



# OECD TEST GUIDELINES PROGRAMME UPDATE

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ICCVAM Public Forum

Wednesday, 23 May 2017

NIH | Natcher Conference Center | Bethesda, Maryland



# APPROVED DOCUMENTS

- **Approved 6 New Test Guidelines**
  - TG on Protozoa Activated Sludge Inhibition Test + Validation Report
  - TG on 10-day Honeybee Toxicity Test + Validation Report
  - TG on Bumblebee Acute Oral Toxicity Test
  - TG on Bumblebee Contact Toxicity Test + Validation Report
  - TG on Dispersion of Nanomaterials + Validation Report
  - TG 433 on Acute Inhalation Toxicity-Fixed Concentration Procedure
- **Approved 2 New Guidance Documents**
  - GD on Fish Bioaccumulation Study (+ Software/User Manual)
  - GD on IATA for Eye Irritation and Serious Eye Damage (US Co-lead)



# APPROVED DOCUMENTS

- **Approved 5 Updated Test Guidelines**
  - TG 402 on Acute Dermal Toxicity-Fixed Dose Procedure
  - TG 412 on 28-day Inhalation Toxicity Study (US EPA Co-lead)
  - TG 413 on 90-day Inhalation Toxicity Study (US EPA Co-lead)
  - TG 492 Eye Irritation Test with SkinEthic as 2nd Validated Reference Method + updated Performance Standards
  - TG 442E Providing Key Event Based TG Including h-CLAT, U-SENS and IL8-LUC + Validation Report
- **Approved 1 Updated Guidance Document**
  - GD 160 for Eye Collection and Histopathology



# NEW PROJECTS APPROVED

- **19 New Proposals Submitted**
  - 16 Proposals Approved
  - 3 Provisionally Included on TG Work Plan
    - PBTG of Defined Approaches for Skin Sensitization (EC, US, CAN)
      - SPSF to be revised before end of May 2017
      - Expert Group meeting planned for the fall 2017
    - TG on Embryonic Stem Cell (Japan) – revise SPSF to include a 2-step approach:
      - Detailed Review Paper and Feasibility Study
    - Vitrigel Eye Irritation Test (Japan) – minor revision needed to the SPSF



# OUTCOME OF DISCUSSIONS

- **Terminology**
  - The term “recommended” means it *should* be done in TGs
- **Intellectual Property Issues in TGs**
  - Create an Advisory Group - include IP experts, licensing cell culture collection experts, regulators, etc.
  - Develop guiding principles – in efforts to help avoid monopoly
    - Insert in Good In Vitro Method Practices (GIVIMP) document
  - Workshop scheduled 21-22 September 2017, Paris, FR
  - Discuss progress at 2018 WNT



# OUTCOME OF DISCUSSIONS

## ▪ **Me-too Assays**

- Issue is also about available resources of TGP and not only about me-too methods
- Number of projects that can be added to the TGP workplan each year must consider the need for the project and resources required
- WNT supported modified SPSF me-too template, submission process, peer-review process, and requesting all available information with submission
- PBTGs are used to expedite validation of me-too methods
  - Suggestion to develop Key Event-based TGs - e.g. TGP project on Skin Sensitization methods grouped by Key Event in an AOP rather than similar test methods
- WNT will discuss next steps, and communication on policy for me-too assays in the TGP

## ▪ **Acute Systemic Toxicity Survey Proposal (ICAPO, US and EC)**

- Better understand what scientific and policy actions are needed to replace and reduce acute systemic toxicity tests



# UPDATES ON RELATED TGP WORK

- **Updates provided on:**
  - Genotoxicity and Non-Genotoxic Carcinogenicity
  - GD on Good In Vitro Method Practices
  - Revisions to GD 150 GD on Standardized TGs for Evaluating Chemicals for Endocrine Disruption
  - AOP Development Programme and Activities of EAGMST
- **Designation of New Bureau**
  - Tim Singer, CAN agreed to remain Chair for another year
- **Next WNT Meetings:**
  - 24-27 April 2018 - Boulogne Annex, Boulogne-Billancourt, Room BBI
  - 09-12 April 2019 - OECD Conference Center, Room CC15



# UPCOMING MEETINGS

| 2017 MEETINGS   | DATE      | LOCATION          |
|---|-----------|-------------------|
| Advisory Group on EDTA  | 18-19 MAY | Paris, FR         |
| ED Criteria Workshop  | 30-31 MAY | Belgium, Brussels |
| 10th Meeting of the Task Force on Hazard Assessment (TFHA)                                | 12-13 JUN | Paris, FR         |
| Meeting of the Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST) | 14-15 JUN | Paris, FR         |
| Advisory Group on EDTA  | 03-04 OCT | Paris, FR         |
| Validation Management Group-Non-Animal  | 05-06 OCT | Paris, FR         |
| Validation Management Group-Ecotoxicity   | 30-31 OCT | Paris, FR         |
| Meeting of the Expert Group on Skin Sensitization   | 07-08 NOV | Paris, FR         |
| Meeting of the Expert Group on Eye Irritation Test Methods                                | 09-10 NOV | Paris, FR         |