

THE ENVIRONMENT, HEALTH AND SAFETY PROGRAMME



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Organisation for Economic Co-operation and Development

* Member countries

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

The OECD is an intergovernmental organisation whose mission is to promote policies that will improve the economic and social well-being of people around the world. It groups 34 member countries committed to democratic government and the market economy. It provides a forum where governments can work together to share experiences, identify good practices and find solutions to common problems. Dialogue, consensus and peer review are fundamental elements of the OECD's work.

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, science, technology, industry and innovation, in addition to environment.

Using this data, the OECD works with governments to understand what drives economic, social and environmental change. It also sets international standards on a wide range of things, from agriculture and tax to the safety of chemicals. Above all, drawing on facts and real-life experience, the OECD recommends policies designed to make the lives of ordinary people better.

The OECD partners are in accession talks with the Russian Federation. Brazil, China, India, Indonesia and South Africa participate in the OECD's work, and the Organisation works on specific issues with many other countries.

Preface

For 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, from paints and insect spray to computers, kitchen appliances, medicines or sun cream.

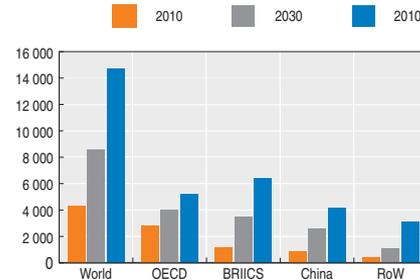
The chemical industry is one of the world's largest, with products worth more than EUR 4 000 billion annually. OECD countries account for about 60% of global chemical production. Their governments and the chemical industry therefore have a major responsibility to ensure that chemicals are produced and 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, avoid duplication of testing, minimise non-tariff distortions to trade and ultimately be more efficient and effective. These OECD activities have been estimated to

save OECD governments and the chemical industry at least EUR 150 million a year.

New challenges are ahead for the OECD. Some deal with the emergence of new products, such as nanomaterials for which the OECD is leading the international effort on their safety. Another challenge is the rapid expansion of the chemicals industry in non-member economies, which increases the potential for risks and heightens the need for co-operation. The OECD aims to work more closely with non-member economies and all partners worldwide to create synergies and facilitate the sound management of chemicals.

Projected chemicals production by region (in sales): Baseline, 2010-2050



Source: OECD (2012) OECD Environmental Outlook to 2050, OECD publishing, Paris.

OECD and the Environment



Angel Gurría
OECD Secretary-General

“ 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. ”

The OECD Environment Programme has been working on environmental policy issues for over 40 years and concentrates on four work areas:

- ▶ environmental reviews, indicators and outlooks
- ▶ climate change, biodiversity, water and waste
- ▶ decoupling environmental pressures from economic growth
- ▶ environment, health and safety.

The OECD provides advice to both OECD and partner economies, providing policy analysis, statistical information and recommendations to help them develop and implement

environmental policies that are economically efficient and environmentally effective.

key publication

- The OECD Environmental Outlook to 2050 projects demographic and economic trends over the next four decades and assesses the impacts of these trends on the environment if more ambitious policies to better manage natural assets are not introduced. It also examines some of the policies that could change that picture for the better. This Outlook focuses on four urgent areas: climate change, biodiversity, water and the health impacts of pollution. It concludes that urgent action is needed now to avoid significant costs of inaction, both in economic and human terms.

key link

- www.oecd.org/env

OECD's Environment, Health and Safety Programme

This programme 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).

Its aims are: 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, initially focusing 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 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.

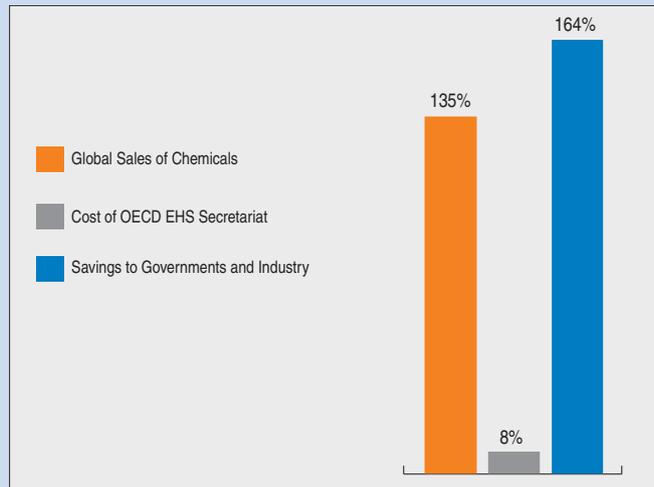
key link

- www.oecd.org/ehs

Savings to governments and industry

For non-clinical health and safety testing, for example, the results of studies done in one OECD country must be accepted by the others as long as they follow the OECD Test Guidelines and Principles of Good Laboratory Practice. This saves the chemicals industry expensive duplicate tests, allows countries to “work share” and reduces the number of animals needed for testing. All total, OECD estimates that this approach saves governments and industry about EUR 150 million each year. Despite minimal growth in the budget of the OECD Environment, Health and Safety Programme in recent years, the savings to governments and industry continue to grow, as does the size of the chemicals industry.

Percent increase of savings from 1998 to 2008



Source: OECD (2010) Cutting Costs in Chemicals Management. OECD publishing, Paris.

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 that 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.

Collaboration

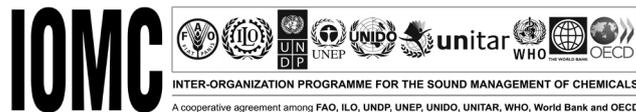
OECD work on chemicals takes places on various levels.

An international team of about 30 experts in the various disciplines dealing with chemical safety, e.g. biology, chemistry, toxicology and also economics or statistics, work together at OECD Headquarters in Paris.

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 partner 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 the eight other UN organisations involved in chemical safety, through the Inter-organization Programme for the Sound Management of Chemicals (IOMC, www.iomc.info) towards 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.



key link

- www.iomc.info

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 150 harmonised test 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, biocide efficacy 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 18) 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, reflect scientific progress, improve the cost-effectiveness of methods, and reduce the number and suffering of test animals. Over the last few years, 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 disruptors (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 18). 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, governments and industry work together with the OECD to 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**. Under such an approach, countries would review and accept each others’ new chemical notification decisions, and companies could submit one notification and then market globally.

For the OECD, this involves working on administrative procedures, providing guidance on definitions of key terms and harmonisation of country notification exemptions, and reducing requirements for some chemical groups (such as polymers of low concern). Also, the **OECD Clearing House on New Chemicals** is developing and implementing work sharing arrangements in which companies can notify new chemicals to multiple jurisdictions and governments can share information when conducting their reviews.

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. In this OECD activity, industry and governments gather (or generate) data on a chemical and carry out a co-operative initial hazard assessment. Governments and stakeholders then participate in a meeting where these hazard assessments are agreed.

key link

- www.oecd.org/env/hazard

Key database

- The OECD **eChemPortal**, launched in 2007, offers free public access to information on chemical properties and hazards of chemicals. It allows for simultaneous search of reports and datasets by chemical name and number and by chemical property. It provides direct access to collections of chemical hazard and risk information prepared for government chemical review programmes. Classification results as well as exposure and use information are provided when available

key link

- 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.

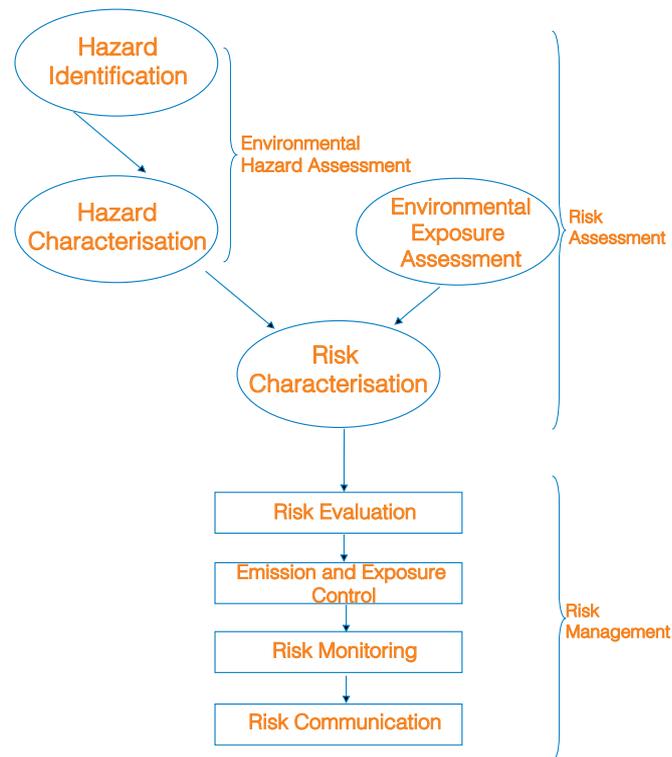
The OECD develops documents on emission scenarios that give quantified estimates of chemical emissions from specific industries (for example, in the semiconductor and microelectronics manufacturing industries or in industrial and institutional laundries) or from specific uses. The scenarios describe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

OECD has also developed an interactive environmental risk assessment toolkit that gives access to practical tools on environmental risk assessment of chemicals (see page 33: Selected software).

key links

- www.oecd.org/env/riskassessment
- <http://envriskassessmenttoolkit.oecd.org>

Flowchart on Environmental Risk Assessment and Management of Chemicals



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), which can be found in outdoor clothing, fire-fighting foams and various surface coatings. The OECD recognises the global nature of the problems posed by these pollutants and has teamed up with UNEP to engage non-member economies that are major producers and users of these chemicals in risk management activities.

key link

- www.oecd.org/ehs/pfc

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 an Internet Platform for information exchange and review of new developments and incentives for sustainable chemistry and analysed the role of environmental legislation and innovation in promoting sustainable chemistry.

A new project has been launched to promote the use of tools and approaches that can support industry and regulators in their efforts to substitute harmful chemicals.

key link

- www.oecd.org/env/riskmanagement

New methodologies: Working towards regulatory use

The OECD promotes the regulatory use 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.

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 but not limited to skin corrosion, phototoxicity and skin absorption, eye corrosion, genotoxicity and endocrine disruption. As new tests which meet the regulatory safety requirements of the OECD member countries are developed and validated, the range of non-animal Test Guidelines available will increase.

(Q)SARs

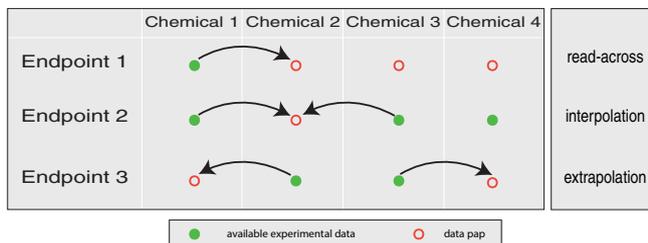
(Quantitative) Structure-Activity Relationships [(Q)SARs] are methods involving computer simulations which estimate properties of a chemical from its molecular structure. While the use of (Q)SARs in chemicals regulation is still relatively limited, the OECD is looking at how these approaches can be implemented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

key software

- The **QSAR Toolbox** is 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 seminal features of the Toolbox are:

- ▶ Identification of relevant structural characteristics and potential mechanism or mode of action of a target chemical.
- ▶ Identification of other chemicals that have the same structural characteristics and/or mechanism or mode of action.
- ▶ Use of existing experimental data to fill data gap(s) by read-across, interpolation or extrapolation.



key link

- www.oecd.org/env/hazard/qsar

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.

OECD’s activity on Molecular Screening and Toxicogenomics takes stock of advances made worldwide on omics tools (e.g. the US ToxCast Programme) to establish long term strategies for rationally and economically prioritising chemicals for further evaluation.

key link

- www.oecd.org/env/testguidelines

Adverse Outcome Pathways

To facilitate the development of the novel methods outlined above and to promote their regulatory use, OECD has launched an activity to improve the mechanistic understanding of how chemicals interact with living organisms. The OECD develops adverse outcome pathway which describe how a chemical or group of chemicals can first reach and then interact with an initial target in the organism and how this molecular initiating event triggers a sequential series of biological activities or key events that ultimately culminate in a final adverse effect in the organism.

These adverse outcome pathways will inform the development of new Test Guidelines for key events (e.g. based on *in vitro* test methods), the interpretation of results from “omics”

technologies as well as the development of methods to group chemicals into chemical categories that can be programmed into the QSAR Toolbox.

key link

- www.oecd.org/env/testguidelines

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 corresponding “harmonised templates” which constitute a guide for structuring data when reporting summaries of the results from those tests. OECD has also created common electronic data export/import formats for these templates to facilitate the exchange of such information across computer systems, as increasingly needed for meta-analyses, cross-check of data and cost saving in chemical testing.

key link

- www.oecd.org/ehs/templates



OECD and the rest of the world

Convergence of policies and tools for managing chemicals

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 the last 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.

MAD: Mutual Acceptance of Data

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 pages 9 & 10). This Council Decision requires OECD countries 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.

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.”

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 150 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 60% of the world total, production in non-OECD economies (both domestic companies and multinational firms), particularly in Brazil, Russian Federation, India and China, is rapidly increasing. The recent *OECD Environmental Outlook* projects

that non-OECD economies' share of world production will surpass OECD production by 2050. 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 that 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 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.

key link

- www.saicm.org

Participation of non-member economies

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 and other full adherents now include Argentina, Brazil, India, Malaysia and Singapore.

Thailand is now a provisional adherent to the system and more countries are expected to join MAD in the coming years.

OECD biosafety work also increasingly involves key non-member economies (e.g. Argentina, Brazil, China, India, Latvia, the Philippines, Russian Federation, South Africa, Thailand, African countries through NEPAD). 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 the safety of emerging and converging technologies such as 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 1/80,000th 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, from electronics and computing, to 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 or fabrics.

New safety issues?

Nanotechnology exploits the novel attributes of materials when their atoms and molecules are manipulated. But could these different technological properties also mean that nanomaterials are different from conventional substances with respect to human health and environmental safety?

In 2006, the OECD agreed to work on the implications of the manufacture and use of nanomaterials for the safety of human health and the environment, addressing whether traditional testing and assessment methods used to determine the safety of traditional chemicals were applicable to nanomaterials. After more than six years of work, the OECD and its member countries concluded that “the approaches for the testing and assessment of chemicals are in general appropriate for nanomaterials but may have to be adopted to the specificates of nanomaterials”. There is still a need to ensure that certain Test Guidelines can be used without being adapted for nanomaterials such as those that address physical-chemical properties or environmental fate and ecotoxicity. Such issues are currently being addressed at OECD.

Much of the work is based largely on the testing of a representative set of manufactured nanomaterials, agreed by countries, such as carbon nanotubes or cerium oxide or silver nanoparticles, using appropriate test methods. This testing has helped understand the types of information on intrinsic properties of manufactured nanomaterials that may be relevant to exposure and effects assessment.

Areas of priority for the OECD

OECD aims to promote international co-operation in human health and environmental safety aspects of manufactured nanomaterials, notably in six specific areas:

- ▶ facilitating international co-operation on risk assessment
- ▶ developing testing methods for MNs (or adapting conventional ones, such as the OECD Test Guidelines) and evaluating the potential of alternative methods, such as *in vitro* tests
- ▶ promoting international co-operation on risk assessment and regulatory programmes
- ▶ developing guidance on exposure measurement and exposure mitigation
- ▶ exploring the sustainable use of nanomaterials.

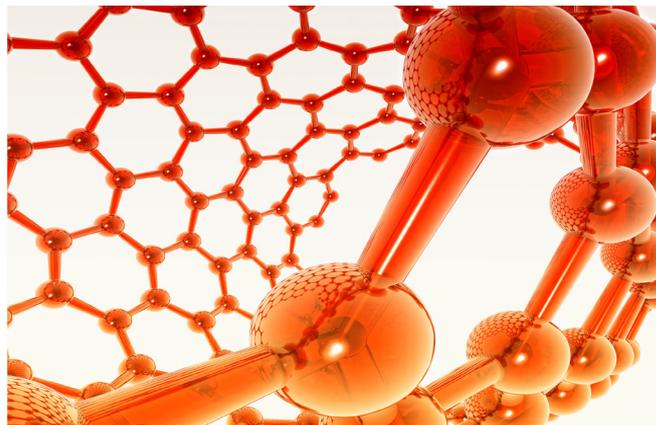
The OECD ensures that the project on nanomaterials builds on existing OECD activities on chemical safety such as the OECD

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, countries are confident that they can do this if they continue to work together. 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 related areas) 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 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. Other risk reduction issues being addressed include protecting pollinators from the risks of pesticides and fighting illegal trade of pesticides.

The OECD also deals with the issue of **minor uses** (i.e. a small-scale pesticide use for pest control in a low acreage crop or a small pest problem in a large acreage crop). Due to the planned insufficient return on investment of the expenditures necessary to get regulatory approval for minor uses, the pesticide industry is reluctant to conduct research for minor crops and farmers lack the authorised options to control pests and diseases. The OECD 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.

The OECD goal is also to promote sustainable pest management strategies and in particular strategies for the adoption and implementation of **Integrated Pest Management** in agriculture.

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 testing and management. These include the harmonisation of the testing of **product efficacy** to ensure the validity of label claims of biocidal products such as disinfectants or insecticides. “**Emission scenarios**” are developed that estimate how much of certain biocides will get into the environment, how long they will last and their effects.

key link

- www.oecd.org/env/biocides



Preventing and responding to chemical accidents

For more than two decades, OECD has been addressing issues related to chemical accidents, a subject that concerns everyone who works in a chemical plant, lives near one or is involved in an 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 three policy guidance documents: the *Guiding Principles for Chemical Accident Prevention, Preparedness and*

Response; the *Guidance on Safety Performance Indicators*; and the *Principles for Corporate Governance for Process Safety*. They are intended for public authorities, industry (including management and labour) and the general public.

► The OECD *Guiding Principles for Chemical Accident Prevention, Preparedness and Response* 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 Principles for Corporate Governance for Process Safety (CGPS) are mainly directed to senior managers. They aim to strike a balance between risk and benefit by drawing attention of those at the top of industry to the need for high standards of corporate governance in relation to the management of high hazard industries. As such, it is focused on: (i) raising the profile of process safety governance; (ii) setting out the essential elements of corporate governance for process safety; (iii) providing a common framework; (iv) taking some of the guesswork out of establishing Corporate Governance Programmes; (v) providing a self-assessment toolkit; and (vi) providing a demonstration of commitment. A CGPS booklet has been translated into several languages.

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.

Finally, 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 publicly 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 dramatically increased. Today, all OECD countries have an operational PRTR in place or are preparing to establish one, and many non-member economies have also taken concrete steps towards establishing a PRTR.

The OECD activity on PRTRs therefor mainly consists of helping countries to implement and their PRTRs. OECD experts currently work: to improve release estimation techniques from various sources such as point sources and diffuse sources including releases from products; to provide guidance on the

application, use and presentation of PRTR data; to describe the role a PRTR can play in global sustainability; and to improve the comparability of national PRTRs by harmonizing the elements of a PRTR system across countries.

Key database

- Three databases on PRTRs have been developed which provide a global portal to PRTR information, contact points in OECD countries, release estimation techniques and national PRTR data (see page 28: Selected databases).
- Finally, the OECD is developing a geographic information system (GIS) for the global portal to PRTR information

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 countries have faced in recent years: safety of products derived from modern biotechnology. Transgenic crops are increasingly cultivated worldwide while human food and animal feeds derived from them are being marketed. Such products have to be 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 elements used in risk/safety assessment, as well as the methods used to collect such information, are as similar as possible among countries. Both programmes identify a common base of scientific information that may be useful in assessing the safety of specific genetically-engineered products with respect to human food and animal feed as well as the environment. The new biotechnology techniques now developed in addition to transgenesis (synthetic biology, “omics” techniques, others) should also be evaluated for their potential safety impact.

The main OECD publications are consensus documents, providing key information on major crops, trees (biology of

plants, food/feed composition), micro-organisms, modified characteristics, which member countries believe are relevant to risk and safety assessment. More than 70 consensus documents are now available.

► An emerging issue: a publication on the biology of Atlantic Salmon is under development. This is the first time the OECD is addressing a genetically engineered animal species. This document will use a similar safety approach as has been used for documents on plants.

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. The products are listed with their basic description, unique identifiers, and with access to their regulatory approval texts for their use in agriculture and food or feed processing. Biotrack Online also makes the OECD consensus documents available.

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 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 and 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

eChemPortal

www.oecd.org/ehs/eChemPortal

Offers free public access to information on properties of chemicals. It allows for simultaneous search of reports and datasets by chemical name and number and by chemical property. It provides direct access to collections of chemical hazard and risk information prepared for government chemical review programmes. Classification results as well as exposure and use information are provided when available.

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 OECD country delegates.

The Global Portal to PRTR Information

www.PRTR.net

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 (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 genetically-engineered products that have been approved for commercialisation (use for crops and/or food & feed processing) in countries. It also makes the OECD Consensus Documents available for risk and safety assessment.

Selected software

QSAR Toolbox

www.oecd.org/env/hazard/qsar

Is 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.

Pov and LRTP Screening Tool

www.oecd.org/env/riskassessment

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.

Environmental Risk Assessment Toolkit

<http://envriskassessmenttoolkit.oecd.org>

Gives access to practical tools on environmental risk assessment of chemicals. It describes the general work flow of environmental risk assessment and provides links to relevant tools developed by OECD and member countries that can be used in each step of the work flow. Examples are provided in the form of roadmaps that illustrate the process for specific risk assessment examples, showing the steps involved in each case and the tools which were used.

IOMC Toolbox for Decision making in Chemicals Management

<http://iomctoolbox.oecd.org>

Is a problem-solving tool that enables countries to identify the most appropriate and efficient national actions to address specific national problems related to chemicals management. The toolbox identifies the available tools that will help the country address the identified national problems or objectives. Special focus is given to identifying simple cost effective solutions to national chemicals management issues.

More information

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▶ Find **Job Vacancies** on the OECD Human Resources website at www.oecd.org/hrm.

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