



EXISTING CHEMICALS REVIEW

OVERVIEW OF OVERSEAS EXISTING CHEMICALS PROGRAMS

Background

Existing chemicals amount to the vast majority of chemicals on the market worldwide. For example, in the European Union (EU) it is estimated that existing chemicals account for more than 99 % of the total volume. However, unlike new chemicals, existing chemicals have not been subject to the same testing requirements and assessment before being placed on the market. Consequently, there is a general lack of knowledge about the properties and uses of existing substances that represent the vast number of chemicals on the market.

In national schemes, i.e., Canada, NZ, USA, EU and Australia, existing chemicals are generally defined as chemicals that were in use between a designated time-period when the schemes were being established. Each scheme has an inventory of existing chemicals, though in some schemes substances can be added to this list, i.e., it is not a closed list, such as Canada, USA and Australia.

Up until recently, overseas programs have generally assessed existing industrial chemicals on a priority basis, e.g., EU, Canada and USA. This has allowed regulatory programs to focus their resources on those chemicals considered to present the greatest risk to human health and/or the environment. Each overseas regulatory authority has developed its own prioritisation framework to identify such chemicals. However, existing chemicals policy is presently, or has recently been, under review in several countries, i.e., Canada, New Zealand, EU. An analysis of overseas existing chemicals programs has been undertaken to identify how overseas regulatory authorities approach the assessment of existing chemicals, what are the changes taking place and are there common trends emerging.

Overseas existing chemical programs

NICNAS undertook a literature search to evaluate overseas programs that assess existing chemicals. The amount of readily available information about each program varied and, thus, overviews were only prepared on existing chemicals programs in:

- Canada;
- EU;
- USA; and
- New Zealand (NZ).

For the EU, an overview is provided of both the present and proposed existing chemicals program, called the **Registration, Evaluation and Authorisation of CHemicals (REACH)**. The current EU program undertakes risk assessments on a priority basis. Under the proposed REACH system, companies will be required to register all chemicals manufactured and imported into the EU at > 1 tonne per annum, and provide a base set of data. It is anticipated under REACH that the rate of assessments will accelerate; it is estimated that 30,000 existing chemicals are marketed in volumes above 1 tonne in the EU, yet over approximately 6 years (nearly) finalised assessments have been carried out on only 41 priority substances under existing regulations.

There is no single chemical assessment scheme in the USA. Instead there are several different organisations that evaluate existing chemicals. Consequently, the overview focused on the activities of the US Environmental Protection Agency (US EPA), which oversees chemical assessment schemes such as the Integrated Risk Information System (IRIS), and the Agency for Toxic Substances and Disease Registry (ATSDR) run by the US Department of Health and Human Services. Recently, the US EPA introduced the High Production Volume (HPV) program, in response to the lack of data on high volume chemicals.

The Canadian scheme is also a risk assessment program focusing on priority chemicals which under amended legislation will systematically categorise approximately 23,000 substances by September 2006, and if necessary, screen existing chemicals. The aim is to speed up the assessment and selection of priority substances for review.

The NZ scheme, which became effective in 2001, aims to conduct hazard assessments on all existing substances by 2005. It is estimated that a total of 70,000 substances (single, mixtures and groups) will be assessed and classified.

Detailed overviews of all the above existing chemical programs are included in Appendix 1.

Summary of trends/issues between overseas existing chemical programs

The aim of this overview is not to comment on the potential benefits or failings of the overseas schemes examined. Instead, a summary of trends and issues identified for these overseas existing chemicals programs are highlighted below to encourage discussion on the different approaches overseas existing chemicals programs have taken or propose to take.

Hazard or risk based scheme?

Existing chemical schemes are generally risk based, and although NZ recently adopted a hazard-based scheme, risk assessments can still be conducted on a priority basis.

Single entity or product based scheme?

Existing chemical schemes generally assess a single chemical entity, however, the NZ scheme also assesses products.

Within the single entity based programs there has been a trend for some schemes to categorise structurally similar chemicals and assess them as a group. This approach has been taken in the US HPV and existing EU schemes for chemicals such as linear alkyl benzenes, e.g., the EU assessed as a single group these chemicals with an alkyl chain group of C₁₀ – C₁₃ carbon atoms.

Are all existing chemicals assessed, or ‘priority’ chemicals only?

Overseas existing chemical schemes have generally assessed a small number of ‘priority’ existing chemicals, that is, chemicals considered to be the greatest risk concern to human health and/or the environment.

Recently, the Canadian, NZ and proposed EU REACH schemes require a level of assessment for all existing chemicals:

- *Canada*: all existing chemicals are being categorised and priority chemicals undertake a screening assessment to determine whether they should go on the Priority Substances List (PSL). Substances on the PSL are given priority for analysis of potential risks to human health and the environment.
- *NZ*: hazards of all existing substances (single chemicals and mixtures) are determined, and substances classified and assigned controls where appropriate.
- *EU REACH*: phased in registration of basic information on all existing chemicals exceeding a production volume of 1 tonne (including preliminary risk assessment) by manufacturers and importers. For the large majority of chemicals (estimated at more than 80%), there would be no need for further assessment.

What types of chemicals are considered a ‘priority’ and how are they identified?

Although each overseas scheme has an approach for identifying priority chemicals that generally takes account of both human health and environmental concerns, there is no consistency in how the criteria are applied. For example:

- *Canada*: categorise chemicals based on potential exposure to the general population and persistent, bioaccumulative and toxic (PBT) criteria. If the criteria are met a screening assessment is conducted. Based on outcomes of screening assessments a full risk assessment may be done.
- *NZ*: although a hazard based scheme, a priority list of nominated potential reassessments is maintained. Reassessments are where the risks and benefits of a substance are reconsidered. Reassessments have to be justified and may be paid for by sponsors or the NZ regulatory authority.
- *Current EU scheme*: only assesses high production volume chemicals, i.e., are produced or imported into the Community in volumes above 10 tonnes per year, using an exposure effect model to score for human health and environmental concerns and, thus, prioritise them.
- *EU REACH*: the proposed scheme is a tiered phase-in of information in the next 3 to 11 years based on volume, with a priority on obtaining information

(within 3 years) for those chemicals that are category 1 and 2 mutagens, carcinogens or reproductive toxicants.

- *US*: different programs with different prioritisation criteria eg EPA manages a chemical program that prioritises chemicals that are PBTs. In contrast, ATSDR ranks existing chemicals based on scores for frequency of occurrence at National Priorities List sites, i.e., sites where there are releases or threatened releases of hazardous substances, toxicity and potential for human exposure.

Who is responsible for generating and assessing the data?

It is generally the responsibility of industry to generate and provide data to the regulatory authorities for assessment. Only the US EPA and the present and proposed EU schemes require that all companies who have submitted data regularly update the information:

- *US*: under the Toxic Substances Control Act 1976, information on production volume is required every 4 years.
- *Current EU scheme*: information on new uses that change the type, form, magnitude or duration of exposure of man or the environment to the chemical and new data on physicochemical properties, toxicological or ecotoxicological effects is required every 3 years.
- *EU REACH*: change in identity of manufacturer or importer, significant changes in volume, new uses, significant new risks and changes in proposed classification have to be notified.

Presently, all regulatory authorities assess the data. However, the proposed EU REACH scheme will shift the responsibility to industry for generating and assessing the data and risks of using the substance.

Do schemes obtain use and exposure information?

With the exception of the NZ scheme, national schemes routinely obtain use and exposure information on existing chemicals. However, the source, and hence 'quality', of the exposure data varies between the schemes. Some schemes obtain 'direct' data whilst others do not.

- *Canada*: a number of data sources are utilised at the categorisation stage to determine human and environmental exposure, including release/emissions from the National Pollutant Release Inventory; survey in the provinces; quantity and use codes from DSL; modelling data; and international reports.
- *Current EU scheme*: manufacturers and importers supply exposure data.
- *EU REACH*: estimate of human and environmental exposure is required at the registration stage.
- *US*: EPA often uses volume as a surrogate for exposure, which is collected every 4 years. ATSDR determines the potential for human exposure based on

the concentration of the substance in environment media and the exposure status of the populations.

Presently, information on use and exposure arising from downstream uses (including formulators) is not readily available in national programs. However, the EU REACH scheme proposes to extend responsibility along the supply chain, with downstream users providing information on use and exposure.

It is also worthwhile noting that within the EU at present, each Nordic country (Norway, Sweden, Denmark and Finland) has its own Product Register; national legislation requires manufacturers and importers to declare chemical substances and products to a Product Register. Furthermore, much of the information provided to the Product Registers is used as support for national and EU risk assessments.

Are modelling data used?

Generally, modelling data has only been used routinely for environmental endpoints, as actual data is usually not available. However, some national authorities use modelled data to predict adverse effect to human health. For example:

- *Canada*: uses quantitative structure-activity relationships (QSAR) in their current program of categorising chemicals.
- *US*: models may be used in certain circumstances in the integrated risk information system (IRIS) managed by the EPA.
- *EU*: proposed REACH scheme makes the development of modelling and screening methods for assessing the potential adverse effects of chemicals on the endocrine system a research priority, along with the development of in vitro test methods in general.

Do national schemes focus on issues identified of concern?

With the exception of NZ, overseas schemes focus on chemicals identified of concern; the Canadian, US EPA and proposed EU REACH scheme all give priority to persistent, bioaccumulative and toxic (PBTs) chemicals.

Although there is no single scheme for the assessment of existing chemicals in the US, there are chemicals programs that focus on issues of concern. For example, US EPA recently announced it is to manage a program that will examine the potential health risks associated with certain chemical exposures, i.e., Voluntary Children's Chemical Evaluation Program.

Do schemes allow chemicals or specific uses of chemicals to be banned?

Generally, the assessment schemes can only implement measures to control the use of an existing chemical, i.e., are approval schemes, although stringent measures may result in the discontinuous use of an existing chemical for a specific use. However, this is not the case for the NZ, US and proposed EU scheme:

- *NZ*: can withdraw approval following a reassessment, thus making its use, manufacture and importation illegal.
- *US*: EPA can limit or prohibit use.
- *EU*: proposed REACH scheme can introduce restrictions (including banning).

Is there public comment on the review programs or access to information?

All these assessment schemes allow public comment on draft reports with the exception of the present EU program, although public interest groups can provide input. Additionally, all the overseas schemes make available to the public published reports, facts sheets and/or lists of approved substances. However, the proposed EU REACH scheme makes increased transparency a key objective, and acknowledges consumers ‘right to know’.

That is, a right to access information about the chemicals to which the public are exposed that will enable them to make informed choices and to avoid products containing harmful chemicals. Thus, the scheme proposes that the public should have access via the internet to the non-confidential information on chemicals assessed under REACH.

Are national assessments used by other overseas programs?

With the exception of NZ, national schemes routinely feed their assessments into international programs. For example:

- *Canada*: feeds its assessments into the OECD Screening Information Data Set (SIDS) and WHO Concise International Chemical Assessment Documents (CICAD) program.
- *US*: HPV program assessments are fed into the OECD SIDS program, and the ATSDR and IRIS schemes feed into the CICADs program.
- *Current EU scheme*: feeds its assessments into the OECD SIDS program.

Additionally, the Canadian schemes routinely use assessments of other overseas regulatory programs at the categorisation stage to determine human and environmental exposure.

APPENDIX 1

CANADIAN EXISTING SUBSTANCES

Legal Framework

The *Canadian Environmental Protection (CEPA) Act, 1988* provides for the protection of the environment and of the health of Canadians from toxic substances and other pollutants. Under the Act, a substance is considered "toxic" if it is entering, or may enter, the environment in a quantity or concentration or under conditions that:

- have, or may have an immediate or long-term harmful effect on the environment or its biological diversity;
- constitute, or may constitute, a danger to the environment on which it depends;
or
- constitute, or may constitute, a danger to human life or health.

One of the initiatives under CEPA is the Priority Substances Assessment Program (PSAP). The assessment of substances on the Priority Substances List (PSL) provides an in-depth analysis of potential risks to human health and the environment posed by environmental contaminants. A Priority Substance may be a chemical, a group of chemicals, effluents or wastes.

There have been two PSLs (PSL1 and PSL2), which were established from the first CEPA, enacted in 1988. These lists were established by the Ministers of Health and Environment, based on the recommendations from the Ministers' Expert Advisory Panel.

The Act was amended in 1999 (CEPA, 1999). The revised legislation requires systematic categorisation and, if necessary, screening of substances on the Domestic Substances List (DSL). The aim is to speed up the assessment and selection of priority existing substances in Canada, and to set firm deadlines for action to control toxic substances.

The responsibility for assessing Priority Substances is shared by Health Canada and Environment Canada. Health Canada assesses the risks to human health from environmental exposure (non-occupational) to Priority Substances. Environment Canada assesses the risks to the environment and non-human organisms.

Inventory

An existing substance is defined as a substance on the DSL. DSL includes all substances manufactured in or imported into Canada in a quantity >100 kg/calendar year, and those substances in Canadian commerce or used for commercial manufacturing between 1 January 1984 and 31 December 1986. DSL currently contains approximately 23,000 substances. The purpose of DSL was to define what was "New to Canada" and it has been amended from time to time.

Operations

The risk assessment of existing substances involves the following activities:

1. Identification of candidates for risk assessment;
2. Data collection to support priority setting;
3. Setting priorities for assessment;
4. Conducting the risk assessment;
5. Risk management.

1 Identification of Candidates

The basis for the identification of candidates for risk assessment include:

- Categorisation and screening of DSL;
- Provincial or international decisions – identify and review decisions on prohibited or substantially restricted substances from other jurisdictions;
- Public nominations – people can write to the Minister requesting that a substance be added to PSL.

The current focus of the Canadian program is the categorisation and screening of DSL.

2 Data Collection for Categorisation and Screening of DSL

Data sources for human exposure can be obtained from release/emissions (National Pollutant Release Inventory – NPRI), survey in the provinces, quantity and use codes from DSL (currently being updated), fugacity modelling (to estimate environmental exposure), physico-chem data and US data, if available.

The information necessary to determine environmental effects is sought from published scientific journals and databases, international reports, computer modelling (TOPKAT, ASTER or OASIS), and through direct contact with stakeholders. Very little experimental data are available for environmental endpoints, therefore, QSAR is used mainly to populate the database and complement all experimental and analogue data available.

Other factors to be considered in categorisation decisions include weight of evidence, model limitations, data validation, comparison with data analogues and, for empirical data, the reliability of the test method, relevance of the data, and adequacy of the data are also considered.

3 Setting Priorities for Assessment

The new process of categorising and screening of substances on DSL is expected to identify most of the candidates for assessment in the future. Under the CEPA (1999), each of the substances on the DSL must be categorised by September 2006 with

subsequent screening and full assessment, where warranted, to determine whether the substances are toxic or capable of becoming toxic as defined in the Act.

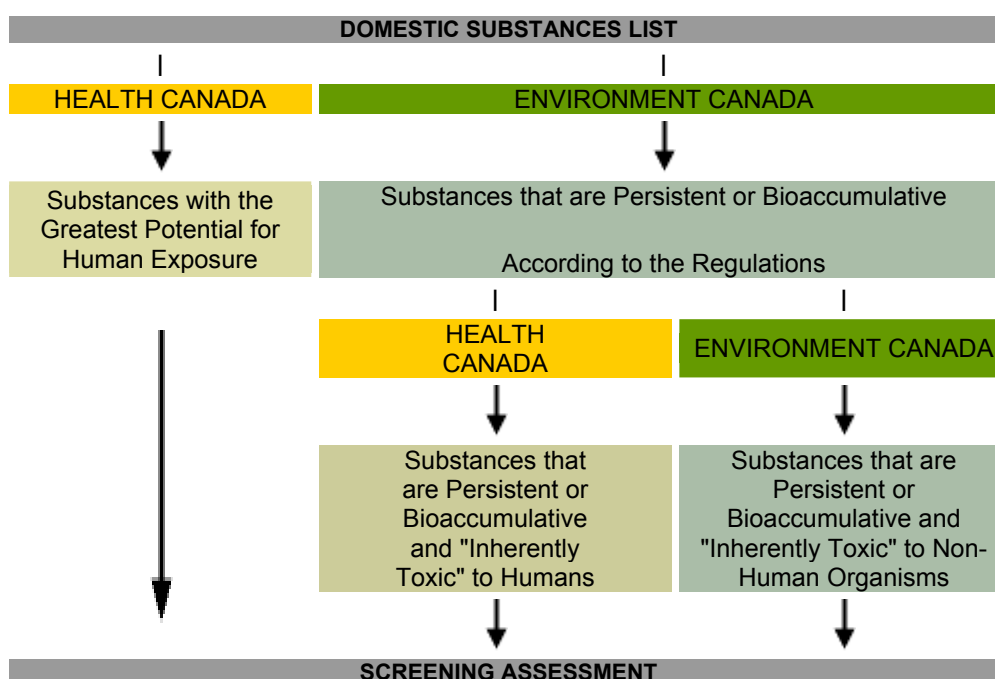
Categorisation and screening are intended for “grandfathered” substances only (these are substances notified in Canada between 1984-1986). Substances on the DSL are categorised according to the following criteria:

- Substances with greatest potential for exposure of the general population; or
- Substances that are persistent or bioaccumulative and “inherently toxic” to humans and non-human organisms.

The approaches to the categorisation of DSL will consist of iterative steps including, calls for relevant information, internal and external peer-review and public review. If a substance does not meet the above criteria, then no further action is required. A survey is conducted to determine human exposure. Data requested in the survey include volume and use codes, which will be used as a surrogate number to rank for exposure.

Endpoints on which substances will be categorised on the basis of “inherent toxicity to humans” include: carcinogenicity; genotoxicity; developmental toxicity; reproductive toxicity; repeated dose and acute toxicity. Predictions based on quantitative structure-activity relationships (QSAR), published assessments and open literature are being developed and tested. The cut-offs of persistence, bioaccumulation potential and inherent toxicity to non-human organisms were set out in the guidance document, Environment Canada’s Guidance for Categorising Organic Substances on the DSL, which was published in March 2002.

Figure 1. CATEGORIZATION OF EXISTING SUBSTANCES ON THE DOMESTIC SUBSTANCES LIST



Screening assessments are conducted on substances identified from the categorisation of DSL and those substances reviewed by other jurisdictions. Screening will involve a comparison of exposure and effect, and a very limited consideration of weight of evidence and mode of action. The screening assessment is considered as a second stage of prioritisation for more in-depth risk assessment.

Data considered for screening may include volume of production, releases resulting from its production, processing, uses and disposal, known environmental concentrations of a substance, and environmental fate on the basis of intrinsic physical/chemical properties, environmental mobility, and its persistence. There is no mandated deadline for the completion of the screening assessment.

There are three possible outcomes of the screening assessment:

- to take no further action on the substance;
- to add the substance to the PSL for a more in-depth risk assessment; or
- to recommend that the substance be added to the List of Toxic Substances in Schedule 1 of CEPA. Substances on Schedule 1 can be considered for regulatory or other controls, or added to the Virtual Elimination List.

The result of the screening assessment and a summary of the scientific considerations upon which the proposal is based, are published for public comment.

A Pilot Project has been initiated to facilitate the screening assessment phase. In the project, 123 substances that meet the categorisation criteria have been identified. Each is currently being assessed to determine whether the substance poses a risk to humans or the environment.

4 Conducting Risk Assessment

The approach to health risk assessment is described in the "Human Health Risk Assessment for Priority Substances" document (Health Canada, 1994) and for environment in the "Administrative Policy and Process for Conducting Environmental Risk Assessments for Priority Substances" (Environment Canada, 1997).

A draft report is made available for a 60-day public comment period. Following consideration of comments received, the Assessment Reports are revised as appropriate and published with final conclusions as to whether or not the substances are considered to be "toxic". The conclusion of each assessment are reported in the Canada Gazette and documented in a report that is available to the public. In addition, several documents, such as fact sheets and scientific journal articles, are published or made available electronically.

When the assessment has been completed, the substance is removed from PSL. The endpoints of the PSL assessment are: a) toxic and b) not considered to be toxic.

Toxic substances are added to the List of Toxic Substances or may be reviewed for options for controlling risk to human health and/or the environment. The designation of a substance as "toxic" does not necessarily mean that controls will be imposed. Decisions on the control of substances can only be made in a subsequent risk

management phase that includes considerations of the risks and benefits associated with the continued use of the substance, e.g. based on subsequent analysis of social, economic and scientific factors.

5 Risk Management

If a substance is found to be "toxic," the federal government works with the provinces, territories, industry, non-government organizations and other interested parties to develop a management plan to reduce or eliminate the harmful effects of the substance both on the environment and the health of Canadians. Controls may include regulations, pollution prevention plans, environmental performance agreement and guidelines and codes of practice. Options for controlling exposure to "toxic" substances are done in consultation with stakeholders.

References

Environment Canada (1997). Administrative Policy and Process for Conducting Environmental Risk Assessments for Priority Substances. Minister of Public Works and Government Services, Ottawa, Canada.

Existing Substances Branch. Available at <http://www.ec.gc.ca/substances/ese/eng/esehome.cfm>. Accessed 4 February 2003.

Existing Substances Division. Available at <http://www.hc-sc.gc.ca/hecs-sesc/exsd/index.htm>. Accessed 17 January 2003.

Health Canada (1994). Human Health Risk Assessment for Priority Substances. Minister of Public Works and Government Services, Ottawa, Canada.

Industry Coordinating Groups (ICG) for CEPA (2002). CEPA Update Conference, 9-10 October 2002, Toronto, Canada.

NEW ZEALAND EXISTING CHEMICALS LEGISLATION

Overview

New legislation for hazardous substances came into effect in New Zealand in July 2001. It is an approval-based scheme, with all hazardous substances (single entities and products) required to be listed on the ERMA New Zealand Register.

All existing substances will be assessed by the Environment Risk Management Authority New Zealand (ERMA) and assigned a classification that reflects the type and degree of its hazard. Substances determined to be hazardous according to criteria will be transferred to the Register. The regulations then provide the controls that apply as a result of that classification.

Legal Framework

Hazardous Substances and New Organisms (HSNO) Act 1996

The hazardous substances part of the *Hazardous Substances and New Organisms (HSNO) Act 1996* began on the 2nd of July 2001. This legislation repealed and amended a number of pre-existing Acts relating to dangerous goods, toxic substances, explosives, pesticides, animal remedies and others.

Existing Chemical Lists

Two databases exist at ERMA NZ and these are the Notified Toxic Substances (NOTS) database contains 217,000 entries both single substances and mixtures and the ERMA NZ Register.

The NOTS database is a 'temporary' database. It is intended that NOTS will be transferred as Approved Substances to the HSNO Act via the Transfer Process (set to end in 2006).

The ERMA NZ Register is a public database that contains all approved hazardous substances (both new and existing) with HSNO classifications and controls (labelling, packaging, exposure limits etc). Each substance will have unique identification number (HSNO Approval Number).

Transfer of Existing Chemicals

Existing substances are divided into two groups:

- *Assessed substances* - substances that have been assessed and approved under previous legislation within NZ before HSNO Act commenced; and
- *Notified toxic substances (NOTS)* - substances that have been notified (but not assessed) under section 32 of the Toxic Substances Act.

For a substance to be an existing substance, it had to be notified to ERMA NZ before the commencement of the hazardous substances side of the HSNO Act. These notifications have been entered into the NOTS database.

Information required was the identity of single substances and compositional details for all mixtures including identification of all the components and their percentages. NOTS are currently being assessed and transferred to the HSNO Act regime in a batch process. The transfer process is scheduled to be completed by 2005.

The process of 'Transfer' involves assigning classifications and controls from the HSNO Act framework to the existing substances. The definition of hazardous lies within the *HSNO Act 1996 Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001*. In the determination of 'hazardous' the following properties are considered: explosiveness, flammability, oxidising capacity, corrosiveness, toxicity and ecotoxicity.

Substances will be assessed using information from existing assessments and any new information and application of the Globally Harmonised System (GHS) for Classification and Labelling of chemicals. Assessed substances, which are determined to be hazardous, will be transferred to the ERMA NZ Register.

Once the hazard classification is complete, controls are automatically assigned. Each classification has a suite of controls designed to prevent any adverse effects caused by the intrinsic hazards of the substance. Controls set under the HSNO Act include the full lifecycle controls (packaging, labelling, disposal etc), occupational (including tolerable exposure limits; TELs) and environmental controls (including environmental exposure limits; EELs).

It is estimated that the NOTS database will be sorted from the 217,000 entries (as at June 2003) to approximately 70,000 substances. Sorting will identify non-hazardous substances; duplicate notifications; obsolete products and substances already assessed. Grouping may further reduce numbers of substances requiring transfer.

Reassessments

The HSNO Act also provides for the reassessment of substances. Reassessments are where the risks and benefits of a substance are reconsidered. Reassessment may be necessary if:

- New information about the effects of the substance becomes available; or
- Its use is changed significantly; or
- Alternative (less hazardous) substances have become available.

In addition, as the Transfer of Substances occurs, it is envisaged that a number of substances will be identified during the comparison of controls process that indicate a more detailed investigation of the substance is required.

For reassessments the public, the Minister, an organisation/association or the Chief Executive of ERMA NZ can nominate a substance for reassessment or ask for a reassessment. ERMA NZ maintains a priority list of potential reassessments. Reassessments may be paid for by sponsors (individuals, companies or organisations) or ERMA. In addition, for a reassessment to occur grounds for reassessment must be supplied to ERMA with supporting information. The timeframe and cost of reassessment is dependant on the quantity and quality of information available, issues raised and general length of review for the substance or group of substances.

The outcome of a Reassessment could range from no action required to withdrawing the existing approval on the substance therefore making its use, manufacture and importation illegal. In addition, when new information not only suggests a reassessment is justified, but indicates that allowing the existing approval to continue could be deleterious, ERMA can suspend the existing approval while the reassessment is conducted. Reassessment reports will be available to the public on the ERMA NZ Register.

No reassessments have been completed to date. One industrial chemical, methylated spirits, is currently undergoing reassessment. The reasons given for the reassessment include the inherent risks of the substance given its pattern of use, the extent to which the existing management regime is achieving effective management of the risks and the level of public concern.

As the Transfer of Substances draws to an end (approximately 2005) the reassessment work is expected to increase. Resources will be transferred from the Transfer of Substances Group to the area of Reassessments, therefore changing the focus from a hazard assessment program into a risk assessment program.

Other Programs

ERMA NZ also maintains an Incidents Database. This database holds reported incidence filed by first response agencies and newspaper reports involving hazardous substances. This information will be used to prioritise reassessments.

References

ERMA New Zealand Transfer of Substances Homepage. <http://www.ermanz.govt.nz/TransferOfSubstances/Index.htm> (Accessed 26/02/03)

ERMA New Zealand Hazardous Substances Homepage. <http://www.ermanz.govt.nz/HazardousSubstances/index.htm> (Accessed 26/02/03)

ERMA New Zealand Quick Guide to the Transfer of Substances. <http://www.ermanz.govt.nz/Publications/pdfs/ER-QG-20-2.pdf> (Accessed 26/02/03)

Hazardous Substances and New Organisms Act Homepage. <http://www.hsno.govt.nz/> (Accessed 26/02/03)

CURRENT EU SYSTEM FOR EXISTING CHEMICALS

Overview

The EU Existing Chemicals Regulation (ESR) program undertakes risk assessment and risk management activities on a priority basis. Industry is required to provide data sets which are then assessed by the regulatory authorities and risk reduction strategies implemented if required. To date, 41 risk assessments have been completed or are near completion.

Legal Framework

Council Regulation (EEC) 793/93 (Existing Substances Regulation) came into force in 1993. The Regulation was intended to complement the already existing rules governed by Council Directive 67/548/EEC for “new chemical substances.”

Inventories

An “existing” chemical substance in the EU is defined as any chemical listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). EINECS is a closed inventory of 100,195 chemical substances that were deemed to be on the European Community market between 1971 and 1981. Information includes chemical name, CAS number, EINECS number and molecular formula (if possible).

Operation

The evaluation and control of the risks posed by existing chemicals is carried out in four steps:

1 Data Collection

The Regulation was initially concerned with High Production Volume Chemicals (HPVCs) that were defined as substances imported or produced in quantities exceeding 1000 tonnes per year between 1990 and 1994. Substances imported or produced in quantities between 10 and 1000 tonnes per year are deemed Low Production Volume Substances (LPVCs). A reduced data set can be submitted for LPVCs. Data for HPVCs had to be submitted by June 1995 and by June 1998 for LPVCs.

Data is submitted using the Harmonised Electronic DataSET (HEDSET) software program, and is managed by the International Uniform Chemical Database (IUCLID). Data required in the HEDSET includes: name of the substance, produced and/or imported quantities, classification and labelling information, and reasonably foreseeable uses. However, for HPVCs data in the following areas are also to be submitted: physico-chemical properties, information related to chemical fate and pathways, and toxicological and ecotoxicological properties.

All companies that have submitted a dataset are required to update the information at least every three years. The update should include, where appropriate, new uses that substantially change the type, form, magnitude or duration of exposure of man or the environment to the substance and new data on physicochemical properties, toxicological or ecotoxicological effects.

An evaluation of the ESR program completed in May 2002 shows that for the data in IUCLID, 14% of the HPVCs have data at the level of the base-set, 65% have less than base-set and 21% have no data. This indicates that there are considerable data gaps for HPVCs.

2 Priority Setting

In order to handle the mass amount of information in IUCLID, HPVC chemicals are ranked and scored using the EU Risk rAnking Method (EURAM). EURAM calculates scores for human health and the environment using a simple exposure-effect model, though the method for calculation is complex. Environmental ranking is based on: environmental exposure, emissions, distribution (into the different environmental compartments), degradation and results in an environmental combined exposure and effects score. Human health ranking is based on: human health exposure, distribution, human health scoring (using the R phrases, the test results from genetic toxicity and reproductive toxicity, and the presence or absence of test results for repeated dose toxicity) and results in a human health combined exposure and effects score (for a comprehensive evaluation of EURAM see Hansen *et al.*, 1999).

The results of the EURAM form the basis for discussions between Member States, Industry and other NGOs on selecting substances for a Working List. Industry is encouraged to include, as a high priority, substances on the Working List in the OECD's High Production Volume Existing Chemicals Program. By doing so, HEROs (High Expected Regulatory Outcome substances) can be better identified and possible NEROs (No Expected Regulatory Outcome substances) can be removed from the working list if convincing evidence is brought forward by industry. A working list of national priorities is also developed.

Using Expert Judgement the Commission combines these two lists, in consultation with Member States, to one EU priority list. Factors taken into account when drawing up the priority list include: the effects of substance to man or the environment, the exposure of man or the environment to the substance, the lack of data on the effects of the substance on man and the environment, work already carried out in other fora, and other Community legislation and/or programmes relating to dangerous substances.

The working list is updated regularly in line with the preparation of regular priority lists. Companies must submit information on priority chemicals to IUCLID within six months of publication of the list. Since 1994, four priority lists have been published containing a cumulative total of 141 substances.

3 Risk Assessment

Member states (the rapporteurs) nominate themselves to be responsible for evaluation of chemicals on the priority list. Substances must undergo an in-depth risk assessment covering the risks posed by the priority substance, at each stage of the chemicals lifecycle, to man (workers, consumers and man exposed via the environment) and the environment (the terrestrial, aquatic, and atmospheric ecosystems and accumulation through the food chain).

The evaluation of the priority substance consists of four steps: hazard identification, dose-response assessment, exposure assessment, and risk characterisation. The risk assessment is conducted following the EU Technical Guidance Documents (TGD) on Risk Assessment for New and Existing Substances.

Exposure of humans from all relevant sources is considered, i.e., workplace, consumer products, through air, food, and drinking water. Each exposure scenario is assessed individually, and where appropriate, an overall combined exposure is also estimated.

Industry is obliged to submit to the rapporteur all relevant available information and corresponding study reports for the substance concerned. If a minimum data set is not available to start identifying the hazards the regulation allows further tests to be requested where there are causes for concern.

Draft risk assessments are distributed to other Member States for comment prior to Technical Meetings, mediated by the Commission, which attempt to reach consensus on the conclusions of the risk assessment. After adoption of the risk assessment three publications are produced:

- the comprehensive risk assessment report (as a book and on the ECB website);
- a summary thereof (as an EUR report and on the ECB website); and
- a listing of the conclusions in the Official Journal of the EC.

4 Outcomes

If a risk cannot be ruled out, then the rapporteur also has to propose a Risk Reduction strategy utilising the Technical Guidance Document on Risk Reduction. Controls can include, emission controls at industrial sites, marketing and use restrictions, or revision/introduction of occupational exposure standards or environmental quality objectives.

Other Existing Chemical Activities

Substances evaluated in the ESR program are brought before the EU Working Group on Classification and Labelling of Dangerous Substances for discussion. Substances are classified in accordance with Directive 67/548/EEC as amended by Directive 2001/59/EC for several end-points concerning physical-chemical properties, health or environmental effects.

Substances are then proposed for entry to the list of harmonised classifications of substances, Annex I to Directive 67/548/EEC, which is legally binding. These regulations also cover classification of consumer products placed on the market containing hazardous substances.

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PROPOSED EU SYSTEM FOR EXISTING CHEMICALS

Overview

The proposed EU Chemicals system will require companies to register all chemicals imported or manufactured at >1 tonne/year and provide a base set of data. The amount of data initially required will depend of the volume of the chemical imported and/or manufactured. The authorities will then evaluate higher volume chemicals and chemicals of concern. Chemicals that pose a risk may be subject to authorisation for use or restrictions. There are also requirements for downstream users to provide information on use and risk management measures.

Background

In recent years the European Commission in consultation with member states, industry, environmental and consumer NGOs as well as representatives from applicant countries has reviewed its chemical policy program. One of the major problems identified was that there is a general lack of knowledge about the properties and the uses of the majority of existing substances (which are not subject to the same testing requirements as new chemicals).

Current legislation only requires the manufacturers and importers of substances to provide information, but not the downstream users (industrial users and formulators). Thus, information on uses of substances is difficult to obtain and information about exposure arising from downstream uses is generally scarce. The current existing chemicals risk assessment process is also slow and resource intensive.

Consultations resulted in the European Commission publishing, in February 2001, a White Paper setting out the strategy for a future Policy for Chemicals. Key elements of the proposed new strategy are:

- a single regulatory framework which provides equivalent knowledge about the hazards of substances marketed before and after September 1981 (“existing” and “new” substances) and their uses, in order to provide coherence in the level of protection;
 - reversal of responsibility from authorities to industry for testing and risk assessment of chemicals;
 - promotion of innovation and competitiveness without compromising the high level of protection;
 - introduction of a tailor-made authorisation system where stringent control is ensured for the most dangerous substances; and
 - increased transparency and information about chemicals.
- The draft legislation was released for consultation in April 2003.

Proposed EU Chemicals Strategy (REACH)

The Commission proposes that existing and new substances should in the future be subject to the same procedure under a single system. The proposed system is called REACH, for the Registration, Evaluation and Authorisation of CHemicals.

REACH will be comprised of the following three elements: Registration, Evaluation and Authorisation.

1 **Registration** of basic information for all existing and new substances exceeding a production volume of 1 tonne to be submitted by companies in a central database.

Information to be submitted for registration purposes includes:

- identity of the registrant(s);
- identity of the substance;
- summary of the intrinsic properties, i.e., physicochemical properties, toxicity and ecotoxicity data requirements, based on tonnage;
- the proposed classification and labelling with justification;
- a statement as to whether or not information has been generated by testing on vertebrate animals;
- a safety assessment so called "Chemical Safety Report", containing information on risk management measures, the safety assessment that led to the choice of these measures and the information on which the assessment is based.

Information requirements are modulated by tonnage as this gives an indication of the potential for exposure.

Proposed deadlines for registration are from date the regulation comes into force:

Substances	Volume threshold*	Deadline (years)
Categories 1 and 2 carcinogens, mutagens and reproductive toxicants (CMRs)	≥ 1 tonne	3
All other substances	≥ 1000 tonnes	3
All other substances	≥ 100 tonnes	6
All other substances	≥ 1 tonne	11

(* tonnes/manufacturer or importer/year)

2 **Evaluation** of testing proposals and priority chemicals as follows:

- *Standard evaluation of Testing Proposals*: requires EU authorities to examine testing proposals for substances >100 tonnes/yr, i.e., substances which require additional testing. The aim is to avoid unnecessary testing; and
- *Priority evaluation*: provides a mechanism for a Member EU State to consider whether industry should be required to obtain more information, including to perform further testing on the basis of the aggregated tonnage (by several registrants) during registration, further testing where there are concerns, more information on uses and support for any justifications. While authorities are expected to concentrate their efforts on high volume substances or those with properties of concern, priority evaluation can also consider randomly selected substances, in order to give confidence that all registrations meet the information requirements of the registration provisions.

3 **Authorisation** of substances of very high concern before they can be used for a particular purpose, marketed as such or as a component of a product. These are substances that are either, carcinogenic, mutagenic or toxic to reproduction (CMRs classification categories 1 and 2), persistent organic pollutants (POPs) or other substances demonstrated to be of equivalent level of concern, such as endocrine disruptors.

An authorisation will be granted if the risks (health and environment) from use of a substance are adequately controlled and also if the socio-economic benefits outweigh the risk to human health and/or the environment. In particular, all of the followings will be taken into consideration:

- the risk posed by the uses of the substance;
- the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interest parties; and
- any available information on alternative substances or technologies. Substitution will be considered, however, the existence of alternatives is in itself insufficient grounds to refuse an authorisation.

Granted authorisations will have to specify to whom the authorisation is given to, the substance and authorised use as well as any conditions that apply including a specified review period. Notwithstanding any conditions of an authorisation, the holder must ensure that the level of exposure is reduced to as low as technically possible. Also, holders of an authorisation must include the authorisation number on any label for a substance so that downstream users will be able to check the conditions of authorisation available on the Agency website.

In addition, any substance may be subject to **Restrictions**. Restrictions may be either conditions for manufacture, use(s) and/or placing on the market or prohibitions of any of these activities.

Obligation For Downstream Users To Report Information

Before commencing a particular use of a registered substance, downstream users are obliged to assess the safety of their uses of substances and to take appropriate risk management measures, especially in the following cases:

- if the downstream user is using a substance in a way not covered by a manufacturer or importer's chemical safety report (CSR, including incorporating it into an article); and
- if the downstream user applies or recommends different risk management measures.

The CSR provided by the supplier may be used as the basis for their safety assessment for "intended" uses while developing the necessary elements of the assessment targeted on "unintended" uses, ie uses not covered in the supplier's safety assessment report.

The information reported by the downstream user must include the following:

- their identity and contact details;
- the identity of the substance;
- if known, the identity of the manufacturer(s) or the importer(s);
- a brief description of the use(s); and
- a proposal for additional testing on vertebrate animals, where this is considered necessary by the downstream user to complete his chemical safety assessment.

Downstream users of substances <250 kg/year have no reporting obligation. The volume threshold for reporting ensures that the obligations are proportionate with the risk. Note, however, that the obligation to perform a risk assessment still applies below this threshold as for all substances.

Downstream users may use a substance for an authorised use providing they obtain the substance from a company for whom an authorisation has been granted and that they keep within the conditions of that authorisation. These downstream users must notify the Agency within 3 months of the first supply of the substance.

Information Through the Supply Chain

All members in the supply chain must communicate information down the supply chain including:

- the safety data sheet
- the chemical safety report
- the registration number (under REACH)

- authorisation requirements
- restrictions imposed
- any other risk management information

The information must be communicated at the latest at the time of the first delivery of a substance following the entry into force of the Regulation. The information must be updated if new information or requirements, e.g., authorisation and restrictions change. Workers must be granted access to the information. Information must also be communicated up the supply chain. Information must also be supplied to distributors and given to immediate downstream users and distributors as appropriate.

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US EXISTING CHEMICALS PROGRAMS

There is no single chemical assessment scheme in the US. Instead there are several organisations that evaluate existing chemicals. This overview has focused on the activities of the US Environmental Protection Agency (US EPA), which oversees assessment schemes such as the Integrated Risk Information System (IRIS), Voluntary Children's Chemical Evaluation Program (VCCEP), Persistent, Bioaccumulative and Toxic (PBT) chemical program and High Production Volume (HPV) program, and the US Department of Health and Human Services which runs such schemes as the Agency for Toxic Substances and Disease Registry (ATSDR).

US ENVIRONMENTAL PROTECTION AGENCY

Legislation

The Office of Pollution Prevention and Toxics (OPPT) within the US EPA is responsible for managing the Existing Chemical Program under the *Toxic Substances Control Act 1976* (TSCA).

Inventory

An existing chemical is defined as a chemical in the TSCA Chemical Substances Inventory. This is not a closed inventory, as substances have been added to it. Chemicals are added to the inventory on receipt of Notice of Commencement (NOC) from manufacturers or importers.

As part of the US EPA's new chemical notification process, manufacturers and importers of a new chemical are required to notify the agency, via NOC that they have commenced introducing the chemical. All industrial chemicals in commerce between 1975 and 1977 were "grandfathered" onto the inventory. Since 1986, at four-year intervals (under the Inventory Update Rule) substances included on the inventory have to be updated with companies providing information on the production volume, plant site and site-limited status of these substances.

Existing Chemicals Program Outline and Its Outcomes

The US EPA's Chemical Information and Testing Branch (CITB) estimated that of the 70,000 chemicals on the TSCA inventory approximately 15,000 are in commerce at this time. The methodology used to determine the number of substances is not available.

The US Existing Chemicals program tends to be reactive rather than proactive. This is primarily due to the legislation, which requires a case to be made to prove that information is required. The Existing Chemical Program focuses on the HPV chemicals, and high profile chemicals such as asbestos, lead, and PCBs.

For those chemicals, which pose a problem, the EPA has a number of means by which they can reduce the risks. These include:

- limit or prohibit use;
- voluntary agreements, alone or in combination with local, regional, federal or state regulatory approaches;
- 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 specified industry groups and federal facilities on the annually updated Toxic Release Inventory, to address site-specific chemical concerns; refined risk assessment and cost/benefits analysis; and challenge industry Product Stewardship and Responsible Care goals.

Other programs managed by the EPA

Four chemical programs managed by the EPA are the Integrated Risk Information Systems (IRIS), Persistent, Bioaccumulative, Voluntary Children's Chemical Evaluation Program (VCCEP), Toxic Pollutants Strategy (PBT Strategy), and the High Production Volume (HPV) Challenge Program.

Integrated Risk Information System (IRIS)

IRIS is an electronic database developed (and maintained) by the EPA containing summaries of human health assessments.

The database contains quantitative and qualitative information on selected chemicals, including hazard identification and dose-response assessment information. Combined with specific exposure information, the data in IRIS can be used for characterisation of the public health risks of a given chemical in a given situation that can then lead to risk management decisions.

EPA develops a list of substances for IRIS assessment on an annual basis. Chemicals are selected based on one or more of the following factors:

- agency statutory, regulatory, or program implementation needs;
- the availability of new scientific information or methodology that might significantly change current IRIS information;
- interest to other levels of government or the public; and
- most of the scientific assessment work has been completed while meeting other Agency requirements, and only a modest additional effort will be needed to complete the review and documentation for IRIS.

Voluntary Children's Chemical Evaluation Program (VCCEP)

In December 2000 the EPA announced the VCCEP that is intended to provide data to enable the public to understand the potential health risks to children associated with certain chemical exposures. The VCCEP consists of 3 tiers of data that a sponsor could commit to separately.

In a pilot program, the EPA asked companies that manufacture and/or import 23 chemicals, found to be in human tissues, i.e., blood, breast milk and exhaled breath, and the environment, i.e., indoor air or drinking water as an unregulated contaminant, in various monitoring programs, to volunteer to sponsor their evaluation in Tier 1. Thirty-five companies and ten consortia responded and volunteered to sponsor 20 chemicals in the VCCEP Pilot. Information was requested on both hazard (human health effects) and exposure. For health effects, information is submitted in three tiers with the Tier 1 tests being the same as those requested in the HPV Challenge Program. Information submitted by the sponsor will be evaluated and EPA will determine whether additional higher tier information is needed.

Persistent, Bioaccumulative, and Toxic (PBT) Chemical Program

In 1998, the EPA released its agency-wide multimedia (environmental) strategy for Priority PBTs. The four main elements of the EPA's strategy are:

- develop and implement national action plans to reduce PBT pollutant, utilising all the tools available to the EPA;
- continue to screen for and select more priority PBT pollutants for action;
- prevent new PBTs from entering the marketplace; and
- measure progress of these action plans against government and national performance indicators.

The action plans mentioned above will use regulatory action where voluntary action is deemed insufficient. The action plans will consider enforcement and compliance, international coordination, place-based remediation of existing PBT contamination, research, technology development and monitoring, community and sector-based projects, the use of outreach and public advisories, and possible integration of efforts across chemicals. Action plans for 12 PBTs are in development or have been published.

High Production Volume (HPV) Challenge Program

In 1998, the US EPA announced its HPV Challenge Program. The program aims to make publicly available a complete set of baseline health and environmental effects data on HPV chemicals.

There are 2800 chemicals on the HPV Chemical List. The list was developed on data reported to EPA as part of its Inventory Update for 1990. It was updated following

the 1994 Inventory Update. HPV chemicals are defined as those manufactured in or imported into the US in amounts equal to or exceeding 1 million pounds per year.

The Program is a voluntary chemical testing effort, in which US EPA works in partnership with industry and environmental groups. Data are collected for all chemicals on the EPA's List of HPV Chemicals. Additional testing will be necessary only when the existing data are inadequate. The program is carried out in a manner consistent with the protocol for the OECD's SIDS Program. This ensures that the US is able to fulfil its international obligations and conversely allows the data from SIDS testing and assessments to be used in the HPV Challenge Program.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Agency for Toxic Substances and Disease Registry (ATSDR)

The ATSDR is an agency of the U.S. Department of Health and Human Services (DHHS), and was created to implement the health-related sections of the *Comprehensive Environmental Response, Compensation, and Liability Act* of 1980 (CERCLA). The ATSDR also has responsibilities under the *Conservation and Recovery Act* of 1976 (RCRA) as amended, and *Superfund Amendments and Reauthorisation Act* of 1986 (SARA).

Toxicological Profiles

The ATSDR produces a list of priority substances, called the CERCLA Priority List of Hazardous Substances. Each substance on this list is a candidate to become an ATSDR toxicological profile. The ranking of hazardous substances on the priority list is based on the three criteria, which are combined to result in the total score. The three criteria are:

- frequency of occurrence at National Priorities List sites: ATSDR's HazDat database is the source of data for the frequency of occurrence of substances at National Priority List hazardous waste sites or facilities;
- toxicity; and
- potential for human exposure: based on two parts, the concentration of the substance in environment media, and the exposure status of the populations. HazDat serves as the source of this information.

ATSDR toxicological profiles characterise the toxicologic and adverse health effects information for the hazardous substance. Peer reviewed by government scientists, a non-government panel and the public, these profiles identify and review the key literature for toxicologic properties. Although other significant literature is presented it is described in less detail. Data needs are also identified that are of significance for the protection of public health.

The ATSDR profiles are used to derive minimum risk levels (MRL). A MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health over specified duration of exposure. Inhalation and oral MRL are determined. Dermal MRL are currently not available.

Other products are Public Health Statements (PHSs) and ToxFAQ, which are taken from their respective ATSDR Toxicological Profiles. Each Public Health Statement serves as a summary for that complete Toxicological Profile. The PHSs provide information in a question and answer format which address the most frequently asked questions about exposure to hazardous substances found around hazardous waste sites and the effects of exposure on human health. The ATSDR ToxFAQs™ are a series of summaries about hazardous substances based on the ATSDR Toxicological Profiles

and Public Health Statements. Each fact sheet serves as a quick and easy to understand guide. Answers are provided to the most frequently asked questions (FAQs) about exposure to hazardous substances found around hazardous waste sites and the effects of exposure on human health.

Other programs managed by the US DHHS

Three chemical programs managed by the DHSS are the National Toxicology Program (NTP), Centre for the Evaluation of Risks to Human Reproduction (CERHR) and the Report on Carcinogens (RoC).

National Toxicology Program (NTP)

In 1978 the US HHS established the NTP to coordinate toxicological testing within the Department. The NTP is an interagency program, and its mission is to evaluate the agents of public health concern by developing and applying tools of modern toxicology and molecular biology.

Centre for the Evaluation of Risks to Human Reproduction (CERHR)

The NTP and the National Institute of Environmental Health Sciences established the CERHR in 1998 to provide uniform assessments of the potential for adverse effects on reproduction and development caused by agents to which humans may be exposed. Independent panels of experts from academia, industry, government research and regulatory agencies:

- evaluate the evidence that the chemical is a potential hazard to human reproduction or development;
- determine patterns of chemical use and human exposure; and
- reach a consensus on the potential human reproductive and developmental health hazard and identify needs for additional research/testing to improve the scientific certainty of a chemicals hazard or risk.

Report On Carcinogens (RoC)

The RoC, which is published biennially by the DHHS, is a scientific and public health document that identifies and discusses substances that may pose a carcinogenic hazard to human health. The document is a compilation of data on:

- carcinogenicity, genotoxicity, and mode of action listed in humans and/or in animals;
- potential for human exposure to the substance; and
- federal regulations to limit exposure.

The RoC does not present quantitative assessments of the carcinogenic risk of the substance, as these are the responsibility of other agencies.

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