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MUT/2023/10

COMMITTEE ON MUTAGENICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COM)

Lay Summaries of COM Statements

First draft non-expert summary for COM guidance document on testing strategies to evaluate the potential of manufactured nanomaterials to cause genotoxicity can be found in Annex A.

First draft non-expert summary for COM guidance document on testing strategies to evaluate the potential of chemicals to cause germ cell mutations can be found in Annex B.

IEH Consulting under contract supporting the UKHSA COC and COM Secretariat

October 2023

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MUT/2023/10 – Annex A

COMMITTEE ON MUTAGENICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COM)

First draft non-expert summary for COM document: Guidance on the genotoxicity testing strategies for manufactured nanomaterials.

First draft non-expert summary for COM guidance document on testing strategies to evaluate the potential of manufactured nanomaterials to cause genotoxicity.

IEH Consulting under contract supporting the UKHSA COC and COM Secretariat

October 2023

Committee on Mutagenicity

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First draft non-expert summary for COM guidance document on testing strategies to evaluate the potential of manufactured nanomaterials to cause genotoxicity.

The Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) is an independent expert advisory committee with specific interest in the inherent properties of chemicals to cause DNA damage. The COM has a remit to provide UK government departments and agencies with advice on the most suitable approaches to testing chemical substances for such properties. More detailed information on the COM can be accessed via the website.

Concerns have been raised across a number of sectors, including within UK government departments and agencies, as to the safety of manufactured nanomaterials. These are defined as manufactured materials with one or more dimensions in the nanometer size range, most commonly between 1 and 100 nm (a diversity of definitions exists) and, due to their inherent properties, present challenges in applying current safety evaluations.

This document provides a summary of the COM opinion on the most appropriate testing strategies to evaluate the genotoxic potential of manufactured nanomaterials, based on currently available information.

Background information is provided on a number of projects and initiatives being conducted to evaluate and harmonise methodologies to assess the genotoxicity of nanomaterials. The applicability of in vitro and in vivo assays, that are currently recommended by the COM for genotoxicity testing, are evaluated to consider how the unique size, surface properties, chemical composition and shape of nanomaterials may influence genotoxicity. The COM recommends that a battery of tests be carried out to assess the genotoxicity of nanomaterials comprised of 2 types of assessment, one to detect gene mutation and the other to detect chromosomal damage.

Committee on Mutagenicity

MUT/2023/10 – Annex B

COMMITTEE ON MUTAGENICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COM)

First draft non-expert summary for COM document: Guidance on the genotoxicity testing strategies for germ cell mutagens.

First draft non-expert summary for COM guidance document on testing strategies to evaluate the potential of chemicals to cause germ cell mutations.

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October 2023

Committee on Mutagenicity

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First draft non-expert summary for COM document: Guidance on the genotoxicity testing strategies for germ cell mutagens.

The Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) is an independent expert advisory committee with specific interest in the inherent properties of chemicals to cause DNA damage. The COM has a remit to provide UK government departments and agencies with advice on the most suitable approaches to testing chemical substances for such properties. More detailed information on the COM can be accessed via the website.

Within its overarching strategy document (Guidance On A Strategy For Genotoxicity Testing Of Chemical Substances) COM considers a number of testing strategies for the identification of different types of genetic damage, including gene mutation. The potential impact of mutation is known to differ, depending on a cell's function. Somatic cells are those that form parts of a body of an organism and any mutation occurring in these may lead to diseases such as cancer, as the mutation is transferred during cell growth. However, in germ cells, which are responsible for reproduction, mutations may be transmitted to offspring, with the possibility of inherited disorders occurring. COM states that, as a general rule, any chemical shown to cause mutations within somatic cells should also be assumed to cause germ cell mutations, although rare exceptions to this rule are noted.

This document provides a summary of regulatory test methodologies (referred to as OECD test guidelines) that are currently available to assess the potential of chemicals to cause mutations within germ cells. At present, the majority of regulatory testing applies to male germ cells due to the accessibility of sperm and the relative inaccessibility of female eggs. The assays included in this document differ in which aspect of sperm development is being evaluated and, in their specificity and sensitivity. However, specified timings for sample collection have been determined for each assay to ensure that the sample reflects the correct phase of sperm development.

In addition, this document discusses new assays and amendments to regulatory tests that are under development and/or validation. It is noted by COM that any classification of a chemical as a germ cell mutagen should only be based on data from several independent and well conducted sources (i.e. a weight of evidence approach).