



Scientific Committee on Consumer Safety (SCCS)

WG on Methodologies

Workshop on strategy for Genotoxicity/Mutagenicity Testing

Venue: Luxembourg

18 September 2013

Minutes

1. WELCOME AND APOLOGIES

The Commission welcomed the participants together with the Chair of the working group.

Some additional external experts, including few industry representatives, were invited and participated to stimulate the debate among the members of the SCCS Working Group (WG) - see attendance list below.

A tour de table was made to introduce each other. Four apologies were announced.

2. ADOPTION OF THE AGENDA

The agenda was adopted as presented.

The goal of that specific meeting is to help the SCCS to update during next WG meetings the SCCS Notes of Guidance, as a draft for public consultation.

3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

No declaration of conflict of interest was declared.

4. INTRODUCTION

The current provisions of the Cosmetics Regulation on the use/non-use of animal data were presented and the implications of the animal testing ban for genotoxicity/mutagenicity testing and risk assessment were discussed.

5. STRATEGY OF GENOTOXICITY /MUTAGENICITY TESTING, UPCOMING ISSUES:

5.1 Focus on the validated in vitro methods

D. Kirkland gave two presentations on the potential of in vitro genotoxicity/mutagenicity tests in predicting genotoxic carcinogens, "Two versus three in vitro tests" and "Analysis of mammalian cell data for Ames-positive chemicals - preliminary analysis of

incomplete dataset”, followed by a presentation by V. Rogiers on the SCCS data base 2000-2012 on genotoxicity/mutagenicity test results. The presentations were discussed.

5.2 Other promising techniques to reduce the safety gap in the risk assessment of genotoxicity/mutagenicity

The following presentations on some non-validated methods or techniques were given: E. Benfenati on in silico techniques, V. Rogiers on toxicogenomics, R. Corvi on cell transformation assays, and S. Pfuhler on in vitro 3-D Models. Finally, based on the data presented by D. Kirkland, S. Pfuhler made a proposal on integrated in vitro testing in case of one or more positive in vitro test results. The presentations were discussed.

6. FINAL DISCUSSION ON THE NEW TESTING STRATEGY IN THE NOTES OF GUIDANCE

Questions:

- 1. Does the group agree with a two test battery sufficient (Ames test and micronucleus test in vitro) versus three tests should the result be negative? Or would a gene mutation assay be needed in addition to a negative result?*

-> General agreement from the group that this two test battery may be sufficient bearing in mind that any future strategy should have some reserve regarding particular substance groups, for instance disinfectants and preservatives (high toxicity to microorganisms) and nanomaterials as well.

- 2. What to do when there are positive test results in the Ames test and/or in a validated in vitro mutagenicity test?*

-> General agreement that the decision tree proposed is useful but may require more discussion, improvement or refinement.

- 3. What can other promising methods or techniques contribute?*

-> General agreement that the tool box exists and should be refined -> which methods/techniques could be used depends on their strengths and further development of the methods and deserves further discussion.

7. ANY OTHER BUSINESS

No other point was raised.

Attendance list of external experts:

Industry: Dr Paul Fowler (P&G), Dr David Kirkland (Consultant), Dr Stefan Pfuhler (P&G), Dr Werner Schuh (Henkel).

EU institutions and national authorities: Dr Raffaella Corvi (JRC), Dr Peter Kasper (BfArM, Germany), Dr Daniela Maurici (EFSA), Dr Pascal Phrakonkham (ECHA).

Academia: Dr Emilio Benfenati, Univ. of Milan.