#### "Protection of people and our environment through NAMs"



Christiane Hohensee

Mirror Group member

Bundesverband Menschen für Tierrechte e.V.

## The Mirror Group

- Consists of representatives of civil society
- Reflects views of academia, animal research organisations, animal welfare organisations and politician
- Members act on a personal capacity, based on expertise
- Acts as a consultation forum in an advisory capacity to the Steering Committee for the implementation of the action programme and EPAA's projects
- Adds a broader societal perspective to EPAA's work
- Quarterly meetings with the Steering Committee

#### **Mirror Group Members**



Tuula Heinonen National 3Rs Center



Christine Hohensee
Animal Welfare



Helena Kandarova National 3Rs Center



Emily McIvor (Chair)

Animal Welfare



Emma Grange
Animal Welfare



Monique Janssens
Animal Welfare



Julia Baines
Animal Welfare



Vera Rogiers
Academia



Winfried Neuhaus

Academia



Sirpa Pietikäinen MEP

## EPAA's task (from broschure "15 years EPAA"):

- "EPAA promotes alternatives to animal testing in priority areas where research gaps need to be identified and to overcome acceptance barriers"
- "...facilitates research and development of new alternative methods to address technology gaps and promote innovative approaches to regulatory safety testing, particularly repeated-dose toxicity"
- "...builds coalitions and synergies to accelerate the adoption of non-animal NAMs"
- "... hosts workshops, provides recommendations and publications, financial and organizational support for expert meetings"

# Chemicals Strategy: current situation

- **Revision** of the EU framework for the authorisation of chemicals has been delayed
- Proposed changes could increase animal testing by millions
- Stronger focus on neurotoxicity, immunotoxicity and endocrine disruption
- **Extension** of the **one-generation study** by two cohorts for immunotoxicology and DNT studies discussed



# EPAA's role; questions raised by MG members

#### These are many and varied!

- Who is responsible for method validation?
- EURL ECVAM's financial resources of are unlikely to be sufficient for the validation authority's now very extensive range of tasks
- Redistribution of financial resources from other projects?
- European Commission funding, Horizon Europe?
- Plans to abandon the extensive, long-lasting validation process?
- Can methods undergo a different qualification system to that currently used?

## DNT testing batterie: first OECD recommendation

- OECD TG 426 on DNT has hardly been used
- New IVB investigates changes in a number of important DNT processes at cellular level
- 2016: Consensus, that IVB can be used for screening and prioritization
- -> Currently animal cells are considered instead of human cells.
- -> Extension of IVB urgently required to investigate e.g. disruption of the hormone and immune system, and create full replacement method.

# No budget for reproductive toxicology



- Non-animal NAMs for tests of reproductive toxicity has not yet been sufficiently addressed
- comparatively large number of animals are used in this area
- Currently **no additional budget** in sight for the development of replacement methods

### Role model: PEPPER

- Public-Private-Partnership between Industry and government on national level (50:50)
- Organizes and finances pre-validation to ensure sufficient quality of developed methods
- Methods and assays for ED testing
- Evidence for international regulatory authorities

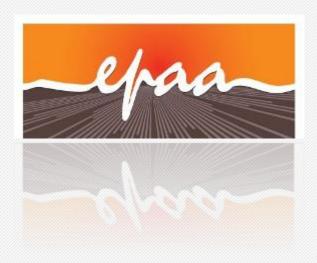




# Validation funding or another qualification system?



# Thank you for your attention!



**EPAA Mirror Group**