



The European Partnership
for Alternative Approaches to Animal Testing



European
Commission

EPAA: 2022 at a glance

Dr Gavin Maxwell, EPAA industry co-chair
EPAA Annual Conference, 15th Nov 2022



European Partnership for Alternative Approaches to Animal Testing (EPAA) in 2022



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)



8 Sectoral Associations



5 DG's of the EC



- DG GROW
- DG ENV
- DG SANTE
- DG JRC
- DG RTD

Including Partner Agencies



Mirror Group (Advisory body)

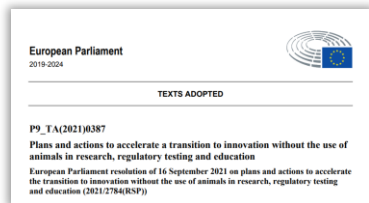
Emily McIvor (Chair), Dr Tuula Heinonen, Dr Christiane Hohensee, Dr Helena Kandarova; Sirpa Pietikäinen (MEP), Prof. Vera Rogiers
 (Thank you to Ana Barros, Belén Pintado, Prof. Horst Spielmann & Marina Pereira)



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

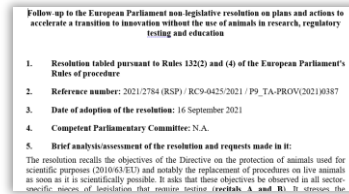


EU Commission response

EU Commission response to

EP resolution stated that:

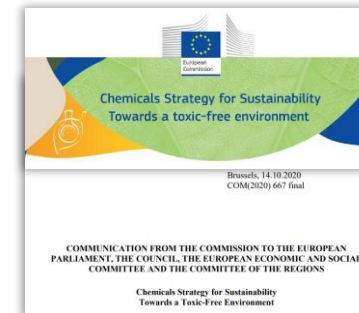
- ‘ultimate goal of full replacement is enshrined in EU legislation’
- ‘transition to innovation without the use of animals is **best supported by focusing on & intensifying current efforts**’



EPAA supports the

transition by bringing together partners & collaborators to:

- Promote **development & acceptance of 3R methods**
- Foster **cross-sector knowledge-sharing**
- Increase **international collaboration**
- Facilitate **stakeholder dialogue**



Goal: Safe & Sustainable Chemicals without Animal Testing

Chemical regulatory testing can evolve...

A paradigm shift in chemical regulatory testing is underway.

New tiered, chemical safety assessment frameworks ensure animal testing is a 'last resort' through early use of NAMs.

Let's use NAMs to reduce and replace chemical regulatory animal testing.

...to better protect people & our planet

Increased use of NAM data, exposure information and/or 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 chemical safety.

...and support new chemical innovation

Work is ongoing to update our chemical safety frameworks to better assess green chemistry / sustainable chemicals.

Let's use NAMs to ensure new chemicals are Safe & Sustainable by Design without Animal Testing.

Archives of Toxicology (2022) 96:743–766
<https://doi.org/10.1007/s00204-021-03215-9>

REGULATORY TOXICOLOGY

eceto**c**

A framework for chemical safety assessment incorporating new approach methodologies within REACH

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Received: 11 October 2021 / Accepted: 21 December 2021 / Published online: 1 February 2022
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Archives of Toxicology
<https://doi.org/10.1007/s00204-022-03365-4>

REVIEW ARTICLE



A framework for establishing scientific confidence in new approach methodologies

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Received: 17 May 2022 / Accepted: 11 August 2022
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Abstract



JRC TECHNICAL REPORT

Safe and Sustainable by Design
chemicals and materials

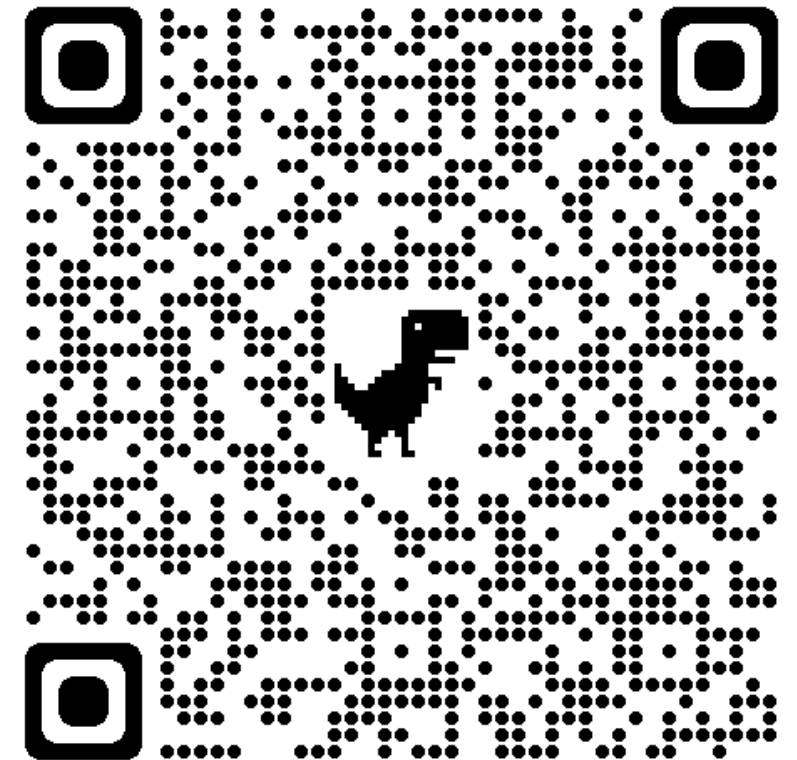
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EPAA 2022 Annual Report



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Available on EPAA website: [here](#)



EPAA 2022 highlights: Project Platform

EPAA project platform has supported **9 projects** each progressed through **multi-stakeholder collaboration** (industry, academia, NGOs & regulatory agencies)

Key 2022 Project Platform impacts:

- a) Results from **Clostridial Vaccines for Veterinary use** project have been used to revise the European Pharmacopoeia (Ph. Eur. 10.8 – published 1st July 2022) replacing *in vivo* with *in vitro* tests and changing the requirement to focus on residual toxicity testing (rather than final product testing)
- d) Working with EDQM the **Harmonisation of 3Rs in Biologicals** project, supports the strategy to **delete the Rabbit Pyrogenicity Test (RPT)** from the Ph. Eur. Monographs and is drafting of new chapters on **use of the Monocyte Activation Test (MAT)** for vaccine and pyrogenicity testing

a. Projects in 2022

- a. Clostridial Vaccines for veterinary use
- b. Human Rabies Vaccines
- c. Acute Toxicity
- d. Harmonisation of 3Rs in Biologicals
- e. Monoclonal Antibody Safety
- f. Carcinogenicity of Agrochemicals
- g. Skin Sensitisation Dissemination (User Forum on use of NAMs)
- h. PBK Modelling in Safety assessments
- i. Non-animal science (NAMs) in regulatory decisions for chemical safety

EPAA 2022 highlights: Project Platform (II)

Key 2022 Project Platform impacts: (cont.)

- g) Following successful **Skin Sensitisation User Forum** discussions, Cosmetics Europe 'Use of **NAMs for Skin Sensitisation Next Generation Risk Assessment (NGRA)**' case studies have been submitted to the **OECD IATA project**
- h) The **PBK Modelling in Safety Assessments** project have developed and published a KNIME platform workflow that can be used to **derive a PBK model for a given chemical through evaluating physico-chemical similarity**
- i) The **NAMs in regulatory decisions for chemical safety** project have held several Working Group 1 discussions focussing on the feasibility of ECETOC 'Framework for **Chemical Safety Assessment incorporating NAMs within REACH**'

a. Projects in 2022

- a. Clostridial Vaccines for veterinary use
- b. Human Rabies Vaccines
- c. Acute Toxicity
- d. Harmonisation of 3Rs in Biologicals
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- h. PBK Modelling in Safety assessments
- i. Non-animal science (NAMs) in regulatory decisions for chemical safety

EPAA 2022 highlights: Dissemination and Communication

External Events

EPAA activities were presented through:

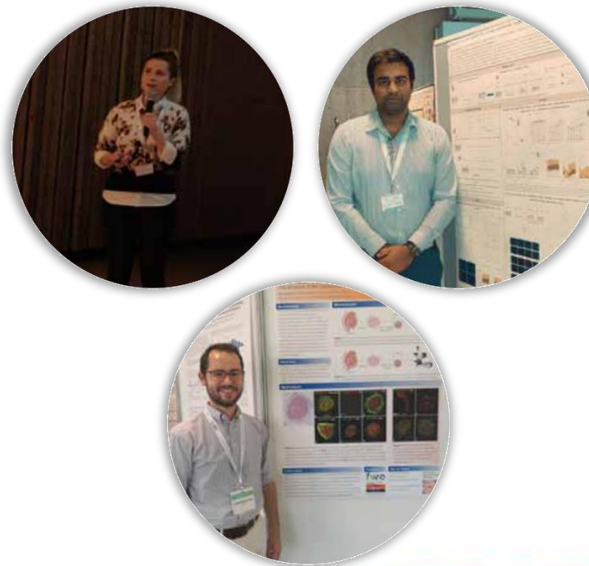
- 8 publications
- 7 oral presentations
- 11 poster presentations

3Rs Student Grants

Six travel grants were awarded to sponsor 3R student and young scientist participation at **ICT 2022, EUSAAT 2022 & ESTIV 2022.**

Science Prize 2022

€10,000 given to a **scientist making an outstanding contribution to 3Rs**, judged by jury evaluation against defined criteria.



EPAA 2022 highlights: Dissemination and Communication (II)

Key EPAA 2022 events



EPAA Partners Forum:
'Exposure Considerations for
Human Safety Assessment'
(6th May & 14th Nov)

Scope:

1. Review State-of-the-Science across 8 sectors
2. Identify opportunities for industry: regulator exchange, cross-sector collaboration & research



Helsinki Chemical Forum:
Hybrid panel discussion hosted by OECD on 'How to accelerate the replacement of animal testing' (8th-9th June) with participation from ECHA, EPAA, Health Canada, HSI & JRC ECVAM.



EPAA Lunch Debate in European Parliament
Discussion with key MEPs on EPAA's contribution to 'Accelerating the transition to animal-free, sustainable innovation' and opportunities for collaboration (13th Sept).

EPAA 2023 : Future Prospects

- EPAA partners will **develop a roadmap with an initial focus on replacing use of Animals for Regulatory Testing of Chemicals** to identify critical needs for an animal-free system and steer NAM developments.
- EPAA's 'Use of NAMs in Regulatory Decisions for Chemical Safety' project will:
 - **Identify priority research challenges** with [APCRA](#), [ASPIS](#) & [PARC](#) consortia.
 - **Kick-off NAM User-Forum** team via an initial case study-led workshop to agree priority topics for future sessions
- **Organise a 2023 Partners Forum** exploring 'Exposure considerations & use of NAMs in **Environmental Safety Assessment**' with [SETAC](#)
- EPAA partners will **organise an EU Parliament workshop & poster exhibition** on 'Accelerating a Transition to Animal-Free, Sustainable Chemical Innovation' to share progress and discuss remaining challenges.
- EPAA will **organise a workshop on 'The Future of Pyrogenicity Testing: Phasing out the Rabbits Pyrogens Test'** with [EDQM](#).



Thank you – EPAA partners, collaborators & secretariat

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[@EPAA3Rs](https://twitter.com/EPAA3Rs)

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