

GUIDANCE ON A STRATEGY FOR GENOTOXICITY TESTING AND MUTAGENIC HAZARD ASSESSMENT OF CHEMICALS WITH EXISTING INADEQUATE GENOTOXICITY DATA.

Introduction.

1. The COM agreed to consider a strategy for the testing and assessment of chemicals with existing limited and inadequate genotoxicity data at the same time as the final postal consultation of the strategy for testing.
2. The draft strategy for chemicals with existing inadequate data (outlined in Annex 1) is based on the drafting previously submitted to the COM. A flow diagram summarising the COM testing strategy is provided as Annex 2. This is based on the flow diagram previously considered by COM at the June 2011 meeting. A flow diagram summarising testing/assessment for chemicals with inadequate data is appended as Annex 3. This is also based on a flow diagram previously seen by COM.
3. In addition a brief review of strategies adopted by the COM on chemical substances considered between 1999-2011 has been considered. This is presented as Annex 4. This is intended to aid Members' consideration of the strategy outlined in Annex 1

COM Discussion

4. One aspect that was raised during the postal consultation of Annex 1 with members was whether the strategy for chemicals with existing possibly inadequate genotoxicity data should be split into a testing section and a hazard assessment section. It was not considered practical to undertake such a split as the two processes are so closely interlinked. However one argument regarding the order of these two processes is that assessment precedes testing for chemicals with existing genotoxicity data. If this is agreed, then that title of the document and logic used in Annex1 would have to be altered to reflect this point.
5. Members are asked to considered the proposed strategy for chemical substances with existing inadequate genotoxicity data and provide the secretariat with comments.
5. Depending on comments received, a revised version may be circulated by post for agreement through Chairman's action or a further draft provided for the March 2012 meeting.

Secretariat August 2011