EPAA 2023 Highlights

EPAA Industry Co-chair:

Dr Gavin Maxwell (Unilever)

European Partnership for Alternative Approaches to Animal Testing (EPAA)

The European Partnership for Alternative Approaches to Animal Testing

Collaboration between European Commission and Industry stakeholders from 8 sectors (est. 2005)

Vision: The replacement, reduction and refinement (3Rs) of animal use for meeting regulatory requirements through better & more predictive science (e.g. New Approach Methodologies (NAMs)).

To join EPAA e-mail:

GROW-EPAA@ec.europa.eu

38 Companies (including 1 SME)

Boehringer Ingelheim, Johnson & Johnson, REVLON, L'ORÉAL, DSM, Dow, LVMH, essity, symrise, ESTĒE LAUDER, KANEBO, MERCK, MSD, SHISEIDO, Gowan, EVONIK, ADAMA, Beiersdorf, Unilever, CHANEL, COLGATE-PALMOLIVE, Henkel, BAYER, CORTEVA agriscience, P&G, Kimberly-Clark, NOVARTIS, Reckitt Benckiser, novo nordisk, sanofi, zoetis, BASF, SOLVAY, GSK, SASOL, novozymes, stratiCell, syngenta

8 Sectoral Associations

A·I·S·E, animalhealth europe, cefic, Cosmetics Europe, ifra, efpia, CropLife EUROPE, sme united

European Commission

DG GROW
DG ENV
DG SANTE
DG JRC
DG RTD

Including Partner Agencies

ECHA European Chemicals Agency, efsa European Food Safety Authority, European Medicines Agency

Mirror Group *(Advisory body)*

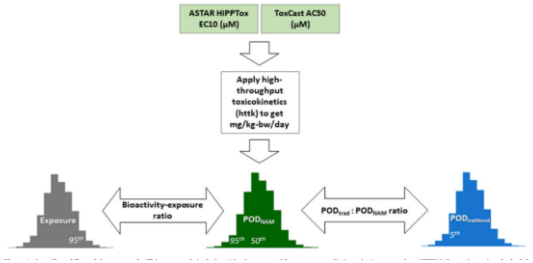
Emily McIvor (Chair), Julia Baines, Emma Grange, Tuula Heinonen, Christiane Hohensee, Monique Janssen, Helena Kandarova, Winfried Neuhaus, Sirpa Pietikaïnen (MEP), Vera Rogiers

Ultimate Goal: Animal-Free, Safe & Sustainable Innovation

Regulatory testing can evolve…

A paradigm shift in regulatory testing is underway as tiered assessment frameworks are enabling greater use of NAMs alongside ‘traditional’ approaches.

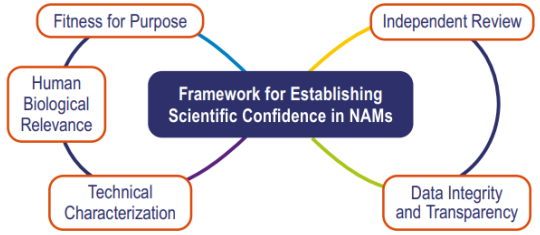
Let’s use NAMs to ensure regulatory animal testing is always a last resort.



…to better protect people & our planet

Integration of NAM and exposure information using computational approaches should allow us to set, and assess against, more meaningful human health & environmental protection goals.

Let’s use NAMs to strengthen confidence in safety science.



…and support new innovation

Safety assessment is rapidly evolving to ensure the latest science is used to assess new chemicals & medicines.

Let’s use NAMs to ensure Safe and Sustainable by Design (SSbD) frameworks also enable Animal-Free Innovation


EUROPEAN COMMISSION

Brussels, 14.10.2020
COM(2020) 667 final

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

{SWD(2020) 225 final} - {SWD(2020) 247 final} - {SWD(2020) 248 final} -
{SWD(2020) 249 final} - {SWD(2020) 250 final} - {SWD(2020) 251 final}


EUROPEAN COMMISSION

Brussels, 25.11.2020
COM(2020) 761 final

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

Pharmaceutical Strategy for Europe

{SWD(2020) 286 final}

Transitioning Europe to Animal-free, Sustainable Innovation

EU Parliament resolution

On 15th Sept 2021 the EU Parliament resolution adopted to '**Accelerate a Transition to Innovation without the use of Animals in Research, Regulatory Testing and Education**' calling for an **action plan with**:

- **ambitious objectives**
- **reduction targets**
- **replacement timelines**


European Parliament
2019-2024

TEXTS ADOPTED

P9_TA(2021)0387

Plans and actions to accelerate a transition to innovation without the use of animals in research, regulatory testing and education

European Parliament resolution of 16 September 2021 on plans and actions to accelerate the transition to innovation without the use of animals in research, regulatory testing and education (2021/2784(RSP))

European Parliament

EU Commission response

EU Commission response to EP resolution stated that:

- '**ultimate goal of full replacement is enshrined in EU legislation**'
- 'transition to innovation without the use of animals is **best supported by focusing on & intensifying current efforts'**
- transition accelerated via **EU Replacement Roadmap**

European Commission

EPAA helps accelerate the transition through driving:

1. **Research to Regulatory Use:** identifying NAM-based frameworks that address regulatory needs
2. **Cross-sector Consensus:** creating fora for scientific dialogue between industry & regulatory safety assessors
3. **Multi-stakeholder Collaboration:** helping coordinate implementation of EU roadmaps to replace regulatory animal testing

EU Replacement Roadmap for Regulatory Animal Testing of Chemicals

In 2022, EFSA published their '**Development of a Roadmap for Action on NAMs in Risk Assessment**' scientific report and hosted the **One Conference** (21st-24th June 2022) to discuss the recommendations.

ECHA's '**Towards an animal-free regulatory system for industrial chemicals**' workshop (31st May – 1st June 2023) broadened the scope of the scientific discussions & focussed everyone on replacement.

We now need to work together to accelerate the transition via the **EU replacement roadmap**. (next workshop – 11-12th Dec)

EXTERNAL SCIENTIFIC REPORT

APPROVED: 2 May 2022

doi:10.2903/sp.efsa.2022.EN-7341

Development of a Roadmap for Action on

New Approach Methodologies in Risk Assessment

Sylvia E. Escher[1], Falko Partosch[1], Sebastian Konzok[1], Paul Jennings[2], Mirjam Luijten[3], Anne Kienhuis[3], Victoria de Leeuw[3], Rosmarie Reuss[4], Katrina-Magdalena Lindemann[4], Susanne Hougaard Bennekou[5]

[1] Fraunhofer ITEM, [2] Vrije Universiteit Amsterdam, [3] National Institute for Public Health and the Environment, [4] Eura AG, [5] The National Food Institute Denmark

Abstract

While whole animal studies have their place in risk assessment of food and feed components, it is thought that more modern approaches such as human focused new approached methodologies (NAMs) would bring advantages including a greater focus to the human species, a focus on molecular mechanism and kinetics and the possibility of addressing susceptible populations. This report outlines the thinking from the authors and culminates in activity proposals in seven distinct but interacting scientific areas i.e. development of additional AOPs/AOP networks (AOPs), advanced cell culture models including Organ on a chip (OoC), toxicokinetic assessment with a focus on physiological based kinetic modelling (PBK), exposome, human susceptibility, data integration and new concepts in human risk assessment. Furthermore, the development of a Forum is proposed to facilitate the implementation of new approaches and concepts in risk assessment. The report was compiled by the project team, renowned experts in the various areas, and recommendations were discussed with EFSA and further refined following consultation with external experts via a dedicated workshop. The authors are convinced that if the recommendations are taken up, there will be a significant impact in the field, resulting in increasing the uptake and utilisation of these emerging technologies by all stakeholders involved.

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Key words: Next Generation Risk Assessment, Nev

Question number: EFSA-Q-2022-00231

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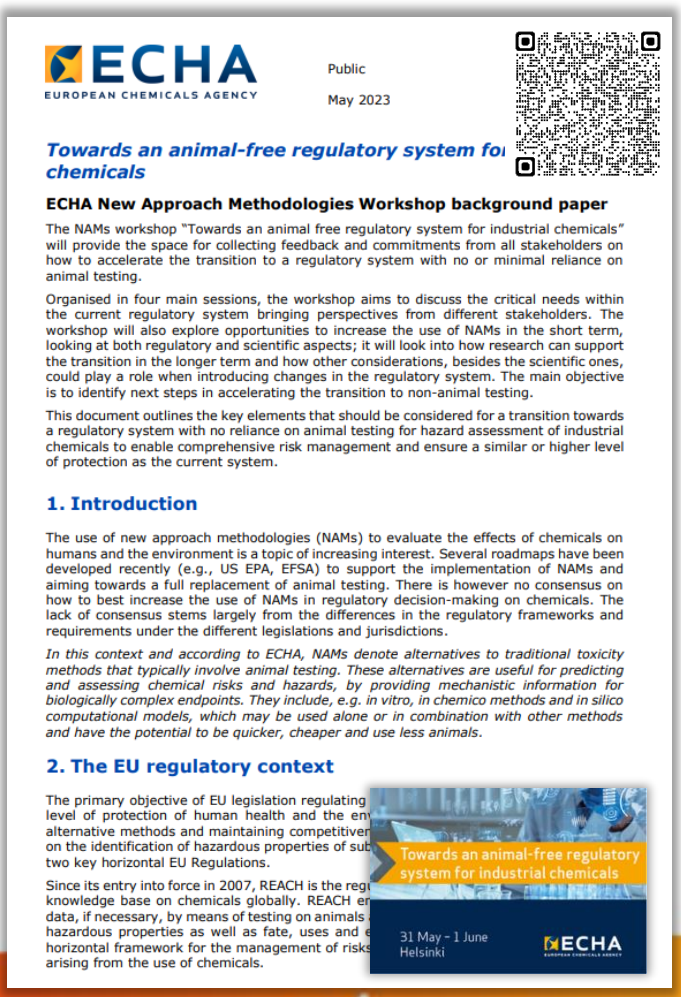


ECHA EUROPEAN CHEMICALS AGENCY

Public

May 2023

Towards an animal-free regulatory system for industrial chemicals

ECHA New Approach Methodologies Workshop background paper

The NAMs workshop "Towards an animal free regulatory system for industrial chemicals" will provide the space for collecting feedback and commitments from all stakeholders on how to accelerate the transition to a regulatory system with no or minimal reliance on animal testing.

Organised in four main sessions, the workshop aims to discuss the critical needs within the current regulatory system bringing perspectives from different stakeholders. The workshop will also explore opportunities to increase the use of NAMs in the short term, looking at both regulatory and scientific aspects; it will look into how research can support the transition in the longer term and how other considerations, besides the scientific ones, could play a role when introducing changes in the regulatory system. The main objective is to identify next steps in accelerating the transition to non-animal testing.

This document outlines the key elements that should be considered for a transition towards a regulatory system with no reliance on animal testing for hazard assessment of industrial chemicals to enable comprehensive risk management and ensure a similar or higher level of protection as the current system.

1. Introduction

The use of new approach methodologies (NAMs) to evaluate the effects of chemicals on humans and the environment is a topic of increasing interest. Several roadmaps have been developed recently (e.g., US EPA, EFSA) to support the implementation of NAMs and aiming towards a full replacement of animal testing. There is however no consensus on how to best increase the use of NAMs in regulatory decision-making on chemicals. The lack of consensus stems largely from the differences in the regulatory frameworks and requirements under the different legislations and jurisdictions.

In this context and according to ECHA, NAMs denote alternatives to traditional toxicity methods that typically involve animal testing. These alternatives are useful for predicting and assessing chemical risks and hazards, by providing mechanistic information for biologically complex endpoints. They include, e.g. in vitro, in chemico methods and in silico computational models, which may be used alone or in combination with other methods and have the potential to be quicker, cheaper and use less animals.

2. The EU regulatory context

The primary objective of EU legislation regulating
level of protection of human health and the en
alternative methods and maintaining competitiver
on the identification of hazardous properties of sub
two key horizontal EU Regulations.

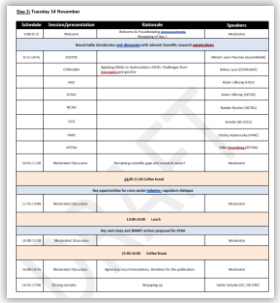
Since its entry into force in 2007, REACH is the regi
knowledge base on chemicals globally. REACH er
data, if necessary, by means of testing on animals
hazardous properties as well as fate, uses and e
horizontal framework for the management of risks
arising from the use of chemicals.

EPAA ‘Use of NAMs in Regulatory Decisions’ New Activities

EPAA ‘NAM Designathon 2023’ Challenge for human systemic toxicity: aims to crowd-source & refine classification systems capable of categorising chemicals based on non-animal data.

EPAA ‘Use of NAMs in Environmental Safety Assessment’ Partners Forum: identify where EPAA can help accelerate the adoption of Env. NAMs (13th-14th Nov 23).

EPAA NAM User Forum: case study-led discussion on addressing chemical regulatory requirements using NAMs – HH systemic tox, DART & EDs (7th-8th Dec 23).



For more info:

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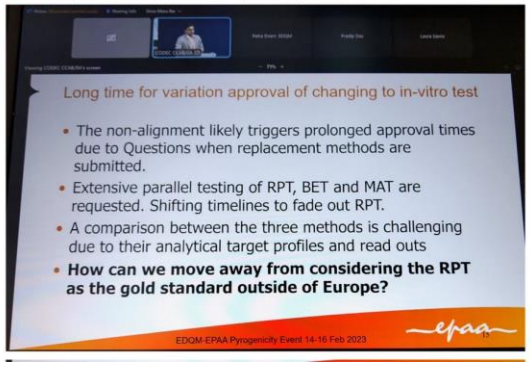
EPAA Dissemination & Communication Highlights



EDQM – EPAA Future of Pyrogenicity testing workshop

14th-16th Feb 2023

World Congress on Alternatives and Animal Use in the Life Sciences 12

27th-31st Aug 2023

EPAA Lunch Debate in EU Parliament, hosted by Tilly Metz MEP

12th Sept 2023

EPAA Annual report 2023

European Commission

The European Partnership for Alternative Approaches to Animal Testing

Contents

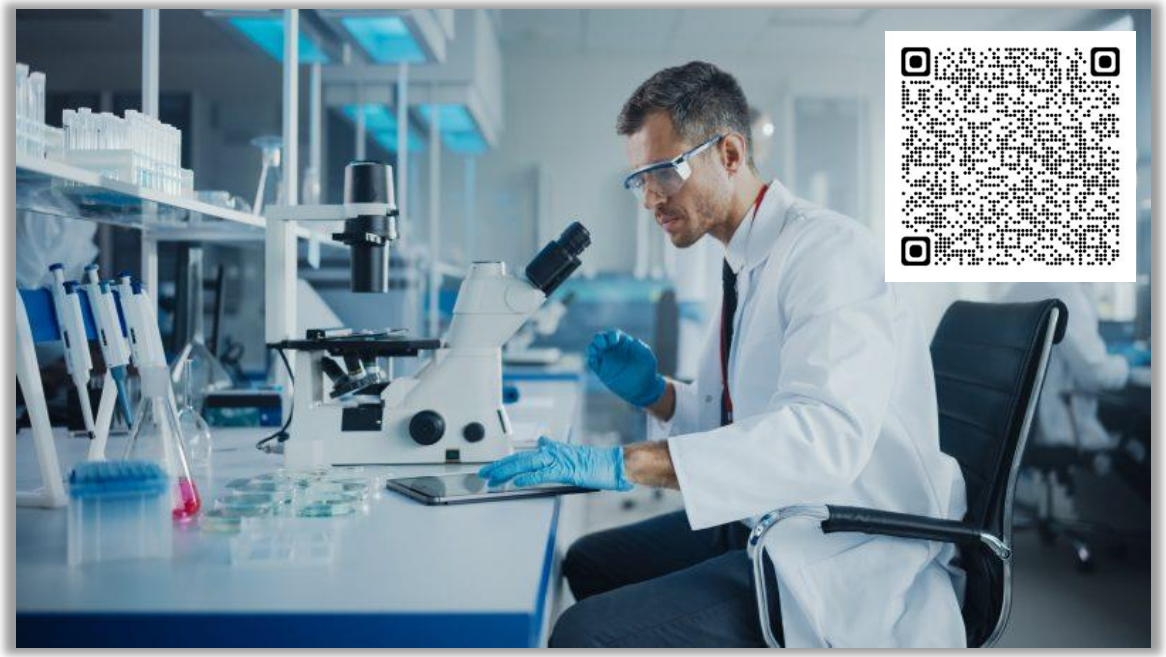
Website:

EURACTIV

EU needs a Commissioner for animal welfare, says Green MEP

Animal welfare should be explicitly mentioned in the title of a Commissioner in the next legislative mandate to make it a priority of the next EU executive and avoid the risks of having more animal testing in Europe, according to Green MEP Tilly Metz.

Making animal welfare a political priority is essential for the Green MEP as some ongoing legislative revisions such as the forthcoming changes to the registration, evaluation, authorisation and restriction of chemicals – also known as REACH regulation – carry the risks of increasing the number of animal testing.



Integrating New Approach Methodologies in Research and Testing Strategy: A Pharmaceutical Industry Perspective

The European debate around the use of animals for scientific purposes and the development and uptake of non-animal methods has recently been emphasized by a new European Citizens' Initiative *"Save Cruelty Free Cosmetics – Commit to a Europe Without Animal Testing"*.

Nicolas Dudoignon who is the Chief Veterinary Officer, Corporate Social Responsibility, at Sanofi

Acknowledgements

38 Companies (including 1 SME)

European Commission

DG GROW
DG ENV
DG SANTE
DG JRC
DG RTD

Website:

Including Partner Agencies

Mirror Group *(Advisory body)*

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