ANNEX X

REFERRED TO IN ARTICLE 4.9

GOOD LABORATORY PRACTICE

ANNEX X

REFERRED TO IN ARTICLE 4.9 (ANNEXES)

GOOD LABORATORY PRACTICE

ARTICLE 1

Scope

This Annex shall apply to all chemicals, including pharmaceutical products, which are industrially manufactured in an EFTA State or Malaysia, and to which Good Laboratory Practice (GLP) requirements apply.

ARTICLE 2

Definition

For the purposes of this Annex, "GLP system" means a system compliant with the most recent internationally recognised standards of the OECD programme on Mutual Acceptance of Data (MAD),[1] related to non-clinical safety studies of chemicals.

ARTICLE 3

Affirmation

1. The Parties acknowledge facing similar challenges when assessing and ensuring the high quality of non-clinical safety testing of chemicals. A key instrument in this regard is the establishment and enforcement of internationally recognised GLP standards to ensure trust in the data resulting from such studies.

2. The Parties recall the importance of internationally recognised GLP standards and compliance monitoring to ensure the generation of high quality and reliable test data for non-clinical safety testing to facilitate the conformity assessment procedures of chemicals.

3. The Parties recognise that international harmonisation of testing procedures facilitates the acceptance of non-clinical test data.

[1] Following the requirements set out in the 1981 OECD Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals, together with the OECD Guidelines for the Testing of Chemicals (C(81)30(Final), as amended) and the OECD Principles of Good Laboratory Practice, the 1989 Council Decision-Recommendation on Compliance with Principles of Good Laboratory Practice (C(89)87(Final), as amended), and the 1997 OECD Council Decision concerning the Adherence of non-Member Countries to the Council Acts related to the Mutual Acceptance of Data in the Assessment of Chemicals (C(97)114 (Final), as amended).

ARTICLE 4

GLP System

Compliance of a Party's GLP system with international GLP standards shall be assumed through full adherence of a Party's competent authority to the MAD.

ARTICLE 5

Acceptance of GLP Testing Data

Following confirmed compliance of a Party's GLP system with international GLP standards, data generated by that Party in accordance with GLP and recognised test methods shall be accepted by another Party for the purposes of assessment and other uses relating to the protection of human health and the environment. In particular, such data shall be accepted as part of the conformity assessment procedures applying to chemicals.

ARTICLE 6

Exchange of GLP Data

Upon request and for use exclusively for the acceptance of GLP testing data, the GLP monitoring authorities shall exchange GLP inspection reports, unless the concerned test facility disagrees.

ARTICLE 7

Internal Procedures

1. The Parties shall set up a GLP compliance monitoring programme and keep an updated register of test facilities in their territories that comply with the principles of the GLP system.

2. When reporting test data, the test facilities referred to in paragraph 1 shall certify that the tests have been carried out in conformity with the principles of the GLP System.

ARTICLE 8

Safeguard Clause for Inspections

In exceptional circumstances, the Parties may ask for a study audit or an inspection of a test facility in the territory of another Party. Such request shall be duly justified, notified in advance to the other Parties and be carried out by the GLP monitoring authority. The latter shall accept members of the GLP monitoring authorities of the requesting Party as observers.

ARTICLE 9

Confidentiality

Each Party shall treat as confidential information submitted by another Party which that Party has designated as confidential.

ARTICLE 10

Contact Points

For the purposes of this Annex, the contact points established under Article 4.11 (Contact Points) of the Agreement shall keep an updated list of contact points within the respective competent authorities for any technical questions, such as exchange of inspection reports or technical requirements.