Related Projects and Outlook

EURL ECVAM Search Guide

The EURL ECVAM Search Guide (SG) provides contemporary, good practices for a systematic and structured data retrieval approach in biomedical sciences and toxicology thereby reducing the reliance on animal use. It includes **search procedures, user guidance and suggested search terms** in addition to an **inventory of relevant resources**.
The first edition of the SG, published in 2012, has found a world-wide application for higher education in academic institutions and by national authorities involved in project evaluations that might involve animal use for research and testing. A fully revised second edition was made available in 2013. The SG has been produced by the Commission's Joint Research Centre in collaboration with the German Federal institute for Risk Assessment and was assisted by an internationally composed project advisory board. Free copies can be obtained from the EU Bookshop as PDF and e-Book. The EURL ECVAM is currently working on providing the web-based version.
EU Bookshop: **http://bookshop.europa.eu**

News on the DB-ALM

- **New interface**
  In 2016 an entirely revised version of **DB-ALM** has been released on the Internet, providing redesigned search interfaces for all data sectors.
- **OECD compliant format**
  In 2015, the *Method Summary* format has been adapted to be compliant with the OECD guidance document n° 211 for describing non-guideline in vitro methods, but was kept flexible to serve various purposes.
- **Content updating-online**
  An interactive application under development will permit to submit new methods to DB-ALM and/or to update methods already online.
- **Serving integrated approaches**
  The DB-ALM structure will be upgraded to improve an integrated use of methods at all stages of development and validation.

TSAR: Tracking System for Alternative methods towards Regulatory acceptance

TSAR provides an overview on alternative test methods proposed for validation with a transparent view on the process leading to eventual acceptance for regulatory safety and efficacy testing of chemicals or biological agents.
TSAR includes short summaries of the methods, integrated with the DB-ALM, and all available records linked to the different steps of the entire process: submission, validation, peer review, recommendations and regulatory acceptance, including international standards.
TSAR was developed by the EU Commission's Joint Research Centre's EURL ECVAM to disseminate information on methods being considered by member and observer organisations of the International Cooperation on Alternative Testing Methods (ICATM) representing the EU, Canada, USA, Republic of Korea, Japan, Brazil and China.
Access: **https://tsar.jrc.ec.europa.eu**

QSAR Model Database

This database, established and managed by the Commission's Joint Research Centre, allows a user to submit, publish, and search robust peer-reviewed summaries of Quantitative Structure-Activity Relationship (QSAR) models by using an internationally recognised reporting format that summarises their main characteristics. It covers physical chemical properties, environmental fate parameters and ecotoxic effects, human health effects and toxicokinetic properties.
Access: **http://qsardb.jrc.ec.europa.eu**

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European Union Reference Laboratory for Alternatives to Animal Testing

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JRC Mission

As the science and knowledge service of the European Commission, the Joint Research Centre's mission is to support EU policies with independenti evidence throughout the whole policy cycle.

Directorate F – Health, Consumer and Reference Materials

European Union Reference Laboratory for alternatives to animal testing (EURL-ECVAM)

EU Science Hub
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Joint Research Centre
EU Science Hub

European Commission

DB ALM

EURL ECVAM

DataBase service on ALternative Methods to animal experimentation (DB-ALM)

https://ecvam-dbalm.jrc.ec.europa.eu

Joint Research Centre

Rationale for DB-ALM

The ready access to comprehensively and adequately described methods is a prerequisite for their use within decision making processes by regulators, scientists or any end-user in biomedical sciences.

Based on a legal requirement[1,2], in 1996 the Commission's Joint Research Centre has established and is managing the DB-ALM to enhance the uptake of alternative methods at all stages of development and acceptance covering various areas of concern.

The target user groups are National Authorities, Industry, Academia, the Animal Welfare Movement as well as Commission Services.

The service is referenced in formal OECD documents; scientific publications and referred to by the European Chemicals Agency.

The OECD recommends DB-ALM as a dissemination platform compliant with its new Guidance for describing non-guideline in vitro test methods (GD 211).

The Database Project

The DB-ALM is a *public, factual* database service that provides *ready-to-use* information on various aspects of animal alternatives in the field *of biomedical sciences and toxicology*.

The content is presented as expert written evaluated data sheets in the form of summary records and/or more detailed information. Current focus is on *in vitro* methods for **toxicological evaluations of chemicals and formulations**, but includes also **biological substances**, **medical devices** and **other approaches to reduce animal use**. An extension to models used in biomedical research is currently ongoing.

Information sectors

- **Topic Summaries**: Executive summary on alternative methods available in the DB-ALM for a given topic (e.g. Percutaneous Absorption, Eye Irritation).
- **Method Descriptions** with two levels of detail:

  Method summary: review of the scientific principle and need for the method, main applications, and current status of development and/or acceptance.

  Protocol: standard operating procedure to enable the transfer of a method to a laboratory.
- **Project & Study Descriptions**: Summary records of method evaluations including EU integrated projects and selected formal validation studies.
- **Compounds & Test Results**: Substances and investigations performed with methods included in the DB-ALM.
- **People & Institutions**: Inventory *(Who is Who)* of main actors active in the field of alternative methods, based on a voluntary participation.
- **Bibliography**: References analysed for the compilation of the data sheets.

A selected example of a reporting format for an *in vitro* **Method Summary** is given hereafter. The indicated criteria for data content can vary depending on the type of method/approach described:

[1] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, Article 48, Annex VII (2)(d), OJ L Nr. 276/33, 20.10.2010.

[2] SEC(91)1794, Communication of the European Commission to Council and the European Parliament in October 1991, pointing to a requirement in Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes, OJ L No. 358, 18.12.1986.

Extract of the Method Summary reporting format

Method name

One-two sentence abstract on the scientific principle of the method

GENERAL INFORMATION

Status
The extent of method's use by laboratories, development and eventual validation status according to internationally recognised principles, regulatory acceptance and standards.

Contacts
Persons and organisations familiar with the method (developers or expert users).

Practicalities
Proprietary or confidentiality issues, throughput with indication on likely resource intensity.

METHOD DEFINITION

Purpose
Structured overview of the objectives and type and level of assessment provided, referring to e.g.: mechanistic information, human health or environmental effects, testing of quality, efficacy, safety or biocompatibility; cell and tissue culturing techniques.

Context and suggested applications
Proposed regulatory and/or non-regulatory uses. For example:
- screening, priority setting or grouping
- test batteries, integrated approaches to testing and assessment
- weight of evidence approaches, adverse outcome pathways
- the respective *in vivo* test addressed (if applicable)
- basic or applied research objectives

Scientific rationale
The origin and need for the method. The scientific principle and mechanistic or biological basis and relevance.

Procedure description
Where applicable, a short summary of the study design and the basic procedures, e.g. the preparations, dosing, exposure, sampling and measurements.
- **Biological endpoint and measurement**
- **Endpoint value**
- **Test system**
- **Exposure regime**

Quality and acceptance criteria
List of criteria ensuring the appropriate and adequate execution of the method (including controls and performance standards).

Data analysis and interpretation
Calculations and statistical methods used for data analysis and interpretation. The rules for the prediction of the *in vivo* effects from the data (if applicable).

METHOD PERFORMANCE

Robustness and applicability
Any performance measure most appropriate for the specific method, such as information on reliability, relevance, accessibility of its results as appropriate.
Possible applicability domains: test materials to which this method can/has been applied and proven compatible or incompatible with.

Discussion
Main advantages and/or limitations of the method, comparison to other related methods, possible adaptations/ modifications for various purposes, challenges ethical concerns and potential for future developments.

NOTE: This format has been adapted in compliance with OECD guidance document n° 211 for comprehensively describing non-guideline in vitro methods. However it is designed **to remain flexible and broad enough** to allow for summary descriptions of methods **for various purposes and applications** covering also methods for research purposes or even non-experimental methods as appropriate. Thus, not all fields are obligatory.

Data coverage

The database covers, so far, **26 different fields of applications**, mainly referring to *in vitro* toxicity testing of chemical compounds, but is not restricted to it:

Information Sector	Number of Data Sheets
Topic Summaries	5
Method Summaries	180
Protocols	159
(Inter)national Projects/Validation Studies	90
Test Compounds	3070
Individual Investigations & Test Results	9128
Persons & Institutions (who's who)	94

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The methods cover approximately **150 biological endpoints** referring to *biological processes, responses* or *effects* that can be assessed at various levels of biological organisation, such as:

- molecular level interactions
- basal cytotoxicity tests
- tissue- and organ-specific mechanisms
- model organism responses

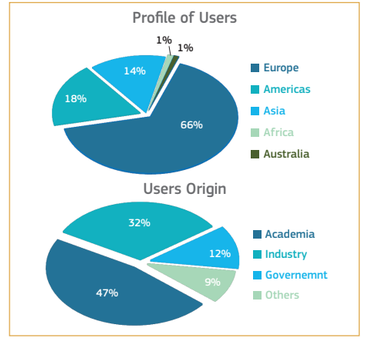
Origin of information

The collected information originates from (inter)national **research projects**, **individual submissions from scientists**, or **validation studies** and **bibliographic reviews** based on selected priority topics.

All documents are compiled by experts in the field and reviewed by JRC staff before inclusion into the database.

Users

5.261 registrations recorded from 82 countries covering the entire period of online access. Even though data requests could be performed without the need of registration and a subset of information is provided, the service still can refer to a solid number of new registrations with more than 280 new registrations between July 2016 and June 2017, and to over **3800 documents downloaded** in the same period, which corresponds to an increase of about 30% compared to the previous year and exceeding 50% compared to 2015, **being the highest in almost 11 years of public access.**



Information retrieval

The DB-ALM offers different levels of information retrieval:

- **Guided search:** Allows the use of different search parameters in any combination, such as field of application, type of method used, biological endpoint measured, status of development or acceptance.
- **Free text search**: This approach scans the entire database contents, but is less precise. Optional search assistance is provided.