

COMMITTEE ON CARCINOGENICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT**OECD GUIDANCE DOCUMENT FOR THE PERFORMANCE OF CHRONIC TOXICITY AND CARCINOGENICITY STUDIES****Chapter 3.6 Investigations (including Histopathological Guidance)****Background**

The Organisation for Economic Cooperation and Development (OECD) is currently developing a Guidance document to accompany the revised Test Guidelines for carcinogenicity studies and chronic toxicity studies. The chapters anticipated for inclusion in the Guidance were discussed by the Committee at the April 2008 meeting. On the proposed Chapter on histopathology, Members considered that, although much guidance already exists on histopathology, it would be important to bring it into an OECD context. The COC recommended that the UK should propose leading on this chapter. The UK offer to lead on this Chapter was accepted by the OECD.

The UK agreed to a request from the OECD Secretariat to expand the contents of the Chapter to include all investigations. A draft outline of the Chapter is supplied at Annex I. The first draft of the Chapter has been developed from existing OECD Guidance¹, using STP Guidance documents and standard texts and published literature.

Members will note that there are considerable gaps and questions in the draft (indicated by bold magenta type). Two COC members and two COT members have already provided assistance or are in the process of providing text for the draft.

The comments of the COC are requested to prepare a draft to be submitted to the OECD in the summer of 2009. The final document will be an OECD document, not a COC document. Detailed discussion of the text is therefore not sought.

Questions to the COC

1. Does COC have any comments on the overall contents and structure of the Chapter?
2. Do any Members, apart from those already actively involved, wish to contribute to specific areas of the Chapter? Any such further assistance with the further development of the draft will be taken forward by correspondence by the UK National Coordinator for the OECD Test Guideline Programme.

Annex I

Draft Chapter 3.6 Investigations (including Histopathological Guidance)

Annex II

Draft Contents of the OECD Guidance Document on the Performance of Chronic Toxicity and Carcinogenicity Studies

¹ OECD Environment, Health and Safety Publications. Series on Testing and Assessment No. 35 and Series on Pesticides No. 14. Guidance notes for analysis and evaluation of chronic toxicity and carcinogenicity studies.