

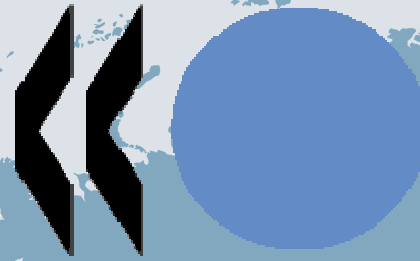
BFR-ZEBET CO-OPERATIONS WITH THE OECD TEST GUIDELINES PROGRAMME AND STRATEGIES FOR REPLACING ANIMAL PROCEDURES

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26 October 2009*

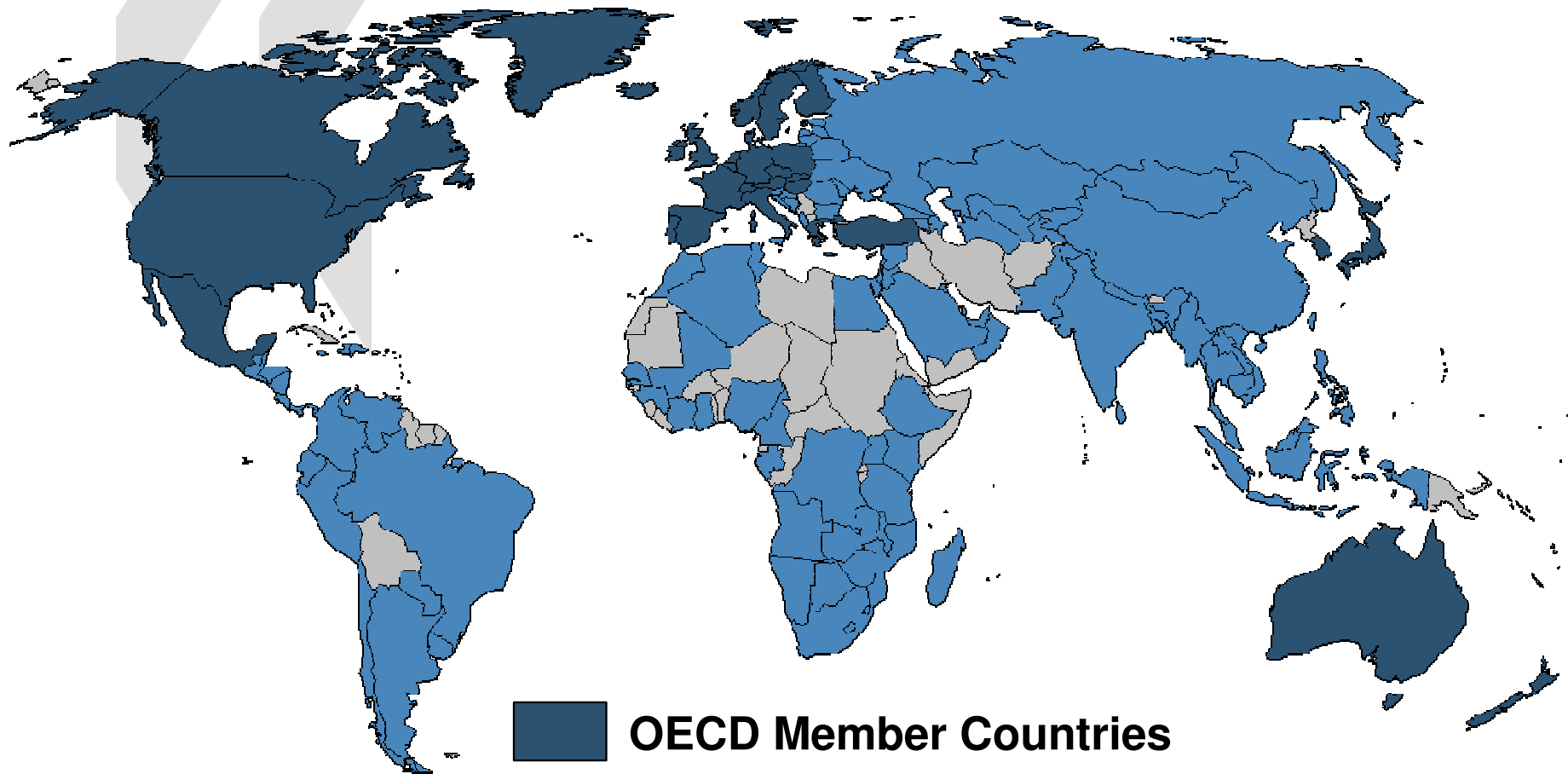


OECD



**The Organisation
for Economic Co-operation
and Development**

A Global Outreach



OECD Member Countries



Countries/Economies Engaged in Working Relationships with the OECD

OECD Environment Directorate Decision Layers



Mutual Acceptance of Data (MAD)

OECD Council Decision from 1981

“Data generated in the testing of chemicals in an OECD member country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice (GLP) shall be accepted in other member countries for purposes of assessment and other uses relating to the protection of man and the environment.”

- Avoids duplicative testing in member countries
- Saves approximately 50 million USD, annually
- Non-Member economies can adhere to MAD & GLP

The Test Guidelines Programme (TGP)

- MAD, GD 1 on “Test Method Submission” and GD 34 on “Validation of Test Methods” is underpinning all work
- TGP focuses on priorities and regulatory needs of member countries for the development and validation of new or updated new methods
- Implementation of the 3R-principles are always high on the agenda
- At presently 80+ projects in the work-plan, with a special programme for ED testing (EDTA AG)

TGP Publications

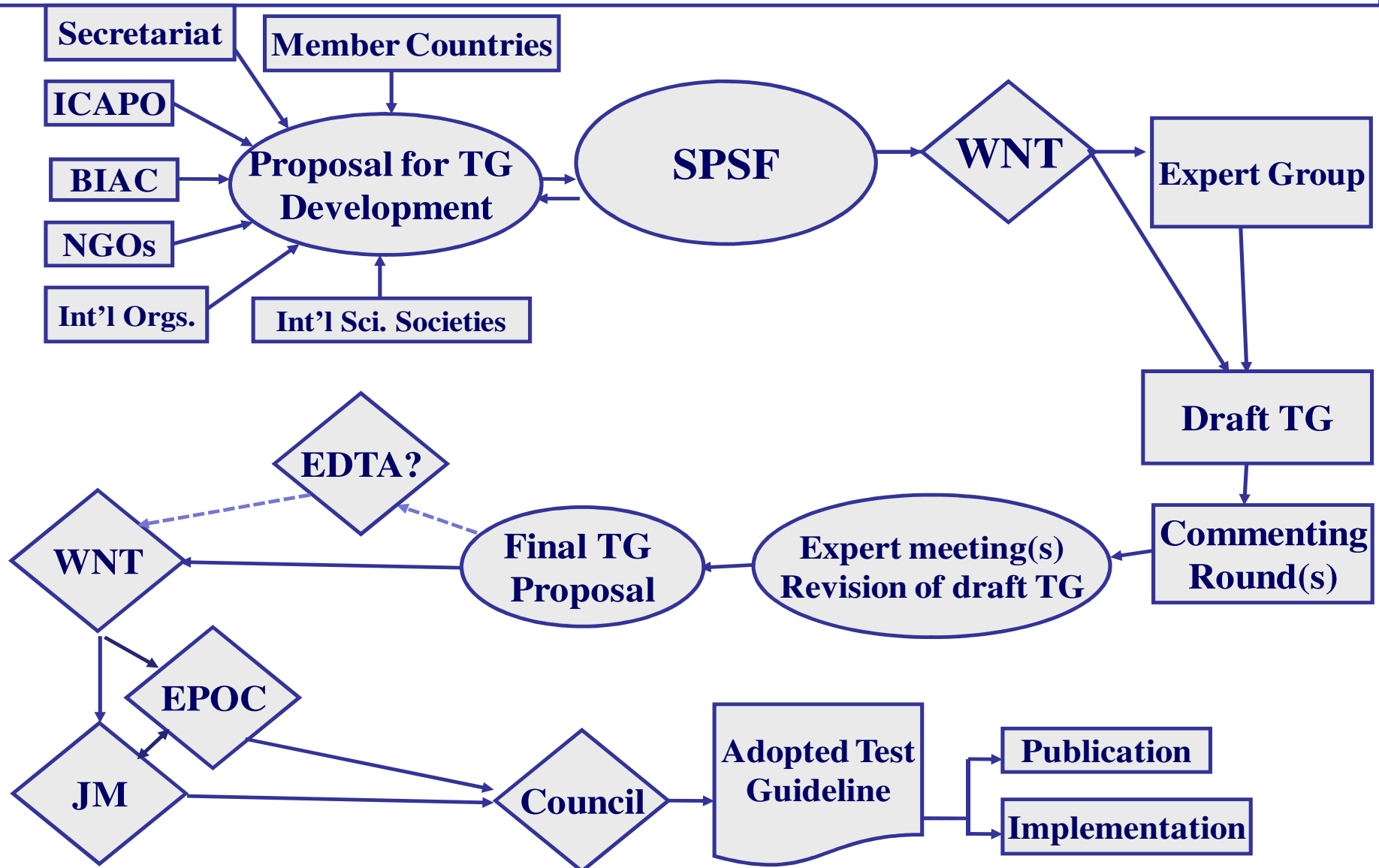
The 5 series of OECD TG's are legally binding instruments in member countries:

100 - Physical-Chemical Properties	(blue)
200 - Effects on Biotic Systems	(green)
300 - Degradation and Accumulation	(yellow)
400 - Health Effects	(pink)
500 - Pesticide Residue Testing	(initiated 2006)

Non-legally binding documents published in the EHS Monograph Series of Testing and Assessment

- Guidance Documents, Detailed Review Papers, Background Review Papers, Performance Assessments, Validation and Peer Review Reports

THE OECD SUBMISSION AND ADOPTION PROCESS



LATEST ALTERNATIVE DEVELOPMENTS

- *In Vitro* Mammalian Micronucleus Assay (TG 487)(UK)
 - provisionally adopted
- Zebrafish Embryo Toxicity TG (Z-FET)(GER-UBA)
 - under validation
- Ocular corrosion and severe irritation TGs 437/438 BCOP/ICE (US)
 - Adopted by council in September 09
- *In vitro* ER Transcriptional Activation Assay, TG 455 (JPN)
 - Adopted by council in September 09
- *In Vitro* Skin Irritation TG (EC)
 - 3rd expert meeting planned for Ispra, Italy in December -09



BfR-ZEBET PROJECTS

1996 - TG 423 Acute Oral Toxicity:

Acute Toxic Class Method (BfR)

2002 - TG 404 Skin irritation / corrosion

(BfR & U.S. EPA: *in vitro/in vivo* strategy)

2002 - TG 405 Eye irritation / corrosion

(BfR & U.S. EPA: *in vitro/in vivo* strategy)



OECD TG 404

OECD/OCDE

404

Adopted:
24th April 2002

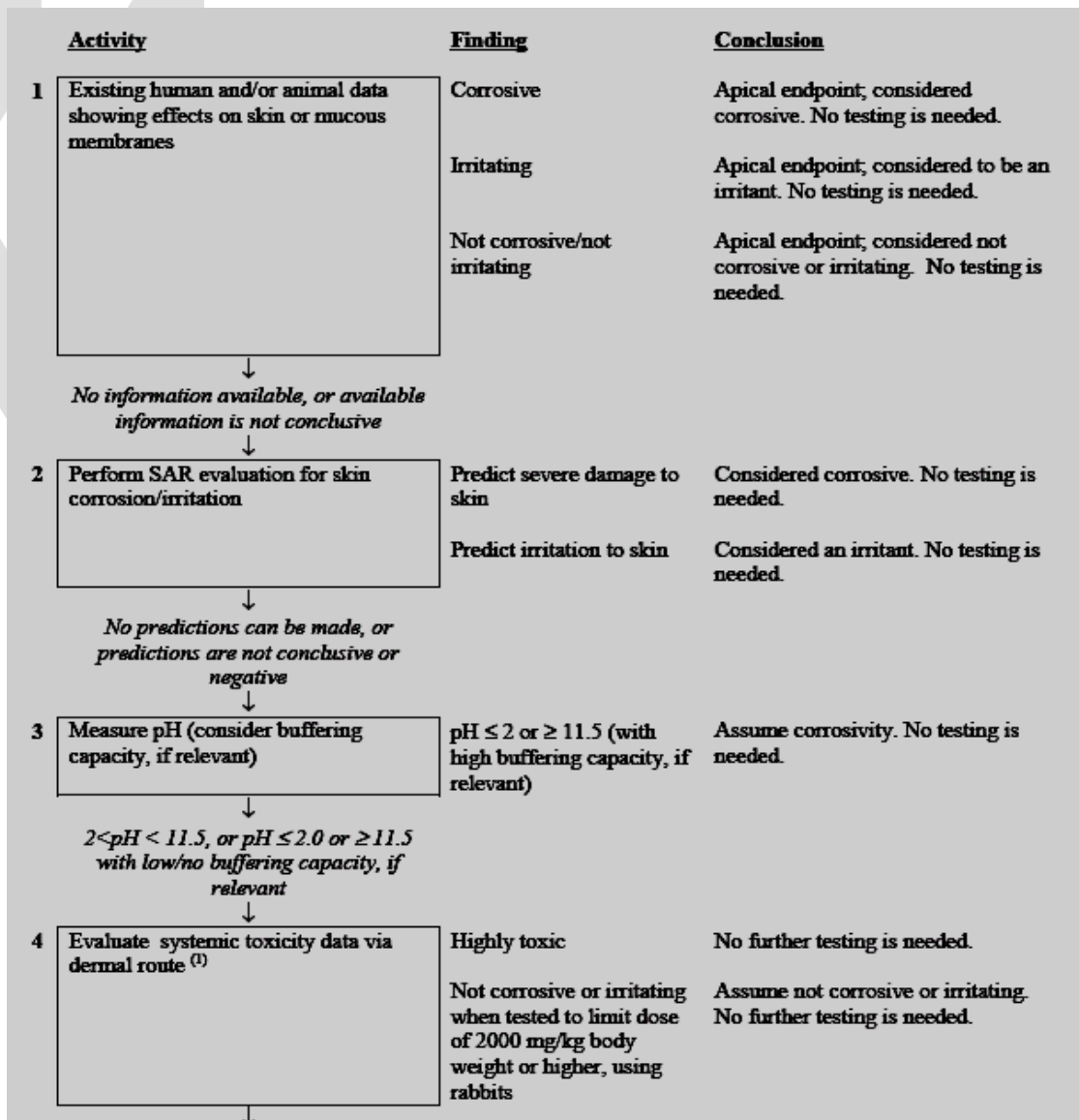
OECD GUIDELINE FOR THE TESTING OF CHEMICALS

Acute Dermal Irritation/Corrosion

INTRODUCTION

1. OECD Guidelines for Testing of Chemicals are periodically reviewed to ensure that they reflect the best available science. In the review of this Guideline, special attention was given to possible improvements in relation to animal welfare concerns and to the evaluation of all existing information on the test substance in order to avoid unnecessary testing in laboratory animals. This updated version of *Guideline 404* (adopted in 1981 and first revised in 1997) includes the recommendation that prior to

TG 404/405 ADDENDUM





BfR-ZEBET PROJECTS

2004 TGs 427/428 Skin Absorption (in vitro/*in vivo*)

2004 GD 28 on Skin Absorption Testing

2004 TG 430 Skin Corrosion: TER

2004 TG 431 Skin Corrosion: human 3D skin model

2004 TG 432 *In Vitro* Phototoxicity: 3T3NRU-PT

2009 TG 436 Acute Inhalation Toxicity: ATC Method

2009 GD 39 on Acute Inhalation Testing

GD 34 on “THE VALIDATION AND INTERNATIONAL ACCEPTANCE OF NEW OR UPDATED TEST METHODS FOR HAZARD ASSESSMENT” (2005)

- Lead by the Secretariat
- The agreement on the “GD34 Principles” by OECD member countries was a major step toward international harmonisation of criteria for validation and regulatory acceptance
- Based on the Solna (1996) and Stockholm (2002) meetings and the ICCVAM/ECVAM validation principals, and expert meetings in Berlin (DIP WS at BfR-ZEBET) and the USA
- The result of the commitments by many member countries

Some ongoing BfR-ZEBET projects

- ⇒ New Test Guideline on Skin Irritation *In Vitro* Reconstructed human Epidermis (RhE) Model (Collaboration with EC)
- ⇒ Implementation of BfR SAR Expert System DSS (skin and eye) into OECD QSAR toolbox
- ⇒ Further work on revision of TG 415: extended One Generation Study
- ⇒ BfR Co-chair of OECD WPMN Steering Group 7 (Alternative Methods to be used in Assessment of Manufactured Nanomaterials)

ACKNOWLEDGEMENT

- BfR and ZEBET is acknowledged for its long-standing commitment and deep engagement in OECD work for the development of new alternative test methods for regulatory uses. By its outstanding contributions of alternative methods for a number of endpoints, the BfR-ZEBET truly exemplifies that a single member country can make a difference!
- The Secretariat look forward to future collaborations and congratulates BfR-ZEBET to 20 successful years of development of alternatives!



For free download of Test Guidelines and
Monographs, please visit:

www.oecd.org

and the Environment Directorate

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