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**INTERNATIONAL**  
**EUROPE**

**REACHing for solutions:**  
**Essential revisions to the EU chemicals**  
**regulation to modernise safety assessment**

# Agenda

Catherine Willett, PhD



Marina Pereira, MSc



Donna Macmillan, PhD



Catherine Willett, PhD



Marina Pereira, MSc &

Donna Macmillan, PhD



- REACH revision context: setting the scene
  - How to modernise REACH to achieve the goals of the Chemicals Strategy for Sustainability
  - Accelerating the transition to chemical safety using non-animal approaches
  - Concluding remarks
- 
- Q&A

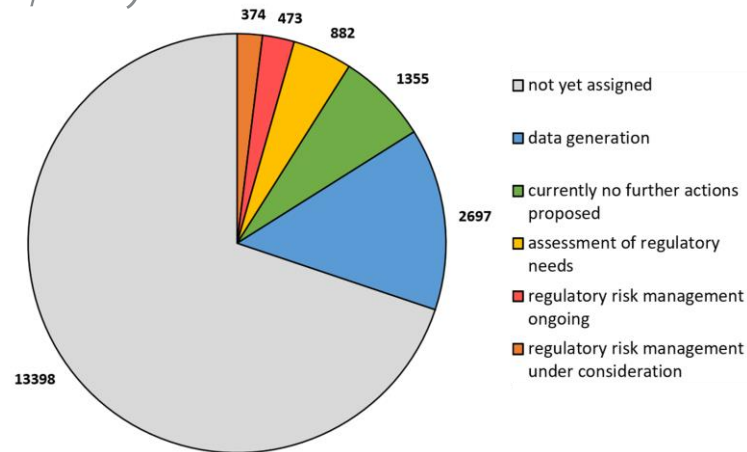
# Setting the scene for REACH revision

Catherine Willett, PhD

# REACH

Registration, Evaluation, Authorisation and Restriction of Chemicals  
(Regulation (EC) No 1907/2006)

- Registration requires toxicological information on all chemicals above 1 tonne
- Created to better protect human and environmental health through generation of information
- Since 2010, 103,365 dossiers for 23,086 substances\*
- Required testing proportional to tonnage listed in annexes
  - Specific methods described
  - “Adaptations” to required testing
- Has become the largest animal testing program in history
- Much of the information generated does not contribute to safety



*\*From: ECHA's map of the chemical universe -  
<https://echa.europa.eu/universe-of-registered-substances>*

- 70% of the substances are yet to be assigned to a regulatory pool (grey) and only 4% of these are currently under consideration for, or have, ongoing risk management measures (red & orange)

# Chemicals Strategy for Sustainability

- Chemicals Strategy for Sustainability
  - Adopted in 2020
  - Part of the European Green Deal
  - Aims to better protect citizens and the environment from harmful chemicals and boost innovation by promoting the use of safer and more sustainable chemicals
- Promises to cover many new safety concerns
- Is a **once in a generation** opportunity to assess and improve chemical safety assessment in the EU
- Capitalise on the > billion € the EU has invested in the development of non-animal safety assessment methods



**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN  
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL  
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

**Chemicals Strategy for Sustainability  
Towards a Toxic-Free Environment**

*“Safety testing and chemical risk assessment need to innovate in order to reduce dependency on animal testing but also to improve the quality, efficiency and speed of chemical hazard and risk assessments.”*

# European and internationally-funded NAM research initiatives

Initiative	Description
The European Partnership for the Assessment of Risks from Chemicals (PARC)	Working to develop next-generation chemical risk assessment. Budget: €400 million (50% funded by the EU and 50% by Member States).
ASPIS cluster: A joint collaboration of Horizon 2020-funded projects <ul style="list-style-type: none"> <li>• ONTOX</li> <li>• PrecisionTox</li> <li>• RISK-HUNT3R</li> </ul>	<p>ONTOX: NAMs to predict systemic repeated dose toxicity effects that, upon combination with tailored exposure assessment, will enable human risk assessment. Budget: €17.2 million.</p> <p>PrecisionTox: biomolecular toxicity pathways Budget: €19.3 million.</p> <p>RISK-HUNT3R: integrated approaches using human-relevant in vitro and in silico mechanism-based NAMs, chemical exposure, toxicokinetics, and for next-generation risk assessment. Budget: €22.9 million.</p>
EU-ToxRisk	Integrating advancements in cell biology, -omic technologies, systems biology and computational modelling to define toxicity pathways. Budget: €30 million.
Accelerating the Pace of Chemical Risk Assessment (APCRA)	An intergovernmental collaboration and dialogue on the scientific and regulatory needs for the application and acceptance of NAMs in regulatory decision making.
The Health and Environmental Sciences Institute (HESI)-coordinated Risk Assessment in the 21st Century (RISK21)	A problem formulation-based approach created to harmonise how the world evaluates chemicals and provide a flexible and transparent framework for efficient risk assessment.

# Animal protective language in REACH

EC 1907/2006



- **Article 1 Aim and scope**

- *“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, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation...”*



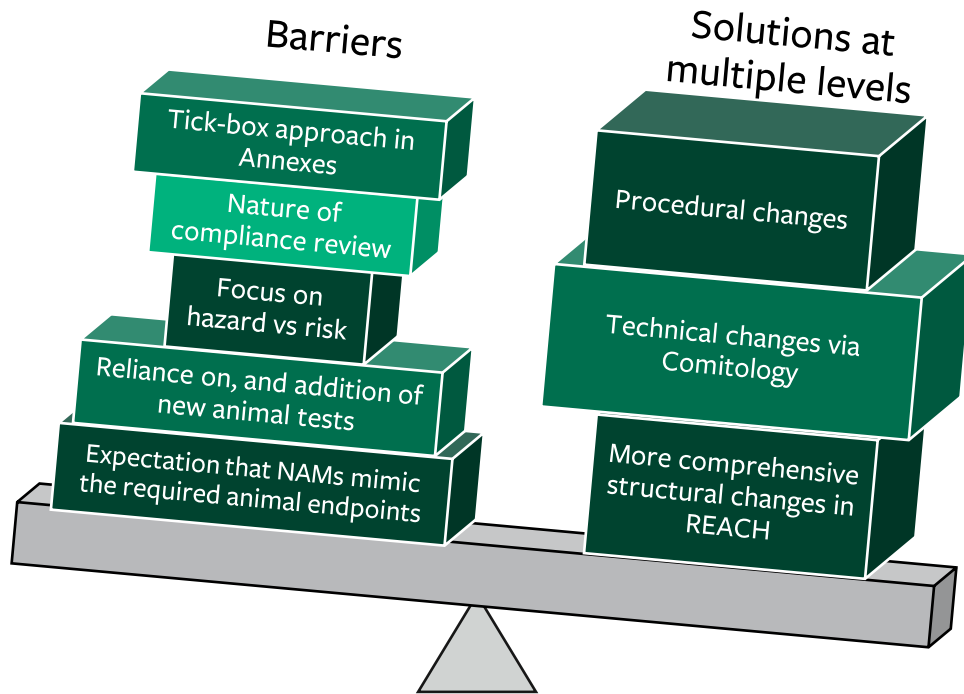
- **Article 17** **And yet...despite the investments, despite the intention, the adoption of non-animal assessment tools is lagging and nearly negligible under REACH** **properties of substances**  
*...other than tests, provided that information shall be generated by alternative methods.”*



- **Article 25 Objectives and general rules**

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

# Barriers (and solutions) to NAM implementation in REACH





# Lessons from experience

- Other jurisdictions have:
  - High-level commitments to move away from animal testing by 2035



EPA administrator memo



Liberal party platform

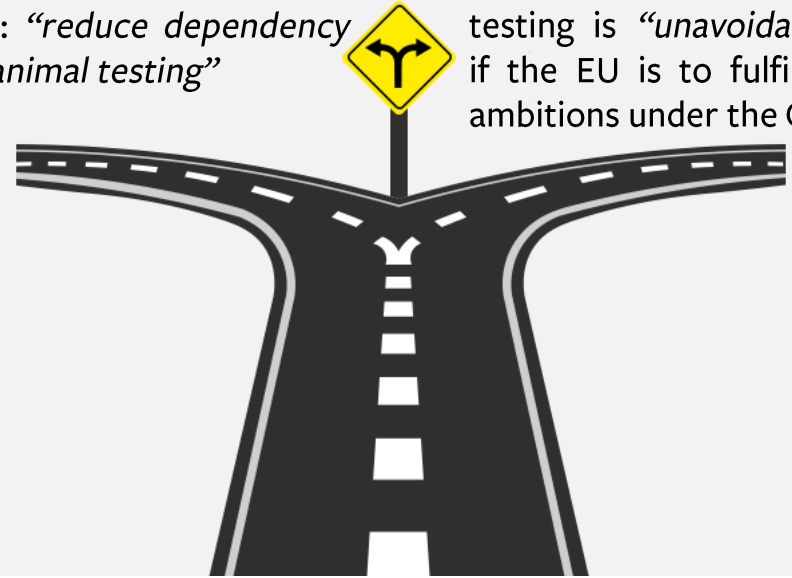
- Information needs described in terms that do not refer to specific methods – ‘*method-agnostic*’
  - NAM-based screening and prioritisation processes
- The EU has invested €€€€ and has the potential to be the global leader in the science of NAM-based testing

# Now is the time to reassess, re-envision REACH

- REACH revision proposal from the European Commission (EC) expected in Q1 2023
- New thinking is needed - it is only through accelerated, science-supported adoption of NAMs that the goals of REACH and the aspirations of the CSS can be achieved in our lifetime
- The proposals we highlight today offer a path towards the promising future intended by the CSS

CSS: “reduce dependency on animal testing”

EC: an increase in animal testing is “unavoidable” if the EU is to fulfil its ambitions under the CSS





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# **How to modernise REACH to achieve the goals of the Chemicals Strategy for Sustainability**

Marina Pereira, MSc

Senior Strategist – Regulatory Policy

Research & Toxicology Department

13 October 2022

# Humane Society International's proposals to modernise REACH

Propose 3 levels of change, aiming for faster and better delivery of protection goals whilst minimising animal testing:

## Procedural changes

- Implement an improved approach to grouping and read-across
- Create an expert scientific committee on application of NAMs for chemical safety assessment
- Improve reporting obligations and establish reviews

## Technical changes via delegated acts

- Consider redundancy of existing information requirements
- Increase the use and regulatory acceptance of NAMs
- Require testing proposals for all annex levels
- No new/expanded animal testing standard information requirements

## More comprehensive structural changes

- Reinforce language around animal testing as a “last resort” and promotion of NAMs
- Optimise the Dossier Review and Substance Evaluation process under REACH
- Implement a NAM-based tiered, optimised testing strategy
- Implement NAM-based risk management for chemicals under REACH

# Reinforce the promotion of alternatives and last resort requirement in REACH

- *Problem:* provisions in REACH are insufficient to promote NAMs and decrease animal testing
- *Solution:* introduce **stronger provisions under REACH:**
  - Stronger language to promote animal welfare:
    - Article 1 (promotion of alternatives + ultimate goal of phasing out animal testing);
    - Article 13 (NAMs as the starting point to safety assessment as opposed to providing same level of information as animal tests);
    - Article 25 ('last resort' requirement augmented with animal testing performed if necessary for improved risk assessment/measures).
  - Create an expert scientific committee on application of NAMs for chemical safety assessment within ECHA (e.g. develop a replacement strategy/roadmap, provide independent advice/recommendations on NAMs to registrants, review of current practices)
  - Improve reporting obligations (by the Member States, ECHA and the Commission) and establish a new yearly review on the use and uptake of NAMs under REACH in light of ongoing technical progress

→ **Mandate on the promotion of alternatives to animal testing reinforced to achieve tangible results**

# Optimise dossier review and substance evaluation processes under REACH

- **Problem:**
    - Regulatory needs for ~70% of REACH-registered substances are still to be assigned (*source: ECHA's map of the chemical universe*)
    - Dossier Evaluation (*compliance check is a laborious 'tick-box' exercise for dossier completeness regardless of the utility of studies*) + Substance Evaluation (*only conducted in certain cases, testing is done only if it would potentially lead to an improvement of the risk management measures*)
  - **Solution: Optimise and merge the Dossier Evaluation and Substance Evaluation processes to expedite the risk management process under REACH**
- This approach would not only lead to a **reduction in animal testing** but would also help to **speed up the review of substances**



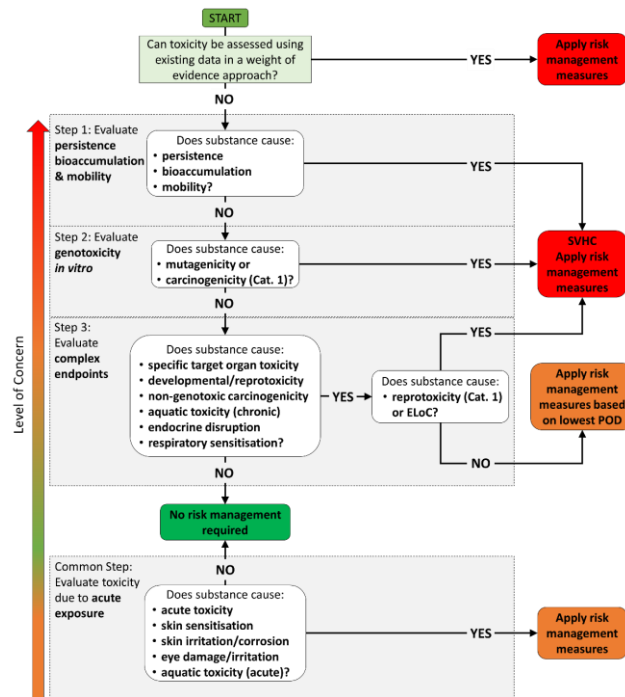
# No new/expanded animal testing standard information requirements

- *Problem:* goal of the CSS is that “Safety testing and chemical risk assessment need to innovate in order to reduce dependency on animal testing but also to improve the quality, efficiency and speed of chemical hazard and risk assessments”, however current proposals will increase dependency and toll on animals
- *Solution:* all new standard information requirements should be NAM-based
  - Additional actions:
    - Remove redundancy of existing information requirements (e.g. PNDT in a second species)
    - Require testing proposals for vertebrate testing at all annex levels (to ensure compliance with the ‘last resort’ requirement and encourage non-animal assessments)

→ Future-proof REACH and invert the trend of animal testing dependency, ensuring that it can **evolve with the pace of progress in science and risk assessment**

# Introduce a process to efficiently identify high-risk substances for regulation

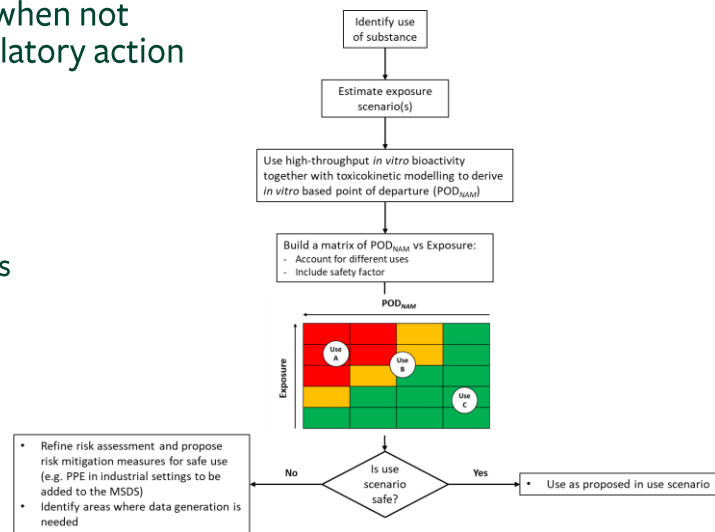
- *Problem:* as stated in the CSS, EU chemicals policy must evolve and respond more rapidly and effectively to the challenges posed by hazardous chemicals
  - *Solution:* Introduce a **tiered, optimised testing strategy** that evaluates hazards in a step-wise manner, with an optimised testing strategy that prioritises the identification of SVHCs and the concerns that would lead to the most stringent risk management measures
- More streamlined and effective approach to the identification of substances of the **most concern for human health and the environment**, whilst **minimising the need for animal testing**





# Implement NAM-based risk management for chemicals under REACH

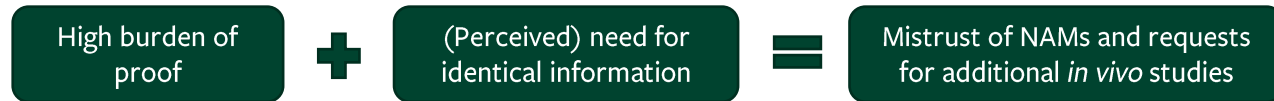
- *Problem:* all standard information requirements need to be met, with redundant and avoidable animal studies. Performing time- and animal-intensive tests when not relevant is inefficient and delays the decision-making process and regulatory action
- *Solution:* apply a **NAM-based risk management approach**\*
  - First identify the use and exposure profile of a substance
  - Use high-throughput NAM data with toxicokinetic modelling to generate NAM-based points of departure ( $POD_{NAM}$ ) for specific uses
  - $POD_{NAM}$  is then plotted against the exposure scenarios
  - The Bioactivity to Exposure Ratio (BER) is then determined by comparing  $POD_{NAM}$  to the exposure
    - Each use can be assessed using the matrix to determine whether the substance can be used safely, and risk management measures needed



→ This approach would not only lead to a **reduction in animal testing** but would also ensure that **risks are addressed as early in the process as possible to ensure protection**

# Use and regulatory acceptance of NAMs

- **Problem:** despite major advances in non-animal methods, their regulatory acceptance remains slow under REACH due to:
  - A higher burden of proof is required for NAMs than for animal tests e.g. a negative *in vivo* test is considered to be reliable, but a negative *in vitro* test often will result in suspicion that a positive has been ‘missed’
  - The expectation is that a NAM will provide identical information to that obtained from animal tests, in a 1:1 **replacement** - instead of a NAM, or several NAMs, providing information that addresses the same safety concern



- **Solution:**
    - Describe regulatory concerns and information needs in **method-agnostic\*** language
    - Allow the use of NAMs within the context of **Integrated Approaches to Testing and Assessment (IATA)**
- This would **facilitate the use and regulatory acceptance** of NAMs and **speed up a transition** to non-animal, innovative science



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# **Accelerating the transition to chemical safety using non-animal approaches**

Donna Macmillan, PhD

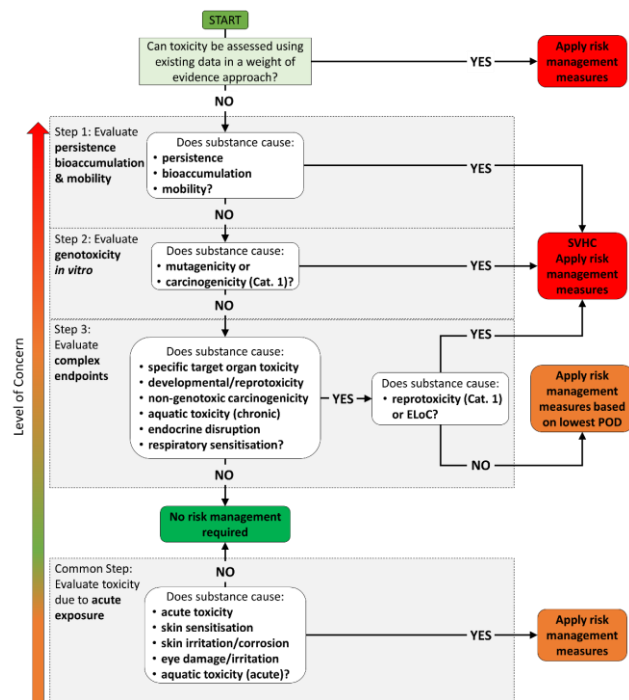
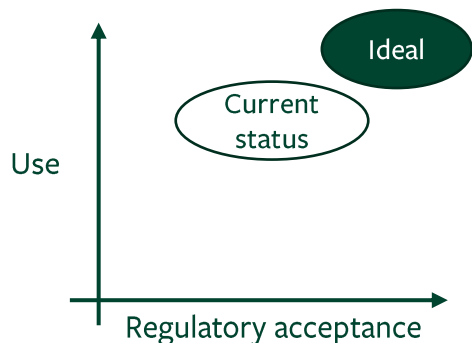
Senior Strategist – Regulatory Science

Research & Toxicology Department

13 October 2022

# A NAM-based tiered, optimised testing strategy

- The tiered, optimised testing strategy proposed by HSI is based on NAMs
- For each endpoint, there are NAMs at different stages:
  - **Available**
    - In routine use and accepted by regulators
    - In use but rarely accepted
  - **In progress/development**



# NAMs for acute oral toxicity

- Acute oral toxicity
  - Available: CATMoS
    - NICEATM collated acute oral toxicity data and invited the development of models from many international collaborators
    - The Collaborative Acute Toxicity Modeling Suite (CATMoS) was created - a consensus (Q)SAR model based on a weight of evidence
    - Has high accuracy against *in vivo* data



Environmental Health Perspectives

Vol. 129, No. 4 | Research

## CATMoS: Collaborative Acute Toxicity Modeling Suite

Is corrected by

Kamel Mansouri, Agnes L. Karmaus, Jeremy Fitzpatrick, Grace Patlewicz, Prachi Pradeep, Domenico Alberga, Nathalie Alepee, Timothy E.H. Allen, Dave Allen, Vinicius M. Alves, Carolina H. Andrade, Tyler R. Auernhammer, Davide Ballabio, Shannon Bell, Emilio Benfenati, Sudin Bhattacharya, Joyce V. Bastos, Stephen Boyd, J.B. Brown, Stephen J. Capuzzi, Yaroslav Chushak, Heather Ciallella, Alex M. Clark, Viviana Consonni, ... See all authors

Published: 30 April 2021 | CID: 047013 | <https://doi.org/10.1289/EHP8495> | Cited by: 4

	0	5	50	300	500	2000	5000 mg/kg
VT	0	0	1	1	1	1	1
NT	1	1	1	1	1	0	0
EPA	0	0	1	1	0	0	0
GHS	0	0	1	0	0	0	0
LD50	0	0	1 160	1 (-0.3) 316	1 (+0.3) 613	0	0
WoE	1	1	5	4	3	1	1

Figure 4. The columns represent the different bins from the EPA and GHS categories combined. The rows represent the five different end points and the WoE prediction. The arrows in each row represent the range of the prediction for each end point which were attributed a value of 1 and outside of it a value of 0. **The winning bin is determined by the maximum of the sum of each column in the WoE row.**

# NAMs for acute oral toxicity

- Acute oral toxicity
  - **Available:** The 3T3 Neutral Red Uptake Cytotoxicity assay
    - Shows correlation between *in vitro* IC50 and rat LD50
  - **In progress:** a human cell-based test for acute oral toxicity from XCellR8
    - Currently being validated
    - Showing promising predictivity against GHS classes
    - Possibly available in early 2023



Regulatory Toxicology and Pharmacology

Volume 65, Issue 3, April 2013, Pages 344-365



Assessment of the predictive capacity of the 3T3 Neutral Red Uptake cytotoxicity test method to identify substances not classified for acute oral toxicity (LD<sub>50</sub> > 2000 mg/kg): Results of an ECVAM validation study

Pilar Prieto <sup>a</sup>, Thomas Cole <sup>a</sup>, Rodger Curren <sup>b</sup>, Rosemary M. Gibson <sup>c</sup>, Manfred Liebsch <sup>d</sup>, Hans Raabe <sup>b</sup>, Anita M. Tuomainen <sup>a</sup>, Maurice Whelan <sup>a</sup>, Agnieszka Kinsner-Ovaskainen <sup>a</sup>

# NAMs for skin sensitisation

- Skin sensitisation
  - **Available:** Many *in vitro* assays
    - OECD TG 442C/442D/442E
  - **Available:** Defined Approaches for Skin Sensitisation - OECD TG 497
    - Combines several information sources including *in vitro* and *in silico*
    - Predicts human sensitisation as well or better than the *in vivo* local lymph node assay
  - **Available:** Other assays
    - EpiSensA
    - PPRA
    - SENS-IS
  - **Available:** (Q)SARs
    - CAESAR
    - Derek Nexus
    - OECD Toolbox
    - PredSkin
    - Toxtree

## Guideline No. 497

Guideline on Defined Approaches for Skin Sensitisation

## Test Guideline No. 442C In Chemico Skin Sensitisation

Assays addressing the Adverse Outcome Pathway key event on covalent binding to proteins

## Test Guideline No. 442D In Vitro Skin Sensitisation

ARE-Nrf2 Luciferase Test Method

## Test Guideline No. 442E In Vitro Skin Sensitisation

In Vitro Skin Sensitisation assays addressing the Key Event on activation of dendritic cells on the Adverse Outcome Pathway for Skin Sensitisation

# NAMs for skin corrosion and skin irritation

- Skin corrosion and skin irritation
  - **Available:** Many *in vitro* assays
    - OECD TG 430: *In vitro* skin corrosion: transcutaneous electrical resistance test method (TER)
    - OECD TG 431: *In vitro* skin corrosion: reconstructed human epidermis (RHE) test method
    - OECD TG 439: *In vitro* skin irritation: reconstructed human epidermis test method
    - OECD TG 435: *In vitro* membrane barrier test method for skin corrosion
  - **Available:** (Q)SARs
    - HazardExpert
    - Derek Nexus
    - MultiCase
    - OECD Toolbox
    - TOPKAT
    - Local models and/or literature-based (Q)SARs

## Environmental Toxicology and Chemistry

Annual Review | [Free Access](#)

### Quantitative structure-activity relationships for predicting skin and eye irritation

Grace Patlewicz ✉ Rosemary Rodford, John D. Walker

First published: 06 November 2009 | <https://doi.org/10.1897/01-439> | Citations: 18

## QSAR & Combinatorial Science

Minireview

### A Review of (Q)SAR Models for Skin and Eye Irritation and Corrosion

Ana Gallegos Saliner ✉ Grace Patlewicz, Andrew P. Worth

First published: 15 January 2008 | <https://doi.org/10.1002/qsar.200710103> | Citations: 26



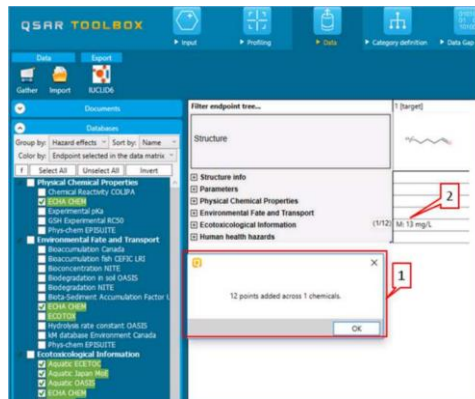
## NAMs for serious eye damage and eye irritation

- **Serious eye damage and eye irritation**
    - **Available:** Several *in vitro* assays
      - OECD TG 491: Short time exposure *in vitro* test method
      - OECD TG 492: Reconstructed human Cornea-like Epithelium (RhCE) test method
      - OECD TG 494: Vitrigel-eye irritancy test method
    - **Available:** Defined Approaches for Eye Irritation - OECD TG 467
      - Combines several information sources including physicochemical parameters and OECD TG methods
      - High predictivity of serious eye damage and eye irritation against *in vivo* Draize test data
  - **Available:** (Q)SARs
    - HazardExpert
    - Derek Nexus
    - MultiCase
    - OECD Toolbox
    - TOPKAT
    - Local models and/or literature-based (Q)SARs
- 



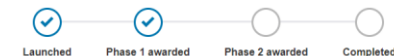
# NAMs for acute aquatic toxicity

- Aquatic toxicity (acute)
  - Available: *In vitro* assays
    - OECD TG 249: Fish Cell Line Acute Toxicity - The RTgill-W1 cell line assay
  - Available: (Q)SARs
    - ECOSAR
    - OECD Toolbox
    - VEGA
- In progress: SAFE - a CRACK-IT sponsored challenge
  - Develop a suite of innovative, scalable bioassays for key AOPs to replace *in vivo* fish studies in chemical safety screening and regulatory environmental risk assessment



Challenge 41

SAFE



● In progress

Budget information

Phase 1 up to **£100k** Phase 2 up to **£700k**

January 2022

Phase 1 awarded

Three Phase 1 awards were made to project teams led by:

- Dr Carlos Barata, Agencia Estatal Consejo Superior de Investigaciones Científicas (AECSIC), €98,749.84
- Prof Christer Hogstrand, King's College London, £99,999.16
- Prof Kristin Schirmer, Swiss Federal Institute of Aquatic Science and Technology (Eawag), £99,968

[News item](#)

# NAMs for persistence, bioaccumulation & mobility

## ■ Persistence

- **Available:** *In silico* predictions of environmental fate and physicochemical properties

- EPISUITE
- OECD Toolbox

## ■ Mobility

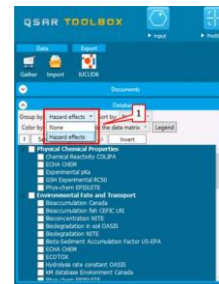
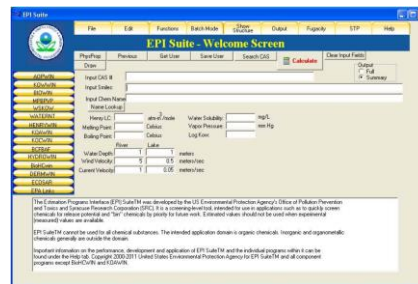
- **Available:** *In silico* predictions of environmental fate and physicochemical properties

- EPISUITE
- OECD Toolbox

## ■ Bioaccumulation

- **Available:** *In silico* predictions of bio-concentration factor (BCF)

- CAESAR
- EPISUITE
- MultiCase
- OECD Toolbox
- VEGA



# NAMs for genotoxicity

- Mutagenicity & carcinogenicity

- **Available:** *In vitro* assays

- OECD TG 471: *In vitro* mutation test (Ames)
    - OECD TG 473: *In vitro* chromosome aberration test
    - OECD TG 476: *In vitro* mutation tests using the Hprt and xprt genes
    - OECD TG 487: *In vitro* micronucleus test
    - ToxTracker – *In vitro* stem cell-based reporter assay



- **Available:** (Q)SARs

- CAESAR
    - Derek Nexus
    - Leadscope Genetox Expert Alerts
    - Leadscope Model Applier
    - MultiCase
    - OECD Toolbox
    - Sarah Nexus

# NAMs for complex endpoints

- Complex endpoints, including systemic endpoints:
  - Developmental & reprotoxicity / DNT
  - Non-genotoxic carcinogenicity
  - Aquatic toxicity (chronic)
  - Specific target organ toxicity
  - Endocrine disruption
  - Immunotoxicity
  - Respiratory sensitisation
- NAMs for these (aptly named) complex endpoints are generally less-well developed than other endpoints but there are still many projects and initiatives undertaking this challenge

# NAMs for complex endpoints

- Developmental & reprotoxicity
  - Available: *In vitro* assay
    - ReproTracker - stem-cell based biomarker assay
  - Available: (Q)SAR
    - CAESAR
  - In progress:
    - *In vitro* test battery - medium- to high-throughput *in vitro* assays
    - Bioactivity predictions - high-throughput *in vitro* assays
- Non-genotoxic carcinogenicity
  - Available: *In vitro* assay
    - ToxTracker - *In vitro* stem cell-based reporter assay
  - In progress: An OECD-supported integrated approach to testing and assessment (IATA) based on adverse outcome pathways (AOPs)



Toxicology and Applied Pharmacology  
Volume 354, 1 September 2018, Pages 24–39



JOURNAL ARTICLE FEATURED

## Utility of *In Vitro* Bioactivity as a Lower Bound Estimate of *In Vivo* Adverse Effect Levels and in Risk-Based Prioritization

Katie Paul Friedman ✉, Matthew Gagne, Lit-Hsin Loo, Panagiotis Karamertzanis, Tatiana Netzeva, Tomasz Sobanski, Jill A Franzosa, Ann M Richard, Ryan R Lougee, Andrea Gissi ... Show more

Toxicological Sciences, Volume 173, Issue 1, January 2020, Pages 202–225,

## Concept Article

## International Regulatory Needs for Development of an IATA for Non-Genotoxic Carcinogenic Chemical Substances

Miriam N. Jacobs<sup>1</sup>, Annamaria Colacci<sup>2</sup>, Kimmo Louekari<sup>3</sup>, Mirjam Luijten<sup>4</sup>, Betty C. Hakkert<sup>5</sup>, Martin Paparella<sup>6</sup> and Paule Vasseur<sup>7</sup>

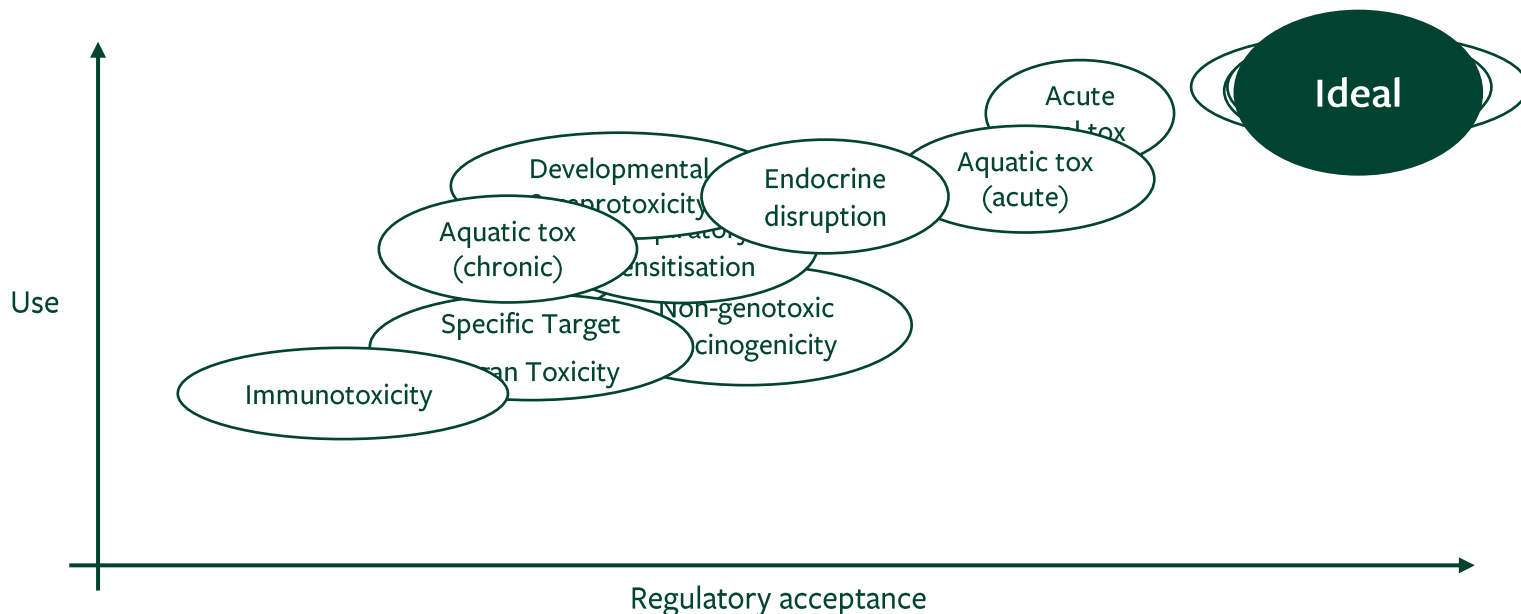
<sup>1</sup>Department of Toxicology, Centre for Radiation, Chemical and Environmental Hazards, Public Health England, Chilton, Oxfordshire, UK; <sup>2</sup>Center for Environmental Toxicology and Risk Assessment, Environmental Protection and Health Prevention Agency, Emilia Romagna Region, Italy; <sup>3</sup>European Chemicals Agency, Helsinki, Finland; <sup>4</sup>Centre for Health Protection, National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands; <sup>5</sup>Bureau REACH, Department for Industrial Chemicals, Centre for Safety of Substances and Products (VSP), National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands; <sup>6</sup>Chemicals & Biocides, Environment Agency Austria, Vienna, Austria; <sup>7</sup>CNRS UMR 7360, University of Lorraine, Metz, France

Testing for developmental neurotoxicity using a battery of *in vitro* assays for key cellular events in neurodevelopment ☆

Joshua A. Hamill<sup>a</sup>, Theresa Freudenrich<sup>b</sup>, Kathleen Wallace<sup>b</sup>, Kenneth Ball<sup>b,c</sup>, Timothy J. Shafer<sup>b</sup>, William R. Mundy<sup>b</sup>

# NAMs - summary

- Not all NAMs are likely to be used as a 1:1 replacement for *in vivo* tests
- BUT there are many human-relevant NAMs at our disposal that can be used alone, in defined approaches, IATA, test batteries or in a weight of evidence to provide the information required to meet regulatory requirements



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# Concluding remarks

Catherine Willett, PhD

# European calls for an end to animal testing

- European Parliamentary Resolution
  - Majority of 667 to 4
  - *“...EU-wide action plan with the aim of driving the active phase-out by reducing, refining and replacing procedures on live animals for scientific and regulatory purposes.”*
- European Citizens Initiative to end animal testing
  - >1.4 million signatures
  - To protect and strengthen the cosmetics animal testing ban
  - To transform EU Chemicals Regulations (no new animal testing)
  - Modernise science in the EU: commit to a roadmap to phase-out all animal testing in the EU before the end of the current legislative term

September 16, 2021

**BREAKING: Win for lab animals! European Parliament votes in favour of plan to end animal experiments**

**European Parliament votes in favour of EU plan to replace animal experiments with cutting-edge science**

Humane

Humane Society International / Europe



HUMANE SOCIETY  
INTERNATIONAL  
EUROPE

# Animal-free chemical safety assessment

- Overwhelming parliamentary support
  - Broad public support
    - Scientific and regulatory progress
      - Enormous investments in non animal safety science

Ø Procedural and structural roadblocks under REACH

# The time is now

- To revise REACH to improve efficiency and chemical coverage
  - New approaches are needed to adopt NAMs at a faster pace
    - Procedural modifications
      - Annex and technical modifications
        - Farther reaching structural changes

➔ The aspirations of REACH and the CSS can be achieved in our lifetime



**HUMANE SOCIETY  
INTERNATIONAL**

# Thank you!

For follow up contact: [dmacmillan@hsi.org](mailto:dmacmillan@hsi.org)



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**EUROPE**

**Q & A**