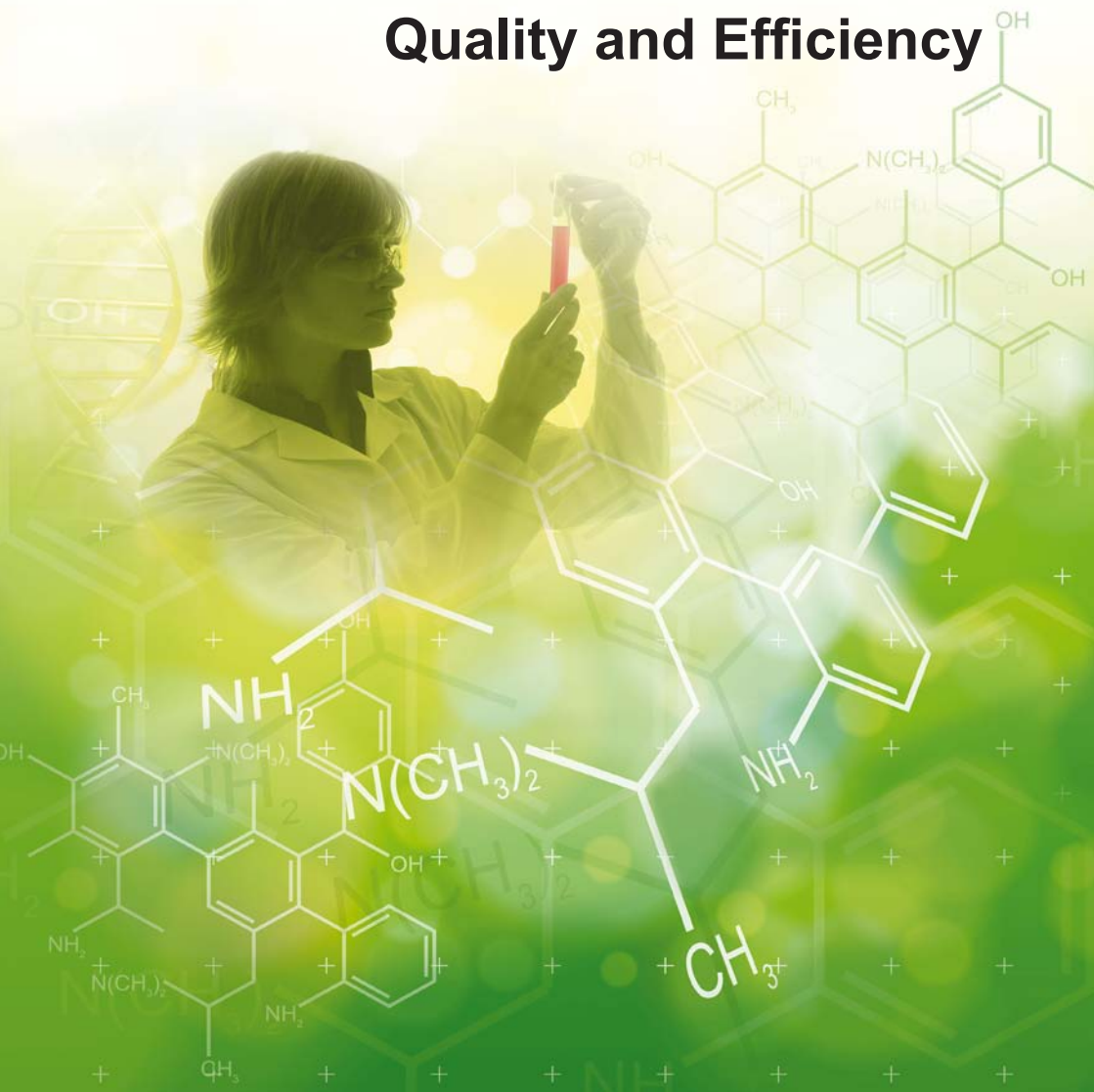


40 Years of Chemical Safety at the OECD:

Quality and Efficiency





IYC 2011
International Year of
CHEMISTRY

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CONTENTS

Foreword

The Rapid Growth of the Chemical Industry

Human Health and Environmental Safety

Crossing Borders: The Route to International Co-operation

Harmonisation: Ensuring Mutual Confidence

Making Efficiencies through MAD

Industrial Chemicals: Changing Emphasis

Minimising Barriers to Trade

Work Sharing among Countries

Installations and Chemical Safety

Emerging Technologies

The Role of Information Technology

Outreach: OECD and Chemical Safety in the Global Context

About the OECD

Additional Sources Information



Foreword

For 40 years, the OECD has been dedicated to protecting human health and the environment by promoting chemical safety worldwide.

Modern life without chemicals is inconceivable; chemicals are part of our daily lives, whether in paints, insect sprays, computers, kitchen appliances, medicines or sun screens, to name a few of the millions of items and products.

The chemicals industry is one of the world's largest, with products worth about 4 trillion US dollars (USD) annually. OECD countries currently account for around 65% of global production. Consequently, governments and industry have a major responsibility to ensure that chemicals are produced and used as safely as possible.

The OECD has been helping its member governments to develop and implement high-quality chemicals management policies and instruments. OECD countries now have science-based, rigorous and comprehensive systems for assessing and managing the risk of chemicals. But implementation of such regulatory systems can be time-consuming and expensive. Therefore, member countries work together to combine their skills and knowledge, to avoid duplication and to share the burden of testing and assessment, to minimise non-tariff distortions to trade and, ultimately, to be more efficient and effective in managing the safety of chemicals and chemical products. These OECD activities have been estimated to save governments and the chemicals industry at least EUR 150 million a year.

New challenges are ahead for the OECD. Some deal with the potential risks of new products, such as manufactured nanomaterials. The OECD is leading international efforts on the safety of these small-scale products. Another challenge is the rapid expansion of the chemicals industry in non-member

economies which increases the potential for risks and the need for global co-operation and convergence in chemicals management policies. As a result, OECD is working closely with non-members and all partners worldwide to create synergies to facilitate the sound management of chemicals.

“The OECD Mutual Acceptance of Data system is a multilateral agreement which saves governments and chemical producers at least EUR 150 million every year by allowing the results of non-clinical safety tests done on chemicals and chemical products – such as industrial chemicals and pesticides – to be shared across OECD and other countries that adhere to the system.”

Angel Gurría, OECD Secretary-General.



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The Rapid Growth of the Chemical Industry

Modern life would not be possible without the use of chemicals. Plastics and other synthetic materials, including textile fibres and building materials, surround us and are part of our everyday lives. Most consumer products are derived from chemical production, from personal care and electronic products to detergents and do-it-yourself consumables. Agrochemicals help crops resist pests and diseases and promote higher yields. Pharmaceuticals are essential in human and animal health care. The list of applications is endless.

The chemical industry is therefore a vital sector of the global economy. Currently, the products of the chemical industry are worth around 4 trillion US dollars (USD) and account for 4.3% of global Gross Domestic Product (GDP). World production of chemicals is projected to grow at a higher rate than that of world GDP, and far more than that of world population.

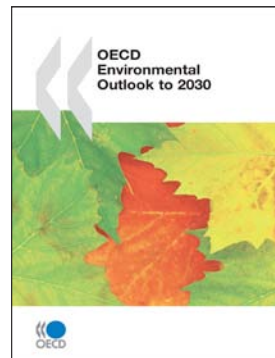
In 1970, OECD countries accounted for 83% of the world production of chemicals. The contribution of non-member economies, however, has been growing rapidly. Currently, the share of OECD countries has dropped to around 65%. The relative growth over the next two decades in non-member economies is projected to be much larger than growth in OECD countries and the effects of globalisation will be significant. In 2030, the OECD countries are projected to contribute only around 50% of world production – a considerable reduction. It is therefore important that there are infrastructures to address safety in non-member countries.

Growth statistics

The global chemicals industry continues to grow rapidly: in 1998, it was more than eight times larger in volume of output than in 1970; and since 1998 it has more than doubled. International trade in chemicals has more than quadrupled between 1980 and 2009.

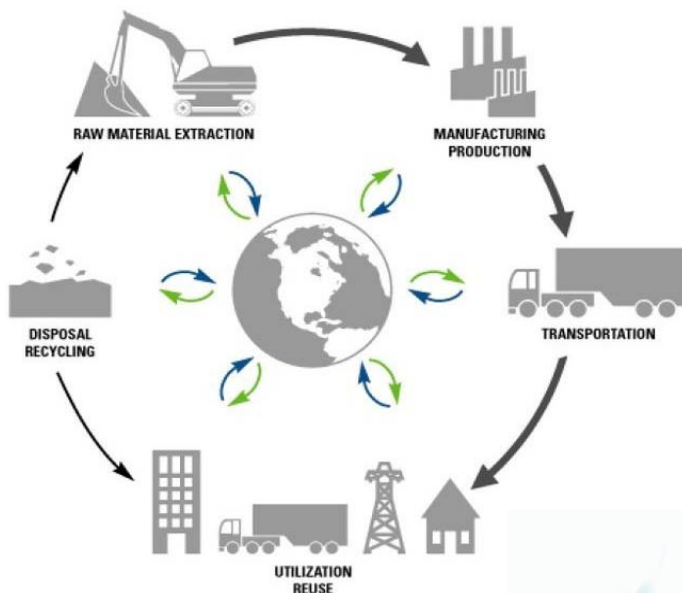
Looking to the Future: The *OECD Environmental Outlook*

This report includes a chapter on chemicals which describes expected changes in the industry to 2030 and analyses the challenges for global chemical safety resulting from these findings.



Strong **competition** among chemical companies and the complexity of production processes means that there is a drive for **innovation**. Most companies allocate on average 4 – 6% of their annual sales to research and development, although this varies among sectors. Research looks at the functions of a chemical in a particular product, as well as the safety of the chemical during its complete life cycle. This cycle includes production, transport, storage, use and disposal or recycling.

The life cycle of a chemical



Source: US Institute of Standards and Technology's Manufacturing Engineering.

Human Health and Environmental Safety

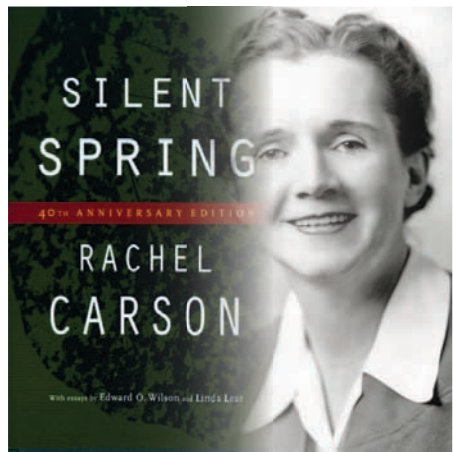
Early Issues

In the 1960s, while the chemical industry was experiencing enormous growth, it was already becoming clear that there were serious issues with regard to the safety of certain chemicals. Concern was steadily growing about their widespread distribution and the fact that their presence in the environment could be provoking profound health and environmental problems.

Most notorious and probably the most widely-publicised in the press were chlorofluorocarbons or 'CFCs' (present in aerosols and in refrigeration systems). CFCs were discovered to be the main cause of the depletion of the global ozone layer. The ozone layer protects humans from overexposure to ultra-violet (UV) radiation; and overexposure can increase the risk of developing skin cancer. Unfortunately, many other examples of damage to the environment or 'fallout' from the unrestrained use of chemicals were to follow.

Sign of the Times

In 1962, Rachel Carson published her book *Silent Spring* on pesticides, particularly on the effects of DDT on birds. Carson's work led to the ban of DDT in 1972 in the United States. The book is widely credited with helping launch the environmental movement, leading to an increased interest in the improved management of pesticides and other chemicals.



Silent Spring by Rachel Carson
(Boston: Houghton Mifflin, 2002)

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In Japan, mercury compounds released by a chemical factory accumulated in fish. When the contaminated fish were eaten by the local population, it led to the deadly Minamata disease. Similarly, cadmium releases from mining companies in the mountains accumulated in rice and those affected developed the painful itai-itai (ouch-ouch sickness) disease. Poly-chlorinated biphenyls or 'PCBs', (widely used around the world in products such as paints and electrical transformers) were also found to be accumulating in human organs and the environment, leading to toxic effects.

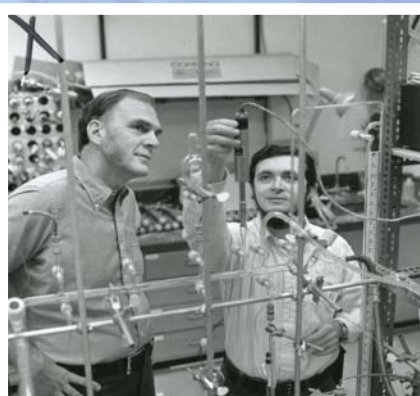
In 1976 in the Italian town of Seveso, highly toxic dioxins released following an explosion in a local chemical factory caused serious health effects in the local people and animals.

In 1978, the US city of Love Canal saw a greatly increased rate of birth defects in children. This was found to be caused by toxic releases from chemicals which had been deposited in the local waste dump by a chemical company.

Clearly, action was needed in order to manage the risks caused by specific chemicals. In response, governments began a two-pronged attack, both at the local and international level. In 1973, OECD countries agreed to a legally binding OECD Council Decision which banned the open uses of **PCBs**. They also agreed to an OECD Council Recommendation to reduce all man-made emissions of mercury to

Atmospheric chemistry - CFCs and the ozone layer

In 1974 F. Sherwood Rowland and Mario Molina published an article in the scientific journal *Nature* giving evidence of the threats CFCs present to the stratospheric ozone layer. They received, together with Paul Crutzen, the Nobel Prize for Chemistry for their work in 1995.



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Image courtesy of the UC Irvine Libraries

the environment. These were forerunning to the 1985 for the United Nations Vienna Convention for the Protection of the Ozone Layer.

Now that these safety issues began to be seriously addressed, it became clear that dealing with specific chemicals on a case-by-case basis would not be adequate to ensure chemical safety in the long term.

The Emergence of Proactive Chemical Safety Policies

Throughout the 1960s and 1970s, countries began to develop environmental policies as a priority. These were national solutions and concentrated mostly on combating local air and water pollution by applying end-of-pipe technologies (methods used to remove contaminants from waste water, air releases and solid waste).

Chemical safety policies, however, required a more systematic approach. First of all, information about the properties and possible effects of chemicals on human health and the environment was needed. At that time such information could only be obtained by carrying out tests. The toxicological tests in use were mostly studies performed using laboratory animals such as rats and mice. In addition, information was needed about acceptable chemical exposure levels for workers and consumers.

Information is also needed about concentrations of chemicals in water, air and soil, as well as the capacity of a chemical to degrade or accumulate in the environment. Such chemical testing would give an indication of the possible hazards to man and/or the environment of a particular chemical, and the level at which they occur. Hazard levels could then be compared with estimated exposure levels to determine risks. **Policy makers** could consider risk management for that chemical and, if action was called for, the necessary measures to take.

Most countries already had systems in place to manage the safety of pharmaceuticals and pesticides. This involved the industry which was introducing a new product, registering it and giving information which would allow the government to foresee any possible associated risks. It seemed logical for countries to develop similar systems to cover industrial chemicals.



Crossing Borders: The Route to International Co-operation

The impacts of chemicals such as PCBs and CFCs on the environment went beyond national borders. The chemical industry was already comprising more and more multinational companies, with chemicals being widely traded around the world. International co-operation to avoid trade barriers due to varying regulatory requirements was therefore in the interest of everyone and the logical way forward.

It was recognised that the hazard information about industrial chemicals could be used globally. Policy makers therefore started to consider international co-operation from the outset, as they began to develop their domestic systems.

In 1971 OECD member countries decided that international co-operation would best be addressed by the OECD and established a Chemicals Group. There were several reasons for this.

- OECD membership (while a relatively small number of countries) included the main chemical-producing countries.
- OECD countries had developed a certain “like-mindedness” and therefore working through the OECD would make reaching agreements relatively easy.
- Through **OECD Council Acts** there was a possibility to make the agreements on co-operation – if the members desired – legally binding (Decisions) or politically binding (Recommendations).
- The OECD had the infrastructure to bring together national experts on specialised scientific issues and provide an interface between government regulators and scientists.
- The OECD was a multidisciplinary organisation and therefore beneficial interactions with other policy areas could be readily established.

The OECD work on chemical safety accelerated significantly in 1978 when an additional “**Special Programme on the Control of Chemicals**” was established, which was funded by assessed contributions from most member countries.

As a result of this additional funding, a Chemicals Division was established in the OECD Secretariat, in the Environment Directorate (in 1992 this Division was renamed the Environment, Health and Safety Division, EHS). A committee of policy makers from governments, called the Joint Meeting, was set up to oversee the work and still meets today. The technical input provided by qualified experts from member countries forms a solid basis for the practical products which are developed through the OECD.

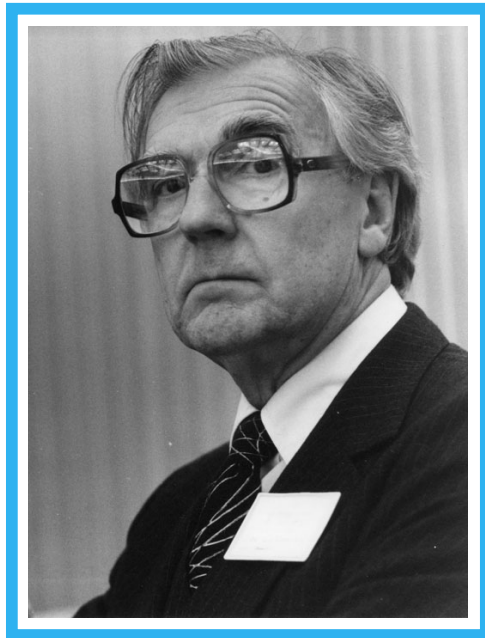
The Day-to-Day Work of the Programme

The staff of the EHS Division carries out the daily work, co-ordinating efforts with the work among experts and policy makers and with other intergovernmental organisations. The staff reviews and revises the first drafts proposed by lead countries, incorporates comments from experts in documents, organises the necessary meetings and teleconferences and works to build **consensus** on documents among member countries. The Secretariat also looks carefully at emerging issues in the chemical safety arena and brings them to the attention of countries, through proposals for work to be undertaken at the OECD.

From the beginning of the work, stakeholders beyond government have also contributed actively through their participation in meetings. Many of the methods which are developed to address safety have to be used by industry, and therefore it has been of great value to include the expertise from the chemical industry in the development of such methods. Stakeholders from organised labour, environmental NGOs and the animal welfare community have also been important in ensuring a wider acceptance of this work.

“In retrospect, the achievements of the OECD chemicals group are remarkable and no doubt the work had a strong influence on the later development of international work on chemicals control.”

R. Longren, Head of Chemical Safety, Sweden, 1992, (in *International Approaches to Chemicals Control: A Historical Overview*, Stockholm: KemI, The National Chemicals Inspectorate, Sweden).



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Harmonisation: Ensuring Mutual Confidence

Methods for the Testing of Chemicals

The starting point for work on the dual objective of safety and efficiency was to harmonise safety testing methods across OECD countries. These methods are used for the testing of properties and effects needed to make hazard assessments. To this end, a first set of **OECD Guidelines for the Testing of Chemicals** were developed and agreed among the OECD countries. This work began in the late 1970s, and new methods are being developed continually to the present day.

The **Test Guidelines** give detailed descriptions for the way in which studies need to be carried out, as well as the reporting of results. The concept was that OECD countries would encourage the chemical industry to make use of these methods when carrying out their safety testing.

Continuing work on Test Guidelines involves keeping them up-to-date in the light of scientific developments. The development of new Test Guidelines is also necessary to address new data requirements (for emerging issues such as testing for endocrine disrupting effects).

To date, almost 150 Test Guidelines have been published. The Test Guidelines cover physical chemical properties, health effects, effects on biotic systems, degradation and bioaccumulation, as well



as pesticide residue testing. This body of work is complemented by many guidance documents on specific aspects of certain Test Guidelines. In recent years the OECD has developed “Harmonised Templates” in order to achieve compatibility in the electronic reporting of test results.

Fostering Confidence through Quality Control

In order for all countries to be able to use the results of OECD Test Guidelines in their safety assessments, a second component is needed. Countries need to be confident in the quality and rigour of the laboratories that generate the test data, and in the studies they carry out. In order to achieve this, the **OECD Principles of Good Laboratory Practices (GLP)** were developed and agreed by countries at the same time as the original set of Test Guidelines.

These are a set of rules concerning the organisation and management of test facilities and the performance of safety studies. Laboratories have to follow these rules in order to guarantee the quality of their work. The standards on Good Laboratory Practice, like that of Test Guidelines, are updated as needed.

To promote consistency in the quality of laboratory testing and studies, member countries agreed to set up national GLP compliance monitoring authorities (inspectorates). These authorities inspect test facilities to ensure that they follow the GLP rules. Working together in OECD and exchanging information on inspections and study audits among countries is crucial to ensure that there is mutual confidence in the quality control of studies. This is important because the information is used as a basis for regulatory decisions related to human health and environmental protection.

What about Animal Welfare?

The OECD has always had a firm commitment to animal welfare. As such it has followed the “3R” principles of **Replacement, Reduction and Refinement** in its approach to safety testing using experimental animals. Developing test methods necessarily involves considerations related to the use of experimental animals. Since the beginning, OECD has looked for possibilities to update its existing Test Guidelines with animal welfare in mind.

For example, many new ***in vitro* Test Guidelines** have been developed, which are designed to reduce the use and suffering of experimental animals. Cutting-edge IT technology, which involves the estimation of safety data through computer models is also the subject of a substantial body of work at the OECD.



The **regulatory acceptance** of new methods, such as *in vitro* tests, is crucial in addressing the animal welfare issue. Regulators make decisions concerning risk management based to a large extent on information derived from tests in which they have confidence. The test methods, many of which use experimental animals, have a long history of application and have generated a wealth of data that has led to much experience in interpreting results. It will therefore take concerted efforts and expertise to build up the same level of confidence for alternative tests. The OECD is well-placed to support a process in which regulators and scientists work together to ensure the regulatory acceptance of these new approaches.

A **validation process** is also necessary in order to establish whether a new method is suitable for a given regulatory purpose. Such a process is based on scientifically sound principles by which the reliability, relevance and transferability of a particular method is established. The OECD has developed a set of **principles and criteria for validation of new or updated test methods**, covering both *in vivo* and *in vitro* tests. As a result, a more harmonised validation and regulatory acceptance procedure has been achieved. This all puts the OECD at the forefront of developing alternative methods which help to address the important issue of animal welfare.



Making Efficiencies through MAD

In 1980 at an OECD High Level Meeting on Chemicals, it was agreed that the Test Guidelines and GLP Principles were of such good quality that they could serve as the basis for a system of **Mutual Acceptance of Data in the Assessment of Chemicals (MAD)**.



High Level Meeting at the OECD in 1980 where Ministers and high level officials discussed chemical safety

©OECD/OCDE

Members agreed that a test carried out using the **OECD Test Guidelines** and in accordance with the **OECD GLP Principles** would be accepted by all members in registrations and notifications related to the safety of chemical products.

With the MAD system, countries still have the prerogative to set their own data requirements, and to make their own assessment of the information provided by the tests. Risk management decisions can, of course, be taken accordingly. Countries cannot, however, ask the industry in an OECD country to do a test using a different method for which an agreed OECD Test Guideline exists.

The advantages of harmonisation

The OECD has developed many *policy instruments, methods and guidance documents* which are of practical use to member countries, non-members and other stakeholders. All these products are available for free on the OECD website. Many member countries and the European Union use these products directly as part of their regulations (which integrate, for example, the Test Guidelines and GLP - the global standards for safety testing) or as a basis for their regulations. Harmonisation efforts have meant that consistency has been ensured throughout the OECD in the quality of instruments used. Scientists and regulators from different countries are much better able to compare their work based on similar standards. This also has ensured that non-tariff trade barriers are minimised.

The **Test Guidelines** and **GLP Principles** have become the standards to be used in non-clinical safety testing. In 1981 they were incorporated into a legally-binding Council Decision (the MAD Decision), of which the Test Guidelines and GLP Principles are an integral part. The fact that governments made this agreement legally binding was an important sign that countries are committed to an international approach to chemical safety.

The benefits of MAD:

- By accepting the same test results OECD-wide, unnecessary duplication of testing is avoided, thereby saving resources for industry and society as a whole.
- Non-tariff barriers to trade, which might be created by differing test methods required among countries, can be minimised.
- The use and suffering of laboratory animals needed for toxicological tests is greatly reduced, which is a significant contribution to animal welfare.
- By establishing the same quality requirements for tests throughout OECD, a level playing field for the industry is ensured.

- By using the results from the same test methods for making safety assessments, mutual understanding among countries about chemical safety assessment and resulting risk management is greatly increased. This allows countries to share work on assessing chemical safety.

Saving Money through MAD

Studies have been carried out by the OECD to quantify the annual savings made as a result of the system of Mutual Acceptance of Data. These studies used data on the costs of tests provided by countries, industry and test laboratories. The report *Cutting Costs in Chemicals Management: How OECD Helps Governments and Industry* (2010) calculates the **net savings for governments and industry resulting from the MAD system to be over EUR 150 million per year.**

Non-member economies with an important chemical industry soon became interested in joining the MAD system. In 1997 the OECD Council agreed to a Decision on the **Adherence of non-members to MAD**. This Decision defines a process by which non-members can join the system with the same rights and obligations as member countries. (This depends on the proviso that the country has a GLP inspectorate which works according to the same standards as that of countries which have joined the MAD system).

Non-Members Sign Up

Israel and Slovenia were full adherents to MAD before they became OECD members. Currently Brazil, India, Singapore and South-Africa are full adherents, which means that data developed in these countries under the conditions of MAD must be accepted for regulatory purposes by other OECD and adhering countries. Argentina, Malaysia and Thailand are “provisional adherents” and on their way to becoming full adherents.



Industrial Chemicals: Changing Emphasis

The safety aspects of new chemicals being introduced to the market were obviously a key issue that needed consideration and relevant policies. In 1982, at a second OECD High Level Meeting on Chemicals, countries decided that, before new chemicals are marketed, governments should have enough information about them in order to ensure that a meaningful assessment of hazards can be carried out. This decision signalled a policy change from a “**react and cure**” mode to “**anticipate and prevent**”.

As a result, most OECD countries began to set up **notification systems** for new chemicals. A **Minimum Pre-Marketing set of Data (MPD)** was agreed in an OECD Council Recommendation, which specifies the information needed in the notification. This data set includes detailed information regarding the toxicity of chemicals and their potential for accumulation and biodegradation in the environment.



Countries also felt that rules needed to be established concerning the availability of information on chemicals received in the notifications. Some of this information is confidential, but other information should be made available to the public. Three Council Recommendations laid down rules for this in 1983, dealing with the protection of proprietary rights to data submitted in notifications of new chemicals; the exchange of confidential data on chemicals; and a list of non-confidential data on chemicals.

Over the years, these three Council Recommendations have provided a solid basis for the policies of governments on the availability of information on all chemicals and chemical products.

How are Hazards and Risks Assessed?

Once test data has been obtained, the information must be assessed to determine if the chemical has any hazardous properties or effects. Estimations regarding likely exposures must also be made. The outcomes of both **hazard** and **exposure assessments** are then used by governments to determine the potential risk posed by a chemical. If risks are identified, these must be considered in relation to the possible benefits of the chemical concerned. A decision about the need to manage the risks of a chemical is made taking into account all this information. Any appropriate measures are then taken to limit or avoid exposure to this chemical.

OECD Guidance Documents assist countries in carrying out hazard assessments. These documents are agreed by countries and then applied as valuable tools across the OECD.

Exposure Scenario Documents are also available which describe the sources, production processes, pathways and use patterns of chemical products. Their aim is to quantify the emissions (or releases) of a chemical into water, air, soil and/or solid waste. Exposure Scenario Documents are used by countries in assessments as the basis for estimating the concentration of chemicals in the environment.

Benefits of Policy Co-ordination

The OECD brings together the major players in the field of chemical safety in the Americas, Europe and the Asia-Pacific region. It provides a *forum for discussion of policies and best practices*. This helps to create a mutual understanding of different national positions. Regulators and scientists from selected non-member countries and stakeholders beyond government are given the opportunity to build networks based on personal trust. The OECD also provides a vehicle for *co-ordination of policy action* in cases where countries would like to engage. This has shown that, if an urgent need arises, co-operation can be organised quickly.

The guidance in these documents is not legally binding. However, a large degree of **compatibility in assessment methods** has been achieved internationally, given that the basics have been agreed by experts from OECD countries.

Risk Management: Milestones made through Co-operative Action

Regarding specific hazardous chemicals, member countries took an important collective step with regard to risk management in 1987 by agreeing to a Council Decision to phase out all uses of PCBs, including those in closed systems. In 1996, Environment Ministers agreed on a Declaration on Risk Reduction for Lead. For Brominated Flame Retardants (BFRs), a Voluntary Industry Commitment was agreed at the OECD, involving risk management actions for a number of BFRs.



Work has also been undertaken on collecting **best practices** and methods to address various aspects of chemical risk management. Given the economic expertise available at the OECD, socio-economic analysis is an obvious focus. Other topics include non-regulatory initiatives, sustainable or “green” chemistry and risk communication. The OECD has currently taken the lead, working with other intergovernmental organisations, in preparing a Toolbox for Decision-Making in the management of chemicals. The Toolbox focuses on simple, cost effective solutions to be applied at national level. It aims specifically to address the needs of countries that do not yet have a well-developed chemical safety management system.



Minimising Barriers to Trade

Trade considerations have always been important in the work of the OECD and, as already demonstrated, the MAD system has been crucial in minimising **non-tariff trade barriers**. There were, however, other barriers to trade which needed to be overcome, most notably in terms of hazard classification and labelling.



The minimisation of non-tariff barriers to trade is both an objective and a result of the harmonisation work at the OECD. Differing regulatory requirements in notification and registration processes could create serious trade barriers as well as substantial delays in products reaching the market. Such problems are now to a large extent prevented, especially as non-members are also taking part in the work and using the products.

Classification and Labelling: The Long Road to Harmonisation

Hazard classification and labelling of chemicals (HCL) is a practice which has been widely used around the world to alert workers and the general public to the possible hazards when using chemicals.

The fact that different national systems existed was limiting the effective application of HCL. In addition, different systems were in place for different target groups and transport modes. When chemical products were shipped across borders these

differences either led to trade barriers because products needed to be re-labelled or to confusion because many different labels would appear on one package to cover all possible requirements.

Since 1952 efforts to achieve harmonisation in HCL had been undertaken by the UN without success. In 1992 the UN Earth Summit in Rio identified HCL harmonisation as one of the six priority action items in its agenda on the sound management of chemicals.

In 1994 the OECD launched a harmonisation initiative. OECD countries, together with a number of non-member economies, worked to harmonise the classification criteria for human health and environmental hazards. A UN expert group and the International Labour Organisation (ILO) worked on physical hazards and hazard communication. In 2001 the results of the OECD work were submitted to the UN and formed the basis for an agreement on the **Globally Harmonised System of Classification and Labelling of Chemicals (GHS)** in 2002, which aimed to achieve its global implementation as a single classification and labelling system by 2008.

The UN nominated the OECD as the focal point for developing criteria in a number of areas not yet covered in the original agreement. The OECD also works with the United Nations Institute for Training and Research (UNITAR) and ILO in a partnership project on the implementation of the GHS in developing countries, whereby OECD provides technical inputs through the other organisations.

GHS: One System for All

The Globally Harmonised System for Classification and Labelling (GHS) *includes classification criteria for: physical hazards, health hazards and environmental hazards.*

The system has many benefits, facilitating trade by promoting consistency in requirements. Companies engaged in international trade must meet these requirements for the classification and communication of all hazards through labelling.

Trade with Non-Members: OECD initiative has worldwide effects

Member countries realised early on that, while many OECD countries were rapidly developing a system for managing the risks of chemicals, other countries were not advancing at the same pace. They agreed therefore that when exporting a chemical considered hazardous from an OECD country, the importing country would be informed. This principle was laid down in 1984 in the Council Recommendation on Information Exchange Related to Export of Banned or Severely Restricted Chemicals. This initiative has had an enormous influence worldwide. It constituted the basis for UNEP (United Nations Environment Programme) and FAO (Food and Agriculture Organization of the United Nations) to develop on the **Rotterdam Convention** on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, which was adopted in 1998.



Work Sharing among Countries

Co-operation on Assessment of High Production Volume Chemicals

Once member countries had established workable systems for managing the safety of new chemicals, their attention turned to so-called "**existing chemicals**". These were the tens of thousands of chemicals already on the market before new chemicals notification schemes had been put in place in the early 1980s. Member countries agreed that the task of investigating the safety of this large number of existing chemicals was too big for one country. Co-operation among countries was then taken a step further when active work sharing in OECD was considered as the solution, and a Council Decision to this effect was adopted. This is where the MAD system was to provide an excellent starting point on which to build.

The Benefits of Work Sharing on HPV Chemicals, Pesticides and Biocides

OECD activities have facilitated *work sharing* among countries. Working together on developing methods, guidance and consensus documents rather than doing this nationally brings efficiencies. Expertise which might not exist in one country is brought into the process by others. Work sharing directly through OECD activities is being achieved with the co-operative assessments of HPV chemicals. Similarly, work sharing between countries in pesticide and biocide registrations saves considerable resources for regulatory agencies.

In order to organise the large amount of work, a number of priorities had to be set. It was agreed to deal first with **High Production Volume chemicals (HPVs)**, because in most cases these would potentially lead to the

largest exposures to man and the environment. Agreement was then reached on the information needed on the HPVs and this set of endpoints made up the **Screening Information Data Set (SIDS)**, which resembled to a large extent the MPD for new chemicals. If the information is not available then it is generated through testing, or by using non-test methods such as Quantitative Structure Activity Relationships (QSARs).

Assessments are reflected in **SIDS Initial Assessment Reports (SIAR)**, where drafts are discussed and agreed at SIDS Initial Assessment Meetings (SIAMs) with the participation of all stakeholders. A Manual for the Investigation of HPV chemicals was prepared, which addresses, among other aspects, quality control and data review. This way of working facilitates “sharing of the burden” in undertaking a task which would otherwise be too large for one country.

The chemical industry holds a great deal of test data and other information on the chemicals it produces. It was therefore obvious that it would be of great benefit to involve the chemical industry in the co-operative work; and this has been done since the beginning. The **International Council of Chemical Associations (ICCA)** made the commitment to voluntarily collect or generate information on 1000 HPV chemicals and to make draft SIDS assessments for them. These are then reviewed in SIAMs. Given the need for transparency, trade unions and environmental NGOs are also involved in the co-operative investigation.

The data and assessments are made publicly available. The OECD worked in collaboration with UNEP to ensure a global dissemination of the reports. Data and assessments are now also made available worldwide through the OECD's Global Portal to Information on Chemical Substances, the **eChemPortal**.

A number of innovations have taken place in the way the investigation of existing chemicals is currently carried out. Based on developing IT possibilities, these innovations make the assessment process faster and more efficient. Not only individual chemicals, but complete categories of chemicals with a similar molecular structure can now be assessed together.

More recently the programme was refocused to better address the changing needs of countries. In addition to assessing the hazards of chemicals, the focus areas of the new Co-operative Chemicals Assessment Programme are to develop new approaches to assessing the hazards of chemicals and avoiding duplication between countries.

HPV Assessment at a Glance

There are a total of 1377 HPVs currently under investigation in OECD, of which 914 are part of an industry effort. Of the 804 reports agreed and published, 518 are based on the industry effort.

Pesticides and Biocides: Sharing the Assessment Load

Pesticides and biocides are designed to have a specific biological effect, since they are used to eliminate unwanted organisms in crops, households or working environments. The biologically active ingredients in the products which target



organisms could have potential consequences for man and the environment. The registration requirements for pesticides and biocides therefore have a strong focus on safety.

Consequently, the dossiers for **pesticide** and **biocide registrations** are extensive and can include up to several metres of test report files. These dossiers must then be evaluated rigorously by scientists in the registering country. The same pesticides are often used in many countries, but evaluations are carried out in each country by their own institutions. Older pesticides are required to go through a re-registration process.

In the early 1990s the OECD investigated how a number of pesticides were handled by regulatory scientists in various countries, and found many similarities. The OECD therefore began to look for ways to facilitate work-sharing among countries in the (re-)registration processes, both for chemical and biological pesticides. This involved aiming for a certain level of harmonisation in registration procedures and building up mutual confidence in national evaluation practices. A detailed and uniform format was developed for use by all OECD governments in writing pesticide assessment reports. This made it easier for countries to use each others' reports. A format was also developed for use by pesticide manufacturers when submitting reports of tests carried out to identify risks. This helped reduce the industry's workload and provided a uniform standard of reports received by governments. This structure now provides a good basis for sharing the work of registrations among countries.

A database listing schedules for regulatory reviews of pesticides was prepared so that a government which is planning a review can identify if other governments have also reviewed the substance, or will review it, which facilitates sharing the work in developing assessment reports. To date, review schedules for more than 1300 active ingredients have been posted on this public database. Thanks to this work sharing, there have been substantial economies and significant savings in time and effort.



A decorative graphic at the top of the page consisting of flowing, wavy lines in shades of blue and cyan, creating a sense of movement and depth.

Installations and Chemical Safety

Chemicals are produced in factories where chemicals or pollutants can be released if an accident occurs. In addition, chemical installations can release chemicals or pollutants on a continuous basis during the manufacturing process. Both situations have been addressed at the OECD.

By working together at the OECD, countries have been able to bring experiences together effectively to develop best practices which have found practical application around the world. OECD work and products in the fields of Chemical Accident Prevention, Preparedness and Response together with Pollutant Release and Transfer Registers have been very important resources for member and non-member countries alike.

Chemical Accidents

In the 1980s there were two major accidents in which hazardous chemicals were released from production sites in Bhopal, India, and in Schweizerhalle, Switzerland. As a result, a group of OECD member countries began to work together on the safety of chemicals in factories. A key element of this work was the development of the *Guiding Principles for Chemical Accident Prevention, Preparedness and Response*. The Principles describe the responsibilities of all parties involved in the production, use and handling of hazardous chemicals. The Guiding Principles continue to be expanded and updated.

Related work includes the development of the *Safety Performance Indicators*, which are also regularly updated, and which can be used by public authorities, communities and the public, as well as by the industry. They can be applied to measure the effectiveness of activities related to the safety of factories. Further work on chemical

accidents has addressed the allocation of the payment of costs to prevent accidents in hazardous installations and to limit their consequences. This led to the 1989 Council Recommendation on the Application of the Polluter Pays Principle to Accidental Pollution.



Continuous Chemical Releases

The OECD has addressed the issue of factories responsible for the continuous emission of pollutants with a **Pollutant Release and Transfer Register (PRTR)**. This is an environmental database or inventory of potentially harmful releases to air, water and soil. As a tool the PRTR can be very effective in helping to limit such releases. Data concerning releases and transfers of pollutants, such as their type and quantity, must be reported by facilities in OECD countries. This information is then made available to the public, so that it may, first of all, compare the environmental performance of facilities and, secondly, engage in discussions with a facility about improvement of its performance if necessary. Governments provide the legal context for this system, decide for which pollutants and under which conditions facilities have to report, and facilitate the dissemination of information.

The OECD has adapted a Council Act calling for countries to set up PRTRs and developed a “Guidance Manual for Governments” to assist them. OECD has many further tools on its website in the **Global Portal to PRTR Information** to help all concerned to make best use of PRTRs. One is the **PRTR Data Centre**, which was set up to share PRTR data as widely as possible within the OECD area. Another is the **PRTR Resource Centre for Release Estimation Techniques**, which gives guidance on making estimates when measured data are not available. These techniques cover point-sources, diffuse sources and off-site transfers.



Use of PRTRs for Environmental Protection

With PRTR programmes in place, government authorities can set priorities for reducing or eliminating the most potentially damaging releases into the environment and track progress toward meeting environmental objectives. A PRTR also provides an incentive for industry to reduce its releases and transfers, because the release information is publicly available.



Emerging Technologies

Biotechnology and Biosafety

Since the 1980s many countries have been developing methods to assess the environmental risks of products derived from modern biotechnology, especially **transgenic crops**. This has also involved looking at which risk management actions would need to be taken based on these assessments. While policies among OECD countries have differed considerably with respect to management issues, there has been much less divergence with regard to the science applied in safety assessment practices. With all of the work already undertaken regarding harmonisation in the chemicals field, the OECD had considerable experience in working on the international compatibility of science-based assessment methods and in generating efficiencies through work sharing.

Therefore, when **biosafety** became an issue in the 1990s, member countries asked the OECD to tackle this in a similar way as they had for chemicals. From the beginning the work was co-ordinated closely with activities related to applications of biotechnology being undertaken in other

Addressing Emerging Technologies

New technologies such as biotechnology and nanotechnologies show much promise, but they inevitably raise safety concerns. The OECD has contributed to addressing these concerns in an important way, not only by looking into their possible applications, but also by addressing safety aspects, essential in order to obtain public acceptance of the new technologies. Through this work, the OECD has shown that it can react quickly to new technological developments. In addition, by working together on these issues, countries can make substantial efficiencies.

parts of OECD and with the UN Convention on Biological Diversity (CBD). In addition, several non-members with expertise in biotechnology became involved, including Argentina, Brazil, China, India, Russia, South Africa, Thailand and others.

The creation of the **BioTrack On-Line** information system was the first notable achievement of the biosafety work. This system gives easy access to safety information for products that have been approved for commercialisation. BioTrack is regularly updated and uses **Unique Identifiers** for biotechnology products which were developed at the OECD and are now used globally. Relevant information is transferred to the Biosafety Clearinghouse of the CBD.

Other main products of the biosafety work include the **Consensus Documents**. These documents comprise technical information for use during the regulatory assessment of products of biotechnology and are intended to be mutually recognised among OECD member countries. They focus on the biology of organisms (crops, trees or micro-organisms), on introduced novel traits, or on other aspects relevant for harmonisation purposes, such as the molecular characterisation of plants derived from modern biotechnology. They are updated regularly to take into account new knowledge. More Consensus Documents are in preparation and this type of work has now also extended to the biology of Atlantic salmon, the first genetically modified animal species to be addressed.

Safety of Novel Foods and Feeds

Following the success of biosafety work, member countries wanted the OECD to work in the same vein on the safety of **novel foods and feeds**, which are foods and feeds that include products derived through modern biotechnology. The work is undertaken in close co-ordination with the work on biosafety. The OECD already had a practical approach to safety assessment based on substantial equivalence. In this

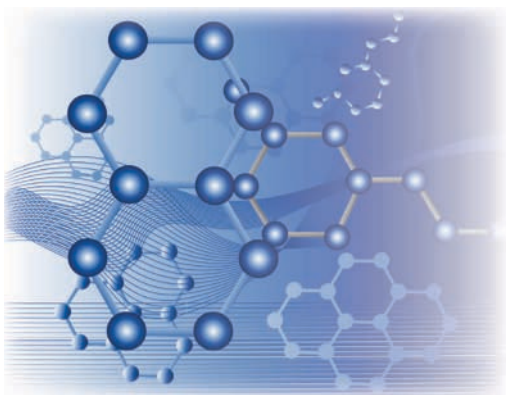


approach a comparison is made between the composition of food or feed between modified and non-modified crops.

In order to facilitate the application of substantial equivalence comparisons, information (such as the key nutrients, toxicants, anti-nutrients and allergens) is collected on the major components of genetically modified crop plants. This information is again reflected in Consensus Documents which are prepared to assist countries in the regulatory assessment of novel food and feed products and to promote harmonisation. The work is undertaken in close co-operation with the UN programmes addressing food safety.

New Technologies: New Challenges

By changing matter at the atomic and molecular scale, **nanotechnologies** are creating new chemicals with different properties by using chemicals that are already on the market. This is promising for a vast range of applications, such as medicine, electronics, strong but lightweight materials and energy production.



Nanomaterials: Potential Health and Environmental Benefits

Some of the wide range of environmental benefits nanotechnologies could bring include the detection of genetic sequences (using DNA-tagged gold nanoparticles), effective waste-water treatment (with carbon nanotube filters) and enhanced renewable energy sources from solar cells (using silicon nanocrystals), provided that safety issues are adequately addressed.

Nevertheless, **nanotechnologies**, with their new properties, raise many of the same issues as most new technologies did in the past, including concerns about the potential effects on health and the environment of the associated products.

Some products derived through nanotechnologies are already on the market. Member countries agree that innovation through nanotechnology and the use of nanomaterials offers an opportunity and potential benefits for society, but that at the same time as these new technologies are being developed safety implications must also be thoroughly investigated. In this way, when large volumes of manufactured nanomaterials reach the market, there will be a good insight into any possible risks to man and environment.

Authorities were relatively late in addressing the safety aspects of biotechnology in a way which was transparent for the public as well as in engaging in international co-operation on this at the OECD. This led to disparities among countries in their acceptance of this technology. In order to avoid this situation for nanotechnology, countries reacted quickly and worked to address from the outset the regulatory aspects of dealing with the safety aspects of nanomaterials. Work on these issues began at the OECD in 2005. Non-members and all other stakeholders are involved. The work has been well co-ordinated with activities in other parts of OECD aimed at looking into the applications which may be derived from nanotechnologies, and with work undertaken in other intergovernmental organisations and in international organisations, such as the ISO (International Organization for Standardization). The work on the safety of manufactured nanomaterials addresses many aspects of the issue. It includes, for example, a **Database on Research into the Safety of Manufactured Nanomaterials**, which can help to co-ordinate research activities.

Safety Testing for Nanomaterials: A Collaborative Effort

The **Sponsorship Programme on the Testing of Manufactured Nanomaterials** is an important current activity at the OECD. Since 2007, a number of member countries, as well as some non-member countries and other stakeholders, are pooling their expertise and funding to test the safety of 13 different types of specific nanomaterials, and tests are being performed for 61 properties.

The nanomaterials tested are well known and some are already in use, so the information being generated is of great practical value for further safety assessments. The main purpose of this work is, however, to evaluate to what extent current test methods (traditionally used to determine product safety) are adequate for testing the safety of nanomaterials. Based on the outcome of this work, it will be easier to determine if existing methods can be used, or if they need to be adapted, or new ones developed in order to evaluate appropriately the risks of manufactured nanomaterials. If new Test Guidelines need to be developed, the work will be undertaken at the OECD in co-operation with the Test Guidelines experts.

Participants in the Sponsorship Programme

In total 15 member countries, the European Commission, the Nordic Council of Ministers and industry participate as lead sponsors, co-sponsors or contributors to the sponsorship programme. Participating countries also include non-members: China (lead-sponsor for one material, contributor to five) and South Africa (lead-sponsor for one). The industry is leading the work for three nanomaterials, is co-sponsor for five and contributes to two.



The Role of Information Technology

The OECD has been quick to see the possibilities offered by information technology, applying them promptly with regard to the work on chemical safety. All **reports, databases, software packages** and **information systems** of the EHS Programme are available free of charge on the OECD website. Specific electronic products/systems to create efficiencies and promote harmonisation have been developed. Some examples are the **Harmonised Templates** for reporting test results, the uniform format for pesticide assessment reports and the format for submitting reports of the tests for use by pesticide manufacturers. Two major initiatives are the **QSAR Toolbox** and the **eChemPortal**.

The QSAR Toolbox

Using computational methods to estimate physical-chemical and biological properties of chemicals based on characteristics of the molecular structure has been a research topic since the early 1960s. In some countries such **Quantitative Structure-Activity Relationships (QSARs)** have been applied for certain aspects of the safety assessment of chemicals. If such methods could be applied more widely and internationally, this would have many benefits in terms of efficiency and animal welfare.

Information technology and chemical safety

Information technology has been applied in a major way in order to create efficiencies in making chemical safety assessments. The QSAR Toolbox is used worldwide to estimate safety data (where scientifically justified), thereby avoiding costly testing. The eChemPortal is currently the most important source throughout the world for one-step easy access to combined safety data on chemicals which are available in countries and international organisations.



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The OECD has worked since the mid-1990s on determining the international applicability of QSARs for chemical safety regulation, based on national experiences. Again, validation of the methods is crucial for achieving this. Principles for the validation of QSAR models were

agreed upon at the OECD in 2004. This meant that the OECD could start work productively on facilitating the acceptance of QSARs for regulatory uses, through the development of the OECD **QSAR Toolbox**.

The Toolbox is a software application which can be used by scientists in governments and by stakeholders to fill gaps in data needed for the assessment of chemicals. The main philosophy of the Toolbox is to group chemicals into categories where the (eco) toxicological properties are expected to follow a regular pattern because of their similarity in chemical structure. By using this **“category” approach** each chemical may not need to be tested for every single toxicological endpoint. The available test data for certain chemicals in the category could allow a credible estimation of the data for the untested chemicals by interpolation, extrapolation or other ways of reading across results. This way of working has been used successfully in recent years at the OECD through co-operation on the investigation of HPV chemicals.

eChemPortal

Information on the safety of chemicals is stored in a variety of national or international databases. It is therefore very difficult to get a good overview of all this information. This is especially important for developing countries, which do not have the means to generate much safety information themselves. In 2002, the World Summit on Sustainable Development in Johannesburg requested “the development of coherent and integrated information on chemicals” with the aim “to support developing countries in strengthening their capacity for the sound management of chemicals”. In

order to respond to this request, the OECD started in 2004 to set up a global portal to safety information on chemical substances – the **eChemPortal**.



The eChemPortal allows individuals to search for information related to the properties and effects of chemicals simultaneously within many information collections on chemical hazards and risks (information which has been prepared for government chemical review programmes at national, regional and international levels). Classification results according to the **Globally Harmonised System of Classification and Labelling of Chemicals (GHS)** are provided when available. Currently the eChemPortal links to 22 major databases of countries, the European Commission and the WHO, and to the OECD databases. Further databases will be continually added. By providing direct access to critical scientific information needed to meet public health and environmental objectives for the safe use of chemicals, the eChemPortal contributes in a major way to the global challenge of making chemical safety information more widely available and better accessible.



Outreach: OECD and Chemical Safety in the Global Context

Non-Member Involvement

Since the early 1990s selected non-members and stakeholders have been involved in the OECD work on chemical safety and related topics. A key example is the adherence of non-members to the MAD Council Decisions. However, non-members also participate very actively in other areas, such as biotechnology, food safety and nanomaterials.

Contributions to the United Nations Work

OECD outputs have been of use not only to its members and certain non-members. The United Nations has also used OECD concepts and products and has given them global application. One example of a UN instrument which found its basis in OECD work is the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*, adopted by the UN in 1998. Another example is the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), adopted in July 2003 by the UN Economic and Social Council.

The OECD has very actively contributed to the **UN International Conference on Chemicals Management (ICCM)**, which first met in 2006 in Dubai in order to set up the voluntary **Strategic Approach to International Chemicals Management – SAICM**. In early 2008 the OECD Council adopted a Resolution on the Implementation of SAICM which made OECD activities to support SAICM an integral part of the Chemicals Programme.

Accordingly, the OECD has continued to provide inputs to SAICM. It has a leadership role in two of the five emerging policy issues addressed by SAICM:

Nanotechnology and Manufactured Nanomaterials; and **Per-Fluorinated Chemicals.** The OECD is also playing a role in the emerging issue of **Chemicals in Products**



A Model for Co-ordination with other IGOs - IOMC

The OECD is an active participant in the **Inter-Organisation Programme for the Sound Management of Chemicals – IOMC**. This is a unique arrangement established through a formal Memorandum of Understanding signed by the Executive Heads of the nine participating intergovernmental organisations (IGOs).

It brings together the FAO, the ILO, the OECD, the UNDP, UNEP, UNIDO, UNITAR, the WHO and the World Bank. IOMC has the task to co-ordinate the chemical safety activities of the nine organisations. In this way duplicative activities can be avoided and gaps filled. In addition, participation of each relevant IGO in the activities of the others can be arranged as necessary, in order to ensure that the IGOs complement each other as well as possible. At large international meetings, such as the ICCM, the nine IGOs speak with one voice.

For those projects of the participating organisations which are included in an IOMC agreed list, reports can be published with the IOMC logo. This has helped to ensure a wider acceptance for the products of participating organisations than by their regular membership alone.

Continuing Co-operation

In addition to the IOMC co-ordination, there is also a direct co-operation with other IGOs on a variety of topics. The following are just a few examples:

- Continued co-operation with the UN on updating of the GHS criteria and developing new ones.
- A long-standing co-operation exists with the WHO in the field of human health hazard and risk assessment.
- Joint work with UNEP, e.g. in the areas of lead in gasoline, multimedia modelling for the transport of persistent substances and the publication and dissemination of SIDS Initial Assessment Reports.
- Co-operation for many years with the FAO has contributed to the fields of pesticides, food safety and biotechnology.
- Partnership projects with the ILO and UNITAR on the implementation of the GHS.
- The OECD and UNITAR have recently begun to work together on the SAICM emerging policy issue of nanotechnology and manufactured nanomaterials. Together they have held workshops in five UN regions to raise awareness of the topic.

IOMC



The Active Role of Stakeholders

Since the early 1990s stakeholders beyond government have participated actively in the OECD meetings concerning chemical safety and related topics. Many of the methods which have been developed and agreed must, to a large extent, be used by industry, and it has therefore made sense to involve industry expertise in the development of such methods.

This is achieved through the Business and Industry Advisory Committee to the OECD (BIAC). In the area of investigation of High Production Volume chemicals the International Council of Chemical Associations has made a major contribution. Trade unions, through the Trade Union Advisory Committee to the OECD (TUAC), take part in the work on an equal footing with industry. It is the same case with NGOs, through the European Environmental Bureau (EEB), who co-ordinate NGO input OECD-wide. The animal welfare community also makes co-ordinated input to relevant work through the International Council on Animal Protection in OECD programmes (ICAPO). While the stakeholders participate as experts in most of the meetings of the EHS Programme and contribute significantly to the quality of the products by offering advice and opinions, final decisions about policies, methods, guidance and work programmes are made by the OECD member countries alone.





About the OECD

The OECD, which traces its roots to the Marshall Plan, groups 34 member countries committed to democratic government and the market economy. It provides a forum where governments can compare and exchange policy experiences, identify good practices and promote decisions and recommendations. Dialogue, consensus, and peer review and pressure are at the very heart of the OECD.

The OECD member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Commission takes part in the work of the OECD. Chile, Estonia, Israel and Slovenia recently became members of the Organisation and OECD membership talks continue with the Russian Federation. In addition, efforts are made to enhance engagement of Brazil, China, India, Indonesia and South Africa in the OECD work programme.

The OECD is working for a stronger, cleaner and fairer world economy. The principle aim of the Organisation is to promote policies for sustainable economic growth and employment, a rising standard of living and trade liberalisation. By “sustainable economic growth” the OECD means growth that balances economic, social, and environmental considerations.

The OECD is one of the world's largest and most reliable sources of comparable statistical, economic and social data. It monitors trends, collects data, analyses and forecasts economic development, and investigates evolving patterns in a broad range of public policy areas such as agriculture, development co-operation, education, employment, taxation and trade, sciences, technology, industry and innovation in addition to environment. The OECD family of organisations also includes the International Energy Agency (IEA), the Nuclear Energy Agency (NEA), and the International Transport Forum (ITF).



Additional Sources of Information

All OECD outputs (Test Guidelines, Guidance Documents, Reports, Databases, Software etc.) concerning chemical safety and related topics are available for downloading free of charge on the OECD website: www.oecd.org/ehs/

Selected databases

OECD eChemPortal: www.oecd.org/ehs/eChemPortal

OECD's Database on Research into the Safety of Manufactured Nanomaterials: www.oecd.org/env/nanosafety/database

Global Portal to PRTR Information: www.PRTR.net

Resource Centre for PRTR Release Estimation Techniques: www.oecd.org/env/prtr/rc

Centre for PRTR Data: www.oecd.org/env/prtr/data

BioTrack Online : www.oecd.org/biotrack

Selected software

QSAR Application Toolbox: www.oecd.org/env/existingchemicals/qsar

Pov and LRTP Screening Tool: www.oecd.org/env/riskassessment

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More Information on the OECD's work on Chemicals

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