NOTIFICATION FROM THE UNITED STATES

Attached is a notification received from the United States in response to the request in GATT/AIR/2087 that contracting parties make available any relevant information which would enable the secretariat to prepare, by mid-1985, basic documentation designed to facilitate discussing the matter.

The following information is furnished in response to GATT/AIR/2087 which requests that contracting parties make available any relevant information which would enable the Secretariat to prepare documentation to facilitate discussion of problems relevant to the GATT in relation to exports of domestically prohibited goods.

The United States believes that it is extremely important for countries to share information concerning domestically banned or severely restricted products in international trade. Consequently, the United States has enacted a series of laws which establishes an extensive notification system. This system is intended to provide relevant information to other countries and interested international organizations concerning certain banned or severely restricted products.

There are twelve principal U.S. statutes1 which set standards for the manufacture or use of various substances in domestic commerce, and establish conditions limiting the entry of substances not meeting these standards into international trade. While the export provisions of these laws differ, a generalization can be made that the laws relating to chemicals and consumer products require notification of the foreign government involved of requests to export a product the sale of which is banned or the use of which is restricted in the United States. Foods which are banned for domestic sale cannot be exported at all. A description of these laws and their implementing regulations is contained on pages 3-8 of this notification.

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As a general matter, the term used in the 1982 Ministerial decision, "banned by their national authorities for sale on their domestic markets on grounds of human health and safety" is not applicable to many U.S. regulatory schemes. In particular, it is not pertinent to U.S. laws relating to chemical products and pharmaceuticals. For example, pesticides and pharmaceuticals must be registered or approved for specific uses prior to being marketed. In obtaining such approval, the regulatory agencies might impose certain restrictions on the sale or use of a product, as in the case of pharmaceuticals which can be sold only by prescription. Furthermore, a regulatory agency may take action to ban a particular use of a product, such as a pesticide for which the Environmental Protection Agency has taken regulatory action on some uses, but permit other uses. Consequently, chemical products are rarely "banned" entirely from sale on the domestic market.

In addition to enacting these domestic statutes, the United States has participated actively in the development of notification schemes in international organizations with a specialization in the health and environment fields. These activities are briefly described on pages 9-10.
Description of Principal U.S. Statutes Relevant to the Export of Domestically Prohibited Goods

1. The Consumer Product Safety Act

The Consumer Product Safety Act provides for the establishment of product safety standards for certain products sold in the domestic market. Under the Act, which is administered by the Consumer Product Safety Commission (CPSC), a product which does not conform with the applicable standards or which is determined to be a hazardous product and banned for sale in the domestic market and which has not been distributed in domestic commerce may be exported if the following requirements are satisfied. First, the prospective exporter must file a statement with the CPSC giving the intended date of shipment, the country and port of destination, the quantity to be exported, and such other information as the Commission may require by regulation. The exporter must file his notice at least thirty days before export, although under certain circumstances this time-period may be reduced to fewer than ten days. Upon receipt of such a notice, the CPSC must promptly notify the government of the importing country of the pending shipment and the basis on which the product does not conform to the safety standard or rule. Following receipt of this notification, the government of the importing country may take such action as it deems appropriate with regard to the pending transaction.

2. The Federal Hazardous Substances Act

The Federal Hazardous Substances Act provides the CPSC with the authority to regulate "hazardous substances," defined to include substances which are toxic, corrosive, irritant, a strong sensitizer, flammable or combustible, or generates pressure through decomposition, heat or other means. Under this statute, a misbranded hazardous substance or a hazardous substance banned for domestic sale which has not been distributed in domestic commerce may be exported if the exporter complies with the procedures and conditions set forth under the Consumer Product Safety Act, as described above.

3. The Flammable Fabrics Act

The Flammable Fabrics Act, also administered by the CPSC, establishes acceptable minimum flammability standards for fabrics. A fabric, related material, or product that fails to conform to the applicable flammability standard or regulation, regardless of whether it has been distributed in domestic commerce, may not be exported unless the exporter complies with the procedures and conditions set forth under the Consumer Product Safety Act, as described above.
4. The Federal Food, Drug and Cosmetic Act

The Federal Food, Drug and Cosmetic Act is administered by the Food and Drug Administration of the Department of Health and Human Services (FDA). In addition to food, drugs, and cosmetics, the Act regulates medical devices.

Under the Act, the export of unapproved new drugs, unapproved new animal drugs, and certain unapproved animal feeds is not permitted, with certain exceptions for investigational drugs.

Medical devices and unapproved investigational medical devices banned, or otherwise not in compliance with the performance standards provisions of the Act, cannot be exported unless, prior to the export, the FDA makes a determination that the device is not contrary to public health and safety and that the foreign country approves of the import.

Foods, drugs, medical devices and cosmetics which would otherwise be considered misbranded or adulterated under the Act may not be exported unless the products conform with the specifications of the prospective foreign purchaser; are not in conflict with the laws of the foreign country; are labeled clearly for export; and are not offered for sale in the domestic market.

5. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which is administered by the Environmental Protection Agency (EPA), establishes a registration system for specific uses of pesticides and sets forth certain labeling and packaging requirements. In addition, manufacturing facilities are required to be registered and to follow certain recordkeeping procedures.

Under FIFRA, pesticides which are not registered for domestic use are subject to two types of notification procedures. First, there is an export notification which requires that a prospective exporter of an unregistered pesticide must receive, prior to the first annual shipment of the pesticide to a particular purchaser in a foreign country, a signed statement from the foreign purchaser acknowledging his understanding of the registration status of the pesticide and that it cannot be sold in the United States. The exporter then must submit the signed purchaser acknowledgement statement to the EPA, along with a certification statement that the shipment did not take place prior to the exporter's receipt of the signed acknowledgement statement. These two statements must be sent to the EPA within seven days of receipt by the exporter, or by the date of export, whichever occurs first. Through the Department of State, the EPA transmits the acknowledgement statement to appropriate officials of the government of the importing country. If the importing country designates a specific agency or office to receive these export notifications,
the Department of State forwards the notice directly to that address.

Second, FIFRA requires control action notification, i.e. EPA must transmit to foreign nations and interested international agencies notification of cancellation or suspension of registration of pesticide products.

Subject to the notification schemes described above, unregistered pesticides can be exported provided that they are produced for export, they are packaged according to the specifications of the foreign purchaser and they comply with certain specified labeling requirements. In order to satisfy these requirements, the labeling of an export must identify the product and the producer in English and in the language of the importing country, and include ingredient statements and appropriate hazard warnings in English and in the language of the importing country. If the pesticide to be exported is not registered for use in the United States, the labeling must also bear the bilingual statement "Not Registered for Use in the United States of America."

As in the case of producers of pesticides for sale in the domestic market, producers of pesticides, devices, and active ingredients used in producing pesticides intended for export are subject to the FIFRA registration and recordkeeping requirements. In addition to registering their establishments, producers for export must submit an annual report to the EPA on the types and amounts of pesticides and active ingredients used in producing pesticides. Furthermore, such producers must keep records of the chemical content of their pesticide products, purchases, shipments, inventories, specifications of foreign purchasers, labeling requirements, purchaser acknowledgement statements if applicable, research data, and methods of disposal. These records must be available for inspection by the EPA. The EPA is responsible for ensuring that these records are maintained, and is authorized to inspect products ready for distribution.

6. The Toxic Substances Control Act (TSCA)

The Toxic Substances Control Act (TSCA) also is administered by the EPA. In general, the purpose of the act is to provide EPA with the authority to develop adequate data regarding the effect of chemicals on health and environment and to regulate those chemicals which the data shows will present an unreasonable risk to health or the environment.

TSCA contains a notification provision which requires that producers who export or intend to export chemicals which have been subjected

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2 Unregistered pesticides are pesticides whose registrations have been cancelled or denied; pesticides for which registration has not been sought; or pesticides for which registration is being sought but has not yet been granted.
to regulation under the Act shall notify EPA, prior to the first annual shipment to a given foreign country, of the prospective export. The notice submitted to EPA by the producer must include the name of the chemical or category of chemicals, the name and address of the exporter, the country of import, the date of intended export, and the section of TSCA under which EPA took regulatory action. This notice must be provided within seven days of forming the intent to export or on the date of export, whichever is earlier. Upon receipt of the first annual notification of the intended export of a regulated chemical, the EPA is required to notify the importing country's ambassador in Washington, D.C., or another official designated by the government of the importing country. The EPA's notice to the foreign government must contain the name of the exported chemical, the fact that it is being exported, a description of the action taken by EPA in regard to the chemical, a summary and copy of the pertinent regulations, and the address of a person to contact for further information. In addition, in the case of chemicals subject to special testing requirements, the EPA is required to inform the importing government of the availability of test data on the particular chemicals.

7. **Federal Meat Inspection Act.**

The Federal Meat Inspection Act, which is administered by the Department of Agriculture (USDA), prohibits the export of meat and meat products which have not been inspected and certified to be sound and wholesome. USDA regulations require that each container for export be labeled with an export stamp and that each consignment be shipped with an export certificate, thereby certifying that the products meet U.S. standards. In addition, although not required by the Act, prospective exports may be inspected and certified for compliance with stricter health and safety standards, if any, of the importing country, if requested by the exporter. Products that do not meet U.S. standards are not permitted to be exported.

8. **Poultry Products Inspection Act**

The Poultry Products Inspection Act, also administered by the USDA, requires that all poultry and poultry products entering interstate or foreign commerce be inspected and certified to be in compliance with applicable U.S. standards. A mark signifying Federal inspection is affixed to certified products. Products that do not meet U.S. standards are not permitted to be exported.

9. **The Egg Products Inspection Act**

The Egg Products Inspection Act, also administered by the USDA, requires that all eggs and egg products entering interstate or foreign commerce meet specific U.S. standards. An inspection
shield indicating compliance must be attached to each shipping package, and any additive must be identified on the package label. Products not meeting U.S. standards cannot be exported.

10. The Public Health Service Act

The Public Health Service Act is administered by the FDA. The Act requires that biologics and their manufacturing facilities be licensed to meet FDA standards. A license number must appear on the product at all times, and the product cannot enter domestic or international trade without it.

11. The Radiation Control for Health and Safety Act

The Radiation Control for Health and Safety Act also is administered by the FDA. The Act allows the export of radiation-emitting electronic products which do not comply with applicable standards established pursuant to the Act, provided the products in question meet all applicable requirements of the importing country and are intended solely for export. The product and the outer cover of any shipping container must be clearly labeled to show that it is intended solely for export. The exporter is responsible for ensuring that the prospective export fully complies with the requirements of the importing country and is correctly labeled. Explicit authorization by the FDA in such cases is not required. However, if such products are medical devices the export restrictions set forth under the Food, Drug and Cosmetic Act (as described above) also would apply.

12. The Controlled Substances Import and Export Act

The Controlled Substances Import and Export Act, which is administered by the Drug Enforcement Agency of the Department of Justice, regulates legal trade in narcotic and dangerous drugs. The Act requires that importers and exporters of controlled substances be registered to conduct their trade, and that each transaction be authorized by specific import or export documents. In cases of export from the United States of all controlled substances on Schedules I and II of the Act, and narcotic controlled substances listed on Schedules III and IV, the exporter must provide an import certificate from the country of destination and obtain an export permit from the Drug Enforcement Administration. In cases involving non-narcotic controlled substances listed on Schedules III and IV, or any controlled substance listed on Schedule V, the exporter must provide an import certificate from the country of destination and file an export declaration with the Drug Enforcement Administration at least fifteen days prior to the date of export. Existing procedures are based upon and implement the requirements of international agreements governing trade in narcotic and psychotropic substances. In addition, the export of controlled substances is subject to the export restrictions set forth under the Food, Drug and Cosmetic Act.
Description of Principal International Activities Relating to Exchange of Information Concerning Domestically Banned Products

A number of international organizations with special expertise in chemical and pharmaceutical issues have developed notification programs in order to provide importing countries with significant information concerning products in international trade that have been banned or severely restricted in the country of origin. The United States has participated actively in establishing and implementing these programs. The United States is in a unique position to assist these efforts because of its experience in providing notifications over a period of many years pursuant to the laws described above.

The following is a list of a number of the major international activities relating to information exchange. While this description is not comprehensive, it provides a general overview of the relevant activities.

1. **United Nations Environment Programme**

In May, 1984, the United Nations Environment Program (UNEP) Governing Council adopted a "Provisional Notification Scheme for Banned and Severely Restricted Chemicals." The purpose of the scheme is to have exporting countries provide information to assist importing countries in making timely and informed decisions concerning risks to human health and environment from trade in banned or severely restricted chemicals.

Under the scheme, countries should provide two types of notification. First, when a country has taken a control action to ban or severely restrict a chemical, it notifies authorities in other countries of the control action. Second, exporting countries provide notification to importing countries triggered by an actual export of banned or severely restricted chemicals in order to remind the country of import of the original notification regarding control action and to alert it to the fact that an export is expected or about to occur. The notification scheme recognizes that it is not always possible to provide the information prior to export and that the notification procedures should not delay the export.

The scheme is being administered by UNEP's International Registry of Potentially Toxic Chemicals (IRPTC). Under the Governing Council decision, the provisional scheme is to remain in effect for three years, during which time UNEP will develop Guidelines and Principles for Exchange of Information on Potentially Harmful Chemicals, based on experience gained from the provisional scheme.

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3 The IRPTC was established in order to facilitate universal access to scientific and regulatory data.
2. United Nations General Assembly

In 1982, the United Nations General Assembly (UNGA) passed a resolution to establish a consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or, in the case of pharmaceuticals, not approved by Governments. In December 1984, the General Assembly decided to issue an updated consolidated list annually and that data should be made available to Governments and other users in such a form as to permit direct computer access to it.

3. The Organization for Economic Cooperation and Development

In April 1984, the Organization for Economic Cooperation and Development (OECD) passed a recommendation which established a scheme for Information Exchange Related to Export of Banned or Severely Restricted Chemicals. The Guidelines established for implementing this recommendation are substantially the same as UNEP's Provisional Notification Scheme. Although the OECD consists of a limited number of countries, the scheme envisions that the member countries provide information to all importing countries.

4. The Food and Agriculture Organization

The United Nations Food and Agriculture Organization (FAO) is in the process of developing an International Code of Conduct on the Distribution and Use of Pesticides. The intent of this draft code is to "establish international standards of conduct for Governments in the exercise of their jurisdiction over public and private enterprises engaged in the manufacture, trade and use of pesticides..." One article of the draft code would establish and Information Exchange Program similar to those established by UNEP and the OECD.

5. The World Health Organization

In 1975, the World Health Organization adopted its "Certification Scheme for Pharmaceuticals Moving In International Commerce." This system, currently agreed to by over 100 countries, permits an importing country to obtain from the government of an exporting country current information on the quality and approval status of a drug in the country of export. Other activities conducted by the WHO for ensuring the flow of information on the safety and efficacy of pharmaceutical products includes the Drug Information Circular and WHO Drug Information Bulletin.