

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

GENOTOXICITY TESTING AND ASSESSMENT OF IMPURITIES

Overview of conclusions reached at March 2011 meeting.

1. The COM reached a number of interim conclusions at the March 2011 meeting which are summarised below for ease of reference.
2. Members are asked if there is any additional information they can provide particularly with reference to ongoing work by ICH and EFSA.
 - i) Members agreed the TTC was a useful concept in identifying impurities requiring genotoxicity assessment, although reference needed to be made to the classes of concern, e.g. aflatoxin-like, azoxy and N-nitroso compounds.
 - ii) Members agreed that a combination of Ames and MNvit would optimise the detection of mutagenic hazard of impurities.
 - iii) Thus, overall, the Committee agreed that impurities should be isolated and tested separately. QSAR data would be helpful, but would be limited in the case of novel structural moieties and in some instances where metabolic activation of pro-mutagens occurred.
3. A revised flow diagram is appended. What are members views?
4. Do Members have any further information to update the COM on international developments regarding impurities?

Secretariat May 2011

Figure 1: Strategy for the testing and assessment of impurities in chemical substances

