CHAPTER 9
HEALTH, PERFORMANCE, QUALITY, AND SAFETY INSPECTION/CERTIFICATION PROGRAMS

U.S.–European Union Safe Harbor Privacy Program, ITA, U.S. Department of Commerce

The Safe Harbor is a voluntary, self-certification system designed to help U.S. companies avoid interruptions in their business dealings with the European Union (EU) or prosecution by European authorities under European privacy laws. The EU Directive on Data Protection took effect in 1998 and prohibits the transfer of personally identifiable information to non-EU nations that fail to meet the European "adequacy" standard for privacy protection. As a result of the differing approaches to privacy established by the European Commission and the United States, this EU directive could significantly hamper the ability of U.S. companies to engage in many trans-Atlantic transactions, including e-commerce. The Safe Harbor framework was developed by the Department of Commerce, in consultation with the EU, industry, and non-governmental organizations, to bridge these different privacy approaches and provide a streamlined means for U.S. organizations to comply with the EU directive.

Contact: Certification may be submitted via the Internet or by sending a letter to Shannon Ballard and Lauren Saadat, Room 2003, International Trade Administration, Department of Commerce, 14th and Constitution Avenue, NW, Washington, DC 20230; (202) 482-3709; fax (202) 482-5522, or e-mail *Shannon.Ballard@mail.doc.gov*, or *Lauren.Saadat@mail.doc.gov*. The home page is *www.export.gov/safeharbor*.

Food and Drug Administration, FDA Export Certificates for U.S. Products

Foreign customers and governments often request that U.S. companies submit an export certificate when they ship products regulated by the Food and Drug Administration (FDA) abroad. FDA export certificates are for export purposes only and may not be used in domestic advertising or promotion. The FDA, at the request of U.S. exporters, will issue export certificates for human drugs and biological products, animal drugs, and medical devices that meet the applicable requirements of the Federal Food, Drug, and Cosmetic Act. The FDA certifies that the products meet domestic U.S. requirements and are eligible for sale in the United States or, in cases where the product may not be marketed in the United States, that the product may be exported under U.S. law. The type of application and information required may differ according to the type of certificate requested and the commodity being exported. Exporters are urged to contact the appropriate center within the FDA for guidance on requesting procedures and export certificate eligibility for their particular country.

Contact: A general information document, *Guidance for Industry—FDA Export Certificates*, is available at *www.fda.gov/cber/gdlns/exprtcert.htm*. The FDA home page, *www.fda.gov*, also provides links to FDA centers. For certificates relating to drugs, contact the Center for Drug Evaluation and Research at (301) 827-8983; for biologics, contact the Center for Biologics Evaluation and Research at (301) 827-6201; for medical devices, contact the Center for Devices and Radiological Health, Office of Compliance, Information Processing, and Office of Automation Branch, at (301) 827-4555, ext. 110; and for animal drugs, contact the Center for Veterinary Medicine at (301) 827-0178.

Inspection Certificates for Food and Agricultural Exports, U.S. Department of Agriculture

Several agencies within the USDA provide inspection services when certificates are required to clear imported products through overseas customs or when requested by foreign buyers:

• The Animal and Plant Health Inspection Service (APHIS) provides exporters information on import and export requirements for plant and animal products and by-products. Phytosanitary inspections for plant materials are offered at ports and interior locations. Animal health certificates for animal products, including hides and pet foods, can be obtained from your local APHIS veterinarian.

Contact: For plant export certification, call (301) 734-8537; for animal health certification, call (301) 734-3277. Visit the APHIS home page at *www.aphis.usda.gov*, and look for "Plant/Animal/Health."

• The Federal Grain Inspection Service (FGIS) provides inspections under the U.S. Grain Standards Act and the Agricultural Marketing Act. The FGIS also conducts mandatory inspections for all exported grain. Products examined by the FGIS include rice, peas, beans, lentils, all grains, and grain-based processed products.

Contact: For more information, call Robert Lijewski, Standards and Procedures Branch, (202) 720-0252, fax (202) 720-1015, e-mail *robert.s.lijewski@usda.gov*, or visit *www.usda.gov/gipsa*.

• The Food Safety and Inspection Service (FSIS) guarantees that meat and poultry products are properly labeled and U.S. inspected and approved.

Contact: Call the FSIS at (402) 221-7400; fax (402) 221-7479, or visit *www.fsis.usda.gov*.

• The USDA's Agricultural Marketing Service (AMS), in cooperation with state agencies, offers official grading, inspection, and certification services; production and processing verification services; and chemical and microbiological testing services for a variety of agricultural products, including organic products. Grading, inspection, and certification services can be based on U.S. grade standards developed by the USDA for these products, or they can be based on applicant specifications and processes.

Contact: For more information about this voluntary food quality certification service, call Kenneth C. Clayton, associate administrator, AMS, at (202) 720-4276, fax (202) 720-8477, or e-mail *kenneth.clayton@usda.gov*. The home page is *www.ams.usda.gov/index.htm*. AMS program areas include cotton—*www.ams.usda.gov/cotton*, dairy—*www.ams.usda.gov/dairy*, fruits and vegetables—*www.ams.usda.gov/fv*, livestock and seed—*www.ams.usda.gov/lsg*, poultry—*www.ams.usda.gov/poultry*, science and technology—*www.ams.usda.gov/science*, tobacco—*www.ams.usda.gov/tob*, and transportation and marketing—*www.ams.usda.gov/tmd*, and *www.ams.usda.gov/civilrights*. The AMS International Services home page is *www.ams.usda.gov/international*.

Seafood Inspection Program, National Oceanic and Atmospheric Administration, U.S. Department of Commerce

The National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program includes consumer safety officers and trade specialists who offer a range of services to assist U.S. fishing industry businesses engaged in the exports of fish and fishery products. Besides inspecting and certifying products for export, staff members advise seafood marketers about foreign regulations and maintain contact with foreign government regulatory agencies to resolve sanitary and hygienic issues. NOAA also promotes and facilitates the trade of U.S. fishery products internationally. The Seafood Inspection Program can verify, through on-site audits, that foreign processors meet U.S. Food and Drug Administration and U.S. Department of Commerce regulations governing the control of food safety hazards and sanitary hygienic conditions including the construction and maintenance of facilities and equipment, processing techniques, and employee practices in the production of fishery products for human consumption.

Contact: For more information, call Kimberly Young, Seafood Inspection Program, (800) 422-2750 or (301) 713-2355; fax (301) 713-1081; or visit *http://seafood.nmfs.noaa.gov*.

Environmental Technology Verification Program, U.S. Environmental Protection Agency

The Environmental Technology Verification (ETV) program verifies the performance characteristics of commercial-ready environmental technologies through the evaluation of objective, quality-assured data. The program provides potential purchasers and permitters, in the United States and abroad, with an independent and credible assessment of innovative environmental technologies. This voluntary program currently verifies technologies in the following categories: drinking water systems, site characterization and monitoring, innovative coatings and coating equipment, indoor air products, advanced monitoring systems, air pollution control technology, greenhouse gas technology, wet weather flow technologies, and source water protection technologies. A center for verifying pollution prevention, recycling, and waste treatment technologies is being planned.

Contact: To learn more, visit the ETV home page at *www.epa.gov/etv*.

Wholesaler's Basic Permit, Alcohol and Tobacco Tax and Trade Bureau, U.S. Department of the Treasury

A Wholesaler's Basic Permit from the Tobacco Tax and Trade Bureau (TTB), the agency that administers regulations relating to alcohol beverages, is required to export wine, beer, and distilled spirits on a wholesale level. A background check is required before issuance of a Wholesaler's Basic Permit. The United States does not require a permit for alcohol sold abroad on a retail level. The foreign country may mandate specific documentation. Specialists at TTB can help companies navigate the application process.

Contact: To find out how to apply for a permit, call the National Revenue Center at (877) 882-3277 (toll free) or (513) 684-3334, or visit *www.ttb.gov*.