THE OECD'S ACTIVITIES ON CHEMICAL SAFETY AND BIOSAFETY

Ester Carregal Romero, PhD

Organisation for the Economic Cooperation and Development (OECD)

ABOUT THE OECD

FORUM & KNOWLEDGE HUB

Data analysis and best practices
in public policy

We work with over 100 countries across the world to build stronger, fairer and cleaner societies - helping to shape **better policies for better lives**

Organisation for the Economic Cooperation and Development (OECD)

Member countries

Key partners

Currently in accession process

Argentina, Brazil, Bulgaria, Croatia, Peru, and Romania

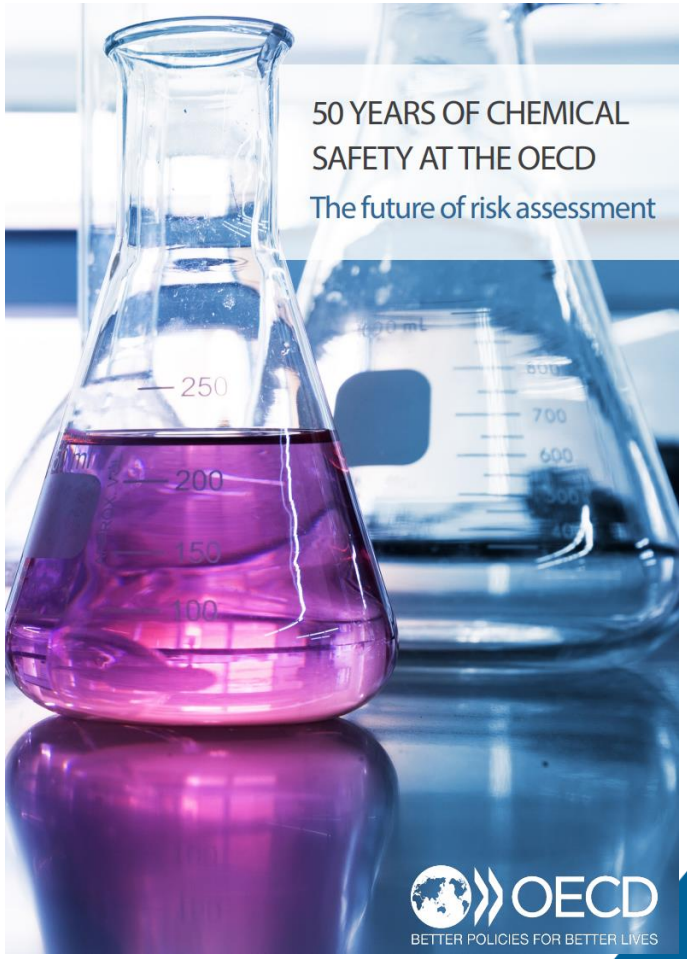
Accession discusssions initiated

Indonesia and Thailand

OECD Chemical Safety Programme

Is a forum for governments and other stakeholders to:

- Develop methods and approaches for evaluating the safety of chemicals
- Discuss and share their experiences on issues of mutual concern;
- Promote harmonised approaches and data sharing



Environment, Health and Safety Programme

Objectives	Protect human health and the environment	Efficiency
Type of outputs	Harmonised instruments for the risk assessment of chemicals and GMOs	
Examples of outputs	• Test Guidelines • Principles of Good Laboratory Practice • Tools for predicting the effects of chemicals (non-animal methods) • Guidance for Hazard and Exposure Assessment • Standards for exchange of information • Global Portal to Information on Chemical Substances	
Scope	Chemicals, nanomaterials, pesticides, biocides, chemical accidents, PRTRs, GMOs	
Practical implications	Safe use of chemicals	Work sharing; avoid duplication; avoid non-tariff trade barriers; shorten time to market

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PARTICIPATION IN EHS WORK

- Members (make decisions)
- European Union
- Selected partner countries
- Other Inter-governmental Organisations
- Industry (BIAC)
- Trade Unions (TUAC)
- Environmental NGOs
- Animal Welfare NGOs

Chemicals and Biotechnology Committee

- Working Party of National Co-ordinators of the Test Guidelines Programme
- Working Party on Good Laboratory Practice
- Working Party on Hazard Assessment
- Working Party on Exposure Assessment
- Working Party on Risk Management
- Working Party on Manufactured Nanomaterials
- Working Party on Pesticides
- Working Party on Biocides
- Working Party on Chemical Accidents
- Working Party on Pollutant Release and Transfer Registers
- Working Party on the Harmonisation of Regulatory Oversight in Biotechnology
- Working Party for the Safety of Novel Foods and Feeds

1981 “MAD” DECISION

- OECD Council Decision on **Mutual Acceptance of Data** in an Assessment of Chemicals C(81)30(Final)
- “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.”
- The Mutual Acceptance of Data (MAD) System | OECD

Estimated annual costs/savings in EUR (mainly due to MAD)

Net Savings 309.5 M EUR/year

http://www.oecd.org/chemicalsafety/saving-costs-in-chemicals-management-9789264311718-en.htm

TEST GUIDELINES AND GOOD LABORATORY PRACTICES

OECD Test Guidelines

Approximately 160 Test Guidelines
split into five sections:

Section 1: Physical Chemical Properties
Section 2: Effects on Biotic Systems
Section 3: Environmental Fate and Behaviour
Section 4: Health Effects
Section 5: Other Test Guidelines

- OECD Guidelines for the Testing of Chemicals | OECD iLibrary (oecd-ilibrary.org)

Test Guidelines Programme

- Most projects on OECD Test Guidelines Programme today are about harmonisation of non-animal methods

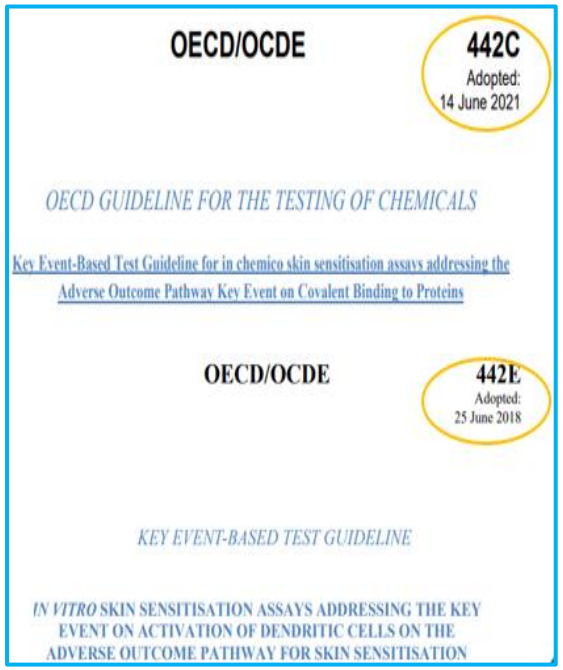
TG 442C

in chemico

Skin Sensitisation

TG 442E

in vitro



Computational data

TG 497

Defined Approaches

Recently adopted Test Guidelines

- TG124 on Volume Specific Surface Area of Manufactured Nanomaterials;
- TG125 on Particle Size and Particle Size Distribution of Nanomaterials;

- TG467 Defined Approaches on eye irritation;
- TG492B on eye hazard potential using a reconstructed human corneal epithelium;
- TG470 on the Mammalian Erythrocyte Pig-a Gene Mutation Assay;
- TG251 on the Rapid Androgen Disrupter Activity Reporter Assay;
- TG320 on Biotransformation of chemicals in liquid manure.
- **Updated** TG 442E with the GARDskin™ for skin sensitization
- + 9 other updated/**corrected TGs**

OECD Principles of GLP (1)

- A single quality standard for test facilities throughout OECD and applied for testing of all chemical substances
- 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
- OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring | OECD iLibrary (oecd-ilibrary.org)

OECD Principles of GLP (2)

- Address the responsibility of and requirements for a test facility's organisation and personnel, quality assurance programme, physical plant, apparatus, materials and reagents.
- Principles governing the following are provided:
  - conditions for establishing and maintaining test systems;
  - receipt, handling, sampling, characterisation and storage of test and reference substances;
  - standard operating procedures;
  - performance of the study;
  - reporting of results;
  - storage, retention and retrieval of records and materials

Activities

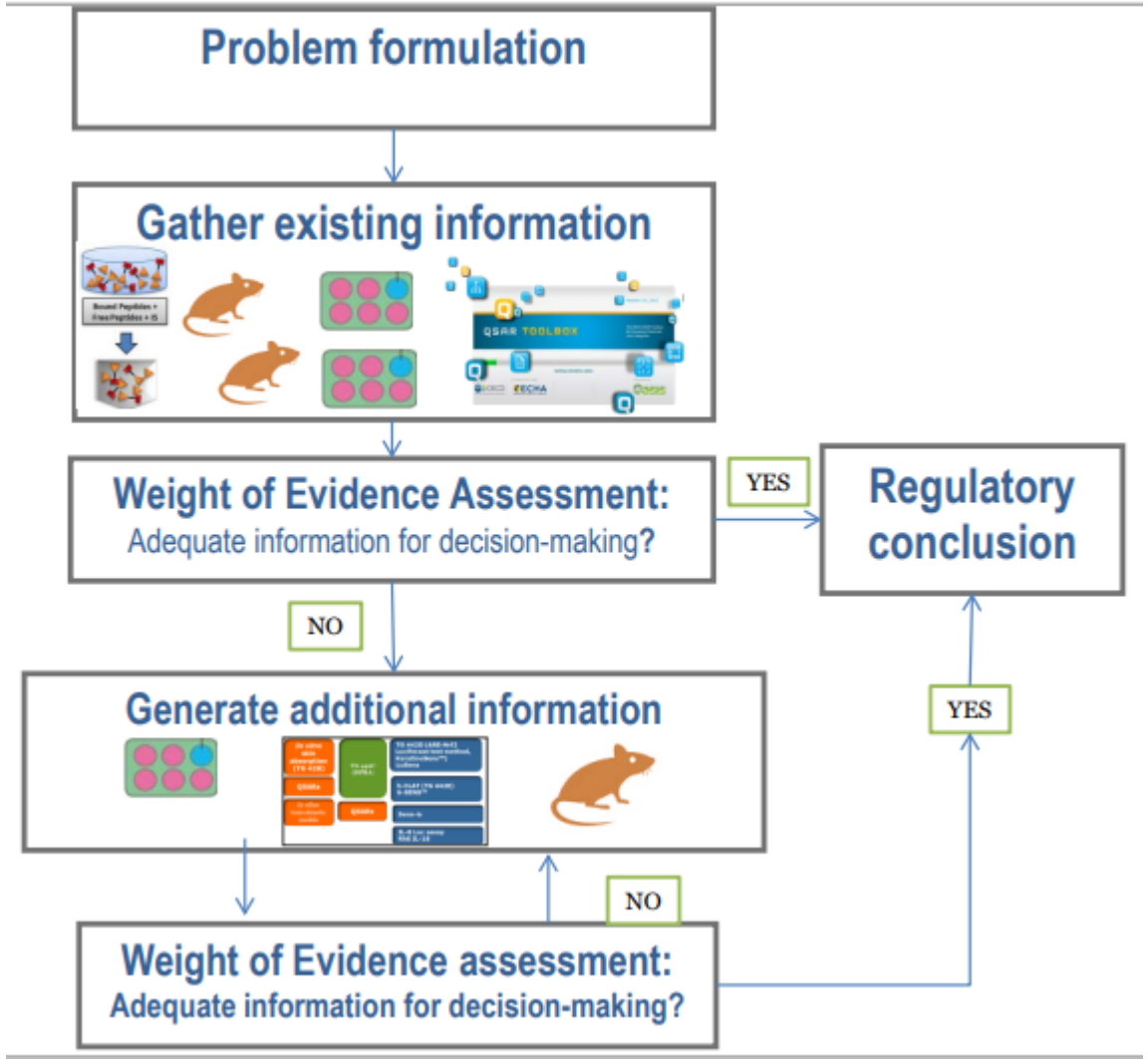
- On-Site Evaluation visits
- Continue to work towards additional countries to adhere to MAD
- OECD GLP Training Course
- Development of new Frequently Asked Questions on identified topics

HAZARD ASSESSMENT

OECD Hazard Assessment: innovative methods to evaluate chemical hazards

- Best approaches and practices for integrating information to come to a regulatory decision
- Forum for sharing experience on new and innovative approaches
  - Discussion on the use of New Approach Methods (NAMs) in regulatory decision-making
    - **How to build confidence in NAMs**
- [OECD Series on Testing and Assessment | OECD iLibrary (oecd-ilibrary.org)]

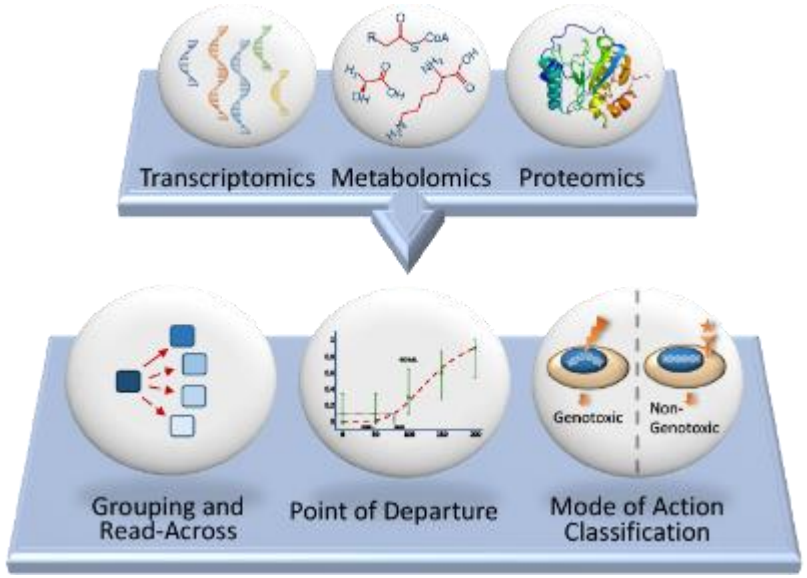
Integrated Approaches to Testing and Assessment (IATA)



IATA approaches are flexible approaches to chemical safety assessment based on the **integration** and translation of **data derived from multiple methods and sources**. In addition to traditional in vitro and in vivo testing, IATA can incorporate NAMs , along with computational methods that are used not only for data generation, but also for interpretation and integration

- Integrated Approaches to Testing and Assessment | OECD

Omics technologies in chemical testing



"Omics" Tool to characterise and quantify the molecular and biochemical changes in cells, tissues and organisms following exposure to chemicals and toxic substances

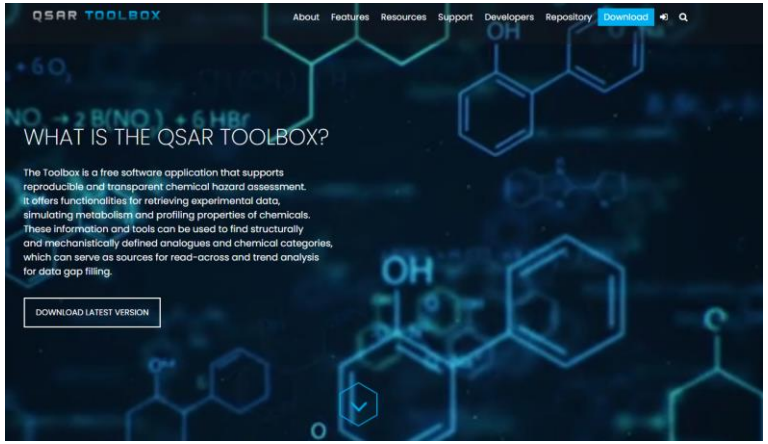
Standardisation of data collection and reporting is needed to facilitate the use of omics data in regulatory decision making

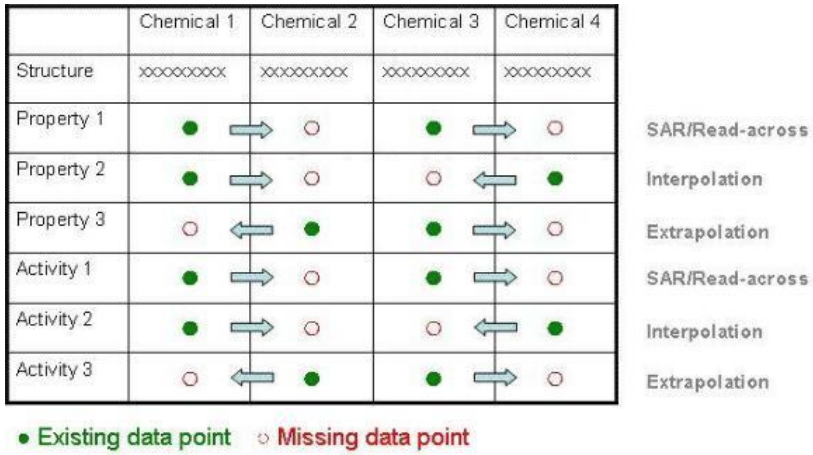
OECD OMICS REPORTING FRAMEWORK (OORF)

Guidance on reporting elements for the regulatory use of omics data from laboratory-based toxicology studies

Chemical Grouping

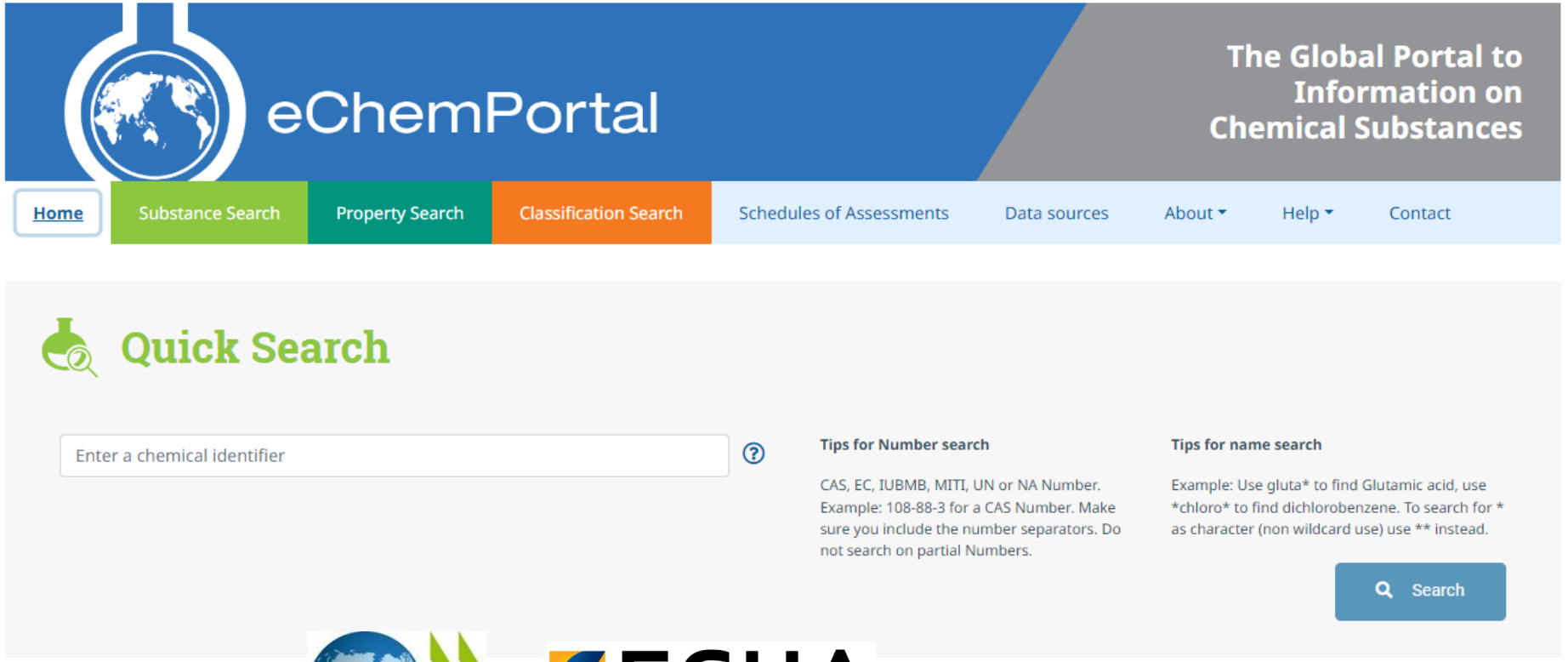
- GD 194: GD on Grouping of Chemicals, Second Edition (2014)
  - Recommendations on grouping strategies
  - Data needs to support groups
- In the process of updating the document to reflect learnings and use of additional methods
  - Lesson learned from IATA Case Study examples on grouping and read across approaches
  - Use of Omics to support chemical groups
  - Extended information on Uncertainty





eChemPortal

Provides free public access and direct links to collections of information prepared for government chemical programmes at national, regional, and international levels



ECHA
EUROPEAN CHEMICALS AGENCY

www.echemportal.org

- Free software application to predict the properties of chemicals

- Estimate missing experimental values by read-across and trend analysis (grouping of similar chemicals, chemical categories)

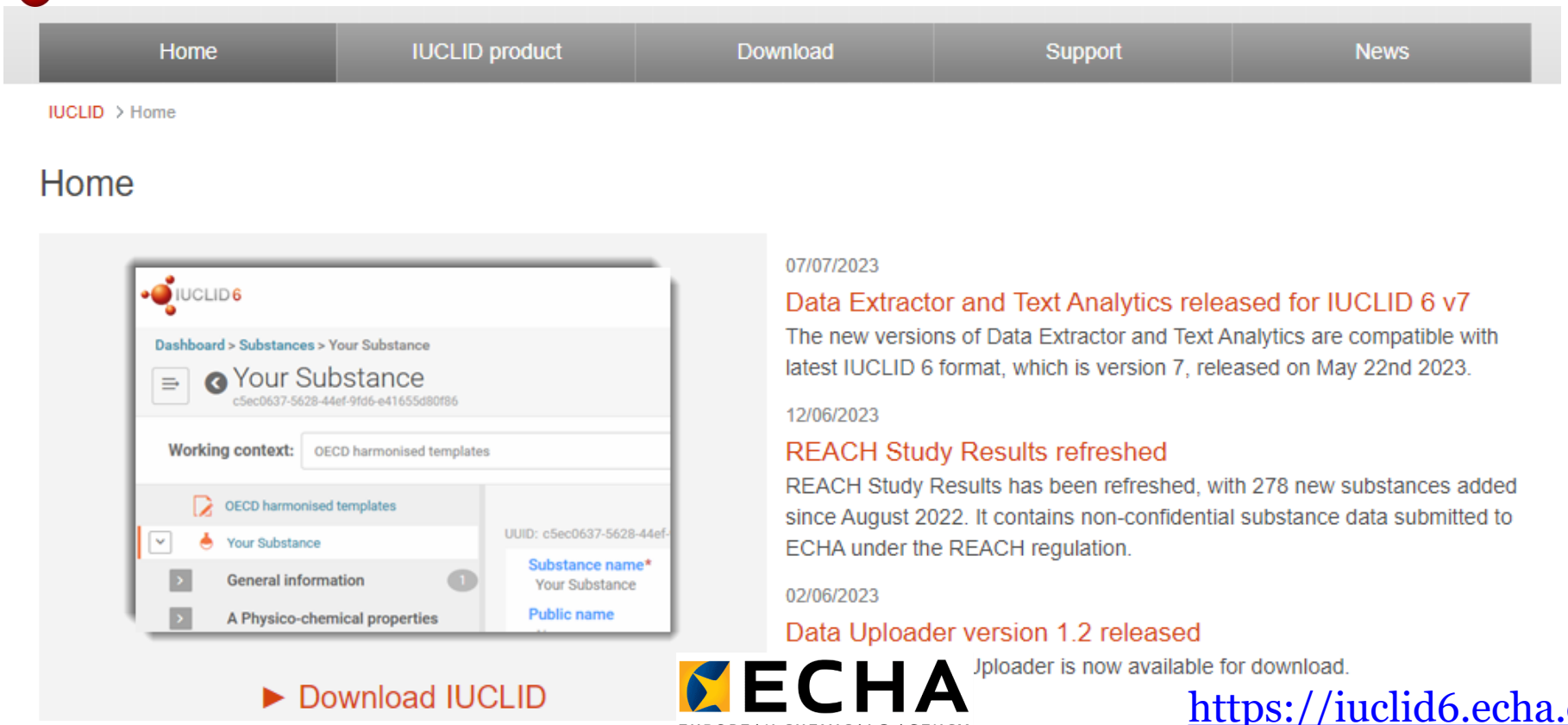
(Q)SAR Assessment Framework: Guidance for the regulatory assessment of (Quantitative) Structure – Activity Relationship models, predictions, and results based on multiple predictions (Glossary

ECHA
EUROPEAN CHEMICALS AGENCY

IUCLID (International Uniform ChemicaL Information Database)

Free Software Application

- Capture, store, submit, exchange data on chemicals substances
- Data storage format= OECD Harmonised Templates



ECHA EUROPEAN CHEMICALS AGENCY

https://iuclid6.echa.europa.eu

METHODOLOGIES FOR EXPOSURE ASSESSMENT

Methodologies for Exposure Assessment

- Development of harmonised methodologies for assessing the exposure of chemicals to the environment and humans
- Types of Outputs:
  - Emission Scenario Documents
  - Guidance documents/Harmonised template and Methodologies
  - Tools/databases
- Assessment of chemicals | OECD

Emission Scenario Documents (ESDs)

- Describe the sources, production processes, pathways and use patterns with the aim of quantifying the emissions (or releases) of a chemical into water, air, soil and/or solid waste.
- Used for default scenarios for exposure assessment
  - to establish the conditions on use and releases of the chemicals.
  - to estimate concentration of chemicals in the environment

Currently under development

1. ESD for uses of fluorocarbon substitutes – Foam Manufacturing (the first draft is under preparation)
2. ESD for uses of fluorocarbon substitutes – Refrigeration (the first draft is under preparation)
3. ESD for uses of fluorocarbon substitutes – Mobile Air Conditioning (the first draft is under preparation)
4. ESD for chemicals used in hydraulic fracturing (the second draft was submitted for review in Q3 2023)
5. ESD on chemicals used in fabric finishing (the first draft was submitted for review in Q2/Q3 2023), and
6. ESD on 3D Printing (the first draft is under preparation)

Children's health Project

- Children can be more vulnerable than adults to chemicals due to their physiological differences and unique behaviours.
- The following activities are on-going:
  - Survey of methodologies/tools to assess the risk of chemicals to children's health
  - Database development of children exposure factors
  - Case study to estimate exposure to chemicals in children's craft and toy products

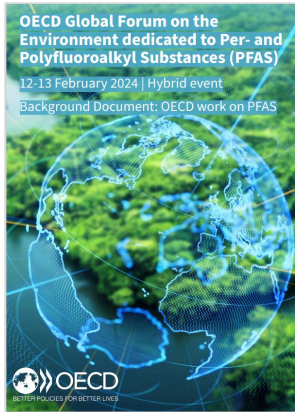
RISK REDUCTION AND SUSTAINABLE CHEMISTRY

Substitution of
Harmful Chemicals

Created in 2021!

Safer and more Sustainable Chemistry

Working Party on Risk Management



Shifting towards Safer Alternatives
for PFAS Substances
(OECD/UNEP Global PFC Group)

Risk Management Tools and Approaches
Including Socioeconomic Analysis

Plastics & Chemicals

Published in 2023

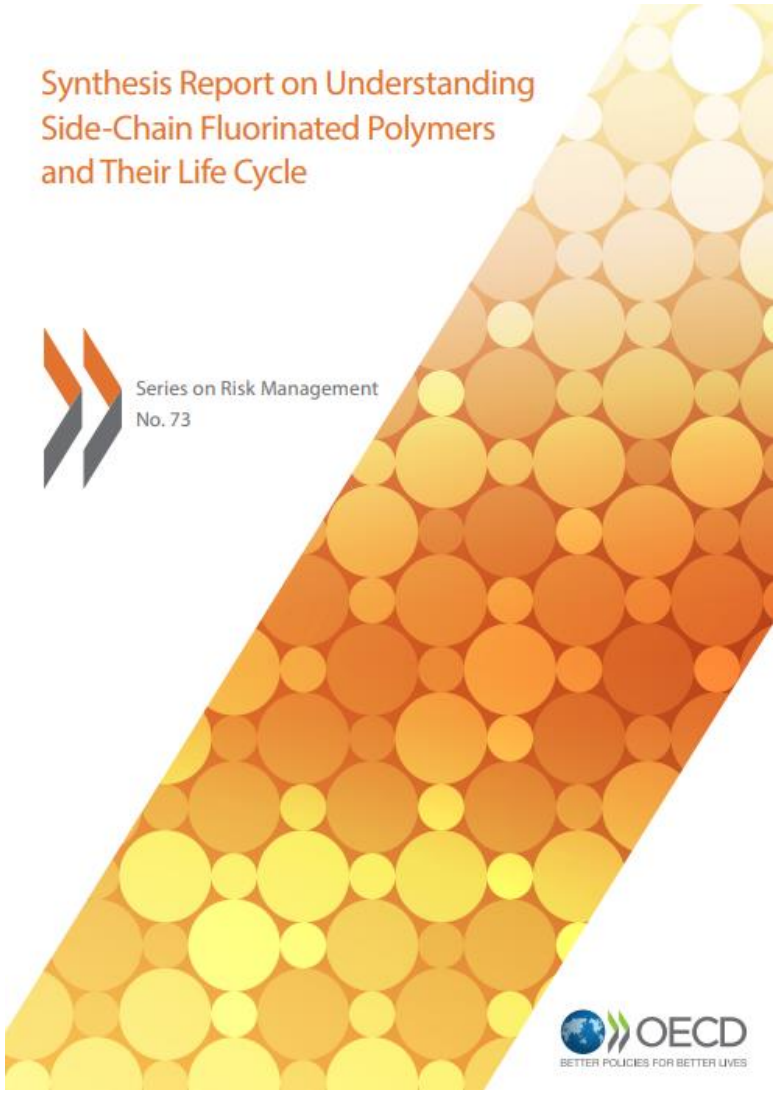
OECD/UNEP GLOBAL PFC GROUP

Collection of Information on Alternatives

Collect info on commercial availability & current uses of alternatives in different industry sectors and on their hazard profile

- PFAS & alternatives in food packaging (paper and paperboard), *published in 2020*
  - ➢ Collection of hazard information on the alternatives identified, *published in February 2022*
- PFAS & alternatives in coatings, paints and varnishes, *published in March 2022*
  - ➢ Collection of hazard information on the alternatives identified, published in 2023

Understanding the life cycle of polymeric PFASs



- Identities of side-chain fluorinated polymers;
- Historical and ongoing production;
- Historical and ongoing use;
- Summary of available info on release of the polymer and release of PFASs from degradation of the sidechain fluoropolymers, during production, use and end-of-life treatment;
- Identification of the key data gaps from above synthesis.

Next: Perfluoropolyethers ; Fluoropolymers

PRESENTATIONS AVAILABLE HERE

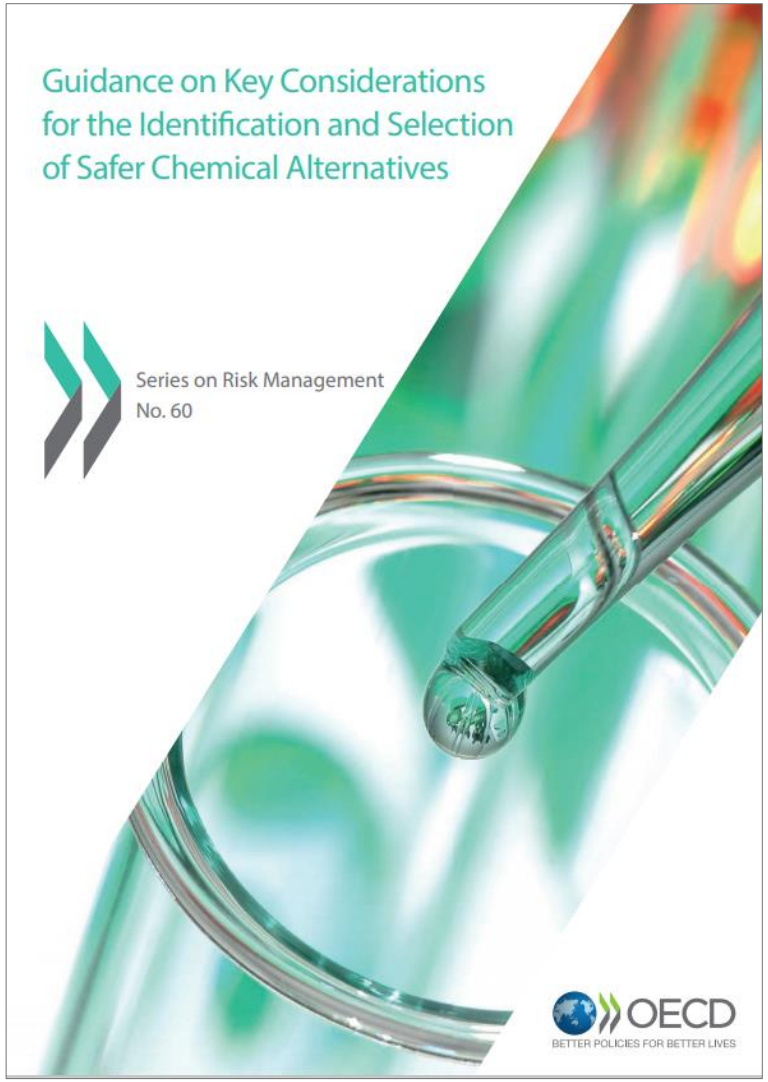
global-forum-on-environment-work-on-pfass (1).pdf

SUBSTITUTION OF HARMFUL CHEMICALS

Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives

Goals of the guidance:

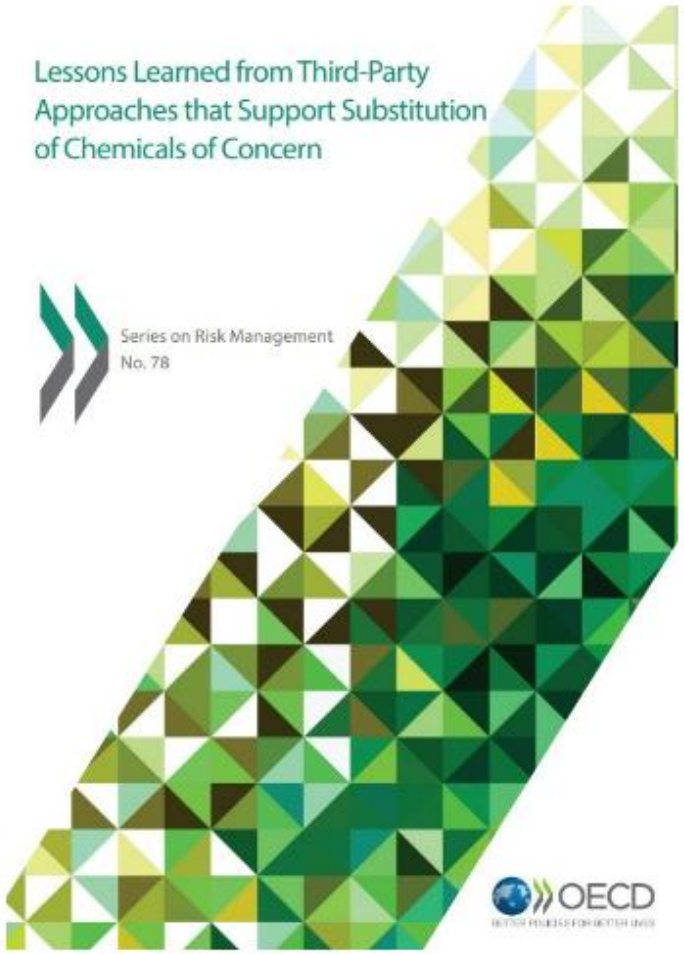
- Define “safer” chemicals in the context of alternatives assessments
- Advance a consistent understanding of the minimum requirements needed to determine whether an alternative is safer



https://www.oecd.org/chemicalsafety/risk-management/substitution-of-hazardous-chemicals.htm

Substitution of Harmful Chemicals

LATEST PUBLICATIONS



•All publications can be found on this link

OECD SAAToolbox- Substitution and Safer Alternatives

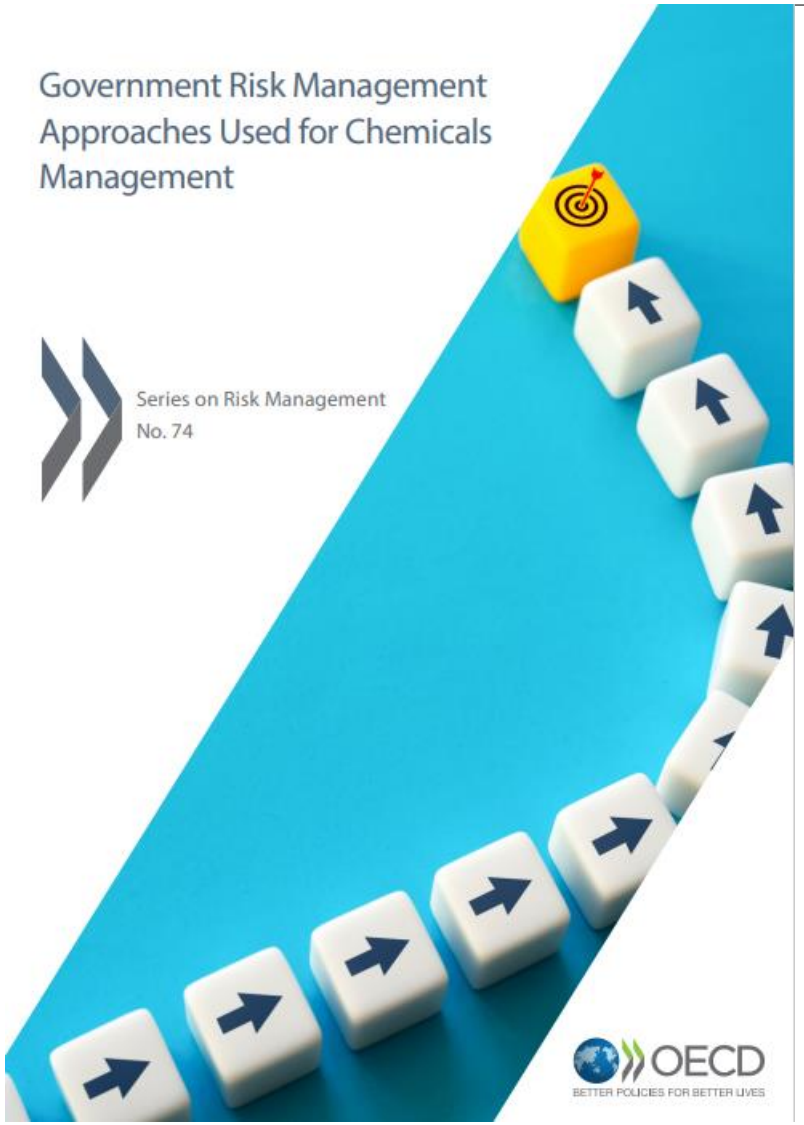
Accessible at:

- https://www.oecd.org/chemicalsafety/risk-management/substitution-of-hazardous-chemicals/
- New interface, searchability functions.

Name	Organisation	Organisation Type
ZINC1220	University of California	Academia
Waste & Toxics Initiative	Washington State Department of Ecology	Government
Washington State Alternatives Assessment Guide for Small and Medium Businesses	Hazardous Waste and Toxics Reduction Program, Washington State Department of Ecology	Government
Using Chemical Hazard Assessment for Alternative Chemical Assessment and Prioritization	Outdoor Industry Association Chemicals Management Working Group and the Zero Discharge of Hazardous Chemicals Programme	Industry
UNEP-SETAC Life Cycle Initiative - Flagship Project 3a	United Nations Environment Programme (UNEP)	Intergovernmental
UL The Wercs™	UL Solutions	Industry
Transitioning to Safer Chemicals	U.S. Occupational Safety and Health Administration	Government
Toxnot	3E	Industry
Toxics Release Inventory (TRI)	U.S. Environmental Protection Agency (EPA)	Government
The Guide to Safer Chemicals	BizNGO	Non-profit organisation
The Circular Design Guide	Ellen MacArthur Foundation / IDEO	Non-profit organisation / Industry
The BizNGO Chemical Alternatives Assessment Protocol	BizNGO	Non-profit organisation
Technical Rule for Hazardous Substances (TRGS) 600 "Substitution"	German Federal Institute for Occupational Safety and Health	Government
TCO Certified	TCO Development	Industry
Sustainability Concepts in Decision-Making	National Academy of Sciences (NAS)	Non-profit organisation
Substitution Support Portal (SUBSPORTplus)	German Federal Institute for Occupational Safety and Health	Government
Substitution Steps	German Federal Institute for Occupational Safety	Government

RISK MANAGEMENT APPROACHES & SOCIOECONOMIC TOOLS

Government Risk Management Approaches Used for Chemicals Management

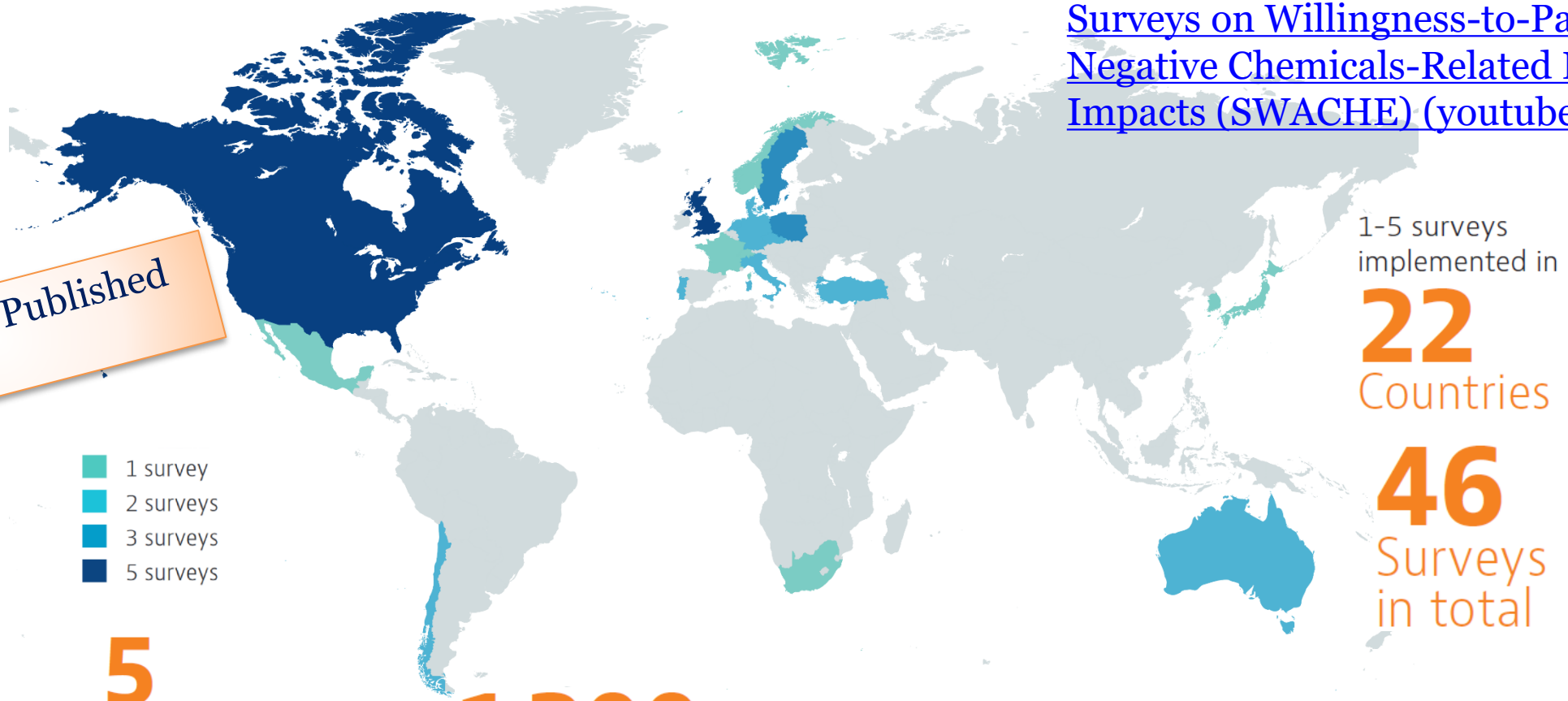


- Synthesis of the various risk management approaches and options that are used by OECD member country chemical regulatory programmes to manage the risk of chemicals

Surveys on Willingness-to-Pay to Avoid Negative Chemicals-Related Health Impacts (SWACHE)

[Surveys on Willingness-to-Pay to Avoid Negative Chemicals-Related Health Impacts (SWACHE) (youtube.com)]

First Round Published
June 2023



5
Health effects
Kidney disease, asthma, infertility, very low birth weight, IQ loss

1 200
respondents
per country, per health effect

Diversity of countries that allows the *transfer* of values to non-surveyed countries

MANUFACTURED NANOMATERIALS

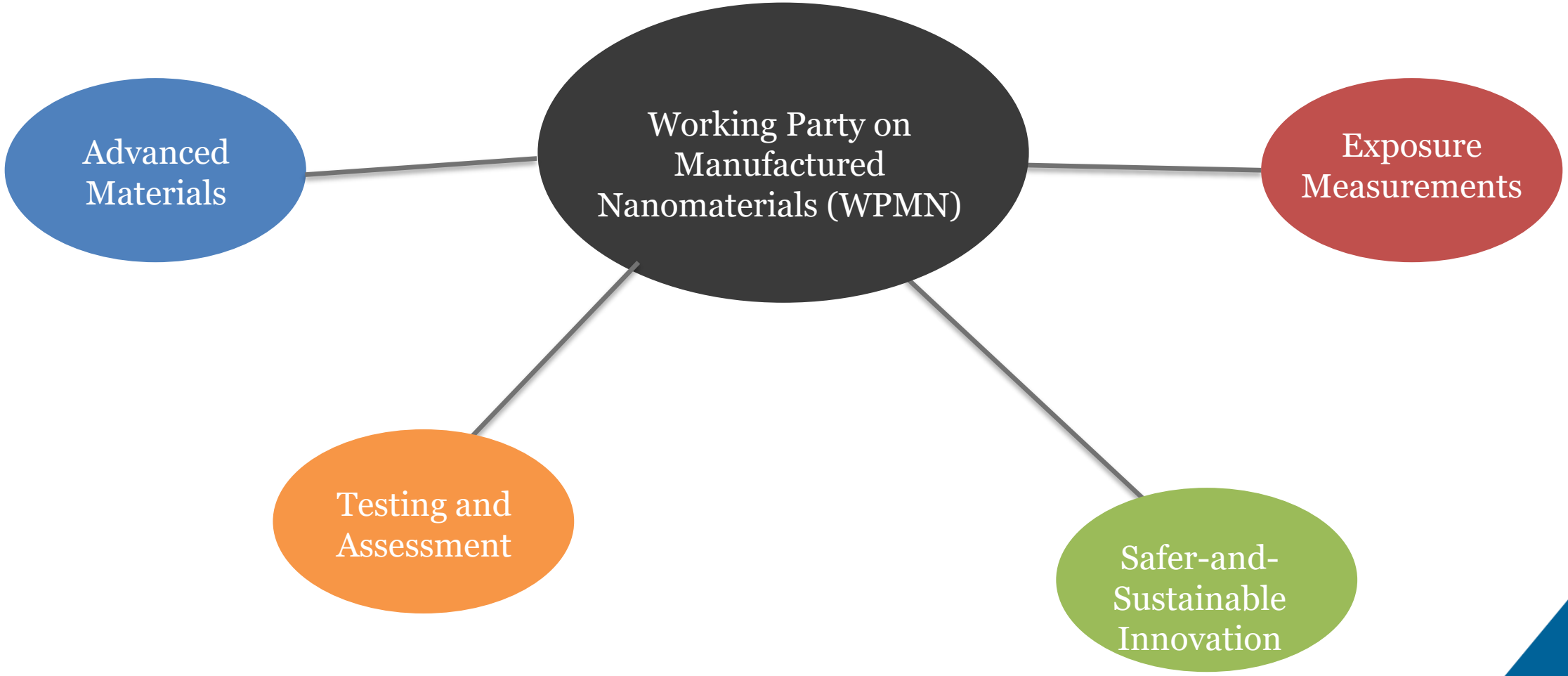
OECD Council Recommendation 2013

- "… the approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials but may have to be adapted to the specificities of nanomaterials."

- The Annex* is being updated to reflect new tools or components developed by the Working Party on Manufactured Nanomaterials (WPMN)

*"*Tools for the adaptation of the existing chemical regulatory frameworks or other management systems to the specific properties of manufactured nanomaterials*"

Nanomateriasl and Advanced Materials



Goals of Safe and Sustainable Innovation Approach (SSIA)

Safe(r) Innovation Approach: Risk Assessment Tools, Frameworks and Initiatives related to Safe(r)-by-Design

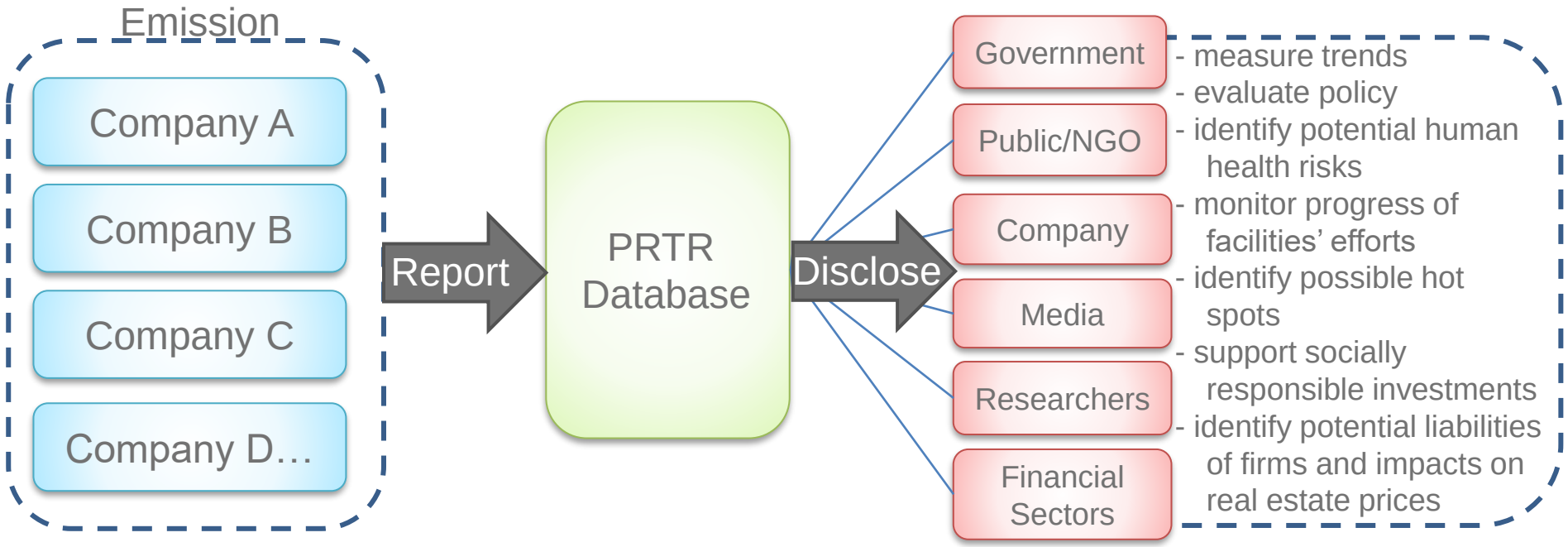
Anticipatory Governance/Regulatory Preparedness: Inventory of Strategies for Awareness and Decision-Making

[Safe(r) and Sustainable Innovation Approach (SSIA): Nano-Enabled and other Emerging Materials | OECD]

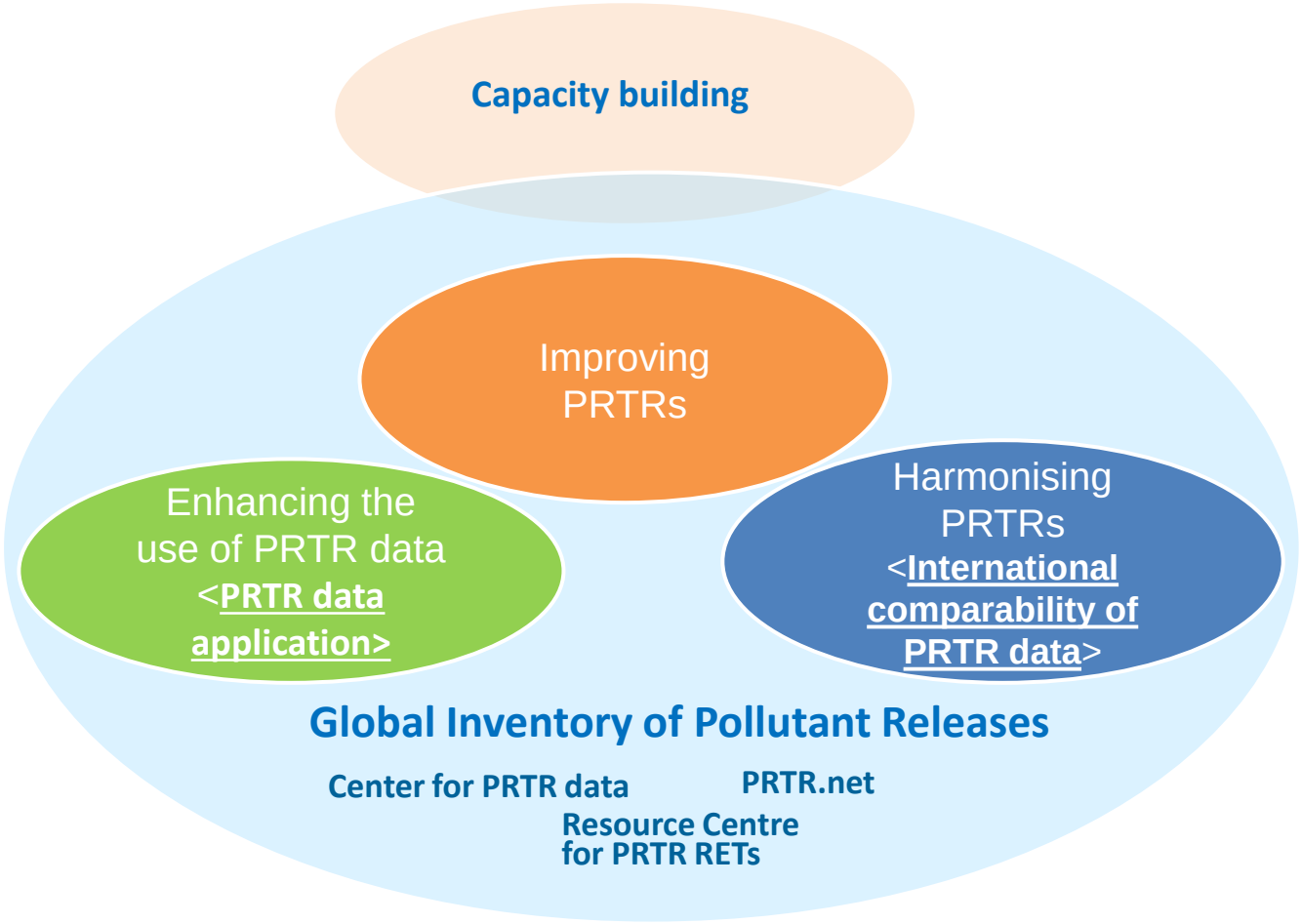
POLLUTANT RELEASE AND TRANSFER REGISTER (PRTR)

What is a PRTR?

- A publicly accessible database of pollutants released to the environment.
- Each industrial facility reports its release of chemicals on a periodic basis



Overall image of OECD activities on PRTR



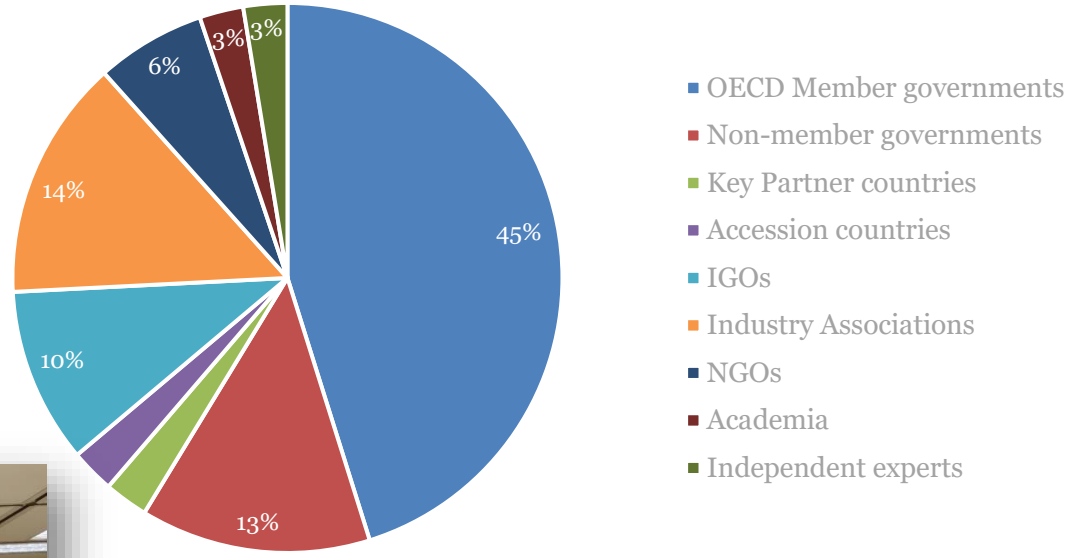
Best Available Techniques (BAT) project

- **Exchange best practices** across countries that already have a BAT-based permitting system
- **Provide guidance** to countries that seek to adopt a BAT-based approach for the first time
- Achieve **progress towards the SDGs**, notably Target 12.4 on the environmentally sound management of chemicals

The OECD Expert Group on BAT

- **Established in 2015** – increased tenfold in size since
- **155 members from 40+ countries and organisations**

Expert Group on BAT Composition



One face-to-face meeting and one webinar per year, plus frequent exchanges by email/phone

- **9th meeting of the Expert Group on BAT**
  22-24 October in London, UK

Deliverables of the OECD's BAT project (2016-2024)

Phase I

(2016-2018)

Act.1- Policies on BAT or Similar Concepts Across the World (2017)

Act.2 -Approaches to Establishing BAT Around the World (2018)

Act.3 - Measuring the Effectiveness of BAT Policies (2019)

Phase II

(2019-2021)

Act.4 - BAT guidance document (2020)

Act. 5 - Study on value chain aspects of determining BAT (2021)

Act. 6 - Cross-country comparison of selected BREFs (2022)

BAT/BEP report on Releases of Mercury to Water and Land (2022)

Phase III

(2022-2024)

Act. 7 - Cross-country comparison of selected BREFs (P.2)

Act. 8 - Capacity building workshops

Act.9 - Identifying innovation and ETs for potential BAT determination

All reports available free of charge: oe.cd/bat

CHEMICAL ACCIDENTS

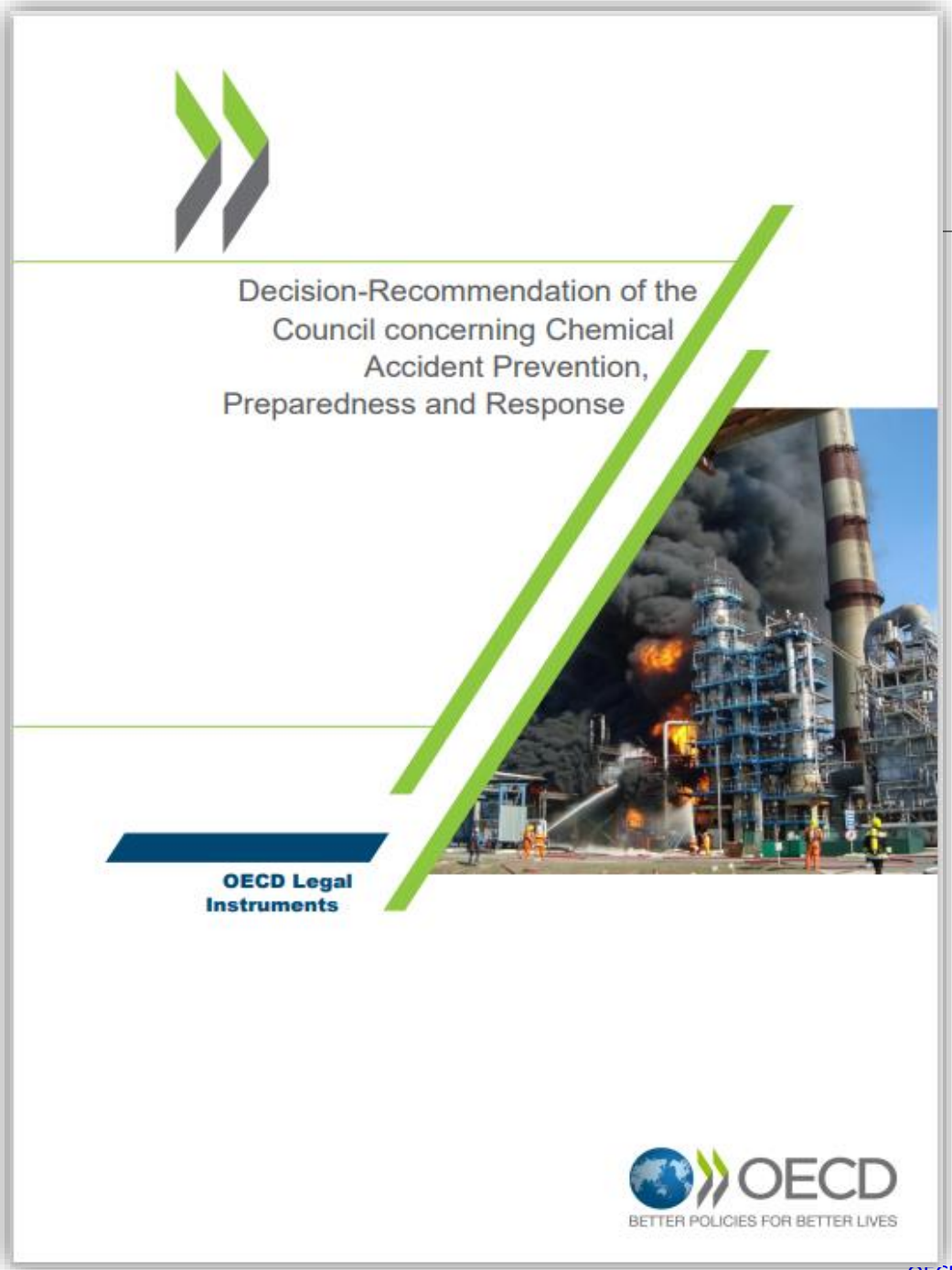
OECD Programme on Chemical Accidents

Share experience and recommend appropriate policy options for enhancing the prevention of, preparedness for, and response to, chemical accidents.

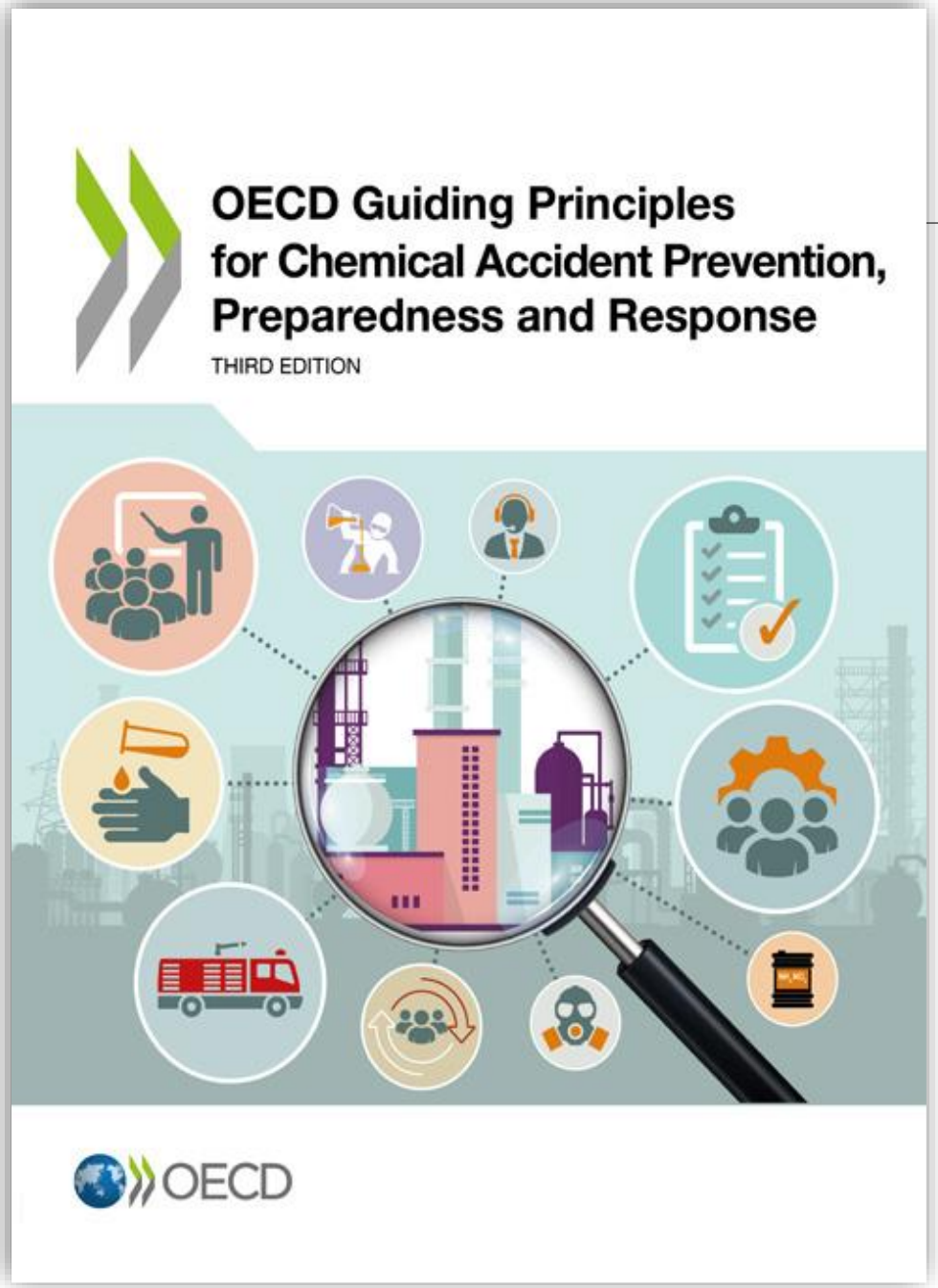
Programme of work designed to:

- support cooperation and knowledge exchange on chemical accidents;
- discuss and provide recommendations on continuing and emerging issues;
- have a particular emphasis on Prevention.

- Series on Chemical Accidents | OECD iLibrary (oecd-ilibrary.org)



- **OECD Legal Instrument**;
- Sets out key high-level elements to support the development of a chemical accidents programme covering the fields of prevention, preparedness, and response:
  - Programmes for the prevention, preparedness and response to chemical accidents;
  - Access to and provision of information to the public;
  - Chemicals accidents capable of causing transboundary damage;
  - Co-operation and technical assistance.
- https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0490



- **Technical guidance supporting the implementation of the Decision-Recommendation;**
- Sets out general guidance for the safe planning and operation of hazardous installations;
- Reflects on lessons learnt from major accidents since the 2nd edition in 2003 and emerging issues such as climate change adaptation and the response to unexpected crises.

Management of Hazardous Substances at Port Areas

- **Port areas are at the interface of landside, transport, ports, and maritime regulations.** Different types of regulations applying at port areas can create challenges in the establishment of the chain of command and in the management of safety - important to ensure that nothing falls outside of regulations and all the different pieces of regulations come together so that the risk from hazardous substances is fully managed
- **Governance and leadership.** Need for clear leadership and accountability at the port area with assigned people who ensure overall safety and coordination.
- **The challenge of temporary storage.** Managing hazardous substances that are considered in temporary storage was highlighted as a major concern - challenges in communicating “real-time” information about the transit of these chemicals.
- **Importance of organising preparedness and response.** Variety of activities at the port, many stakeholders present, ports are often located in densely populated areas make as many challenges for responders. In recent port disasters, emergency responders were among the first victims of the disaster.
- **Risk from new energy sources.** Concerns about energy security combined with the fast development of low carbon/carbon free fuels strategies are changing the landscape of activities at port areas.
- **Risks from natural hazards.**

Managing Natech Accident Risk: A Guide for Senior Leaders in Industry & Public Authorities

- **Joint OECD/UN/EC JRC Guidance**; Publication planned in November 2024 with a launch at the next UNECE Industrial Accidents CoP meeting

- Draw attention to senior leaders in industry & public authorities to the risk of Natech:

  - What should I do as a leader to ensure good governance of Natech risk;
  - How do I gather and organise the capabilities and competences to do it;
  - How do I ensure my organisation continues to adapt to a changing environment.

- Help support:
  - ✓ a high level of commitment for the governance of Natech risk,
  - ✓ long term sustainable development at hazardous installations, including as a response to climate adaptation.

OECD BETTER POLICIES FOR BETTER LIVES

UNECE

PESTICIDES & BIOCIDES

Objectives

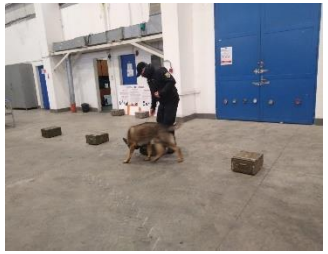
- Objective:
  - Cooperation in assessing and reducing risks of pesticides and biocides, and on sustainable pest management
- Types of Output:
  - Risk assessment methodologies for novel pesticides and biocides
  - Tools for registration of bio-pesticides
  - Indicators for integrated pest management
  - Best practices in fighting illegal trade of pesticides
  - Electronic tools for data submission and review

OECD Network on Illegal Trade of Pesticides

Council Recommendation on Countering the Illegal Trade of Pesticides

- Adopted 20 February 2019
  - https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0446
- Includes:
  - Best Practice Guidance to Identify Illegal Trade of Pesticides
- Practical demonstration by inspectors at Ukraine border





Risk assessment of using drones

ENV/CBC/MONO(2021)39, ANN

- Report published in 2021 identified data gaps in knowledge for assessing human health risks
  - Made several recommendations
- Expert group refocused on providing input to industry consortium to generate data to fill gaps
  - deliver database, and drift curve model
  - identify representative current and future drone design and working practices
  - identify representative flying practice and approach to designing drift studies
  - develop standard set of methodologies
  - encourage manufacturers to develop improved application equipment

Sustainable Management of Harmful Organisms

SuMaHO

BIOTECHNOLOGY PRODUCTS SAFETY

Bio-Food Safety

Working Party for the Safety of Novel Foods and Feeds

Working Party on the Harmonisation of Regulatory Oversight in Biotechnology

GUIDANCES AND TOOLS FOR

Safety assessment of foods and feeds derived from

Genetically-Engineered Organisms (GEOs)

Environmental safety assessment (Biosafety) of

Consensus Documents on the **COMPOSITION** of…

Consensus Documents on the **BIOLOGY** of…

[Biosafety, novel food and feed safety | OECD]

[Consensus documents: safety of novel foods and feeds | OECD]

[Consensus documents: harmonisation of regulatory oversight in biotechnology | OECD]

Bio&Food safety work: main outputs

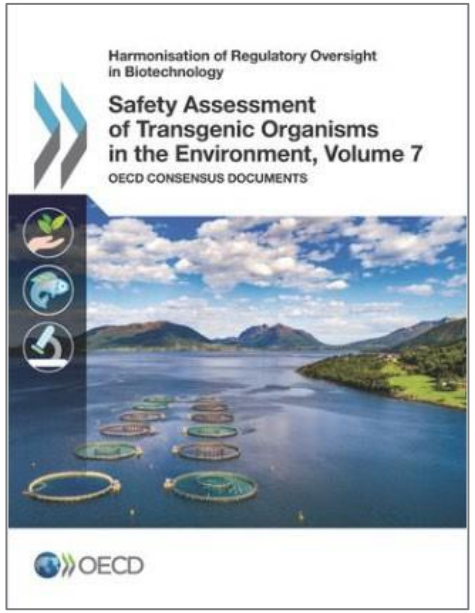
- **Exchange/cooperation** between Authorities towards harmonised approaches on current and new bio-food safety issues (e.g. genome editing)

- '**Consensus' and Guidance Documents** on information relevant to environmental and novel food/feed safety assessment

  - to help national assessment and decision-making process
  - practical tools for comparing conventional products and GMOs
  - Scientific info, internationally-recognised; however NOT prescriptive

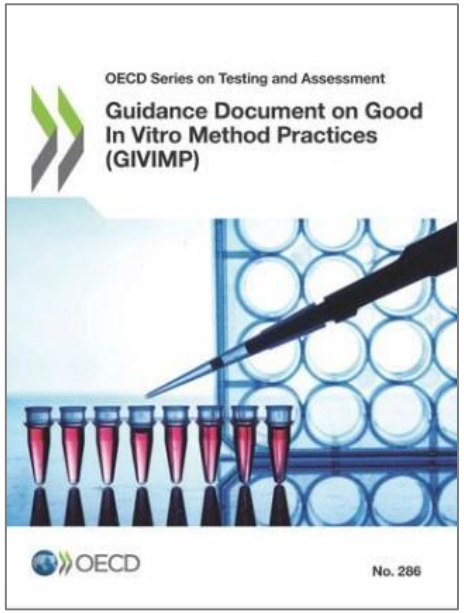
- **Database on GM plant varieties** approved for release in the environment and/or for food & feed use – info. from 17 countries and the E.C. BioTrack Product Database - Home page (oecd.org)

Top performing publications (EHS) – 2023 downloads



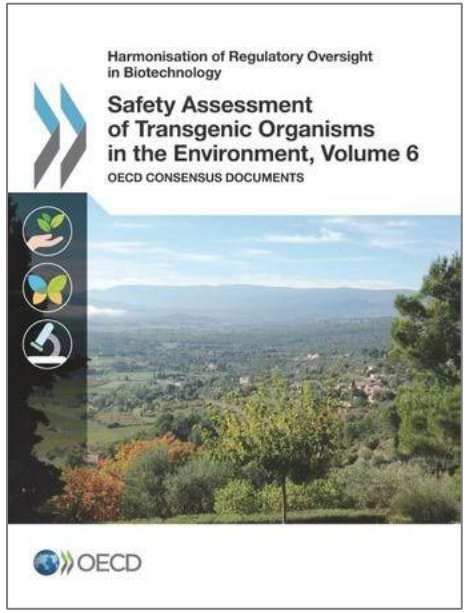
41k views

Safety Assessment of Transgenic Organisms in the Environment, Volume 7: OECD Consensus Documents (2017)



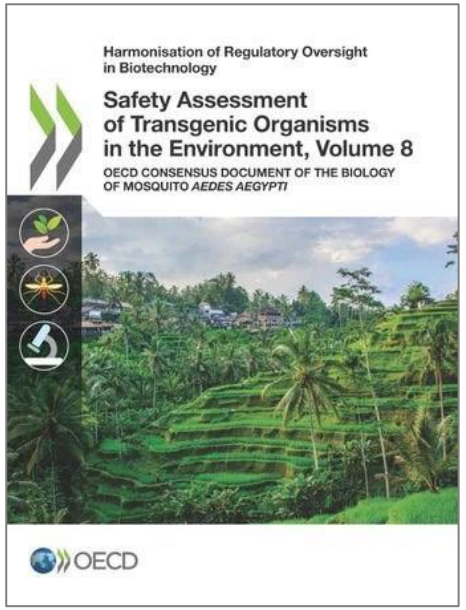
35k views

Guidance Document on Good In Vitro Method Practices (GIVIMP) (2018)



27k views

Safety Assessment of Transgenic Organisms in the Environment, Volume 6: OECD Consensus Documents (2016)

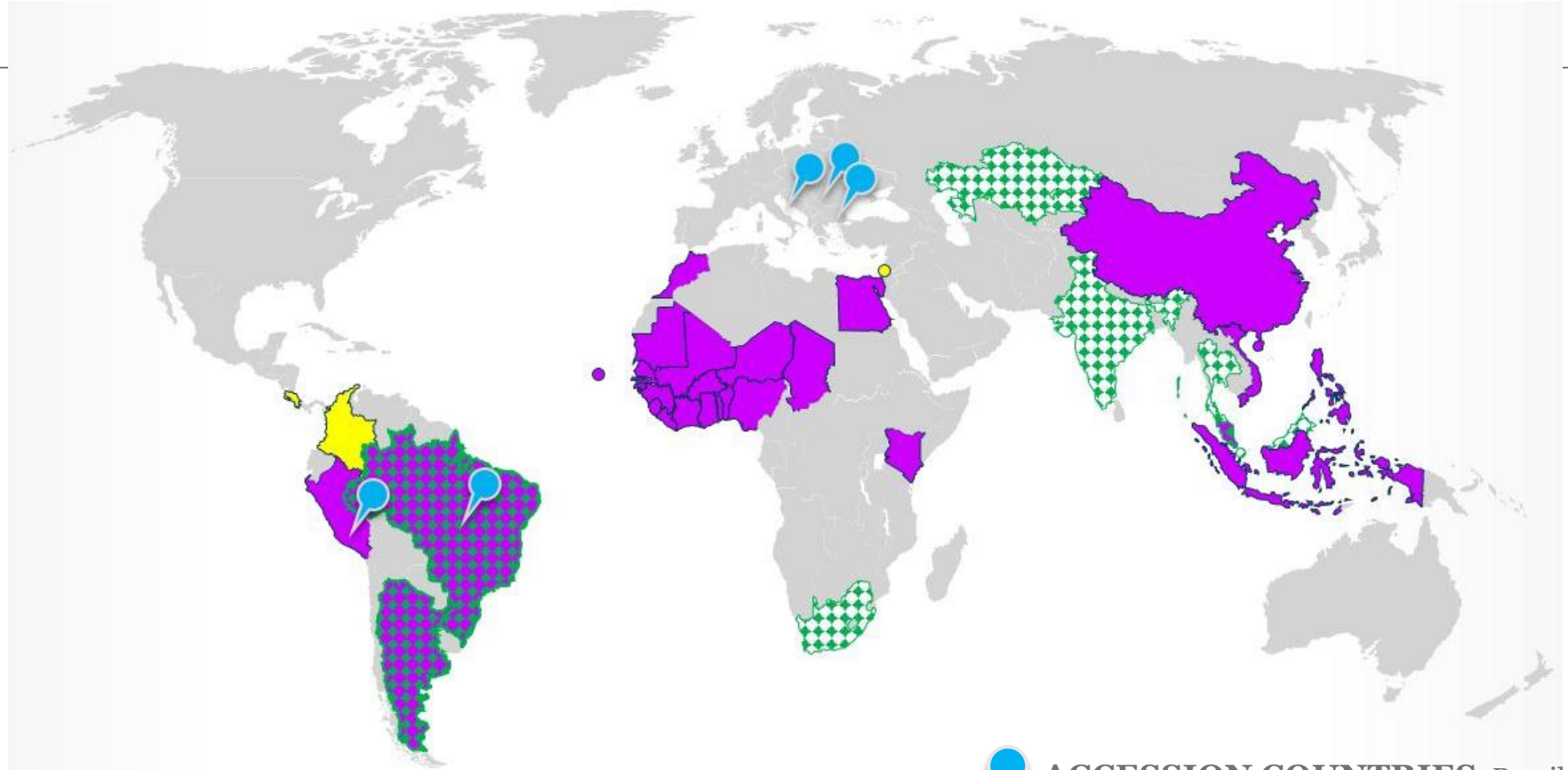


24k views

Safety Assessment of Transgenic Organisms in the Environment, Volume 8: OECD Consensus Document of the Biology of Mosquito Aedes aegypti (2018)

GLOBAL RELATIONS/ ACCESSION/ CAPACITY BUILDING

Global relations/Accession/Capacity Building



AWARENESS RAISING AND CAPACITY BUILDING

Drafting chemicals law: Ghana, Kenya, Viet Nam

Pesticides: Burkina Faso, Cape Verde, Gambia, Guinea Bissau, Mali, Niger, Senegal, Benin, Ivory Coast, Guinea, Togo, Ghana, Liberia, Nigeria, Sierra Leone, Chad, Egypt, Mauritania, Brazil

Various management schemes: China, Philippines, Viet Nam, Indonesia, Malaysia, Morocco, Kenya, Peru

Closing the gaps with OECD legal instruments: Brazil, Argentina

ACCESSION COUNTRIES: Brazil, Bulgaria, Croatia, Peru, Romania

POST-ACCESSION COUNTRIES: Colombia, Costa Rica and Israel

ASSOCIATES / PARTICIPANTS IN THE CBC: Argentina, Brazil, India, Malaysia, Singapore, South Africa, Thailand, Kazakhstan

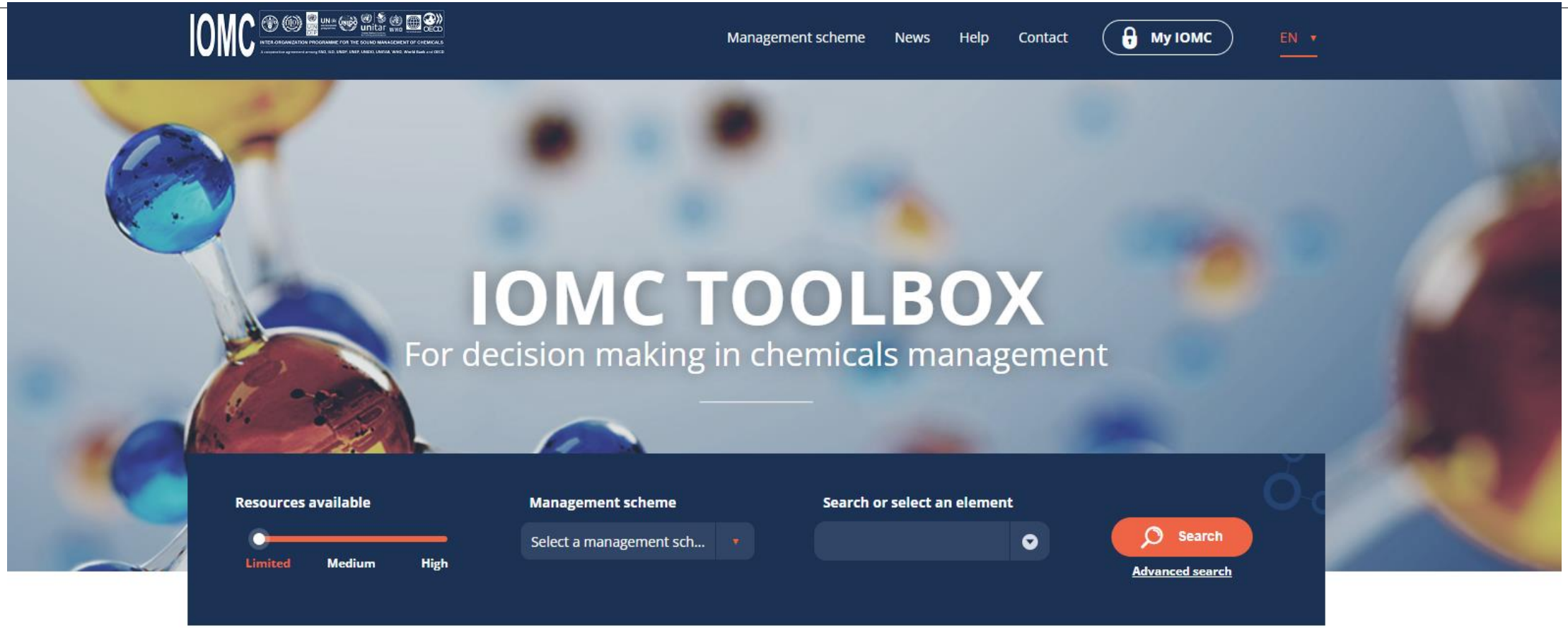
IOMC Toolbox for Decision Making in Chemicals Management

- One stop shopping on the web for resources for countries who wish to set up or improve their chemicals management system to find answers to and ways of dealing with their specific needs and objectives.

Home | IOMC-Toolbox (iomctoolbox.org)

IOMC Toolbox

Home | IOMC-Toolbox (iomctoolbox.org)



THANK YOU

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