists, and cost estimates.
- The manufacturing site where a substance is produced may be Confidential Business Information since it would reveal the identity of the manufacturer
- Also, any information which provides linkages to and among the information listed above may be considered Confidential Business Information.

This list is not exhaustive. There may be other kinds of Confidential Business Information beyond those I've mentioned.

Why should Confidential Business Information be protected? The answer is because it is in society's best interest. Let me explain. Progress is the fruit of innovation. Whether it is a new polymer used to make packaging to keep food products safe and sanitary, or a more economical and effective chemical used to treat drinking water, innovative, new technologies in the chemical industry lead to improved lives of people everywhere. Therefore, supporting and encouraging innovation is certainly in society's best interest.

Innovation is the result of research and development efforts. But R&D is expensive and time consuming. Companies are able to undertake R&D efforts only if they have a reasonable probability of being able to recover their investment through marketing the products they create. Robust protection of Confidential Business Information provides industry confidence that they will be able to reap the benefits from their expenditure of both the time and resources to create new and better products. In the absence of Confidential Business Information protection, R&D efforts may not be undertaken at all. Alternatively, the products which result from those R&D efforts will be withheld from the countries failing to provide proper protection. In today's increasingly global marketplace, this is often the only way companies have to protect their intellectual property all around the world.

Now that I've explained why Confidential Business Information should be protected, let me discuss how it should be protected. There are three necessary elements for any effort to protect Confidential Business Information. These are appropriate facilities, appropriate procedures, and sanctions for disclosure.

By having appropriate facilities, I mean that the authority receiving Confidential Business Information must have in place, before the information is collected, the infrastructure to protect the information once it is in the authority's possession. This capability must be in place in advance since once it is released, even by mistake, Confidential Business Information can never be retrieved -- you can never put the genie back in the bottle. Necessary infrastructure includes the ability to physically separate Confidential Business Information from other information. This means separate storage areas or at least separate file containers. These storage areas must be secure from either inadvertent or intentional entry by unauthorized individuals. This may be just common sense, but the

file room should have a proper lock on the door and the number of keys to the lock should be restricted. The storage containers must also have proper locks. And it is not just the area where the Confidential Business Information is stored which must be secure. The area where the Confidential Business Information is used should also be properly secured. It makes little sense to lock away files containing Confidential Business Information in a vault for storage but then allow an authorized staff person to have the files open on a desk in an office area where anyone can walk by and read the information over the person's shoulder.

Protection of Confidential Business Information also requires appropriate administrative procedures. For example, the most basic of these procedures is not to collect any Confidential Business Information unless it is really needed, unless there is a well identified need for the information. Collecting unnecessary Confidential Business Information just creates a bigger burden for both government and industry with no attendant benefits. Authorization for access to the Confidential Business Information should be limited to those within the regulatory authority who have a "need to know" the information in order to carry out the provisions of the legislation underlying the collection of the information. No one should have access to Confidential Business Information simply because it would be "useful" for him to see it. There should be a well defined procedure in place for requesting and obtaining authorization to have access to Confidential Business Information and the criteria for granting such authorization should be clearly spelled out and available for public comment. One of these criteria should be that authorization for access to Confidential Business Information should not be granted to any one unless and until he receives training in the proper handling and use of Confidential Business Information. In addition to authorization procedures, there should also be procedure in place for tracking the Confidential Business Information within the regulatory agency. This should begin with logging in the CBI when it is received. Subsequently, when an authorized person accesses the Confidential Business Information, that fact should be recorded. This procedure should apply to every copy of Confidential Business Information. If it is appropriate to create additional copies of the information, when these copies are created, used or returned, this should also be recorded.

The third key element in a program to securely handle Confidential Business Information is sanctions for disclosure. Just as there are penalties for those who do not comply with other provisions of any legislation which would create a chemical management system, there should be penalties for the unauthorized disclosure of Confidential Business Information. These penalties should be severe; up to and including criminal penalties -- by that I mean time in jail -- for those who disclose Confidential Business Information in an unauthorized manner. Failure to provide adequate sanctions for CBI disclosure provides a huge disincentive to those who would submit Confidential Business Information to be completely open and honest.

Let me leave you with a few concluding thoughts about securely handling Confidential Business Information. First, consider the definition of Confidential Business Information broadly. As I mentioned, what is confidential varies from company to company and situation to situation. Second, the most secure way to handle Confidential Business Information is not to handle it at all. Don't collect any Confidential Business Information unless it is really necessary. Third, in order to protect Confidential Business Information, it is necessary to ensure there are appropriate facilities, appropriate procedures, and

sanctions for unauthorized disclosures. Finally, it is critical that Confidential Business Information protection be in place before any information is collected.

