

The European Partnership for Alternative Approaches to animal testing (EPAA)

Dr. Irene MANOU

Virtual Joint EDQM-JRC-EPAA Workshop (9-10 March 2021)

"Novel *in vitro* model as alternative to *in vivo* toxoid vaccines testing:

Clostridium septicum vaccine as proof of concept"

EPAA at a glance

Status: Unique **voluntary collaboration between the European Commission and Industry stakeholders** (companies and associations)

Purpose: To facilitate development, validation, acceptance & implementation of alternative approaches.

Scope: Operates since **2005** across 7 industry sectors (Animal Health, Chemicals, Cosmetics, Crop Protection, Fragrances, Pharmaceuticals (incl. vaccines), Soaps & Detergents). Focuses on Regulatory testing

Vision : The replacement, reduction and refinement (3Rs) of animal use for meeting regulatory requirements through better and more predictive science.

Mission:

- Promote **development and acceptance** of alternative methods
- Enhance **international collaboration** & mutual recognition of alternatives
- Foster **knowledge-sharing** on 3Rs among the partners
- **Facilitate dialogue** between stakeholders contributing to **animal welfare**

EPAA Members

37 companies (incl. 1 SME)



5 DG's of the EC



DG GROW
DG ENV
DG SANTE
DG JRC
DG RTD

8 Sectoral associations



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Governance

Steering Committee Chairmanship

EC: Salvatore D'Acunto, DG GROW
Industry: Rob Roggeband, P&G

Projects Platform Chairmanship

EC: Raffaella Corvi, DG JRC
Industry: Paul Benndorf, Henkel

Mirror Group

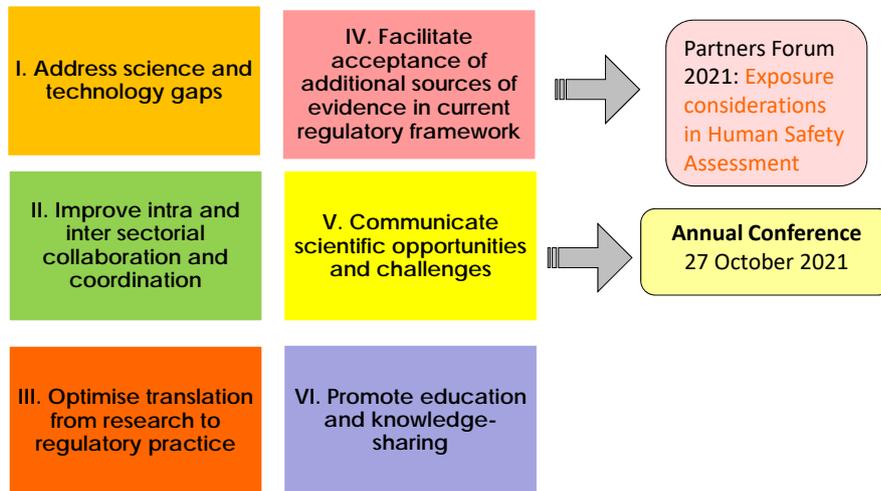
11 experts from various backgrounds, such as Academia, National 3Rs Centers, Animal Welfare groups and a MEP
Chair: Marina Pereira, HSI

EPAA secretariat

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

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EPAA Action Programme 2021-2025



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EPAA Projects in 2021



1. Clostridial vaccines for veterinary use
 2. Human Rabies vaccines (supporting BSP148)
 3. Harmonisation of 3Rs in Biologicals
 4. Acute toxicity
 5. Optimal duration of non-clinical studies to assess safety of monoclonal antibodies
 6. Prediction of Carcinogenic potential of agrochemicals
 7. Optimised strategies for assessing Skin Sensitisation – User Forum
 8. New Ideas for Systemic Toxicity (Blue Sky WS) - *completed*
 9. *In vitro* to *in vivo* extrapolation (CIVIVE)
 10. PBK modelling in safety assessment
- A bracket groups items 1, 2, and 3, with the text: Promoting alternatives in vaccines testing

More information on the projects at:

https://ec.europa.eu/growth/sectors/chemicals/epaa/project-platform_en

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The Clostridial vaccines project



- Has been supported by EPAA since 2013 (*Workshop March 2013*)
- Stemmed as a focus area from the **EPAA Vaccines Consistency Approach project (2010-2015)**
- **2013:** Collaborative study on *Clostridium septicum* vaccine: cell line assays for toxicity & antigenicity testing was discussed and designed with the EDQM (BSP130, Phase II)
- **2014:** BSP130, Phase II coordinated by EDQM validated *in vitro* assays using Vero cells vs *in vivo* tests
- **2015:** Joint EDQM-JRC-EPAA “BSP130 Participants Workshop” (15-16 Sept, Egmond aan Zee, NL)
- **2016-2018:** BSP130, Phase III Inter-laboratory study with optimised *in vitro* protocol was coordinated by EDQM and successfully completed

The Clostridial vaccines project



The EPAA supported this activity by providing:

- a link to the member manufacturers (companies & association)
- a neutral, high-visibility **scientific-based platform** for regular exchanges between the relevant stakeholders
- **scientific** and **funding support** (for shipment of study materials, International Workshop 2015 (NL) and expert meetings)
- a platform for **dissemination** of the study results

The ultimate goal remains the **regulatory acceptance** of the validated *in vitro* assays through their inclusion in the Ph. Eur. Monographs => achieve replacement of the current animal tests



EPAA promoting the 3Rs (Dissemination)

Science Prize

10.000€ prize for outstanding contribution to the use of the 3Rs

Refinement Prize

6000€ prize

Student grants

Grants for students to attend the high profile science events (EUROTOX, ESTIV, FELASA, WC11, etc.)

Social Media

Twitter (1372 followers)

LinkedIn (1009)



Media coverage

EURACTIV campaign



Recent EPAA documents for download (*hyperlink*):

[Achievements Brochure](#)

[Annual Report 2020](#)



Full list of EPAA publications at:

<https://ec.europa.eu/docsroom/documents/43243>

Summary

- EPAA, a **unique, multi-sectoral, science-based collaboration** between **industry partners** and the **European Commission**.
 - Effective platform for **communication** and **information exchange** across sectors and the scientific community (incl. regulators, academia, NGOs).
 - Facilitates **acceptance** and **implementation** of **alternative methods**.
 - Strong **commitment** from the partners to promote regulatory acceptance of **new 3Rs Science and Technology**, **promote international harmonization** and improve **animal welfare** on a world-wide basis.
 - Has a long-standing and fruitful **collaboration with EDQM**.
- Looking forward to working further together to progress the use of 3Rs approaches in regulatory safety decisions.



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Thank you for your attention !

Visit the EPAA website at :

https://ec.europa.eu/growth/sectors/chemicals/epaa_en

e-mail: GROW-EPAA@ec.europa.eu



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