SECTORAL ANNEX
ON
GOOD LABORATORY PRACTICE (GLP)
FOR CHEMICALS

PART A

1. This Sectoral Annex applies to:

   (a) the confirmation of the compliance of test facilities with the principles of GLP for the testing of chemicals, being either substances or preparations, as set out in the laws, regulations and administrative provisions of each Party specified in Section I of Part B of this Sectoral Annex; and,

   (b) the acceptance of the data generated by confirmed test facilities.

2. (a) For the purpose of this Sectoral Annex:

   (i) “criteria for confirmation” are the principles of GLP as stipulated in the laws, regulations and administrative provisions of each Party specified in Section III of Part B of this Sectoral Annex and that are consistent with Annex II of the OECD Council Decision of 12 May 1981 [C(81)30(Final)] as amended by the OECD Council Decision of 26 November 1997 [C(97)186(Final)]; and

   (ii) “verification” means the monitoring of the compliance of a test facility with the principles of GLP by procedures such as study audits and inspections that are set out in the laws, regulations and administrative provisions of each Party specified in Section III of Part B of this Sectoral Annex and that are consistent with the OECD Council Decision – Recommendation of 2 October 1989 [C(89)87(Final)], and in particular its Annexes I and II, as amended by the OECD Council Decision of 9 March 1995 [C(95)8(Final)].

(b) For the purpose of this Sectoral Annex, any term, unless otherwise defined in this Agreement, 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.

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

3. With respect to paragraph 2 of Article 2 of this Agreement, 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.

4. (a) The list of the confirmed facilities referred to in paragraphs 3 and 6 of Article 8 of this Agreement 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.

(c) Each Party shall transmit to the other Party, without delay, information on any withdrawal of the certificate of a confirmed test facility if the facility has been found to be non-compliant with the principles of GLP.

5. (a) Each Party may request the other Party, by indicating in writing a reasoned doubt on whether a study was conducted in accordance with the principles of GLP, to conduct further inspections or study audits on a confirmed test facility, in accordance with the applicable laws, regulations and administrative provisions of that other Party.

(b) The requested Party shall inform the requesting Party of the results of the inspections or study audits, or provide an explanation why such an inspection or study audit has not been carried out.

(c) The requesting Party shall not be obliged to accept the data generated by the test facility concerned from the date on which the request is made, until the results of the further inspection or study audit conducted by the Competent Authority of the requested Party have re-confirmed the compliance of the test facility with the principles of GLP.

(d) If, in exceptional cases, doubts persist, and the requesting Party can justify a specific concern, that Party may contest the compliance of the test facility concerned in accordance with the provisions of Article 7 of this Agreement.

PART B

SECTION I: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE COVERAGE OF CHEMICALS SUBJECT TO TESTING IN ACCORDANCE WITH THE PRINCIPLES OF GLP

EUROPEAN COMMUNITY	JAPAN
1. Medicinal Products: (a) Council Directive 87/19/EEC of 22 December 1986 amending Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products and amendments thereto (b) Commission Directive 91/507/EEC of 19 July 1991 modifying the Annex to Council Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products and amendments thereto	1. Pharmaceuticals: (a) Pharmaceutical Affairs Law (Law No.145, 1960) and amendments thereto (b) Ordinance of the Pharmaceutical Affairs Law (Ordinance of the Ministry of Health and Welfare No.1, 1961) and amendments thereto 2. Veterinary Drugs: (a) Pharmaceutical Affairs Law (Law No.145, 1960) and amendments thereto (b) Ordinance on the Control of Veterinary Drugs etc. (Ordinance of the Ministry of Agriculture and Forestry No.3, 1961) and amendments thereto 3. Agricultural Chemicals: Agricultural Chemicals Regulation Law (Law No.82, 1948) and amendments thereto

2. Veterinary Medicinal Products:

(a) Council Directive 87/20/EEC of 22 December 1986 amending Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products and amendments thereto

(b) Commission Directive 92/18/EEC of 20 March 1992 modifying the Annex to Council Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products and amendments thereto

3. Plant Protection Products:

Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market as last amended by Commission Directive 95/35/EC of 14 July 1995 and amendments thereto

4. Feed Additives:

(a) Law concerning Safety Assurance and Quality Improvement of Feed (Law No.35, 1953) and amendments thereto

(b) Re: the Establishment of the Standards for Evaluation of Feed Additives (4 Chiku A No.201 (1992)) and amendments thereto

5. New Substances and Designated Substances:

(a) Law concerning the Examination and Regulation of Manufacture etc. of Chemical Substances (Law No.117, 1973) and amendments thereto

(b) Ordinance prescribing Test Items etc. Relating to New Chemical Substances and Toxicity Research of Designated Chemical Substances (Ordinance of the Prime Minister’s Office, the Ministry of Health and Welfare and the Ministry of International Trade and Industry No.1, 1974) and amendments thereto

4. Biocides:

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market and amendments thereto

5. Feed Additives:

Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition as amended by Commission Directive 94/40/EC of 22 July 1994 and amendments thereto

6. New and Existing Chemicals:

(a) Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances and amendments thereto

(b) Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations and amendments thereto

6. Substances Controlled for the Prevention of Health Hazard of Workers:

(a) Industrial Safety and Health Law (Law No.57, 1972) and amendments thereto

(b) Ordinance on Industrial Safety and Health (Ordinance of the Ministry of Labour No.32, 1972) and amendments thereto

(c) Council Regulation (EEC) No.793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances and amendments thereto 7. Food Additives: (a) Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs and amendments thereto (b) Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs and amendments thereto 8. Cosmetics: Council Directive 93/35/EEC of 14 June 1993 amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products and amendments thereto	

SECTION II: COMPETENT AUTHORITIES

EUROPEAN COMMUNITY	JAPAN
Competent Authorities of the European Community are the following authorities of the Member States of the European Community or authorities succeeding them: Belgium For all: Institut scientifique de la santé publique/ Wetenschappelijk Instituut Volksgezondheid Denmark For industrial chemicals: Erhvervsfremme Styrelsen For medicinal products: Lægemiddelstyrelsen Germany For all: Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit Greece For all: Γενικό Χημείο του Κράτους	Competent Authorities of Japan are the following authorities or authorities succeeding them: For Pharmaceuticals: Ministry of Health, Labour and Welfare For Veterinary Drugs: Ministry of Agriculture, Forestry and Fisheries For Agricultural Chemicals: Ministry of Agriculture, Forestry and Fisheries For Feed Additives: Ministry of Agriculture, Forestry and Fisheries For New Substances and Designated Substances: Ministry of Health, Labour and Welfare Ministry of Economy, Trade and Industry For Substances Controlled for the Prevention of Health Hazard of Workers: Ministry of Health, Labour and Welfare

Spain For medicinal products: Agencia Española del Medicamento, Subdirección General de Seguridad de Medicamentos For pesticides: Ministerio de Agricultura, Pesca y Alimentación, Dirección General de Agricultura For industrial chemicals: Ministerio de Ciencia y Tecnología, Subdirección General de Calidad y Seguridad Industrial For additives: Ministerio de Sanidad y Consumo, Subdirección General de Seguridad Alimentaria For biocides: Ministerio de Sanidad y Consumo, Subdirección General de Sanidad Ambiental y Salud Laboral France For industrial chemicals, pesticides and other than medicinal products and cosmetics: Groupe interministériel des produits chimiques For medicinal products (except veterinary medicinal products) and cosmetics: Agence française de sécurité sanitaire des produits de santé (AFSSAPS) For veterinary medicinal products: Agence française de sécurité sanitaire des aliments Agence nationale du médicament vétérinaire Ireland For all: National Accreditation Board	

Italy For all: Ministero della Sanità Netherlands For all: Ministerie van Volksgezondheid, Welzijn en Sport, Inspectie voor de Gezondheidszorg (GLP - afdeling) Austria For all: Bundesministerium für Land– und Forstwirtschaft, Umwelt und Wasserwirtschaft Portugal For industrial chemicals and pesticides Under the authority of the Government of Portugal: Instituto Português da Qualidade (IPQ) Ministério da Economia For medicinal products and veterinary medicinal products: Instituto Nacional da Farmácia e do Medicamento (INFARMED) Finland For all: Sosiaali- ja terveydenhuollon tuotevalvontakeskus/Social- och hälsovårdens produkttillsynscentral Sweden For medicinal products, veterinary medicinal products, hygiene and cosmetics products: Läkemedelsverket For all other products: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) United Kingdom For all: Department of Health, Good Laboratory Practice Monitoring Authority	

SECTION III: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE PRINCIPLES OF GLP, VERIFICATION AND CONFIRMATION

EUROPEAN COMMUNITY	JAPAN
1. Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances as last amended by Commission Directive 1999/11/EC of 8 March 1999 and amendments thereto 2. Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of Good Laboratory Practice (GLP), as last amended by Commission Directive 1999/12/EC of 8 March 1999 and amendments thereto	1. Pharmaceuticals: (a) Pharmaceutical Affairs Law (Law No.145, 1960) and amendments thereto (b) Ordinance prescribing Standards for the Conduct of Non-clinical Laboratory Studies on Safety of Drugs (Ordinance of the Ministry of Health and Welfare No.21, 1997) and amendments thereto (c) Re: Treatment of Materials concerning Non-clinical Laboratory Studies on Safety of Drugs Which Should be Attached to the Application for the Product (import) Approval etc. (Yakushin No.253 (1997) - Yakuan No.29 (1997)) and amendments thereto (d) Re: the Establishment of the Guidelines for the Conduct of GLP On-site Inspection (Yakushin No.254 (1997) - Yakuan No.30 (1997)) and amendments thereto 2. Veterinary Drugs: (a) Pharmaceutical Affairs Law (Law No.145, 1960) and amendments thereto

	(b) Ordinance prescribing Standards for the Conduct of Non-clinical Laboratory Studies on Safety of Veterinary Drugs (Ordinance of the Ministry of Agriculture, Forestry and Fisheries No.74, 1997) and amendments thereto (c) Re: Management of the Pharmaceutical Affairs Law (12 Chiku A No.729 (2000)) and amendments thereto 3. Agricultural Chemicals: (a) Agricultural Chemicals Regulation Law (Law No.82, 1948) and amendments thereto (b) Re: the Proper Implementation of Toxicological Studies on Agricultural Chemicals (11 Nosan No.6283 (1999)) and amendments thereto 4. Feed Additives: (a) Law concerning Safety Assurance and Quality Improvement of Feed (Law No.35, 1953) and amendments thereto (b) Re: Standards for the Conduct of Animal Studies on Feed Additives (63 Chiku A No.3039 (1988)) and amendments thereto (c) Re: the Establishment of the Guidelines for the Inspection based on the Standards for the Conduct of Animal Studies on Feed Additives (1 Chiku A No.3441 (1990)) and amendments thereto

	5. New Substances and Designated Substances: (a) Law concerning the Examination and Regulation of Manufacture etc. of Chemical Substances (Law No.117, 1973) and amendments thereto (b) Re: Standard concerning Testing Facility Provided for in Article 4 of the Ordinance prescribing Test Items etc. Relating to New Chemical Substances and Toxicity Research of Designated Chemical Substances (Kanpogyo No.39 (1984) – Yakuhatsu No.229 (1984) - 59 Kikyoku No.85 (1984)) and amendments thereto (c) Re: Test Results Used as Criteria for Determination at the Examination etc. of New Chemical Substances (Eisei No.39 (1988) – 63 Kikyoku No.822 (1988)) and amendments thereto 6. Substances Controlled for the Prevention of Health Hazard of Workers: (a) Industrial Safety and Health Law (Law No.57, 1972) and amendments thereto (b) The Standard to be Satisfied by the Test Facility etc. under the Provisions of Article 34-3 (2) of the Ordinance on Industrial Safety and Health (Notice of the Ministry of Labour No.76, 1988) and amendments thereto

	(c) Re: Implementation of the Ordinance to Amend a Part of the Ordinance on Industrial Safety and Health, the Ordinance to Amend a Part of the Ordinance on Safety of Boiler and High Pressure Vessels and the Ordinance to Amend a Part of the Ordinance on Preventing Organic Solvents Poisoning, etc. (Kihatsu No.602 (1988)) and amendments thereto (d) Re: the Establishment of the Guideline of Certification of Compliance of Test Facilities etc. with GLP under the Industrial Safety and Health Law (Kihatsu No.123 (1989)) and amendments thereto