JOINT HH + ENV ENDOCRINE ASSESSMENT

Parallel session

Simone Rizzuto, Jukka Sund

Session 2.1

Reflections from stakeholders

JOINT (HH + ENV)

Roadmap-specific technical opportunities and challenges for pesticides and biocides



MODERATOR

Simone Rizzuto

Scientific Officer

EFSA (Pesticide Peer Review Unit)



MODERATOR

Jukka Sund

Scientific Officer

ECHA (Biocides Active Substances Unit)

Session 2.1

JOINT (HH + ENV)

Reflections from stakeholders

Roadmap-specific technical opportunities and challenges for pesticides and biocides



Laurent Lagadic

Senior Science Fellow, Environmental Safety Assessment and Strategy

Bayer Crop Science



Eva Bay Wedebye

Senior Executive Officer, Head of Research Group

Technical University of Denmark



Lisa Baumann

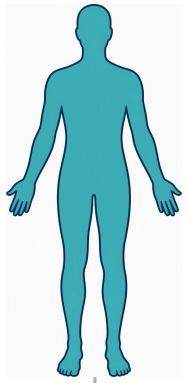
Assistant Professor of Ecotoxicology

Vrije Universiteit Amsterdam

NAMS FOR ENDOCRINE ASSESSMENT

Human health: in vitro / in silico

ECHA/EFSA 2018 framework



Oestrogen
ER assays
TG 455

Androgen
AR assays
TG 458

Steroid synthesis
H295R: TG 456
Aromatase

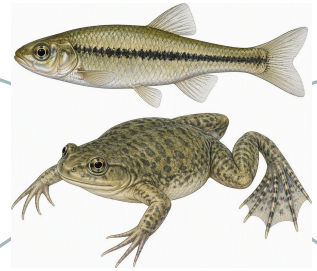
In silico / HTS
ToxCast / Tox21

Thyroid
Mechanistic assays

Environment: eleutheroembryo screens

Eleutheroembryo OECD assays adopted after 2018

EASZY
TG 250
Zebrafish
Oestrogen



REACTIV
TG 252
Medaka
Oestrogen

RADAR
TG 251
Medaka
Androgen

XETA
TG 248
Xenopus
Thyroid

AOPs (adverse outcome pathways) link NAM activity data to adverse outcomes.
ED identification still requires adversity and a biologically plausible link.

Sources: ECHA/EFSA (2018), EFSA Journal 16(6):5311.

WHAT'S NEXT?

Predicting adversity	AOPs are useful but still demanding in terms of *in vivo* data. Quantitative AOPs could help but effort in development.
Biological coverage	No *in vitro* methods for non-mammalian species. How sound is the extrapolation?
Mechanistic understanding	Helpful if the focus would be on endocrine active substance. Breaking of the silos between human health and environment.
Regulatory integration	*In vitro* methods are useful but based on the current Regulations laying down the criteria, negative results are not sufficient.

PANEL DISCUSSION

	What can we use now?	What is missing?	What should we do next?
Predicting adversity			
Biological coverage			
Mechanistic understanding			
Regulatory integration			

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EUROPEAN FOOD SAFETY AUTHORITY

Three complementary routes to regulatory confidence

From mechanistic evidence to decisions that reduce animal testing without weakening protection

LL

Laurent Lagadic

INDUSTRY • Bayer Crop Science

Implementing the EC roadmap: challenges and opportunities for environmental ED assessment

Environmental NAMs remain limited. Cross-species extrapolation needs empirical checks, potency and kinetic considerations; qAOPs are needed to connect molecular activity with population-relevant adversity.

EBW

Eva Bay Wedebye

ACADEMIA • Technical University of Denmark

Endocrine disruptors: learnings for grouping and read-across approaches

Grouping and read-across can use existing evidence efficiently when category boundaries are explicit and predictions integrate QSAR, mechanistic, adversity and ADME information across relevant species.

LB

Lisa Baumann

ACADEMIA • Vrije Universiteit Amsterdam

Zebrafish embryos as NAMs for endocrine disruptor testing: insights from ERGO

Zebrafish embryos can bridge cell-based assays and protected-animal tests. ERGO supports cross-vertebrate thyroid extrapolation, while tFET links activity- and adversity-relevant endpoints within an IATA.

JOINT TAKE-AWAY **Break HH–ENV silos and define contexts of use, evidence thresholds and validation needs for regulatory uptake.**

PANEL DISCUSSION

	What can we use now?	What is missing?	What should we do next?
Predicting adversity			
Biological coverage			
Mechanistic understanding			
Regulatory integration			