OECD WORK ON
CHEMICAL SAFETY
AND BIOSAFETY

2021-24
OECD WORK ON Chemical Safety and Biosafety
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The OECD, which traces its roots to the Marshall Plan, groups 38 member countries committed to democratic government and the market economy. It provides a forum where governments can compare and exchange policy experiences, identify good practices and adopt decisions and recommendations. Dialogue, consensus, and peer review and pressure are at the very heart of the OECD.

The Organisation for Economic Co-operation and Development

What is the OECD?

The OECD, which traces its roots to the Marshall Plan, groups 38 member countries committed to democratic government and the market economy. It provides a forum where governments can compare and exchange policy experiences, identify good practices and adopt decisions and recommendations. Dialogue, consensus, and peer review and pressure are at the very heart of the OECD.

Our mission

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

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

The OECD Environment Directorate helps countries design environmental policies that are both economically efficient and effective at achieving their environmental objectives.

The Environment Directorate provides policy tools and evaluations focused on:

- Environmental reviews, indicators and outlooks
- Climate change, biodiversity, water and waste
- Decoupling environmental pressures from economic growth
- Green growth
- Chemical Safety and Biosafety.

OECD Environmental Outlook to 2050

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.
Overview of the chemical industry

For 50 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:

**Inorganic Chemicals, Petrochemicals, Petrochemical Derivatives**

**Speciality Chemicals Derived from Basic Chemicals**

**Products Derived from Life Sciences**

**Consumer Care Products**
The chemical industry is one of the world’s largest, with sales worth more than EUR 4 000 billion annually and is expected to grow to almost EUR 22 000 billion by 2060. OECD countries account for about 52% 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.

**Annual global sales of the chemical industry, 1998-2017, and OECD projections for 2060 (USD billion)**

Sources: ACC (2018), 2017 Guide to the Business of Chemistry; OECD (2019), Global Materials Resources Outlook to 2060: Economic Drivers and Environmental Consequences,
Evolving challenges for countries

The OECD is 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.

The OECD is also working on nanomaterials and other advanced materials for which the OECD is leading the international effort on their safety, and with countries wishing to implement a circular economy which requires more sustainable chemistry. 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.

OECD work on chemicals takes places on various levels. An international team of about 30 experts in the diverse disciplines dealing with chemical safety (biology, chemistry, toxicology) and 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 at the 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 the development and future implementation of the UN post-2020 framework for the sound management of chemicals and waste which brings together governments from more than 150 countries and various stakeholders.
OECD work on chemical safety and biosafety

The OECD work on chemical safety and biosafety deals with the safe use of chemicals, nanomaterials, pesticides, biocides, and products of modern biotechnology. It also addresses related areas of concern and interest, such as chemical accidents, Pollutant Release and Transfer Registers (PRTRs) and Best Available Techniques (BAT). 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.

History

The OECD has been working on environment, health and safety since 1971, initially focusing on specific chemicals known to pose health or environmental problems, such as mercury or chlorofluorocarbons (CFCs) responsible for depleting the ozone layer. The purpose of this work was to share information about these chemicals with member countries and to act jointly to reduce risks.

One of the important achievements of the early years was the 1973 OECD Council Decision to restrict the use of polychlorinated biphenyls (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 potential risks of new chemicals before they were manufactured and marketed, and of biotechnology products before their release in the environment and use for food and feed.

This led in 1981 to the Mutual Acceptance of Data (MAD) system of chemical safety data among OECD countries and adherents, a crucial step towards international harmonisation and reduction of trade barriers.

The work on the safety of biotechnology products started in mid-1980s. Initially focused on the environmental implications of transgenic crops (biosafety), scientific principles for novel food safety assessment were developed from the end of 1990. The concepts of case-by-case risk analysis, familiarity, comparative approach are part of the safety considerations and common approaches elaborated at OECD.
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, 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: oe.cd/chemical-safety

Working together to tackle chemical management issues

<table>
<thead>
<tr>
<th>Year</th>
<th>Savings to governments and industry (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998</td>
<td>EUR 90 280 000</td>
</tr>
<tr>
<td>2010</td>
<td>EUR 176 850 000</td>
</tr>
<tr>
<td>2019</td>
<td>Total savings: EUR 309 516 000</td>
</tr>
</tbody>
</table>

Note: Figures have been adjusted for inflation.

Savings to governments and industry due to EHS work on pesticides and industrial chemicals

Savings to governments and industry due to EHS work on biocides; these savings were not calculated in previous reports.
### International strategies and agreements

<table>
<thead>
<tr>
<th>Year</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>Strategic Approach to International Chemicals Management, adopted by the International Conference on Chemicals Management (ICCM) in Dubai.</td>
</tr>
<tr>
<td>2002</td>
<td>Paragraph 23 of the Johannesburg Plan of Implementation, adopted at the World Summit on Sustainable Development.</td>
</tr>
<tr>
<td>1992</td>
<td>Chapters 19 and 20 of the UNCED’s Agenda 21 adopted in Rio de Janeiro.</td>
</tr>
</tbody>
</table>

### Chemical safety, a prerequisite for meeting the UN Sustainable Development Goals

Chemicals play an important role in development, and so the sound management of chemicals is an important component to achieve sustainable, inclusive and resilient human development and the Sustainable Development Goals. The sound management of chemicals and waste is specifically mentioned in several targets, such as:

- **Target 3.9**: By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination.
- **Target 12.4**: By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimise their adverse impacts on human health and the environment.
OECD Legal Instruments

The OECD governing body, the Council, has the power to adopt legal instruments. Council Decisions are legally binding on all those member countries which do not abstain at the time they are adopted. The Council also issues Recommendations, which are not legally binding, but which have great moral force. There is an expectation that member countries will do their utmost to fully implement a Recommendation.

Other legal instruments developed within the framework of the OECD include:

- Declarations, arrangements and understandings, which are not legally binding, but their application is generally monitored by the responsible OECD body.
- International Agreements which are legally binding on the parties.

A number of OECD Council acts in force are related to chemicals management and biosafety, and cover areas as diverse as chemical accidents, exchange of confidential data on chemicals or the Polluter-Pays Principle.

Did you know?

21 OECD legal instruments are dedicated to chemical safety.

Link: oe.cd/council-acts-chemicals
Mutual Acceptance of Data (MAD)

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 Good Laboratory Practice Principles. This Council Decision requires OECD member and adhering countries to accept test data developed for regulatory purposes in another member of adhering 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.

Key publication:

The Saving Costs in Chemicals Management - How the OECD Ensures benefits to Society report examines the net benefits that accrue to governments and industry from the work of the OECD Environmental, Health and Safety (EHS) Programme, estimates that the programme saves governments and industry approximately EUR 309 million a year. It also describes the programme’s equally important non-quantifiable benefits.

Key link: oe.cd/chemicals-costs
Which countries participate in the MAD system?

Member countries

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

Full adherents

- Argentina
- Brazil
- India
- Malaysia
- South Africa
- Singapore
- Thailand

Watch our video on Saving costs in Chemicals Management with the Mutual Acceptance of Data system:

Key link: https://youtu.be/dD7e1sfsh3A

13 - OECD WORK ON CHEMICAL SAFETY AND BIOSAFETY
Helping non-OECD economies establish chemicals management systems

While production in OECD countries still accounts for about 52% of the world total, production in non-OECD economies (both domestic companies and multinational firms), particularly in Brazil, India, the Russian Federation, and the People’s Republic of China is rapidly increasing. 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 works with non-member economies to establish 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.

The OECD organised its first Global Forum meeting open to all stakeholders to raise awareness and provide advice on designing and implementing a cost-effective industrial and consumer chemicals sound management system. Discussions with panelists and participants helped to identify areas for future OECD work on chemicals.

The OECD established a network of experts for setting up chemicals management systems and is working with selected partner countries to provide assistance in improving their chemicals management frameworks.

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 the 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.

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, Singapore and Thailand.

OECD biosafety work also increasingly involves key non-member economies (e.g. Argentina, Brazil, China, India, Kenya, Paraguay, the Philippines, Russian Federation, South Africa, Viet Nam, African countries through the African Union Development Agency (AUDA-NEPAD)).
3 Common policies and high-quality instruments for chemical safety

Testing: Developing international testing and quality standards

OECD Test Guidelines

Since 1981, the OECD has been developing Guidelines for the Testing of Chemicals for determining their physical and chemical properties (e.g. water solubility), effects on human health and wildlife (e.g. short and long-term toxicity), environmental fate and behaviour, biocide efficacy and pesticide residue chemistry. Test Guidelines are prepared with input from experts working in governments, academia, industry and other non-governmental organisations such as environmental protection groups 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 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 that can be used alone or in defined combinations to predict a hazard property and its potency.

In addition, there has been considerable activity to develop test methods to detect endocrine disrupters (chemicals that have effects on hormone systems of humans and wildlife) as well as to update Test Guidelines or develop new ones to ensure that they can be used to test for the properties of manufactured nanomaterials.

During their development, draft Test Guidelines, and supporting information, and guidance documents are available on the OECD website and the public is invited to comment on these drafts. Final approval is the decision of member countries.

Did you know?

More than 150 harmonised test methods have been developed for determining physical and chemical properties of chemicals, their effects on human health and wildlife, environmental fate and behaviour, and pesticide residue chemistry.
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. 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.

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.

Key link: oe.cd/glp
Risk assessment: increasing global assessments of chemicals

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.

Exposure assessment

The OECD develops tools for predicting or measuring the exposure of chemicals to humans or the environment. For example, 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.

Children may be particularly vulnerable to the exposure of chemicals and in some cases, governments may have to develop risk assessments that specifically address the risks of chemicals to children. The OECD has developed a decision scheme to serve as a basis for determining the need for a child-specific exposure assessment. Furthermore, the OECD has developed tools to estimate the exposure of children through mouthing of objects. Currently, the OECD is gathering information on child-specific parameters to properly estimate the exposure of children.
Hazard assessment

In order to meet the goals of Sound Management of Chemicals, many countries have moved to systematically address the safety of all the chemicals on the market. After completing a collaborative programme where hazard assessments have been agreed for more than 1200 chemicals, countries have now turned their focus to work together on using novel hazard assessment methodologies for regulatory decision making, especially Integrated Approaches to Testing and Assessment.

However, countries are also collaborating on issues such as assessing the combined exposures to multiple chemicals as well as understanding the kinetic behaviour of chemicals within organisms.

Overview of Concepts and Available Guidance related to Integrated Approaches to Testing and Assessment (IATA)

This report provides an overview of existing guidance on Integrated Approaches to Testing and Assessment (IATA) and their component parts. This overview document is expected to contribute to a common understanding of IATA, by explaining key concepts and providing basic definitions, and to support easier access to existing resources. An accompanying annex provides a short description of the mapped guidance documents.

Risk Assessment Toolkit

The OECD has also developed an interactive environmental risk assessment toolkit that gives access to practical tools on environmental risk assessment of chemicals.

Key link: http://envriskassessmenttoolkit.oecd.org

Database:

The OECD eChemPortal 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 and classification. It provides direct access to collections of chemical hazard and risk information prepared for government chemical programmes. Classification results as well as exposure and use information are provided.

Key link: oe.cd/echemportal

Key link: oe.cd/concepts-and-guidance-on-iata
Management: reducing chemical risks

The term “risk management” applies to an important stage of 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 per and polyfluoroalkyl substances (PFASs) 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 engages globally with countries, producers and users of these chemicals to move to safer alternatives. This work has included the development of reports to share risk reduction experience, identification of alternatives and to bring together information on global progress.

Read our latest report on PFASs and alternatives in food packaging (paper and paperboard):

This report addresses the commercial availability and current uses of alternatives (chemical and non-chemical) to PFASs in food packaging (paper and paperboard). PFASs are synthetic substances that are widely used in numerous technologies, industrial processes and everyday applications. This report also includes a number of policy recommendations aimed at government authorities, international organisations and industry.

Key link: oe.cd/pfass

Watch the OECD webinars on Per and Polyfluoroalkyl substances

The OECD Per- and Polyfluoroalkyl Substances (PFAS) webinar series brings world experts together to share vital information and best practices regarding PFASs. These free webinars are open to the general public. Video recordings of our PFASs webinars are made available online afterwards. Register for an upcoming webinar or watch the video recordings of our past webinars below.

Key link: oe.cd/pfas-videos
Alternatives assessment, substitution and innovation towards 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.

Guidance on key considerations for the identification and selection of safer chemical alternatives

As the demand for safer chemicals and technologies grows, the field of alternatives assessment is becoming increasingly important in guiding the transition towards safer, less toxic alternatives. While the use and practice of alternatives assessment approaches have advanced considerably in the last decade, a major limitation that can hinder efforts to evaluate and adopt alternatives for priority chemicals is the lack of consistent criteria for defining “safer” alternatives. This guidance outlines key considerations for the identification and selection of safer alternatives.

Design of Sustainable Plastics from a Chemicals Perspective

Building on the OECD Global Forum on Design of Sustainable Plastics from a Chemicals Perspective, the OECD is working with countries and other stakeholders to develop criteria for the sustainable design of plastics from a chemicals perspective. This takes into consideration case studies regarding sustainable design of different types of plastic products to determine if more generalised criteria can be identified.

Key link: oe.cd/plastics-forum
New methodologies: Working towards regulatory use

The OECD promotes the regulatory use of 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, serious eye damage, skin sensitisation, 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. There is an on-going effort to combine alternative test methods for a same endpoint and provide guidance for their rational use. A long-term goal is to reach agreement among countries on defined replacement methods to avoid or strongly reduce animal testing.

Key link:
www.oecd.org/chemicalsafety/testing/animal-welfare
(Quantitative) Structure Activity Relationships [(Q)SARs]

(Q)SARs are methods involving computer simulations which estimate properties of a chemical from its molecular structure. The use of (Q)SARs in chemicals regulation is growing and the OECD is looking at how these approaches can be further implemented in member countries.

The OECD QSAR Toolbox allows users to predict the properties of chemicals from the knowledge of close structural analogues.

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:
[oe.cd/qsar-toolbox](http://oe.cd/qsar-toolbox)
Adverse outcome pathways (AOPs)

Faced with the daunting task of assessing the safety of thousands of chemicals using existing data or alternative approaches to animal testing, member countries have no choice but to develop new tools and decision frameworks.

The OECD Adverse Outcome Pathways Development (AOP) Programme was launched in 2012 to enable collaborative efforts among researchers to delineate structured knowledge derived from chemicals interactions with biological targets and subsequent testable key events leading to adverse health or environmental effects.

Chemicals initially interact with a molecular target (molecular initiating event or MIE). The MIE initiates a biological cascade of events; triggering effects in cells, tissues and organs (Key Events (KE)) that potentially result in an adverse outcome (AO) in an individual (solid line) or population (dotted line). The description of this cascade of biological events is called an Adverse Outcome Pathway (AOP).
What is an AOP?

An AOP is an analytical construct that describes a sequential chain of causally linked events at different levels of biological organisation that lead to an adverse health or ecotoxicological effect (see figure on page 24). AOPs are the central element of a toxicological knowledge framework being built to support chemical risk assessment based on mechanistic reasoning.

The knowledge gathered in AOP’s can then be used to:

- develop (Q)SARs and non-animal test methods
- develop testing strategies
- interpret non-standard test results published in the scientific literature.

Key publication

The Guidance Document on the Use of the Adverse Outcome Pathways in developing Integrated Approaches for Testing and Assessment (IATA):

- Provide a framework for developing and using IATA
- Describe how IATA can be based on the Adverse Outcome Pathway (AOP concept)
- Provide examples on how AOPs can be used in the development of IATA.

Where can I find AOPs?

The AOP Knowledge-Base and tools:

The eAOP Portal is the main entry point of the AOP Knowledge Base. As a search engine, the Portal enables search by key words in AOP titles and key events in the AOP Wiki and Effectopedia platforms.

The AOP Wiki provides a system that organises, via crowd-sourcing, the available knowledge and published research into a verbal description of individual pathways, using a user friendly Wiki interface.

AOPs are the central element of a toxicological knowledge framework, promoted by member countries through OECD, built to support chemical risk assessment based on mechanistic reasoning. These AOPs are available in the AOP Wiki, an interactive and virtual encyclopedia for AOP development. Following their development and review, the endorsed AOPs are published in the OECD Series on Adverse Outcome Pathways.

Key links:

https://aopkb.oecd.org
https://aopwiki.org
https://doi.org/10.1787/2415170X

Key link: oe.cd/iata
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 each of the Test Guidelines, the OECD has developed a corresponding “harmonised template” which constitute a guide for structuring data when reporting summaries of the results from those tests.

The 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 data management.

Key links:
www.oecd.org/ehs/templates

OECD IT tools supporting chemicals management

In this presentation, you will find a full description of each tool, how they fit in the general process of chemicals management, e.g. information gathering and information generation, risk assessment (hazard and exposure assessment) and risk management and how they facilitate retrieval and exchange of data within and between programmes and jurisdictions.

Key link: oe.cd/it-tools
Safety of manufactured nanomaterials

OECD work continues to evolve in response to the safety of emerging and converging technologies such as manufactured nanomaterials (MNs).

What is nanotechnology?

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 100,000 nm 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 many commercial applications ranging from lotions, creams and shampoos in the cosmetics sector to self-cleaning glass, tyres or fabrics.

Promoting safer(r) and more sustainable nanomaterials

The OECD keeps abreast of major policy issues related to manufactured nanomaterials, advanced materials and other emerging issues. For instance, to minimise the gap between technological innovations and the development of suitable risk assessment tools and frameworks. A report addressing safe(r) innovation approach for sustainable nanomaterials and nano-enabled products has recently been published. Further work is underway to assist countries in bringing together safety and sustainability.

Other efforts include developing tools to assist countries in assessing the exposure to nanomaterials. To this end, the OECD is reviewing the applicability of exposure existing tools/models to manufactured nanomaterials in occupational, consumer and environmental domain.

Key link:
oe.cd/nanosafety nanomaterials
Towards tailored safety testing methods for nanomaterials

Because Nanomaterials may have different properties compared to the same substance in bulk form, there is a need to have internationally standardised test methods to characterise nanomaterials, their physical-chemical properties, environmental fate, effects on environmental species and on human health. To intensify this endeavour, the NANOMET project, funded by the European Union, was launched in May 2020. Webinars are regularly organised to inform governments, industry and independent laboratories on the use of OECD testing methods.

OECD legal instrument on Nanomaterials

The OECD Council Recommendation on the Safety Testing and Assessment of Manufactured Nanomaterials was approved in 2013 following seven years of work on the topic. It recommends applying existing regulatory frameworks for traditional chemicals to nanomaterials, while it is understood that some adaptation might needed to take into account the properties specific to nanomaterials. It also recommends applying the OECD Test Guidelines in the testing of MNs, updating existing Test Guidelines and developing new ones specific to MNs. This has important consequences in that the safety assessment data of MNs will fall within the scope of the OECD system for the Mutual Acceptance of Data.

Webinars on nanomaterials:

• Webinar on aquatic (including sediment) ecotoxicity testing of nanomaterials for the purposes of determining their hazard.

This webinar presented the scope and use of the guidance document No. 317 on aquatic and sediment ecotoxicity testing of nanomaterials. The guidance addresses practical aspects of carrying out valid tests on nanomaterials, and modifications or additions to OECD Test Guidelines procedures intended to improve the accuracy of test results.

  ● https://youtu.be/MKhSzqQIHZc

• Webinar on the dispersion stability and dissolution rate of nanomaterials in the environment.

This webinar presented the scope, content, and use of the Test Guideline No. 318: Dispersion Stability of Nanomaterials in Simulated Environmental Media and its accompanying Guidance Document.

  ● https://youtu.be/ODEQgkFonAo

Key link:

  oe.cd/nanomet
OECD 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 has developed 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.

**Key recommendation on pesticides:**

On 20 February 2019, OECD Council adopted the **Recommendation on Countering the Illegal Trade of Pesticides** to strengthen co-operation between countries and inspectors. A Best Practice Guidance helps countries identify illegal pesticides throughout their lifecycle to ensure the safety of consumers and the environment.

**Link:**
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 risks associated with aspects of drone technology, 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.

**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.

Promoting the sustainable use of biocides is another objective of OECD.

The COVID-19 pandemic called for urgent policy responses to support the supply of disinfectant products such as hand sanitisers and wipes. The OECD has been collecting and providing available information in countries to manage the emergency supply to increase availability of disinfectant products from different competent authorities and industry organisations.

The Covid-19 pandemic has challenged regulators, health professionals, industry and the public in responding quickly, decisively and efficiently to the impact and consequences of this virus. The OECD is looking at ways to improve the efficiency in emergency responses through more co-ordinated action. Specific activities are underway such as the creation of a lessons-learned document, developing best practices for emergency situations in general, investigating approaches for more efficient communication between regulatory authorities during crises, and further development of test methods on the efficacy of disinfectants.

**Key links:**
https://oce.d/disinfectants-covid-19
Preventing and responding to chemical accidents

Chemical accidents concern everyone who manufactures, uses or handles hazardous chemicals, works in a chemical plant, or lives nearby. Since 1988, the related OECD Programme helps public authorities, industry, labour and other interested parties preventing chemical accidents. The programme offers a forum for participating stakeholders to share experiences on accidents and to learn from each other challenges and progress. The OECD has published policy guidance documents on this topic. Some of the key ones are:

the OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response describe the responsibilities of parties involved in the production, use and handling of hazardous chemicals. They address all aspects of preventing and managing chemical accidents, from the planning, construction, operation and maintenance of installations, training and education, community awareness, and emergency planning and response.

The Principles for Corporate Governance for Process Safety (CGPS) provides guidance to senior managers. They aim to strike a balance between risk and benefit by drawing attention of industry top leaders to the need for high corporate governance standards in relation to the management of high hazard industries.

The Guidance documents on Safety Performance Indicators for Industry and the Guidance documents on Safety Performance Indicators for Public Authorities and Communities/Public 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.

The Guidance on Change of Ownership in Hazardous Facilities provides a framework to assist stakeholders to identify, understand and minimise the risks during and after a change of ownership at a hazardous facility, and help make the change of ownership a better-informed process.

Key link: oe.cd/chemical-accidents
Ongoing projects of the chemical accidents programme include work on the impact of natural hazards, such as earthquakes and floods, on the operation of hazardous installations. Accidents triggered by such events are known as ‘Natech’ - Natural Hazards Triggered Technological Accidents. The OECD teamed up with the European Commission Joint Research Centre, the UNEP/OCHA Joint Environment Unit, and the UNECE to investigate the specificities of Natech for the prevention, preparedness and response to chemical accidents, exchange experience across countries, and provide guidance on Natech risk management.

Other projects underway aim to share good practices for the management of inspections at hazardous installations, and to develop guidance for evaluating the benefits of regulations related to chemical accidents.
7 Communicating chemical emission information through Pollutant Release and Transfer Registers (PRTRs) and Best Available Techniques (BAT)

Pollutant Release and Transfer Registers (PRTRs)

A PRTR is a publicly available database or inventory of potentially harmful chemicals and/or pollutants released to air, water and soil, and transferred as wastes. A PRTR 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.

Key databases:
Three databases on PRTRs have been developed to provide a global portal to PRTR information, contact points in OECD countries, release estimation techniques and national PRTR data

- Centre for PRTR Data: www.oecd.org/env_prtr_data
- Resource Centre for release Estimation Techniques: www.prtr-rc.fi
- PRTR.net: www.prtr.net

Key publication:
Guidance Document on Elements of a PRTR
Part I: oe.cd/GD-prtr-part1
Part II: oe.cd/GD-prtr-part2

The 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, almost 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 therefore mainly consists of helping countries to implement 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 of PRTR data to track environmental performance; and to improve the comparability of national PRTRs by harmonising the elements of PRTRs across countries.
Best Available Techniques (BAT) to Prevent and Control Industrial Pollution

An increasing number of countries use BAT as a tool to establish evidence-based environmental permit conditions for industrial installations, in order to prevent and control industrial pollution, and thus to ensure a high level of human health and environmental protection. BAT are state-of-the-art techniques that are developed at a scale that enables implementation under economically and technically viable conditions.

BAT is a tool to establish legally binding emission limit values in environmental permits for industrial installations. The determination of BAT is based on a comprehensive collection of information on existing techniques for prevention and control of pollution, and subsequently a thorough assessment of the economic, environmental and technical aspects of these techniques.

Government, industry, and environmental NGOs are all involved in the process to determine BAT and associated emission levels. This evidence-based and transparent approach is more likely to result in reductions of pollution. Countries spend significant resources on designing, developing and implementing policies for BAT-based permitting. Therefore, there is an added value in sharing experience, knowledge and best practices on this topic amongst OECD member and partner countries.

The overall objectives of the OECD’s BAT project are to assist governments to implement policies and practices that embody BAT (or similar concepts) to prevent and control industrial pollution, and to contribute to progress towards achieving the Sustainable Development Goals (SDGs).

Latest publication on BAT

This guidance aims to provide the governments with relevant steps, tools and best practices on how to identify and establish BAT, BAT-associated emission levels (BAT-AELs) and other environmental performance levels (BAT-AEPLs), as well as BAT-based permit conditions, including emission limit values.

There are two other reports under development which will be published towards the end of 2021. One of these reports will look into the value chain aspects of determining BAT by discussing the challenges and opportunities linked to incorporating value chain aspects when establishing BAT. The latest report of the year will be on the findings of cross-country comparisons of BAT and associated emissions levels (BAT-AELs) for Thermal Power Plant, Cement and Textiles industries for selected BREFs (Best Available Technique (BAT) Reference Document).

Key links:
oe.cd/bat
oe.cd/infographic-bat
Reaching consensus on biosafety and food safety

The OECD runs two programmes related to biotechnology products safety: Harmonisation of Regulatory Oversight in Biotechnology addressing environmental safety (or biosafety), and Safety of Novel Foods and Feeds issued from these products.

Both programmes deal with the challenging issues of the safety of products derived from modern biotechnology. Transgenic crops are increasingly cultivated worldwide while foods 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.

The programmes identify a common base of scientific information that may be useful in evaluating the safety of specific genetically-engineered products with respect to food and feed as well as the environment. The new biotechnology techniques now developed in addition to transgenesis (gene editing, “omics” techniques, others) are also discussed for their potential safety impact.

The main OECD publications are consensus documents, providing key information on major crops, trees, animals (biology, food/feed composition), micro-organisms, modified characteristics, which countries believe are relevant to risk and safety assessment. More than 80 consensus documents are now available.

Type of organism:

Crops

Trees

Mushrooms

Animals
Composition Documents

These documents cover the compositional considerations of major crop and fruit plants: production, uses, processing, nutrients, allergens, toxicants, and other metabolites, as well as suggested constituents to be analysed related to food/feed use. They provide science-based information to the risk/safety assessment of foods/feeds derived from transgenic organisms.

Biology Documents

Documents of the biology of plants (crops, fruits, trees) describe centres of origin, reproduction, genetics, hybridisation, production, ecology, etc. These publications provide science-based information to the risk/safety assessment of transgenic organisms intended for release in the environment.

Biology documents for animal species include already Atlantic Salmon and mosquito Aedes aegypti. Others are currently under preparation.

Key links:
oe.cd/biosafety
www.oecd.org/environment/genome-editing-agriculture/
These 15 OECD tools are available for your use

**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.


**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.


**BioTrack Online**

Provides ready access to food/feed/environment safety information for those genetically-engineered products that have been approved for commercialisation (use for cultivation and/or food & feed processing) in countries. It also makes the OECD Consensus Documents available as tools for risk and safety assessment.

Link: [www.oecd.org/biotrack](http://www.oecd.org/biotrack)

**OECD Environmental Risk Assessment Toolkit**

The OECD Environmental Risk Assessment Toolkit outlines the work flow for environmental risk assessment and management of chemicals with links to available OECD material relevant for the different steps in risk assessment and management. Partner countries will find practical tools on environmental risk assessment of chemicals and examples of risk assessments.

Link: [oe.cd/erat](http://oe.cd/erat)
IOMC Toolbox for decision making in chemicals management

The IOMC Toolbox for Decision-Making in Chemicals Management, available in English and soon in French and Spanish, is an internet-based tool that enables countries to identify the most relevant and efficient tools to address specific national problems in chemicals management. It contains recommendations for setting-up eight types of national management schemes: a pesticides management scheme; an occupational health and safety system; a chemical accidents prevention, preparedness and response system for major hazards; a PRTR system; an industrial chemicals management system; a Globally Harmonised System for Classification and Labelling (GHS) implementation scheme, a public health management scheme of chemicals and a Best Available Techniques scheme. Countries can find different options proposed, according to their level of available resources (low, medium, high), for setting up or improving their chemical management scheme and more than 500 related guidance documents, tools and training materials available for each implementation step. The IOMC Toolbox has been redesigned to provide easier and more direct access to these resources. This new and improved platform enables users to access information with less steps and less clicks.

Link: https://iomctoolbox.org/

Chemical legislation indicator: How are countries tackling the risks of industrial and consumer chemicals?

The new chemical legislation indicator allows you to explore the legal frameworks set up by each country to support the safety of human health and the environment.

This map measures the progress in countries with setting up management systems specifically dedicated to managing the risks of industrial and consumer chemicals, i.e. chemicals which are not covered by specific legislations such as pesticides or pharmaceuticals. It is specifically identifying legislation allowing countries to prioritise chemicals for risk management, perform a risk assessment on priority chemicals and implement, if needed, risk reduction measures based on the outcome of the risk assessment.

Link: www.compareyourcountry.org/chemical-legislation
IUCLID is a software application designed to record, store, maintain and exchange data on the intrinsic and hazard properties of chemical substances or mixtures, as well as the uses of these substances and the associated exposure levels.

Link: https://iuclid6.echa.europa.eu/

The OECD Substitution and Alternatives Assessment Toolbox supports decision making for the substitution of chemicals of concern. It compiles resources relevant to chemical substitution and alternatives assessments.

Link: www.oecdsaatoolbox.org/

The Global Harmonised Submission Transport Standard (GHSTS) is a standardised set of technical specifications used to assemble electronic files for any pesticide package in a predefined manner. Microsoft Word and Excel, Adobe PDF, and XML data files are just some of the file types which can be transferred using the GHSTS according to business needs. Once the files are assembled according to the specifications, they can be transferred from a business entity to a regulatory authority.

Link: www.oecd.org/chemicalsafety/submission-transport-standard/

The OECD Harmonised Templates (OHTs) are standard data formats for reporting information used for the risk assessment of chemicals, mainly studies done on chemicals to determine their properties or effects on human health and the environment, but also for storing data on use and exposure. By using these templates, governments and industry are easily able to electronically exchange test study summary information.

Link: www.oecd.org/ehs/templates/

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International Uniform Chemical Information Database (IUCLID)

Harmonised templates for reporting chemical test summaries

Globally Harmonised Submission Transport Standard (GHSTS)
Adverse Outcome Pathways to evaluate chemicals for adverse effects

The eAOP Portal is the main entry point of the AOP Knowledge Base. As a search engine, the Portal enables search by key words in AOP titles and key events in the AOP Wiki and Effectopedia platforms.

Link: https://aopkb.oecd.org/

The AOP Wiki provides a system that organises, via crowd-sourcing, the available knowledge and published research into a verbal description of individual pathways, using a user friendly Wiki interface.

Link: https://aopwiki.org/

Resource Centre for Release Estimation Techniques

This online centre is a web-based clearinghouse of guidance manuals and other documents. It provides information on available release estimation techniques, overarching documents and general information among OECD countries for estimating releases from various sources.

Link: www.prtr-rc.fi/

PRTR.net

This website provides a global portal to Pollutant Release and Transfer Registers (PRTR) information and activities from countries and organisations around the world. The website aims to assist countries in the development, implementation and improvement of PRTR programmes.

Link: www.prtr.net/

Centre for PRTRs

The Centre for PRTR Data presents national PRTR data from OECD countries at one Internet location. The purpose is to include PRTR data from as many OECD countries as practicable and feasible on a national or regional level, but does not include PRTR data of individual sites of facilities. Users can create a report of PRTR data according to years, countries, regions, industry sectors, chemicals, types of release sources, and types of releases and transfers.

Link: www.oecd.org/env_prtr_data/
More information on OECD work on chemical safety and biosafety

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