Testing for DNT, a scientific and societal need in the context of the EU Chemicals Strategy

European stakeholders' workshop on new approach methodologies (NAMs) for developmental neurotoxicity (DNT) and their use in the regulatory risk assessment of chemicals

7 March 2022

Karin Kilian
DG Environment, Sustainable Chemicals Unit

#ChemicalsStrategy
#EUGreenDeal
Societal need to address chemical pollution

• Impact of chemical pollution on health and environment has been increasingly acknowledged in recent decades (e.g. UN Global Chemicals Outlook II, 2019)

• Chemical-induced neurobehavioural deficits identified as one of the effects that have severe (cost) implications for society

• 2018 Consensus statement by scientific stakeholders from regulatory agencies, academia and industry: Need to better address developmental neurotoxicity, demand for a new framework for the assessment of chemicals with the potential to disrupt brain development.

• Progress needs scientific advancements (appropriate methods) and regulatory changes (requirement for data, use in regulatory assessments)
The European Green Deal (2020)

- Increasing the EU's Climate ambition for 2030 and 2050
- Supplying clean, affordable and secure energy
- Mobilising industry for a clean and circular economy
- Building and renovating in an energy and resource efficient way
- Mobilising research and fostering innovation
- A zero pollution ambition for a toxic-free environment
- Preserving and restoring ecosystems and biodiversity
- From 'Farm to Fork': a fair, healthy and environmentally friendly food system
- Accelerating the shift to sustainable and smart mobility
- Financing the transition
- Leave no one behind (Just Transition)
- The EU as a global leader
- A European Climate Pact
The EU Chemicals Strategy for Sustainability (Oct. 2020)

> 50 key actions in 5 areas:

- Innovating for safe and sustainable EU chemicals
- Providing a comprehensive and transparent knowledge base on chemicals
- Simplification and consolidation of the legal framework
- Stronger EU legal framework to address pressing environmental and health concerns
- Provide a model inspiring chemicals management globally

European Commission
CSS - Strengthening legislation to address pressing environmental and health concerns

- Protect consumers, vulnerable groups and workers from the most harmful chemicals
- Protecting people and the environment from the combination effects of chemicals
- Towards zero chemical pollution in the environment

- Most harmful chemicals
- Mixtures
- Environmental impact
- New/revised hazard classes
- Extension of the generic approach to risk management
CSS - Most harmful chemicals/critical hazards

CMR
Respiratory Sensitisation
Immunotoxicity
Neurotoxicity
STOT

PBT
ED HH
ED ENV
vPvB
Risk management - REACH and product legislation

Generic approach to risk management (GRA):

• Substances with harmonized classification for certain hazards are not allowed in mixtures/articles for consumers

• Currently in place for CMR substances (REACH, product legislation)

• CSS: extent GRA to endocrine disruptors and PBT/vPvB substances, assess further extension to immunotoxictants, neurotoxicants, substances toxic to specific organs and respiratory sensitisers

• Derogations possible for essential uses

• before extension of GRA is implemented, prioritise most harmful chemicals for (group) restrictions under REACH
Classification and hazard information—CLP and REACH

- Currently not all critical hazards are included in the CLP regulation
- **CSS:** ensure that the CLP Regulation is the central piece for hazard classification by adding EDs and PBTs/vPvBs, assess the need for specific criteria for immunotoxicity and neurotoxicity
- **CSS:** allows the Commission to initiate harmonised classifications for critical hazards

- Currently limited information requirements for some critical hazards in REACH (especially low-tonnage substances)
- (D)NT: as follow-up to concerns from RDT or trigger-based inclusion of DNT cohort in EOGRTS
- **CSS:** amend REACH information requirements to enable identification of substances with critical hazard properties, including effects on the nervous and the immune systems.
Where are we now? CLP/classification

- CLP revision ongoing
- Public consultation finished
- Impact assessment under development for planned changes, including addition of new hazard classes for EDs, PBT/vPvB and PMT/vPvM
- Commission proposal for change of CLP Annexes expected Mid-2022
- Adoption by end 2022
- Proposal for new hazard classes to UN GHS as a new work item for biennium 2023/24
- For hazards that are already covered in existing GHS hazard classes (neurotoxicity, immunotoxicity): proposal for a new work item to review and strengthen criteria
Where are we now? REACH data requirements

- REACH revision under preparation,
- Public consultation ongoing (until 15 April 2022)
- Commission proposal expected end 2022
- Project to develop options for expansion of REACH data requirements, led by JRC
- Options to be covered in the impact assessment include strengthening of data requirements for low tonnage substances and for critical hazards
- Assess the possibility to include NAMs (e.g. for EDs, ADME/TX, (developmental) immunotoxicity, (developmental) neurotoxicity, bioaccumulation)
Open questions and challenges

• How to use the information obtained with NAMs in regulatory decision-making? Can they drive/support risk assessments and classification? Support grouping and read-across?

• How to ensure relevance, reliability and reproducibility of the methods? Should the approach to validation change for NAM?

• Are the NAMs sufficient availability/accessible for registrants? What are the costs of testing?