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 4

1 Each year, Member States shall draw up a report relating to the implementation of GLP within their territory.

This report shall contain a list of laboratories inspected, the date on which such inspection was carried out and a brief summary of the conclusions of the inspections.

2 The reports shall be forwarded to the Commission each year, not later than 31 March. The Commission shall communicate them to the Committee referred to in Article 7(1). The Committee may request information in addition to those elements mentioned in paragraph 1 of this Article.

3 Member States shall ensure that commercially sensitive and other confidential information to which they gain access as a result of GLP compliance monitoring activities is made available only to the Commission, to national regulatory and designated authorities and to a laboratory or study sponsor directly concerned with a particular inspection or study audit.

4 The names of laboratories subject to inspection by a designated authority, their GLP compliance status and the dates upon which laboratory inspections or study audits have been conducted shall not be considered to be confidential.