JaCVAM statement on the Defined Approach for skin sensitization

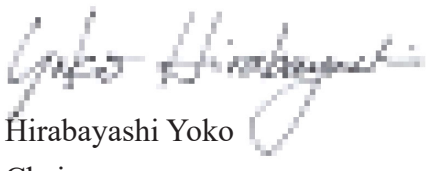
At a meeting held on 26 November, 2024 at National Institute of Health Sciences (NIHS) in Tokyo, Japan, the Japanese Center for the Validation of Alternative Methods (JaCVAM) Regulatory Acceptance Board unanimously endorsed the following statement:

Proposal: This evaluation method provides valuable information from the perspective of sensitization assessment based on the AOP. In both the 2o3 DA and ITS DA approaches, there are no UN GHS Category 1A substances predicted as NC, indicating the hazard predictability is considered appropriate. Regarding the potency predictability of ITS DA, although the number of reference substances is limited, the potency predictability is generally comparable to that of LLNA, making it is generally considered appropriate. However, it is important to note that a certain number of substances tend to be underestimated. Specifically, some substances classified as UN GHS Category 1B are predicted as NC, and some substances classified as UN GHS Category 1A are predicted as 1B.

This statement was released following a review prepared by the skin sensitization test JaCVAM Editorial Committee to acknowledge that the results of the review and study by the JaCVAM Regulatory Acceptance Board have confirmed the usefulness of this evaluation method.

Based on the above, we proposed the Defined Approach for skin sensitization as a useful means for assessing skin sensitization potential and potency during safety assessments by regulatory agencies.

Nishikawa Akiyoshi
Chairperson,
JaCVAM Regulatory Acceptance Board.



Hirabayashi Yoko
Chairperson,
JaCVAM Steering Committee.

January 16, 2025

The JaCVAM Regulatory Acceptance Board was established by the JaCVAM Steering Committee, and is composed of nominees from the industry and academia.

This statement was endorsed by the following members of the JaCVAM Regulatory Acceptance Board:

Nishikawa Akiyoshi (Division of Pathology, Center for Biological Safety and Research: CBSR, NIHS / Nagoya Tokushukai General Hospital) : Chairperson
Hirabayashi Yoko (CBSR, NIHS)
Ishii Yuji (Division of Pathology, CBSR, NIHS)
Kojima Koichi (Food and Drug Safety Center)
Matsumoto Kazuhiko (Nagoya City University)
Nakamura Ruriko (National Institute of Technology and Evaluation)
Nishimura Jihei (Pharmaceuticals and Medical Devices Agency)
Nishimura Takuya (Division of Cellular and Molecular Toxicology, CBSR, NIHS)

Term: From 1st April 2024 to 31st March 2026

This statement was endorsed by the following members of the JaCVAM steering Committee after receiving the report from JaCVAM Regulatory Acceptance Board:

Hirabayashi Yoko (CBSR, NIHS): Chairperson
Honma Masamitsu (NIHS)
Ishii Koji (National Institute of Infectious Diseases)
Kanda Yasunari (Division of Pharmacology, CBSR, NIHS)
Kitajima Satoshi (Division of Cellular and Molecular Toxicology, CBSR, NIHS)
Masumura Kenichi (Division of Risk Assessment, CBSR, NIHS)
Miyasaka Tomohiro (Ministry of Health, Labour and Welfare)
Nishimura Jihei (Pharmaceuticals and Medical Devices Agency)
Sugiyama Keiichi (Division of Genome Safety Science, CBSR, NIHS)
Takahashi Akiko (Pharmaceuticals and Medical Devices Agency)
Tanaka Rie (Ministry of Health, Labour and Welfare)
Taquahashi Yuhji (Animal Management Section of the Division of Cellular and Molecular Toxicology, CBSR, NIHS)
Toyoda Takeshi (Division of Pathology, CBSR, NIHS)
Tsukano Masaaki (Ministry of Health, Labour and Welfare)
Ashikaga Takao (Division of Genome Safety Science, CBSR, NIHS): Secretary
Ohno Akiko (Division of Genome Safety Science, CBSR, NIHS): Secretary