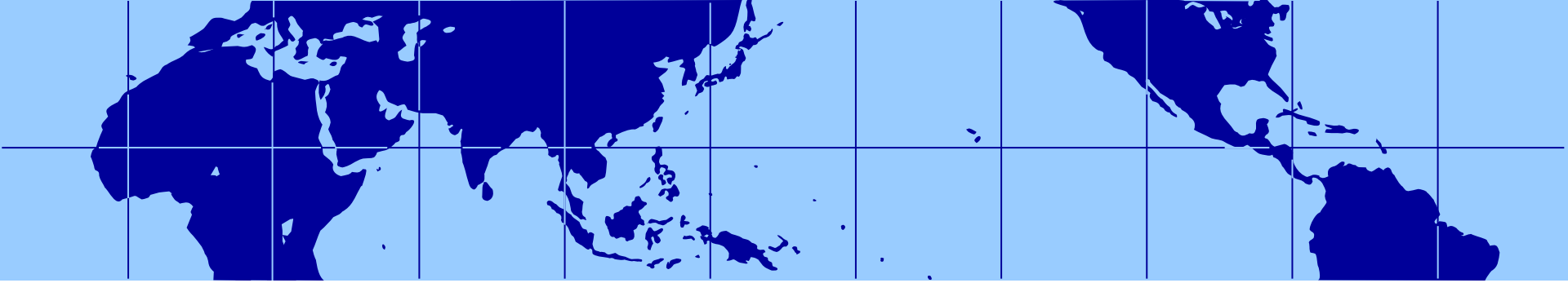


Breakout Group 1: The Process of Regulatory Acceptance

What is the process for AOP development, peer review and application within OECD? How do you go from OECD acceptance to agency acceptance?

Christine Olinger

US National Coordinator for the OECD Test Guideline Program

Melissa Panger

Agenda

- Introduction to OECD and the Test Guideline Program
- General Test Guideline Process
- AOP Process

WHAT IS OECD?

Organisation for Economic

Co-operation and Development

- Estab. 1961, Headquarters – Paris
- 34 Countries (incl. AU/NZ, Japan, Chile, Mexico, Israel)
- Other countries have provisional membership and have agreed to accept data generated under OECD TGs
- Promote policies to improve economic and social well-being of people around world
- Provide forum for governments to work together for solutions to common problems

OECD Test Guidelines

- A collection of the most relevant internationally agreed testing methods used by governments, industry and independent laboratories to assess the safety of chemical products.
- They are primarily used in regulatory safety testing to support labeling and product registration.
- Test Guidelines are not data requirements, which are the prerogative of national authorities.
- Subject to MAD, or Mutual Acceptance of Data.

What is MAD?

- **MAD = Mutual Acceptance of Data**
  - **Decision** by the Council, highest level of OECD

- <u>Two types of Council Acts:</u>
  - **Decision – legally binding** on nations
  - **Recommendation** – strong expression of political will

Guidelines vs Guidance

OECD test guidelines (GDL)

- Harmonized test methods included in the Council Decision on MAD
- Data generated in an OECD country in accordance with test GDL and OECD GLP principles **shall be accepted** in other member countries for purposes of assessment

OECD guidance documents (GD)

- Developed to supplement a GDL Or assist its development
- **NOT** under **MAD**
- Advisory in nature and not obligatory

GDL/GD Process (1)

- Process falls under OECD
- Test Guidelines Programme (TGP)
- TGP overseen by **W**orking Group of the **N**ational Coordinators of the **T**est Guideline Programme (WNT)

GDL/GD Process (2)

- Final proposed document submitted to WNT for approval at annual meeting
- Guidance documents (GD) approved by WNT, endorsed by Joint Meeting, and published in *Series on Testing and Assessment*
- Guidelines need additional approvals prior to publication
- Endorsement by Environmental Policy Committee (EPOC)
- Adoption by Council

US National Coordinator

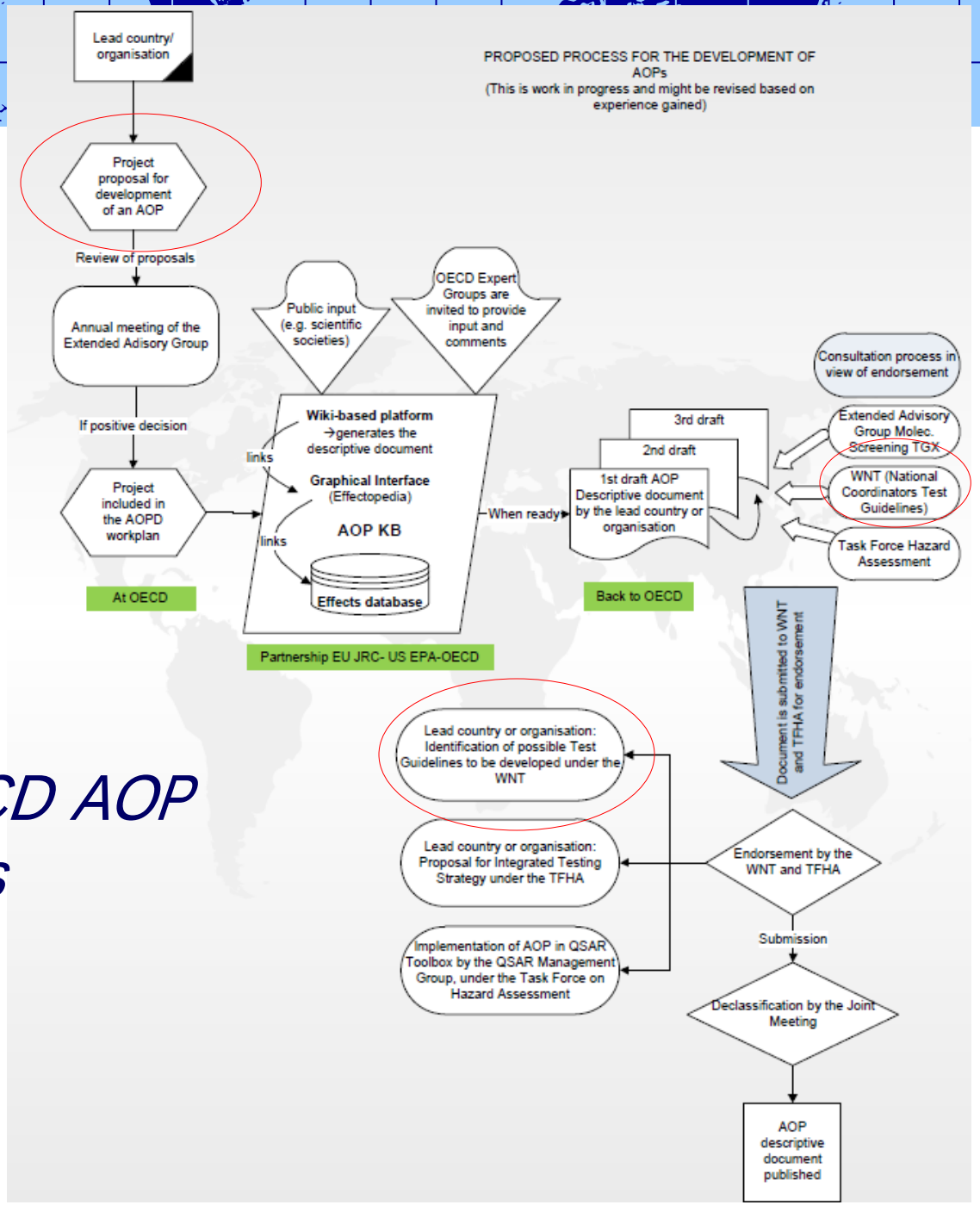
- Responsible for Coordinating OECD Test Guideline Work across USG
- Submits new project proposals on behalf of USG
- Nominates experts to serve on expert groups and attend meetings
- Submits US comments during open comment periods and represents US position on TGs at annual meeting

Adverse Outcome Pathway Program Goals

- Aid the Task Force for Hazard Assessment (TFHA) in the design of Integrated Approaches to Testing and Assessment (IATA)
- Inform the Test Guidelines Programme in the selection of methods to be developed into international Test Guidelines (supporting MAD)
- Guide the development of computational profilers for forming chemical categories and doing read-across in the QSAR Toolbox

http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm

Proposed OECD AOP Process



Points for Consideration and Discussion

- Challenges to the OECD program, *e.g.*:
  - limited resources
  - how best to focus on AOPs that have regulatory significance
  - specific needs of member countries may var.
- What could be some challenges of integrating OECD AOPs and TGs into a regulatory program?
- Is there a need to develop a testing strategy as the AOPs are being developed?
- How do we ensure that the people who may be impacted by the TG are commenting on the TG drafts and are aware of any new TG once it becomes final?
- How could the National Coordinator facilitate the process?