

APPLY INTEGRATED APPROACHES TO TESTING AND ASSESSMENT

All of the work on alternative methods is undertaken at the OECD with the objective of contributing to more integrated approaches to testing and assessment. In practice, integrated approaches, which take into account the tools outlined above, are used in the OECD Existing Chemicals Programme which generates internationally agreed initial hazard assessments of chemicals.

This practical application of integrated approaches improves their regulatory acceptance and facilitates their implementation into national and regional chemical assessment schemes in OECD member countries.

AVOID DUPLICATION OF TESTING

The OECD **Mutual Acceptance of Data** (MAD) framework has had a major impact on testing practices. MAD guarantees that data generated in the testing of chemicals in an OECD member country, or adhering non-member country, in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other member or adhering countries for purposes of chemical assessment and other uses relating to the protection of man and the environment. This proactive framework saves thousands of animals every year and its impact increases as non-OECD economies join the MAD system.

Furthermore, the OECD has developed the **Global Portal to Information on Chemical Substances** (eChemPortal). eChemPortal offers free public access to information on properties of chemicals through a simultaneous search of multiple databases, thereby improving the access to existing test results and reducing the risk of unnecessary testing.

WHERE CAN I FIND OECD TOOLS RELATED TO CHEMICAL SAFETY AND ANIMAL WELFARE ?

(Q)SARs, Grouping of Chemicals and the (Q)SAR Application Toolbox

www.oecd.org/env/existingchemicals/qsar

Test Guidelines, *in vitro* test methods, molecular screening and toxicogenomics

www.oecd.org/env/testguidelines

Integrated Approaches to Testing and Assessment

www.oecd.org/env/existingchemicals

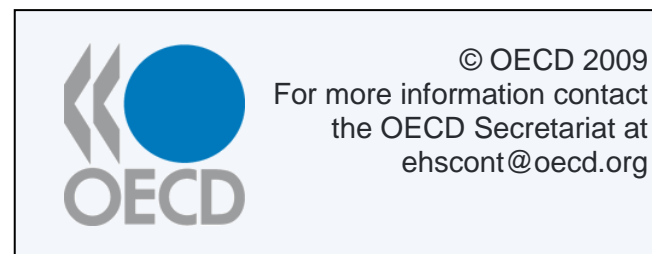
Mutual Acceptance of Data

www.oecd.org/env/glp

Global Portal to Information on Chemical Substances

www.oecd.org/ehs/eChemPortal

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Chemical Safety and Animal Welfare



Progress made at the OECD



www.oecd.org/env/ehs

COMMITMENT TO ANIMAL WELFARE

Over 25 years ago, an OECD High Level Meeting on Chemicals recognised the need to protect animals in general and in particular those used in testing for chemical safety. It addressed this ethical issue and adopted the following statement at that time:

"The welfare of laboratory animals is important; it will continue to be an important factor influencing the work in the OECD Chemicals Programme. The progress in OECD on the harmonisation of chemicals control, in particular the agreement on Mutual Acceptance of Data, by reducing duplicative testing, will do much to reduce the number of animals used in testing. Such testing cannot be eliminated at present, but every effort should be made to discover, develop and validate alternative testing systems".

In the meantime OECD has made major efforts to develop and implement tools which will reduce or replace animal testing in chemical safety.

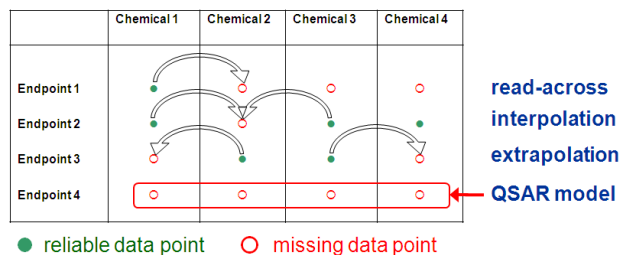
ESTIMATE PROPERTIES WITH (Q)SARs

(Quantitative) Structure Activity Relationships or (Q)SARs are used to estimate properties of a chemical based on its molecular structure and can thus provide information on potential hazards of chemicals without animal testing.

To facilitate practical application of (Q)SAR approaches in regulatory contexts by governments and industry, the OECD has adopted **principles for the validation of (Q)SAR models**. These principles provide member countries with the basis for evaluating the regulatory applicability of (Q)SAR models and thus contribute to their wider use.



ESTIMATE PROPERTIES FOR GROUPS OF CHEMICALS



The OECD has developed guidance for grouping chemicals into **chemical categories**, i.e. groups of chemicals whose (eco)toxicological properties are likely to be similar or follow a regular pattern because of their similar chemical structure. Using this approach, every chemical does not need to be tested for every endpoint (e.g. skin sensitization, mutagenicity etc), because the available test results for some chemicals in the category allow an estimation of the results for the untested chemicals by **read-across, interpolation or extrapolation**.

To facilitate the use of the category approach in filling data gaps, the OECD has developed a software application called the **(Q)SAR Application Toolbox**. This application allows users to systematically group chemicals into categories and fill data gaps without animal testing.

SCREEN LARGE NUMBERS OF CHEMICALS WITH MOLECULAR SCREENING ASSAYS AND TOXICOGENOMICS

In response to a need to increase health protection through testing more chemicals and for more endpoints, member countries are contributing to a new OECD project on **Molecular Screening**, which is based on the US ToxCast Program. The objective of this work is to develop large batteries of **high-throughput screening in vitro** assays (that can be applied rapidly to thousands of chemicals to identify those that need further evaluation), thereby limiting the number of chemicals subjected to animal testing.

Work is also underway on the use of **toxicogenomics** (the study of the response of a genome to hazardous chemicals) for ecotoxicity assessment, which will reduce unnecessary animal testing.



DEVELOP ALTERNATIVE TEST METHODS

OECD Test Guidelines have been validated and adopted for **in vitro test methods** for genotoxicity, skin corrosion, skin absorption, phototoxicity, ocular severe irritation and corrosion, as well as for screening potential endocrine disrupters (i.e. chemicals that affect the hormone system).

Many Test Guidelines for *in vivo* methods have been specifically **designed to reduce the number of animals** used, e.g. for oral and inhalation toxicity testing. To reduce the number of animals used in tests for reproductive toxicity, a draft *Test Guideline for an Extended One-Generation Reproductive Toxicity Study* has recently been developed and is close to adoption.

Furthermore, *in vivo* Test Guidelines request users to follow the provisions laid out in the OECD *Guidance Document on the Recognition, Assessment and Use of Clinical Signs as Humane Endpoints for Experimental Animals used in Safety Evaluations*.