



uOttawa



Risiken erkennen – Gesundheit schützen

International Implications of the U.S. NRC Report on Toxicity Testing in the 21st Century: Challenges and Opportunities in Implementation

University of Ottawa, June 29 – 30, 2009

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Centre for Alternative Methods to Animal Experiments - ZEBET



Biological Safety >>>



Food Safety >>>



Safety of substances >>>



Product Safety >>>

- Remit
- Organisation Chart
- Structure
- Commodities
- Biocides
- BSE
- Chemicals
- Dangerous goods transport
- Cosmetics
- Foods
- Microbial risks
- Pesticides
- Substance risks
- Textiles
- Poisonings
- Research
- GLP
- EFSA Focal Point
- Cooperations
- Committees
- Breastfeeding Committee
- Reference Laboratories
- Risk communication
- ZEBET
- Databases
- Publications
- Masthead

Water pipes: Each puff carries a risk



Water pipes, also called shishas, are popular mainly amongst adolescents in Germany. After evaluating the data available at the time, the Federal Institute for Risk Assessment already announced in 2005 that the smoking of water pipes did not mean scarcely any lower health risks than smoking cigarettes. New data from sources including the Institute's own research work now indicate that users of water pipes take in far higher levels of carbon monoxide from the smoke than cigarette smokers. This toxic gas binds to the red blood pigment, haemoglobin, and can impede oxygen transport in the body. Pregnant women and individuals suffering from cardiovascular diseases in particular should not, therefore, smoke water pipes. Pregnant women should not spend too much time in shisha cafes either.

www.bfr.bund.de

Federal Institute for Risk Assessment designated a family-friendly employer

Health risks from fumigated ship containers

Ship containers are sometimes fumigated with pesticides to protect goods during transport from pests and fungi. This also prevents the spread of insects or other pests from one country to another. The BfR has received reports of health impairments suffered by the dock workers who opened these containers. [more >>>](#)

FAQs about glycidamide in food

In the summer of 2008 research scientists at the

History of the BfR



Risiken erkennen – Gesundheit schützen

- Imperial Health Agency (1876-1919)
- Health Agency during the German republic and the „Third Reich“ (1919-45)



Federal Health Agency (1952-1994)

Federal Institute for Health Protection of Consumers and Veterinary Medicine (1994-2002)



Risiken erkennen – Gesundheit schützen

Risk Assessment

August 6, 2002

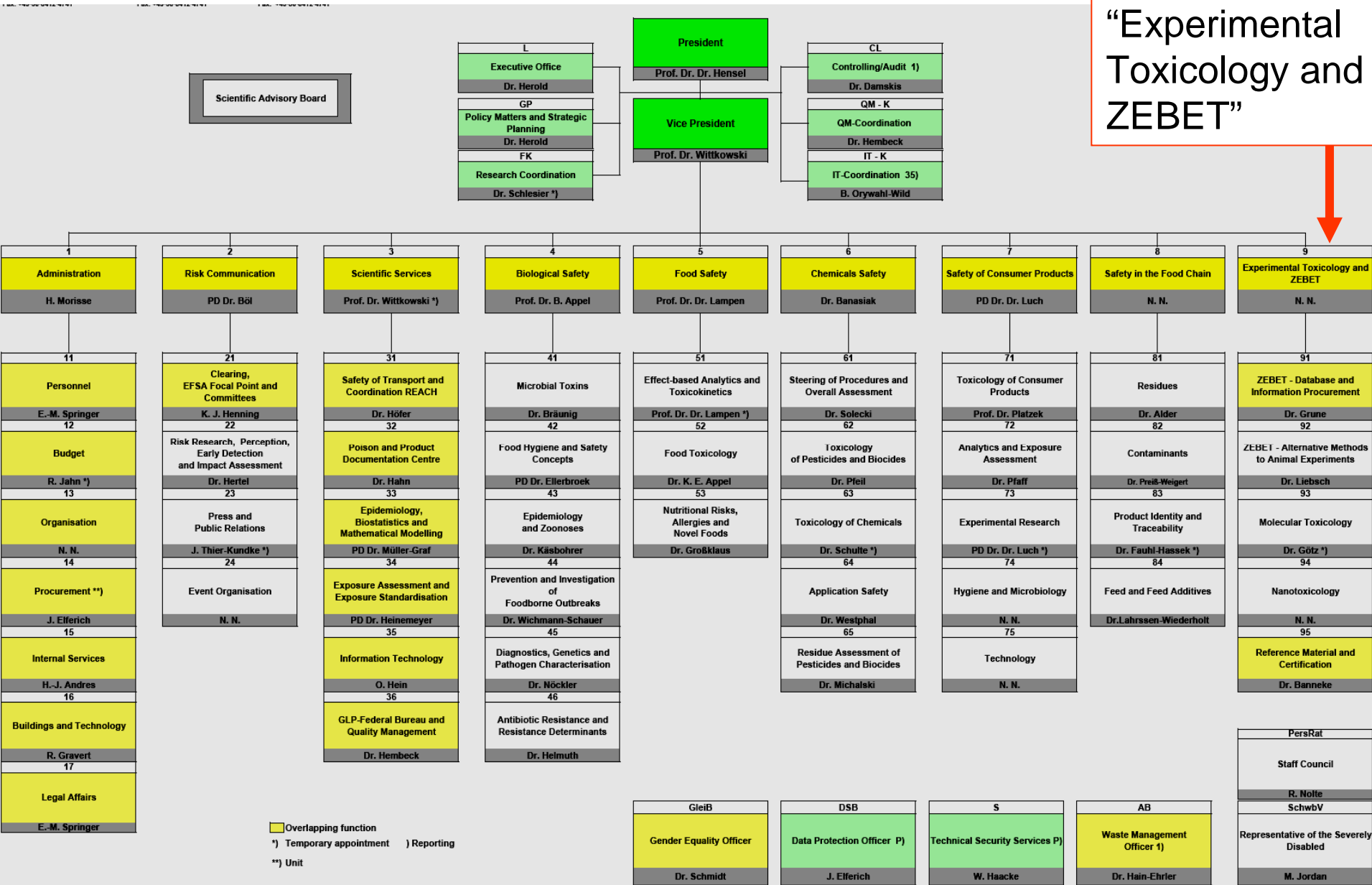


Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Risk Management

The BfR since February 2009

Department
 “Experimental
 Toxicology and
 ZEBET”



BfR New Department 9

General Mission:

In the BfR,
Toxicology goes
in vitro
and molecular

9	
Experimental Toxicology and ZEBET	
N. N.	
91	★
ZEBET - Database and Information Procurement	
Dr. Grune	
92	★
ZEBET - Alternative Methods to Animal Experiments	
Dr. Liebsch	
93	★
Molecular Toxicology	
Dr. Götz *)	
94	
Nanotoxicology	
N. N.	
95	★
Reference Material and Certification	
Dr. Banneke	

Contribution of BfR to OECD Work

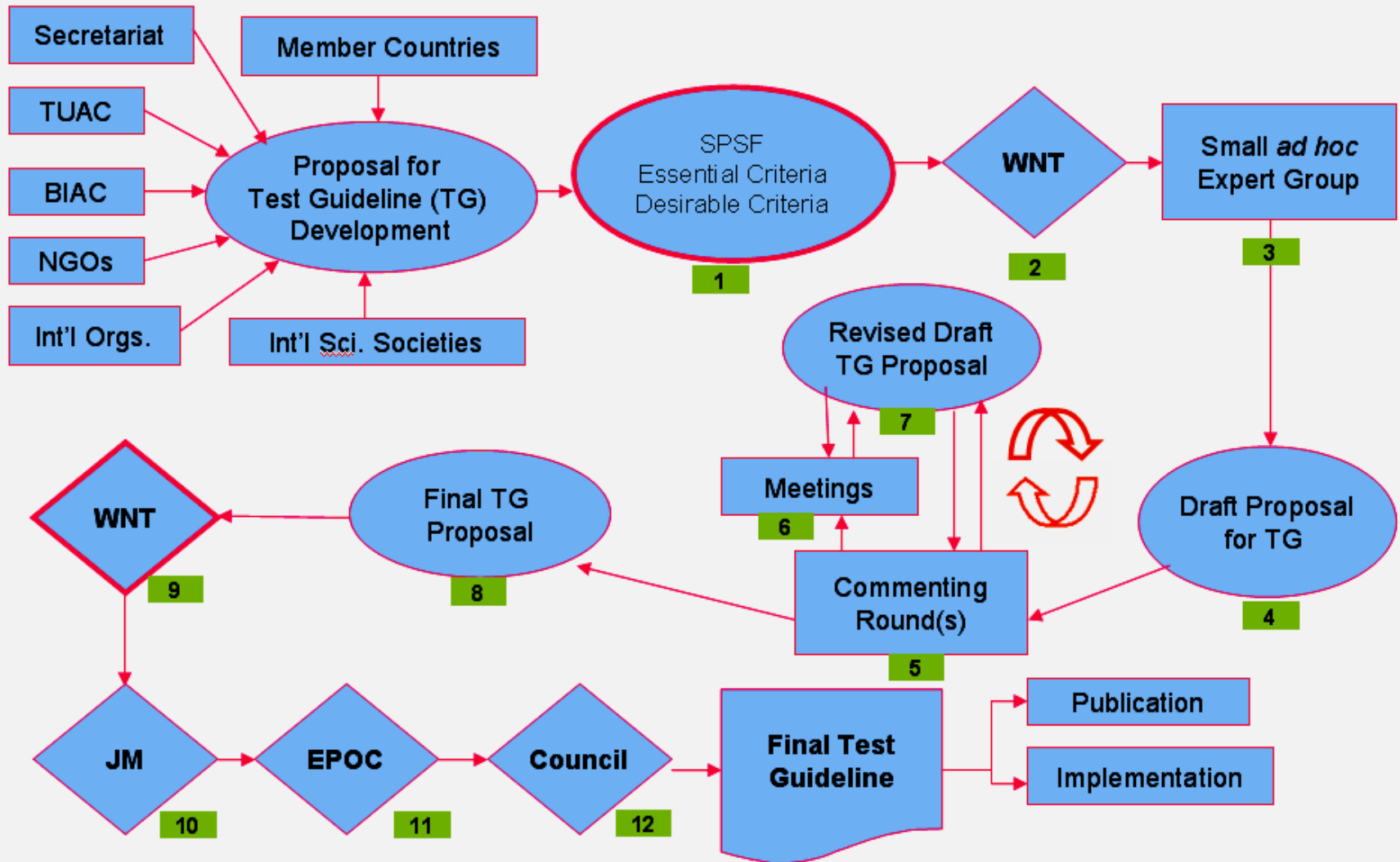
- 1996 TG 423 **Acute Oral Toxicity**: ATC Method
- 2002 TG 404 **Skin irritation / corrosion**
(BfR & U.S. EPA: *in vitro/in vivo* strategy)
- 2002 TG 404 **Eye irritation / corrosion**
(BfR & U.S. EPA: *in vitro/in vivo* strategy)
- 2004 TG 427 **Skin Absorption** (*in vivo*)
- 2004 TG 428 **Skin Absorption** (*in vitro*)
- 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
- 2005 GD 34 on Validation and Acceptance
- 2008 TG 436 **Acute Inhalation Toxicity**: ATC Method
- 2008 GD 39 on **Acute Inhalation Testing**

Contribution of BfR to OECD Work

...currently ongoing

- ⇒ Implementation of BfR SAR Expert System DSS (skin and eye) into OECD QSAR toolbox
- ⇒ Completion of consolidation process on new Test Guideline 4xx: Skin Irritation *In Vitro* Reconstructed human Epidermis (RhE) Model
- ⇒ Further work on revision of TG 415: extended One Generation Study
- ⇒ Co-chair of OECD WPMN Steering Group 7 (Alternative Methods to be used in Assessment of Manufactured Nanomaterials)

Development of a New OECD Test Guideline



SPSF = Standard Project Submission Form

WNT = Working Group of the National Coordinators for the Test Guidelines Programme

JM = Joint Meeting (OECD ENV/EHS)

EPOC = Environment Policy Council

A hurdle? The OECD needs 100% Consensus !



majority decisions, like in the EU Test Guidelines Program possible, don't pass

OECD TG 404 (updated 2002)

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

New since 2002: Tiered Testing Strategy

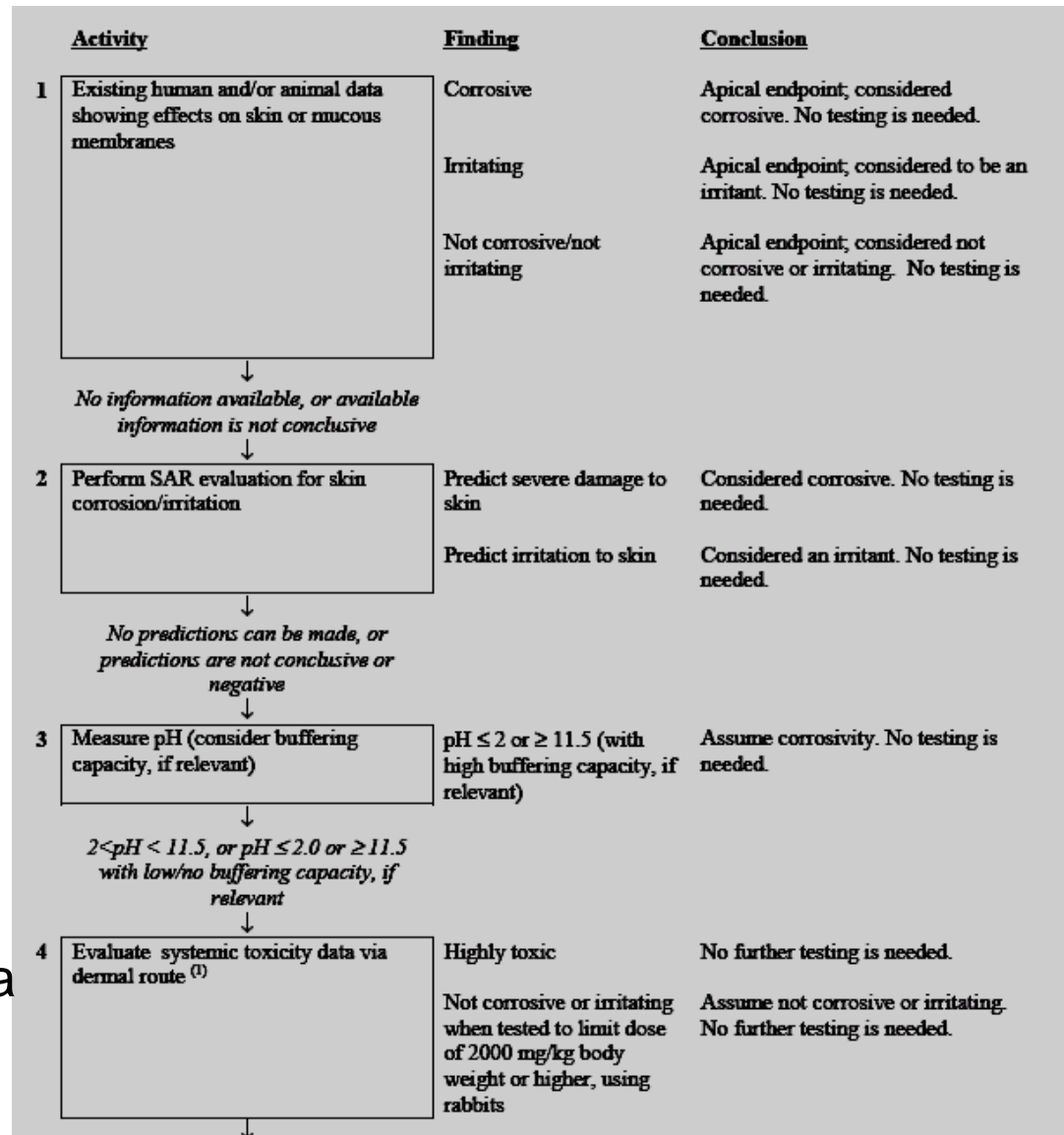
OECD TG 404, Annex: STRATEGY (1)

Use of existing human and animal data

Use of SAR

Use of pH
(& acid / alkaline reserve)

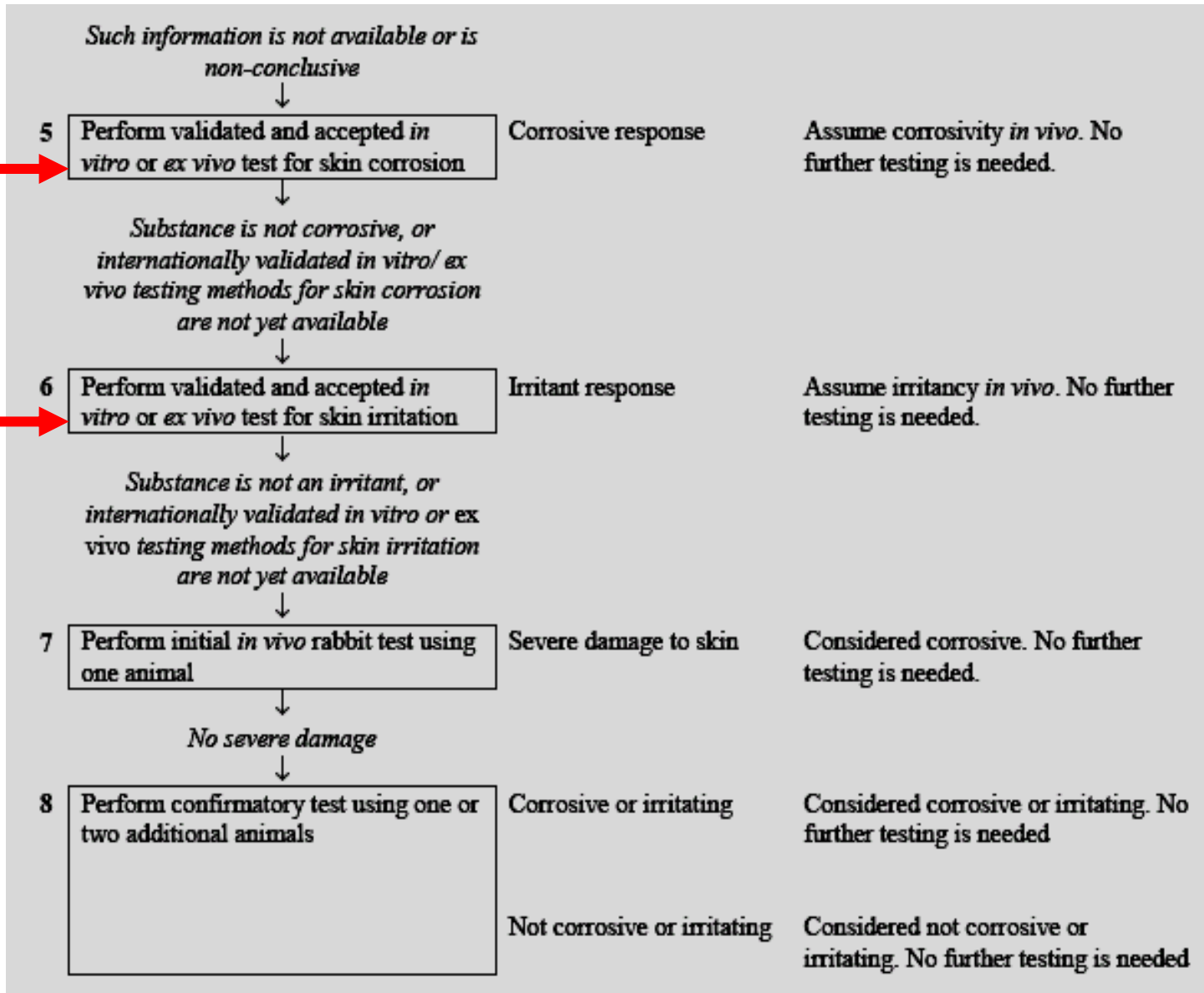
Use of acute dermal tox data



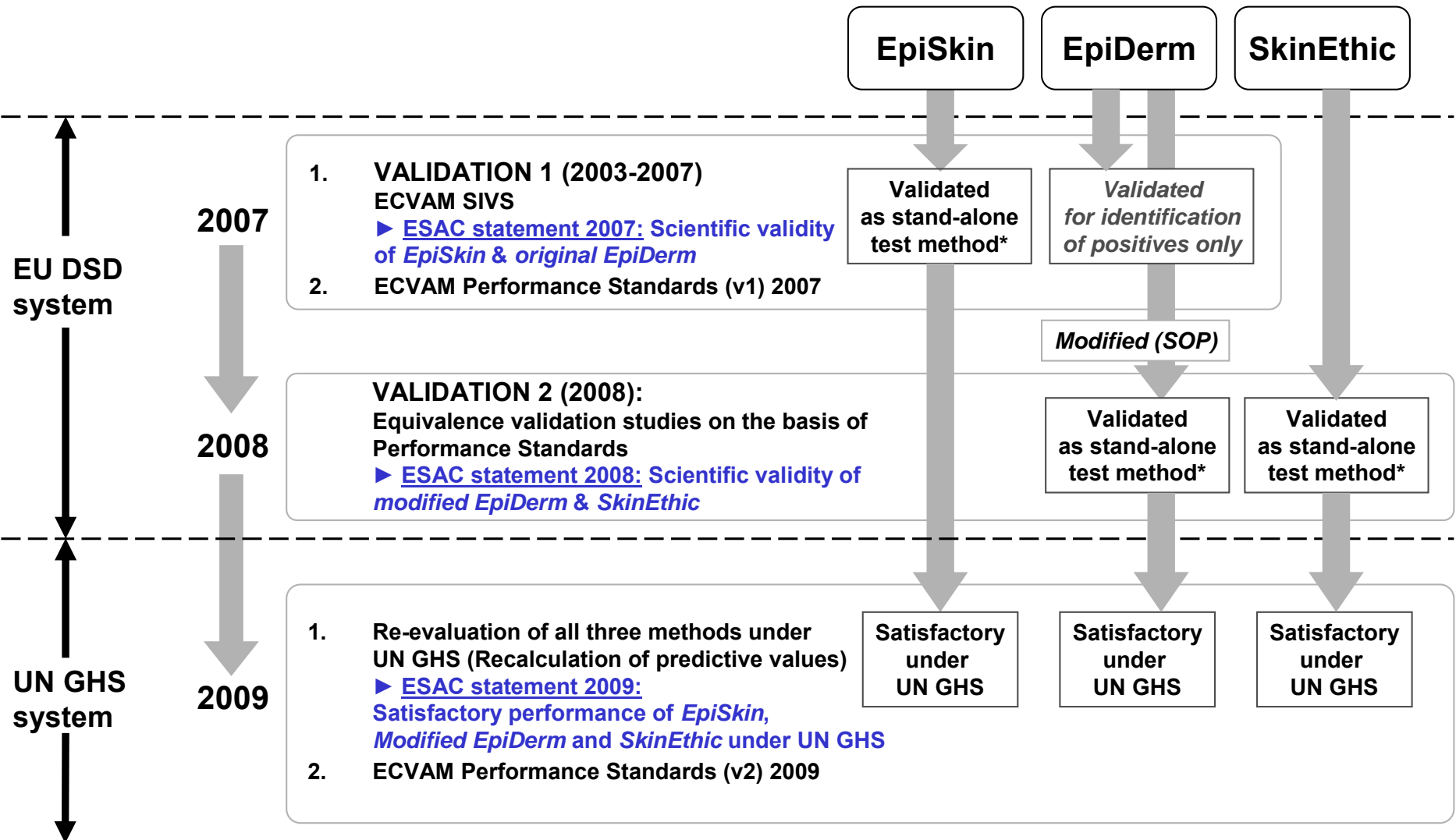
OECD TG 404, Annex: STRATEGY (2)

Accepted
EU B.40
OECD 430
OECD 431
(OECD 435)

Accepted
in EU only
EU B.46
...not yet
by OECD



Trust & consensus building: Review Documents



Summary

The OECD has policies, but no opinion

The “opinion” of the OECD is always the consensus reached among the 30 Member Countries

Consequently, the OECD is 100% open to the change of paradigm associated with the vision of Tox-21

...you just need 29 more to convince



An OECD policy that supports this vision, is the general OECD commitment to reduce the need of animals wherever possible

An OECD policy that may become a problem, is the requirement of non proprietary OECD methods available for everyone and everywhere

THANKS FOR YOUR ATTENTION!