

THE ENVIRONMENT, HEALTH AND SAFETY PROGRAMME

Managing Chemicals through OECD



The Environment, Health and Safety Programme

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Preface

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

Modern life without chemicals would be inconceivable; chemicals are part of our daily life, whether in paints, insect spray, computers, kitchen appliances, medicines or sun cream.

The chemical industry is one of the world's largest, with products worth about EUR 1 800 billion annually. OECD countries account for about 75 percent of global chemical production. Their governments and the chemical industry therefore 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. These countries now have science-based, rigorous and comprehensive systems for assessing and

managing the risks of chemicals. But implementation of such regulatory systems can be time-consuming and expensive. Therefore OECD countries work together to combine their skills and knowledge, to avoid duplication of testing, to minimise non-tariff distortions to trade and ultimately to be more efficient and effective. These OECD activities have been estimated to save OECD governments and the chemical industry at least EUR 60 million a year.

New challenges are ahead for the OECD. Some deal with the emergence of new products, such as nanomaterials and their safety. The OECD is leading the recently-launched international effort on the safety of these very 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 co-operation. As a result, OECD will work more closely with non-member economies and all partners worldwide to create synergies and facilitate the sound management of chemicals.

The OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation which includes 30 member countries committed to democracy and the market economy. Its principal aim 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 brings together its member countries to discuss and assist them in developing both domestic and international policies. It analyses issues, recommends actions and provides a forum in which countries can compare their experiences, seek answers to common problems, identify good practices, work to co-ordinate policies and engage non-member economies.

Dialogue, consensus and peer review are at the very heart of OECD.

The OECD has programmes of work on:

- ▶ Economic policy
- ▶ Education
- ▶ Employment, labour and social affairs
- ▶ Energy
- ▶ Environment
- ▶ Financial, fiscal and enterprise affairs
- ▶ Food, agriculture and fisheries
- ▶ International trade
- ▶ Public governance and territorial development
- ▶ Science, technology and industry
- ▶ Statistics
- ▶ Development co-operation

The OECD also has inter-disciplinary programmes on issues such as sustainable development, strategies for innovation and regulatory reform.

- ▶ **key link:** www.oecd.org

The OECD at a Glance

- ▶ OECD share of world Gross National Income (GNI) (current USD): 78%
- ▶ OECD share of world trade: 68%
- ▶ OECD share of world population: 18%
- ▶ OECD share of world development assistance: 94%
- ▶ OECD contribution to world CO2 emissions: 49%
- ▶ OECD share of world energy production: 34%
- ▶ OECD share of world electricity consumption: 59%

Some facts

- ▶ Established: 1961
- ▶ Location: Paris, France
- ▶ Membership: 30 countries
- ▶ Secretariat staff: 2 500
- ▶ Secretary-General: Mr. Angel Gurría (Mexico)
- ▶ Publications: 250 new titles/year
- ▶ Official languages: English/French



OECD and the Environment

« A healthy economy needs a healthy environment. In line with its mission to promote sustainable economic growth and rising living standards, the OECD promotes better integration of environmental concerns into economic and sectoral policies. »

Angel Gurría, OECD Secretary-General

The OECD works on four environmental areas:

- ▶ Environmental reviews, indicators and outlooks
- ▶ Climate change and biodiversity
- ▶ Decoupling environmental pressures from economic growth
- ▶ Environment, health and safety

The OECD Environment Programme has been working on environmental policy issues for nearly 40 years. It helps countries improve their environmental performance by providing policy advice based on reliable environmental data, sharing experiences and outlooks.

Key publication

- ▶ The *OECD Environmental Outlook to 2030* provides analyses of economic and environmental trends in the coming decades and simulations of policy actions to address the key challenges. Natural resources are needed to support economic growth and without new policies, there is a risk of the environment being irreversibly damaged. The costs of inaction are high. But policy solutions to the key environmental problems – including climate change, biodiversity loss, water scarcity and the health impacts of pollution and toxic chemicals – are both available and affordable compared with the various estimates of costs of inaction, assuming cost-effective policies are put in place today. The OECD Environmental Outlook highlights a mix of policies that can address these challenges in a cost-effective way.

The OECD provides advice to both OECD and non-member economies, providing policy analysis, statistical information and recommendations to help them develop and implement environmental policies that are economically efficient and environmentally effective.

key link: www.oecd.org/env

OECD's Environment, Health and Safety Programme

The aim of the OECD is to make the world economy stronger and fairer while ensuring a better and cleaner environment. Part of the OECD work on environment deals with the safe use of industrial chemicals, nanomaterials, pesticides, biocides, and novel foods and feeds. It also addresses related areas of concern and interest, such as chemical accidents and Pollutant Release and Transfer Registers (PRTRs).

The aims of this work on Environment, Health and Safety are double: to protect health and the environment, while avoiding duplication of effort and ensuring that efficiencies are made and barriers to trade avoided.

A short history

The OECD has been working on environment, health and safety since 1971.

At first, the OECD focused on specific industrial chemicals known to pose health or environmental problems, such as mercury or CFCs (chlorofluorocarbons responsible for depleting the ozone layer). The purpose was to share information about the risks of these chemicals and to act jointly to reduce them. One of the important achievements of the early years was the 1973 OECD Council Decision to restrict the use of PCBs. This was the first time concerted international action was used to control the risks of specific chemicals.

By the mid-1970s, however, it became clear that concentrating on a few chemicals at a time would not be enough to protect human health and the environment. With thousands of new chemical products entering the global market every year, OECD countries agreed that a more comprehensive strategy was needed. The OECD therefore began developing harmonised, common tools that countries could use to test and assess the risks of new chemicals before they were manufactured and marketed. This led to a system of mutual acceptance of chemical safety data among OECD countries, a crucial step towards international harmonisation and reduction of trade barriers.

During the 1980s, the OECD launched new projects to develop methods for risk assessment, approaches to risk management, and principles for chemical accident prevention, preparedness and response. To complement the work on new chemicals, member countries began a systematic investigation of high production volume “existing” chemicals that had been placed on the market before safety evaluations for new chemicals were required. In the 1990s, new work began on the safety of pesticides, biocides and products of modern biotechnology, as well as on PRTRs. In 2006 the safety of nanomaterials was added as a new area of activity.

Working together on chemical safety

OECD governments regulate chemicals based on a system of testing chemicals to identify hazards, determining exposure and assessing risks. This system requires chemical manufacturers to carry out a battery of tests in order to determine how individual chemicals might affect human health and the environment. Governments then evaluate the test results and potential exposure in order to decide how each chemical should be managed. The advantage of this system is that it is rigorous and comprehensive. But it is very resource-intensive and time-consuming for both governments and industry.

In order to achieve its twin objectives of protecting human health and the environment and making efficiencies for governments and industry, the OECD has developed high-quality common policies and instruments (further described in the next section), that form the frameworks for co-operation and work sharing among countries. These frameworks help governments and industry achieve significant efficiencies while maintaining high levels of safety. This means saving time and money, and animals from suffering, by avoiding duplication of testing and assessment, and by minimising non-tariff barriers to trade.

The foundations of OECD work on chemicals

The OECD work draws on the common interests and values that member countries share because they often face the same domestic problems.

OECD Council Acts, which are international legally-binding instruments, may be issued to support the work more formally at a political level. Around 20 Acts deal specifically with chemical safety issues and cover areas as diverse as chemical accidents, exchange of confidential data on chemicals or the polluter-pays principle.

The following texts are important international references which take into account OECD work on chemical safety:

- ▶ Chapters 19 and 20 of the UNCED's Agenda 21 adopted in 1992 in Rio de Janeiro
- ▶ The OECD Environmental Strategy for the First Decade of the 21st Century, adopted by OECD Environmental Ministers in 2001
- ▶ Paragraph 23 of the Johannesburg Plan of Implementation, adopted at the World Summit on Sustainable Development in 2002
- ▶ Strategic Approach to International Chemicals Management, adopted by the International Conference on Chemicals Management (ICCM) in Dubai in 2006.

Those involved

OECD work on chemicals takes place on various levels.

At the OECD Headquarters in Paris, about 30 staff members carry out the daily work and co-ordinate the projects. They form an international team of experts in the various disciplines dealing with chemical safety, *e.g.* biology, chemistry, toxicology and also economics or statistics.

In member countries, OECD government representatives from various ministries or agencies (health, labour, environment, agriculture, etc.) work on OECD projects at the national level. These key policy and technical experts all meet regularly in OECD meetings, workshops or fora.

In addition, experts from industry, academia, labour, environmental and animal welfare organisations, and several non-member economies participate in projects and meetings. The participation of all these stakeholders ensures the acceptance and use of the products developed and agreed on in OECD.

The OECD also co-operates closely with other international organisations, most notably in the global effort to implement the recommendations of the UN Conference on Environment and Development (UNCED, Rio de Janeiro, 1992) and the Plan of Implementation of the World Summit on Sustainable Development (WSSD, Johannesburg, 2002). The OECD participates, along with eight other UN organisations involved in chemical safety, in the Inter-Organization Programme for the

Sound Management of Chemicals (IOMC, www.iomc.info) and in the implementation of the Strategic Approach to International Chemicals Management (SAICM, www.saicm.org) which bring together governments from more than 150 countries and many stakeholders.

How OECD addresses chemical safety issues

When the OECD addresses a new chemical safety issue, the starting point is often a survey of current practices in OECD countries. The analysis helps determine similarities and differences among national approaches, and also helps identify the areas where the OECD can add value. OECD countries may then agree on a programme of work with clear, practical objectives and specific timelines.

Countries then work together towards the common objectives. They prepare proposals, technical guidance, recommendations and policy documents that are usually reviewed in meetings. The work is undertaken with full transparency among member countries and agreed upon following a key OECD rule: consensus.

After policies are adopted, the OECD plays a facilitator role and assists countries in the implementation of the decisions by developing high-quality tools and instruments and regularly reviewing the implementation in member countries. It also reaches out to non-member economies to promote a worldwide convergence of chemical safety policies.

key link: www.oecd.org/ehs

Common policies and high-quality instruments for chemical safety

Testing: developing international testing and quality standards

The OECD Test Guidelines

Since 1981, the OECD has been developing the *OECD Guidelines for the Testing of Chemicals*, a collection of more than 120 harmonised test methods for chemicals. They cover methods for determining physical and chemical properties (such as flammability and water solubility), effects on human health and wildlife (such as short and long-term toxicity), environmental fate and pesticide residue chemistry. Test Guidelines are prepared using expertise from governments, academia, industry and other non-governmental organisations such as environmental organisations and the animal welfare community.

The OECD Test Guidelines are recognised internationally as the standards for non-clinical environment and health safety testing of chemicals and chemical products. They are an integral part of the Council Decision on the Mutual Acceptance of Data (see page 17) and are used to support chemical safety regulations in many countries. Each Test Guideline provides

sufficient detail for chemicals to be tested in the same manner in laboratories around the world.

There is an ongoing need to develop new OECD Test Guidelines, or update existing ones to meet new regulatory needs, to reflect scientific progress, to improve the cost-effectiveness of methods, and to reduce the number and suffering of test animals. Recently, the OECD has been particularly active in the development of non-animal and alternative test methods. In addition, there has been considerable activity to develop test methods to detect endocrine disrupters, i.e. chemicals that have effects on hormone systems of humans and wildlife.

Test Guidelines are available free of charge on the public website. Draft Test Guidelines and guidance documents are available on the OECD website and the public is invited to comment on these drafts.

key link: www.oecd.org/env/testguidelines

Good Laboratory Practice

The *OECD Principles of Good Laboratory Practice (GLP)* complement the OECD Test Guidelines by setting quality standards for the organisation and management of test facilities and for performing and reporting studies. The Principles are an integral part of the Council Decision on Mutual Acceptance of Data (see page 17). The GLP Principles cover all aspects of a laboratory's daily activity, such as the layout of testing and storage areas to prevent contamination, cleaning and calibration of equipment, handling of test animals, and recording and archiving of test results.

The GLP Principles thereby help ensure that studies submitted to regulatory authorities, to notify or register chemicals, are of sufficient quality and rigour and are verifiable.

Like the Test Guidelines, the GLP Principles are accepted worldwide as the quality standard for non-clinical environmental health and safety testing of chemicals. The first set of Principles was published in 1981. They were updated in 1997 to take into account new requirements and techniques such as field studies, and electronic capture and storage of data.

A 1989 OECD Council Decision requires governments to establish and maintain procedures for ensuring that test facilities have complied with the OECD GLP Principles through

inspections and study audits. It also gives governments guidance for ensuring international liaison.

Work continues to produce new documents to assist test facilities interpret and apply the GLP Principles and to provide guidance to government authorities who inspect test facilities and audit studies, in order to help them monitor compliance with the OECD GLP Principles.

The OECD works with the heads of GLP inspectorates in OECD and certain non-member economies, and they meet regularly to discuss compliance issues. This process strengthens international ties and builds inspectors' and governments' confidence in one another's monitoring systems. A continuing programme of peer reviews of national compliance monitoring procedures ensures harmonisation in the way test facilities are inspected worldwide.

To expand the use of the GLP Principles and compliance monitoring procedures on an internationally harmonised basis, the OECD also undertakes activities such as training courses for inspectors, workshops to develop the various guidance documents and outreach to non-member economies.

key link: www.oecd.org/env/glp

Assessment: increasing global assessments of chemicals

New chemicals

'New chemicals' are chemicals that companies wish to introduce to the market for the first time. Since many new chemicals will be marketed in more than one country, and each government reviews much the same information, by working together in OECD on these chemicals, governments and industry can reduce duplication of work and animal testing, speed up new product introduction to markets and reduce non-tariff trade barriers due to different systems for managing new chemicals.

The ultimate objective is the mutual acceptance of new chemicals notifications among countries. This involves working on issues such as administrative procedures or harmonised assessment templates. The OECD also provides guidance on definitions of key terms and works to harmonise countries' notification exemptions and reduced requirements for some chemical groups (such as polymers of low concern). Also, the OECD is currently piloting a parallel notification process in which companies can notify new chemicals to multiple jurisdictions and governments can share information when conducting their reviews. Finally, to reduce costs and simplify exchanges, a web-based notification system is being developed.

key link: www.oecd.org/env/newchemicals

Existing chemicals

'Existing chemicals' are the thousands of chemicals that were put on the market before new chemical notification systems were established and whose hazards have not been thoroughly evaluated by governments. This OECD activity deals with the testing and assessment of existing chemicals in general, but focuses on high production volume or "HPV" chemicals.

Industry and governments gather (or generate) a basic set of data (Screening Information Data Set or SIDS) on a chemical. Co-operative initial hazard assessments are carried out in the OECD to determine the need for further work. Governments and stakeholders then participate in a meeting where these assessments are agreed. This is an extensive undertaking as there are approximately 5 000 HPV chemicals whose production volume is greater than 1 000 tonnes per year in at least one OECD member country or in the EU region.

Work is shared among the OECD countries, with each government putting its sponsored chemicals through an agreed investigation procedure. This entails gathering the SIDS data, filling data gaps and writing a report that will ultimately become an agreed OECD hazard assessment. When testing is necessary to fill data gaps, new studies are done voluntarily by the chemical industry, which takes part in all of the work.

Today about 1 000 HPV chemicals have been assessed and several hundred more will be investigated by 2012.

Lower volume chemicals are also considered by the OECD. There are now a number of databases and information technology tools that gather information on thousands of chemicals worldwide.

Key database

- ▶ The OECD *eChemPortal*, launched in 2007, offers free public access to information on properties and hazards of chemicals. It provides direct access to critical scientific information prepared for government chemical review programmes. *eChemPortal* allows for simultaneous search of multiple international databases and provides clearly described sources and quality of data.

key links: www.oecd.org/env/existingchemicals
www.oecd.org/env/hpvchemicals/globalportal
www.oecd.org/ehs/eChemPortal

Harmonising assessment methods

In simple terms, risk to human health and the environment posed by chemicals is determined by the equation: “*hazard*” (chemical-specific properties that lead to harmful effects) x “*exposure*” to chemicals (amount of human intake or environmental concentration). The OECD assists countries in developing and harmonising methods for assessing such risk, including methodologies for hazard and exposure assessment.

The OECD develops documents on emission scenarios that give quantified estimates of chemical emissions from specific industries (for example, in the semiconductor and microelectronics manufacturing industries or in industrial and institutional laundries) or from specific uses. The scenarios describe releases of a chemical into water, air, soil and/or waste, during different life stages such as production, use and disposal.

As well as addressing the individual components of risk assessment, the OECD is working to facilitate co-operation and improve the process as a whole. For example, OECD and WHO have developed the elements of a simplified tool kit for hazard assessment and a list of harmonised terminology to help countries work together.

key link: www.oecd.org/env/riskassessment

Management: reducing chemical risks

The term “risk management” applies to the final step in regulatory oversight of chemicals: how to manage the life-cycles of chemicals so that society can take advantage of their benefits while minimising their risks.

The OECD develops tools to support the efforts of government and industry to manage and reduce risks posed by chemicals, and, when appropriate, to harmonise risk management activities on particular chemicals. The OECD also encourages exchange of information and experiences on useful policies and practical tools. For example, the OECD currently focuses on assisting countries in risk management of specific chemicals of concern for human health and the environment, such as PFCs, perfluorinated compounds, or brominated flame retardants (BFRs), chemicals applied to plastics and textiles to prevent electronics, clothes and furniture from catching fire. The OECD recognises the global nature of the problems posed by these pollutants and the need for international co-operation as major producers are in non-member economies and the products are used world wide.

key link: www.oecd.org/env/riskmanagement

Innovation: encouraging sustainable chemistry

Sustainable chemistry involves the design, manufacture and use of efficient, effective, safe and more environmentally-benign chemical products and processes. This implies maximising resource efficiency through activities such as energy and non-renewable resource conservation, risk minimisation, pollution prevention, minimisation of waste at all stages of a product's life-cycle, and the development of products that are durable and can be reused and recycled.

The OECD promotes the exchange of information related to research and development in order to help governments support the development of inherently safer chemical products. The OECD has also developed a new Internet Platform for information exchange and review of new developments and incentives for sustainable chemistry.

In the future, the OECD will analyse the success of various policies for the promotion of safer chemical products and develop guidance for governments. The OECD is also looking at the role of environmental legislation and innovation in promoting sustainable chemistry. This work contributes to OECD's Innovation Strategy (www.oecd.org/innovation/strategy).

Communication: harmonising the classification of hazardous chemicals

The OECD has been a lead actor in the development of the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, a new internationally agreed system which will ensure that the dangers presented by chemicals are clearly communicated.

The GHS includes:

- ▶ harmonised criteria for classifying substances and mixtures according to their health, environmental and physical hazards;
- ▶ harmonised hazard communication elements for labelling (symbols, signal words, risk statements) and Safety Data Sheets.

It does not include lists of classified chemicals.

In the OECD, harmonised criteria for classification were developed as the basis for a GHS. Chemicals are labelled according to the requirements of their category.

The GHS applies to all hazardous chemicals and mixtures, including pesticides. It is used mostly by chemicals producers and importers. Target audiences are consumers, workers and emergency responders.

The GHS provides a basis for harmonisation of rules and regulations on chemicals at national, regional and worldwide level, and is an important factor for trade facilitation.

The GHS was adopted by the UN and published in 2003 (and is periodically updated). The 2002 World Summit on Sustainable Development in Johannesburg encouraged all countries to implement the GHS as soon as possible, with a view to having the system fully operational in 2008. A number of countries have implemented the GHS. The UN Sub-Committee of Experts on GHS has the primary responsibility for the maintenance and implementation of the system. The OECD is the UN focal point for the work related to human health and environmental hazards.

In addition, the OECD works with ILO and UNITAR to help developing countries that lack the infrastructure to implement the GHS. The goal is to help them build their capacity to manage chemicals and, in particular, to protect workers, consumers and the environment.

key link: www.oecd.org/env/classify

New methodologies: working towards regulatory acceptance

The OECD promotes the use and regulatory acceptance of various promising new instruments for gathering information on the safety of chemicals and for making best use of scientific advances in chemicals management. With these tools, it becomes possible to obtain more safety information and maintain quality while reducing costs, time and animal testing.

(Q)SARs

(Quantitative) Structure-Activity Relationships [(Q)SARs] are methods involving computer simulations which estimate properties of a chemical from its molecular structure. While the use of (Q)SARs in chemicals regulation is currently relatively limited, the OECD is looking at how these approaches could be implemented in member countries.

Key software

- ▶ The *QSAR Application Toolbox* is to be used by governments, chemical industry and other stakeholders in filling gaps in (eco)toxicity data needed for assessing the hazards of chemicals. It incorporates information and tools from various sources into a logical workflow. Grouping chemicals into chemical categories is crucial to this workflow.

key link: www.oecd.org/env/existingchemicals/qsar

Non-animal testing

The OECD is committed to reducing or avoiding animal suffering and limiting the number of test animals used. Many of the current OECD Test Guidelines are based on tests conducted on animals, with clear guidance to minimise pain and suffering in the animals during testing. The OECD is actively working towards the development of methods to replace animal tests where possible, or to refine existing tests to reduce the number of animals used and minimise suffering. A number of OECD Test Guidelines are already based on non-animal tests, including skin corrosion, phototoxicity and skin absorption. As new tests which meet the regulatory safety requirements of the OECD member countries are developed and validated, it is expected that the range of non-animal Test Guidelines available will increase.

Toxicogenomics and molecular screening

Toxicogenomics is the study of the response of a genome to hazardous substances and uses “omics” technologies such as genomic-scale mRNA expression (transcriptomics), cell and tissue-wide protein expression (proteomics), and metabolite profiling (metabolomics), in combination with bioinformatic methods and conventional toxicology.

To date the use of this emerging science has been limited to exploratory research. The OECD has therefore decided to survey the availability of omics tools. The report of the second survey was published in 2009.

The Molecular Screening project is based on the US ToxCasr Program. It consists in selecting a number of chemicals and evaluating them in a series of molecular screening assays. The aim is to establish a strategy for rationally and economically prioritising chemicals for further evaluation.

Common (electronic) formats

The formats used by companies and governments to report summary results of chemical tests vary widely, making it difficult for governments to share this information. As a result, for every Test Guideline, the OECD has developed a corresponding “template” which is a guide for structuring data for reporting summaries of the results from those tests. OECD has also developed common electronic data export/import formats for each template to facilitate the exchange of such information across computer systems.

key link: www.oecd.org/ehs/templates



OECD and the rest of the world

Convergence of policies and tools for managing chemicals in the OECD and non-member economies

The OECD promotes convergence of policies among member countries in order to create a level playing field in areas where information sharing, understanding and confidence, if not harmonisation, are of great mutual benefit. OECD also addresses the new challenges of globalisation by making its material accessible and useful to non-member economies which are establishing their own chemicals management framework.

For about four decades the role of OECD has been to assist member countries to meet the aims of developing and implementing policies and high-quality instruments to protect human health and the environment, and to make their chemicals management systems and processes as efficient as possible. While trying to eliminate duplication of work as far as possible and avoid non-tariff barriers to trade, emphasis has been on developing frameworks for work sharing in gathering and assessing information on the potential risks of chemicals and chemical production. The MAD system is a foundation for harmonisation of chemicals management policies throughout OECD, and their implementation.

MAD: Mutual Acceptance of Data

Key legal decision

- ▶ The Council Decision on MAD “decides that the data generated in the testing of chemicals in an OECD member country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other member countries for purposes of assessment and other uses relating to the protection of man and the environment.”

The 1981 OECD Council Decision on the *Mutual Acceptance of Data (MAD)* is the cornerstone for the system of standards represented by the OECD Test Guidelines and GLP Principles (see previous sections for details of these OECD instruments). This Council Decision requires OECD governments to accept test data developed for regulatory purposes in another country if these data were developed in accordance with the Test Guidelines and GLP Principles. The 1989 Council Decision on Compliance with GLP ensures that compliance with the latter is monitored by countries in a harmonised and internationally acceptable manner.

Together, these Council Decisions mean that new non-clinical environment, health and safety data for notification or registration of a chemical have to be developed only once by industry and can then be used for regulatory purposes across OECD countries and non-OECD countries which adhere to the system.

MAD increases the efficiency and effectiveness of chemical notification and registration procedures for both governments and industry. It ensures high-quality test data and a common basis of information for assessing risks to human health and the environment, thereby facilitating government evaluations and work sharing. MAD also helps limit the number of animals used in testing and their suffering, and saves time and money for industry by avoiding duplicative testing. The combined net savings for governments and industry are estimated to be at least EUR 60 million a year.

Assisting non-OECD economies to manage chemicals

Working with non-member economies is increasingly important for OECD.

While production in OECD countries still accounts for almost 75% of the world total, production in non-OECD economies (both domestic companies and multinational firms), particularly in Brazil, Russia, India and China, is rapidly increasing, and

the recent OECD *Environmental Outlook* projects that OECD's share of world production will drop to 63% by 2030. Non-OECD economies too will need to address the risks of exposure of humans and the environment during production and use of chemicals and chemical products. As non-member economies play an ever-increasing role in the manufacturing of chemicals, convergence of their chemicals safety frameworks with those of OECD countries will have economic, environmental and health advantages for all concerned.

OECD countries are working with non-member economies to establish similar chemicals management systems which will ensure that products imported into OECD do not contain hazardous chemicals which have not been subject to a safety evaluation. It is also in the interest of both OECD countries and non-member economies that OECD policies and instruments are used. This will help protect the environment and human health from the risks of chemicals, limit the time it takes for chemicals to reach the market, minimise duplication and resources needed for testing and assessment, and avoid trade barriers.

In this context, in 2008, the OECD Council adopted a Resolution on the Implementation of the UN Strategic Approach to International Chemicals Management (SAICM). This calls for countries to work together in OECD to ensure that, as chemicals management programmes are established or upgraded, OECD products will be accessible, relevant and useful to non-

members in order to assist them in developing their capacities for managing chemicals.

A key international strategy on chemical safety

- ▶ The 2006 UN Strategic Approach to International Chemicals Management (SAICM) is having an impact on national policies in OECD and non-member economies alike. As a result, increased efforts related to chemicals management are required in all countries. The instruments already developed in the OECD are being made as accessible and useful to non-members as possible. Through the development, implementation and distribution of these tools, countries, both members and non-members, are working together in OECD to ensure that the chemical safety policies of OECD and non-members converge in view of global regulatory efficiency and related trade issues.

Participation of non-member economies

The OECD work on Environment, Health and Safety already involves many non-OECD economies. For example, the MAD system has been open to non-OECD economies since 1997, allowing them to participate with the same rights and obligations as member countries once they have implemented the two Council Decisions mentioned above. South Africa was the first to participate as a full adherent to the Council Decisions

(2003), followed by Slovenia (2004) and Israel (2005). India, Argentina, Brazil, Malaysia and Singapore are now provisional adherents to the system; more countries (*e.g.* China, Russia and Thailand) are expected to join MAD in the coming years.

Another example is the global issue of the products of modern biotechnology. The need to meet environmental and health safety standards goes beyond OECD member countries. For this reason, the OECD biosafety work now involves key non-member economies (*e.g.* Argentina, Brazil, Cameroon, Chile, China, Egypt, India, Latvia, the Philippines, Russia, Slovenia, South Africa and Thailand). The OECD also benefits from input provided by the UN Convention on Biological Diversity, FAO (UN Food and Agriculture Organization), WHO (UN World Health Organization) and industry representatives.



Focus: Safety of manufactured nanomaterials

OECD work continues to evolve in response to emerging issues such as the safety of *manufactured nanomaterials*.

What are nanomaterials?

“Nano” comes from the Greek word for “dwarf”. It is used in the metric measurement system to refer to a “billionth” – so a nanometre (nm) is a billionth of a metre.

Nanotechnology is the engineering of materials at the atomic or molecular level to produce nanomaterials. Nanotechnologists normally work with nanomaterials which have dimensions typically within the range of 1-100nm. A nanometer is about 1/50,000th the width of a human hair and a sheet of office paper is about 100,000nm thick.

Nanomaterials are not specific to one industrial sector but appear in many, such as electronics and computing, the chemicals industry, environmental technologies, medicine, cosmetics, foods, the military and the energy sector. Nanomaterials are already used in a number of commercial applications ranging from lotions, creams and shampoos in the cosmetics sector to self-cleaning glass.

Different properties and new safety issues

Nanotechnology exploits the novel attributes of materials when their atoms and molecules are carefully manipulated. But different technological properties also mean that nanomaterials are different from conventional substances with respect to human health and environmental safety. The question is whether these properties raise new concerns.

The traditional testing and assessment methods used to determine the safety of traditional chemicals are not necessarily fully applicable to nanomaterials. There is a need for a responsible and co-ordinated approach to ensure that potential safety issues are being addressed at the same time as the technology is developing.

In 2006, the OECD agreed to work jointly on the implications of the manufacture and use of nanomaterials for the safety of human health and the environment.

Eight areas of priority for the OECD

OECD aims to promote international co-operation in human health and environmental safety aspects of manufactured

nanomaterials (MNs) in order to assist in the development of a rigorous system for safety evaluation of nanomaterials.

The OECD is addressing eight specific areas. It is

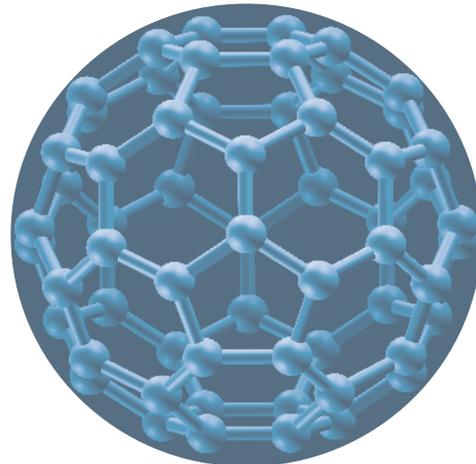
- ▶ Creating a database on safety research;
- ▶ Formulating research strategies on MNs to address research “hot spots” and “gaps”;
- ▶ Testing a representative set of MNs;
- ▶ Developing testing methods for MNs (or adapting conventional ones, such as the OECD Test Guidelines);
- ▶ Promoting co-operation on voluntary schemes and regulatory programmes;
- ▶ Facilitating international co-operation on risk assessment;
- ▶ Evaluating the potential of alternative methods, such as *in vitro* tests, in nanotoxicology; and
- ▶ Developing guidance on exposure measurement and exposure mitigation.

Currently, the OECD is focusing on the testing of an agreed representative set of 14 manufactured nanomaterials, such as carbon nanotubes or silver or iron nanoparticles, using appropriate test methods. The aim is to understand the types of information on intrinsic properties that may be relevant to exposure and the effects assessment of MNs. As an important first step, OECD members and industry are therefore sharing the task of testing the agreed set of MNs.

The OECD ensures that the project on nanomaterials builds on existing OECD activities on chemical safety such as the OECD Test Guidelines and the on-going work on chemical accidents and on pesticides.

There is still much to learn to fully understand how to work safely with some nanomaterials. However, if countries continue to work together in the OECD, as they have started to do, this should ensure that as the economic opportunities of the technology advance, the human health and environmental safety aspects are addressed appropriately and efficiently at the same time.

key link: www.oecd.org/env/nanosafety



Co-operation in other areas of environment, health and safety

Improving the safety of pesticides and biocides

OECD's activities focus on both *pesticides* (chemical or biological products to protect plants, used in agriculture) and *biocides* (a diverse group of products including disinfectants used in homes and hospitals, products to preserve wood, products to prevent fouling on boats and products to control insects, mice or rats in homes and industries).

Agricultural pesticides

The OECD helps governments to co-operate in assessing and reducing the risks of agricultural pesticides by sharing the work of pesticide registration and developing tools to monitor and minimise risk to health and the environment.

To assist countries to co-operate in the review of pesticides, the OECD has created internationally agreed formats for the two main documents used in registering agricultural chemical pesticides: the “dossiers” of pesticide test data submitted by industry, and the “monographs” containing OECD governments’ evaluation of the test data.

These agreed formats improve the quality and consistency of pesticide reviews. They also make it easier for OECD countries to work together and reduce the workload for industry by making it possible to submit similar data packages to different countries.

In 2004, OECD governments agreed that by 2014 they would routinely:

- ▶ accept submissions prepared by industry in the OECD dossier format
- ▶ exchange and use reviews of the data prepared in the OECD monograph format to support independent risk assessments and regulatory decisions
- ▶ generate just one review report (or monograph) for each new pesticide that could be used across all OECD countries, where feasible.

In parallel, the OECD is developing electronic tools to facilitate exchanges of pesticide data and promote work sharing among countries.

The OECD has developed similar dossier and monograph guidance for the registration of microbials and pheromones/semiochemicals which are used as biological pesticides.

The OECD also promotes pesticide risk reduction by facilitating information exchange, proposing strategic options for risk reduction and promoting international awareness for certain risk reduction tools and measures. It has reviewed and tested several pesticide risk indicators that can be used to measure progress in risk reduction. To date, the OECD has addressed several issues related to pesticide risk reduction, including better user compliance, container management and labelling, better training and education programmes, and reducing pesticide spray drift.

Recently, the OECD has started to deal with the issue of minor uses (small-scale pesticide use such as pest control in a minor crop or a small pest problem in a major crop). This new project should facilitate mechanisms that enable international co-operation on minor use issues, including work-sharing, technical guidance on the preparation of data submissions and minimising barriers to approval of safe products for minor uses.

key link: www.oecd.org/env/pesticides

Biocides

As with agricultural pesticides, the OECD has been helping governments to increase efficiency in the registration of biocides. Facilitating the sharing of biocide data and reviews among governments has been a primary objective.

In addition, the OECD carries out a number of activities related to biocides management such as harmonising the testing of product efficacy to ensure the validity of label claims and producing “emission scenarios” that estimate how much of certain biocides will get into the environment, how long they will last and their effects. Work is also ongoing on testing the efficacy of biocide products – such as those used to disinfect surfaces or swimming pool water – against microorganisms.

key link: www.oecd.org/env/biocides



Preventing and responding to chemical accidents

For two decades OECD has been concerned with chemical accidents, a subject that concerns everyone who works in a chemical plant, lives near one or is involved in emergency response. The OECD has been helping countries not only to prevent chemical accidents but also to respond in an appropriate manner if one occurs.

The most important achievement of the OECD work has been the publication of two policy guidance documents: the *Guiding Principles for Chemical Accident Prevention, Preparedness and Response* and the *Guidance on Safety Performance Indicators*. They are intended for public authorities, industry (including management and labour) and the general public.

► The OECD *Guiding Principles* describe the responsibilities of all parties involved in the production, use and handling of hazardous chemicals. They address all aspects of preventing and managing chemical accidents, from the planning and construction of installations to operation and maintenance, training and education, community awareness, and emergency planning and response. The *Guiding Principles* have been translated into several languages. An Internet version allows the user to navigate the document and search by keyword and topic.

► The *Safety Performance Indicators* serve to help stakeholders in determining whether their implementation of the *OECD Guiding Principles* has led to improved safety. It gives them tools with which they can design their own safety performance indicators programme. A navigable web version allows the user to search the document and create a customised indicator programme.

The OECD also organises international workshops to identify and recommend best practices for specific issues of concern, such as *inter alia*, environmental consequences of chemical accidents, training of engineers, human factors in chemical accidents, cost of accidents versus cost of prevention, or lessons learned from chemical accidents and incidents.

The OECD helps countries share information and learn from each other's experiences. Current activities include management of the joint OECD-EU accident reporting scheme, the collection and analysis of data on chemical accidents, including economic data, and the development of scientific methods to establish acute exposure levels.

key link: www.oecd.org/env/accidents

Communicating through Pollutant Release and Transfer Registers

A key tool that governments use to provide data to the public about the releases and transfers of potentially hazardous chemicals and other pollutants is the Pollutant Release and Transfer Register (PRTR).

A PRTR is a database or inventory of potentially harmful chemicals and/or pollutants released to air, water and soil, and transferred off-site for treatment. A PRTR, which is publically available, brings together information about which pollutants are being released, where, how much and by whom.

PRTRs are an invaluable resource for tracking pollution trends in industries, identifying “hot spots” and setting priorities for environmental protection. A variety of stakeholders use PRTR data on a regular basis. PRTRs can provide valuable information and data for industries who want to improve chemical management and environmental performance, for government regulators, for citizens living near industrial facilities who want to know about potential exposure, for environmental justice movements, for the investment community to move towards sustainable investments and for research purposes in academia.

OECD has developed a guidance manual to assist countries to set up PRTRs. Since 1996, when the OECD started to encourage the development of PRTRs, the number of OECD countries with operating PRTR systems has more than doubled. By the end of 2009 almost all OECD countries should have an operational PRTR in place, but also many non-member economies have already taken concrete steps towards establishing a PRTR.

The OECD activity on PRTRs consists of helping countries to develop and implement their PRTRs. OECD experts currently work to improve release estimation techniques, to provide guidance on the quality aspects of PRTR data production and on tracking releases from various sources, such as products and SMEs (small and medium-sized enterprises). They also encourage the sharing of PRTR data among countries.

Finally, the OECD is developing a geographic information system (GIS) for the global portal to PRTR information (www.prtr.net).

key link: www.oecd.org/env/prtr

Reaching consensus on biosafety and food safety

The OECD has two programmes related to safety of the products of modern biotechnology: *Harmonisation of Regulatory Oversight in Biotechnology*, dealing with environmental safety, and *Safety of Novel Foods and Feeds*, addressing human food and animal feed safety. They both focus on one of the most challenging issues that OECD countries have faced in recent years: safety of products derived from modern biotechnology. Genetically modified crops are increasingly cultivated world wide and human food and animal feeds derived from such crops are being marketed. Such products are rigorously assessed by governments to ensure that they meet high-level safety standards.

The main focus of the OECD work is to ensure that the types of information used in risk/safety assessment, as well as the methods used to collect such information, are as similar as possible. Both programmes identify a common base of scientific information that may be useful in assessing the safety of specific products with respect to human food and animal feed as well as the environment.

The main OECD publications are *consensus documents*, compilations of key information on major crops, which member countries believe are relevant to risk and safety assessment. More than 60 consensus documents are now available.

- ▶ *An emerging issue*: a consensus document on the biology of Atlantic Salmon is under development. This is the first time the OECD has addressed a genetically modified animal species. This document will use a similar safety approach as has been used for biology documents of plants.

Finally, the OECD also looks at similarities and differences in regulatory frameworks among countries. This helps reduce misunderstandings which could lead to trade disputes.

Key database

- ▶ *BioTrack Online* provides ready access to food/feed/environment safety information for those products that have been approved for commercialisation in member countries. It also makes the OECD *consensus documents* available and allows access to a database of field trials of transgenic organisms.

key link: www.oecd.org/biotrack

Publications on the Internet

All outputs of the OECD Environment, Health and Safety Programme are available for downloading free of charge on the EHS web page at www.oecd.org/ehs/publications. Hard copies are also available on request on a limited basis.

All environment, health and safety publications are free. All publications below are available in English; some have been translated into other languages.

There are series of publications in the following areas:

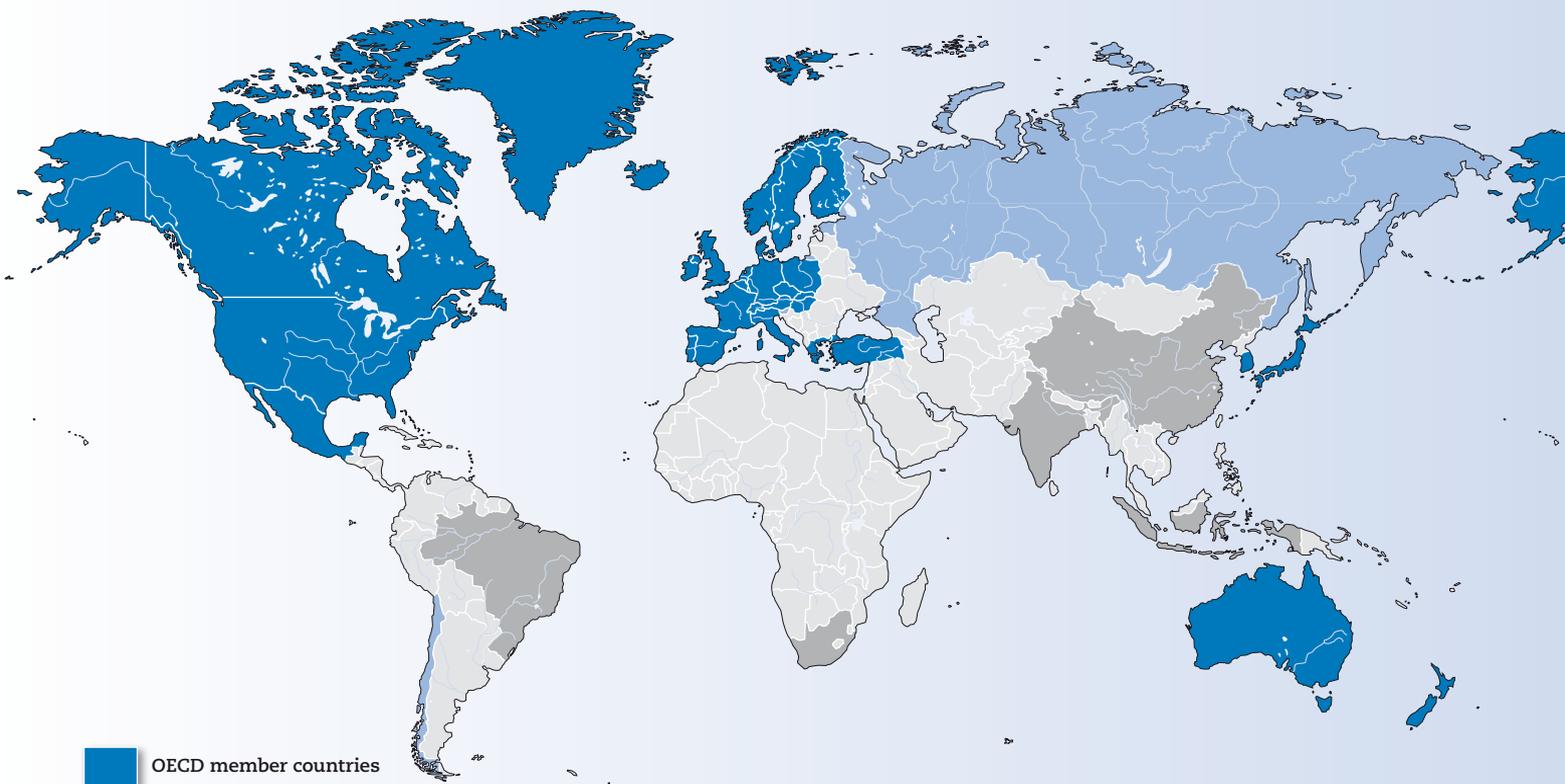
- ▶ Testing and Assessment
- ▶ Good Laboratory Practice and Compliance Monitoring
- ▶ Emission Scenario Documents
- ▶ Risk Management
- ▶ Safety of Manufactured Nanomaterials
- ▶ Pesticides
- ▶ Biocides
- ▶ Chemical Accidents
- ▶ Pollutant Release and Transfer Registers
- ▶ Harmonisation of Regulatory Oversight in Biotechnology
- ▶ Safety of Novel Foods and Feeds

Selected databases

- ▶ The OECD eChemPortal (www.oecd.org/ehs/eChemPortal), launched in 2007, offers free public access to information on properties and hazards of chemicals. It provides direct access to critical scientific information prepared for government chemical review programmes. eChemPortal allows for simultaneous search of multiple international databases and provides clearly described sources and quality of data.
- ▶ OECD's Database on Research into the Safety of Manufactured Nanomaterials (www.oecd.org/env/nanosafety/database) includes information on research projects that address safety issues of manufactured nanomaterials. It holds details of completed, current and planned research projects on safety, which are to be updated and managed electronically by delegations to the OECD Working Party on Manufactured Nanomaterials.
- ▶ The Global Portal to PRTR Information (www.PRTR.net), launched in 2007, provides free access to PRTR information and activities from countries and organisations around the world, such as the Resource Centre for PRTR Release Estimation Techniques providing information on available release estimation techniques, overarching documents and general information (www.oecd.org/env/prtr/rc) and the Centre for PRTR Data presenting national PRTR data at one Internet location (www.oecd.org/env/prtr/data).
- ▶ BioTrack Online (www.oecd.org/biotrack) provides ready access to food/feed/environment safety information for those products that have been approved for commercialisation in member countries. It also makes the OECD *consensus documents* available and allows access to a database of field trials of transgenic organisms.

Selected software

- ▶ The *QSAR Application Toolbox* is to be used by governments, chemical industry and other stakeholders in filling gaps in (eco) toxicity data needed for assessing the hazards of chemicals. It incorporates information and tools from various sources into a logical workflow. Grouping chemicals into chemical categories is crucial to this workflow. The software can be downloaded from this webpage: www.oecd.org/env/existingchemicals/qsar.
- ▶ The *Pov and LRTP Screening Tool* which has been developed with the aim of using multimedia models for estimating overall persistence (Pov) and long-range transport potential (LRTP) of organic chemicals at a screening level in the context of PBTs/POPs assessments. The Tool calculates metrics of Pov and LRTP from a multimedia chemical fate model, and provides a graphical presentation of the results. (This software can be downloaded from this webpage: www.oecd.org/env/riskassessment.)



OECD member countries

- | | | |
|----------------|-------------|-----------------|
| Australia | Hungary | Norway |
| Austria | Iceland | Poland |
| Belgium | Ireland | Portugal |
| Canada | Italy | Slovak Republic |
| Czech Republic | Japan | Spain |
| Denmark | Korea | Sweden |
| Finland | Luxembourg | Switzerland |
| France | Mexico | Turkey |
| Germany | Netherlands | United Kingdom |
| Greece | New Zealand | United States |



Accession countries

- Chile
- Estonia
- Israel
- Russian Federation
- Slovenia



Enhanced engagement countries

- Brazil
- China
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