

**OECD WORK ON**  
CHEMICAL SAFETY  
AND BIOSAFETY



2019-20



OECD WORK ON

# Chemical Safety and Biosafety

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“A healthy economy needs a healthy environment. In line with its mission to promote sustainable economic growth and raise living standards, the OECD promotes better integration of environmental concerns into economic and sectorial policies.”

**Angel Gurría**, OECD Secretary-General

# Contents

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<b>The Organisation for Economic Co-operation and Development</b>	<b>2</b>
<b>1. OECD work on chemical safety and biosafety</b>	<b>8</b>
History	8
Working together to tackle chemical management issues	9
<b>2. International strategies agreements that reflect OECD chemical safety work</b>	<b>10</b>
International strategies and agreements	10
Chemical safety, a prerequisite for meeting the UN Sustainable Development Goals (SDGs)	10
OECD legal instruments	11
Mutual Acceptance of Data (MAD)	12
Helping non-OECD economies establish safe chemicals management systems	13
SAICM: A key international strategy on chemical safety	14
<b>3. Common policies and high-quality instruments for chemical safety</b>	<b>16</b>
Testing: developing international testing and quality standards	16
Risk assessment: increasing global assessments of chemicals	18
New methodologies: working towards regulatory use	22
<b>4. Safety of manufactured nanomaterials</b>	<b>28</b>
<b>5. Improving the safety of pesticides and biocides</b>	<b>30</b>
Agricultural pesticides	30
Biocides	31
<b>6. Preventing and responding to chemical accidents</b>	<b>32</b>
<b>7. Communicating chemical emission information through PRTRs</b>	<b>34</b>
<b>8. Reaching consensus on biosafety and food safety</b>	<b>36</b>
<b>9. OECD tools available for your use</b>	<b>38</b>

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# The Organisation for Economic Co-operation and Development

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## What is the OECD?

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The OECD, which traces its roots to the Marshall Plan, groups 36 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

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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).



## Member countries



LITHUANIA



IRELAND



ESTONIA



AUSTRIA



AUSTRALIA



BELGIUM



COLOMBIA



COSTA RICA



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

## Candidates for accession

## Key partners



BRAZIL



INDIA



INDONESIA



PEOPLE'S REPUBLIC  
OF CHINA



SOUTH AFRICA

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# OECD and the environment

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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

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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 45 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**

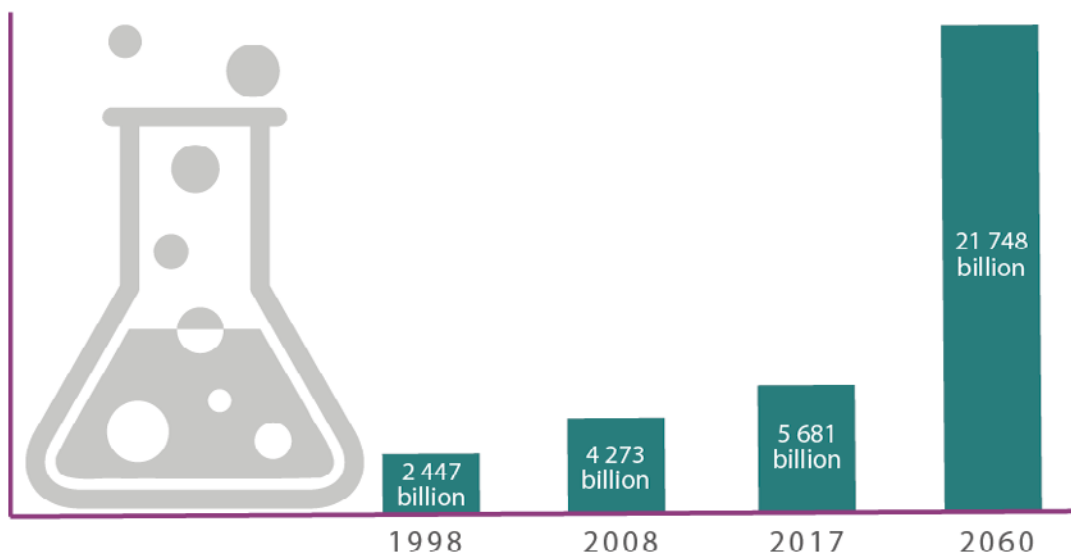


**CONSUMER CARE PRODUCTS**

## DID YOU KNOW?

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 24 000 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

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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 new products, such as nanomaterials 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 place 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](http://www.iomc.info)) towards the implementation of the Strategic Approach to International Chemicals Management (SAICM, [www.saicm.org](http://www.saicm.org)) which bring together governments from more than 150 countries and various stakeholders.

# 1

## 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 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.*

### 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.

This led 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.



## Working together to tackle chemical management issues

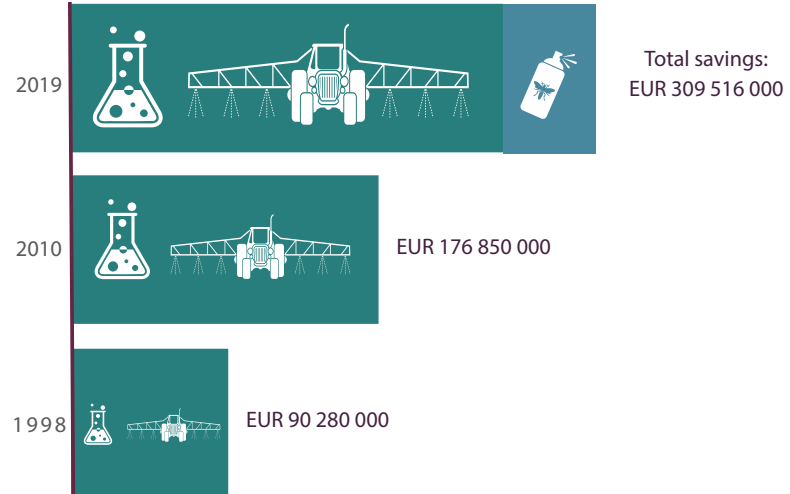
OECD governments regulate chemicals based on a system of testing to identify hazards, determining exposure and assessing risks. This system requires chemical manufacturers to carry out a battery of tests in order to determine how individual chemicals might affect human health and the environment. Governments 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:

<https://oe.cd/chemical-safety>

Annual savings to governments and industry from the OECD's Chemical Safety Programme in 1998, 2010 and 2019



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.

# 2 International strategies and agreements that reflect OECD chemical safety work

*Many important international strategies and agreements take into account OECD work on chemical safety.*

## International strategies and agreements

2015

The Sustainable Development Goals, adopted by the United Nations.

2006

Strategic Approach to International Chemicals Management, adopted by the International Conference on Chemicals Management (ICCM) in Dubai.

2002

Paragraph 23 of the Johannesburg Plan of Implementation, adopted at the World Summit on Sustainable Development.

2001

The OECD Environmental Strategy for the First Decade of the 21st Century, adopted by OECD Environmental Ministers.

1992

Chapters 19 and 20 of the UNCED's Agenda 21 adopted in Rio de Janeiro.

## 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:

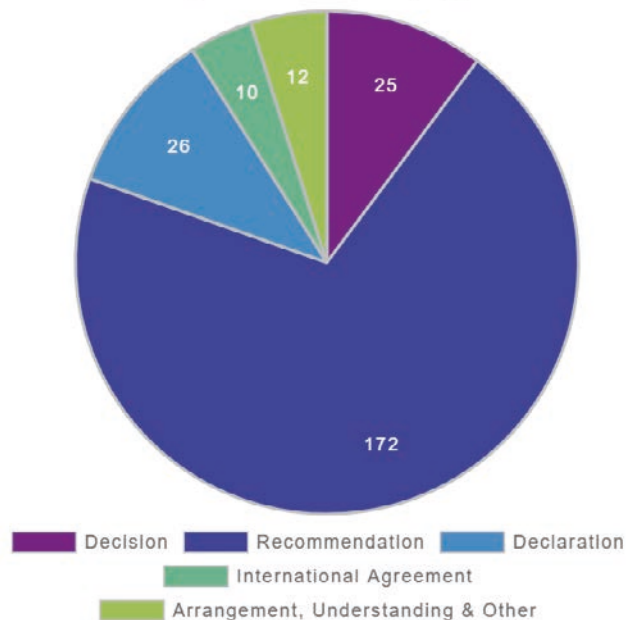
- Declarations, arrangements and understandings, which are not legally binding, but their application is generally monitored by the responsible OECD body.
- International Agreements which are legally binding on the parties.

A number of OECD Council acts in force are related to chemicals management and cover areas as diverse as chemical accidents, exchange of confidential data on chemicals or the Polluter-Pays Principle: 11 legally-binding OECD Council Decisions, 15 Council Recommendations and 3 other Legal Instruments.

### Did you know?

A large number of OECD legal instruments are dedicated to chemical safety.  
<https://oe.cd/council-acts-chemicals>

Legal Instruments by Type





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## Mutual Acceptance of Data (MAD)

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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 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.

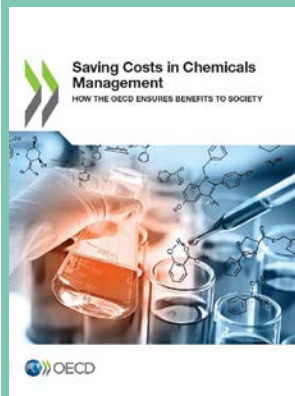
Together, these Council Decisions mean that new non-clinical environment, health and safety data for notification or registration of a chemical have to be developed only once by industry and can then be used for regulatory purposes across OECD countries and non-OECD countries which adhere to the system.

### Did you know?

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.”

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:** <https://oe.cd/chemicals-costs>

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## Helping non-OECD economies establish safe chemicals management systems

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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, India, the Russian Federation, and the People's Republic of China is rapidly increasing. The *"OECD Environmental Outlook to 2050"* 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 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.

1997

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.

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).

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.

2017

The OECD establishes 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 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 developed in the OECD are being made as accessible and useful to non-members as much 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. The OECD actively participates in discussions on the future of the sound management of chemicals and waste and SAICM beyond 2020.

**Key link:**

[www.saicm.org](http://www.saicm.org) | [www.oecd.org/env/ehs/development-cooperation-sound-management-chemicals.htm](http://www.oecd.org/env/ehs/development-cooperation-sound-management-chemicals.htm)



# 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. 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) as well as to update Test Guidelines to ensure that they can be used to test for the properties of manufactured nanomaterials.

During their development, draft Test Guidelines 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.

**Key link:** <https://oe.cd/test-guidelines>





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## Good Laboratory Practice

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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:** <https://oe.cd/glp>

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.



## Risk assessment: increasing global assessments of chemicals

### Harmonising assessment methods

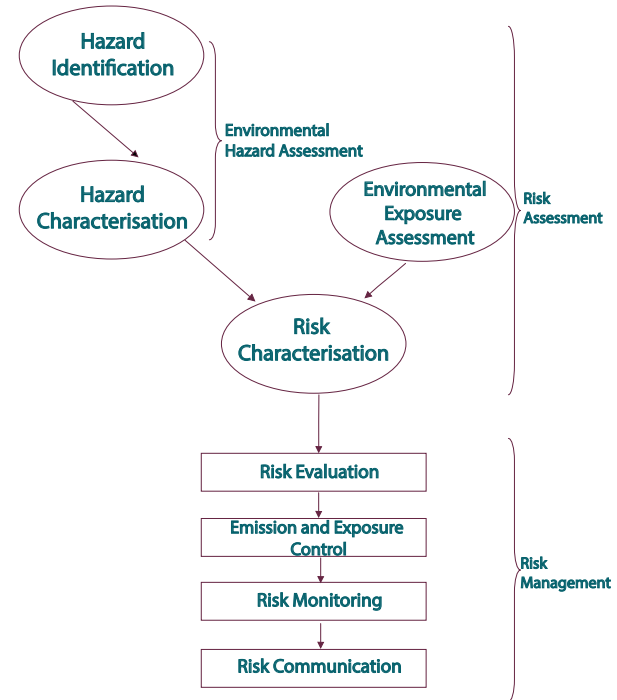
In simple terms, risk to human health and the environment posed by chemicals is determined by the equation: “hazard” (chemical-specific properties that lead to harmful effects) x “exposure” to chemicals (amount of human intake or environmental concentration).

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 is developing a decision scheme to serve as a basis for determining the need for a child-specific exposure assessment. Furthermore, the OECD is developing tools to estimate the exposure of children through mouthing of objects.



## Hazard assessment

In order to meet the 2020 goals for the 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 and specific approaches, for example, for metals risk assessment.

**Key link:** <https://oe.cd/hazard-assessment>

## 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:



eChemPortal

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 review programmes. Classification results as well as exposure and use information are provided.

**Key link:** <https://oe.cd/echemportal>

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## Management: reducing chemical risks

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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 per and polyfluoroalkyl substances 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 UN Environment to engage 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 and to bring together information on global progress.

Watch the OECD webinars on Per and Polyfluoroalkyl substances on our Youtube channel



The OECD Per- and Polyfluoroalkyl Substances (PFASs) 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.

**Key link:** <https://oe.cd/pfass>

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## Alternatives assessment, substitution and innovation towards sustainable chemistry

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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.

### Design of Sustainable Plastics from a Chemicals Perspective



The OECD Global Forum was held on 29-31 May 2018 in Copenhagen, Denmark and sought to incentivise a shift in sustainable chemistry thinking at the product design stage by identifying good practices, including tools and approaches, as well as a policy framework to reduce the environmental and health plastics impacts.

**Key link:** <https://oe.cd/plastics-forum>

### Did you know?

The OECD was awarded the Silver Award in the research category at the **2018 Global Chemical Leasing Award** for its report on the *Economic Features of Chemical Leasing*.

### The Economic Features of Chemical Leasing



This report presents a review of the literature on the economic features of the chemical leasing, a service-orientated business model that intends to shift the focus from increasing the sales volume of chemicals towards an innovative and functional-based approach, leading to a more efficient use of chemicals. It focuses on the drivers and barriers and comparing their functioning to traditional contracts, the economic impacts, and the challenges that might arise to its use and implementation.

**Key link:**

[www.oecd.org/env/ehs/risk-management/sustainablechemistry.htm](http://www.oecd.org/env/ehs/risk-management/sustainablechemistry.htm)



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## 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.

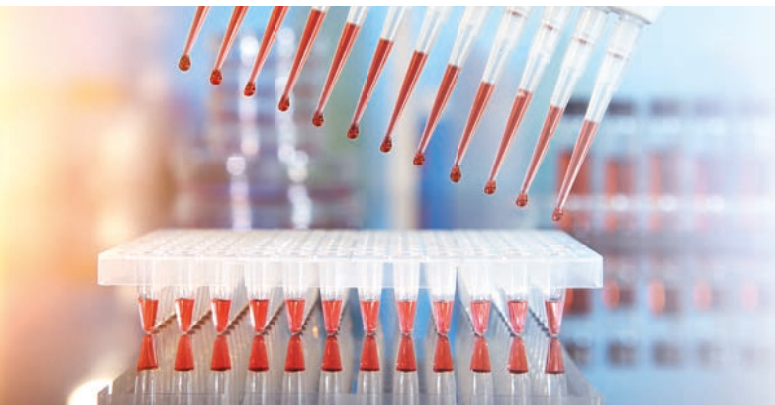
### Non-animal testing

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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 group alternative test methods and provide guidance for their rationale use. A long-term goal is to reach agreement among countries on defined replacement methods to avoid or strongly reduce animal testing.



## (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.



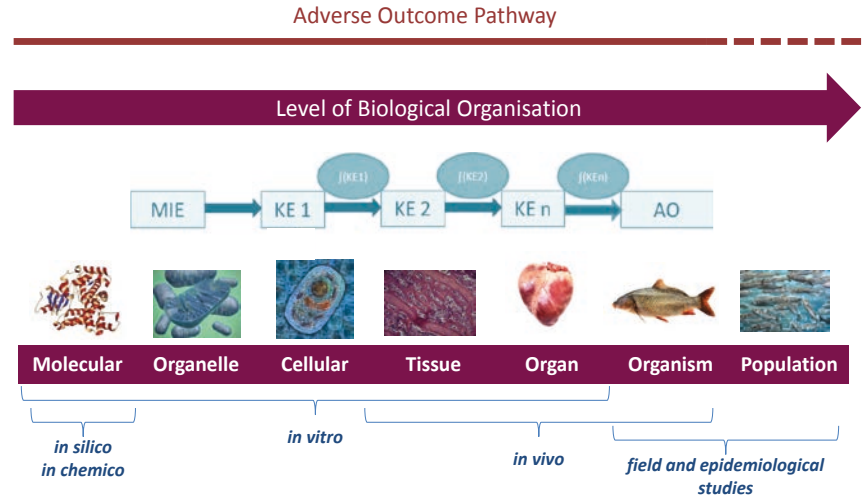
### Key link:

<https://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 add intelligence to existing knowledge of toxicity pathways and 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 integrated approaches for testing and assessment
- 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.

**Key link:** <https://oe.cd/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.



Effectopedia is an open-knowledge and structured platform able to display information on Adverse Outcome Pathways. It uses visually expressed modular structures to capture semantically annotated knowledge and algorithms together with all the supporting evidence.

### Key links:

<https://aopkb.oecd.org>

<https://aopwiki.org>

<https://www.effectopedia.org>

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## Common (electronic) formats

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The formats used by companies and governments to report summary results of chemical tests vary widely, making it difficult for governments to share this information.

As a result, for every Test Guideline, the OECD has developed a corresponding “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 links:

<http://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:** <https://oe.cd/it-tools>





# 4 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 100,000nm 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 many commercial applications ranging from lotions, creams and shampoos in the cosmetics sector to self-cleaning glass, tyres or fabrics.

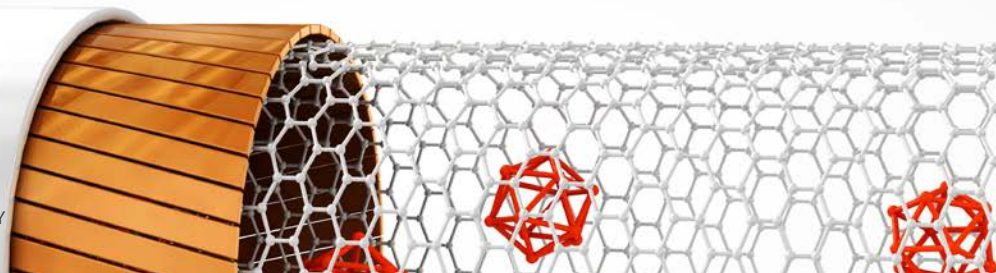
## New safety issues

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?

The OECD works on the implications of the manufacture and use of nanomaterials for the safety of human health and the environment, adapting traditional testing and assessment methods used to determine the safety of traditional chemicals to nanomaterials.

### Key link:

<https://oe.cd/nanosafety>



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 be 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.

## Key publication on nanomaterials:



*Nanotechnology and Tyres: Greening Industry and Transport* considers the development of an environmental and health risk management framework for nano-enabled tyres in the context of life-cycle assessment.

**Link:**  
<https://oe.cd/nano-tyres>

# 5

## Improving the safety of pesticides and biocides

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 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.





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.

## 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:

<https://oe.cd/pesticides-biocides>

### 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.

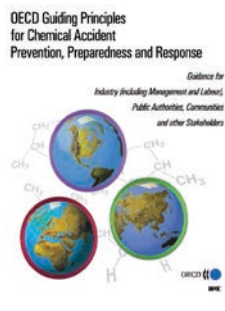
### Link:

<https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0446>

# 6

## Preventing and responding to chemical accidents

For more than two decades, the 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 helps countries not only to prevent chemical accidents but also to respond in an appropriate manner if one occurs. The OECD has published three policy guidance documents on this topic:



The OECD *Guiding Principles for Chemical Accident Prevention, Preparedness and Response* which describes 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 *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.

Corporate Governance for Process Safety  
Guidance for Senior Leaders in High Hazard Industries



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 those at the top of industry to the need for high corporate governance standards in relation to the management of high hazard industries.

### Key link:

<https://oe.cd/chemical-accidents>



The OECD 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-UNECE 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 publication:



*The OECD Guidance on Change of Ownership in Hazardous Facilities* is a concise document providing 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.

**Link:**

<https://oe.cd/guidance-on-change-of-ownership>

# 7 Communicating chemical emission information through Pollutant Release and Transfer Registers (PRTs)

*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.

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 a PRTR across countries.


## Key publication:

Guidance Document on Elements of a PRTR

Part I <https://oe.cd/GD-prtr-part1>

Part II <https://oe.cd/GD-prtr-part2>





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](http://www.oecd.org/env/prtr_data)

Resource Centre for release  
Estimation Techniques:  
<http://www.prtr-rc.fi>

PRTR.net:  
<http://www.prtr.net>

# 8

## Reaching consensus on biosafety and food safety

*The OECD runs 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.*

Both programmes 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 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.

### Type of organism:



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 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 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 80 consensus documents are now available.



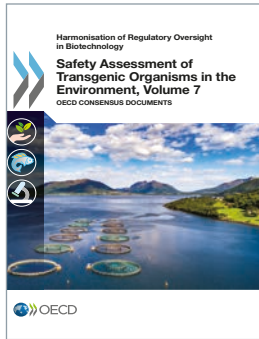
## Publication scheduled for 2019:

*Safety Assessment of Foods and Feeds Derived from Transgenic Crops, Volume 3: common bean, cowpea, rice, apple*



For the first time, the OECD addressed the biology of genetically-engineered **animal species**. Two consensus documents on the biology of Atlantic Salmon and mosquito *Aedes aegypti* were published.

### Volume 7



This volume covers the biology of two major crops: tomato and sorghum (centres of origin, genetics, hybridisation, production, uses, ecology) and an animal species: Atlantic salmon (ecology, rearing and genetics for 'wild' and 'farmed' forms). This publication compiles science-based information to the risk/safety assessment of transgenic organisms intended for release in the environment.

### Volume 8



This volume deals with the biology of an insect, the mosquito *Aedes aegypti* (taxonomy, morphology, life cycle, reproductive biology, genetics, ecology, interactions with other species and the environment). This publication provides science-based key insights for biosafety assessments aiming to fight against disease outbreak (yellow fever, dengue, Zika and Chikungunya).

### Key links:

<https://oe.cd/biosafety>  
[www.oecd.org/environment/genome-editing-agriculture/](http://www.oecd.org/environment/genome-editing-agriculture/)

# 9

## These OECD tools are immediately available for your use

### eChemPortal



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.

Link: <https://oe.cd/echemportal>

### BioTrack Online



Provides ready access to food/feed/environmental 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

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

### 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.

Link: [www.oecd.org/env/hazard/qsar](http://www.oecd.org/env/hazard/qsar)

### 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: <https://oe.cd/erat>

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## IOMC Toolbox for decision making in chemicals management

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The IOMC Toolbox for Decision-Making in Chemicals Management, soon available in English, 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 seven 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 and a public health management scheme of chemicals. Countries will find different options proposed, according to their level of available resources (low, medium, high), for setting up or improving their chemical management scheme and all the related guidance documents and tools available for each implementation step.

Link: <https://iomctoolbox.oecd.org>



# More information on OECD work on chemical safety and biosafety

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