

Guidance Statements

The COM terms of reference include generic advice to Government Departments and Regulatory Agencies on the risk assessment of mutagens and the assessment of genotoxicity. These guidance documents present COM conclusions on these topics and are considered accurate at time of publication. As the science which underpins each of these guidance statements advances, the COM may consider it necessary to review a statement and issue a revised version.

Risk Assessment Strategies

A Strategy for Testing of Chemicals for genotoxicity	2000	G01	v 3
An overarching statement which presents the Committee's recommended general approach to assessing the genotoxicity of a chemical.			
Assessment of chemical structure and pre-screening tests in the assessment of the genotoxicity of chemicals		G02	
Details of the Committee's conclusions on use of QSAR and pre-screening tests for mutagenicity.			
A strategy for <i>in vitro</i> assessment of the genotoxicity of chemicals		G03	
Details of the recommended principal and supporting assays for investigating the mutagenicity of chemicals <i>in vitro</i> .			
A strategy for <i>in vivo</i> assessment of the mutagenicity of chemicals including germ cell genotoxicity.		G04	
Details of the recommended <i>in vivo</i> studies for investigation of chemicals testing for potential <i>in vivo</i> genotoxicity.			
Nanomaterial Toxicology	2005	G05	v 1
A position statement from COT, COC and COM with a suggested initial strategy for toxicology testing of nanomaterials.			
Assessment of Chemical Mixtures for Mutagenicity	2008	G06	v 1
A statement on the dissection of chemical mixtures for			

testing and suggested potential targets for interaction regarding mutagenic activity.

[Assessment of Threshold for *in vivo* Mutagens](#) 2009 G07 v 1

A statement on the definitions of threshold mutagens, possible modes of threshold activity, and experimental approaches to the experimental determination of thresholds.

[Some aspects of the risk assessment of mutagens \(Genotoxic potency, Threshold of Toxicological Concern, Thresholds, etc.\)](#) G08

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Genotoxicity Tests

These Statements are not intended as new or alternative guidelines on the conduct of genotoxicity studies. They are intended to provide recommendations on the interpretation of test results. Statements may also offer comments on new and emerging tests.

[Syrian hamster embryo cell transformation assay](#) 2002 G10 v 1

A statement on COM conclusions on the SHE assay. The COM concluded that this assay has no value in a testing strategy for genotoxicity.

[Considering high dose positive *in vivo* mutagenicity data in the bone marrow assays that may not be biologically significant with regard to considering a chemical to be an *in vivo* mutagen](#) 2003 G11 v 1

A statement on COM guidance on interpretation of high dose positive assays. Data from assays where there is severe toxicity/lethality cannot be interpreted.

[The use of toxicogenomics in toxicology](#) 2004 G12 v 2

A joint COT, COC and COM statement. Toxicogenomics may assist in the interpretation of data (particularly on mode of action) on a case-by-case basis but cannot be used routinely to screen for hazards.

[The cII transgenic mutation assay](#) 2005 G13 v 1

A statement on the interpretation of the cII transgenic mutation assay. Mutant colonies should be routinely screened for mutagenic spectra.

Use of target organ mutagenicity data in carcinogen risk assessment

2005 G14 v 1

The COC and COM agreed that data from *in vivo* target organ genotoxicity studies can aid in the interpretation of mode of action of carcinogenic effects seen in long term rodent studies.

Comparison of the relative performance of the *in vivo* rat liver UDS assay and the *in vivo* comet assay

2006 G15 v 1

The rat liver UDS and comet assays have a broadly similar response to a number of known rodent carcinogens.

Risk factors affecting the formation of chromosomal aberrations and micronuclei in peripheral blood lymphocytes

2006 G16 v 1

A statement on risk factors which affect background levels of DNA damage and are important in designing biomonitoring studies.