WORKSHOP DICLA
BOAS PRÁTICAS DE LABORATÓRIO

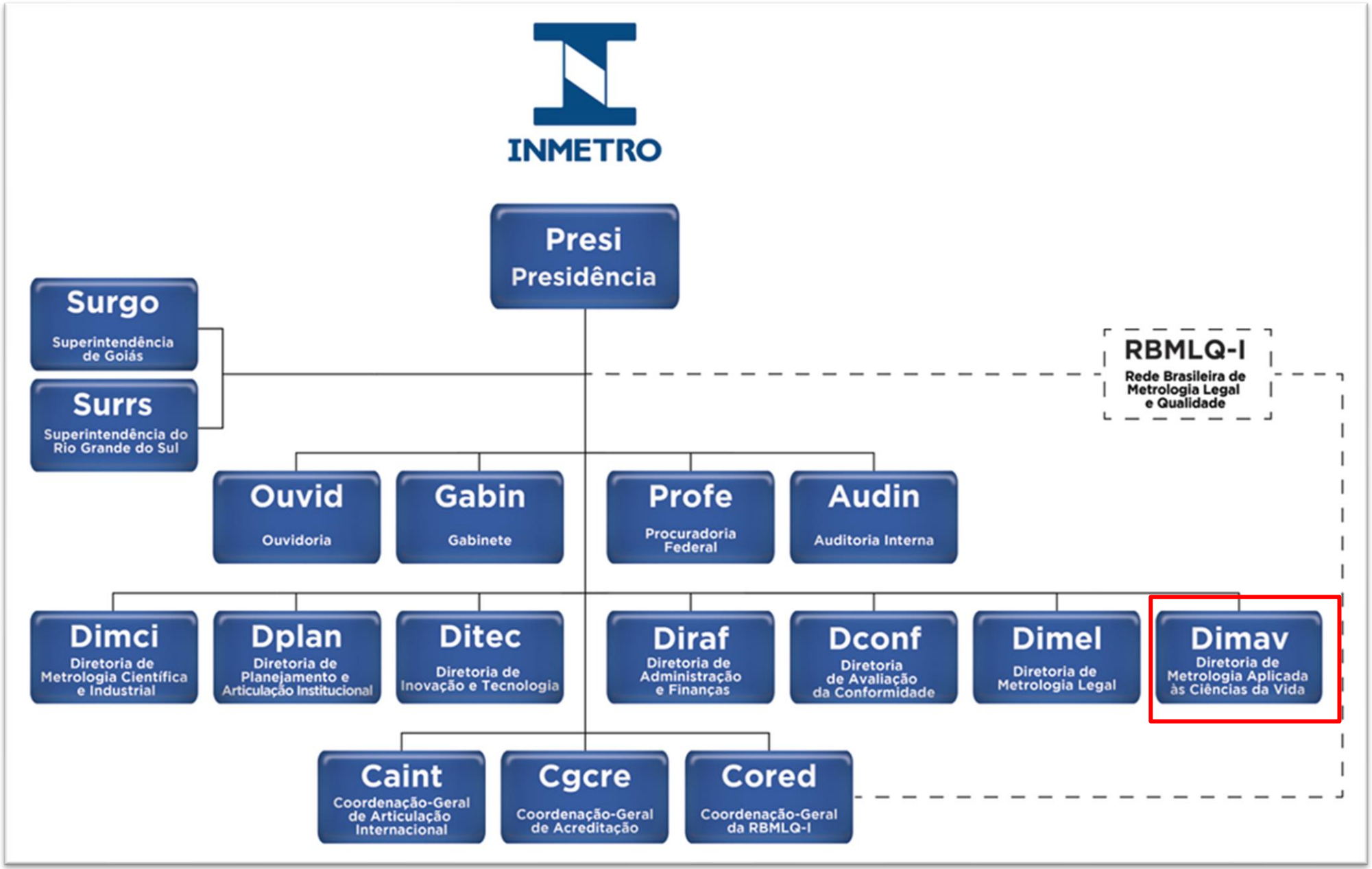
11 e 12 de abril de 2022

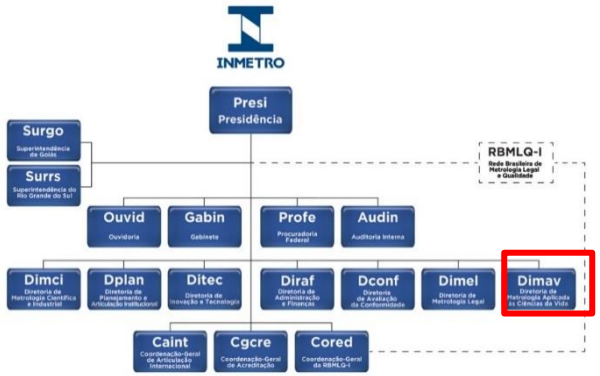
INMETRO

DIRETRIZES DE TESTE APROVADAS E EM DESENVOLVIMENTO NA OCDE

Luciene Bottentuit López Balottin, Ph.D.
Pesquisadora em Metrologia e Qualidade

LABIO/DIMAV/INMETRO


INMETRO
Presi
Presidência
Surgo
Superintendência de Goiás
Surrs
Superintendência do Rio Grande do Sul
RBMLQ-I
Rede Brasileira de Metrologia Legal e Qualidade
Ouvid
Ouvidoria
Gabin
Gabinete
Profe
Procuradoria Federal
Audin
Auditoria Interna
Dimci
Diretoria de Metrologia Científica e Industrial
Dplan
Diretoria de Planejamento e Articulação Institucional
Ditec
Diretoria de Inovação e Tecnologia
Diraf
Diretoria de Administração e Finanças
Dconf
Diretoria de Avaliação da Conformidade
Dimel
Diretoria de Metrologia Legal
Dimav
Diretoria de Metrologia Aplicada às Ciências da Vida
Caint
Coordenação-Geral de Articulação Internacional
Cgcre
Coordenação-Geral de Acreditação
Cored
Coordenação-Geral da RBMLQ-I



Metrologia Aplicada Às Ciências da Vida (DIMAV)

Laboratórios

- Macromoléculas
- Química biológica
- Microscopia Aplicada às Ciências da Vida
- Microbiologia
- Bioengenharia Tecidual

PReMASEL

RENAMA
Rede Nacional de Métodos Alternativos

Implementação e disseminação de métodos alternativos para fins de registro / superação de barreiras não tarifárias (OECD-WNT)

A **Organização para a Cooperação e Desenvolvimento Econômico** (**OCDE**) é uma organização internacional que trabalha para construir melhores políticas para uma vida melhor.

SISTEMA DE ACEITAÇÃO MÚTUA DE DADOS (MAD)

[OECD/LEGAL/0194] A "Council Decision on the Mutual Acceptance of Data in the Assessment of Chemicals" de 1981

[OECD/LEGAL/0252] A "Council Decision-Recommendation on Compliance with Principles of Good Laboratory Practices" de 1989 que estabelece procedimentos para monitorar a conformidade aos princípios de BPL por meio de inspeções e auditorias de estudo, bem como um *framework* de ligação internacional entre as autoridades governamentais de monitoramento e recebimento de dados.

[OECD/LEGAL/0194] revisão1997 [C(97)114/Final] Decisão do Conselho sobre a **adesão dos países não-membros aos Atos do Conselho relacionados à Aceitação Mútua de Dados** na Avaliação de Produtos Químicos que estabelece um procedimento para que as economias não-OCDE participem como membros plenos deste sistema.

SISTEMA DE ACEITAÇÃO MÚTUA DE DADOS (MAD)

BOAS PRÁTICAS LABORATORIAIS

Os Princípios de Boas Práticas Laboratoriais são um sistema de qualidade que abrange o processo organizacional e as condições sob as quais **estudos não-clínicos** de segurança à saúde humana e ao meio ambiente são planejados, desenvolvidos, monitorados, registrados, arquivados e relatados.

DIRETRIZES DE TESTE DA OCDE

As Diretrizes da OCDE para o teste de produtos químicos são **uma coleção de metodologias de teste, internacionalmente acordado, usados por governos, indústria e laboratórios independentes para avaliar a segurança dos produtos químicos.** Eles são usados principalmente em testes de segurança para fins regulatórios, de notificação e de registro.

SISTEMA DE ACEITAÇÃO MÚTUA DE DADOS (MAD)

CRITÉRIOS

O estudo deve ter sido realizado de acordo com as **Diretrizes de Testes da OCDE e os Princípios de BPL da OCDE**

O estudo deve ter sido realizado em uma **instalação de teste que tenha sido inspecionada por um programa nacional de monitoramento de conformidade às BPLs**

O programa nacional de monitoramento de conformidade às BPLs deve ter sido submetido a uma **avaliação bem-sucedida da OCDE**

Se todos os três critérios forem atendidos, todos os países membros da OCDE, bem como os *full adherents* da MAD, devem aceitar os dados do estudo.

SISTEMA DE ACEITAÇÃO MÚTUA DE DADOS (MAD)

ESCOPO

Estudos não-clínicos de segurança à saúde humana e ao meio ambiente (**TG OECD XXX**)

QUÍMICOS INDUSTRIAIS
PRODUTOS FARMACÊUTICOS
PESTICIDAS
BIOCIDAS
PRODUTOS MÉDICOS VETERINÁRIOS
ADITIVOS DE ALIMENTAÇÃO

ESCOPO BRASILEIRO BPL:
Produtos Químicos Industriais
Produtos farmacêuticos
Produtos Médicos Veterinários
Pesticidas
Aditivos de alimentação
Cosméticos e higiene pessoal
Biocidas
Outros produtos:
- Saneantes
- Corretivo para tratamentos de efluentes e ecossistemas naturais
- Conservante de Madeiras

SISTEMA DE ACEITAÇÃO MÚTUA DE DADOS (MAD)

O mercado global de testes em animais US$ 10,74 bilhões em 2019 e de testes alternativos não animais foi avaliado em US$ 1,11 bilhão em 2019. Espera-se que este mercado cresça a um TCAC de 10,40% durante 2019-2025 e com um TCAC de 11,62% durante 2025-2035

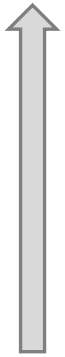
ESTRUTURA: **Conselho (embaixadores dos países membros)**
Comitês e Grupos de Trabalho
Secretariado

SISTEMA MAD

The Chemicals and Biotechnology Committee (CBC)

Working Party of National Co-ordinators of the **Test Method Guidelines Programme**
Working Party on Good Laboratory Practice

Working Party on Hazard Assessment
Working Party on Exposure Assessment
Working Party on Risk Management
Working Party on Manufactured Nanomaterials
Working Party on Pesticides
Working Party on Biocides



Working Party on Chemical Accidents
Working Party on Pollutant Release and Transfer Registers
Working Party on the Harmonisation of Regulatory Oversight in Biotechnology
Working Party on the Safety of Novel Foods and Feeds.

TEST METHOD GUIDELINE PROGRAMME

Section 1: Physical Chemical Properties

Section 2: Effects on Biotic Systems

Section 3: Environmental Fate and Behaviour

Section 4: Health Effects

Section 5: Other Test Guidelines

RISCO = PERIGO X EXPOSIÇÃO

- Project proposals (SPSF)

TEST METHOD GUIDELINE PROGRAMME

STANDARD PROJECT SUBMISSION FORM (SPSF)

OECD TEST GUIDELINES PROGRAMME

Standard Project Submission Form

If you require further information please contact the OECD Secretariat
Return completed forms to:
Anne Gourmelon (anne.gourmelon@oecd.org)
and Anna Rourke (anna.rourke@oecd.org)

PROJECT TITLE

SUBMITTED BY (Country / European Commission / Secretariat)

DATE OF SUBMISSION TO THE SECRETARIAT

DETAILS OF LEAD COUNTRY/CONSORTIUM

Country /Organisation:	
Agency/ministry/Other:	
Mail Address:	
Phone/fax:	
Email:	

PROJECT OUTCOMES

- ☐ New Test Guideline
- ☐ Revised Test Guideline
- ☐ Deletion of an existing Test Guideline
- ☐ Guidance document
- ☐ Detailed Review Paper
- ☐ Other, please specify below

MAIN OBJECTIVE OF THE PROPOSAL (max. 150 words)

PROPOSED WORK PLAN and RESOURCE NEEDS:

1. Draft workplan for development of the proposal, including any need to establish Ad Hoc Expert Group and mode of meetings (face-to-face, teleconference, electronic discussion group). Indicate key milestones, including first and subsequent drafts of documents and timing of meetings.

2. Will additional information, including generation or collection of data, be required? If yes, please describe the anticipated process and timelines.

3. Indicate the estimated overall resource need (time/money) for member country / consortium and Secretariat

4. Is this proposal intended to replace an existing Test Guideline or lead to the deletion of an existing Test Guideline?

ESSENTIAL INFORMATION

In this section, please provide the information required by the Working Group of National Coordinators of the Test Guidelines Programme to assess the suitability of the project for the workplan of the Test Guidelines Programme

1. What is the existing or expected regulatory need/data requirement that will be met by the proposed outcome of the project? Please provide details below or as an attachment.

or as attachment No.__

2. How will the work contribute to further international harmonisation of hazard and risk assessment? Please provide details below or as an attachment.

or as attachment No.__

3. How will the proposed project address issues and /or endpoints which are of major human health or environmental concerns? If there are existing Test Guidelines or projects in the work plan of the Test Guidelines Programme covering the same endpoint, please refer to these and describe the added value and usability of the proposed new test method. Please provide details below or as an attachment.

or as attachment No.__

4. Will the project have general support from OECD member countries or is the outcome relevant for just one or a few member countries / stakeholders? Provide details of the countries and the rationale for this view below.

☐ Many countries ☐ A few countries ☐ Only for the submitting country

5. If the Test Guideline is not intended for general use, indicate if the Test Guideline would be intended for:

- ☐ Specific (limited) applications such as pesticide usage, or
- ☐ for specific classes of chemicals (e.g. surfactants) rather than for chemicals in general.

6. If the expected outcome of this proposal is a Test Guideline or a Guidance Document, provide information on the intended use, applicability and limitations of the test method.

TEST METHOD GUIDELINE PROGRAMME

STANDARD PROJECT SUBMISSION FORM

7. Provide supporting information on the validation status (i.e. relevance and reliability) of the method. Principles for validation of test methods for OECD Test Guidelines are described in Guidance Document 34.

Provide justification and rationale for the test, including data.

If there are no or limited data available to support the reliability and relevance of the proposed test, indicate if validation work is included in the project.

If there is no need for validation, provide a detailed justification.

8. Describe if the test method includes components, equipment or other scientific procedures that are covered (or pending) by Intellectual Property Rights (IPR) (e.g., patents, patent applications, industrial designs and trademarks). Information should be provided on the overall availability of the IPR-protected components including whether they are commercially available or require a Material Transfer Agreement (MTA) or other licensing agreements. In addition, a description of the IPR-covered component/test system should be disclosed. Note that the OECD has developed Guiding Principles on good practices for the availability/distribution of protected elements in OECD Test Guidelines. The test method developer will be requested to fill in and sign the FRAND Terms Licensing Declaration Form annexed to the Guiding Principles.

8.1 Nature of protected elements (e.g. reagent identity, cell line identity, specific process, etc.):

8.2 Form of protection (e.g. trademark, patent, etc.):

8.3 For users to access protected elements, please tick the relevant box(es):

☐ MTA required ☐ License requirement ☐ No agreement required

If a license or other agreement is foreseen, please note that terms and conditions should comply with FRAND and a signed declaration needs to be submitted if the project gets onto the work plan. See Annex 2 of the OECD Guiding Principles on Good Licensing Practices for Protected Elements in OECD TGs (2019).

8.4 Are you providing the agreement document(s) referred to in 8.3 with the SPSF:

☐ Yes ☐ No If no, what's the reason?

8.5 How and where can users get access to protected elements?

8.6 Has any search for existing patent(s) possibly associated with this test method been performed (e.g. through patent search or Freedom-To-Operate search). If yes, what was the outcome?

8.7 Does the test method include any Confidential Business Information? Y/N N/A

If yes, which ones?

IMPORTANT NOTE: Should the OECD and Expert Group working on the Test Guideline development discover that the information provided under Item 3 on IP elements be erroneous or be evolving in the course of the project, the project itself might be re-considered, suspended or cancelled.

9 Have Performance Standards been developed? ☐ Yes ☐ No ☐ N/A

ADDITIONAL INFORMATION

In this section please provide further information to allow the Working Group of National Coordinators of the Test Guidelines Programme to assess the suitability of the project for the workplan of the Test Guidelines Programme

1. If the expected outcome of the project proposal is a Test Guideline and is based on existing, regional or international documents such as guidelines, protocols or guidance material, please provide that information here or as an attachment.

or as attachment No.__

2. If Animal Welfare considerations are addressed in the project proposal, provide details below or as an attachment. Explain if the project is aimed at refining, reducing and/or replacing the use of animals.

If the project is not specifically developed for animal welfare purposes, indicate if the animal welfare considerations have been a component of the project proposal.

Indicate if animal welfare considerations are irrelevant to the project, for example for physico-chemical properties.

or as attachment No.__

3. Provide information on expected or possible resource savings in member countries as a result of this project.

4. If the expected outcome of the proposed project is a Guidance Document or Detailed Review Paper, will it be directly linked to the development of a particular Test Guideline or a series of Test Guidelines?

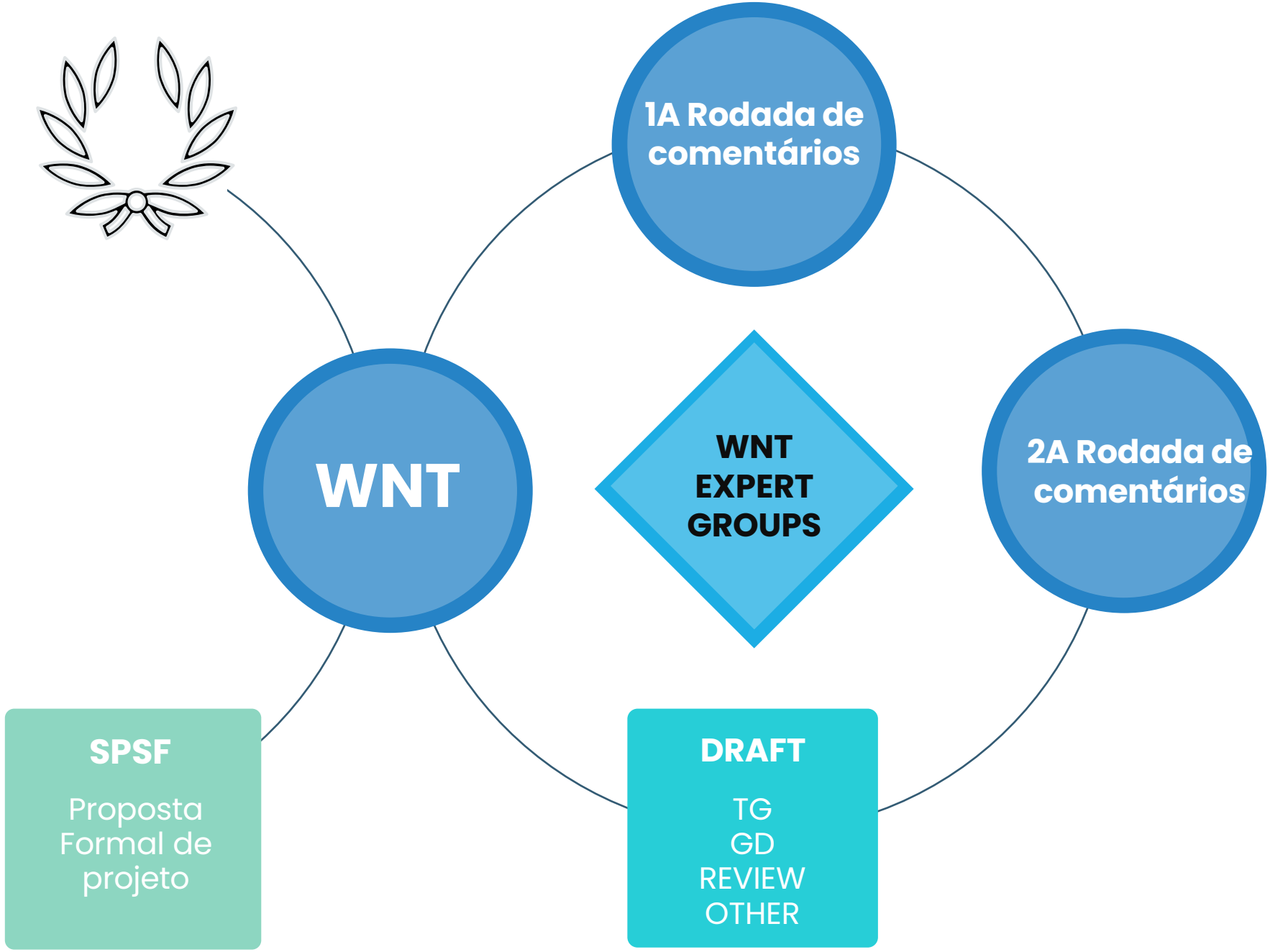
☐ Yes, it is the initial step in the development of a new or revision of existing Guidelines.

☐ Yes, additional guidance is needed for the most appropriate selection of the Guidelines on the subject.

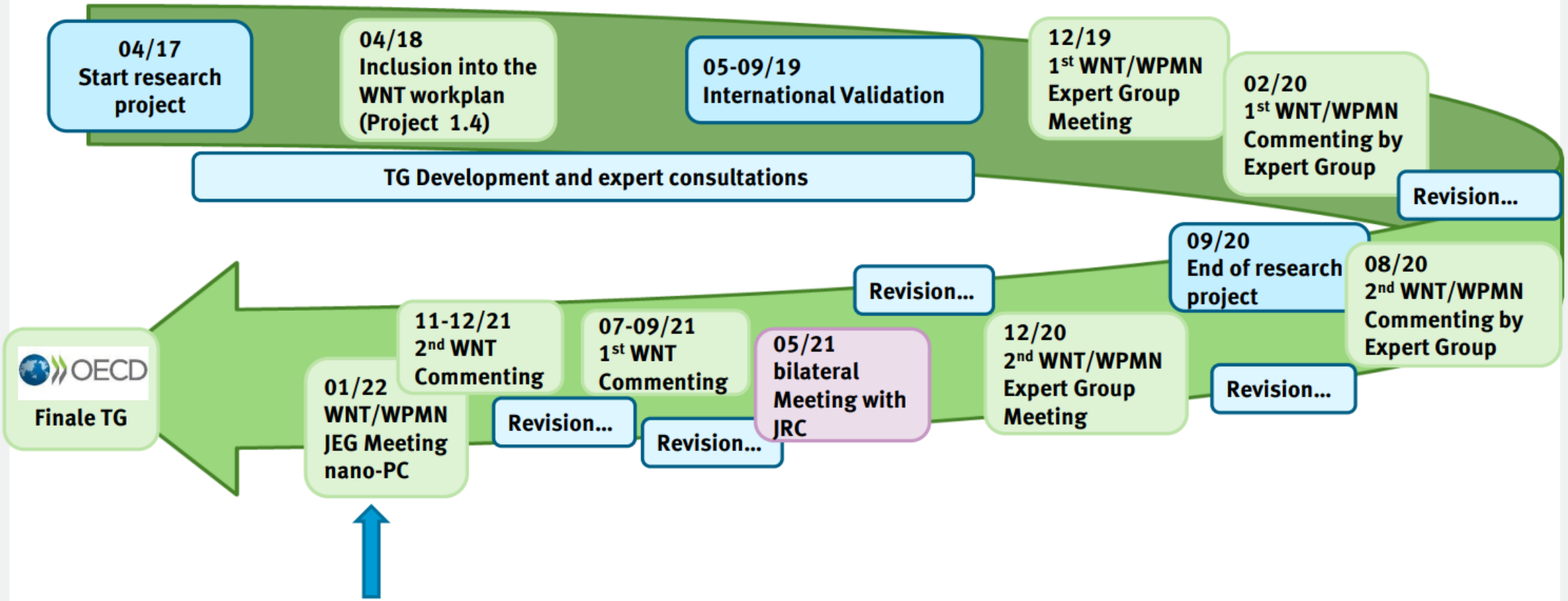
☐ No, the guidance is on issues related to testing or the development of Test Guidelines in general.

There are ___ attachments added to this form.

TEST METHOD GUIDELINE PROGRAMME



Process of the draft TG PSD Development



* WNT: Working Group of the National Coordinators of the Test Guidelines Programme

Nature of tools developed in the TG Programme

Covered my MAD

- Test Guidelines
- Guideline on Defined Approaches
  - Combinations of information sources have been individually evaluated

Other important documents

- Guidance Documents in support of testing and assessment
- Detailed Review Papers in new areas of chemical toxicity testing
- Validation reports
- Peer review reports

Other tools (courtesy of the test developers)

- Excel spreadsheets for raw data collection and calculation sheets
- COTS software

PANORAMA DAS METODOLOGIAS

METODOLOGIAS PUBLICADAS

PROPOSTAS DE PROJETOS

DOCUMENTOS EM VIAS DE APROVAÇÃO

TEST METHOD GUIDELINE PROGRAMME

Section 1: Physical Chemical Properties

Section 2: Effects on Biotic Systems

Section 3: Environmental Fate and Behaviour

Section 4: Health Effects

Section 5: Other Test Guidelines

RISCO = PERIGO X EXPOSIÇÃO

Section 1: Physical Chemical Properties

12/05/1981	Test No. 101: UV-VIS Absorption Spectra
12/05/1981	Test No. 108: Complex Formation Ability in Water
12/05/1981	Test No. 110: Particle Size Distribution/ Fibre Length and Diameter Distributions
27/07/1995	Test No. 102: Melting Point/ Melting Range
27/07/1995	Test No. 103: Boiling Point
27/07/1995	Test No. 105: Water Solubility
27/07/1995	Test No. 107: Partition Coefficient (n-octanol/water): Shake Flask Method
27/07/1995	Test No. 115: Surface Tension of Aqueous Solutions
14/06/1996	Test No. 118: Determination of the Number-Average Molecular Weight and the Molecular Weight Distribution of Polymers using Gel Permeation Chromatography
14/06/1996	Test No. 119: Determination of the Low Molecular Weight Content of a Polymer Using Gel Permeation Chromatography
21/01/2000	Test No. 106: Adsorption -- Desorption Using a Batch Equilibrium Method
21/01/2000	Test No. 120: Solution/Extraction Behaviour of Polymers in Water
22/01/2001	Test No. 121: Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)
23/11/2004	Test No. 111: Hydrolysis as a Function of pH
23/11/2004	Test No. 117: Partition Coefficient (n-octanol/water), HPLC Method
11/07/2006	Test No. 123: Partition Coefficient (1-Octanol/Water): Slow-Stirring Method
11/07/2006	Test No. 104: Vapour Pressure
11/10/2006	Summary of Considerations in the Report from the OECD Expert Group on Physical Chemistry
02/10/2012	Test No. 109: Density of Liquids and Solids
02/10/2012	Test No. 114: Viscosity of Liquids
26/07/2013	Test No. 122: Determination of pH, Acidity and Alkalinity

Section 1: Physical Chemical Properties

SPSF

Project 1.3: TG on Determination of the (Volume) Specific Surface Area of Manufactured Nanomaterials (EU)

Project 1.4: TG on particle size and size distribution of Manufactured Nanomaterials (GER)

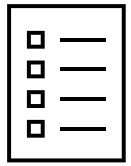
Project 1.5: GD on Determination of solubility and dissolution rate of nanomaterials in water and relevant synthetic biological media (DNK/GER)

Project 1.6: GD on Identification and quantification of the surface chemistry and coatings on nano- and microscale materials (DNK/GER)

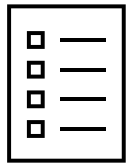
Project 1.7: TG on Determination of Surface Hydrophobicity of Manufactured nanomaterials (EU)

Project 1.8: TG on Determination of the Dustiness of Manufactured Nanomaterials (DNK/ FRA)

Project 1.10 GD on the determination of concentrations of nanoparticles in biological samples for (eco)toxicity studies (United Kingdom)



TG on Determination of the (Volume) Specific Surface Area of Manufactured Nanomaterials



TG on particle size and size distribution of Manufactured Nanomaterials

34ª Reunião do WNT para aprovação!

Section 2: Effects on Biotic Systems

Test No. 204: Fish, Prolonged Toxicity Test: 14-Day Study	04 Apr 1984
Test No. 205: Avian Dietary Toxicity Test	04 Apr 1984
Test No. 206: Avian Reproduction Test	04 Apr 1984
Test No. 207: Earthworm, Acute Toxicity Tests	04 Apr 1984
Test No. 212: Fish, Short-term Toxicity Test on Embryo and Sac-Fry Stages	21 Sep 1998
Test No. 213: Honeybees, Acute Oral Toxicity Test	21 Sep 1998
Test No. 214: Honeybees, Acute Contact Toxicity Test	21 Sep 1998
Test No. 215: Fish, Juvenile Growth Test	21/jan/00
Test No. 216: Soil Microorganisms: Nitrogen Transformation Test	21/jan/00
Test No. 217: Soil Microorganisms: Carbon Transformation Test	21/jan/00
Test No. 202: Daphnia sp. Acute Immobilisation Test	23/nov/04
Test No. 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment	23/nov/04
Test No. 219: Sediment-Water Chironomid Toxicity Using Spiked Water	23/nov/04
Test No. 221: Lemna sp. Growth Inhibition Test	11/jul/06
Test No. 227: Terrestrial Plant Test: Vegetative Vigour Test	17 Aug 2006
Test No. 208: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test	17 Aug 2006
Test No. 224: Determination of the Inhibition of the Activity of Anaerobic Bacteria	25/jan/07
Test No. 225: Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment	15 Oct 2007
Test No. 230: 21-day Fish Assay	08 Sep 2009
Test No. 231: Amphibian Metamorphosis Assay	08 Sep 2009
Test No. 209: Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation)	23/jul/10
Test No. 233: Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment	23/jul/10
Test No. 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test	28/jul/11
Test No. 234: Fish Sexual Development Test	28/jul/11
Test No. 235: Chironomus sp., Acute Immobilisation Test	28/jul/11
Test No. 211: Daphnia magna Reproduction Test	02 Oct 2012
Test No. 229: Fish Short Term Reproduction Assay	02 Oct 2012
Test No. 236: Fish Embryo Acute Toxicity (FET) Test	26/jul/13
Test No. 237: Honey Bee (Apis Mellifera) Larval Toxicity Test, Single Exposure	26/jul/13
Test No. 210: Fish, Early-life Stage Toxicity Test	26/jul/13
Test No. 238: Sediment-Free Myriophyllum Spicatum Toxicity Test	26 Sep 2014
Test No. 239: Water-Sediment Myriophyllum Spicatum Toxicity Test	26 Sep 2014
Test No. 240: Medaka Extended One Generation Reproduction Test (MEOGRT)	28/jul/15
Test No. 241: The Larval Amphibian Growth and Development Assay (LAGDA)	28/jul/15
Test No. 242: Potamopyrgus antipodarum Reproduction Test	29/jul/16
Test No. 243: Lymnaea stagnalis Reproduction Test	29/jul/16
Test No. 220: Enchytraeid Reproduction Test	29/jul/16
Test No. 222: Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)	29/jul/16

Section 2: Effects on Biotic Systems

Test No. 223: Avian Acute Oral Toxicity Test	29/jul/16
Test No. 226: Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil	29/jul/16
Test No. 228: Determination of Developmental Toxicity to Dipteran Dung Flies(Scathophaga stercoraria L. (Scathophagidae), Musca autumnalis De Geer (Muscidae))	29/jul/16
Test No. 232: Collembolan Reproduction Test in Soil	29/jul/16
Test No. 244: Protozoan Activated Sludge Inhibition Test	09 Oct 2017
Test No. 245: Honey Bee (Apis Mellifera L.), Chronic Oral Toxicity Test (10-Day Feeding)	09 Oct 2017
Test No. 246: Bumblebee, Acute Contact Toxicity Test	09 Oct 2017
Test No. 247: Bumblebee, Acute Oral Toxicity Test	09 Oct 2017
Test No. 203: Fish, Acute Toxicity Test	18/jun/19
Test No. 248: Xenopus Eleutheroembryonic Thyroid Assay (XETA)	18/jun/19
Test No. **250**: EASZY assay - Detection of Endocrine Active Substances, acting through estrogen receptors, using transgenic tg(cyp19a1b:GFP) Zebrafish embryos	17/jun/21
Test No. **249**: Fish Cell Line Acute Toxicity - The RTgill-W1 cell line assay	18/jun/21

Section 2: Effects on Biotic Systems

SPSF

2.47	New TG on Determination of Effects of Earthworms in Field Studies	**GER**
2.51	Guidance Document on Aquatic (and Sediment) Toxicity Testing of Nanomaterials	**CA, US**
2.54	Guidance Document on IATA for fish acute toxicity	**AT**
2.55	Use and analysis of control fish in toxicity studies	**EC**
2.57	Guidance Document on Juvenile medaka anti-androgen screening assay	**JP**
2.58	Short-term Juvenile Hormone Activity Screening Assay using Daphnia magna	**JP**
2.59	Zebrafish Extended One Generation Reproduction Test (ZEOGRT)	**GER**
2.60	Test Guideline: Homing flight test on honeybee (Apis mellifera L.) after single exposure to sublethal doses	**FR**
2.61	**New TG RADAR assay – Rapid Androgen Disruption Animal Replacement assay**	**UK/FR**
2.62	Growth Inhibition Test for the Rooted, Emergent Aquatic Macrophyte, Glyceria maxima	**NL/UK**
2.64	Inclusion of thyroid endpoints in OECD fish tests	**DK**
2.65	Acute Contact Toxicity Test for the solitary living Mason Bee (Osmia spp.)	**CH**
2.66	REACTIV (Rapid Estrogen Activity In Vitro) Assay	**FR/UK/JP**
2.67	**Revision of Freshwater Alga and Cyanobacteria, Growth Inhibition Test (TG201) relating to algal strain New**	**JP**

TG for the Rapid Androgen Disruption Activity Report (RADAR) assay

34ª Reunião do WNT para aprovação!

Section 3: Environmental Fate and Behaviour

Test No. 301: Ready Biodegradability	17/jul/92
Test No. 302A: Inherent Biodegradability: Modified SCAS Test	12 May 1981
Test No. 302B: Inherent Biodegradability: Zahn-Wellens/ EVPA Test	17/jul/92
Test No. 302C: Inherent Biodegradability: Modified MITI Test (II)	08 Sep 2009
Test No. 303: Simulation Test - Aerobic Sewage Treatment -- A: Activated Sludge Units; B: Biofilms	22/jan/01
Test No. 304A: Inherent Biodegradability in Soil	12 May 1981
Test No. 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure	02 Oct 2012
Test No. 306: Biodegradability in Seawater	07/jul/92
Test No. 307: Aerobic and Anaerobic Transformation in Soil	24 Apr 2002
Test No. 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems	24 Apr 2002
Test No. 309: Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test	23/nov/04
Test No. 310: Ready Biodegradability - CO2 in sealed vessels (Headspace Test)	26 Sep 2014
Test No. 311: Anaerobic Biodegradability of Organic Compounds in Digested Sludge: by Measurement of Gas Production	11/jul/06
Test No. 312: Leaching in Soil Columns	23/nov/04
Test No. 313: Estimation of Emissions from Preservative - Treated Wood to the Environment	15 Oct 2007
Test No. 314: Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater	16 Oct 2008
Test No. 315: Bioaccumulation in Sediment-dwelling Benthic Oligochaetes	16 Oct 2008
Test No. 316: Phototransformation of Chemicals in Water – Direct Photolysis	16 Oct 2008
Test No. 317: Bioaccumulation in Terrestrial Oligochaetes	23/jul/10
Test No. 318: Dispersion Stability of Nanomaterials in Simulated Environmental Media	09 Oct 2017
Test No. 319A: Determination of in vitro intrinsic clearance using cryopreserved rainbow trout hepatocytes (RT-HEP)	07/jun/18
Test No. 319B: Determination of in vitro intrinsic clearance using rainbow trout liver S9 sub-cellular fraction (RT-S9)	27/jun/18

Section 3: Environmental Fate and Behaviour

SPSF

3.8	New TG on Agglomeration behaviour of nanomaterials in different aquatic media	GER
3.9	Decision - Tree for Dispersion and Dissolution Behaviour of Nanomaterials in Aquatic Media	GER
3.10	New TG on Dissolution Rate of Nanomaterials in Aquatic Environement	US
3.11	New TG for Nanomaterial Removal from Wastewater	US
3.12	New GD on Assessing the Apparent Accummulation Potential for Nanomaterials	UK, FI, SP
3.14	Guidance Document supporting OECD TG 312 (soil leaching) for the testing of nanomaterials	GER
3.15	New Test Guideline to determine the uptake of chemicals by plant roots	GER
3.16	Environmental abiotic transformation of nanomaterials	AT
3.17	Hyalella azteca Bioconcentration Test (HYBIT)	FR/GER
3.18	**Anaerobic Transformation of Chemicals in Liquid Manure**	Ger
3.19	**A new Test Guideline for a marine biodegradation screening test for chemical persistence assessment (MaP test) New**	UK

TG to determine Anaerobic Transformation of Chemicals in Liquid Manure

34ª Reunião do WNT para aprovação!

OECD
BETTER POLICIES FOR BETTER LIVES

Section 4: Healtl
Effects

New York Times on 15 April 1980,

ANIMAL MODELS

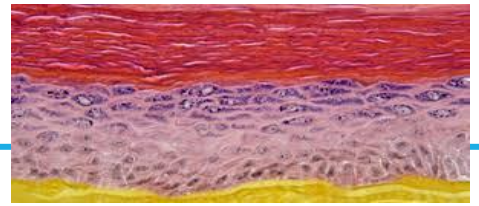
LD50

3R PRINCIPLES

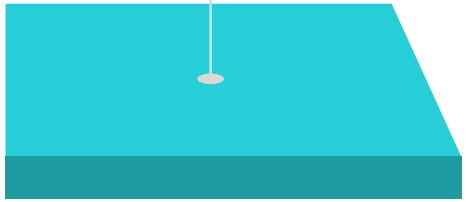
REFINAMENT

REDUCTION

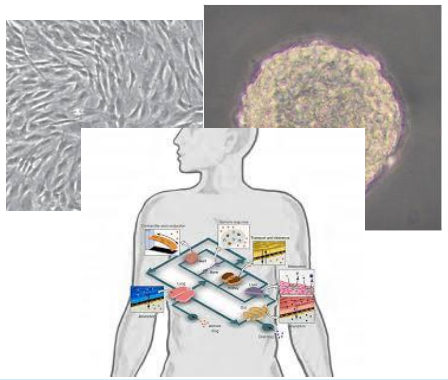
REPLACEMENT



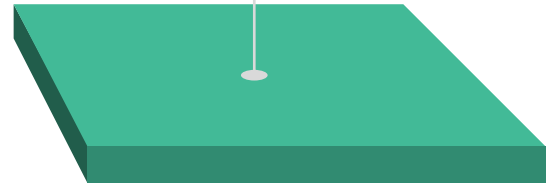
MECANISTIC (Adverse Outcome Pathways)



HUMAN RELEVANT MODELS, IN SILICO, IN VITRO TOOLS



ANY NON-ANIMAL-BASED APPROACHES

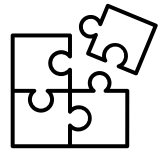


NEW APPROACH METHODS

IATA,

defined approaches

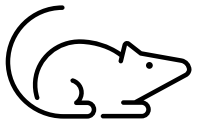
for data interpretation, and performance-based evaluation of test methods.



Animal free

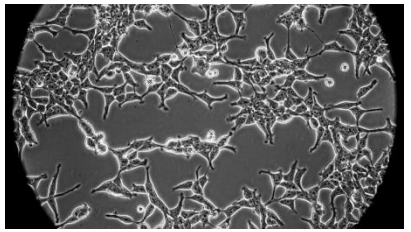
Complexity

Section 4: Health Effects

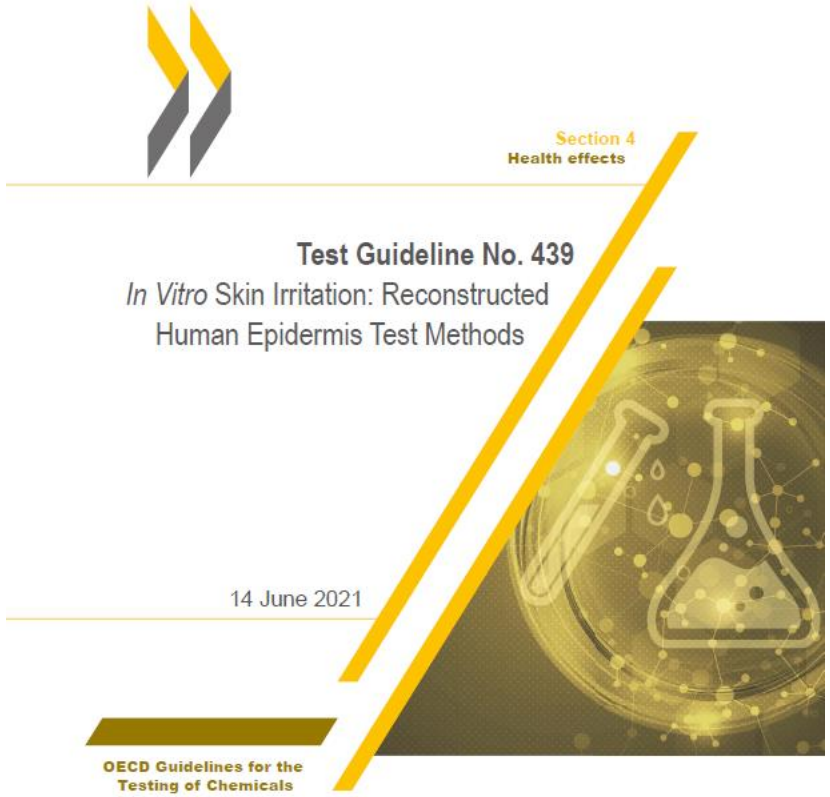


- Test No. 401: Acute Oral Toxicity
- Test No. 402: Acute Dermal Toxicity
- Test No. 403: Acute Inhalation Toxicity
- Test No. 404: Acute Dermal Irritation/Corrosion
- Test No. 405: Acute Eye Irritation/Corrosion
- Test No. 406: Skin Sensitisation
- Test No. 407: Repeated Dose 28-day Oral Toxicity Study in Rodents
- Test No. 408: Repeated Dose 90-Day Oral Toxicity Study in Rodents
- Test No. 409: Repeated Dose 90-Day Oral Toxicity Study in Non-Rodents
- Test No. 410: Repeated Dose Dermal Toxicity: 21/28-day Study
- Test No. 411: Subchronic Dermal Toxicity: 90-day Study
- Test No. 412: Subacute Inhalation Toxicity: 28-Day Study
- Test No. 413: Subchronic Inhalation Toxicity: 90-day Study
- Test No. 414: Prenatal Developmental Toxicity Study
- Test No. 415: One-Generation Reproduction Toxicity Study
- Test No. 416: Two-Generation Reproduction Toxicity
- Test No. 417: Toxicokinetics
- Test No. 418: Delayed Neurotoxicity of Organophosphorus Substances Following Acute Exposure
- Test No. 419: Delayed Neurotoxicity of Organophosphorus Substances: 28-day Repeated Dose Study
- Test No. 420: Acute Oral Toxicity - Fixed Dose Procedure
- Test No. 421: Reproduction/Developmental Toxicity Screening Test
- Test No. 422: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test
- Test No. 423: Acute Oral toxicity - Acute Toxic Class Method
- Test No. 424: Neurotoxicity Study in Rodents
- Test No. 425: Acute Oral Toxicity: Up-and-Down Procedure
- Test No. 426: Developmental Neurotoxicity Study
- Test No. 427: Skin Absorption: In Vivo Method
- Test No. 429: Skin Sensitisation
- Test No. 433: Acute Inhalation Toxicity: Fixed Concentration Procedure
- Test No. 436: Acute Inhalation Toxicity – Acute Toxic Class Method
- Test No. 440: Uterotrophic Bioassay in Rodents
- Test No. 441: Hershberger Bioassay in Rats
- Test No. 442A: Skin Sensitization
- Test No. 442B: Skin Sensitization
- Test No. 443: Extended One-Generation Reproductive Toxicity Study
- Test No. 451: Carcinogenicity Studies
- Test No. 452: Chronic Toxicity Studies
- Test No. 453: Combined Chronic Toxicity/Carcinogenicity Studies
- Test No. 471: Bacterial Reverse Mutation Test
- Test No. 474: Mammalian Erythrocyte Micronucleus Test
- Test No. 475: Mammalian Bone Marrow Chromosomal Aberration Test
- Test No. 477: Genetic Toxicology: Sex-Linked Recessive Lethal Test in Drosophila melanogaster
- Test No. 478: Rodent Dominant Lethal Test
- Test No. 480: Genetic Toxicology: Saccharomyces cerevisiae, Gene Mutation Assay
- Test No. 481: Genetic Toxicology: Saacharomyces cerevisiae, Miotic Recombination Assay
- Test No. 483: Mammalian Spermatogonial Chromosomal Aberration Test
- Test No. 484: Genetic Toxicology: Mouse Spot Test
- Test No. 485: Genetic toxicology, Mouse Heritable Translocation Assay
- Test No. 488: Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays
- Test No. 489: In Vivo Mammalian Alkaline Comet Assay

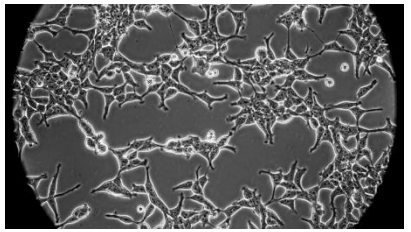
Section 4: Health Effects



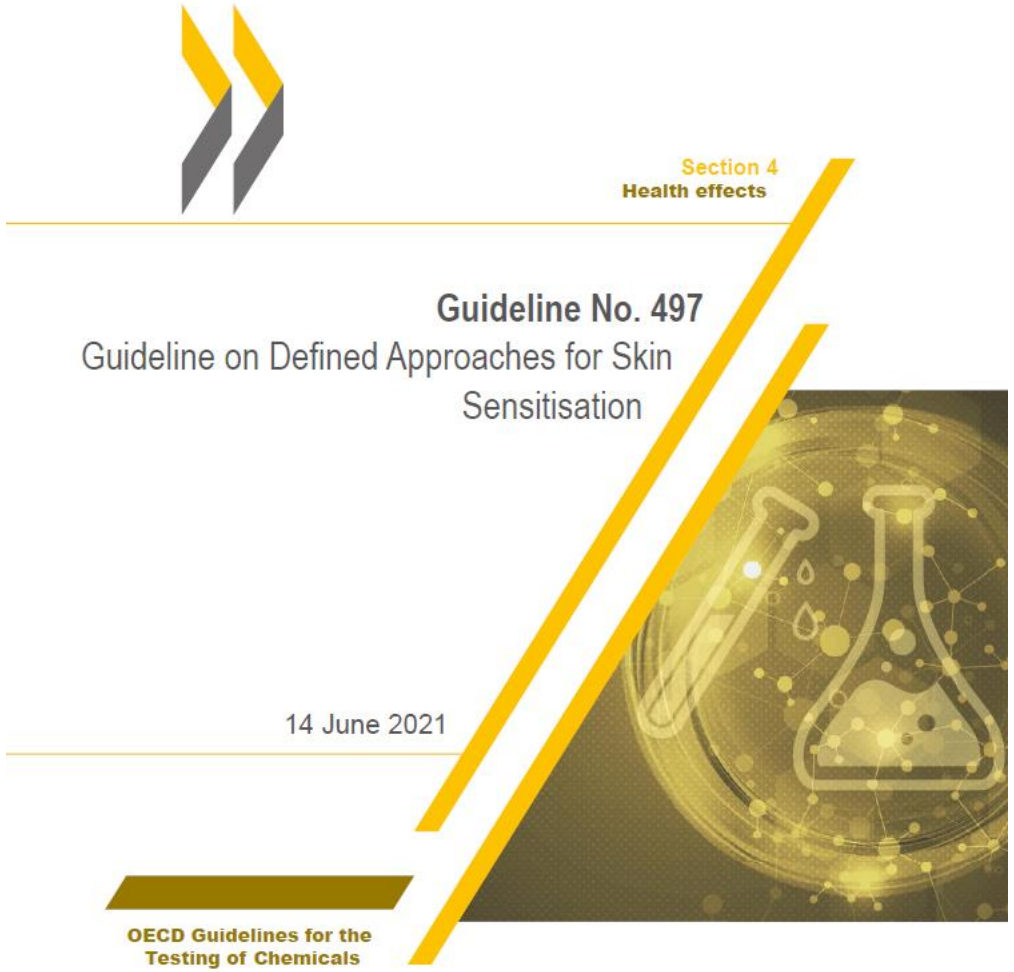
- Test No. 428: Skin Absorption: In Vitro Method
- Test No. 430: In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test Method (TER)
- Test No. 431: In vitro skin corrosion: reconstructed human epidermis (RHE) test method
- Test No. 432: In Vitro 3T3 NRU Phototoxicity Test
- Test No. 435: In Vitro Membrane Barrier Test Method for Skin Corrosion
- Test No. 437: Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage
- Test No. 438: Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage
- Test No. 439: In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method
- Test No. 442C: In Chemico Skin Sensitisation
- Test No. 442D: In Vitro Skin Sensitisation
- Test No. 442E: In Vitro Skin Sensitisation
- Test No. 455: Performance-Based Test Guideline for Stably Transfected Transactivation In Vitro Assays to Detect Estrogen Receptor Agonists and Antagonists
- Test No. 456: H295R Steroidogenesis Assay
- Test No. 457: BG1Luc Estrogen Receptor Transactivation Test Method for Identifying Estrogen Receptor Agonists and Antagonists
- Test No. 458: Stably Transfected Human Androgen Receptor Transcriptional Activation Assay for Detection of Androgenic Agonist and Antagonist Activity of Chemicals
- Test No. 460: Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants



Section 4: Health Effects



- Test No. 473: In Vitro Mammalian Chromosomal Aberration Test
- Test No. 476: In Vitro Mammalian Cell Gene Mutation Tests using the Hprt and xprt genes
- Test No. 479: Genetic Toxicology: In vitro Sister Chromatid Exchange Assay in Mammalian Cells
- Test No. 486: Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells in vivo
- Test No. 487: In Vitro Mammalian Cell Micronucleus Test
- Test No. 490: In Vitro Mammalian Cell Gene Mutation Tests Using the Thymidine Kinase Gene
- Test No. 491: Short Time Exposure In Vitro Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage
- Test No. 492: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage
- Test No. 493: Performance-Based Test Guideline for Human Recombinant Estrogen Receptor (hrER) In Vitro Assays to Detect Chemicals with ER Binding Affinity
- Test No. 494: Vitrigel-Eye Irritancy Test Method for Identifying Chemicals Not Requiring Classification and Labelling for Eye Irritation or Serious Eye Damage
- Test No. 495: Ros (Reactive Oxygen Species) Assay for Photoreactivity
- Test No. 496: In vitro Macromolecular Test Method for Identifying Chemicals Inducing Serious Eye Damage and Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage
- Guideline No. 497: Defined Approaches on Skin Sensitisation
- Test No. 498: In vitro Phototoxicity - Reconstructed Human Epidermis Phototoxicity test method



Section 4: Health Effects

SPSF

>30 projetos: maioria sobre metodologias livre de animais para irritação cutânea e ocular, sensibilização dérmica, genotoxicidade, neurotoxicidade embrionária, imunotoxicidade e identificação e desreguladores endócrinos.

4.73	New TG: Performance-Based Test Guideline on AR Transactivation Assays	EC
4.76	Performance-Based Test Guideline for the Establishment on Human-derived hepatic system to investigate biotransformation and toxicity of compounds by evaluation of CYP450 induction comptence	EC
4.77	Feasibility Study for a Guidance Document on Study Designs to be used in revision of TGs	NL
4.78	**Updated TG 488, Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays**	CAN
4.93	**Developing a new Test Guideline for the Pig-a Assay an in vivo Gene Mutation Assay that Promotes the 3R principles**	US
4.94	Two stage IATA for non-genotoxic carcinogens project: 1. Thought starter ; 2. Development of na IATA for non-genotoxic carcinogens	UK
4.95	Guidance Document on the Adaptation of In Vitro Mammalian Cell Based Genotoxicity TGs for Testing of Manufactured Nanomaterials	EC
4.97	Detailed Review Paper on the Retinoid System	SE
4.98	Development of a set of reference chemicals for testing in vitro metabolism systems in Estrogen-Androgen-Steroidogenesis assays	UK
4.99	Androgen-Receptor Transactivation assay for the detection of compounds with (anti)androgenic potential using 22Rv1/MMTV cells	KO
4.106	**Genomic Assay Rapid Detection test for skin (GARDskin) test: An in vitro method for identification of skin sensitizers based on a genomic interpretation of the impact of chemicals on human dendritic cell-like cells (AOP key event 3)**	SE

34ª Reunião do WNT para aprovação!

Section 4: Health Effects

SPSF

>30 projetos: maioria sobre metodologias livre de animais para irritação cutânea e ocular, sensibilização dérmica, genotoxicidade, neurotoxicidade embrionária, imunotoxicidade e identificação e desreguladores endócrinos.

4.107	**Toxicogenomic analysis on 3D reconstituted epidermis** for measuring skin sensitization potency–the SENS-IS assay	FR
4.109	Miniaturized Ames Microplate Fluctuation Assay (Ames MFA) in a liquid format	BE/NL/US
4.114	Update of TG 437 for inclusion of laser light-based opacitometer (LLBO)	BE
4.115	**Update of Guidance Document 28, Guidance Notes 156 and possibly TG 428 on skin absorption**	EFSA
4.116	Performance-Based Test Guideline on **Defined Approach(es)** for skin sensitisation	EC/US/CAN
4.118	Update of TG 442E on in vitro skin sensitisation ARE- Nrf2 luceriferase for use of animal-free serum	UK
4.119	Update of TG 455 with introduction of a metabolic step in the ERalpha CALUX transactivation bioassay for ER	NL
4.120	Update of TG 458 with introduction of a metabolic step in the AR CALUX transactivation bioassay for (ant-)agonist of AR	NL

34ª Reunião do WNT para aprovação!

Section 4: Health Effects

SPSF

>30 projetos: maioria sobre metodologias livre de animais para irritação cutânea e ocular, sensibilização dérmica, genotoxicidade, neurotoxicidade embrionária, imunotoxicidade e identificação e desreguladores endócrinos.

4.123	Review and feasibility of an Embryonnic Stem Cell Test: in vitro assay detecting disruption to differentiation of rodent embryonnic stem cells into cardiomyocytes using the Hand1 gene	JP
4.124	New Guidance Document on Developmental Neurotoxicity (DNT) in vitro assays	EFSA/EC/ US/DEN
4.125	Detailed Review Paper on ToxTracker assay: a stem-cell-based reporter assay for mechanistic carcinogenicity hazard assessment	NL
4.132	A feasibility study for establishing TGs for in vitro human hepatic metabolic clearance and metabolite formation	NL
4.133	Applicability of the key event based Test Guideline 442D for in vitro skin sensitisation testing of nanomaterials	CH
4.134	**Detailed Review Paper on application and interpretation of in vitro immune-toxicity assays and definition of a tiered approach to testing and assessment**	JP
4.135	Revision of the TG 491 Applicability Domain for the Short Time Exposure Test Method for Ocular Toxicity Predictions	JP
4.136	**Two Defined Approaches for Ocular Toxicity Predictions Based on in vitro Bottom-Up Approach Combined with Physico-Chemical Properties**	FR
4.137	The kinetic Direct Peptide Reactivity Assay (kDPRA): An in chemico Method to characterize the Skin Sensitisation Potency of Chemicals	CH/GER
4.138	**In Vitro Phototoxicity Test Using the Reconstructed Human Epidermis (RhE) for Identifying Phototoxic Chemicals Upon Exposure to Skin- PERFORMANCE STANDARDS**	US
4.139	In vitro genotoxicity test for dermal exposure using 3D models	FR/GER

34ª Reunião do WNT para aprovação!

Section 4: Health Effects

SPSF

>30 projetos: maioria sobre metodologias livre de animais para irritação cutânea e ocular, sensibilização dérmica, genotoxicidade, neurotoxicidade embrionária, imunotoxicidade e identificação e desreguladores endócrinos.

4.140	Inclusion of the **LbL-3D Skin model** skin irritation test to OECD test guideline 439 validated reference method	JP
4.141	**Revision of Appendix II in Test Guideline 442C: Amino acid Derivative Reactivity Assay (ADRA) for predicting sensitization potential**	JP
4.142	Revision of OECD TG 439 to include a new me-too reconstructed human epidermis test method – KeraSkin™ skin irritation test	KO
4.143	**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 Test Guideline 492.**	FR
4.144	Revision of the TG 494 for the Vitrigel-Eye Irritancy Test Method for Identifying Chemicals not requiring Classification and Labelling for Eye Irritation or Serious Eye Damage	JP
4.145	Guidance document on an integrated approach on testing and assessment (IATA) for phototoxicity	JP
4.146	Development of new Test Guideline on toxicokinetics to accommodate testing of nano-particles	NL/UK
4.147	Detailed Review Paper on the State of the Art of Metabolic Disruption by Chemicals	NL/UK/SE/GER/DK
4.148	**The modification of the prediction model of the IL-8 Lu assay (OECD TG442E) to improve its performance New**	JP
4.149	**Development of Test guideline for identifying the immunotoxic potential of chemicals using the IL-2 Luc assay New**	JP
4.150	**New TG on the CYP induction New**	UK

34ª Reunião do WNT para aprovação!

Section 5: Other Test Guidelines

Section 5 – Part A - TEST GUIDELINES ON PESTICIDE RESIDUES CHEMISTRY

	Introduction to OECD Test Guidelines on Pesticide Residues Chemistry - Section 5 Part A	26/jul/13
	Test No. 501: Metabolism in Crops	25/jan/07
	Test No. 502: Metabolism in Rotational Crops	25/jan/07
	Test No. 503: Metabolism in Livestock	25/jan/07
	Test No. 504: Residues in Rotational Crops (Limited Field Studies)	25/jan/07
	Test No. 505: Residues in Livestock	25/jan/07
	Test No 506: Stability of Pesticide Residues in Stored Commodities	15 Oct 2007
	Test No. 507: Nature of the Pesticide Residues in Processed Commodities - High Temperature Hydrolysis	15 Oct 2007
	Test No. 508: Magnitude of the Pesticide Residues in Processed Commodities	16 Oct 2008
	Test No. 509: Crop Field Trial	17/jun/21

SPSF

5.6	Development of efficacy **Test Guidelines** and **Guidance Document** for public health antimicrobial biocides used on hard surfaces
5.16	**Guidance Document** on Laboratory Assays for Evaluating the Efficacy of Biocides against Bed Bugs
5.17	**Guidance Document** on the Testing of Efficacy of Baits against Tropical Ants

Template for writing OECD Test Guidelines

[*This document is to be used as a reference for writing Test Guidelines. Its goal is to help standardise the writing process. Using this document will save time and allow for harmonisation in the presentation of Test Guidelines. The headings that appear in this reference document are the ones that should generally be used as a basic frame for all Test Guidelines.*]

[*Standard presentation is: the title, sub-title and headings should be written in* ***bold and underlined****. Title font size is* ***16****, sub-title font size is* ***13****, heading* ***11****, capital letters. Sub-headings 11 lower case. Paragraphs should be written in size* ***11*** *and justified. Tables added to the main part or the annexes of the Test Guideline are preferably kept hold when it is possible (a new page may be started to keep a table whole).*]

[*Paragraphs should each be numbered by order of appearance, and systematic cross-referencing of paragraphs should be avoided. To reference a document, a number (corresponding to the order of appearance) is written in parenthesis. Reference numbers are all listed in the literature section just before the annex section at the end of the Test Guideline. The literature list is a numbered catalogue of the different references based upon the order in which they appear in the Test Guideline.*]

[The term 'test chemical' should generally be used to designate what is tested, unless otherwise justified.]

Draft Title

INTRODUCTION

[*Mentions the origin of the Test Guideline and briefly mentions the process and supporting references*].

DEFINTIONS

[*Usually this section references an Annex where definitions are provided. So this is just a placeholder in the main body of the Test Guideline*].

INITIAL CONSIDERATIONS AND LIMITATIONS

purpose. Such considerations are not needed, when there is a regulatory requirement for testing of the mixture."

PRINCIPLE OF THE TEST

[*This section provides a summary of the test method. This section lays out the skeleton of what is going to be done in a general chronological order. The test system, the exposure route, the exposure duration, the number of treatments and the timing of observations and measurements are described.*]

INFORMATION ON THE TEST CHEMICAL [*Aquatic toxicity tests*]

[*This section is intended to require prerequisite knowledge about the physical-chemical properties, (e.g. solubility) of the test chemical*].

DEMONSTRATION OF PROFICIENCY [depending on the situation]

[*Contains the reference substances, criteria and expected outcomes laboratories need to achieve to demonstrate their capacity in applying test methods correctly.*]

[*Table with proficiency chemicals or substances*]

VALIDITY OF THE TEST

"For the test to be valid, the following criteria apply:"

[Description of the criteria].

DESCRIPTION OF THE METHOD

Test preparation

[*In this heading details are given of the way in which each individual task is to be performed in the chronological order they should be accomplished in. Here, many different sub-headings contain details on topics such as:*]

Test No. 439: In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method | OECD Guidelines for the Testing of Chemicals, Section 4 : Health Effects | OECD iLibrary (oecd-ilibrary.org)

BRASIL SISTEMA MAD

RENAMA

PReMASUL

2008

Lei 11.784, 2008

CONCEA

2014

Nenhum escopo definido

CONCEA NR 17, 2014
Reconhece métodos alternativos validados para pesquisa científica de acordo com o Princípio 3Rs.

2019

CONCEA NR 18, 2014

17 métodos alternativos para testes em animais

Corrosão/Irritação da Pele: OCDE TG 430, 431, 435 e 439;
Corrosão dos olhos: OCDE TG 437, 438 e 460;
Fototoxicidade: OCDE TG 432;
Absorção de Pele: OCDE TG 428;
Sensibilização da Pele: OCDE TG 429, 442A e 442B;
Toxicidade Aguda: OCDE TG 420, 423, 425 e GD 129*;
Genotoxicidade: OCDE TG 487

2021

CONCEA NR 31, 2016

7 Métodos Alternativos para testes em animais

Corrosão/Irritação dos Olhos: OCDE TG 491 e 492;
Sensibilização da Pele: OCDE TG 442C e 442D;
Reprodução/Toxicidade do Desenvolvimento: OCDE TG 421 e 422)

2024

CONCEA NR 45, 20

1 Método Alternativo testes em animais

Avaliação da contaminação piro em produtos injetá
Teste de ativação monócitos (MAT) (Farmacopia brasil

2025

I - Saúde humana
- **1-Sensibilização dérmica**
- **OECD TG 442E**
- **2 Efeitos estrogênicos**
- **OECD TG 455**
- **OECD TG 493**
- **3 – Efeitos endócrinos**
- **OECD TG 456**
- **4 – Efeitos androgênicos**
- **OECD TG 458**
- **5 – Mutagenicidade**
- **OECD TG 471**
- **OECD TG 473**
- **OECD TG 476**
- **OECD TG 490**
- **6 – Irritação/corrosão ocular**
- **OECD TG 494**
- **OECD TG 496**

7 – Fotorreatividade
OECD TG 495

II – Efeitos em sistemas bióticos
OECD TG 212
OECD TG 236
OECD TG 319-A
OECD TG 319-B

OBRIGADA

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