

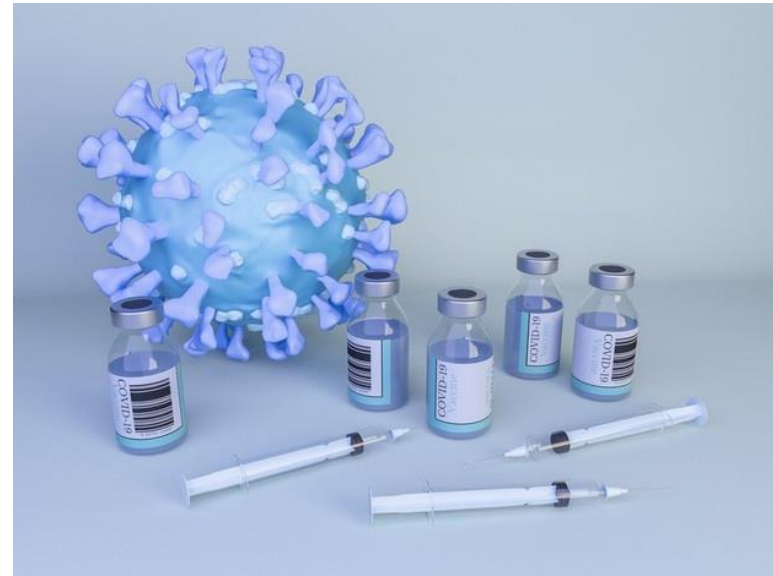


2021: EPAA at a glance

Rob Roggeband
Industry Co-Chair

2021 At a glance / Updates on

- 1. Relevant EU policies and EPAA**
- 2. Governance**
- 3. Project activities**
- 4. Communication/Dissemination**
- 5. Membership**
- 6. Outlook**



1. Relevant EU policies and EPAA



At the **crossroads** of scientific, ethical, public pressure, EU and global policy considerations for the use of animals for scientific and regulatory purposes

- **EU Chemical Strategy for Sustainability (CSS):** part of EU Green Deal
 - aim to innovate safety testing and chemical risk assessment
 - important to reduce dependency on animal testing
- **Revision of REACH**
- **Revision of CLP – Classification, Labelling, Packaging**
- **Dir. 2010/63/EU** on protection of animals used for scientific purposes

➤ The EPAA more than ever before is a **key partnership** able to



foster progress and continued dialogue between **regulators** and **industry** on the opportunities of using **New Approach Methodologies (NAMs)** in regulatory decisions

2. Governance



Steering Committee Co-Chairs

EC : Giacomo Mattinò, DG GROW

Industry : Rob Roggeband, P&G (next: Gavin Maxwell, Unilever)

Project Platform Co-Chairs

EC : Raffaella Corvi, DG JRC

Industry : Paul Benndorf, Henkel

Mirror Group

11 experts from various backgrounds, such as Academia, National 3Rs Centers, Animal Welfare groups and a MEP

Chair : Marina Pereira, Humane Society International

EPAA secretariat

2 FTE from Industry and support from the EU Commission (DG GROW)

Ad hoc consultants

3. Project activities

Ten ongoing EPAA projects in 2021

Ten project teams overseen by the **Project Platform**



Full report available for download on the **EPAA website**
https://ec.europa.eu/growth/sectors/chemicals/epaa_en

3. Project activities highlights



1. **Clostridial vaccines for veterinary use**
Joint EDQM-EPAA-DG JRC Workshop, 9-10 March 2021
2. **Human Rabies vaccines Phase 2 is ongoing;**
31 participants, 8 vaccine manufacturers
3. **Acute toxicity** oral tox data for 200 substances; **statistical analysis** ongoing
4. **Harmonisation of 3Rs in Biologicals** agreed with EDQM strategy to amend Ph. Eur monographs to **remove Rabbit Pyrogenicity Test**
5. **Optimal duration of non-clinical studies to assess safety of monoclonal antibodies**
EPAA-NC3Rs-MEB Workshop, 26 & 28 April 2021



3. Project activities highlights (*continued*)

6. Applying Non-Animal strategies for Skin Sensitisation (**User Forum**)
7. Prediction of Carcinogenic potential of agrochemicals work for identifying **Modes of Action** (MOAs) in progress
8. *In vitro* to *in vivo* extrapolation (**QIVIVE**) - 3 publications for derivation of **human BMD** (benchmark dose) values for 3 chemicals completed
9. **PBK modelling in safety assessment** Systematic **review of PBK models** has been published; **large spreadsheet** tool that facilitates searching of existing models established
10. **(new) Non-animal science in regulatory decisions for chemical safety. NAMs Deep-Dive Workshop planned for 23-24 November and facilitating industry's input into the JRC survey on NAMs**

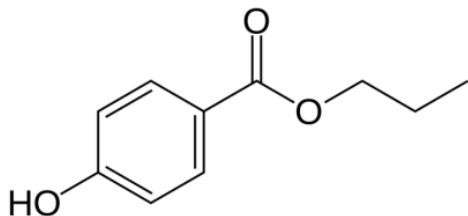
Applying Non-Animal strategies for assessing Skin Sensitisation

User Forum (webinars)

- How Defined Approaches (DAs) can be used to create a Weight of Evidence for skin sensitiser potential and potency assessment in absence of *in vivo* data
- 3 virtual sessions held in April, July and October 2021

Case studies

e.g. propyl paraben risk assessment

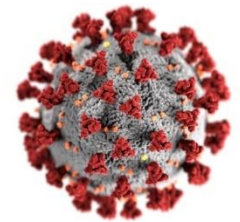


4. Communication / Dissemination



EPAA as a facilitator and supporter of 3Rs approaches

- i. Refinement Prize 2021
- ii. 3Rs Student grants 2021
- iii. EPAA events
- iv. EPAA at the WC11
- v. EPAA at other external events
- vi. Publications
- vii. Social media & campaigns



Leading through **cross-sector** collaboration & networking

4. Disseminating the 3Rs

i. Refinement Prize 2021

6.000€ prize,
awarded every other year (*more to follow later today !*)

ii. Student grants 2021

2 grants for presentations at **WC11** and 2 for **EUROTOX**

iii. EPAA events

- EPAA Annual Conference

- 3 expert Workshops

- Clostridial vaccines (March 2021)
- Monoclonal antibodies (April 2021)
- Deep-Dive NAMs workshop (November 2021)



iv. EPAA at the WC11

11th World Congress on Alternatives and Animal Use
in life Sciences (23 August – 2 September 2021)



- EPAA was a **BRONZE** sponsor and exhibitor at the Congress
- Members of EPAA participated in the **Local Organising Committee**
- EPAA-sponsored scientific session entitled:
“Promoting the use of 3Rs through partnership: EPAA”
- **Training session** on the use of New Approach Methodologies for skin sensitisation in collaboration with Alvertox Academy
- Virtual information **booth**

v. EPAA at other external events



In addition to WC11, the EPAA participated in:

1. Meeting with the **PARC* consortium** to present each other's activities and identify possible areas for collaboration (21 April)
2. **Immunity for Health 2021**: Presentation by Marie-Emmanuelle Behr-Gross on "Update on the EPAA projects on vaccines"; Flanders Vaccines Conference; Ghent (14 October)
3. **BfR Symposium**: Challenges in Public Health Protection in the 21st Century: New Methods, Omics and Novel Concepts in Toxicology; Workshop on Future concepts and strategies; Berlin (15-17 Nov. 2021)



*PARC = Partnership for the Assessment of Risk from Chemicals

vi. Publications



Four peer-reviewed, open-access publications were produced:

1. **Behr-Gross M-E, et al. (2021)** Collaborative study for the validation of cell line assays for in-process toxicity and antigenicity testing of *Clostridium septicum* vaccine antigens - Part 2: Optimisation of cell line assays. *Pharmeuropa Bio Sci Notes* (2021) 101-156
<https://pharmeuropa.edqm.eu/app/BioSN/content/BioSN-0/2021-5-Clostridium-septicum-vaccine-antigens-Part2.pdf>
2. **Loizou G, et al. (2021)** Derivation of a Human In Vivo Benchmark Dose for Perfluorooctanoic Acid From ToxCast In Vitro Concentration–Response Data Using a Computational Workflow for Probabilistic Quantitative In Vitro to In Vivo Extrapolation. *Frontiers in Pharmacology* 12. 630457.
<https://doi.org/10.3389/fphar.2021.630457>
3. **Loizou G, et al. (2021)** Derivation of a Human In Vivo Benchmark Dose for Bisphenol A from ToxCast In Vitro Concentration Response Data Using a Computational Workflow for Probabilistic Quantitative In Vitro to In Vivo Extrapolation. *Frontiers in Pharmacology: Predictive Toxicology* (in press)
4. **Thompson CV, et al. (2021)** A systematic review of published physiologically-based kinetic models and an assessment of their chemical space coverage. *Alternatives to Laboratory Animals* (in press)

vi. Social Media & campaigns

Twitter (1 479 followers)



LinkedIn (1 182 contacts)

EURACTIV campaign



5. Membership

38 companies (incl. 1 SME)



5 DG's of the EC



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

8 Sectoral associations



6. Outlook

FUTURE

- ☞ **Guided by our Action Programme 2021-2025:**
 - Enhance **communication of scientific reality**
 - Facilitate **communication** between industry, academia, policy makers, regulators and NGOs
 - Optimise **translation** from research to **regulatory practice**
 - Help establish more human relevant **exposure-based testing for risk assessment**
- ☞ **Partners Forum 2022 on Exposure considerations in human safety assessment**
- ☞ **User Forum on Skin sensitisation:** continue sharing to build confidence in **New Approach Methodologies**
- ☞ **EPAA Prizes 2022:**
 - 3Rs Science prize
 - Student grants (ESTIV, EUROTOX, FELASA)



6. Outlook (continued)

FUTURE

➔ **Contribute to the successful implementation of CSS** mainly via our **new EPAA project on NAMs** :

- **Seek expert input from industry and regulators across sectors**
- **Interact with PARC, ASPIS and other relevant research consortia**
- **Foster communication and dialogue on the challenges and opportunities of NAMs, e.g. :**

- How can information on **exposure** be more integrated in chemical risk assessment and risk management?
- How to ensure **Protection** of humans & the environment using NAMs vs. prediction of outcome of current animal tests?
- How can we achieve “validation” of using NAMs in chemicals legislation?
- How can we ensure reliable NAMs that won't generate false positive or false negative results that need to be followed up with animal testing or will compromise useful ingredients?
- How can the REACH annexes open-up to allow use of NAMs?

EPAA committed to the 3Rs science



- ✓ Our industry partners are committed to **the 3Rs** and the **use of NAMs** as soon as this is scientifically possible.
- ✓ Great progress on **all 3Rs** has been made thanks to voluntary industry efforts at company and sectoral level.
New approaches have been and are being developed in pharma, cosmetic, agrochemical and chemical sectors (IMI, LRSS, LRI, ECETOC)
- ❖ A big thank you to all **industry partners** for their continued support !
- ❖ Thanks to the **EC partners** for their open-mindedness and good teamwork !
- ❖ Special thanks to the **EPAA Mirror Group** for their excellent advice and constructive input !



**EPAA's work is more important than ever !
Let us continue this unique collaborative effort together !**

Many thanks to:

Commission Co-Chair Giacomo Mattinò

Steering Committee members

Project Teams & Project Platform members

EPAA Secretariat

... and thanks to *you* for listening !