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Advisory Document of the Working Group on Good Laboratory Practice

Requesting and Carrying Out Inspections and Study Audits in Another Country

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No. 12

Advisory Document of the Working Group on GLP

Requesting and Carrying Out Inspections and Study Audits in Another Country

Environment Directorate

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No. 1, *OECD Principles of Good Laboratory Practice* (as revised in 1997)

No. 2, *Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice* (1995)

No. 3, *Revised Guidance for the Conduct of Laboratory Inspections and Study Audits* (1995)

No. 4, *Quality Assurance and GLP* (as revised in 1999)

No. 5, *Compliance of Laboratory Suppliers with GLP Principles* (as revised in 1999)

No. 6, *The Application of the GLP Principles to Field Studies* (as revised in 1999)

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No. 8, *The Role and Responsibilities of the Study Director in GLP Studies* (as revised in 1999)

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This publication was produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC).

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. UNITAR joined the IOMC in 1997 to become the seventh Participating Organization. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

Foreword

Environmental health and safety studies for the assessment of chemicals and chemical products are increasingly being carried out in multiple sites. This holds not only for field studies, but also for various phases of toxicology studies. The Revised Principles of Good Laboratory Practice[*], adopted by OECD in 1997, cover the various aspects of the organisation of such studies. Nevertheless, the Working Group on Good Laboratory Practice felt that further guidance was needed about requesting and carrying out inspections and study audits of multi-site studies when the study site(s) are located in another country than that of the main test facility, as accorded by the 1989 Council Decision-Recommendation on Compliance with Principles of GLP [C(89)87(Final), Part II, 2.iii].

The Working Group therefore established a Steering Group on Multi-site Studies under the leadership of Germany. The Group met in Berlin on 2nd and 3rd September 1999 and included participants from the following countries: Denmark, France, Germany, the Netherlands, Sweden, Switzerland, the United Kingdom and the United States. It was chaired by Hans-Wilhelm Hembeck (Germany). The document prepared by the Steering Group was examined by the Working Group at its 12th Meeting in January 2000, where it was amended and endorsed.

The Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology at its 30th Meeting in turn endorsed the document and recommended that it be declassified under the authority of the Secretary-General. The Joint Meeting recommended that it be published as an Advisory Document of the Working Party on GLP in the OECD series on GLP and Compliance Monitoring.

[*] See No. 1 of the Series on GLP and Compliance Monitoring, OECD, Paris, 1998

Advisory Document of the Working Group on GLP

RECOMMENDATIONS FOR REQUESTING AND CARRYING OUT INSPECTIONS AND STUDY AUDITS IN ANOTHER COUNTRY

Introduction

In the 1989 Council Decision-Recommendation on Compliance with the Principles of Good Laboratory Practice (C(89)87/Final), Member countries decided that, for purposes of the recognition of the assurance by another Member country that test data have been generated in accordance with GLP Principles countries "shall implement procedures whereby, where good reason exists, information concerning GLP compliance of a test facility (including information focusing on a particular study) within their jurisdiction can be sought by another Member country." It is understood that such procedures should only be applied in exceptional circumstances.

The Working Group on Good Laboratory Practices proposed clarification of this decision based on the Revised OECD Principles of GLP and recommended the procedures set out below. This clarification was considered necessary, since it was recognised that some test facilities have test sites located under the jurisdiction of another country. These facilities or sites may not necessarily be part of the GLP compliance monitoring programme of the country of location, although many Member countries consider this desirable and useful.

The Working Group agreed, that the use of the term "test facility" in the 1989 Council Act encompassed both "test facility" and "test site" as defined in the Revised OECD Principles of GLP. Therefore any Member country can request an inspection/study audit from both test facilities and test sites located in another country. This request could concern any organisation associated with regulated GLP studies, whether these be main test facilities or test sites (dependent or independent of the test facility) which carry out phases of a study such as chemical analysis, histopathology or field studies.

Requests can also be made to inspect associated organisations such as independent Quality Assurance or archiving facilities if national legislation allows. However, this information exchange could be of a more informal nature and such operations need not necessarily appear in the Annual Overviews of Inspected Facilities exchanged among Members of the Working Group on GLP. These Annual Overviews should, however, include test facilities and test sites which were inspected or in which study audits were carried out.

In order to "implement procedures" to allow for this information exchange to take place smoothly and efficiently among monitoring authorities, to avoid duplication and wasting of resources and to assure that there is adequate compliance monitoring, the Working Group agreed that a process needed to be established for requesting inspections or study audits in another country.

The Working Group agreed that if justifiable requests to confirm compliance with GLP are made, every effort should be made to accommodate requests for inspections or study audits of test facilities or sites in other countries. If the country where the facility or site is located cannot accommodate the request in the framework of its current GLP monitoring programme and/or schedule, an alternative could be to allow the

requesting country to undertake the inspection and/or audit itself (at its own expense as mutually agreed by both parties). Refusal to accommodate such requests may result in rejection of studies from the facility or site concerned. It was agreed that all Members of the Working Group on GLP should be informed of such refusals and that the circumstances should be discussed in the Working Group.

Recommended Procedures to be followed in requesting and carrying out inspections and study audits in another country

1. The request for an inspection and/or study audit in another country should be made in writing and justified. The two countries should work out the arrangements to accommodate the request and for provision appropriate materials in a timely manner.

2. The liaison and lines of communication should be between the two national GLP Monitoring Authorities concerned.

3. The inspection/study audit will normally be led by the monitoring authority where the facility and/or site is located. An inspector or inspectors from the requesting country can be present at the inspection/study audit. Receiving authorities may participate if appropriate. The requesting country shall cover any costs involved for its own personnel.

4. The inspection/study audit report should be submitted to the requesting country (in an appropriate language as agreed between the two countries), with the appropriate measures taken to cover concerns about protection of commercial and industrial secrecy as required by national legislation.

5. Any major findings during such inspections/study audits should be followed up by the appropriate monitoring authority(ies).

6. Financial arrangements for inspections and study audits undertaken in this context will be made by the country in which they take place. The requesting country cannot be charged for this work.

7. Inspections and study audits undertaken in this context should appear in the Annual Overview of the country that led the inspection/study audit.