(b) For the purpose of this Sectoral Annex, any term, unless otherwise defined in this Protocol, has the meaning assigned to it in the "OECD Principles of Good Laboratory Practice" as contained in Annex II of the OECD Council Decision of 12 May 1981 [C(81)30(Final)], the "Guides for Compliance Monitoring Procedures for Good Laboratory Practice" as contained in Annex I of the OECD Council Decision – Recommendation of 2 October 1989 [C(89)87(Final)], the GLP Consensus Document "The Application of the GLP Principles to Field Studies" (OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 6), and all amendments made thereto.

(c) It is understood that the term "amendment" referred to in Part B of this Sectoral Annex includes the following cases:

(i) a Party entirely or partially changes its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex, whether or not those names are changed;

(ii) a Party repeals its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex and adopts new laws, regulations and/or administrative provisions substituting for the previous laws, regulations and/or administrative provisions, whether or not the previous names are changed; and

(iii) a Party incorporates the whole or a relevant part of its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex into other laws, regulations and/or administrative provisions.

3. In making amendments to the laws, regulations and administrative provisions specified in Section III of Part B of this Sectoral Annex, the Parties should take account of the need to maintain consistency with the relevant decisions and recommendations of the OECD.

4. With respect to paragraph 2 of Article 2 of this Protocol, each Party shall, as a result of the acceptance of the confirmation of test facilities by the Competent Authorities of the other Party, accept the data for a test item generated by the confirmed test facilities as equivalent to the data generated by its own test facilities which are confirmed to be compliant with the principles of GLP, taking into account the equivalence of GLP compliance monitoring programme of both Parties, which are consistent with the OECD Council Decision-Recommendation of 2 October 1989 [C(89)87(Final)] as amended by the OECD Council Decision of 9 March 1995 [C(95)8(Final)], provided that:

(a) a certificate or an alternative document on the GLP compliance status of the test facility issued by the Competent Authority of that other Party, in accordance with the applicable laws, regulations and administrative provisions of that other Party specified in Section III of Part B of this Sectoral Annex, is attached to the data; and

(b) the testing for which the data is generated is covered by the principles of GLP in both Parties pursuant to the applicable laws, regulations and administrative provisions of each Party.

5.(a) The list of the confirmed facilities referred to in paragraphs 3 and 6 of Article 8 of this Protocol shall be provided in an appropriate agreed format and include the following information:

(i) the name and address of the test facility;

(ii) the dates of verification or confirmation;

(iii) the GLP compliance status; and

(iv) the areas of expertise as listed in point 4 of the Appendix to Annex III of the OECD Council Decision-Recommendation of 2 October 1989 [C(89)87(Final)].

(b) Each Party shall, to the extent possible, provide the other Party with additional information on the confirmed facilities upon a reasoned request by that other Party.