



OECD TEST GUIDELINES PROGRAMME UPDATE

ICCVAM Public Forum Webcast

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NEW PROJECTS APPROVED

No.	Title	Lead
2	Rapid Estrogen ACTivity <i>In Vivo</i> (REACTIV) Assay	FR/UK/JP
3	Anaerobic Transformation of Chemicals in Liquid Manure	DE
4	Inclusion of LbL-3D Skin Model Skin Irritation Test to TG 439 Validated Reference Method	JP
5	Revision of Appendix II in TG 442C: Amino Acid Derivative Reactivity Assay (ADRA) for Predicting Sensitization Potential	JP
7	Revision of TG 439 to Include a New Me-too Reconstructed Human Epidermis Test Method – KeraSkin™ Skin Irritation Test	KR
8	Implementation of the SkinEthic™ Human Corneal Epithelium (HCE) Eye Irritation Time to Toxicity Test (TTL-TTS) for Identifying Chemicals not Requiring a Classification for Eye Irritation and Serious Eye Damage under UN GHS in the Existing TG 492	FR
9	Revision of TG 494 for the Vitrigel-Eye Irritancy TM for Identifying Chemicals not Requiring Classification and Labeling for Eye Irritation or Serious Eye Damage	JP
10	Guidance Document on an Integrated Approach on Testing & Assessment for Phototoxicity	JP
11	Development of New TG on Toxicokinetics to Accommodate Testing of Nano-particles	UK/NL
12	Detailed Review Paper on the State of the Art of Metabolic Disruption by Chemicals	UK/NL w/ SE/DE/DK



NEW PROJECTS NOT APPROVED

No.	Title	Lead	Outcome of Evaluation
1	Bioelution Test Method	EC	To be decided in May in follow-up TC
6	Revision of TG 442E on Applicability Domain for h-CLAT for Skin Sensitization Predictions	JP	Not included Scientific issues regarding the applicability domain need to be resolved
13	Feasibility Study for Development and Validation of IL-2 Luc Assay: An In Vitro Method for Identifying the Immunotoxic Potential of Chemicals	JP	Not included WNT will re-examine following completion of the DRP
14	Adaption of the Beuhler Test within OECD TG 406	NL/DK	Not included as such but discussion to take place on rewording of the introduction of TG 406 in the EG on skin sensitization



DOCUMENTS APPROVED

- **2 New Guidance Documents**

- GD on Aquatic Toxicity Testing of NMs (US ACE & NIST)
- GD for the Testing and Interpretation of Data on Dissolution Rate and Dispersion Stability of NMs for Effects and Exposure Assessment

- **1 New Detailed Review Paper and Validation Report**

- DRP on the *In Vivo* Erythrocyte Pig-a Assay for Genotoxicity Testing (US FDA)

- **4 Updated Test Guidelines**

- **TG 437: BCOP Test Method for Eye Irritation**
- **TG 458: Androgen Receptor Transactivation Assay (ARTA)**
- TG 488: Transgenic Rodent Assay
- TG 491: STE Test Method for Eye Irritation



CORRECTIONS AND REVISIONS

- **4 Test Guidelines Corrected**
 - **TG 405: Acute Eye Irritation/Corrosion**
 - Figure replaced in the Annex of TG 405 with one from GD 263
 - **TG 439: In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method**
 - Corrected the acceptability range of OD of the negative control tissue ≥ 4.0 ~~0.8~~ and ≤ 2.8
 - **TG 442C: In Chemico Skin Sensitization: ADRA**
 - MW of Propyl paraben was corrected to 180.20 in Table 1 of Appendix II, Annex 1
 - **TG 471: Bacterial Reverse Mutation Test**
 - Mismatch between CAS # and the associated positive control substance for ENNG
 - ENNG and MNNG can be recommended as positive controls in TG 471
- **WNT Terms of Reference 2021-2024**
 - Joint Meeting will become the Chemicals and Biotechnology Committee (CBC) end of 2020
 - All sub-committees (level II bodies) will become Working Parties, including the WNT



EXPERT GROUP UPDATES

- **Joint Session of the WPHA, WNT and EAGMST**
 - Regulatory relevance should be an overarching consideration for AOP development and review and coordination between OECD groups
 - AOPs selected for review need to be integrated with TMs and IATA under development in other on-going projects
- **Extended Advisory Group on Molecular Screening & Toxicogenomics**
 - Developed an implementation plan of the prioritization approach recommended at the Joint Session
 - Introduced a consultation step of the WPHA and WNT for new AOP project proposals
 - Enhanced EAGMST subgroup structure
 - More precisely defined scope and roles of subgroups to increase new/more people involved and increase work sharing



EXPERT GROUP UPDATES

- **Expert Group on Dermal Absorption**
 - Discussed project to revise OECD GN No.156 on Dermal Absorption Studies
 - WNT agreed to wait until end of 2020 for US/CAN to amend policy and allow stand-alone *in vitro* data to be used before resuming OECD project to update document(s)
- **Expert Groups on Skin and Eye Irritation & Phototoxicity Testing**
 - TG 437 on the BCOP
 - Revisions to use histopathology as an additional endpoint and use the LLBO device in place of OP-KIT were approved by WNT
 - DA for Eye Irritation:
 - Focused on selection of reference chemicals
 - Discussed criteria for the reference chemicals and
 - Requests on the modes of action of eye irritation effects were addressed
 - Phototoxicity testing using RhE skin tissue
 - UN GHS Working Group on Chapter 3.3 on eye irritation/serious eye damage



EXPERT GROUP UPDATES

- **Validation Management Group for Non-Animal Testing**
 - TG 458 for *In Vitro* Detection of Chemicals that Interact with the Androgen Receptor
- **Expert Group on Retinoid Pathway Signaling**
 - Draft DRP on chemical effects on retinoid pathway signaling was circulated
 - Updates and progress will be shared during the EDTA
- **Expert Group on Defined Approaches for Skin Sensitization**
 - Q3 2019 revised draft TG and supporting document circulated for commenting
 - Conference calls are scheduled for 2020 to discuss updates/comments received
 - WNT noted progress and involvement of experts and lead countries, timelines and process
 - Goal is to have TG approved by written approval or special (virtual) WNT session in 2020



DISCUSSIONS AND DECISIONS

- **Inclusion of Good Computational Practices (GCP) under MAD**
 - WNT wants to be involved in future consultations
 - Structured proposal for NOV 2020 Joint Meeting discussion on GCP
 - WNT Bureau to advise Secretariat when WNT input would be most valuable
 - Suggested GCP document be drafted by targeted expert group consisting of subject matter experts on scientific computing and QA/QC
- **CYP Induction and GD on Hepatic Induction and Clearance Methods**
 - Interested member countries to consider their level of involvement/leadership upon call from Secretariat
 - Current activities for Project 4.76 moved to Annex 1
- **Dose Selection in Chronic, Reproductive and Developmental Toxicity Studies**
 - WNT noted OCT 2020 workshop in US and invited an OECD debrief via webinar
 - Noted presentation from the NL around statistics and dose-response curve issues
 - Recommended an expert group to be formed to discuss development of guidance on study design and dose selection