ADMIN

GENOTOX BP

EXPERT PANEL MEETING

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Jinqiu Zhu, PhD, DABT, ERT, DCST, CIR Toxicologist
Date: May 22, 2026
Subject: Genotoxicity Boilerplate

At the March Panel meeting, the Panel discussed the limitations, interpretability, and current regulatory relevance of several historical genotoxicity assays, such as sister chromatid exchange (SCE) assays, unscheduled DNA synthesis (UDS) assays, the mouse spot test, and other older or non-standard assays that have appeared in published literature and prior CIR safety assessments. The Panel noted that these assays are no longer considered acceptable for evaluating genotoxic potential in light of updated OECD guidance and the availability of current guideline-based approaches for evaluating gene mutation, chromosomal damage, and other relevant genotoxicity endpoints. The Panel determined that a standard boilerplate statement should be included in the genotoxicity section of CIR reports to clarify how obsolete genotoxicity assays are handled.

Based on the Panel meeting discussion, the following boilerplate language is proposed:

Some genotoxicity assays (e.g., sister chromatid exchange (SCE), unscheduled DNA synthesis (UDS), gene mutation assay with Saccharomyces cerevisiae) are no longer considered acceptable for genotoxicity testing, according to OECD guidance. Although these assays are reported in the published literature, the results from these assays are of limited interpretability and therefore the studies are not summarized herein.

The Panel may also wish to clarify whether citations to historical or obsolete genotoxicity assays should be omitted, or retained for transparency. Because these assays include a broader range of older or non-standard methods than can be fully listed in a boilerplate statement, it may not always be clear which studies were identified but not summarized in the report. Examples of additional omitted studies include the bacteriophage T4D assay, host-mediated assay, SOS response assays such as the SOS chromotest and umu assay, *Bacillus subtilis* Rec assay, and other DNA repair or recombination-based assays that have not been incorporated into OECD genotoxicity test guidelines, and are not generally used as validated standard methods in current regulatory genotoxicity assessment. Omitting citations will avoid implying that such studies were relied upon in the safety assessment; conversely, retaining limited citations may provide transparency by documenting that the studies were identified and considered. If citations are retained, the boilerplate language should make clear that such studies were identified but not summarized or relied upon in the weight-of-evidence evaluation.

Because this boilerplate has not been discussed by the full Panel, it is not included in the reports prepared for review at this meeting. Instead, the obsolete genotoxicity studies have been deleted from each document as applicable, and the study types that were deleted are identified in the transmittal memo to maintain transparency, and provide the Panel with the opportunity to assure that this filtration was applied properly.

To facilitate your discussion, the attached tables are provided as supporting information for the Panel's review. Table 1 lists obsolete OECD genotoxicity test guidelines, Table 2 summarizes currently adopted OECD genotoxicity test guidelines, and Table 3 provides examples of emerging New Approach Methodologies (NAMs) that may be considered within a weight-of-evidence framework but are not currently adopted OECD test guidelines.

The Panel is requested to: 1.) discuss whether to adopt the proposed genotoxicity boilerplate language; 2.) to review the attached tables and determine if you agree with the classification of each study; and 3.) to provide direction on whether citations to historical/obsolete genotoxicity assays should be omitted or retained in the genotoxicity section.

Table 1. Obsolete OECD Genotoxicity Test Guidelines

TG	Guideline	Status
477	Sex-linked recessive lethal test in *Drosophila melanogaster*	Deleted in 2014
479	In vitro sister chromatid exchange (SCE) assay in mammalian cells	Deleted in 2014
480	*Saccharomyces cerevisiae* gene mutation assay	Deleted in 2014
481	*Saccharomyces cerevisiae* mitotic recombination assay	Deleted in 2014
482	DNA damage and repair, unscheduled DNA synthesis (UDS) in mammalian cells in vitro	Deleted in 2014
484	Mouse spot test	Deleted in 2014
485	Mouse heritable translocation assay	Retained, but not revised
486	Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo	Retained, but not revised

Table 2. Current OECD Genotoxicity Test Guidelines

Endpoint	TG	Guideline	System	Current version
Gene mutation	470	Mammalian erythrocyte Pig-a gene mutation assay	*in vivo*	2025
Gene mutation	471	Bacterial reverse mutation test (Ames)	*in vitro*	2020
Gene mutation	476	In vitro mammalian cell gene mutation tests (HPRT/XPRT)	*in vitro*	2016
Gene mutation	488	Transgenic rodent somatic and germ cell gene mutation assays	*in vivo*	2025
Gene mutation	490	In vitro mammalian cell gene mutation tests (TK)	*in vitro*	2016
Chromosomal damage	473	In vitro mammalian chromosomal aberration test	*in vitro*	2016
Chromosomal damage	474	Mammalian erythrocyte micronucleus test	*in vivo*	2016
Chromosomal damage	475	Mammalian bone marrow chromosomal aberration test	*in vivo*	2016
Chromosomal damage	478	Rodent dominant lethal test	*in vivo*	2015
Chromosomal damage	483	Mammalian spermatogonial chromosomal aberration test	*in vivo*	2016
Chromosomal damage	487	In vitro mammalian cell micronucleus test	*in vitro*	2023
DNA strand breaks	489	In vivo mammalian alkaline comet assay	*in vivo*	2016

Table 3. Examples of New Approach Methodologies (NAMs) for Genotoxicity

Method	Note
ToxTracker gene reporter assay	Under OECD consideration
Reconstructed skin micronucleus test (RSMN)	Under OECD consideration
Reconstructed skin comet assay (RS Comet)	Under OECD consideration
In vitro γH2AX/pH3 multiplexed biomarker method	Under OECD consideration
In vitro alkaline comet assay and enzyme-linked comet assay (ACA/ELCA)	Under OECD consideration
BlueScreen HC™ / GreenScreen HC™	Supporting Evidence Considered by the SCCS
γH2AX assay	Supporting Evidence Considered by the SCCS
Hen's Egg Test for Micronucleus Induction (HET-MN)	Supporting Evidence Considered by the SCCS
Enzyme-linked comet assays for oxidative DNA damage	Supporting Evidence Considered by the SCCS