Beyond REACH: DG GROW perspective for moving towards animal-free regulations

New approach methodologies workshop: Towards an animal free regulatory system for industrial chemicals

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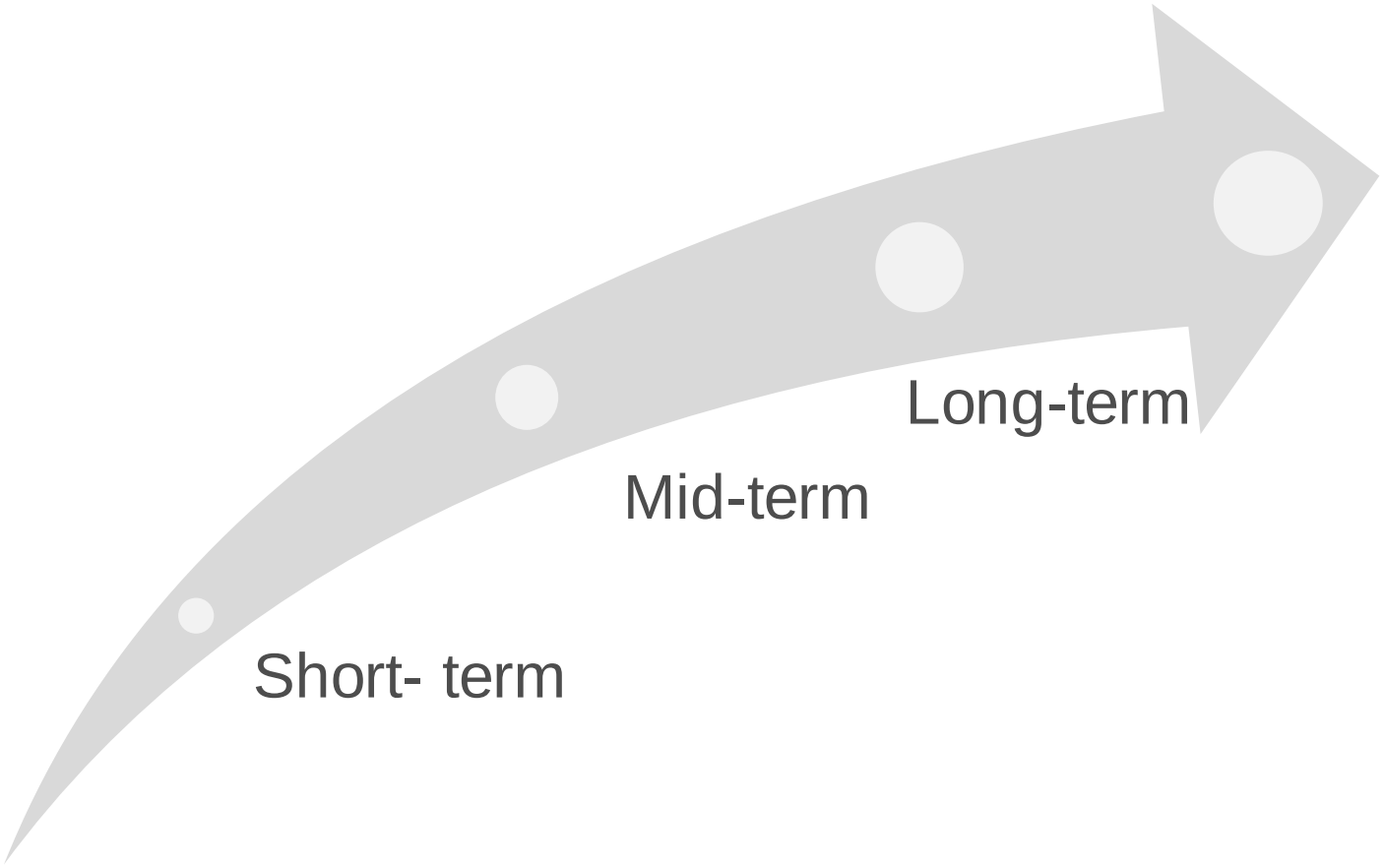
NAMs – a definition

- No formally or legally accepted definition for the term ‘New Approach Methodologies’
- NAM is used in a broad sense as any methodology, approach or technology that provides information for the hazard or risk assessment of chemicals **without using intact animals** or that has **the aim to reduce animal testing**. That includes e.g.
  - In silico (incl. read-across, QSARs…), in chemico and in vitro approaches
  - Integrated approaches to testing and assessment (IATA) and defined approaches (DA)
  - Omics approaches or omic-enhanced studies
- Animal testing corresponding to the scope of Directive 2010/63/EU

Moving towards animal-free regulations



Ultimate goal: Phase out animal testing for regulatory purposes

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Moving towards animal-free regulations

- REACH: Animal testing needed to fulfil Standard Information Requirements (SIR) (Annexes VII-X)
- Similarly, other pieces of chemical legislations (Biocidal Product Regulation, Plant Protection Products Regulation, …) based on Information Req. (IR)

Acute toxicity (oral, dermal, by inhalation)	Carcinogenicity study
Short-term repeated dose toxicity study (28-days)	Short-term toxicity on fish
OECD TG 421/422	Long-term toxicity on fish
EOGRTS (OECD TG 443)	Bioaccumulation in aquatic species, pref. fish

Moving towards animal-free regulations

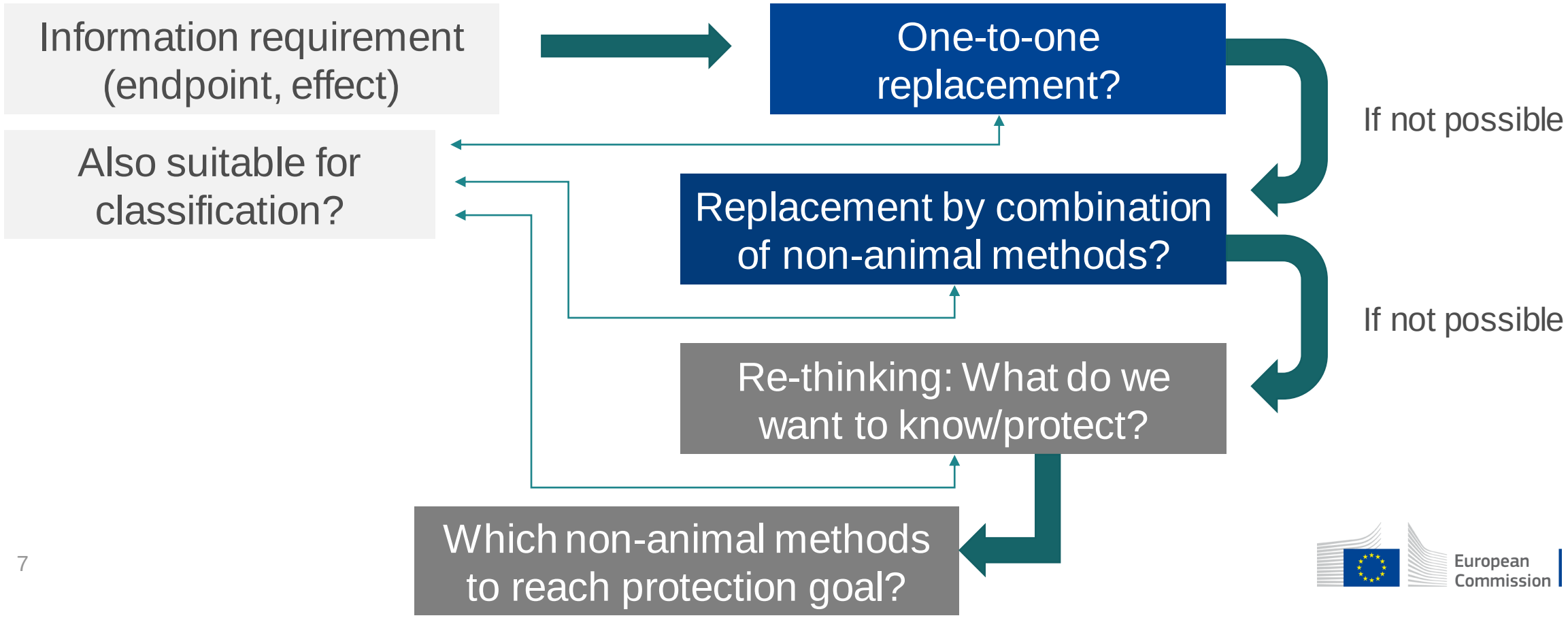
- Basing CLP hazard classes on NAMs/non-animal methods?
  - Classification based on available information
  - Information gathered under REACH (or other legislations) feed into classification

Reproductive toxicity	Carcinogenicity
Specific target organ tox. - repeated exposure	Aquatic toxicity

- Both CLP hazard classes and IRs to be taken into account when considering replacing animal testing
- Or do we need to ask why do we need the information, what do we want to protect?

Moving towards animal-free regulations

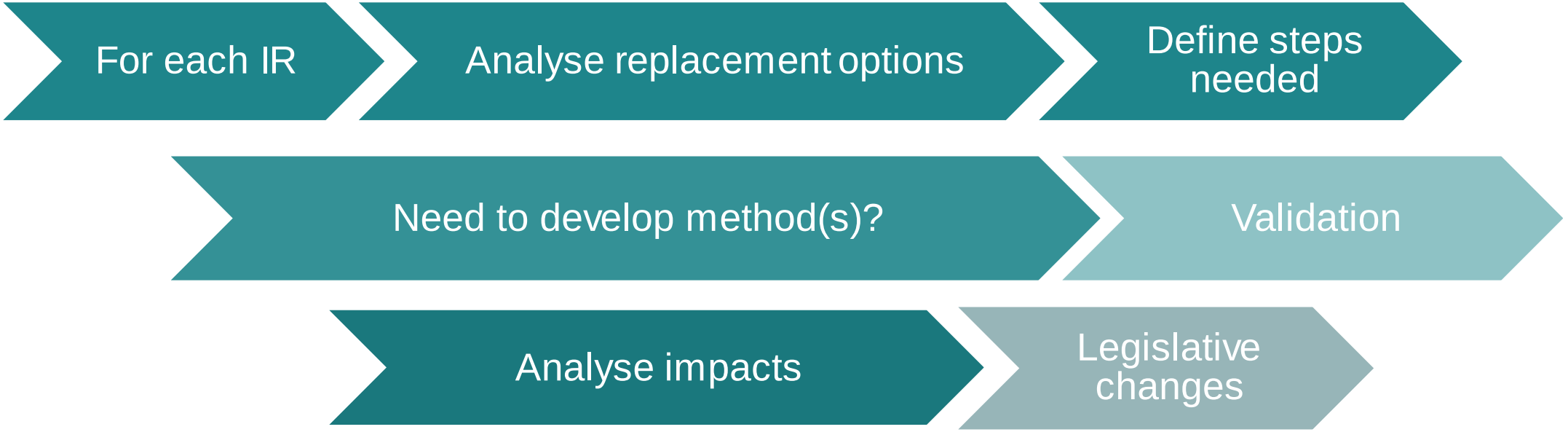
- Stepwise approach for each information requirement



Moving towards animal-free regulations

- One-to-one replacement
  - Skin sensitisation, skin and eye irritation
  - Hyalella Azteca bioconcentration test (HYBIT) instead of fish bioaccumulation test
  - …
- Combination of methods/complex approaches
  - Skin sensitisation, skin and eye irritation
  - Weight-of-Evidence approaches
  - …

Moving towards animal-free regulations



- One-substance-one-assessment – need to look beyond REACH/CLP
- Involvement of Agencies, Member State authorities and stakeholders necessary

Other possibilities to reduce/phasing out animal testing

- Substance-tailored exposure driven testing
- REACH Annex XI, section 3: Testing may be omitted for specific tests (OECD 421/422); 28-day repeated dose test (for < 100 tonnes))
  - If no significant exposure **and** DNELs/PNECs are available relevant for the omitted information and for risk assessment **and** exposure < DNELs/PNECs
  - For substances not incorporated in articles: strictly controlled conditions throughout life-cycle
  - For substances in articles, in which it is embedded/contained: no release during life-cycle; negligible exposure; conditions for transported isolated intermediate applies

Other possibilities to reduce/phasing out animal testing

- Lower tonnages manufactured/imported might lead to lower emissions/exposure
  - For environmental hazards: Relationship normally assumed
  - For human health hazards: Link between tonnage level and emission/exposure might depend greatly on uses
  - Refinements possible by taking into account uses and physico-chemical properties

→ Potential for reducing animal testing for lower tonnages by including waivers

Other possibilities to reduce/phasing out animal testing

- Use-based triggering/waiving
- Triggering of testing for uses with high potential for emissions/exposure/risks
- Triggering/waiving based on consumer/professional/industrial uses (in connection with proportionality or prioritisation considerations)

→ Exposure driven, emission/exposure- and use-based waiving/triggering underemployed due to database architecture, challenges for checking compliance etc.

→ Further analysis required of what would be needed to more often apply such approaches, overcome challenges etc.

Other possibilities to reduce/phasing out animal testing

- Grouping: Require animal testing for some group members (+ read-across or other methods, e.g. Omics)
  - Need to clarify how biological information (e.g. Omics) can support grouping based on structural similarity hypothesis
  - Base grouping approaches only on biological information?

→ Which group members to test, cost sharing, data sharing rules…

→ Templates for reporting biological information (see OECD Omics Reporting Framework)

→ Guidance on the use of biological information

Mutual acceptance of data/UN GHS

- Using NAM data under different jurisdictions (outside EU) → Mutual Acceptance of Data (MAD)
  - Crucial for reducing/phasing out animal testing globally
  - Important for exporting companies/international trade
- OECD system of Mutual Acceptance of data
  - Multilateral agreement as a basis for OECD members (and several non members) to share data using OECD methods and principles
  - > 150 OECD Test Guidelines (validated), principles of Good Laboratory Practice (GLP); guidance on GLP and compliance monitoring

  → Need to work under the OECD umbrella to reach mutual acceptance of NAMs

Mutual acceptance of data/UN GHS

- UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
  - Crucial for reducing/phasing out animal testing globally
  - Important for facilitating international trade
- Harmonises globally classification criteria and communication tools on chemicals
  - Importance to move forward on UN GHS level for changing classification criteria/introducing NAMs for classification

Legal certainty

- Clarity for industry how to fulfil their obligations and the conditions for acceptance by authorities (information requirements; waivers and adaptations; testing proposals)
- Clarity for authorities that data fulfil requirements – facilitates checking of compliance/enforcement
- Importance of legal certainty for industry and authorities for
  - Predictability
  - Replacing/avoiding animal testing
  - Avoiding delays in providing information for the assessment of chemicals

→ Description of IR/classification criteria as clear as necessary

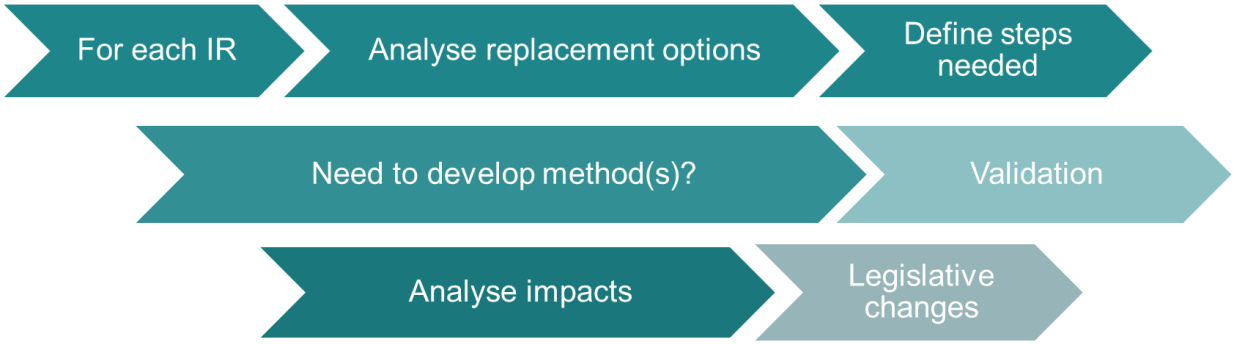
→ Reporting templates, guidance

Moving forward

- European citizens' initiative *'Save cruelty-free cosmetics - Commit to a Europe without animal testing'* submitted to EU Commission on 25 January
- Communication replying to ECI will outline legal and political conclusions as well as action(s) the Commission intends to take (adoption by 25 July)

Moving forward

- Need for a process to define steps for replacing animal testing



- Short-term, mid-term, long-term actions?
- Involvement of all stakeholders: Member States, Agencies, industry, NGOs, scientific community

Thank you

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