ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

Working Group on Good Laboratory Practice

DRAFT ANNOTATED AGENDA

Fourteenth Meeting of the Working Group on Good Laboratory Practice,
5-7 December 2001, beginning at 9h00 on Wednesday 5th December,
Hotel Vienna, Prague, Czech Republic

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DRAFT ANNOTATED AGENDA

Fourteenth Meeting
5th-7th December 2001, beginning at 9:00 on Wednesday, 5th December
Hotel Wienna, Prague, Czech Republic

1. Adoption of the draft agenda

2. Adoption of the draft summary record of the 13th Meeting

3. Secretariat’s report on events since the last meeting

4. Pilot project on mutual examination of compliance monitoring procedures
   a) Final interim evaluation of the Mutual Joint Visits: Report from the 4th MJV Steering Group
   b) Consideration of 17 MJV reports
   c) Preparation of evaluation phase:

5. Issues related to non-Member countries
   a) Progress report on implementation of C(97)114(Final)
   b) Implementation by South Africa of the Council Acts related to MAD: report from visiting team and follow-up

6. Technical issues

7. Draft Consensus Document on the Organisation and Management of Multi-Site Studies

8. Schedule of Activities for 2002


10. Any other business
Notes to the Agenda

ad 4a: The Steering Group for the MJV pilot project will have met in Montreal on 23 to 25 October to review the remaining MJV reports and to discuss the project overall. The conclusions and recommendations of the Steering Group on the specific MJV reports are the subject of item 4b. The Steering Group will also deal with any issues related to procedural aspects of the project based on the experience gained and these points will be discussed in Document No 1.

ad 4b: The remaining 17 MJV reports will have been finalised and reviewed by the MJV Steering Group, and conclusions and recommendations proposed. The reports will be circulated to Working Group Members only in preparation for the meeting (Documents Nos. 2-18). They will be introduced by the team leaders. The task of the Working Group is to note the reports of the MJV teams and the comments made by the visited authority as well as the conclusions and recommendations of the Steering Group. The opportunity will be given to clarify any issues related to the specific programmes and to provide guidance which will help improve them.

ad 4c: The first half of 2002 will be devoted to the evaluation of the MJV pilot phase, culminating in a discussion by the November Joint Meeting of the conclusions and recommendations of the Working Group for the future. Members of the Working Group have been requested to relate to the Secretariat in writing their experiences regarding the influence the project has had on data acceptance and issues related to potential non-tariff trade barriers, the benefits and disadvantages of the project as well as any information on real costs involved. Document No. 19 will present this information as a basis for a discussion of the outcome of and follow-up to the pilot project.

ad 5a: The Council has noted a document on the implementation to date of the 1997 Council Decision related to Adherence of Non-Member Countries to the OECD Council Acts related to the Mutual Acceptance of Data. This document is available for information to the Working Group. Slovenia will give a status report in light of its provisional adherence to the Council Acts. The Secretariat will report on progress made in the interim, especially with Brazil and India.

ad 5b: Document No. 20 sets out the report of the evaluation team which visited South Africa in February 2001. The Working Group is invited to discuss the report with the team and the Observer with South Africa and to agree on whether South Africa should be invited to participate as a full member in the MAD system.

ad 6: Room Document No. 1 sets out technical issues for discussion provided by Members of the Working Group. It also describes the reaction of the Working Group to the proposal to make citations from the summary records of the Working Group on the resolution of technical issues available to the public. The Working Group is invited to discuss whether and how such information should be disseminated in the future.
ad 7: Comments from many Member countries were received on the draft Consensus Document on the Organisation and Management of Multi-Site Studies. The Secretariat will work with the Chair and Vice-Chair of the Consensus Workshop and attempt to provide a revised draft to reflect these comments and get it to the Working Group for its consideration in advance of the meeting.

ad 8: The schedule of work to be undertaken in 2002 is set out in Document No. 22. The possible activity to be undertaken on the application of the GLP Principles to *in vitro* testing will be presented by the Chairman.

ad 9: Members of the Working Group were invited to provide their ideas on improving the exchange of information on specific test facilities among themselves, including development of an on-line system and specific information needs. Any responses received will be forwarded to the Steering Group on Information Exchange as input for its status report.