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ANNEX 1: EVALUATION FRAMEWORK TO THE THE OECD SUPPORTING DOCUMENT ON DEFINED APPROACHES FOR SKIN SENSITISATION

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ANNEX 1 EVALUATION FRAMEWORK
THE OECD SUPPORTING DOCUMENT ON DEFINED APPROACHES FOR SKIN SENSITISATION

IOMC
INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS
A cooperative agreement among FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD

Environment Directorate
ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT
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About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 36 industrialised countries in North and South America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in eleven different series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Pesticides**; **Biocides**; **Risk Management**; **Harmonisation of Regulatory Oversight in Biotechnology**; **Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents;** and **Safety of Manufactured Nanomaterials.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (www.oecd.org/chemicalsafety/).

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

1 Annex 1: Evaluation Framework

1. The below evaluation framework was developed at the request of the WNT during the special session in December 2017, and subsequently agreed upon and considered by the expert group for the evaluation of the DAs included in the draft GL. The DAs included in the GL were evaluated according the elements described in this framework.

Structure: Information Provided, DA Elements

2. The DA should be described using the template provided in GD 255. The DA should allow an equivalent regulatory use as the reference animal test. The required resolution of the DA output depends on the regulatory application. The DA should at minimum provide hazard information (discriminate between sensitisers and non-sensitisers). For other regulatory applications the DA should provide partial classification (e.g. able to discriminate GHS Cat 1A) and/or sufficient information for classification and labelling (e.g. discriminate GHS Cat 1A and Cat 1B). Some DAs may also provide a point of departure for quantitative risk assessment. The purpose of the DA (e.g. hazard, potency classification, etc.) should be clearly stated, and the DA should be evaluated with respect to that purpose.

Relevance: Mechanistic Coverage

3. The DA should be mechanistically and biologically relevant with respect to the existing skin sensitisation AOP framework. The quality of information provided with respect to each KE or the overall AOP should be characterised. It is not necessary that the DAs cover all the key events within the AOP but at least one key event should be covered.

Predictive Capacity: Performance Compared to Reference Data

4. The predictive capacity of the DA should be equivalent or better than that of the animal tests to predict responses in humans, where human data are available, and equivalent to the reproducibility of the animals test where human data are not available. Therefore, the predictive capacity of the DA should be compared against reference animal data and to the extent possible (where these exist) also against human data. The output of the DA (e.g. hazard, potency prediction) should be compared to the corresponding level of information from the reference data. For the evaluation of the predictive capacity of the DA, the variability of the reference data used should be taken into account.

Reliability: Reproducibility

5. The reproducibility of the DA should provide a level of confidence no less than that provided by the reproducibility of the reference animal test (i.e. the LLNA, as described above). The reproducibility of the individual information sources used in the DA should be characterised (not necessarily through a prospective validation study; existing/published data can be used for the characterisation of the reproducibility).

Applicability: Technical Limitations, Chemical Space Coverage

6. The applicability domain of the DA should be characterised and described to the extent possible, both in terms of technical limitations of the DA elements (e.g. *in vitro* assays, *in chemico* assays, *in silico* models, expert systems) and in terms of the coverage of chemical space.

Complexity: Data Interpretation Procedure

7. The DA should use a data interpretation procedure that is sufficiently well described (using the template from GD 255) that it can be conceptually understood and practically applied by end-users (i.e. regulators and regulated industry).

Transparency: Availability of Elements for Review

8. Independent evaluation and implementation by third parties must be possible (i.e., all of the DA elements must be readily accessible and all the relevant protocols must be available). The DA should include one or more OECD TG methods to facilitate acceptance. The DA can include non-guideline test methods as long as sufficient information exists to allow their assessment (i.e. allow evaluation of their reliability and relevance). Careful consideration will be given to proprietary elements. Quantitative structure activity relationship (QSAR) models can be part of the DA if they are characterised according to the five OECD principles for QSAR model validation (OECD 2014) and reported using the QSAR Model Reporting Format or Annex II to GD 256; information on the training set should be available. When incorporating *in silico* elements (e.g. OECD Toolbox, QSARs), careful documentation should be provided to record all choices made (e.g. software version, protocol used) such that the predictions can be replicated.