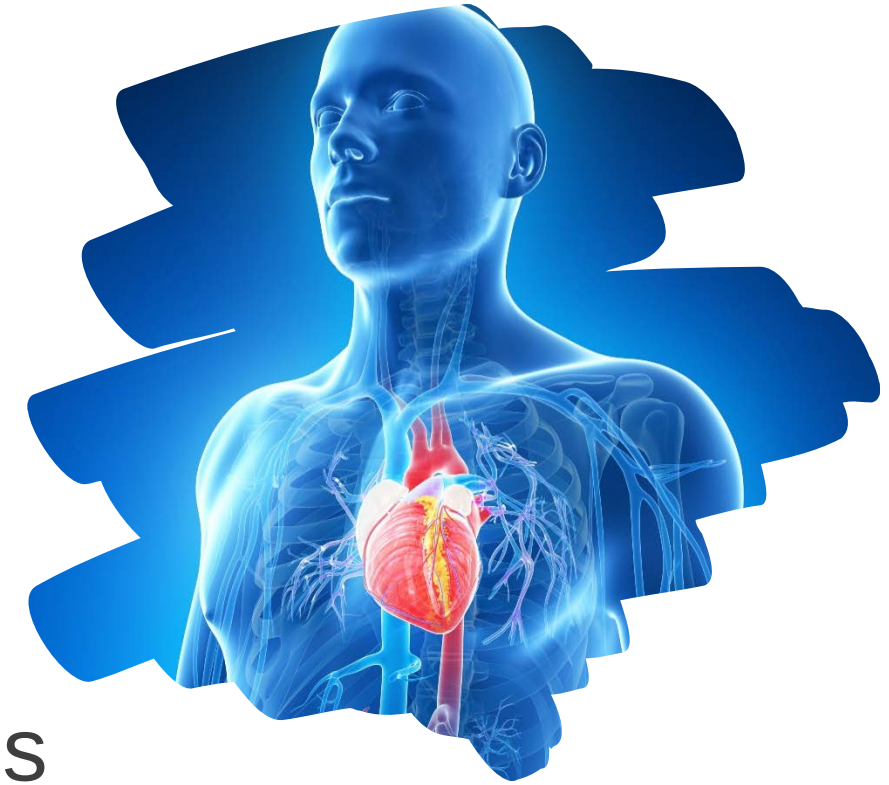
Replacement of animal testing with new approach methodologies



What are the opportunities?

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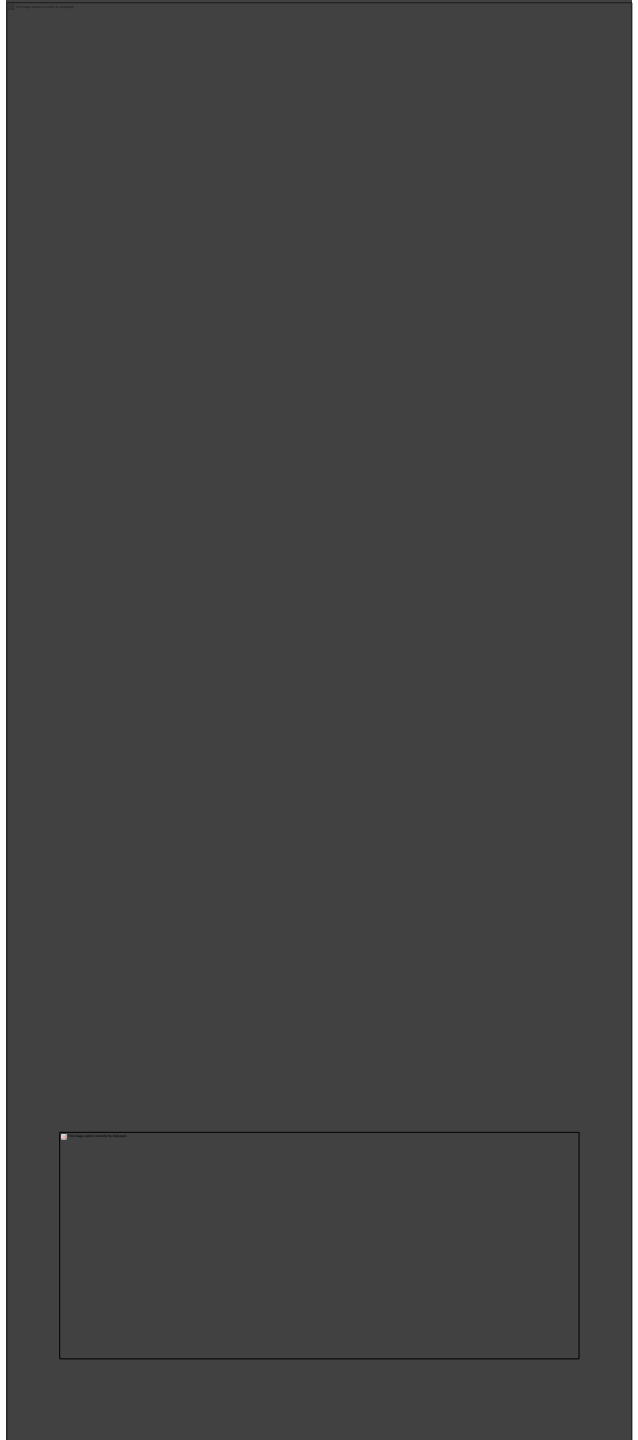
Overview

- About HSI and the Human Toxicology Project Consortium
- REACH, animal testing and replacement
- ECHA draft strategic plan
- Opportunities for change
- A look at Canada
- Challenges to change
- Conclusion

- HSI is active in 60+ countries, including Europe, the Americas and Asia-Pacific
- Our Research & Toxicology Department brings together experts in eco/toxicology, regulatory science, biomedicine, law, etc.
- Observer to ECHA MSC, CARACAL, OECD Test Guidelines and AOP programmes, government and industry advisory bodies, etc.
- Working with diverse stakeholders to find constructive solutions to complex science-policy challenges

HSI is the leading international NGO working to advance non-animal safety testing and bioscience research worldwide.

- Coalition of corporate, academic and NGO stakeholders who share the goal of advancing a mechanistic, biology pathway-based approach to toxicology and disease studies
- Providing strategic support for advances in key technologies and sciences; educating and building consensus among diverse stakeholders; ensuring support for research and implementation of 21st century science



CAAT JOHNS HOPKINS Center for Alternatives to Animal Testing

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HUMANE SOCIETY LEGISLATIVE FUND

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ScitoVation INNOVATIVE CELL BASED SCIENCE

Unilever

REACH, animal testing & replacement

Legal mandate

Article 1:

"The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances"

Article 13:

1. "… information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, *in vitro* methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across)…"
2. "These methods shall be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved."

Article 25:

1. "In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort."

ECHA draft strategic plan 2019-2023

Strategic priority	Objective	Measure of success[13]
1. Identification and risk management of substances of concern	[1] Accelerate data generation and intensify identification of substances of concern	By 2025, conclusions are available on whether registered substances i. Are of concern; ii. Are currently not of concern; or iii. Need more data for a judgement to be made and the data that is missing has been defined.
	[2] Accelerate regulatory action on substances of concern	By 2025, all substances of concern are identified and regulatory action initiated

HSI comments

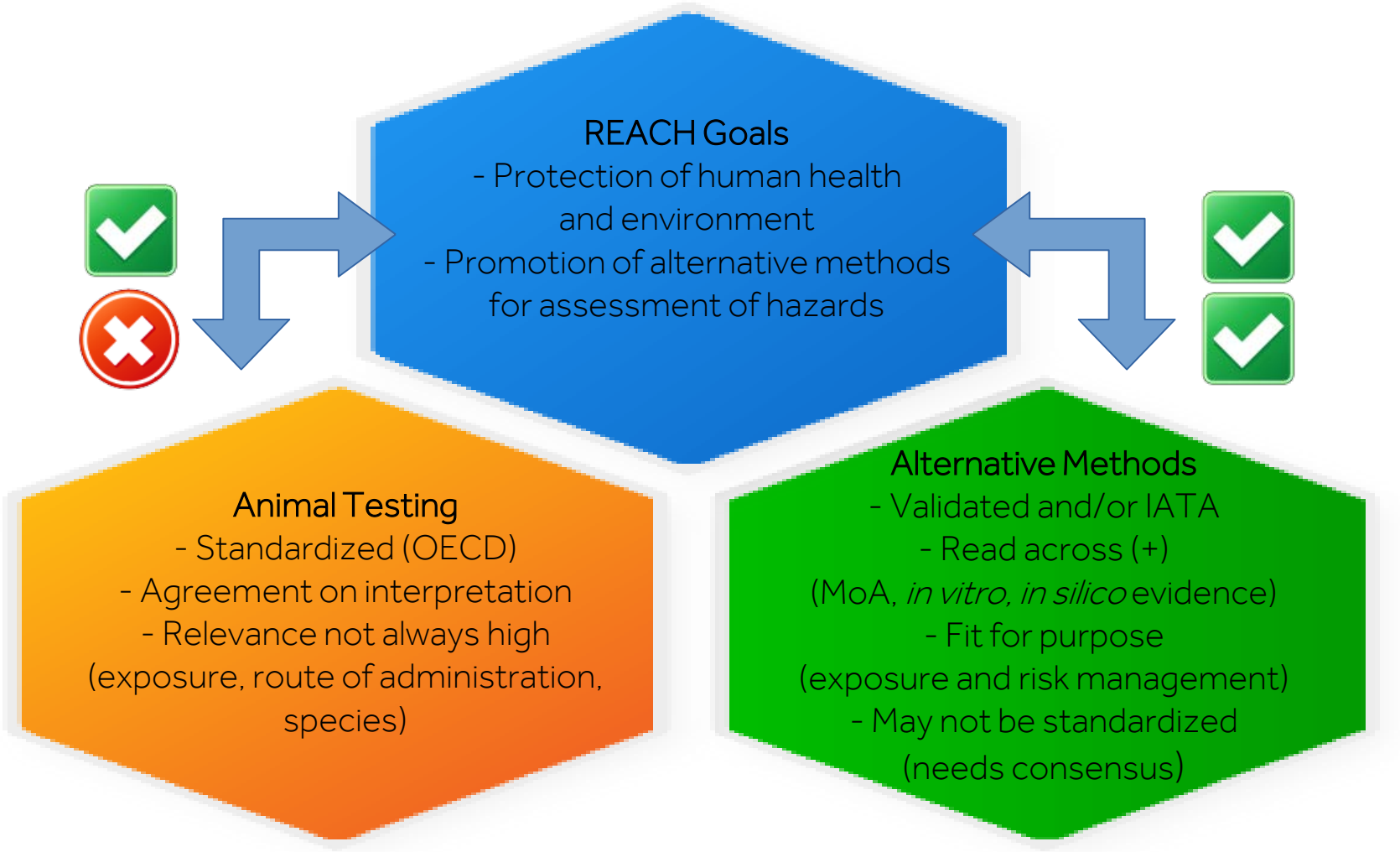
- Notably absent from ECHA's mission statement is the REACH Article 1 aim of "promotion of alternative methods for assessment of hazards of substances".
- We recommend the creation of an additional high-level strategic aim that is responsive to the alternatives-promotion mandates under REACH and BPR.

Opportunities for change

REACH Refit evaluation

“Respondents from almost all stakeholder groups agreed that the principle of ‘animal testing as a last resort’ is not yet fully implemented. Respondents explain this problem by strict information requirements coupled with a low acceptance of alternative methods.”

Opportunities for change



Availability of existing data and use in read-across(+) is the biggest opportunity, and readily available

How are other authorities evaluating?

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan-3-substances/uvcb-group.html

Sector-specific Inorganic UVCBs Group

These substances were identified for action under the Chemicals Management Plan (CMP).

- Summary of publications
- Timelines

Information sheet

- Sector-specific Inorganic UVCBs Group

Summary of publications

Substance group	CAS RN	Common name	DSL name	Final screening assessment	Conclusion on section 64 criteria	Follow-up activities
Sector-specific Inorganic UVCBs Group	65996-69-2	Blast furnace slag	Slags, ferrous metal, blast furnace	HTML	Does not meet	None planned at this time
	65996-71-6	Steelmaking slag	Slags, steelmaking			
	66071-92-9	Black liquor or red liquor	Sulfite liquors and cooking liquors, spent			
	67711-90-4	Copper smelting dusts	Flue dust, copper-refining			
	67711-91-5	Copper matte	Matte, copper			
	67711-95-9	Electrowinning cell sludge	Slimes and Sludges, copper electrolytic			
	67712-00-9	Precipitates and slurries, copper refining	Slimes and Sludges, copper refining			
	68131-30-6	Green pulping liquor	Sulfite liquors and Cooking liquors, green			

Government of Canada | Gouvernement du Canada

https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/chemicals-glance/uvcb-group.html

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- Sector-specific Inorganic UVCBs Group

Overview

- The Government of Canada conducted a science-based evaluation, called a screening assessment, of 57 substances in the Sector-Specific Inorganic UVCBs Group, to address the potential for harm to Canadians and to the environment.
- Under the Canadian Environmental Protection Act, 1999 (CEPA 1999), the risk posed by a substance is determined by considering both its hazardous properties (its potential to cause adverse human health or ecological effects) and the amount of exposure there is to people and the environment. A substance may have hazardous properties; however, the risk to human health or to the environment may be low depending upon the level of exposure.
    - More information on assessing risk can be found in the Overview of Risk Assessment and related fact sheets, particularly on Types of Risk Assessment Documents and the Risk Assessment Toolbox.
- Exposure to these 57 substances is either not expected or negligible. Therefore, it is concluded that these 57 substances are not harmful to human health or to the environment.

Challenges to change

- Will require acceptance of non-standardised approaches by all stakeholders
- Will require expert agreement by ECHA, Member States and industry to build trust in assessments
- Shift in mindset of evaluation, from **data gap filling by testing to an alternative toxicological hazard and risk assessment** to meet REACH goals on both human safety and animal protection
- Regulators and industry have a shared responsibility for successful change

Conclusion:

Accelerate joint acceptance of non-animal strategies (read-across)

- Urgent need to modify approaches **now** – for filling perceived information gaps where needed for hazard and risk assessment
- Solutions are available today for immediate application, foremost among them being read-across (+)
  - **Although the REACH 2018 registration deadline has passed, many evaluations on 2010 and 2013 registrations are still ongoing**
- Ongoing R&D efforts such as EU-ToxRisk, US Tox21 and organ-on-a-chip programmes offer great promise in the mid- to longer-term future
- Initiatives such as CatApp offer a **science-based solution for today** that should be fully embraced by ECHA and Member States

Thank you!

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