New Approach Methodologies (NAMs)

Activities at the JRC

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76th MEETING OF THE EFSA ADVISORY FORUM, 1-2 July 2020
The Joint Research Centre Mission

We are the science and knowledge service of the Commission. Our mission is to support EU policies with independent evidence throughout the whole policy cycle.
Unit F3: Chemicals Safety & Alternative Methods

European Union Reference Laboratory for alternatives to animal testing

3Rs mandate under Directive 2010/63

- research & evaluation of non-animal approaches
- validation of alternative methods
- dissemination of information, knowledge sharing & promotion of alternative methods and the Three Rs
Unit F3: Chemical Safety & Alternative Methods

- Regulation 1107/2009 on the placing of Plant Protection Products on the market
- Regulation 528/2012 on authorisation of Biocidal active ingredients and Products
- Regulation 1272/2008 on classification, labelling and packaging of chemical substances and mixtures 'CLP'
- Directive 2001/82/EC on Veterinary Medicinal Products
- Directive 2001/83/EC on Human Medicinal Products
- Regulation 1223/2009 on Cosmetic Products
- Community Strategy on Endocrine Disrupters
- Community Strategy on combined exposures 'Mixtures'
- Regulation 1907/2006 on registration, evaluation, authorisation and restriction of chemical substances 'REACH'

EU chemicals acquis: >40 pieces of legislation
Chemical assessment methodologies

ICATM
ESTAF
PARERE
ESAC

Validation

Regulatory acceptance & implementation

Reliability & Relevance

EU-NETVAL
ECVAM lab

Standards

ECVAM

OECD

PARERE
ESAC
EU-NETVAL
ECVAM lab
EURL ECVAM Status Report
on the Development, Validation and Regulatory Acceptance of Alternative Methods and Approaches (2019)

Annex 1 — Summary status of the adoption of Test Guidelines based on *in vitro* methods in the OECD TG programme

Table 1 summarises the status of adoption of OECD test guidelines based on *in vitro* methods. It should be noted that, beside TGs, also Guidance Documents and new projects on alternative methods were respectively adopted and included in the OECD Work programme. For additional information, please consult the OECD website of the Test Guidelines Programme: https://www.oecd.org/chemicalsafety/testing/test-guidelines-testing-chemicals-related-documents.htm

Table 1 — Status of adoption of OECD Test Guidelines based on *in vitro* methods

https://tsar.jrc.ec.europa.eu/

JOINT RESEARCH CENTRE
Tracking System for Alternative methods towards Regulatory acceptance (TSAR)
Replacement in acute systemic toxicity testing


Selected as best manuscript published in ALTEX in 2019
AOP upstream events leading to systemic toxicity

**UPSTREAM EVENTS**

- **In silico or In chemico prediction**
- **Scientific knowledge**
- **In vitro study of hepatocytes**
- **In vitro study of a tissue or/and 3D co-cultured hepatocytes, stellate and Kupfer cells**

**FINAL EVENT**

- **Existing clinical data**
Integrated Approaches to Testing and Assessment

OECD Guidance on application and interpretation of in-vitro DNT assays

Non-genotoxic carcinogenicity moving away from the 2-year bioassay
Cross-endpoint evaluation

Madia F., submitted