

REPORT FOR INTERNATIONAL COOPERATION ON COSMETICS REGULATION (ICCR)



Inventory of validated Alternatives to Animal Testing applicable for cosmetic products and their ingredients in all ICCR Regions¹

Report is:

Prepared For ICCR

☒ ICCR Report

ICCR Guidance

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¹The inventory is based on the report issued bi-annually to ICCR by the International Cooperation on Alternatives to Animal Testing (ICATM) and is not necessarily exhaustive.

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Note: A separate document is attached to this ICCR report. It concerns the table with Internationally Accepted Alternative Test Methods for Cosmetic Products/Ingredients Safety Testing, successfully worked upon by ICATM (see below for further details).

1. PURPOSE

Today's drivers (legal, scientific, business and ethical) towards Alternatives to Animal Testing are of international relevance. All ICCR regions are supporting the reduction, refinement and replacement of animal tests in the area of cosmetics wherever this is possible and compatible with the objective of high level of consumer protection.

Within the existing legal frameworks, ICCR can contribute to

- easier identification of alternative methods that are applicable for cosmetics and available to industry in compliance with the respective legal frameworks
- reducing the risk of duplication of testing
- identifying areas of opportunity to streamline regulatory acceptance process between ICCR regions

The topic of alternatives to animal testing in the area of cosmetics has been a working item for ICCR since its first meeting in 2007, where ICCR regulatory authorities committed to increased collaboration in the area of validation of alternative methods, leading to the creation of the International Cooperation on Alternatives to Animal Testing (ICATM) in 2008. The purpose of ICATM is to promote consistent and enhanced voluntary international cooperation, collaboration and communication among the validation partners of the ICATM in the EU, US, Canada, Japan and Korea.

At the ICCR 3 and 4, ICATM presented updates on the validation of alternative methods in the ICCR regions. ICCR 4 also concluded that attention should be given to regulatory acceptance as a means of promoting the use of alternative approaches to animal testing.

ICCR 5 accepted a report to ICCR on the Applicability of Animal Testing Alternatives in Regulatory Frameworks within ICCR Regions. It describes the processes and proposed mechanisms in each ICCR jurisdiction for regulatory acceptance of the use of alternative methods in the area of cosmetics. Contributions were prepared by the respective lead industry association, in consultation with their respective regulatory representatives to ICCR.

Stakeholders present in the open session of ICCR 5 welcomed the work of ICCR in the area of alternative methods and proposed to create an easily accessible overview of those methods that are considered as validated and applicable to cosmetic products and their ingredients, most notably the test methods that have been internationally accepted for regulatory use by the OECD Member Countries. ICCR industry representatives agreed that such an overview would provide interested companies with a useful and user-friendly entry point in the identification of applicable alternative methods.

2. SCOPE

This report by ICCR is meant to provide an easily accessible inventory of methods, which are recognised by ICCR as validated alternative methods, applicable to cosmetics in the four ICCR regions.

It is a subset of the ICATM status list on validation of alternative methods that is updated on a bi-annual basis and shared with ICCR. As such, the list concentrates on methods, worked upon by the regional validation organizations comprising ICATM (ICCVAM, ECVAM, JaCVAM, HC, and KoCVAM) that are validated, available to industry and regulators and are considered appropriate elements for cosmetic product/ingredient safety assessments, within the limitations

and applicability domains identified for each method. Most methods have also received larger international acceptance as OECD test guidelines.

However, it should be noted that the list is not exhaustive. There are additional alternative methods available that have been accepted for international regulatory use by OECD that are not included in this inventory, as they were neither developed nor validated by ICATM partners.

The report can serve as a starting point and orientation for companies in the identification of alternative methods that are applicable and available for cosmetics and their ingredients in the ICCR regions. The report does not provide specific testing protocols nor does it describe the applicability domain of these methods. This information is available via the regional validation organizations comprising ICATM (ICCVAM, ECVAM, JaCVAM, HC, and KoCVAM) and for several methods, from OECD. This report is also not necessarily exhaustive, as there are additional validated methods available via OECD, which have not been worked upon by ICATM partners.

It should be noted that the scope of this document is strictly restricted to cosmetic products. Methods included are not necessarily applicable in all ICCR regions for products (or their ingredients) that are considered as cosmetics in only a part of the ICCR regions (e.g. Japanese Quasidrugs, US Cosmetic Drugs). For such cases, specific regulatory requirements regarding safety testing may be in place and need to be checked.

It should also be noted that, in the EU, only replacement methods will be acceptable after the entry into force of the 2013 marketing ban on 11 March 2013.

This inventory will be regularly updated by ICCR with the help of ICATM every 6 months and may serve as a basis for further discussions and possible development of guidance on the use of alternative methods in safety assessment.

3. ACRONYMS AND DEFINITIONS

ICATM	International Cooperation on Alternative Test Methods
ICCR	International Cooperation on Cosmetics Regulation
OECD	Organisation for Economic Co-operation and Development

4. RESPONSIBILITIES

This report by ICCR has been prepared jointly by the lead industry associations represented in ICCR: Cosmetics Europe (EU), CCTFA (Canada), JCIA (Japan) , PCPC (US).

5. CONCLUSION

Valid(ated) alternative approaches can be routinely and successfully used in cosmetic regulatory safety assessments, e.g. in the area of

- Phototoxicity
- Dermal penetration
- Skin corrosivity/skin irritation
- Genotoxicity
- Eye irritation
- Skin sensitisation
- Acute toxicity

There are still diverging levels of acceptance of alternative methods across the world. Companies considering the use of non-animal safety information face the uncertainty that the resulting safety assessment might be challenged or not accepted by regulators. Companies also face uncertainty concerning how such alternatives to animal testing would fare in product liability civil lawsuits at trial in court cases.

The attached table provides an inventory of methods that have been worked upon by ICATM partners and that are recognised by ICCR as validated alternative methods applicable to cosmetics in the four ICCR regions based on a report issued biannually by ICATM to ICCR.

These methods are available to industry and regulators and, in the common objective of promoting the 3 Rs², are considered appropriate elements for cosmetic product/ingredient safety assessments, within the limitations and applicability domains identified for each method. Although one-to-one replacements of an animal study with one alternative method works only in few cases, successful test batteries/tiered approaches can be built utilizing alternative methods in a way that lead to reduction, refinement and replacement of animal tests.

This report contributes to an easier identification of alternative methods available to industry in compliance with the respective legal frameworks and a reduced the risk of duplication of testing. However, this report is not necessarily exhaustive, as there are additional validated methods available via OECD, which have not been worked upon by ICATM partners.

² Reduction, Refinement and Replacement of animal studies