Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (Codified version) (Text with EEA relevance)

Article 6

1 Where a Member State has sufficient reason to believe that a laboratory in another Member State claiming GLP compliance has not carried out a test in accordance with GLP, it may request further information from that Member State and in particular may request a study audit, possibly in conjunction with a new inspection.

Should it not be possible for the Member States concerned to reach agreement, the Member States in question shall immediately inform the other Member States and the Commission, giving reasons for their decision.

2 The Commission shall examine as soon as possible the reasons put forward by the Member States within the Committee referred to in Article 7(1); it shall then take the appropriate measures in accordance with procedure referred to in Article 7(2). It may in this connection ask for expert opinions from the designated authorities in the Member States.

[[F1]3 The Commission is empowered to adopt delegated acts in accordance with Article 6a amending this Directive in order to resolve the matters referred to in paragraph 1. Amendments to Annex I shall not change its nature of providing guidance for compliance monitoring procedures for GLP and for the conduct of test facility inspections and study audits.**]**

Textual Amendments

F1 Substituted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).