

How the OECD Ensures Benefits to Society

HIGHLIGHTS

The chemical industry is one of the world's largest industrial sectors, with sales worth USD 5 681 billion in 2017. It includes producers of industrial chemicals, polymers, pharmaceuticals pesticides, biocides, food and feed additives, and cosmetics. The industry is expected to grow to almost USD 22 000 billion by 2060.

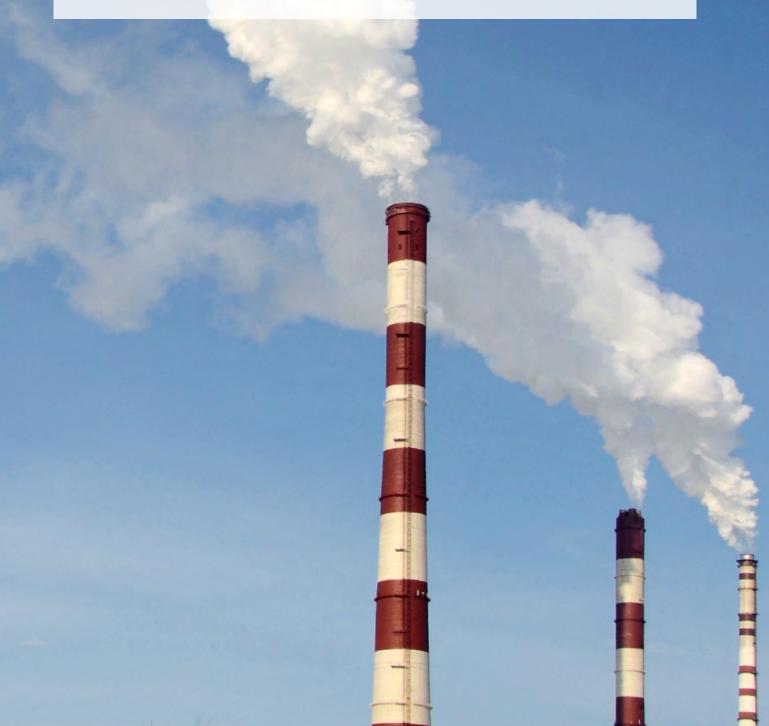
While chemicals provide vital benefits to our societies and economies, they can also be damaging to human health and the environment. Therefore, governments and the chemical industry have a major responsibility to ensure that chemicals are produced and used as safely as possible.

Governments regulate chemicals based on a system of testing to identify hazards, determine exposure and assess risks. This system requires chemical manufacturers to carry out a battery of tests – often on animals – on the health and environmental effects of their products. Companies submit their test data to governments, so that they can assess whether the chemicals are safe before they can be placed on the market. This framework, while rigorous and comprehensive, is very resource-intensive and time-consuming for both parties. As many countries are struggling with stretched public finances, governments need cost-effective policies for regulating chemicals.

The OECD Environmental, Health and Safety (EHS) Programme was set up for governments to cooperate to develop and implement high-quality chemicals management policies and instruments. In so doing, the work reduces barriers to trade, optimises the use of their resources, and saves governments and industry time and money for testing and assessing the safety of biocides, industrial chemicals, pesticides, biotechnology and nanotechnology products. The programme achieves these goals through harmonisation, burden sharing and exchange of technical and policy information.



The report *Saving Costs in Chemicals Management* (OECD, 2019), the third in a series of reports examining 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. These net savings have grown by 75% since the last report (2010) and by over 240% since the initial report (1998). The current report also describes the programme's equally important non-quantifiable benefits. This brochure highlights some of the report's key findings.



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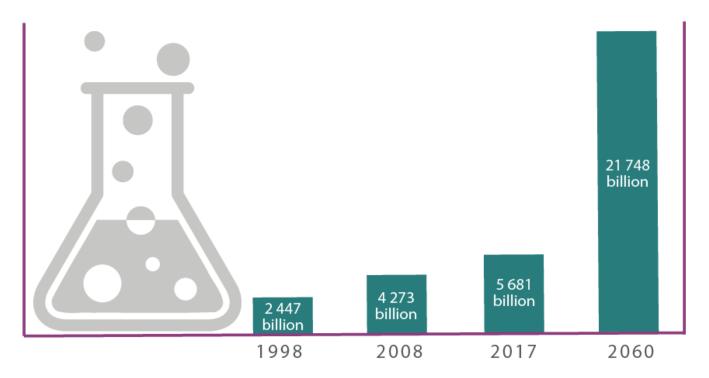
The chemical industry at a glance

Every manmade material is made of, or contains, one or more of the thousands of chemicals produced by the industry each year. It is a very diverse industry comprising:



The chemical industry is one of the largest in the world, and has grown in value more than ten-fold over the past 40 years, from approximately USD 520 billion in 1978 to USD 5 681 billion in 2017. This number is projected to reach USD 21 700 billion by 2060.

Figure 1. Annual global sales of the chemical industry and OECD projections for 2060 (USD)



Sources: ACC (2018), 2017 Guide to the Business of Chemistry; OECD (2019), Global Materials Resources Outlook to 2060: Economic Drivers and Environmental Consequences, www.oecd.org/publications/global-material-resources-outlook-to-2060-9789264307452-en.htm

Chemicals can improve people's health and enhance well-being for example by improving energy efficiency, treating diseases and increasing crop yields. But they can also potentially have a negative impact on human health and the environment.

Although the impacts are complex and sometimes open to debate, some deleterious effects are well documented, such as those toxic chemicals that persist in the environment and accumulate in wildlife (e.g. DDT and PCBs), and chemicals that affect human reproduction and development.

As OECD countries account for over 42% of the world's production of chemicals, their governments and industry have a very important role to play in chemicals management.

How governments work together to tackle the risks posed by chemicals?

Today, OECD governments have comprehensive regulatory frameworks for preventing and/or minimising the health and environmental risks posed by chemicals. Indeed, the chemical industry is one of the most regulated of all industries. Such a framework, while rigorous, is very resource-intensive and time-consuming for both governments and industry. Moreover, as many chemicals are produced in more than one OECD country (or are traded across countries), different national chemical control policies can lead to duplication in testing and government assessment, thereby wasting the resources of industry and governments alike.

In order to make the process of testing and evaluating chemicals as efficient and cost effective as possible for governments and industry while maintaining a high level of health and environmental protection, OECD countries agree on overall policies, develop harmonised instruments for their implementation, and participate in work-sharing.

The OECD Environment Health and Safety (EHS) Programme was set up to help OECD governments reduce barriers to trade, optimise the use of their resources, and save governments and industry time and money by co-operating to test and assess the safety of biocides, industrial chemicals, pesticides, biotechnology and nanotechnology products.



The EHS programme achieves these goals through a number of activities as described below.





The EHS Programme provides a forum to exchange technical and policy information. This creates greater confidence in, and acceptance of, each other's approaches, which fosters more efficient, effective and more closely harmonised national chemicals management programmes. In addition, governments have access to the experience of the many scientific and policy experts from other governments, industry and academia who participate in the work of the EHS Programme.

As many large commodity chemicals are produced in multiple countries, there are great opportunities for OECD countries to work together on risk assessments. Further, companies that produce and market these chemicals in several countries can reduce their costs when they are assessed by multiple countries. By using common risk assessment methodologies and pooling resources, OECD countries can work together to ensure the safe use of chemicals.



HARMONISATION

The principal tools for harmonisation are a set of OECD Council Decisions that make up the OECD Mutual Acceptance of Data (MAD) system. In endorsing these acts, OECD countries – and nonmembers who adhere to the system – have agreed that a safety test carried out in accordance with the OECD Test Guidelines and OECD Principles of Good Laboratory Practice in one OECD or adherent country must be accepted by other participating countries for assessment purposes. This saves the chemical industry the expense of duplicating testing for products that are marketed in more than one country.

In addition, the MAD system significantly reduces the number of animals needed for testing, as fewer tests are carried out globally. The Test Guidelines and GLP Principles are continuously expanded and updated to



To address the rapid expansion of the chemical industry in non-member economies, the EHS Programme has a proactive outreach strategy encouraging the participation of non-member countries in its work. It is one of the leading international programmes in the field and its products are used widely by non-member countries. This co-operation contributes to ensure that new national chemical management systems do not lead to duplicative testing and assessments or to new trade barriers.

DID YOU KNOW?

ensure they are state-of-the-art.

In 2008, the OECD Council adopted a Resolution on the Implementation of the UN Strategic Approach to International Chemicals Management, which called for countries to work together through the OECD to ensure that, as chemicals management programmes are established or upgraded, OECD products will be accessible, relevant and useful to non-member countries to help them develop their capacity to manage chemicals.

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Saving time, money and animal lives

As regulators face tighter budgets and chemical companies cut costs to remain competitive, governments increasingly count on the OECD's chemical policies and instruments to ensure that products are safe in the most cost-effective way.

One of the principal values of the EHS Programme is that it helps to reduce duplication of work for industry and governments. Thanks to MAD, a test conducted on a chemical in one country must be accepted by all 36 OECD countries as well as the 6 non-member countries that adhere to MAD. Participation in the MAD system requires that testing be carried out following OECD standards for testing and data quality. Governments participating in the MAD system have confidence that chemical safety test data generated in other countries is of high quality and can be used for regulatory assessments, thus reducing duplicative testing, saving laboratory costs, promoting worksharing by countries that assess the same data and removing potential non-tariff trade barriers.

In addition, companies save money by using OECD harmonised dossiers formats for pesticide registrations. Once a company compiles a dossier for one country, the cost and time involved in developing dossiers for other countries will be significantly reduced. Similarly, by using OECD harmonised pesticide review formats, governments can share information that allows for joint reviews of the same pesticides.



DID YOU KNOW?

- Testing one new pesticide costs a company about EUR 22 million. Without the OECD MAD system, this testing might have to be repeated in every country in which the pesticide is sold. But thanks to MAD, about EUR 207 million is saved every year as a result of reduced duplicative testing.
- Reviewing a full industry dossier on a new pesticide and writing a comprehensive report (monograph) costs a government 1.95 person-years. Using another country's monograph based on the OECD monograph format saves 1.02 full person-years of time (i.e. 52%).

36 OECD member countries



6 non-member adherents to MAD















Further, the OECD guidance on the use of (Quantitative Structured Activity Relationship models, or (Q)SARs, reduces the need for animal testing to generate information on industrial chemicals. (Q)SARs are mathematical approaches designed to find relationships between chemical structures (or structure-related properties) and biological activity (or target property) of the studies compounds.

In order to quantify the savings that result from the work of the EHS Programme, data were collected via surveys of OECD governments and industry. Additional data were collected from OECD databases and relevant reports in the literature.

The net financial savings brought by the programme for harmonising the testing and assessment of new biocides, new and existing industrial chemicals, and pesticides, are estimated to be more than EUR 309 million annually. (The OECD Secretariat costs and costs to delegates of participating in, and contributing to, the work of the EHS Programme have been deducted from the savings.)

In addition to saving time and money for governments and industry, the MAD system saves at least 30 000 animal lives every year, as testing does not have to be repeated. Furthermore, predictive models such as (Q)SAR and read-across allow for grouping chemicals into categories and filling data gaps, which also reduces the number of animals used for testing.

Savings	
From no repeat pesticide testing	EUR 206 937 500
From no repeat new industrial chemical testing	EUR 44 728 943
From no repeat biocide testing	EUR 61 250 000
From no repeat existing chemical testing	EUR 780 570
From harmonised pesticide monographs	EUR 2 218 145
From harmonised pesticide dossiers	EUR 1 951 125
Savings subtotal (rounded)	EUR 317 870 000
Costs	
Country participation in the EHS Programme	EUR 4 290 000
OECD Secretariat	EUR 4 545 000
Costs subtotal (rounded)	EUR 8 835 000

Reduction in animals needed for testing new industrial chemicals 32 702

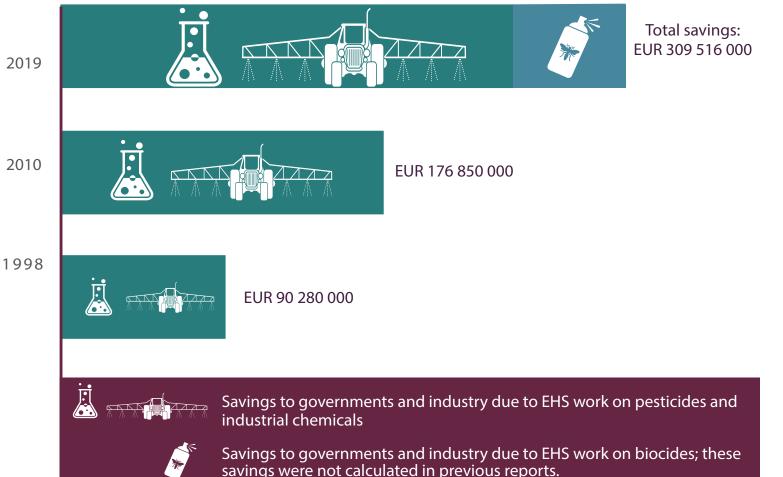
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Generating a substantial increase in savings over time

Saving Costs in Chemicals Management is the third in a series of three reports that examine the costs and benefits of the OECD's EHS Programme.

The savings estimated in this report have grown by 75% since 2010 and by 240% since 1998. And there is strength in numbers: the OECD's membership has grown from 30 member countries in 2010 to 36 today. The more countries that participate in the EHS Programme, the greater the savings will be.

Figure 2. Annual savings to governments and industry from the EHS Programme in 1998, 2010 and 2019



Note: Figures have been adjusted for inflation.

Qualitative benefits to governments and industry

Some activities within the EHS Programme can currently only be described in qualitative terms, either because the benefits are not easy to measure in direct monetary gains, or because the activities have not been implemented for a sufficient length of time to gauge their impact. However, these qualitative benefits are no less real, less likely to occur or less important than the quantifiable benefits.



Safer nanomaterials due to harmonised tools for testing and assessment, generating savings to governments and industry. In 2013, the OECD adopted a Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials. An important consequence of this Recommendation is that much of the data collected as part of the safety assessment of nanomaterials will fall within the scope of the MAD system.

Exchange of information on chemical accidents to identify methods for prevention, preparedness and response

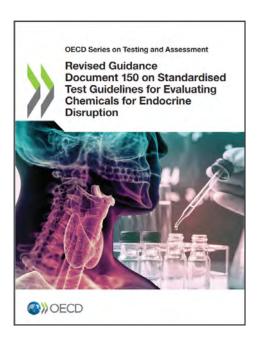
The EHS' Chemical Accidents Programme has developed some of the EHS Programme's most widely used documents, including the OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response. The Programme ensures cost savings across countries by avoiding duplication of efforts to identify adequate methods for prevention, preparedness and response, and thus by reducing economic losses caused by chemical accidents.



Harmonisation of the safety assessment methodologies for products of modern biotechnology

A considerable portion of the cost of product approval involves environmental risk (biosafety) assessments. Since the environmental information required is largely the same in every country, national authorities and experts involved in the EHS Programme develop Consensus Documents that contain common technical elements for use during the regulatory assessment of products of modern biotechnology. To date, these OECD consensus documents constitute official reference tools in risk and safety assessment of the regulatory systems of many economies worldwide.





Harmonised tools to identify the risks of endocrine disrupters

Endocrine disrupters are chemicals that interfere with the body's endocrine system and produce adverse effects such as developmental, reproductive, neurological and immune effects in humans or wildlife. The OECD has developed 35 Test Guidelines for evaluating chemicals for endocrine disruption, in addition to publishing the first comprehensive, international guide for identifying endocrine disrupting chemicals in 2012 (updated in 2018).

OECD Harmonised Templates for reporting information used for the risk assessment of chemicals

Countries increasingly implement the OECD Harmonised Templates in their IT systems, reducing the costs of preparing different data sets for different national/regional regulatory assessment schemes.



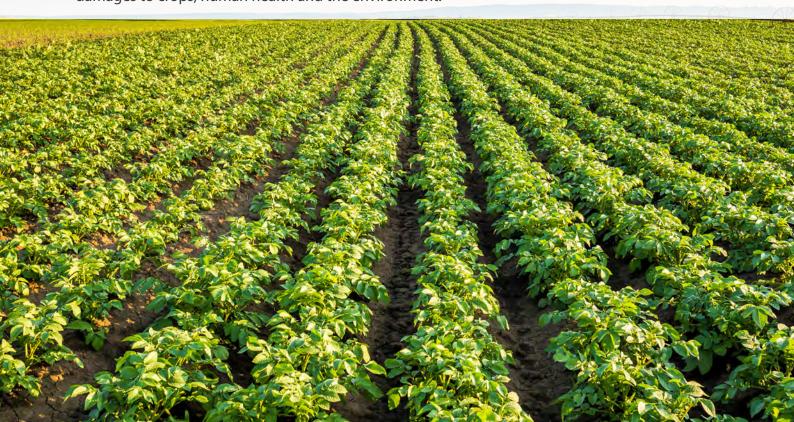
Reduced need for national government inspections of chemical test facilities in other countries

In the past, if a government that relied on critical health and safety test data generated in another country had concerns about the quality of that data, it would have to travel to the other country to conduct an inspection of the test facility that produced the data, or conduct a study audit to verify the quality of the data. Thanks to the MAD system, a government can request that the other country conduct an inspection of a test facility or a study audit of the test facilities. This significantly reduces travel costs for the requesting country.



Counteracting the illegal trade of pesticides and thus reducing the chance that unregulated, unsafe and ineffective products are used on crops

Costs for introducing a new pesticide to the market are substantial; production costs are, however, relatively low. This creates opportunities for illegal traders to try to introduce cheaper, untested and possibly dangerous illegal products onto the market. The OECD Rapid Alert System allows regulators to exchange information on suspicious or rejected shipments of pesticides, thereby reducing the risk of illegal pesticides entering the market. This helps prevent possible damages to crops, human health and the environment.

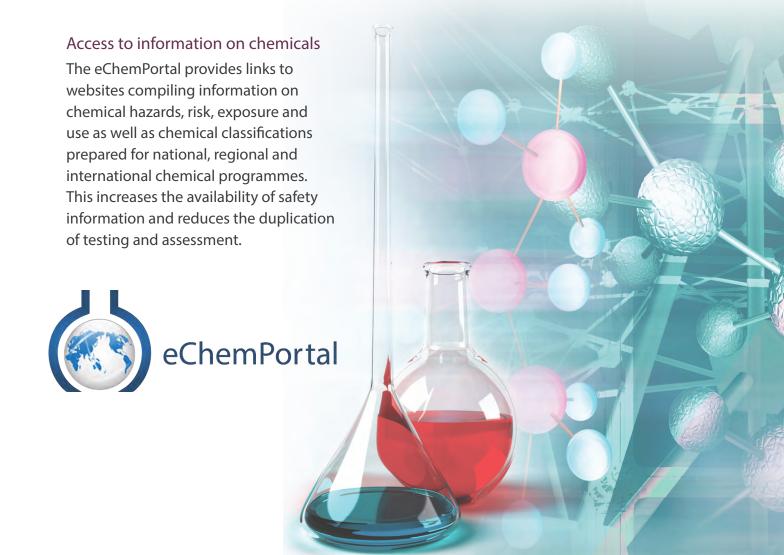




Harmonisation of biocides regulations and testings

As there is a wide variety of applications for biocides, estimating potential releases of these products can be very complex.

The OECD has developed a number of Emission Scenario Documents on biocides, including on insecticides, anti-fouling products and wood preservatives. This reduces the need for any one government to develop such documents independently, and promotes the harmonisation of release estimations across regulatory agencies.



Saving Costs in Chemicals Management

How the OECD Ensures Benefits to Society

READ THE FULL REPORT

oe.cd/chemicals-costs

OECD WORK ON CHEMICAL SAFETY AND BIOSAFETY

oe.cd/chemical-safety

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