Introductory presentation
Long-term aquatic toxicity as area of concern

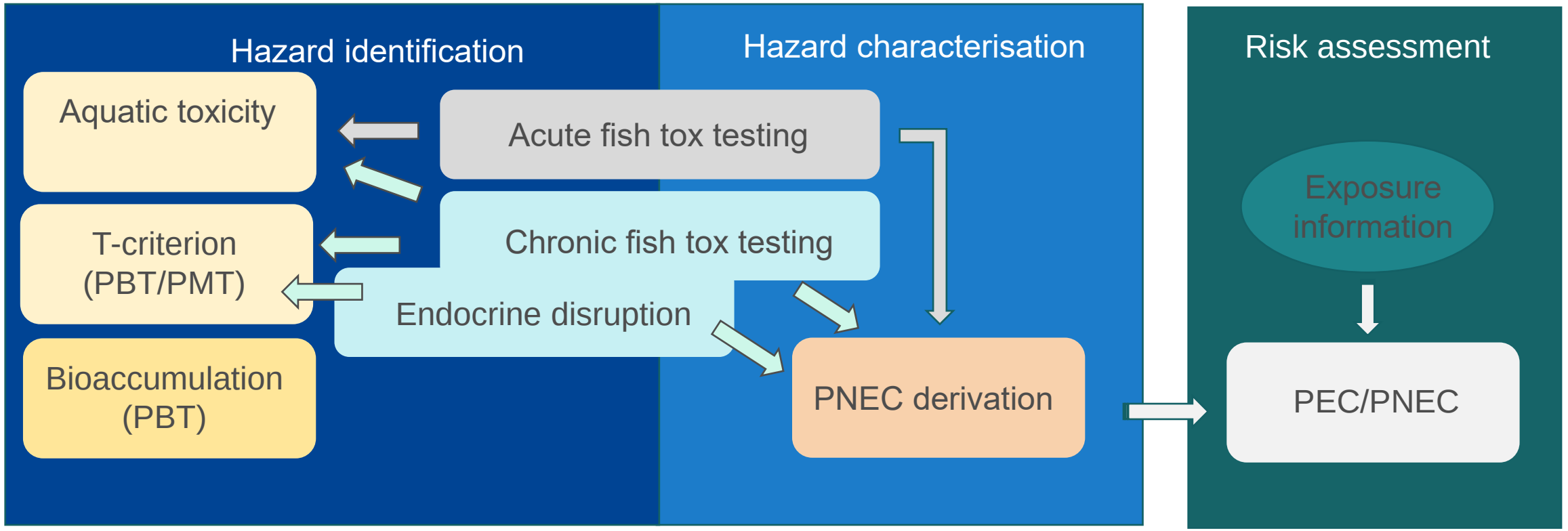
Current regulatory status – roadmap development

Georg Streck (European Commission)

Session 3: How to replace animal testing for the concern of long-term aquatic toxicity?

Introductory presentation: Long-term aquatic toxicity as area of concern – current regulatory status – roadmap development	Georg Streck (EU Commission, DG GROW)
How to address fish aquatic toxicity with alternative approaches? – Possibilities, gaps and challenges to be addressed	Adam Lillicrap (Norwegian Institute for Water Research) (online)
NGRA for the aquatic environment	Stephanie Bopp (EU Commission, JRC)(online)
Presentation by a MS authority on their view how to replace fish long-term toxicity testing	Gerd Maack (Environment Agency, UBA)
Feedback from the EPAA Partner Forum: Possibilities to address the area of long-term aquatic toxicity	José Vicente Tarazona Lafarga (Instituto de Salud Carlos III)
Panel discussion	

Aquatic toxicity and bioaccumulation – current requirements



Aquatic toxicity and bioaccumulation – current requirements

Hazardous aq. Environment – Cat. Acute 1

- Short-term testing with fish
- Short-term testing with crustacea
- Short-term testing with algae /aquatic plants

Hazardous aq. Environment Cat. Chronic 1 - 4

- Long-term testing with fish
- Long-term testing with crustacea
- Long-term testing with algae /aquatic plants
- Bioaccumulation
- Degradation

CLP-Regulation (Classification & Labelling)

- NB: Classification is based on available data

PBT/vPvB – cat. 1

PMT/vPvM – cat. 1

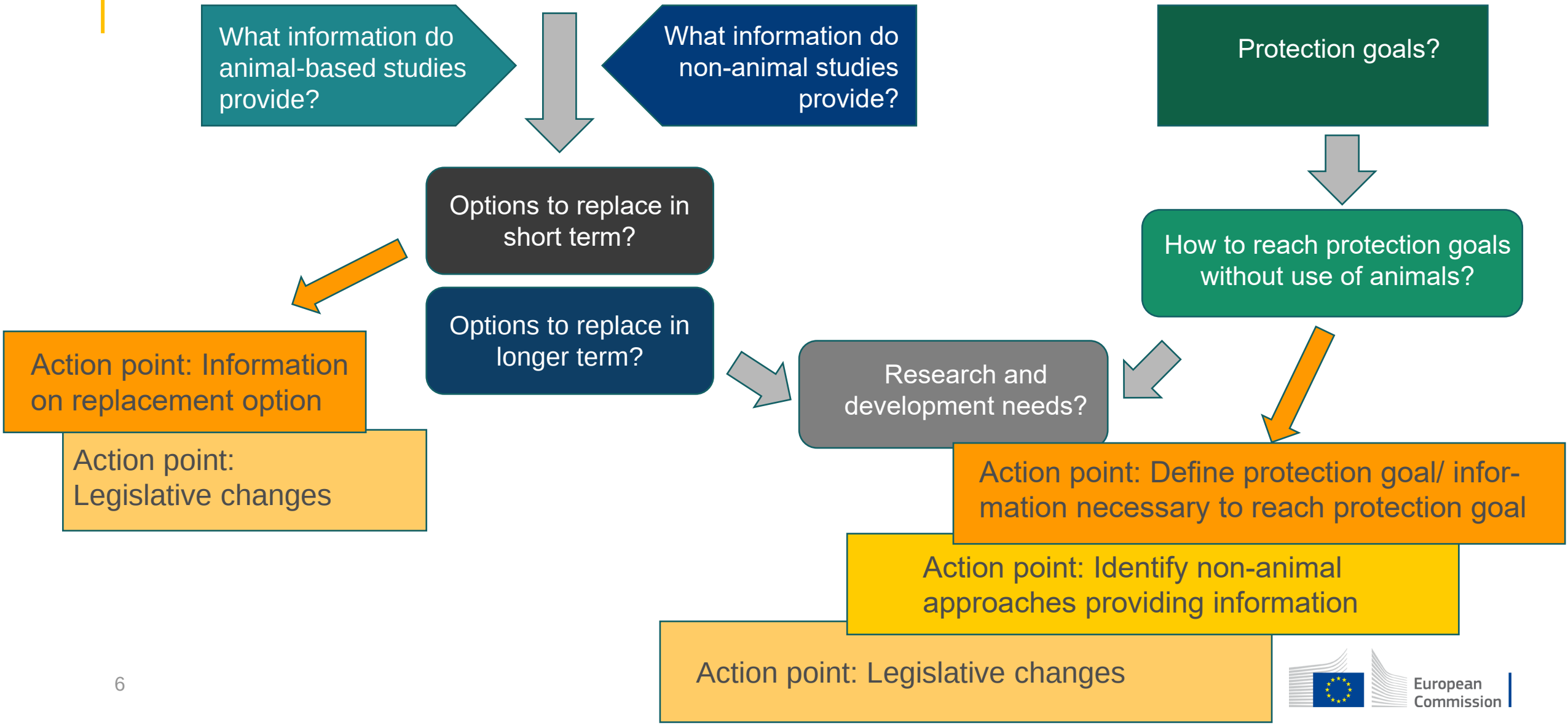
Endocrine disruption – cat. 1- 2

Aquatic toxicity and bioaccumulation – current requirements

Example REACH – Information Requirements

≥ 1 tonne per year	Short-term toxicity testing on invertebrates (preferred species *Daphnia*)
	Growth inhibition study aquatic plants (algae preferred)
≥ 10 tonnes per year	Long-term aquatic toxicity testing if needed for further refinement of the PNEC or for the PBT-assessment
	Short-term toxicity testing on fish
≥ 100 tonnes per year	Long-term toxicity testing on invertebrates (preferred species *Daphnia*),
	Long-term toxicity testing on fish: • Fish early-life stage (FELS) toxicity test (OECD TG 210), or • Fish juvenile growth test (OECD TG 215)
	Other long-term toxicity testing for aquatic toxicity if necessary for the chemical safety assessment (e.g. for PBT assessment, assessment for endocrine disruption)
	Bioaccumulation in aquatic species, preferably fish (e.g. OECD TG 305)
≥ 1.000 tonnes per year	Long-term toxicity to sediment organisms

Roadmap development: Action plan to replace animal testing



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Roadmap development: Action plan to replace animal testing

Options to replace in short term?

Bioaccumulation

- Methods available that potentially replace fish bioaccumulation test
  - Bioaccumulation in invertebrates (e.g. HYBIT study)
  - OECD TG 319a and 319b -*in-vitro* intrinsic clearance tests (combined with IVIVE bioaccumulation models)
- Remarks:
  - Need for further information on applicability domain – replacement for which substances?
  - Development need for IVIVE bioaccumulation models (?)
- Other possibilities for reducing animal testing, e.g. read-across and grouping approaches

Roadmap development: Action plan to replace animal testing

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Potential action points:

- Coordination across different pieces of legislation
- Initiate legislative changes / guidance updates
- Consider need for case studies/research on domain of applicability, IVIVE bioaccumulation models etc.

Roadmap development: Action plan to replace animal testing

Options to replace in short term?

Chronic fish toxicity

?

Roadmap development: Action plan to replace animal testing

Chronic fish toxicity

Protection goals?

- Define/list protection goals / regulatory needs
- Information required for hazard identification (including ED, PBT, PMT), hazard characterisation
- Exposure information/risk assessment

What information do animal-based studies provide?

- Map endpoints

What information do non-animal studies provide?

- Map information space of non-animal methods
- Match with endpoints of animal-based studies?
- Which information relevant for reaching protection goals / regulatory needs do non-animal studies cover?

Action point(s): Report providing information
Time-frame: short

Roadmap development: Action plan to replace animal testing

Chronic fish toxicity

Possibilities to reduce the need for chronic fish toxicity tesing?

- Map possibilities for waiving:
  - Threshold of ecotoxicological concern
  - Exposure-based waiving/assessment
- Map options for merging methods
- Grouping, read-across and integration of different approaches, e.g. Omics

Research/Development needs?

- Gap analysis – what is missing
- Which methods can be developed?

Action point(s): Report providing information
Time-frame: short / mid-term

Roadmap development: Action plan to replace animal testing

Options to replace in longer term?

Chronic fish toxicity

Action points, milestones: How to replace chronic fish toxicity testing??

Roadmap development: Action plan to replace animal testing

Options to replace in longer term?

Chronic fish toxicity

Considerations on requirements for animal-free approaches

- Approaches for different regulatory requirements needed (hazard identification and characterisation, aquatic toxicity, endocrine disruption…)
- Protective for different / most sensitive species (of different taxonomic groups)
- Harmonising approaches across legislation
- Moving forward on the international level, mutual acceptance of data

Thank you

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