EXPERIENCES FROM THE OECD WITH HAZARD ASSESSMENT AND ITS TOOLS

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Organisation for the Economic Cooperation and Development (OECD)

29 October 2025- online

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

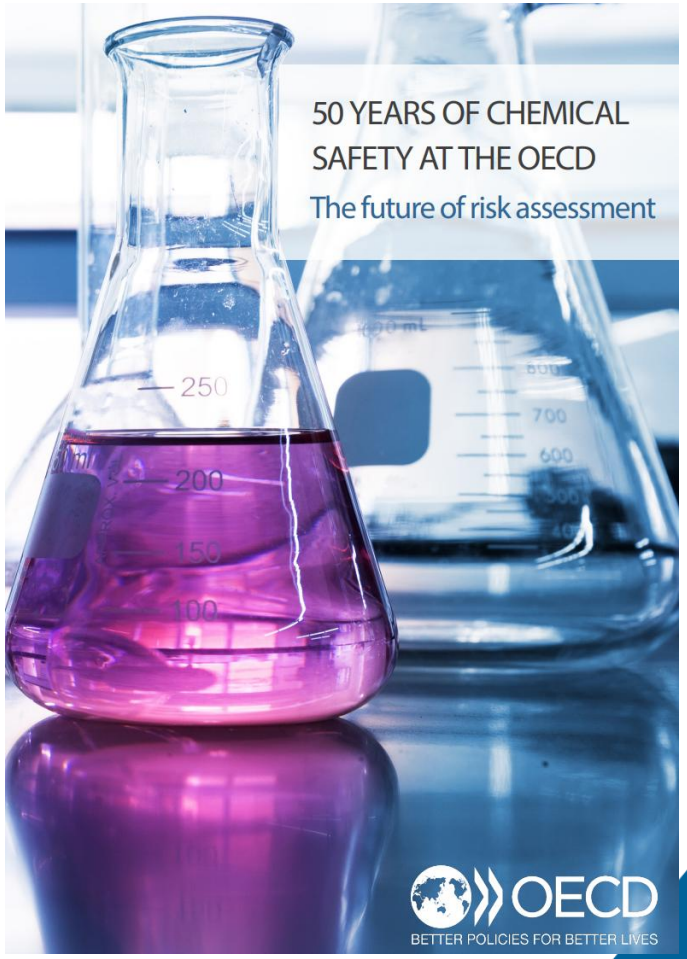
Accession discusssions initiated

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 (EHS) 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

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

International consensus

Multi-stakeholder development

Process for all OECD projects

- Once approved and added to workplan
- Nomination of relevant experts requested of all delegations
  - Asked to contribute to drafting, data analysis, review, scientific advice, feedback, etc.
  - Some projects supported by subgroups with specific tasks
- Expert group (EG) convened
- EG meets via TC on appropriate timeline
- Project leads provide updates at Working Party meetings

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)

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)

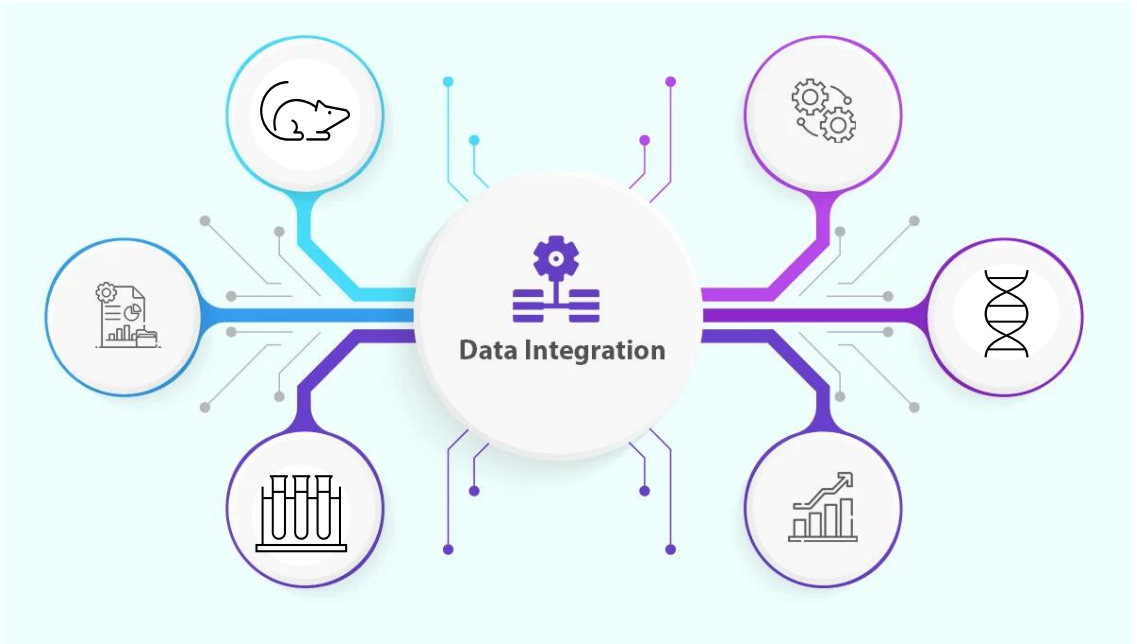
OECD Principles of GLP (2)

- 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

HAZARD ASSESSMENT PROGRAMME

OECD Hazard Assessment Programme: Innovative methods to evaluate chemical hazards

- Best approaches and practices for integrating information to come to a regulatory decision [i.e. **an assessment**]
- 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**



Uptake of New Approach Methods (NAMs): How "new"?

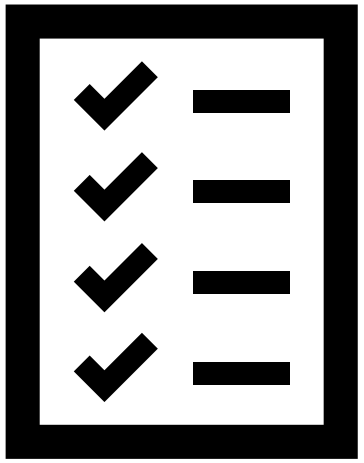
- In this context "New Approach Methods" include everything that is not an "old approach"
  - *in chemico*, *in vitro*, computational, *in vivo* methods
  - stand-alone or (more often) integrated combinations of methods
- Not "non-animal methods", but aligned with the 3Rs-Replacement, Reduction and Refinement
  - More relevant to the target species (e.g. humans)
  - Faster time to safety decisions
  - Fewer resources intensive (e.g. cheaper, less time for testing/analyses, fewer/no animals used)

Hazard Assessment tools supporting NAMs

eTools

e.g. QSAR Toolbox, IUCLID, eChemPortal, AOP wiki

Standardise/ structure data formats

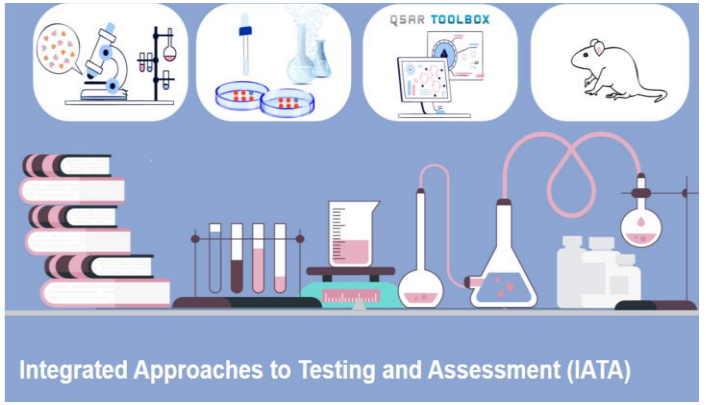


e.g. OHTs, OORF, PBK, QSARs

Guidance on specific topics

e.g. grouping, RAx, PBK, use of research data, data integration

Integrated testing strategies and Case Studies



e.g. reporting information in Defined Approaches, Use of AOPs to build IATAs, examples

OECD TOOLS FOR CHEMICALS DATA MANAGEMENT

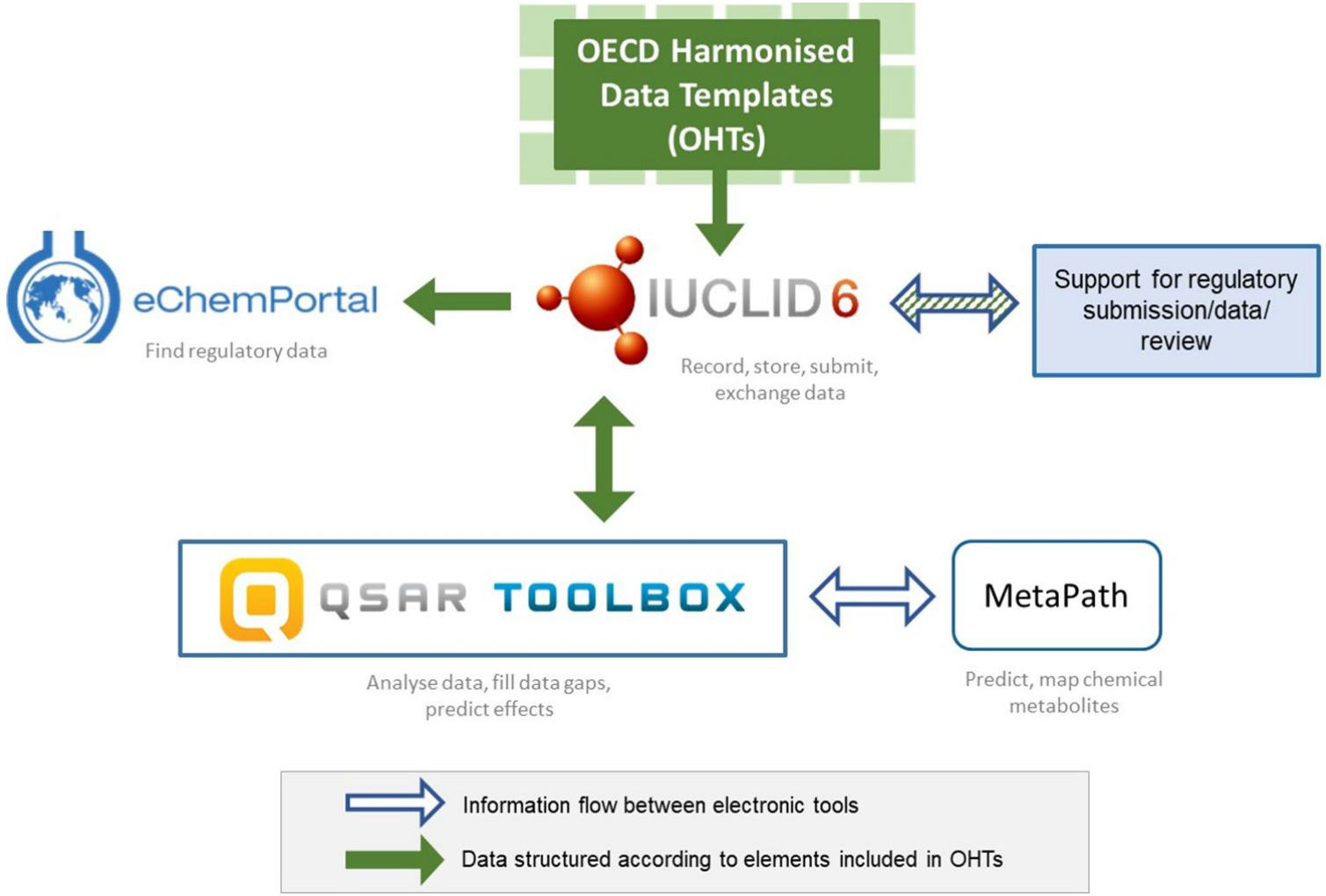
Number of chemicals and knowledge of chemical properties continues to expand

- **~86,000 chemicals registered U.S. TSCA**
- **~27,000 chemicals registered EU REACH**
- **~3,000 chemicals OECD Existing Chemicals**

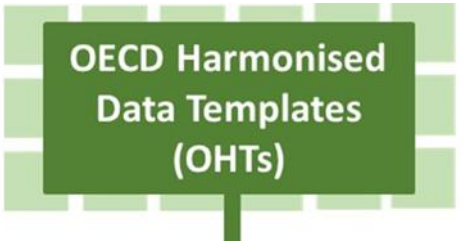
- Chemical industry expected to grow 4x in the next ~30 yrs

- Proliferation of databases capturing some information (limited number of chemicals, uses, endpoints)
  - Same substance - Different regions, different regulations, different data requirements, different reporting formats, different ontologies
  - Duplication of efforts, divergences

OECD Ecosystem of Electronic Tools



OECD Harmonised Templates (OHTs)



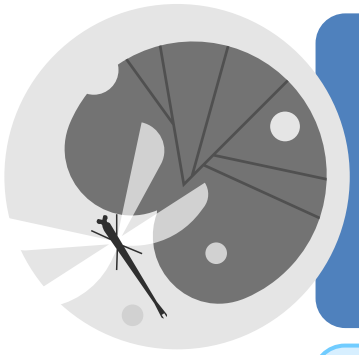
- Standard data formats for **reporting information used for the risk assessment of chemicals**, mainly (eco)toxicological studies, but also for storing data on use and exposure
- Aimed at **developers of database systems**, as they prescribe the formats by which information can be entered into and maintained in a database
- By using these templates, regulatory authorities and industry, can easily **electronically exchange information**

OHTs Series

Phys-chem properties (including nanomaterials)

Environmental fate and behaviour

Efficacy



Effects on biotic systems

Analytical methods

Health Effects

Intermediate effects

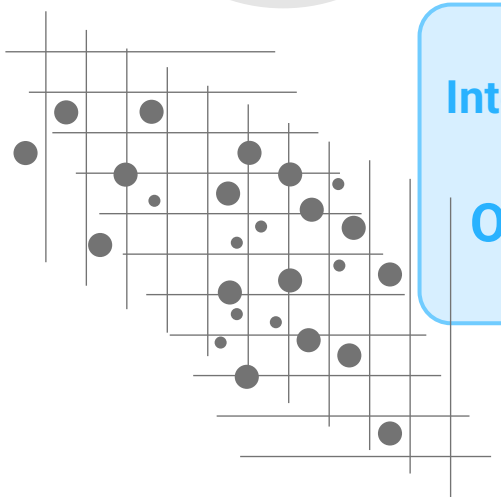
OHT 201

Emission from treated articles

Generic elements for all OHTs

Pesticide residue chemistry

Use and exposure information



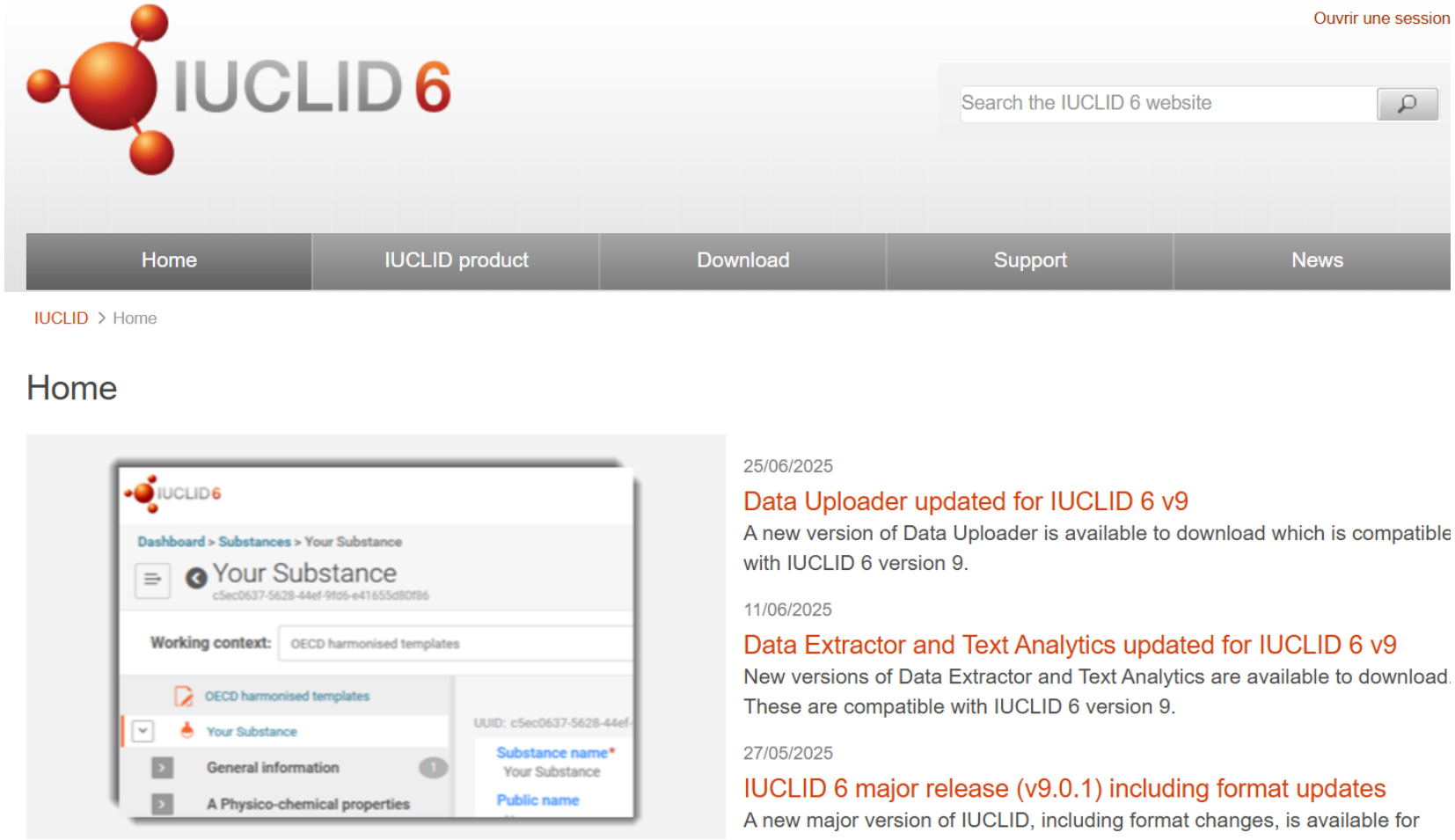
Endpoint summary record

Flexible record

International Uniform Chemical Information Database (IUCLID)

Free Software Application

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



ECHA EUROPEAN CHEMICALS AGENCY

Free software application to predict the properties of chemicals (version 4.8, July 2025)

- **experimental data** from **~60 databases**, **100 000 chemicals** and > **3M data points**
- **Structural profilers**
  Mechanistic profilers
- Results from **5 experimental metabolic databases** and **11 metabolic simulators**

- Variety of 3rd party QSARs and computational tools
  - EPISuite models by US EPA
  - Danish QSAR Database predictions
  - OPERA, US National Toxicology Program

ECHA EUROPEAN CHEMICALS AGENCY

QSAR reporting formats

	REPORTING STANDARDS AND FRAMEWORKS	
QSAR	QSAR Model Reporting Format	Description of model (for developer)
	QSAR Prediction Reporting Format	For user
	QSAR Result Reporting Format	Results derived from multiple predictions

2nd version, 2024

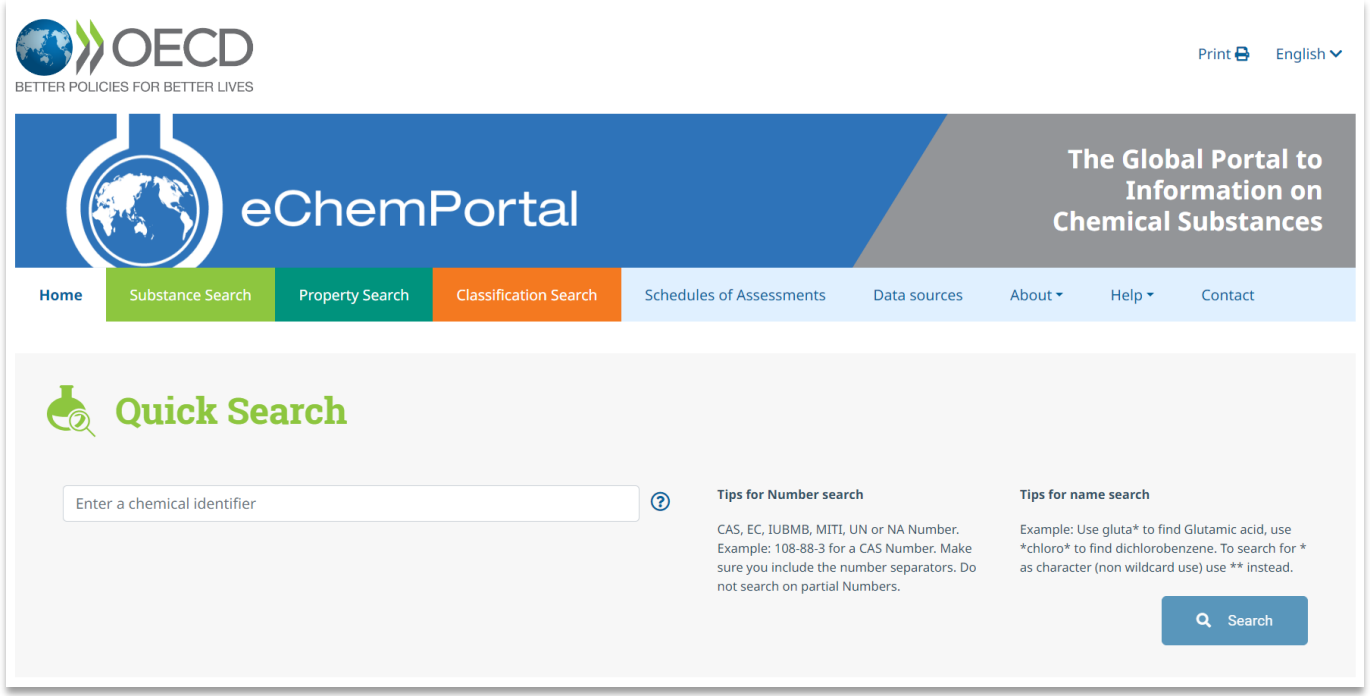
What is eChemPortal?

https://echemportal.org

eChemPortal

Free and easy access to information on chemicals of regulatory relevance prepared for government chemical programmes

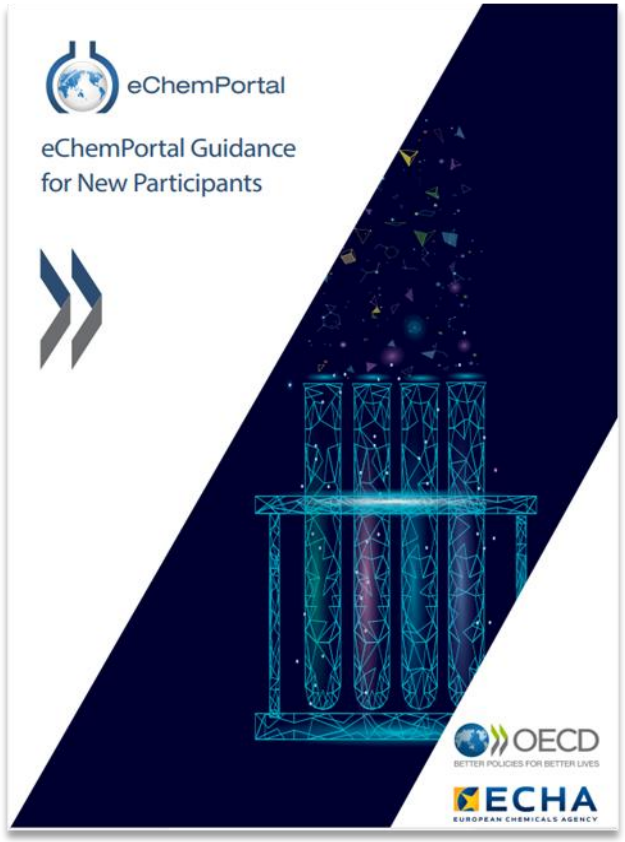
- **Property information (e.g. hazard & risk assessments, test data)**
- **Exposure and use information**
- **National classification results according to the GHS**



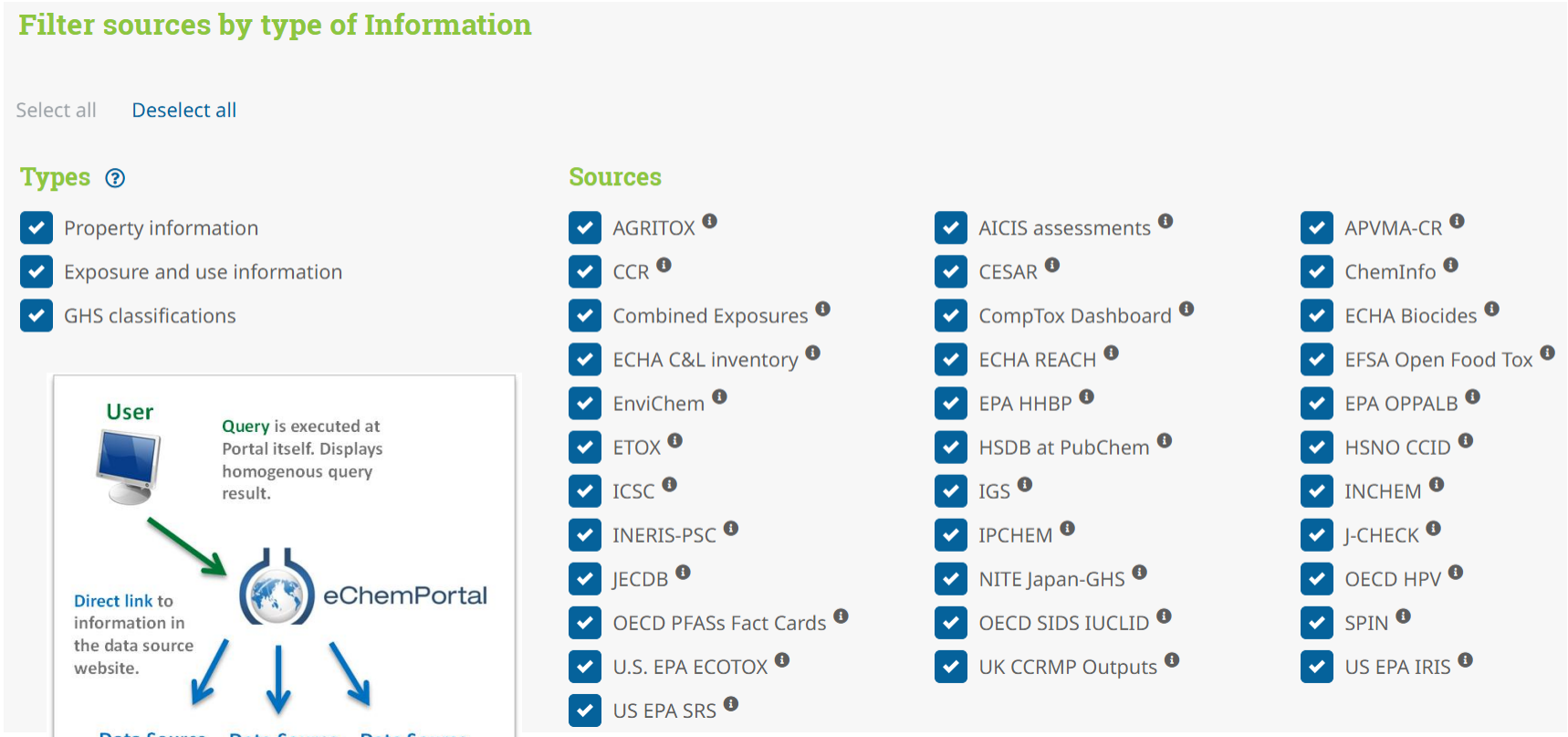
Focus

- Existing industrial chemicals
- New industrial chemicals
- Pesticides
- Biocides

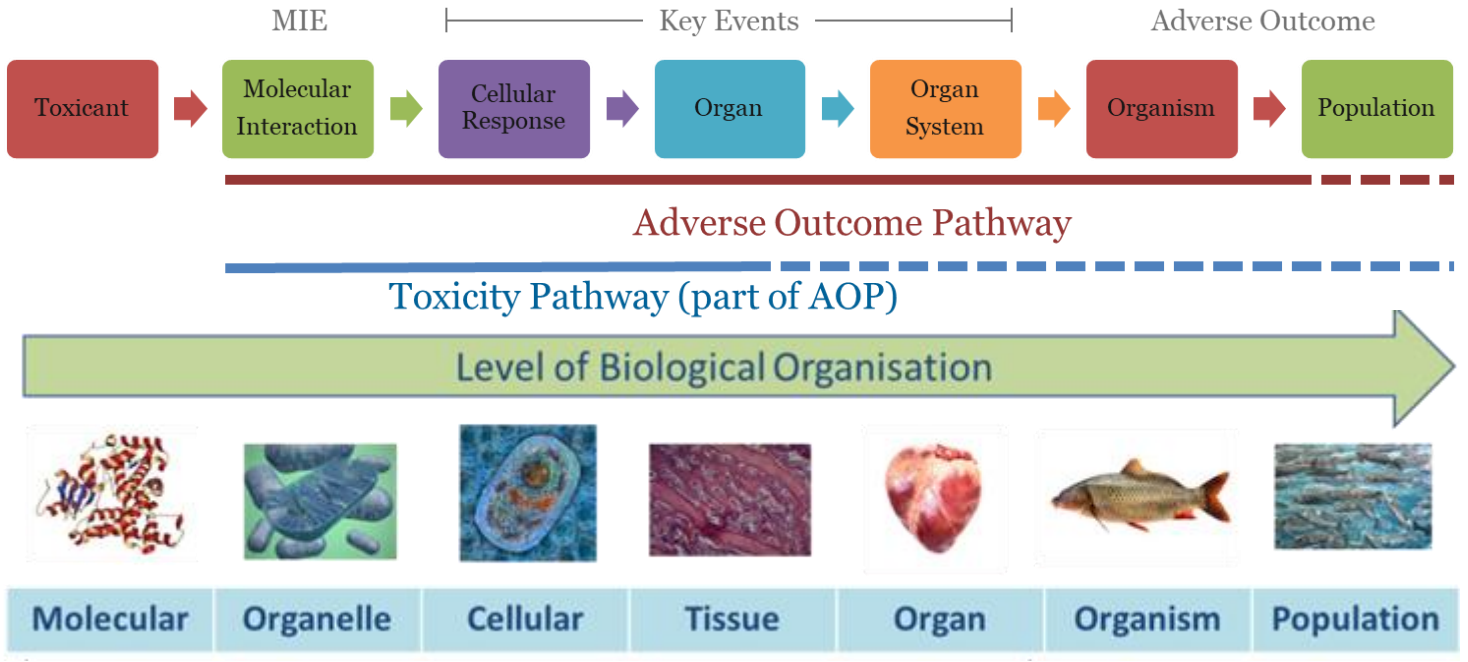
eChemPortal



eChemPortal Guidance for New Participants
https://oe.cd/guide-echemportal

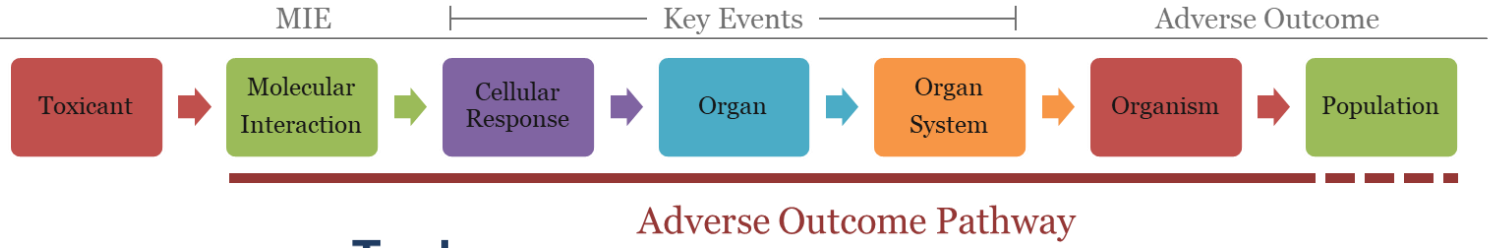


Adverse Outcome Pathway Framework

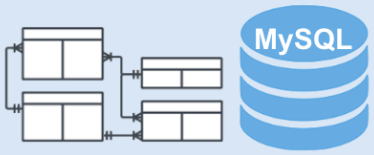


- AOPs were always imagined as organising frameworks for:
  - building predictive methods (including test guidelines)
  - building integrated testing strategies
  - guiding next steps for chemical safety testing
  - identifying gaps in information

AOP Knowledge Base



AOP-KB



AOP Database Schema & Content

Accessible AOP Content hosted at aopwiki.org

READ

WRITE

READ

Tools

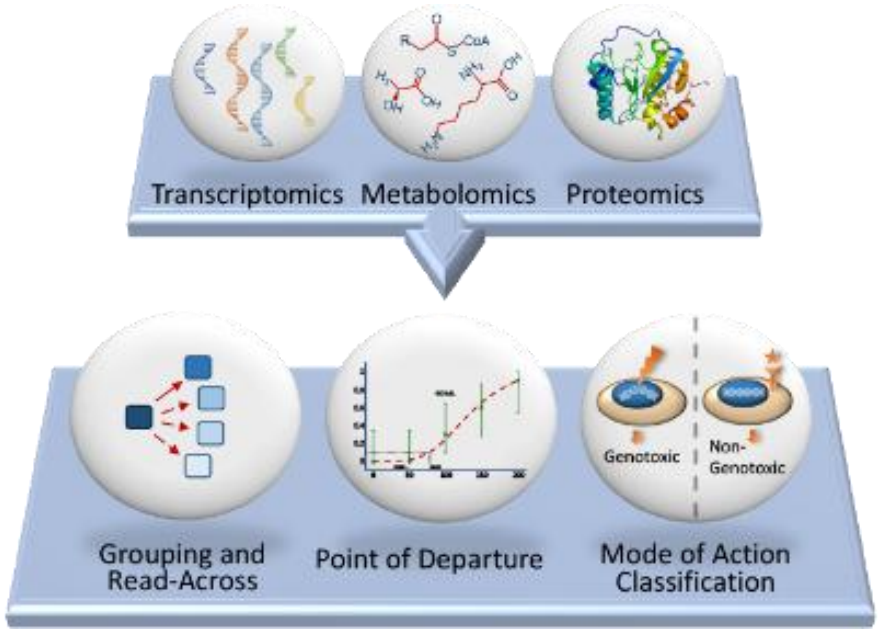
AOP-Wiki

Sole AOP Authoring tool

AOP Forum: For collecting community perspectives on the AOP framework.

Other tools developed & supported by the community

Omics technologies in chemical testing



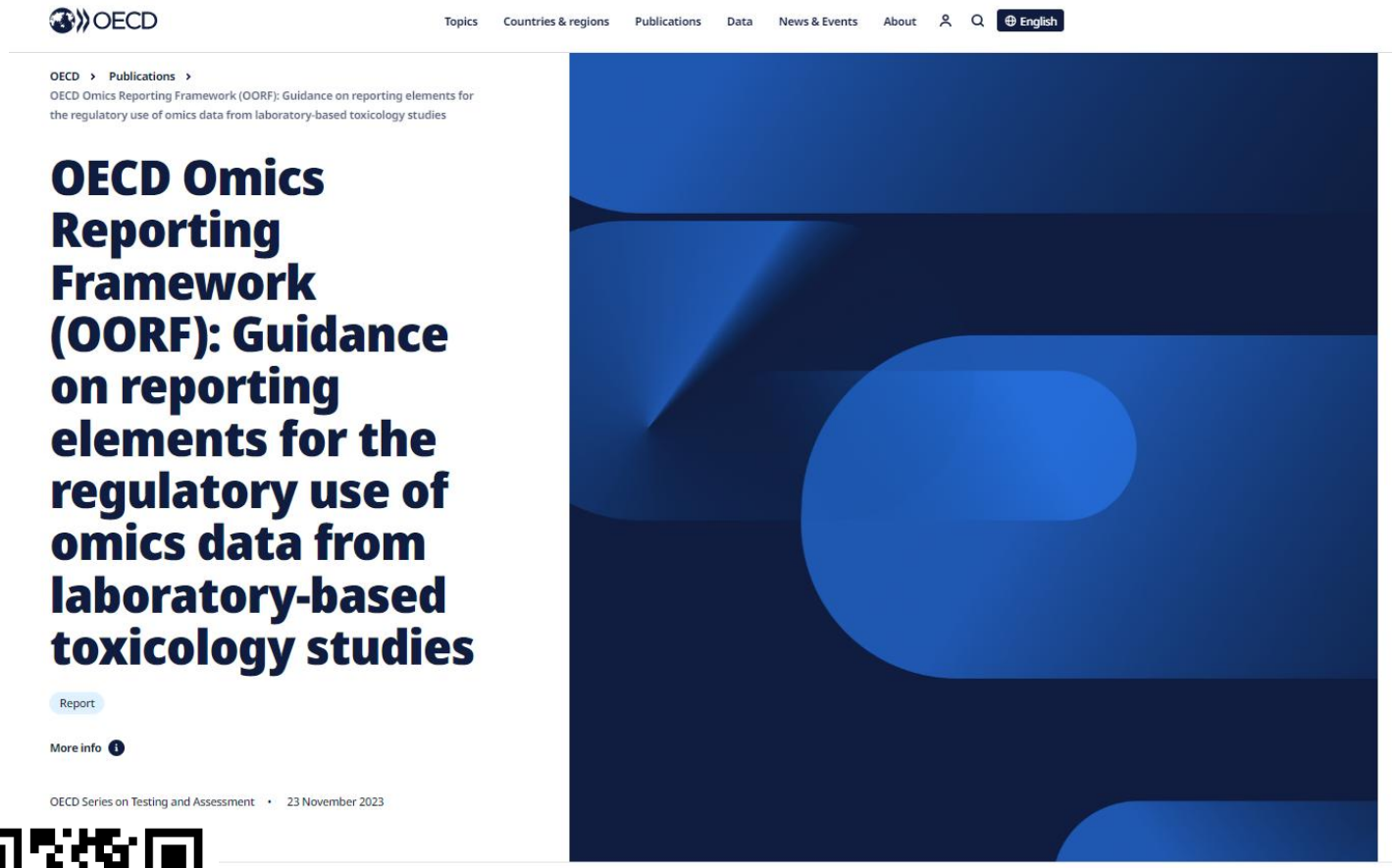
"Omics" Tool to characterise and quantify the molecular and biochemical changes in cells, tissues and organisms following exposure to chemicals and toxic substances

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

OECD Omics Reporting Framework



Framework for the standardisation of reporting of 'omics data generation and analysis, to ensure that all of the information required to understand, interpret and reproduce an 'omics experiment, and its results are available.

Purpose: to ensure that sufficient information is available to enable an **evaluation of the quality of the experimental data and interpretation**, and support **reproducibility**.

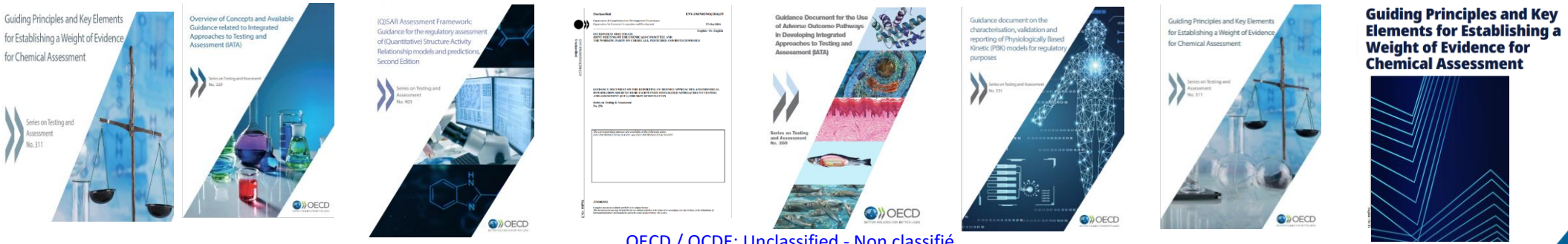
NOT to stipulate the methods of data analysis or interpretation….**Rather**, provide guidance on reporting of information that fosters **transparency** and **reproducibility**.

Slide courtesy of Magda Sachana

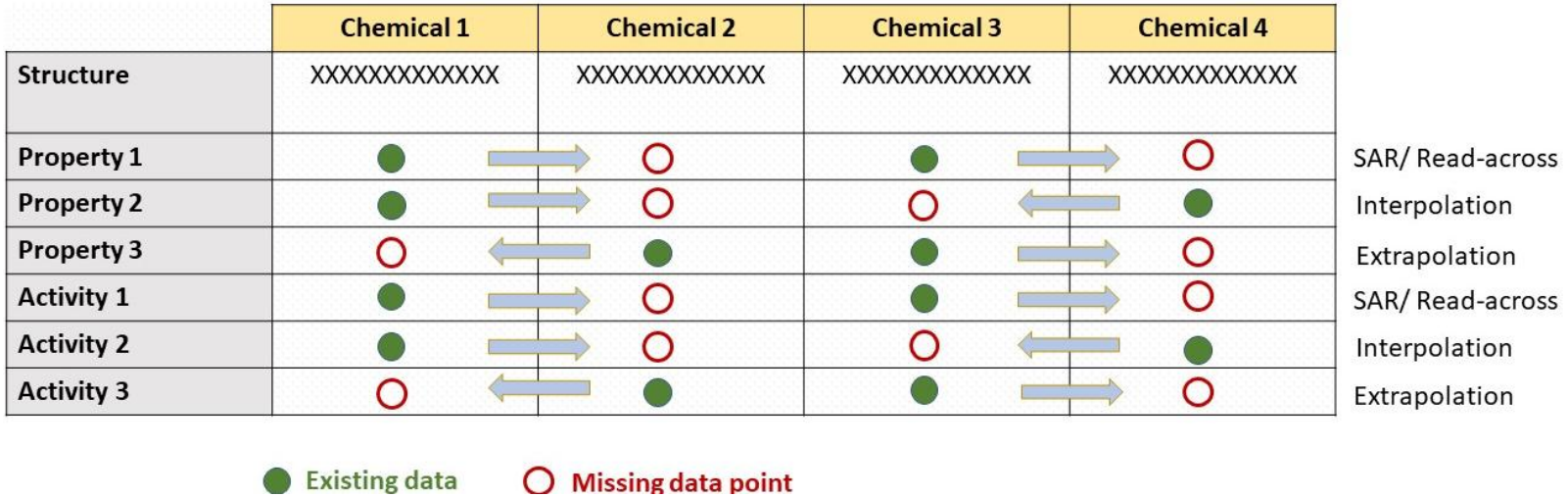
GUIDANCE ON SPECIFIC TOPICS

HA: Guidance on specific topics

- GD on the Characterisation, Validation and Reporting of PBK Models for regulatory purposes – 2nd ed **2026**
- GD on Grouping of Chemicals, 3rd Edition - **2025**
- Guidance on Good Practices and Standardisation of Sample Collection for Omics - **2025**
- Workshop Proceedings for QIVIVE for DNT Risk Assessment - **2025**
- Guidance on the Generation, Reporting and Use of Research Data for Regulatory Assessment – **2025**
- Report on the state of the science for identifying Endocrine Disrupters under the UN GHS – **2025**
- QSAR Assessment Framework
- Concepts and Available Guidance related to IATA
- GD for Use of AOPs in Developing IATA
- Guidance on WoE
- Guidance on Mixtures Assessments



Guidance on Grouping of Chemicals



What is GROUPING?

The process of identifying a collection of substances that are likely to be similar or follow a regular pattern as a result of **SIMILARITY***

*structure, physico-chemical properties, chemical reactivity profile, bioactivity, conventional toxicological profile and ADME/ Toxicokinetics including metabolism

Guidance on Grouping of Chemicals, 3rd Edition

- Expanded guidance for
  - Metals
  - Nanomaterials
- More detailed guidance on grouping using
  - Omics
  - Mechanistic information
  - AOP frameworks
  - QSARs
  - How to evaluate uncertainties
- Examples of recent grouping and read-across approaches

Released October 2025!

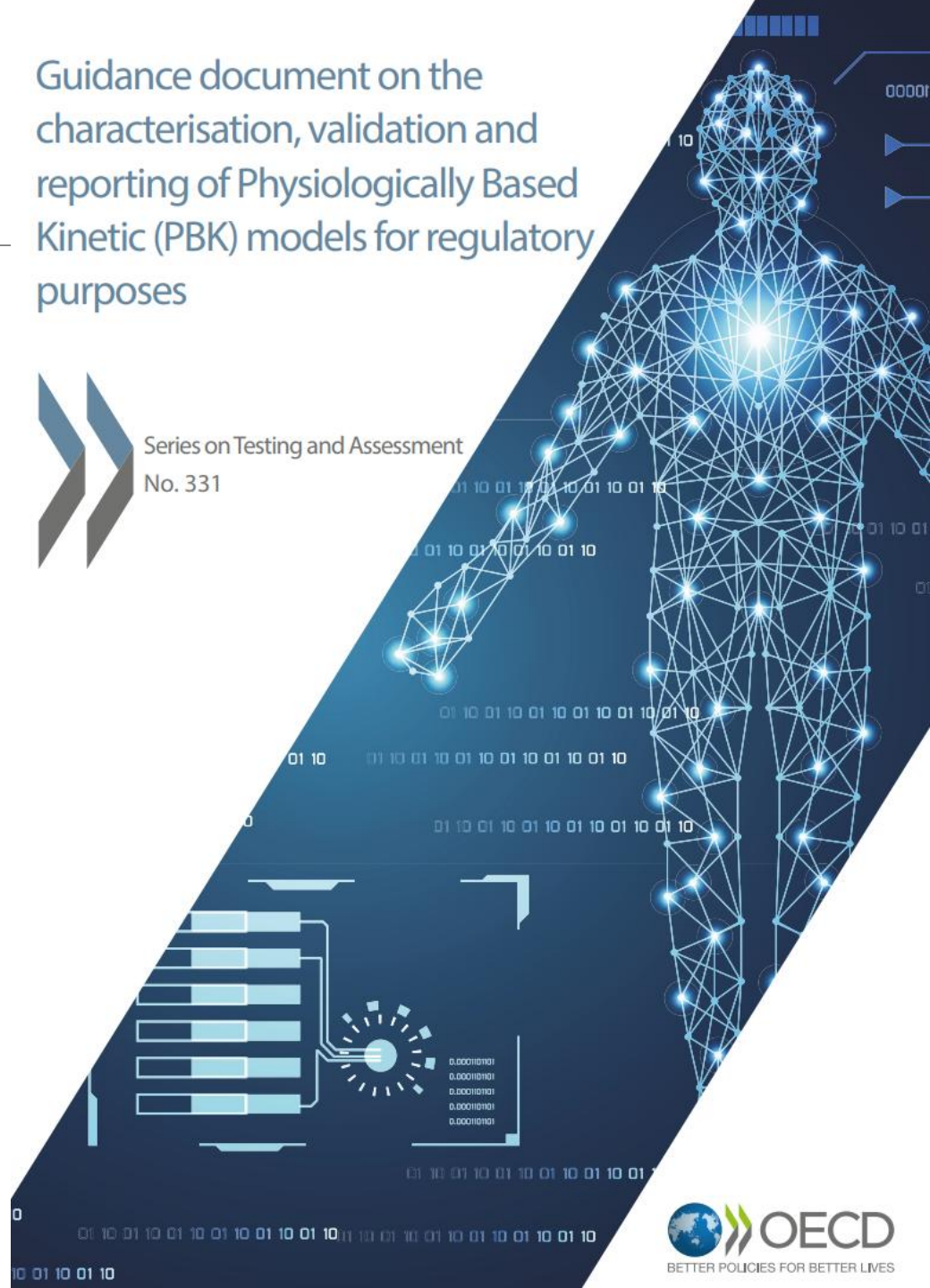
QSAR Assessment Framework: overview

- Objective
  - develop a systematic and harmonised framework for the regulatory assessment
- Scope
  - (Q)SAR models
  - (Q)SAR predictions and results based on multiple predictions
- Relevance/applicability
  - irrespective of the technique used to build the model, the predicted endpoint, and the intended regulatory purpose
- Audience
  - primarily, regulatory authorities
  - as reference for other stakeholders using (Q)SARs for regulatory purposes

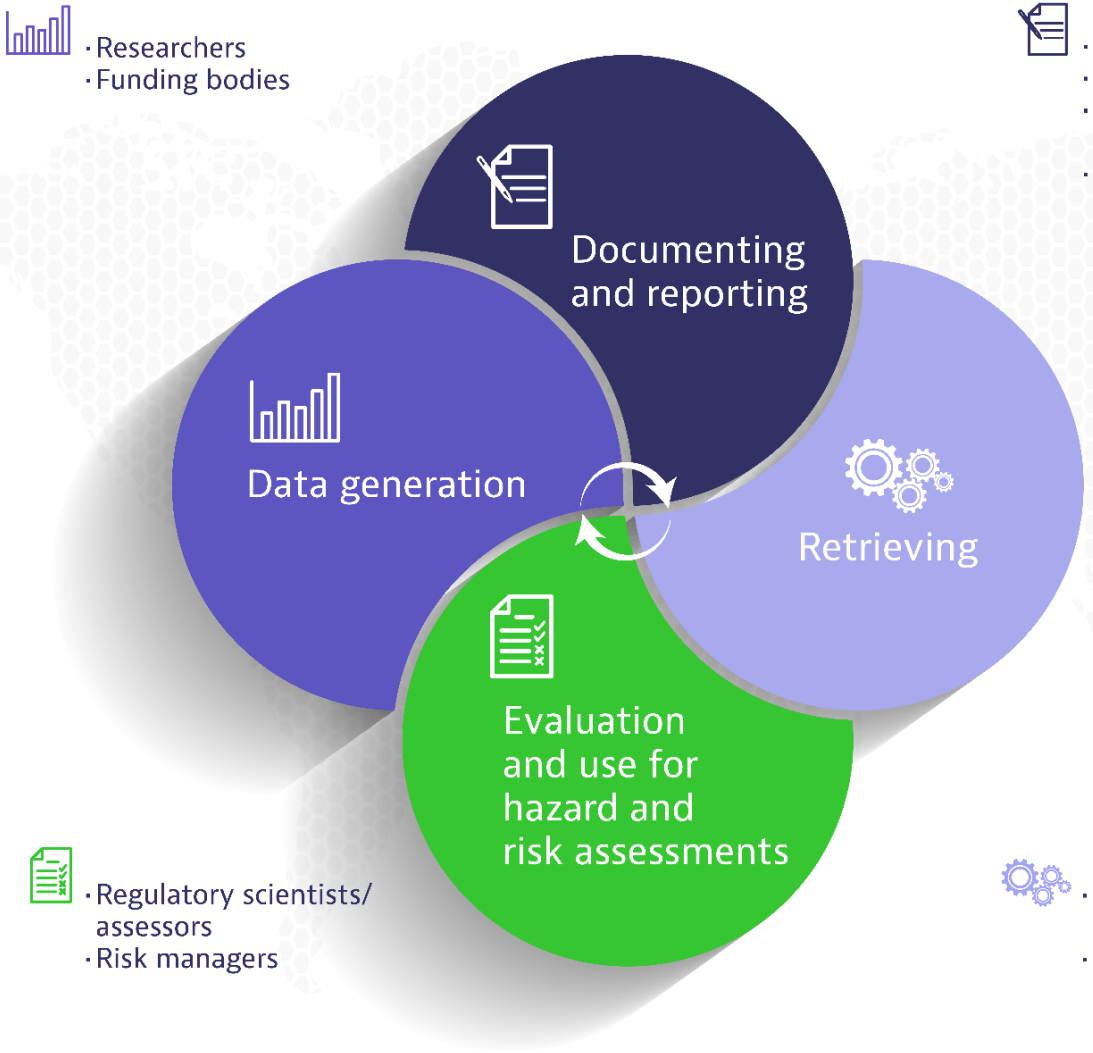
Slide courtesy of Patience Browne

Guidance on PBK modelling

- A PBK model is a mathematical model (set of equations) that describes the absorption, distribution, metabolism and excretion of a chemical in a given organism (e.g. human, fish, cattle) under a given exposure scenario.
- **Purpose**: to provide guidance on the characterisation and reporting of PBK models used in the regulatory assessment of chemicals.
- **NOT** intended to provide technical guidance on PBK model development for modellers
- Work on the 2nd edition of GD started in 2025



Guidance Document on the Generation, Reporting and Use of Research Data for Regulatory Assessments



Released October 2025!

Improving the utility of Research Data

📢 The **Guidance Document on the Generation, Reporting, and Use of Research Data for Regulatory Assessments** is coming soon!

🌎 Designed for researchers, regulators, funders, publishers, and more, it promotes the use of all **reliable and relevant** data, including non-guideline studies, in chemical safety assessments

🔬 **Make your (eco)toxicology data fit for regulatory use** by adopting structured reporting and reliability criteria aligned with regulatory expectations

💡 Discover **practical tools and approaches to improve searching and evaluation of research data**, supporting better decisions for human health and the environment

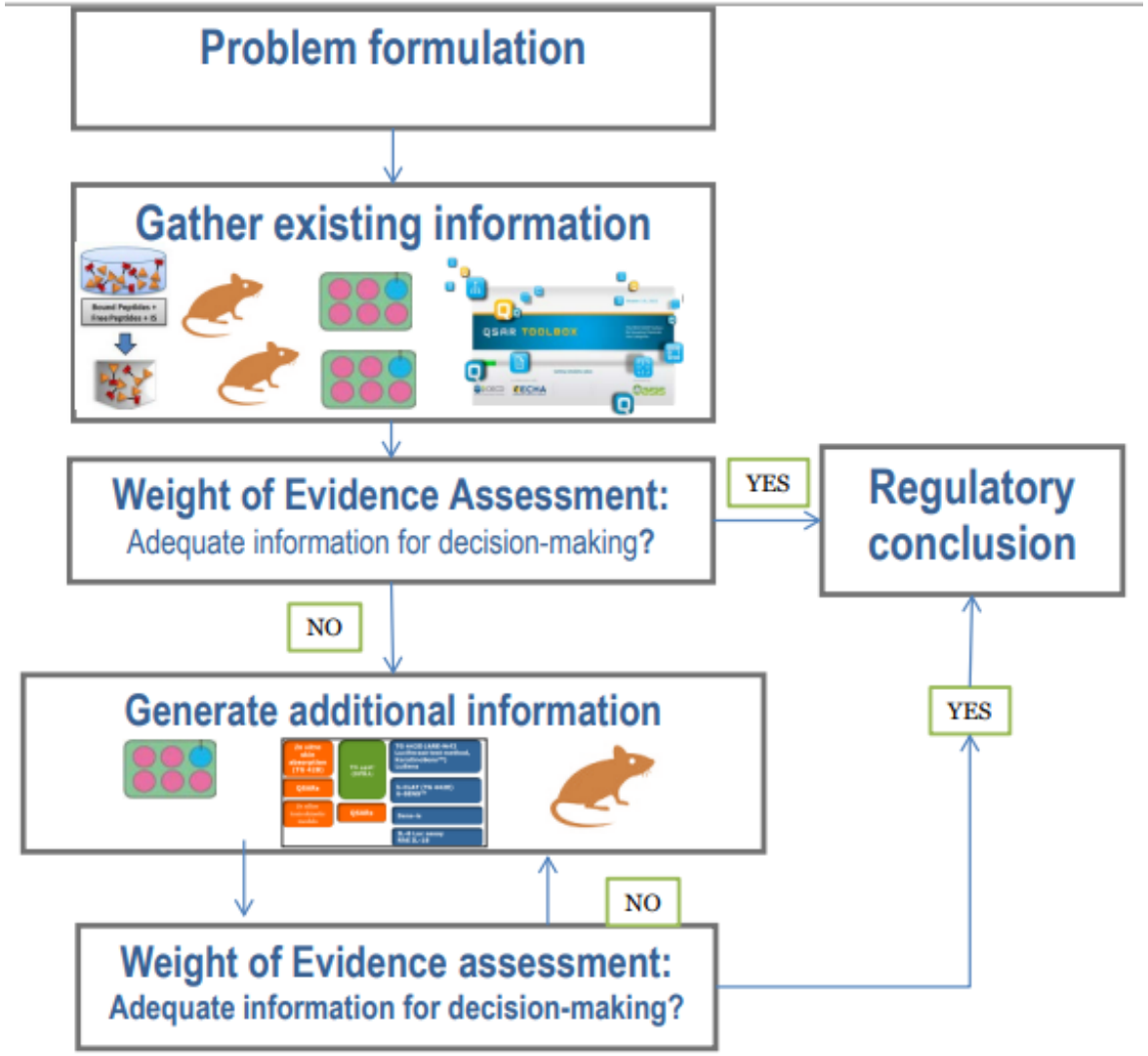
UPCOMING OECD WEBINAR

14 November 2025, 13h CET, Paris time

REGISTER HERE!

INTEGRATED TESTING STRATEGIES AND CASE STUDIES

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 (IATA) | OECD]

OECD IATA Case Studies Project

Objective:

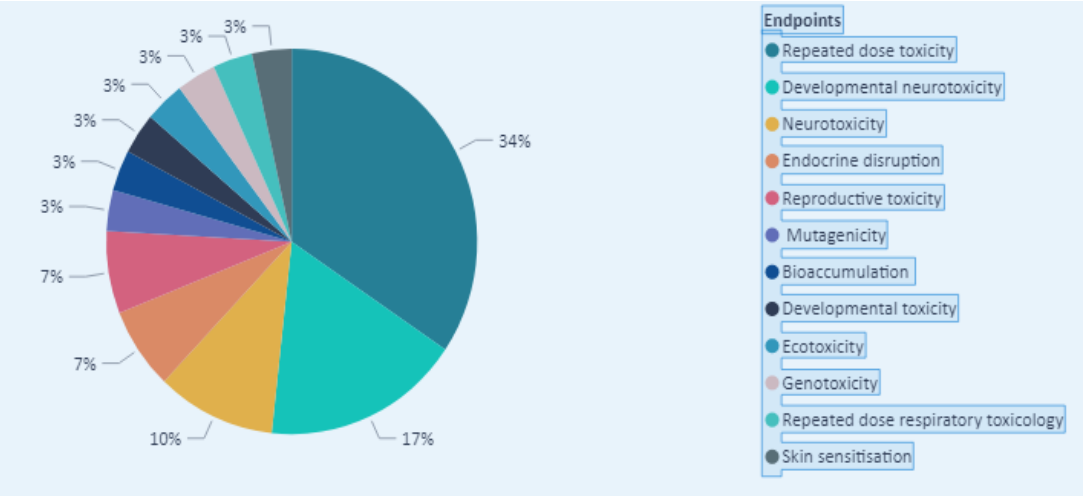
- To **increase experience** with the use of IATA by developing CSs, which constitute examples that are fit for regulatory use.
- To create **common understanding** of using NAMs and the **generation of considerations/guidance** stemming from these CSs.

Experience gained:

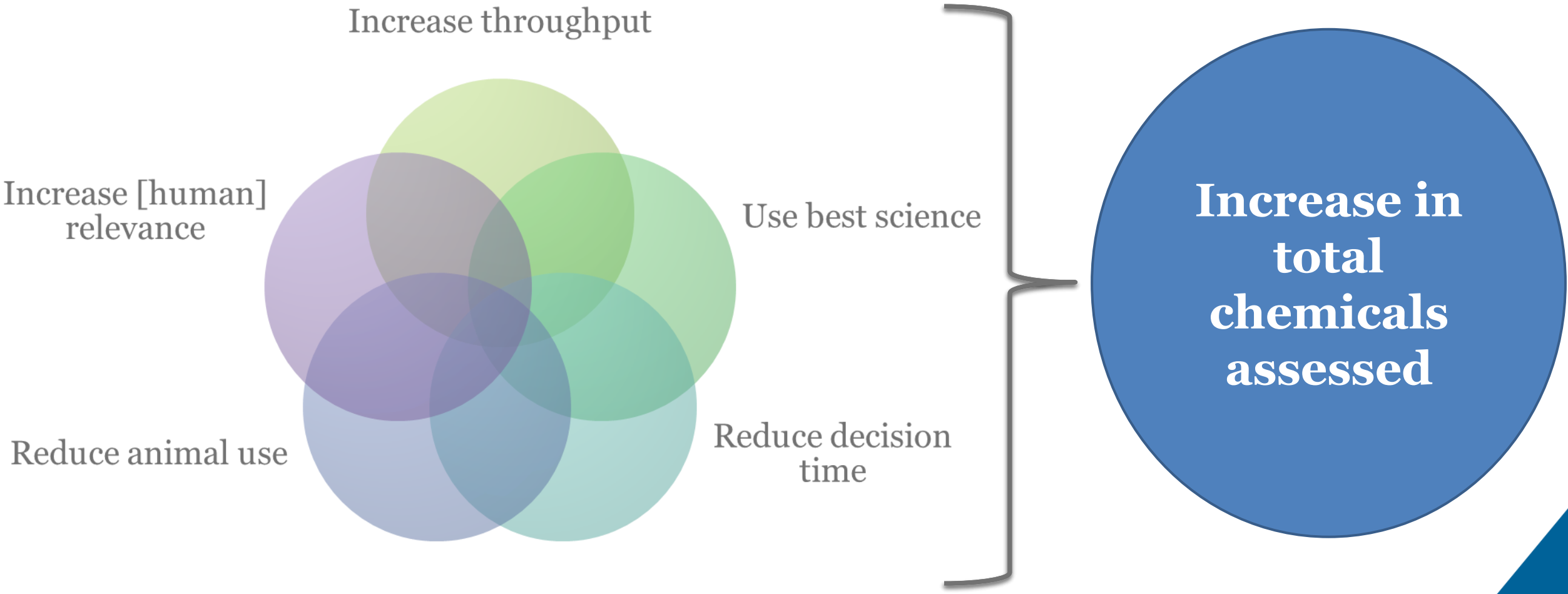
- Published ~40 CSs on the OECD public site.

Also intended to provide a possible path for

- NAMs used in TG
- Defined Approach GL
- Testing Strategies
- Testing Batteries



Global drivers to use NAMs in chemical risk assessment



Hazard Assessment Programme

- Assessments are not harmonised and fit respective legal frameworks
  - Results are **not covered by MAD ('Mutual Acceptance of Data")**
  - But… countries may wish to **'opt–in' and accept** approaches or assessments
- **Building confidence**

THANK YOU

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