OECD WORK ON

ENDOCRINE DISRUPTING CHEMICALS

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BETTER POLICIES FOR BETTER LIVES

OECD WORK ON

Endocrine disrupting chemicals

> 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


“The OECD has developed important testing tools, assessment methodologies and guidance for countries to use in their regulatory programmes when addressing the issue of endocrine disrupters. This work will be instrumental in Europe’s efforts to identify endocrine disrupters.”
Bjorn Hansen, ECHA Executive Director

Overview of OECD work on Environment

The Environment Directorate of the OECD 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;
- Environment, health and safety.

Key link:
www.oecd.org/env

THE ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

The Organisation for Economic Co-operation and Development (OECD) is a multi-disciplinary inter governmental organisation, tracing its roots back to the post-World War II Marshall Plan. Today, it comprises 35 member countries and the European Commission committed to democratic government and the market economy, with the major emerging economies increasingly engaged directly in the work. The OECD provides a unique forum and the analytical capacity to assist governments to compare and exchange policy experiences, and to identify and promote good practices through policy decisions and recommendations.

OECD
BETTER POLICIES FOR BETTER LIVES

1 Environment, Health and Safety Programme

The Environment, Health and Safety (EHS) Programme deals with the safe use of chemicals, nanomaterials, pesticides, biocides, and novel foods and feeds. It also addresses related areas of concern and interest, such as chemical accidents and Pollutant Release and Transfer Registers (PRTRs).

EHS 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 among OECD countries, a crucial step towards international harmonisation and reduction of trade barriers (see page 20).

Key link:
www.oecd.org/chemicalsafety

The OECD Test Guidelines Programme

Key projects within the Environment, Health and Safety Programme are the development of Test Guidelines and Guidance Documents.

Since its establishment, the OECD has been an international forum for sharing scientific information. In addition to expert discussion and scientific collaboration, OECD has fostered an institutional framework for developing test methods to be used to identify and characterise hazards of environmental chemicals.

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 groups and the animal welfare community.

OECD Guidelines for Testing of Chemicals are a collection of internationally accepted methods for assessing the safety of chemicals. These Guidelines are used by industry in product development and by regulators in the chemical registration process for determining safety of chemicals in commerce.

The OECD Test Guidelines are intended to harmonise safety testing methods across OECD countries to:

- Enhance the validity and international acceptance of test data;
- Make the best use of available resources in both governments and industry;
- Avoid the unnecessary use of laboratory animals;
- Minimise non-tariff trade barriers.

In response to an identified international need, OECD established special expert groups to adapt existing Guidelines and develop new Guidelines to evaluate endocrine disrupters.

Did you know?

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:
www.oecd.org/chemicalsafety/testing

2 Introduction to 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 human or wildlife.

A short history

The ability of both natural and synthetic chemicals to mimic the effects of hormones in humans and other vertebrates has been recognised for decades (Schueler, 1946, and Walker and Janney 1930). Synthetic steroids were used as ingredients in pharmaceuticals to deliberately alter reproductive cycles of livestock animals beginning around 1940.

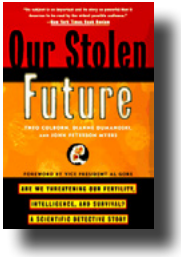
In the 1950s, endocrinologists began to measure the levels of hormones in human blood samples. Unusually high or low levels of these hormones were associated with altered endocrine function.

In the 1962 book, Silent Spring, Rachel Carson examined the effect of chemical pesticide spraying on wildlife. We now know that Dichlorodiphenyltrichloroethane (DDT), chemical discussed in the book, is an endocrine disrupter.

Cases of wildlife reproductive failure due to eggshell thinning in wild birds or sexual inversion in fish associated had been reported for decades in scientific literature.

Furthermore, decreased sperm quality and increasing trends of endocrine-related cancers in some industrialised countries in the last few decades have raised concerns that there may be links between environmental chemicals to which humans are exposed and such diseases.

In the 1990s, new attention was focused on endocrine disruption. The Wingspread Conference held in 1991 brought together experts from a variety of disciplines such as toxicology, ecology, immunology, psychiatry, and law to discuss the evidence on endocrine disrupters available at that time. The outcome of this conference was a consensus statement hypothesizing that environmental chemicals could be potentially detrimental to wildlife and humans by acting on endocrine systems.



Books, such as Our Stolen Future (Theo Colborn, Dianne Dumanoski and John Peterson Myers, 1996) by raised public and government awareness. Around the same time, reproductive failure in fish downstream from water treatment plants leading to population declines, and species of mollusks affected in coastal areas due to a particular chemical (i.e. tributyltin) contained in anti-fouling paints on boats were reported. In response, countries began to develop research programmes and methods for investigating the potential of chemicals in the environment to cause endocrine disruption.

References:

Schueler F.W. (1946), "Sex-hormonal action and chemical constitution" , *Science* , Vol. 103, Issue 2669, pp. 221-223.

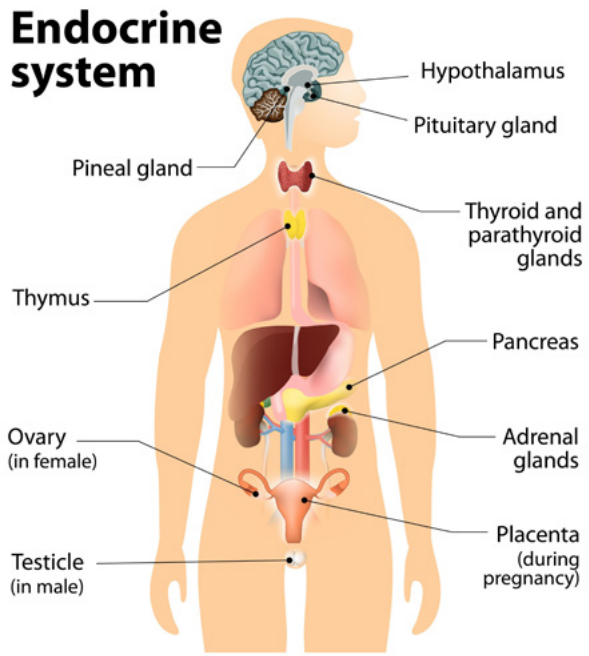
Walker B.S., and J.C. Janney (1930), Endocrinology, Oxford University Press.

Carson R. (1962), *Silent Spring*, Houghton Mifflin Company, Boston.

Theo Colborn, Dianne Dumanoski and John Peterson Myers, (1996) *Our Stolen Future: Are We Threatening Our Fertility, Intelligence, and Survival? A Scientific Detective Story, Dutton, New York.*

How do endocrine disrupters work?

An endocrine disrupter is a chemical that acts like the body's naturally occurring hormones or alters the ability of the body to synthesise, release, or eliminate hormones, and thus, disrupts the delicate balance of the endocrine system.



The nervous system (brain, spinal cord, sensory organs and nerves) exerts control on the body by directly connecting organs via nerves. In contrast, the endocrine system is considered the body's "second control system" and consists of a series of organs that synthesise and secrete hormones. The hormones act as chemical messengers and these chemicals, transported in blood and other body fluids, can signal any organ that has a receptor for that chemical messenger. Hormones and their receptors are often thought of as "locks" and "keys". The effect of hormones on their target organs is highly specific, and the same hormone binding to its receptor may have a very different effect depending on the organ and life stage.

Many organs can synthesise and release hormones, but the classical endocrine organs in the body are the brain, gonads (ovaries and testes), thyroid, pancreas, and adrenal glands. The endocrine system is biologically conserved, meaning most vertebrates and even some invertebrates have very similar hormones and receptors that serve similar functions in the organism, thought the action of endocrine disrupting chemicals can vary between species.

Certain chemicals are structurally similar to hormones and can bind to the receptor causing a similar effect or blocking the action of the natural hormone. Other chemicals can block the synthesis, degradation or the transport of the natural hormone to the receptor.

Possible sources of endocrine disrupting chemicals

Endocrine disrupting chemicals (EDCs) can be difficult to identify because they may produce effects that vary with chemical, species, and life stage.

Possible sources of Endocrine Disrupting Chemicals:
-Diet
-Environment
-Household and industrial products
-Pharmaceuticals

Susceptible life stages:
-Gestation and Lactation
-Early postnatal development
-Puberty
-Reproduction

Potential Mechanisms:
-Receptor interaction
-Altered hormone release
-Altered synthesis
-Altered clearance

How do endocrine disrupters affect humans and wildlife?

Research has established a link between some chemical exposures, effects on hormone levels, and altered physiological responses such as changes in growth, development, fertility, fecundity and lactation. In some cases, there may be a long timelapse between the chemical exposure and the manifestation of effects on the individual.

Examples of adverse effects on humans

Examples of adverse effects on wildlife

3 Chemical safety testing for endocrine disrupters

OECD's work on endocrine disrupting chemicals

Work on endocrine disrupting chemicals is part of the OECD's Environment, Health and Safety Division.

The OECD uses the 2002 World Health Organization (WHO) definition of an endocrine disrupting chemical. The WHO defines an endocrine disrupter as "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations". WHO also defines "a potential endocrine disrupter (as) an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub)populations."

The OECD is working to help countries identify the effects of endocrine disrupting chemicals. A multi-disciplinary team comprised of representatives from within the OECD and member countries experts with diverse specialties contribute to the development of harmonised methods to identify endocrine disrupting chemicals with the view to protect human health and the environment.
OECD member countries highlight issues, address challenges and find solutions for identifying endocrine disrupters by sharing knowledge and understanding, developing methodologies to test and evaluate chemicals, and thereby fostering a common approach.

Did you know?

Oestrogen, androgen, and thyroid hormone systems are highly conserved among vertebrates, meaning the production and effects of these hormones are similar between humans and wildlife.

Areas of work

Many of the early concerns about endocrine disruption were based on chemicals in the environment that could mimic the effects of oestrogen in humans and wildlife.

Based on knowledge and understanding of effects reported in scientific literature and the needs in OECD countries, the OECD has focused on the development of test methods for detecting perturbations of the oestrogen, androgen and thyroid hormone systems which are critical for growth, development, and reproduction in vertebrates.

- Oestrogens are a group of hormones, primarly produced in the ovaries; that are important for female sexual and reproductive development.
- Androgens are a group of hormones, primarly produced in the testes; that are important for male sexual and reproductive development.
- Thyroid hormones are produced in the thyroid gland and are important for regulation of metabolism and development of many organ system; particularly including brain development and function.

Expert groups on endocrine disrupting chemicals

The work on endocrine disrupters testing and assessment is overseen by the Working Group of National Coordinators of the Test Guidelines Programme (WNT). The National Coordinators nominate experts and scientists from research and regulatory sectors to work together to develop tools and guidance.

In addition, representatives from the Business and Industry Advisory Committee (BIAC), Environmental Non-Governmental Organisations, and the International Council on Animal Protection (ICAPO) in OECD Programmes provide input.

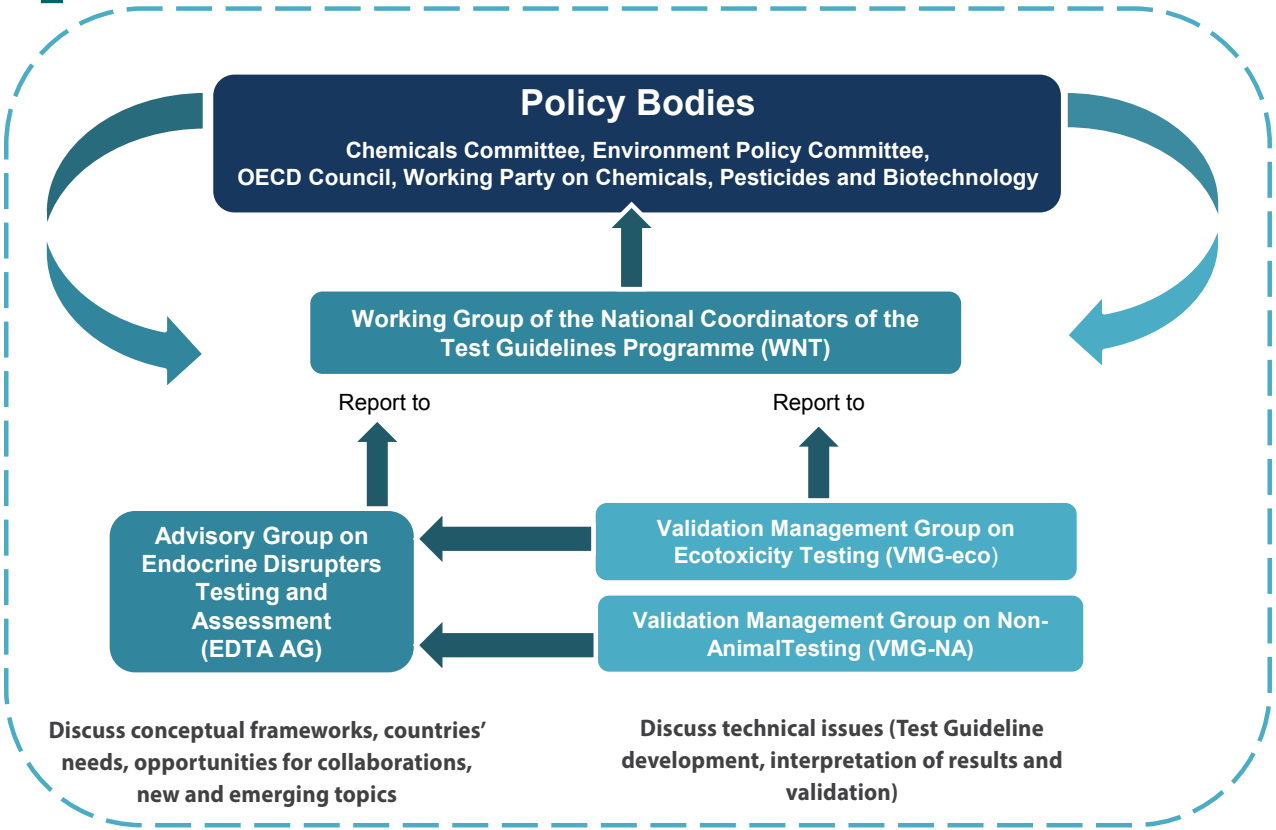
Currently, OECD work on endocrine disrupters is managed by three main expert groups:

- An advisory group on endocrine disrupters testing and assessment (EDTA AG);
- A validation management group on ecotoxicity testing (VMG-ECO);
- A validation management group on non-animal testing (VMG-NA).

Key link:

www.oecd.org/env/ehs/testing/oecdworkrelatedtoendocrinedisrupters.htm

4 Organisation of the work on endocrine disrupters

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5 OECD key achievements on endocrine disrupters

Testing chemicals for endocrine disruption

In 1996, an Advisory Group on Endocrine Disrupters Testing and Assessment (EDTA) was set up at the OECD to develop new or update existing OECD Test Guidelines to identify chemicals with endocrine disrupting properties. One of the most important outcomes of the Advisory Group's work on endocrine disruption is the Conceptual Framework for Testing and Assessment of Endocrine Disrupters consisting of information measured at different biological levels, ranging from biochemical, to organism and population.

The Conceptual Framework includes all available OECD test methods for evaluating chemicals for endocrine disruption. To identify a chemical as an endocrine disrupter, a relationship has to be established between a physiological response mediated via a hormone system, and an adverse effect measured at the organism or (sub-)population level. The Conceptual Framework (CF) helps to organise information into levels increasing in biological complexity and aids the interpretation of results. Information for Levels 1 and 2 of the CF are relevant to both mammal and non-mammalian toxicology. However, separate Test Guidelines have been developed for mammals and non-mammal for Levels 3, 4, and 5.

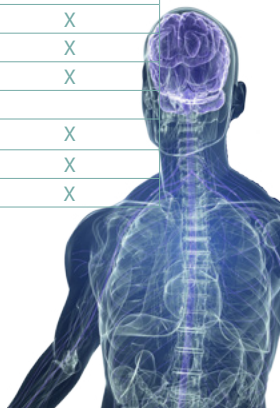
Conceptual Framework for testing and assess endocrine disrupters

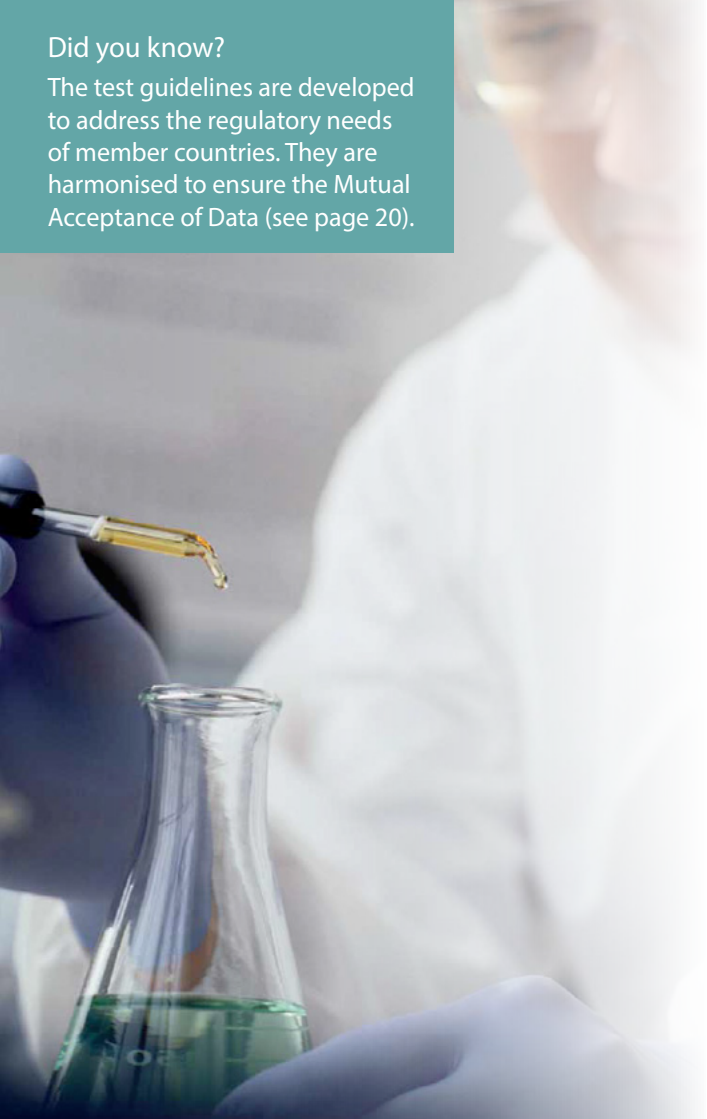
<table>
<tr><td colspan="2">Mammalian and non-mammalian Toxicology</td></tr>
<tr><td colspan="2">Level 1
Existing Data and Non-Test Information</td></tr>
<tr><td colspan="2">Level 2
In vitro assays providing data about selected endocrine mechanism(s) / pathway(s)</td></tr>
<tr><td>Mammalian Toxicology</td><td>Non-mammalian Toxicology</td></tr>
<tr><td colspan="2">Level 3
In vivo assays providing data about selected endocrine mechanism(s) / pathway(s)</td></tr>
<tr><td colspan="2">Level 4
In vivo assays providing data on adverse effects on endocrine relevant endpoints</td></tr>
<tr><td colspan="2">Level 5
In vivo assays providing more comprehensive data on adverse effects on endocrine relevant endpoints over more extensive parts of the life cycle of the organism</td></tr>
</table>

Relevant OECD Test Guidelines for the detection of endocrine disrupting chemicals

Test Guidelines Number and Name*	Level of Conceptual Framework	Pathway Addressed			
		Oestrogen	Androgen	Thyroid	Steroidogenesis
TG 493: *In Vitro* Oestrogen Receptor Binding Assay	2	X			
TG 455: *In Vitro* Oestrogen Receptor Transactivation Assay	2	X			
TG 458: *In Vitro* Androgen Receptor Transactivation Assay	2		X		
TG 456: H295R Steroidogenesis Assay	2	X	X		X
TG 440: Uterotrophic Bioassay	3	X			
TG 441: Hershberger Bioassay	3		X		
TG 229: Fish Short-Term Reproduction Test	3	X	X		X
TG 230: Fish Screening Assay	3	X	X		X
TG 231: Amphibian Metamorphosis Assay	3			X	
TG 407: 28-day Repeated Dose Toxicity Study in Rodents	4			X	X
TG 408: 90-day Repeated Dose Toxicity Study in Rodents	4			X	X
TG 414: Prenatal Developmental Toxicity Study	4	X	X	X	X
TG 421: Reproduction/Developmental Toxicity Screening Test	4	X	X	X	X
TG 422: Combined Repeated Dose Reproduction/Developmental Toxicity Screening Test	4	X	X	X	X
TG 426: Developmental Neurotoxicity Study	4	X	X	X	X
TG 451-3: Combined Chronic Toxicity/Carcinogenicity Study	4	X	X	X	X
TG 234: Fish Sexual Development Test	4	X	X		X
TG 241: Larval Amphibian Growth and Development Assay	4			X	
TG 443: Extended One-Generation Reproductive Toxicity Study	5	X	X	X	X
TG 240: Medaka Extended One-Generation Reproductive Toxicity Study	5	X	X	X	X
TG 416: Two Generation Reproduction Toxicity Study	5	X	X	X	X

*Test guidelines may evolve following best practices and emerging science.

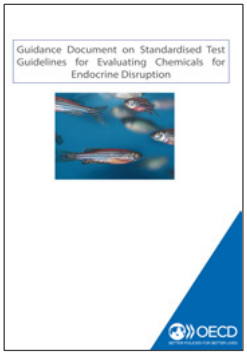




Did you know?

The test guidelines are developed to address the regulatory needs of member countries. They are harmonised to ensure the Mutual Acceptance of Data (see page 20).

Interpreting the results from Test Guidelines



OECD Guidance Document No. 150, published in 2012, provides guidance for interpreting the outcome of individual tests and compiling evidence on whether or not a substance may be an endocrine disrupter.

The document was the first comprehensive, international guide on the identification of endocrine disrupting chemicals. It provides step-by-step guidance for analysing results from standard tests, weighing evidence for an endocrine mode of action and identifying adverse effects in whole organisms.

The Guidance Document also provides a general description of each standardised Test Guideline, a tabular presentation of the endpoints measured in each test and the endocrine pathway affected, as well as testing costs.

Guidance Document 150 will be updated in 2018 to include recent advances in endocrine testing, such as new Test Guidelines, revision to Test Guidelines, and lessons learned in the area of endocrine disruption.

Key link:
www.oecd-ilibrary.org/content/book/9789264221413-en

6 OECD Progress in the area of endocrine disrupters

Regular updates to include best science

Every year, new projects are proposed to develop state-of-the-art scientific approaches reflecting the increasing understanding of endocrine toxicology.

There is an ongoing need to develop new methodologies or update existing ones to :

- Meet new regulatory needs;
- Reflect scientific and technical progress;
- Improve the cost-effectiveness of testing;
- Reduce the number and suffering of test animals;
- Include novel and informative endpoints; and
- Take into account increased understanding of underlying biology.

Alternatives to animal testing for endocrine disrupters

Traditional chemical safety testing relies on testing the effects of chemicals in animals. There are tens of thousands of chemicals in commerce and hundreds more enter the market each year.

Chemical regulation is challenged by the large number of chemicals that have yet to be assessed for endocrine disruption and by approaches that require time, money and animals.

Member countries are looking for innovative ways to maximise the benefits of existing knowledge and develop new tools and decision frameworks that are cost and time-effective and circumvent animal testing.

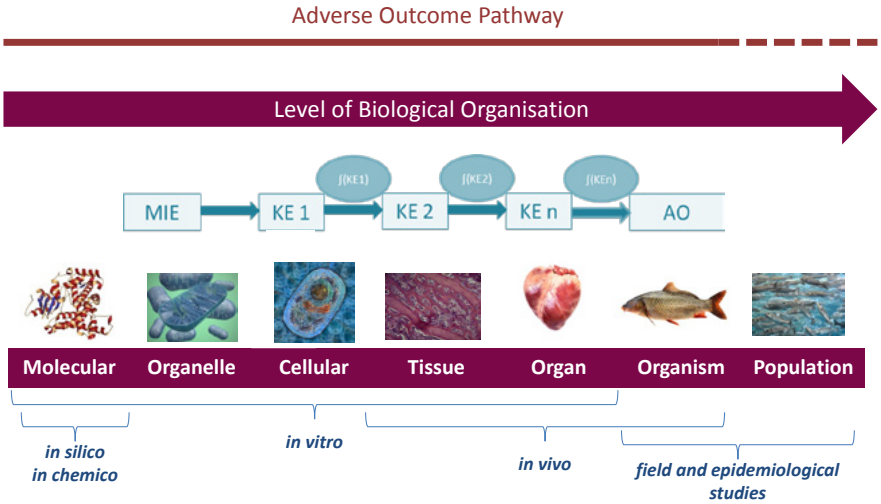
The drawbacks of traditional *in vivo* testing may be overcome by methods that use cells, molecules and/or computational approaches to predict toxicity, but because of the biological complexity of whole organisms, data from several methods usually need to be considered in combination to predict chemical hazards. Results from multiple methods can be integrated to aid in the understanding and interpretation of how chemicals exert their effects.

This approach combining results from multiple methods can be used to predict an adverse outcome *in vivo* from methods that can be conducted quickly, at low cost, and do not use animals (called predictive toxicology).

This structured organisation of biological events leading to an adverse effect is the Adverse Outcome Pathway (AOP) concept.

AOPs are conceptual frameworks that help to build biologically supported links between data measured at different biological levels and in different tests. AOPs can help to organise available data, identify information gaps, direct next steps for safety testing, and develop novel approaches for chemical safety testing that, in some cases, may reduce the need for testing chemicals in animals.

OECD has been a pioneer in promoting novel methods for chemical safety testing and hosts the Adverse Outcome Pathway Knowledge-Base (AOP-KB). The AOP-KB is a resource for research, test method development, and regulatory decision making. At the time of publication, there are 40 endocrine-related AOPs : 4 Androgen AOPs, 6 Oestrogen AOPs, 9 Thyroid AOPs, 21 other endocrine AOPs.



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).

Key links:
www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm
www.aopkb.org

7 Benefits for countries and industry of working together

A common understanding of endocrine disrupting chemicals stimulates converging policies

OECD helps to ensure sound science and international regulatory acceptance of test methods by engaging broad participation in work on endocrine disrupters.

International involvement

National Co-ordinators maintain broad networks of experts from academia, regulatory agencies and research institutes that are nominated to participate in discussions on Test Guideline and Guidance Documents development. Industry, animal welfare and environment Non-Governmental Organisations can also nominate experts to participate.

OECD documents are rigorously reviewed

OECD Test Guidelines and Guidance Documents are thoroughly reviewed and the underlying science is validated by subject matter experts. Once the technical components are finalised, documents undergo additional expert review for policy implications and OECD also makes documents available for public comment. During the development of documents, consensus among experts is achieved through a series of teleconferences and face-to-face meetings to help ensure regulatory acceptance of resulting data.

Mutual Acceptance of Data (MAD) system

OECD Test Guidelines are covered by the Mutual Acceptance of Data. This multi-lateral agreement allows participants to share test data generated in any member country, or partner country adhering to MAD, in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP), for assessment purposes and other uses relating to the protection of human health and the environment.

Key links:

www.oecd.org/chemicalsafety/testing/good-laboratory-practiceglp.htm
www.oecd.org/env/ehs/mutualacceptanceofdatamad.htm

Did you know?

More than €150m annual savings to governments and industry are generated by avoiding duplicate testing and therefore eliminating the use of thousands of animals for chemical safety assessment due to the OECD system of Mutual Acceptance of Data on chemicals (MAD).

Cutting Costs in Chemicals Management (OECD, 2010). www.oecd.org/env/ehs/47813784.pdf

OECD Mutual Acceptance of Data (MAD) Member Countries and Key Partners

Member Countries


OECD


IRELAND


ESTONIA


AUSTRIA


AUSTRALIA


BELGIUM


ICELAND


POLAND


DENMARK


GERMANY


FRANCE


FINLAND


SOUTH KOREA


LUXEMBOURG


CANADA


CZECH REPUBLIC


NETHERLANDS


UNITED STATES


MEXICO


NORWAY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SLOVAKIA


SLOVENIA


TURKEY


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GREECE


NEW ZEALAND


HUNGARY


ISRAEL


ITALY


LATVIA

Key Partners adhering to MAD


ARGENTINA[1]


BRAZIL


INDIA


MALAYSIA

SOUTH AFRICA

SINGAPORE

THAILAND[2]

Notes:

[1] Full adherence for Argentina only applies to industrial chemicals, pesticides and biocides.

[2] Provisional adherent.

More information on the OECD's work on Endocrine Disrupters

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Page 218 Scientific background. Multichannel pipette tips filled in with reaction mixture to amplify DNA in plastic wells (this image is toned) © Anyaivanova / Shutterstock.com and Laboratory mouse on the researcher's hand © UnoL / Shutterstock.com

Page 21: National flag ball of OECD (Organisation for Economic Co-operation and Development) members © ShenTao / Shutterstock.com

> Thanks to the OECD's work on screening and testing chemicals for endocrine disrupting potential, countries are now using the tools to implement their policies for assessing and managing the risk of potential endocrine disrupting chemicals in humans and wildlife.

Taisen Iguchi, Ph.D.
Professor, Yokohama City University, helping Ministry of the Environment, Japan from 1997, the beginning of Endocrine Disrupters Issue.

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http://oe.cd/endocrine-disrupters