

# EU Chemicals Strategy for Sustainability

## *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*

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Karin Kilian  
DG Environment, Sustainable Chemicals Unit

#ChemicalsStrategy  
#EUGreenDeal



European  
Commission

# 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)





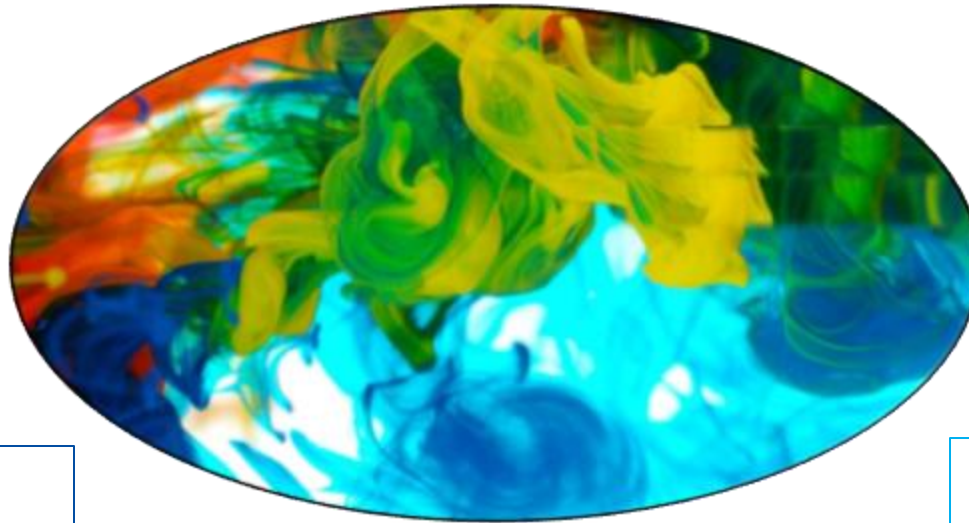
# The EU Chemicals Strategy for Sustainability (Oct. 2020)

> 50 key actions in 5 areas:

Innovating for safe and sustainable EU chemicals

Stronger EU legal framework to address pressing environmental and health concerns

Simplification and consolidation of the legal framework



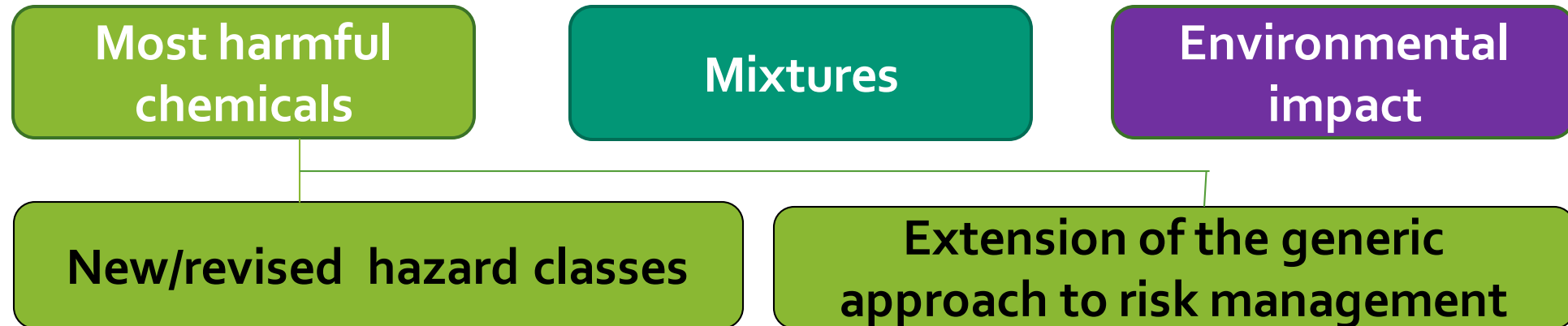
Providing a comprehensive and transparent knowledge base on chemicals

Provide a model inspiring chemicals management globally

# 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



# CSS- Most harmful chemicals/critical hazards



CMR

Respiratory  
Sensitisation

PBT

ED HH

ED ENV

vPvB

Immunotoxicity

Neurotoxicity

STOT



# 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 immunotoxicants, 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
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- 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/TK, (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?

# Thank you

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