# EUROPEAN UNION

## TRADE SUMMARY

The U.S. trade deficit with the European Union was $94.3 billion in 2003, an increase of $12.2 billion from $82.1 billion in 2002. U.S. goods exports in 2003 were $150.5 billion, up 4.8 percent from the previous year. Corresponding U.S. imports from the European Union were $244.8 billion. European Union countries, together, would rank 2nd (behind Canada) as an export market for the United States in 2003.

U.S. exports of private commercial services (i.e., excluding military and government) to the European Union were $95.7 billion in 2002, and U.S. imports were $77.2 billion. Sales of services in the European Union by majority U.S.-owned affiliates were $220.3 billion in 2001 (latest data available), while sales of services in the U.S. by majority EU-owned firms were $216.8 billion.

The stock of U.S. foreign direct investment (FDI) in the European Union for 2002 was $700.0 billion, up from $632.8 billion in 2001. U.S. FDI in the European Union is concentrated largely in the manufacturing, finance, and wholesale sectors.

## OVERVIEW

In most respects, the enormous U.S.-EU trade and investment relationship operates smoothly and to the great benefit of companies, workers, and consumers on both sides of the Atlantic. However, as outlined in this report, U.S. exporters in some sectors continue to face chronic barriers to entry in the EU market. A number of these barriers (e.g., restrictions on U.S. poultry and meat exports) have been highlighted in this report for several years, despite repeated efforts to resolve them through consultations or, in some cases, the dispute settlement provisions of the WTO. Other EU barriers cited in this report (for example, wine restrictions and agricultural biotechnology) are the result of restrictive regulatory approaches that often fail to reflect a sound assessment of actual risks posed by the goods in question and that rely on ill-defined concepts of precaution. This year's report also outlines concerns of U.S. exporters with respect to a number of emerging EU policies that may represent future trade disruptions, such as the proposed new EU chemicals regulation. And while the United States acknowledges the important achievement of EU enlargement to include 10 new Member States as of May 2004, this report also highlights the U.S. determination to negotiate appropriate compensation arrangements to account for the possible expansion into the new EU Member States of EU tariff, non tariff, and services-related barriers to U.S. trade.

## IMPORT POLICIES

### Restrictions Affecting U.S. Wine Exports

Since the mid-1980s, U.S. wines have been permitted entry to the EU market through temporary exemptions from several EU wine regulations. One such regulation requires wines imported into the EU to be produced with only those oenological practices (wine-making practices) that are authorized for the production of EU wines. Other regulations require extensive certification procedures for imported wines and prohibit the use of wine names and grape varieties as regulated in the United States. Without derogations from these regulations, many U.S. wines would be immediately barred from entering the EU. U.S. wines that are produced with practices for which there is no EU derogation are barred already. By contrast, U.S. law effectively grants automatic acceptance of EU wine-making practices absent a health or safety concern. EU derogations for U.S. wines were set to expire on December 31, 2003, but the EU has agreed to further extend the current arrangement for two years to permit ongoing U.S.-EU wine negotiations to continue.

U.S.-EU negotiations on a bilateral wine agreement were launched in 1999 and continued throughout 2003. In this negotiation, the United States is pressing the EU to provide U.S. wine makers equitable access to the EU wine market, particularly in light of Europe's considerable surplus in wine trade with the United States. A key U.S. objective is EU acceptance of current U.S. wine-making practices, to obviate the need for future short-term derogations. The United States also continues to press for approval of all future U.S. wine-making practices, removal of EU wine import certification requirements, transparent protection of U.S. wine names in the EU, and reductions in the EU's export subsidies and subsidies to its grape growers and wine producers.

For its part, the EU is seeking a U.S. commitment to phase out the use in the United States of semi-generic names (e.g., burgundy, champagne, chablis) on labels of non-EU origin wines and greater protection of its wine names in the United States. The United States has indicated its willingness to negotiate on these issues within the U.S. regulatory framework for wine labeling.

On April 29, 2002, the EU adopted a new wine labeling regulation (Commission Regulation No. 753/2002), which entered into only limited enforcement on January 1, 2003, after the United States, along with a number of other WTO Members, raised serious concerns about its lack of clarity and, more importantly, about its WTO-consistency, and submitted written comments outlining these concerns and urging withdrawal of the regulation. Specifically, the regulation appears more trade restrictive than necessary to meet any legitimate objective, as it would prohibit the presentation on imported wine of information important for the marketing of wine unless certain conditions are met (e.g., the marketing information used must be regulated in the producing country). In addition, the EU imposes restrictions on the use of traditional terms listed in the regulation, in some instances granting exclusive use of a term to an EU wine in a manner akin to intellectual property. Traditional terms are, for the most part, terms used with certain other expressions (often geographical indications) to describe wine or liqueur, and in many cases the terms are generic (e.g., ruby and tawny). The United States does not recognize the concept of traditional terms as a form of intellectual property, nor is this subject covered under the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS).

EU authorities began fully enforcing the new regulation as of March 15, 2004. Amendments to the original regulation fail to address key U.S. industry concerns, including restrictions on the use of certain wine terms, bottle shapes and labeling information on non-EU origin wines.

**Customs Administration Procedures**

While customs procedures are regulated by the EU Community Customs Code -- which aims to establish a standard legal framework for basic customs procedures such as customs entry and release -- the EU does not currently operate as a single customs administration. Application of the Community Customs Code to individual cases is the responsibility of EU Member State Customs administrations, which do not have identical working practices and are not obliged to follow each other's decisions.
In terms of day-to-day customs operations, differences from Member State to Member State exist in areas such as the automated systems used, risk criteria used by administrations to determine when to examine goods, VAT levels, and licenses required for food products, as well as disparities in certificate of origin requirements, treatment of express shipments. The difficulties presented by less than uniform procedures are increased by the absence of EU-wide administrative management of customs operations.

This problem is further compounded by the absence of tribunals and procedures that would provide for the prompt review and EU-wide correction of administrative actions relating to customs matters, as is required by Article X:3(b) of the GATT 1994. Review by the European Court of Justice of national decisions regarding customs administrative matters may be available in some cases, but generally only after a review is conducted at the national level. Obtaining corrections with EU-wide effect for administrative actions relating to customs matters may take years. For example, Customs Valuation and Tariff Classification are dealt with by Committees on those issues, respectively, that serve as platforms for Member States' customs authorities, under encouragement of the Commission, to strive toward common approaches in these areas. Experience has shown that achieving consensus among Member States on particular issues is time-consuming with significant uncertainty to exporters. Moreover, decisions by a Committee may not specifically address all elements of an individual exporter's case -- thereby resulting in less than uniform implementation when decisions are applied to identical imports by the same companies in different Members States.

The lack of access for traders to prompt review and correction by a tribunal with EU-wide jurisdiction is not a new phenomenon. However, the concern it has engendered is heightened by the May 2004 enlargement of the EU from 15 to 25 Members. The United States also regards the work on trade facilitation within the Doha Development Agenda negotiations as an opportunity for addressing concerns surrounding EU customs administration.

**EU Enlargement**

The European Union will expand from 15 to 25 members on May 1, 2004, with the accession of 10 Central and Eastern European and Mediterranean countries (Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia). While this expansion of the single European market represents important opportunities for United States exporters, it may result in negative commercial consequences in some instances.

Among U.S. concerns related to enlargement are: increases in certain acceding country tariff rates when new Member States begin applying the EU common external tariff; potential withdrawal or modification of services market access commitments, and changes to various GATS MFN exemptions, by new Member States in order to align with the EU's existing GATS commitments; application by acceding countries of certain EU non-tariff barriers (such as sanitary and phytosanitary measures or other technical barriers); and uncertainty surrounding the adjustment of import quotas or tariff-rate quotas applied to EU imports of agricultural products. The United States has expressed concern about EU intentions to extend the application of EU antidumping and countervailing duty orders to new Member States without conducting appropriate economic or market analyses. In addition, the United States desires to ensure that incoming EU Member States abide fully by the terms of trade agreements to which the European Community is bound, such as the WTO Agreement on Government Procurement, the WTO Agreement on Trade in Civil Aircraft, and various bilateral U.S. EU agreements.

The United States has initiated early discussions with the European Commission about enlargement-related concerns, including within the framework of GATT provisions relating to the expansion of customs unions.

**Market Access Restrictions for U.S. Pharmaceuticals**

U.S. pharmaceutical companies encounter persistent market access problems throughout the EU due to the price, volume, and access controls placed on medicines by national governments. The pharmaceutical industry views these controls as limiting access by patients to innovative products and diminishing the contribution of Europeans to research and development.

While the EU's single market ensures that pharmaceuticals, like other goods, can move freely across borders among EU Member States, Member States' public health authorities impose their own strict price controls on pharmaceuticals. As controlled prices vary greatly from one Member State to another, intermediaries engage in parallel trade (buying drugs in countries where the price is lower and selling them in Member States where the price is set at a higher level).

The proposed Future Medicines Legislation is still under review. At time of this writing, the proposal would reduce regulatory data protection and provide a new definition for generics B two issues, which if mismanaged, could affect market access.

*Austria*: A pharmaceutical firm seeking to include a product on the list of reimbursable drugs in Austria must first obtain the approval of the umbrella organization of social insurance funds (Hauptverband/HVB). Pharmaceuticals not approved for reimbursement have higher out-of-pocket costs. According to many U.S. and European pharmaceutical companies, the HVB approval process (particularly the long delay in obtaining HVB decisions) limits market access for innovative pharmaceutical products. They also complain that the problem is compounded by often relatively quick HVB approvals of generic competitor products even before patents for the innovative products have expired. U.S. companies operating in Austria reported cumulative losses between $25 million and $100 million due to these practices. Further, the Austrian Government is preparing a major health care reform that provides Austria with an opportunity to come closer to European norms in pharmaceuticals pricing and transparency of decision-making on reimbursement approvals. However, an initial draft raises doubts that Austria will follow through on EU average pricing and transparent decision-making. The U.S. Government will closely monitor implementation of the reforms to ensure that they do not limit market access, while maximizing patient access to innovative medications.

*Belgium*: Pharmaceutical companies consider Belgium among the most inhospitable markets for their sector in Europe. The approval process for new drugs has come down from an average of 560 days to around 200 days since the Belgian Government passed legislation in Spring 2002 that will conform Belgian practice to relevant EU directives. Nonetheless, tax, pricing, and patient access restrictions remain, and discourage investment in research and development. Despite promises by the Economics Minister to lift pharmaceutical price controls, a price freeze continues on drugs reimbursed through the Belgian social security system. There is also strong pressure to reduce drugs under patent. Further, a 3.5 percent turnover tax is charged on total sales of pharmaceutical products, and companies are also obligated to reimburse to the government 65 percent of any amount the government spends over its budget for drugs in a given year. The two measures together amount to a seven percent additional tax levy on the pharmaceutical industry.

*France*: The government that assumed office in 2002 has taken steps to accelerate the approval process and make prices for the most innovative drugs more comparable to those in other European markets. At present, however, France's health care provisions are still based on a 1997 law.

*Germany*: As part of a broader health-care reform package, Germany in October 2003 mandated a 16 percent reduction in reimbursed prices for patented medicines and will introduce a reference pricing scheme by the end of 2004. U.S. pharmaceutical firms have commented that this pricing scheme may not appropriately value innovative drugs.

*Italy*: In 2001, the Government of Italy began a series of reforms to control health care expenditures, which stemmed in part from the elimination of patient co-payments for pharmaceuticals. The government transferred responsibility for health care expenditures from the central to regional governments, with the central government capping overall health care expenditures, and limiting pharmaceuticals expenditures to 13 percent of the overall budget. In April 2002, a government decree temporarily reduced pharmaceutical reimbursements by five percent across the board. Italy's 2003 financial law not only makes this reduction permanent, it increases the cuts by an additional one to two percent. U.S. companies also question the fairness of the government's cost-efficacy formula to determine reimbursement levels. U.S. pharmaceutical companies are concerned that the devolution of marketing approval authority to regional governments, in addition to the Ministries of Health and Economy, will cause unwarranted delays in bringing new products to market.

*The Netherlands*: U.S. companies have complained that the criteria used by the Dutch health insurance board (CVZ) too often result in their new-to-market products being incorrectly classified with drugs determined by the board as therapeutically equivalent (and therefore reimbursable at a lower rate) rather than as unique, innovative drugs, reimbursed at a higher price. They have also voiced concerns that the Dutch health insurance board procedures have resulted in considerable and unnecessary delays in classifying products for reimbursement.

*Spain*: Pharmaceuticals and drugs must go through an approval and registration process with the Ministry of Health lasting several years, unless previously registered in a EU Member State or with the London-based EU pharmaceutical agency (in which case, the process is shortened to a few months). Regardless of registration process, actual access to the Spanish market is often delayed due to a lengthy administrative pricing process plus onerous government reimbursement procedures. Many U.S. pharmaceuticals sold in Spain are still protected under the former pharmaceutical process patent regime. U.S. pharmaceutical manufacturers assert that effective patent protection for these drugs is limited.

In July 2002, the Spanish Ministry of Health approved a regulation requiring that consumers obtain special approval (called a "visado") from a state inspector before pharmacies can fill prescriptions for two specific drugs produced by U.S. pharmaceutical manufacturers. Adoption of the measure has resulted in sharply decreased sales for both drugs. In 2003, the regional government of Andalucia followed suit and imposed a visado on all anti-psychotic drugs. This move affected several U.S. pharmaceutical companies, among others. The Law of Cohesion, approved in 2003, states that once a drug has been on the Spanish market ten years (and regardless of its patent status), it will be subject to a newly revised reference pricing system. "Innovative drugs" will be exempted from the measure. However, U.S. industry is concerned that the government of Spain has not clearly defined what will be considered innovative.

## STANDARDS, TESTING, LABELING, AND CERTIFICATION

### Overview

With the decline of traditional transatlantic trade barriers, EU regulatory measures are increasingly viewed as impediments for U.S. exporters of manufactured and agricultural products. Compliance with unnecessarily divergent technical regulations and standards for products sold in the United States and the EU imposes additional costs on U.S. exporters (e.g., duplicative testing, product redesign) and increases time required to bring a product to market. Such costs for U.S. exporters are compounded by inadequate transparency in the development of EU regulations and a lack of meaningful opportunity for non-EU stakeholders to provide input on draft EU regulations and standards. To address these systemic concerns, the United States continues to promote greater U.S.-EU regulatory cooperation and enhanced transparency in the EU regulatory system.

Despite often sharing similar regulatory objectives, U.S.-EC dialogue frequently is unable to resolve promptly regulatory-based trade problems. In particular, the EU's growing use of a precautionary principle to restrict or prohibit trade in certain products, even in the absence of full scientific justification, is viewed increasingly by many U.S. exporters as a pretext for market protection. Further, EU regulatory barriers are often compounded by multiple and/or overlapping measures affecting particular products. Wine, poultry, and agricultural biotechnology products are examples of products that confront multiple layers of restrictive regulation in the EU marketplace. To illustrate:

- U.S. efforts to reopen the EU to U.S. poultry exports have been hindered by the fact that there are multiple obstacles. As a result, resolution of one obstacle (the EU allowing the use of alternative antimicrobial treatments on poultry meat) would not necessarily result in reopening of trade due to the existence of other obstacles (such as requirements regarding on-farm practices for raising poultry).

- U.S. wine exporters are confronted not only by the uncertainty surrounding the EU's restrictions based on wine-making practices, but also by high tariffs, heavy subsidization of EU wine producers, and cumbersome certification and labeling requirements.

- U.S. exporters of agricultural biotechnology products have been harmed not only by the de facto moratorium on approving new products, but also by the existence of legally-questionable member state prohibitions on products already approved for marketing within the European Community.

**Standardization**

Given the large volume of U.S.-EU trade, EU standardization work in regulated market segments is of considerable importance to U.S. exporters. Although there has been some progress with respect to the EU's implementation of legislation, a number of problems continue to impede U.S. exports. These include: delays in the development of EU standards; delays in the drafting of harmonized legislation, inconsistent application and interpretation by EU Member States of legislation; overlap among Directives dealing with specific product areas; gray areas between the scope of various Directives; and, in some cases, reliance on design-based, rather than performance-based, standards. In addition, there are concerns related to the respective procedures, responsibilities (e.g., accountability, redress) and transparency in both the Commission and the European standards bodies that require careful monitoring and more frequent advocacy efforts. The following two examples illustrate the type of standards-related problems affecting U.S. exporters.

*Gas Connector Hoses:* The European Standardization organization, CEN, drafted a standard for gas connector hoses, which impedes EU market access for a U.S. product because of design specifications. The U.S. manufacturer has experienced considerable difficulties in gaining access to the standardization process, and has been unsuccessful in countering assertions by the CEN Technical Committee that only fixed/welded connections can be considered safe methods for gas hose connectors. Both U.S. industry and the U.S. Government have argued in favor of performance-based standards for years, and the U.S. Government has persistently raised this case with national CEN members and Commission officials to press for more transparency and performance criteria in the CEN standardization process.

*Pressure Equipment*: In May 2002, the EU Pressure Equipment Directive (PED) entered into force, imposing new requirements on manufacturers of such equipment. Previously, pressure equipment manufacturers could demonstrate conformity based on standards for material specifications, including the

U.S. ASME Code. Manufacturers using the ASME Code may now be excluded from the EU market, as the European standards incorporate material specifications slightly different from those found in the ASME Code. In the absence of a full set of harmonized EU standards, the PED permits manufacturers to file for an EAM (European Approval of Materials); however, few requests for EAMs have been approved so far. Another option, the Particular Material Appraisal (PMA), is a costly, repetitive process for which there are no clearly defined procedures in the PED. In light of these factors, U.S. manufacturers question the need for the retesting of products, and seek the grandfathering of existing materials.

**Agricultural Biotechnology**

With some minor exceptions, the EU has failed to approve new biotechnology products since 1998. Several products have been under review for more than six years, as compared with an average 6-9 month process in Canada, Japan, and the United States. This de facto moratorium on approvals has virtually stopped U.S. exports of corn to Spain and Portugal (the most significant EU importers of U.S. corn) and threatens U.S. exports of soya.

Directive 2001/18, governing the approval of biotechnology products, including seeds and grains, for environmental release and commercialization entered into force in October 2002, replacing the moribund older approval system embodied in Directive 1990/220. However, EU Member States have refused to lift the approvals moratorium despite the new legislation, saying they needed to wait for new biotechnology-related traceability and labeling and biotechnology food and feed authorization rules to come into force. In April 2004, those new regulations will be fully applied. The regulations include mandatory traceability and labeling requirements for all biotechnology products and downstream products. Exporters expect the new rules to be onerous and expensive for producers and foreign suppliers to meet.

In May 2003, the United States announced that it would initiate a WTO dispute settlement process focused on the EU's *de facto* moratorium on approvals of biotechnology products, and on the existence of individual Member State marketing prohibitions on previously approved biotechnology products. The dispute settlement case is expected to continue to develop through 2004.

Several Member States including Austria, Luxembourg, and Italy have imposed marketing bans on some biotechnology products despite existing EU approvals. The European Commission has not taken steps to overturn these bans, despite the fact that the EU's Scientific Committee has found no justification for the bans. In addition, Portugal and Germany have suspended approvals for planting certain biotechnology products.

*Austria*: Austria has imposed a marketing ban on some biotechnology products despite existing EU approvals. Under current Austrian rules, unapproved biotechnology events must not be detected in conventional seeds ("zero tolerance"), but EU-approved events may be present in conventional and organic seeds up to 0.1 percent. This standard is more restrictive than what is commonly accepted practice in the EU.

*France*: There are six bioengineered products approved for sale in France (Bt 176 corn, Bt 11 corn, MON 810 corn, T25 corn, Roundup Ready soybeans, and ITB-1000-0X tobacco), with restrictions on use for some, such as on planting. However, no bioengineered crops are grown in France other than for research purposes. On July 4, 2002, the French Ministry of Agriculture approved eight applications for open-field testing of bioengineered crops, but none of them could be planted in 2002. The number of bioengineered test plots, mainly corn, is 59.

*Greece*: Greece has not been responsive to applications to introduce bioengineered seeds for field tests, despite support for such tests by Greek farmers and Greece's agricultural science community.

*Italy*: There are varying positions on agricultural biotechnology among Italy's Ministries of Health, Agriculture, and Environment. The Ministry of Agriculture is trying to minimize the risk of adventitious presence by imposing extremely rigorous thresholds for seed purity, which threaten U.S. exports of conventional corn and soybean seed. The stated objective of the Ministry of Agriculture is to disallow any bioengineered presence in seeds. In the case of soybeans used for animal feed, the Ministry of Agriculture tacitly allows biotechnology, since it is unable to segregate in storage or in processing the locally produced non-bioengineered soybeans from those of imported origins. Italy has not rescinded its ban on four EU-approved bioengineered corn varieties (BT11, MON 810, MON 809, and T25), which was enacted by the previous government.

*Luxembourg:* Although several biotechnology products have been approved for sale in Luxembourg, the government continues to support the *de facto* moratorium on the approval of new products of agricultural biotechnology. In 1997, the Ministry of Health placed an administrative ban on Bt 176 corn. In December the Parliament enacted a new biotechnology law for the approval of agricultural biotechnology products in Luxembourg. The law adds several new requirements to the process for biotech approvals, including an environmental impact study requirement, and a financial guarantee requirement to cover unintended financial consequences resulting from the introduction of a crop or product into Luxembourg.

**Barriers Affecting Trade in Cattle and Beef Products**

A variety of EU measures, outlined as follows, have the effect of severely restricting U.S. exports of beef and cattle products to the European Union market.

***EU Hormone Directive***

In 1988, the EU provisionally banned the use of substances that have a hormonal growth promoting effect in raising food-producing animals. This action effectively banned the export to the EU of beef from cattle raised in the United States. The use of hormone implants is approved by the U.S. Food and Drug Administration and is a common practice in U.S. beef cattle production. The United States launched a formal WTO dispute settlement procedure in May 1996 challenging the EU ban. In 1999, the WTO ruled that the EU's ban is inconsistent with the WTO Agreement on Sanitary and Phytosanitary (SPS) measures because it is imposed without a risk assessment based on scientific evidence of health risks and authorized the United States to impose sanctions on EU products with an annual trade value of $116.8 million.

In September 2003, the EU announced the entry into force of an amendment (EC Directive 2003/74) to its hormone directive (EC Directive 96/22). The new directive recodified the ban on the use of estradiol for growth promotion purposes and extended the provisional bans on the five other growth hormones included in the original EU legislation. With enforcement of this new directive, the EU argues that it is now in compliance with the earlier WTO ruling. The United States has rejected this claim and continues to maintain its WTO-authorized sanctions on EU products. The United States and the EU continue to explore possible approaches to resolve this longstanding dispute.

**Animal By-Products Legislation**

In October 2002, the European Commission approved legislation (EC Directive 1774/2002), strictly regulating the importation of animal by-products not fit for human consumption. Though full enforcement of the regulation for third countries has been delayed twice based on requests from the U.S. and other countries the EU is scheduled to enforce the Directive as of May 1, 2004. During 2003, intensive technical discussions between U.S. and EU officials successfully addressed various issues that should prevent trade disruption for a significant portion (about $300 million) of U.S. exports to the EU of animal by products. However, publication of the final text of the EU regulation has been delayed, including the specifics necessary for USDA to develop certification procedures for establishments exporting affected products. Therefore, unless the implementation date for third countries is delayed significantly beyond May 1, all U.S. animal by-products exports to the EU of about $400 million will be disrupted.

In addition, the United States remains concerned about various outstanding issues for which the EU has not provided risk assessments, such as a proposed ban on the use of dead-in-transport poultry in pet food. It is estimated that at least $100 million of U.S. animal by-product exports to the EU could be adversely impacted because of these outstanding provisions. Those U.S. exports remaining most exposed to this regulation are dry pet food, other animal protein products, and some hides and skins.

**Poultry Restrictions**

U.S. poultry meat exports to the EU have been banned since April 1, 1997 because U.S. poultry producers currently use washes of low-concentration chlorine as an anti-microbial treatment (AMT) to reduce the level of pathogens in poultry meat production, a practice not permitted by the EU sanitary regime.

In 2003, the United States made significant progress in its work with the EU to address differences between U.S. and EU food safety rules for poultry. The U.S. goal remains to restore U.S. poultry exports to the EU and preserve existing markets for U.S. poultry in Central and East European countries that are moving to adopt EU standards in this area. The European Commission has accepted a U.S. residue program, U.S. water standards, and a U.S. proposal on use of alternative AMT substances. However, the Commission has linked the use of alternative AMTs with adoption by the United States of an integrated production control system that includes specific on-farm good management practices (GMPs) directly overseen by U.S. government officials. In the United States, on-farm practices are routinely overseen by private sector veterinarians who are certified by the U.S. Government. The U.S. Government has made the case that while our poultry industry is significantly different from the EU's, the results of our respective sanitary systems are the same. The United States and the European Union are now discussing final details of a series of steps aimed at reopening the EU market to U.S. poultry products.

*France*: According to a 1961 decree of the Ministry of Agriculture, poultry originating from countries which allow the use of compounds incorporating arsenic in poultry feed, cannot enter France for human use. As the United States does not ban these products, this decree creates a *de facto* ban on exports to France of U.S. poultry meat for human consumption.

**Triple Superphosphate Fertilizer**

EU legislation (EC Directive 76/116) requires Triple Superphosphate (TSP) B a phosphate-based fertilizer used to enhance soil fertility and to increase crop yields B to meet a standard of 93 percent water solubility in order to be marketed as EC-Type fertilizer. Scientific studies done to date on typical crops cultivated in Europe show that water solubility rates of 90 percent or higher are not necessary to gain the agronomic benefits associated with adding TSP to the soil. While in theory, TSP of any origin can be imported and sold in the EU, the inability to market TSP with less than 93 percent water solubility as EC-Type restricts its marketability, depresses its price, and has the effect of unfairly discriminating against products of countries that cannot meet the 93 percent water solubility requirement. EU imports of non-EC-Type TSP have been virtually eliminated. The U.S. fertilizer industry, which accounts for 20 percent of total world TSP exports, has been working with the European Commission and European industry to amend the water solubility requirements to reflect current scientific and agronomic studies. The United States continues to seek from the European Commission a justification for the 93 percent standard in light of scientific evidence and trade rules.

**Emerging Regulatory Barriers**

In addition to the foregoing current trade barriers arising from EU policies regarding standards, testing, labeling, and certification, the United States has serious concerns about the ongoing development of new regulations that would appear to have serious adverse consequences for U.S. exporters in the future. The United States is actively engaging the European Union with respect to the issues outlined below.

*Chemicals*

In October 2003, the European Commission approved its proposal for a massive overhaul of existing EU chemicals regulation called **A**REACH (Registration, Evaluation, and Authorization of Chemicals). REACH would be applicable to all existing and new chemicals. Under this proposed system, chemicals producers and downstream users would be responsible for registering and testing chemicals, conducting risk assessments, and reporting this information to a central database. Virtually every industrial sector, from automobiles to textiles, could be impacted by the new policy.

While the United States fully supports the EU**'**s objectives to protect human health and the environment, it is concerned this proposed approach is unworkable and could have significant adverse implications for U.S. exports. Many of the EU**'**s trading partners have expressed similar concerns. U.S. industry has stressed that the Commission**'**s proposal could present obstacles to trade and innovation, possibly distorting global markets for thousands of products.

The European Council and European Parliament are in the early stages of considering the proposal under the EU**'**s legislative approval process. The U.S. Government continues to underscore the importance of transparency, openness, and accountability throughout the EU regulatory process, as this will contribute to a balanced and cost-effective regulation.

*Cosmetics*

On January 27-28, 2003, the EU formally adopted the seventh amendment to Directive 76/768/EEC on Cosmetics. EU Member States were required to transpose the Directive into national law by January 1, 2004, at which time a series of amendments came into effect. One of the provisions of particular U.S. concern is a ban on the marketing of cosmetic products tested on animals. The amended Directive calls for an EU-wide ban on animal testing within the EU for cosmetic products as well as an EU-wide ban on the marketing/sale of cosmetic products which have been tested on animals, whether such testing has occurred inside or outside the EU. The ban will take effect by 2009 at the latest for the majority of tests (11 out of 14 tests). For the remaining three tests B toxicity of repeat doses, toxicity for reproduction, and toxicity for toxicocinicity B the ban will come into effect by 2013 at the latest. The testing and marketing bans will take effect on the proposed dates unless an alternative (non-animal) method of testing has been adopted and validated at the European Community level. The amended Directive states that any alternative testing methods should also take into account the developments of validation measures within the OECD.

Two-way trade between the United States and European Union could be disrupted by the EU testing and marketing ban, as it could conflict with existing U.S. regulations. The sale in the EU of U.S. cosmetics products tested on animals as of 2009 or 2013, depending on the type of test, or earlier if an alternative testing method is approved by the European Community. At the same time, however, EU exports to the United States of certain cosmetics could be prohibited as well. Some products sold in the EU as cosmetics are regulated by the U.S. Food and Drug Administration (FDA) as over-the-counter (OTC) drugs. These include products claiming to provide a medicinal benefit, such as anti-dandruff shampoos and sunscreens. The FDA requires OTC products to be tested on animals in order to ensure their safety for human use. Thus, EU cosmetic products falling into the OTC category would be prohibited from sale in the United States if they have not undergone FDA-recognized animal testing for human safety.

To minimize possible trade disruption, the U.S. Government and the European Commission agreed to pursue a joint project to develop harmonized, alternative, non-animal testing methods. The project involves cooperation between the U.S. Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the European Center for the Validation of Alternative Methods (ECVAM). The aim is to develop mutually agreeable alternative testing methods that would be submitted to the OECD process for international validation.

*Waste Management*

In June 2000, the European Commission issued proposals for a Directive focusing on the take back and recycling of discarded equipment (known as Waste from Electrical and Electronic Equipment or WEEE), and a second Directive addressing restrictions on the use of certain substances in electrical and electronic equipment, such as lead, mercury, cadmium, and certain flame retardants (known as Restrictions on the Use of Hazardous Substances or RoHS). Both Directives were adopted on December 18, 2002. Member States are obliged to transpose the legislation into national law by August 13, 2004.

Under the WEEE Directive, producers will be held individually responsible for financing the collection, treatment, and recycling of the waste arising from their new products starting in August 2005. Producers will have the choice of managing their waste on an individual basis or by participating in a collective scheme. Waste from old products will be the collective responsibility of existing producers based on their market share. Under the WEEE Directive, Member States must ensure that a target of at least 4 kg of electrical and electronic equipment (EEE) per inhabitant per year is being collected from private households. This target is to be met by 31 December 2006 at the latest. The policy is intended to create an incentive for companies to design more environment-friendly products.

Under the RoHS Directive, as of July 1, 2006, the placing on the European market electrical and electronic equipment containing lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers will be prohibited. Existing national measures on these substances can continue to apply until that date. Exceptions to the ban exist for spare parts used for repair, or the re-use of electrical and electronic equipment put on the market before July 1, 2006. Exemptions from the ban on hazardous substances in EEE can be found in the annex of the RoHS Directive. Responding to concerns about the basis for the substance bans, the Commission pledged to conduct risk assessments before 2004. To date, the United States is not aware of the results of any such risk assessments.

The United States supports the directives' objectives to reduce waste and the environmental impact of discarded products. However, the United States has expressed concerns that development of these directives lacked transparency and meaningful input from non-EU stakeholders, and would adversely affect trade in products where viable alternatives may not exist. The annexes (covering scope, exemptions, substance concentration) of WEEE and RoHS are currently being discussed in an EU technical adaptation committee. Industry has expressed strong interest in ensuring uniform implementation of the waste management directives in all EU Member States.

*Battery Directive*

On November 25, 2003 the European Commission proposed a new EU Battery Directive. The overall aim of the Directive is to require collection and recycling of all batteries that are placed on the community market. Unlike previous proposals, the current one does not call for a ban on nickel-cadmium batteries, but it does propose strict collection and recycling targets, which the Commission considers will provide for an equivalent level of environmental protection. For all types of batteries, Member States are to ensure that producers finance collection, treatment, and recycling activities. In addition to the collection rate of 160 grams per inhabitant per year in each member state, the proposal includes an additional collection target for nickel-cadmium batteries of 80 percent of all such batteries generated annually in the member state. The Commission expects final adoption by the European Parliament and Council sometime in early 2005. The collection rates being proposed in the Directive are to come into force four years after transposition of the Directive. Industry is concerned about the costs and feasibility of reaching the minimum collection and recycling rates, and would like clearance to operate a permanent visible fee on new battery sales to fund collective treatment schemes for all waste.

*Energy Using Products (EuP)*

In August 2003, the European Commission issued a draft Directive referred to as "EuP" (energy using products), which combines the essence of two earlier proposals on product design -- one on electrical and electronic equipment and the other on energy efficiency. The stated objective of the new draft is to minimize harmful effects on the environment. It would be issued as a "new approach" Directive, consisting of a framework and "implementing measures" according to product groups. As with other precursors of the directive, industry is most concerned about the need for product life cycle analysis, fearing adverse impacts on design flexibility, new product development and introduction, and increased administrative burdens.

*Acceleration of the Phase-outs of Ozone-depleting Substances and Greenhouse Gases*

In June 2000, the EU adopted Regulation 2037/2000, a new Regulation for phasing-out all ozone depleting substances in the EU. The timetable in the directive is faster than that agreed under the Montreal Protocol. The U.S. Government actively opposed early drafts, which proposed phase-outs of HCFCs by 2001 without yielding appreciable environmental benefits. The existing Regulation requires the air-conditioning industry to have phased out its use of Hydrochlorofluorocarbons by 2001 while most other HCFC uses may continue until 2004. Small (100 kW) fixed air conditioners and heat pump units have been exempted from the initial phase-out.

The European Commission introduced its Climate Change Program in 2001 and is expected to issue approximately 10 new directives in order to implement the program (the most recent Directive was adopted October 2003 Establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Directive 96/61/EC, Official Journal L 275). The Commission's annual progress report on greenhouse emissions assesses the actual and projected progress of Member States toward fulfilling their emission commitments under the UN Framework Convention on Climate Change and the Kyoto Protocol. The Second European Climate Change Program progress report, released in May 2003, reveals that the emissions of greenhouse gases from the European Union have increased for a second consecutive year, and that more stringent measures and policies in Member States are needed in order to meet the Kyoto Protocol objectives (i.e., 8 percent emission reduction) by 2010.

One of the most recent proposals under the Climate Change Program, was adopted on August 12, 2003, by the European Commission. It is a new Regulation on certain fluorinated greenhouse gases. The proposal sets 2010 as the deadline for reducing fluorinated greenhouse gases by almost a quarter, with even greater reductions in the period after. The proposal also aims to phase-out the use of fluorinated gas HFC-134a in air-conditioning systems in new vehicles B a measure which is expected to heavily impact U.S. car manufacturers. There are strong concerns that the regulation could be amended to target domestic refrigeration units using HFCs, the vast majority of which are produced in the United States. Final adoption of the proposal is expected in 2005. The United States will monitor Commission and Member State activity closely and carefully examine new directives for the impact on business.

**Additional Information on Member State Practices**

Some EU Member States have their own national practices regarding standards, testing, labeling, and certification. A brief discussion of the additional national practices of concern to the United States follows:

*Austria*: Austria became the second EU nation after Denmark to ban a range of uses of the three fluorinated gases (F-gases) controlled under the Kyoto protocol on climate change. An ordinance that took effect on November 22, 2002, prohibits the use in new sprays, solvents, and fire extinguishers of hydrofluorocarbons (HFCs), perfluorocarbons (PFCs), and sulphur hexafluoride (SF6). The ordinance phases out their use in foams between mid-2003 and the end of 2007. It bans their use in new refrigeration and air-conditioning equipment by the end of 2007. The ban appears to exempt production of HFCs for the export market. The European Commission (EC) and some Member States raised serious objections, forcing the Austrian government to re-draft the proposal, particularly with regard to export exemptions. The EC will re-examine the resulting new draft. European industry has pressed the Commission to launch an infringement proceeding against Austria and Denmark. The United States hopes that the Austrian government will consider alternate policy responses.

*Denmark*: On July 2, 2002, the Danish Environment Minister signed into effect a ban of HFCs, PFCs, and SF6, with the first phase-out dates being January 1, 2006 (although new products using these chemicals in tires, spray cans, and district heating pipes are not allowed after September 1, 2002). The ban covers the import, use, and sale, but does not cover HFCs for the export market. There are numerous exemptions provided, the most notable being cooling systems with between 150g and 10kg of HFC gas, mobile refrigeration units, vehicle air-conditioning units, and vaccine coolers. In addition, Denmark established an HFC consumption tax on March 1, 2001.

The Danish Environment and Energy Minister in November 2000 signed an Executive Order banning (as of December 1, 2000) the import and marketing (but not export) of certain products containing lead over the next four years. The ban is at odds with the EU Scientific Committee on Toxicity, Ecotoxicity, and the Environment (CSTEE) report on lead that concluded that there are no scientific grounds for the Danish ban. Products for which viable alternatives do not exist, for example car batteries, are not affected by the ban. U.S. industry estimates that if the ban were lifted, U.S. exports would increase by less than $10 million based on current export levels.

*Finland*: A ban on the importation and sale of new appliances containing HCFC was imposed on January 1, 2000, and remains in place. The importation of the chemical HCFC is allowed when used for maintenance of old appliances using HCFC. New HCFC compounds used for maintenance of refrigeration equipment will be banned as of 2010 and use of all HCFC compounds, including recycled compounds, will be banned as of 2015.

*France*: National standards impose restrictions on the import of U.S. products in several areas, including enriched flour, bovine genetics, and exotic meats. French regulations prohibit the import of any products made with flour enriched with vitamins, since added vitamins are permitted only in dietetic food products. Current French government marketing controls and regulations restrict trade in bovine semen and embryos. Prior to import, a license must be obtained from the French Customs service and approved by the Ministry of Agriculture. Imports of exotic meats are prohibited by the French government unless authorized by a special waiver.

*Germany*: The German Economics Ministry completed consultations with industry and economic groups to review the Environment Ministry's proposal to restrict fluorinated gases. The Economics Ministry criticized the proposal, and produced a detailed, technical report that echoed German industry's concerns. The two ministries are currently studying the EU Commission's proposal on fluorinated gases, to determine whether to adopt this regulation directly into national legislation or to make national legislation on fluorinated gases more restrictive than the EU proposal.

## GOVERNMENT PROCUREMENT

### Discrimination in the Utilities Sector

In an effort to open government procurement markets within the Member States, the EU in 1990 adopted a Utilities Directive covering purchases in the water, transportation, energy, and telecommunications sectors. The Directive, which went into effect in January 1993, required open, objective bidding procedures (a benefit for U.S. firms) but discriminated against bids with less than 50 percent EU content that are not covered by an international or reciprocal bilateral agreement. The Directive's discriminatory provisions were waived for the heavy electrical sector in a May 1993 Memorandum of Understanding (MOU) between the United States and the EU. On April 15, 1994, the United States and the EU concluded a procurement agreement that expanded upon the 1993 MOU. The 1994 agreement extended nondiscriminatory treatment to more than $100 billion of procurement on each side, although it did not cover telecommunications procurement, which remained subject to the discriminatory provisions of the Utilities Directive.

The European Commission in 2000 proposed new legislation that, *inter alia*, included a formal exemption of the entire telecommunications sector from the Utilities Directive. Although the restrictions remain theoretically in place until the new Directives are finally adopted, they are no longer implemented by European telecommunications operators. Several years ago, the European Commission decided not to launch infringement procedures against telecommunications operators who do not abide by the rules of the Utilities Directive.

Starting in 2001, the Council of Ministers and the European Parliament undertook review of the proposed legislation. A political agreement on the adoption of the new Directives was reached by the Council and the Parliament in December 2003. The compromise was formally adopted in February 2004 and the new Directives will now be transposed into the national law of the Member States. The new Directives are not expected to be implemented before 2005.

### Member State Practices

EU Member States have their own national practices regarding government procurement. A brief discussion of some of the national practices of particular concern to the United States follows:

*Austria*: The Federal Procurement Law in effect since September 1, 2002, brought Austria into conformity with applicable EU guidelines, particularly on services. However, U.S. firms continue to report a strong pro-EU bias, often even a bias for purely Austrian solutions, in government contract awards and some privatization decisions. In major defense purchases, most government procurement regulations do not apply, offset agreements up to 200 percent are common, political considerations remain key, and transparency remains limited. Austria's largest military procurement ever, the $2 billion purchase of fighter jets in 2002, continues to raise allegations locally regarding lack of transparency and apparent bias against a U.S. fighter jet proposal.

*Germany*: In 1999, the German Ministry of Economics promulgated a protection clause that would have prohibited firms from bidding on certain German government contracts if they have employees that attend or participate in, among other things, Scientology seminars. The United States expressed concern in bilateral consultations about the clause's potentially discriminatory effects on government procurement. In response, the German government revised its protection clause and no longer prohibits firms from competing for government contracts on the basis of the affiliation of its management or employees with the Church of Scientology unless the contracts involve government information systems or sensitive areas of national security. The U.S. Government will continue to monitor the implementation of the revised policy to ensure that U.S. firms and workers are not discriminated against in German government procurement.

*Greece*: U.S. suppliers of defense material and services express concern that firms from other EU Member States are favored over U.S. firms in competitions for procurement contracts; U.S. firms believe that they are more likely to win defense-related contracts if they compete jointly with EU partner firms. Greece continues to insist on offset agreements as a condition for the purchase of defense items.

*Ireland*: Some U.S. companies competing for government contracts have expressed concern about procurement practices in Ireland. Several unsuccessful U.S. bidders on Irish government tenders have indicated that they are unable to get debriefings on their unsuccessful bids by the contracting agencies, contrary to Irish procurement guidelines. U.S. companies have also questioned the transparency of some awards, and have alleged that unqualified companies have won bids over more qualified firms. In addition, U.S. companies that have been awarded contracts have experienced delays in finalizing contract and commencement dates, and, in a few instances, tenders have been cancelled just prior to contracts being signed.

*Italy*: Italy's government procurement practices have, at times, created obstacles for U.S. firms. Italy has made progress in increasing the transparency of its procurement laws and regulations and has updated its government procurement code to implement EU Directives. The pressure to reduce government expenditures while increasing efficiency has resulted in increased use of competitive procurement procedures and greater emphasis on obtaining the best value. Italy has been receptive to the U.S. Government's suggestion that some government tender practices have tended to disadvantage market entrants that lack the capacity to bundle services to parallel those offered by a single incumbent. Italy's 2001 public works procurement law may streamline the bureaucracy that undertakes major infrastructure work.

The Italian Government agency, CONSIP (Consulenza, Tecnologia, e Project Management per la Pubblica Amministrazione, or Consulting, Technology, and Project Management for Public Administration), overseen by the Ministry of Economy and Finance, is now playing a major role in Italy's public procurement process. CONSIP manages procurements of all goods on behalf of public administration entities, issuing tenders that stipulate framework agreements for specific products and services with suppliers that win the tenders. Framework agreements are executed between a supplier and CONSIP, but the eventual business transaction for a specific product or service is between the supplier and the ordering government entity. CONSIP monitors and ensures that transactions are implemented correctly. U.S. firms have mixed views on the effectiveness and transparency of CONSIP operations to date.

*Spain:* Following the Prestige oil spill, a U.S. firm bidding on a remediation contract found the bidding process arranged by Spanish government authorities at the regional level to lack transparency. After losing the contract, the U.S. company and its Spanish partner learned that the regional authorities awarded the remediation contract to a construction company in which the government has shareholder participation. The winning company's bid price was significantly higher than the bid offered by the U.S. firm and its Spanish partner.

## EXPORT SUBSIDIES

### Government Support for Airbus

Since the inception of Airbus in 1967, the governments of France, Germany, Spain and the United Kingdom have provided direct subsidies to their respective Airbus member companies to aid in the development, production and marketing of Airbus civil aircraft. Airbus member governments have borne a large portion of the development costs for all Airbus aircraft models and provided other forms of support, including equity infusions, debt forgiveness, debt rollovers and marketing assistance, including political and economic pressure on purchasing governments.

The United States, therefore, is concerned about the prospect for further subsidization of Airbus by EU Member States governments. Any distortions caused by WTO inconsistent subsidies would only exacerbate an already difficult situation for the U.S. large civil aircraft industry, brought on by the terrorist attacks of September 11, 2001 and a cyclical industry downturn. Moreover, the Airbus Integrated Company – successor to the original Airbus consortium and representing a partnership of the European Aeronautic, Defense, and Space Company (EADS-80 percent equity share) and BAE Systems (20 percent equity share) – is now the second largest aerospace company in the world. With about half the new aircraft commercial sales worldwide over the last few years, Airbus is a mature company that should face the same commercial risks as its global competitors.

In 2001, the EU announced that seven of the nine EU Member State governments that have companies participating in the Airbus A380 superjumbo airliner project had committed approximately one third of the total cost of the development of the aircraft, then estimated to be $12 billion. France has begun providing 1.3 billion euros in reimbursable advances. The German government has committed to provide one billion euros in loans. The British government announced a commitment of 530 million pounds to underwrite BAE System's participation in the project. The Airbus repayment obligations are to be success-dependent, which means they are repayable only through royalties when aircraft are sold and delivered, and at interest rates that do not appear to reflect the commercial risks involved. The United States, prior to the EU decision, had repeatedly urged the Airbus member governments to ensure that the terms and conditions of their support of the A380 were consistent with commercial terms.

In addition, the city of Hamburg is spending some 750 million euros to lengthen the runway and expand the facilities for Airbus at the EADS Hamburg-Finkenwerder airport to accommodate the expansion of EADS Airbus assembly facility there, including that of the A380. French national and local authorities are providing 46 million euros in aid for road expansion and facility construction for Airbus in Toulouse. These government funds appear to constitute production support for the manufacture of the A380. Furthermore, the EU's aeronautics research programs are driven significantly by a policy intended to enhance the international competitiveness of the European civil aeronautics industry. Through these large research programs, the EU and many of the Airbus member governments have provided significant additional funding to support the development of Airbus aircraft programs, including the A380.

European officials claim that Member State support for Airbus is in compliance with the 1992 U.S.-EU Agreement on Large Civil Aircraft. However, the United States believes that government support to Airbus raises serious concerns about the Member States' adherence to their bilateral and multilateral obligations, including the WTO Agreement on Subsidies and Countervailing Measures (SCM Agreement). Further information continues to be sought from the EU on how its government support comports with the obligations of the 1992 agreement and the SCM Agreement. The United States also believes that increased transparency regarding government support to large civil aircraft manufacturing could reduce the potential for disputes and also foster greater international cooperation in the aerospace industry.

**Government Support for Airbus Suppliers**

**Belgium:** The government of Belgium and Belgian regional authorities subsidize Belgian aircraft component manufacturers (operating as the Belairbus/Flabel consortium), which supply parts to the Airbus Integrated Company. In November 2000, the Belgian federal government reached an agreement with the three regional governments responsible for aviation research and development on a euro195 million package for the development and prefinancing of components for the new Airbus A380. Since then, Belairbus has already received orders worth $1.3 billion for the A380 from Airbus. Although the regional governments of Wallonia, Flanders and Brussels are usually responsible for industrial assistance, this authority has been ceded to the national level for the A380 project. The government of Belgium states that they have discontinued an earlier Belgian exchange rate subsidy program. There is concern that these supports may be inconsistent with the obligations of the U.S.-EU 1992 Agreement on Trade in Large Civil Aircraft and the WTO SCM Agreement.

**France:** In addition to the 1.3 billion euros in reimbursable advances, spread out over several years, for development of the Airbus A380 super-jumbo aircraft, the government of France has committed to provide an additional 59 million euros in reimbursable advances to other aero-structure companies, which have concluded supplier partnership agreements with Airbus for development of the A380 airframe. France's 2004 government budget appropriates 317 million euros toward its A380 reimbursable advance program, to be disbursed to French companies Airbus, Latécoère, Socata and Aircelle. In addition to R&D, specific funds (43.5 million euros in 2004 and 32 million euros in ongoing programs) are earmarked for the development of on-board avionics and structural systems for the Airbus A380 and the Dassault Falcon F7X, a long-range business jet.

**Spain:** The recently completed Puerto Real factory in Spain's Andalucia region is responsible for constructing 10 percent of Airbus' new A380 aircraft. Spain's Ministry of Science and Technology currently subsidizes A380 construction through its agreement to provide 376 million euros in direct assistance through 2013. To date, the ministry has provided 92.5 million euros of that obligation. Furthermore, the regional government of Andalucia has channeled an additional 13 million euros of State General Administration regional incentive funds and 17.5 million euros of its own funds to subsidize the A380 project.

**Government Support for Aircraft Engines**

**United Kingdom:** Since 1988, the government of the United Kingdom has committed 949 million pounds to direct product development of Rolls-Royce civil aircraft engines. Despite Rolls-Royce's substantial market share during this period, the UK government has been repaid only 314 million pounds. This amount would not appear to cover the cumulative interest expense on equivalent commercial debt over the period, let alone provide a return on the loan's principal.

In February 2001, the UK government announced its intention to provide up to 250 million pounds to Rolls-Royce to support development of two additional engine models for large civil aircraft, the Trent 600 and 900. The UK government characterized this engine development aid as an "investment" that would provide a "real rate of return" from future sales of the engines.

The European Commission announced its approval of a 250 million pounds "reimbursable advance" without opening a formal state investigation into whether the advance constituted an illegal (under EU law) state aid. According to the European Commission's statement, the "advance will be reimbursed by

Rolls-Royce to the UK government in case of success of the program, based on a levy on engine deliveries and maintenance and support activity."  Detailed terms of the approved launch aid were not made public.

As the United States noted in last year's NTE report, continuing UK government support of Rolls-Royce raises serious concerns about UK and EU adherence to the WTO SCM Agreement.  U.S. engine suppliers have lost sales of engines and claim that they have encountered suppressed prices in the United States and world markets.  In March 2004, United Kingdom officials stated their expectation that Rolls-Royce would not seek government funding for the development of a new engine to power the Boeing 7E7 aircraft.

**France:**  The government of France-owned engine manufacturer SNECMA will receive 102 million euros in support under a royalty-based system authorized by the European Commission for SNECMA's development work on a family of large engines, including its participation in the Engine Alliance (a joint venture between General Electric Aircraft Engines and Pratt and Whitney).  The proposed 2004 budget appropriates 18.7 million euros for SNECMA in this ongoing program of reimbursable advances for research into new generation engines.  The French government has stated that this support for engine development is not covered by the U.S.-EU 1992 Agreement on Trade in Large Civil Aircraft.

## INTELLECTUAL PROPERTY RIGHTS (IPR) PROTECTION

The EU and its Member States support strong protection for intellectual property rights (IPR), and they regularly join with the United States in encouraging other countries to adhere to and fully enforce such IPR standards as those covered by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).  However, there are a few Member States with whom the United States has raised concerns either through Special 301 or WTO Dispute Settlement procedures about failure to fully implement the TRIPS Agreement.  The United States continues to be engaged with the EU and individual Member States on these matters.

### Copyrights

In April 2001, the EU adopted a Directive establishing pan-EU rules on copyright and related rights in the information society.  The Directive was the result of more than three years of debate and work by the Commission, the European Parliament, and the Council.

The Directive is meant to provide a secure environment for cross-border trade in copyright-protected goods and services, and to facilitate the development of electronic commerce in the field of new and multimedia products and services.  It harmonizes the rights of reproduction, distribution, communication to the public, and the legal protection of anti-copying devices.  The Directive includes a mandatory exception for technical copies on the Internet for network operators in certain circumstances; an exhaustive list of exceptions to copyright which includes private copying (all of the exemptions are optional to the Member States); the harmonization of the concept of fair compensation for rights holders; and a mechanism to secure the benefit for users for certain exceptions where anti-copying devices are in place.

### Designs

The EU adopted a Regulation introducing a single Community system for the protection of designs in December 2001.  The Regulation provides for two types of design protection, directly applicable in each EU Member State: the registered Community design and the unregistered Community design.  Under the registered Community design system, holders of eligible designs can use an inexpensive procedure to register them with the EU's Office for Harmonization in the Internal Market (OHIM), based in Alicante, Spain.  They will then be granted exclusive rights to use the designs anywhere in the EU for up to twentyfive years. Unregistered Community designs that meet the Regulation's requirements are automatically protected for three years from the date of disclosure of the design to the public.

**Patents**

Patent filing and maintenance fees in the EU and its Member States are significantly more expensive than in other countries. Fees associated with the filing, issuance and maintenance of a patent over its life far exceed those in the United States.

**Patenting of Biotechnological Inventions**

On June 16, 1998, after years of debate, the EU adopted a Directive (98/44) on the legal protection of biotechnological inventions. The Directive harmonizes EU Member State rules on patent protection for biotechnological inventions. Member States were required to bring their national laws into compliance with the Directive by July 30, 2000. By the beginning of 2004, some Member States had not yet fully met that obligation.

*Austria*: There is considerable resistance to the Directive in Austria. The Austrian Parliament held a conference on the pros and cons but the Parliament has not yet decided on a timetable for legislation to implement the Directive.

*France*: France has not yet brought its national law into compliance with Directive 98/44. The French government's draft bill transposing the directive into national law is not expected to be approved by Parliament before mid to late 2004. The final disposition of the bill is likely to be compatible with French civil code, which prohibits commercialization of the human body or any of its parts. Also the French seed industry is asking that the Directive be changed so that plant breeders could be authorized to use protected varieties to conduct their research. The French seed industry prefers to use Plant Variety Rights rather than the patent system. The Plant Variety Rights system provided for under the International Convention of 1991 of the Union for Selected Plant Protection, signed by 60 countries, allows varieties protected under the system to be freely used for research and selection of other varieties. Under a patent system, by contrast, such a use would generally be considered infringement.

**Trademarks**

Registration of trademarks with the European Union's Office for Harmonization in the Internal Market (OHIM) began in 1996. OHIM issues a single Community trademark that is valid in all 15 EU Member States.

*Madrid Protocol*: The World Intellectual Property Organization (WIPO) Madrid Protocol, negotiated in 1989, provides for an international trademark registration system permitting trademark owners to register in member countries by filing a standardized application. The EU has taken the political decision to accede to the Protocol and has adopted Regulations needed to effect its accession. The EU accession will be effective in October 2004.

*Geographical Indications*: The EU's system for the protection of geographical indications, apparently reflected in Community Regulation 1493/99 for wines and spirits and Regulation 2081/92 for certain agricultural products and foodstuffs, appears to fall short of what is required under the TRIPS Agreement; notably, that system does not appear to be available to other WTO Members on a national treatment or MFN basis. Under the TRIPS Agreement, the EU is obligated to make such protection available to nationals of all WTO Members. In addition, both regulations appear to deprive trademark owners of

TRIPS-level ownership rights. U.S. industry has been vocal in raising concerns about the impact of these EU regulations on U.S.-owned trademarks.

For these reasons, in 1999 the United States initiated formal WTO consultations with the EU on Regulation 2081/92. Bilateral discussions continued in 2000 and 2001 and intensified in 2002, following the European Commission's release of a number of proposed amendments to the regulation. While some of the proposed amendments to 2081/92 are intended to address the WTO concerns expressed by the United States, they do not address all of these concerns and, in some instances, raise new concerns. In August 2003, the United States requested the establishment of a WTO dispute settlement panel to consider the WTO-consistency of the EU's geographic indications regime. A panel was appointed in February 2004 and the case is expected to continue through the rest of the year.

**Member State Practices**

*Belgium*: Although parallel imports of DVDs from North America have decreased slightly in recent periods, they are still distributed by specialist stores, key retail outlets, and on local and international Internet sites. Parallel imported DVDs also lead to pre-video-release copies on VHS, CD-R, and DVD-R. To date, the Belgian Anti-Contraband Force's (BAF) primary focus on Internet piracy has been hard goods sales. The BAF cooperates with Internet Service Providers to remove offers of illegal goods. Most problems of illegal downloading come from websites located outside the country. Companies report it is difficult to obtain the cooperation of the Police Forces in Internet cases, as they are preoccupied with other security priorities. Annual losses to the U.S. motion picture industry due to audiovisual piracy in Belgium are estimated to be approximately $15 million in 2003. Belgium's 1994 Copyright Law provides deterrent penalties for piracy, but the court system is slow and overburdened. Obtaining a judicial restraining order against Internet piracy, for example, takes two to three months. The importation and sale of DVDs from the United States or elsewhere outside the European Economic Area without the authorization of the rights holders are forbidden under the Copyright Law. The Belgian courts have confirmed that U.S. rights holders are entitled to a distribution right in Belgium, and that such a right can only be exhausted with regard to a specific copy of a work imported by the rights holder or with his consent. The courts have further confirmed that the burden of proof of consent to importation rests solely with the importer.

*France*: The French government has stepped up its efforts to fight piracy. On November 12, 2003, the French government sent to Parliament a bill transposing the May 2001 EU Copyright Directive, which imposes stiffer penalties on offenders than current law. It is expected to be approved during the first half of 2004. The government has also initiated collaborative efforts against piracy with Asian countries. Video piracy and unauthorized parallel imports continue to impose significant losses on U.S. industry. Cable piracy and Internet piracy present further problems in this area. The deterrent effect of law enforcement is limited by the relatively mild penalties imposed on offenders by French courts.

*Germany*: Non-retail outlets (Internet, print media, mail order, open-air markets) represent Germany's major piracy problem. Pirated videos, VCDs, and DVDs are sold primarily by residential mail-order dealers who offer the products via the Internet, newspaper advertisements, or directly sell them in flea markets. German copyright legislation currently allows the making of private copies, which, although it theoretically does not include sharing or downloading of music, has been a legal gray area. German authorities have yet to prosecute pirates who download music or videos from the Internet and then distribute burned CDs or DVDs. The German government in July 2003 passed amendments to the German Copyright Act to bring it in line with the EU Copyright Directive. The amendments entered into force in September 2003. Certain articles of the amendments which allow limited distribution of scientific and technical articles over the Internet have caused consternation among U.S. scientific, technical, and medical publishers, who fear that their German market could be negatively impacted. The Ministry of Justice is consulting with domestic publishers (as well as with USTR) to address these concerns.

*Greece:* Although Greece was removed from the Special 301 Watch List in recognition of progress made in reducing the illegal broadcast of unlicensed films, problems involving copyrighted products and trademarks still exist, especially in the audiovisual and software sectors. The United States looks to the Greek government to strengthen its enforcement of laws governing the protection of patents, copyrights and trademarks.

*Italy*: In 2000, Italy passed a long-awaited anti-piracy law, which had been introduced in Parliament in 1996. The U.S. Trade Representative moved Italy from the Special 301 Priority Watch List to the Watch List as a result. The law and its implementing regulations provide for significant administrative penalties and increased criminal sanctions for violations of music, film, and software copyrights as well as the creation of an anti-piracy steering committee in the Prime Minister's Office to develop national anti-piracy strategies. The law and ensuing efforts by authorities to implement it have led to increased anti-piracy efforts by law enforcement officials. In addition, in June 2003, the Industry Ministry signed a Joint Declaration of Cooperation on Intellectual Property with the U.S. Patent and Trademark Office. Under the Declaration, the parties are developing, in consultation with each other, compatible, Madrid Protocol-compliant web-based registration systems for trademarks. The parties will also share information on the use of legislation to stimulate commercialization of new inventions and on judicial aspects of intellectual property protection. Piracy, however, remains a serious problem. There is still no coordination of anti-piracy efforts at the national level. Moreover, despite having the laws on the books, the judiciary has failed to impose meaningful sanctions against pirates and counterfeiters, thus undermining law enforcement's capacity to deter chronic violations.

*Spain*: In a long-standing case, a well-known U.S. apparel and footwear manufacturer has pursued legal action against infringement of its brand name. While the Spanish Supreme Court ruled against the U.S. company's claims in September 1999, the company appealed to the Spanish Constitutional Court. The Constitutional Court accepted the case for review. In February 2004, the Constitutional Court remanded the case to the Supreme Court. The Supreme Court is expected to issue its revised decision within a year. Copyright infringement has become an increasing problem in Spain's major urban centers. In 2001 there was a sudden surge in street sales of pirate compact disks (CDs). More recently, street sellers have also begun offering pirate CDs and videogames. An estimated 30 percent of CDs sold in Spain are pirated; the estimated pirate sales rate for new releases of the most popular artists is 50 percent. Enforcement and government authorities have taken the threat seriously. The government has revised its Penal Code to better combat IP crime, and has launched consumer and judicial education programs. Spain's Guardia Civil, national police and various municipal police forces have special units and plans focused specifically on fighting CD piracy. By third quarter 2003, Spanish enforcement authorities had seized several million pirated CDs and conducted numerous raids on production and distribution centers.

*Sweden*: U.S. copyright industries have raised concerns about a provision in Swedish copyright law that denies to authors and producers of U.S. audiovisual works, and to the performers that appear in those works, the right to be compensated for private reproductions. U.S. industry questions the consistency of this practice with Sweden's national treatment obligations under the Berne Convention and its national treatment and MFN obligations under the TRIPS Agreement. The government of Sweden has promised to rectify these problems, as well as problems related to levies on blank tapes, through the process of implementing the EU Copyright Directive. According to Swedish Justice Ministry officials, the Swedish Parliament will not address this issue until late Summer 2004 at the earliest.

**SERVICES BARRIERS**

**Concerns Related to 1995 EU Enlargement**

# EUROPEAN UNION

In July 2003, the European Commission notified members of the World Trade Organization of a proposed consolidation of the EU's schedule of specific commitments under the General Agreement on Trade in Services (GATS) pursuant to GATS Article V in order to reflect the 1995 accession to the European Union of Austria, Finland, and Sweden. As a result of this proposed consolidation, a number of previous GATS commitments by these three countries have been modified in a way that may reduce sector-specific or horizontal market access commitments. Although not within the scope of the GATS Article V notification, the consolidation also entails the extension to Austria, Sweden, and Finland of most-favored nation exemptions reflected in the EU's schedule of GATS commitments. As provided for under GATS rules, the United States held initial consultations with the European Commission on this matter in November 2003 in order to evaluate possible adverse consequences to U.S. services trade of the consolidation and the potential for EU compensation to the United States for such consequences. Both sides agreed to consult further. As of March 2004, the United States was considering next steps.

**Television Broadcast Directive (Television with Frontiers Directive)**

In 1989, the EU issued the Broadcast Directive (also known as the Television without Frontiers Directive) which includes a provision requiring that a majority of television transmission time be reserved for European origin programs where practicable and by appropriate means. By the end of 1993, all EU Member States had enacted legislation implementing the Directive. The Commission is currently considering the parameters of a scheduled revision of the Directive.

Several countries have specific legislation that hinders the free flow of some programming. A summary of some of the more salient restrictive national practices follows:

*France*: France continues to apply its more restrictive version of the EU Broadcast Directive, which was first introduced into French legislation in 1992. In implementing the Directive, France chose to specify a percentage of European programming (60 percent) and French programming (40 percent), which exceeded the requirements of the Broadcast Directive. Moreover, the 60 percent European / 40 percent French quotas apply to both the 24-hour day and to prime time slots. (The definition of prime time differs from network to network according to a yearly assessment by France's broadcasting authority, the Conseil Supérieur de l'Audiovisuel, or CSA.) The prime time rules are a significant barrier to access of U.S. programs to the French market. France's broadcasting quotas were approved by the European Commission and became effective in July 1992.

In addition, the United States continues to be concerned about the French radio broadcast quota (40 percent of songs on almost all French private and public radio stations must be Francophone), which took effect on January 1, 1996. The measure limits the broadcast share of American music.

*Germany*: The German Youth Protection Authority has the power at any time to designate or index films that it believes to be unsuitable for minors, in addition to the ratings and classification procedure currently in place. Indexed videocassettes, DVDs, etc., cannot be advertised or publicly displayed. For Internet websites with indexed materials, adult users must register in person at a post office to receive an access code to the sites.

In 2003, in order to streamline youth protection measures and to adapt to new media developments, the Youth Protection Act, applying to videocassettes and DVDs, and an agreement among German states, applying to telemedia services such as the Internet, were promulgated. A Commission for Youth Media Protection was established as a central supervisory authority.

U.S. industry has expressed particular concern that a film may be indexed at any time, thereby exposing distributors and retailers to the constant risk that their business may be subject to onerous restrictions for the sale and rental of indexed products. While countries do have a legitimate interest in protecting minors, regulations should be crafted so as to minimize the disruption for the overall market. These provisions are dampening the fledgling DVD market, given that the costs to withdraw a particular title from release and/or re-edit it to comply with the standards of the Youth Protection Authority are prohibitive. The indexing system could result in rights holders manufacturing separate DVDs for Germany, whereas most DVDs are manufactured on a regional basis.

*Italy*: In 1998, the Italian Parliament passed Italian government-sponsored legislation including a provision to make Italy's national TV broadcast quota stricter than the EU Broadcast Directive. The Italian law exceeds the EU Directive by making 51 percent European content mandatory during prime time, and by excluding talk shows from the programming that may be counted toward fulfilling the quota. Also in 1998, the Italian government issued a regulation requiring all multiplex movie theaters of more than 1,300 seats to reserve 15 percent to 20 percent of their seats, distributed over no fewer than three screens, to showing EU films on a stable basis. In 1999, the government introduced antitrust legislation to limit concentration in ownership of movie theaters and in film distribution, including more lenient treatment for distributors that provide a majority of made in EU films to theaters.

*Spain*: Despite remaining protectionist elements, Spain's theatrical film system has been modified sufficiently in recent years so that it is no longer a major source of trade friction. New government regulations issued in 1997 eased the impact of a 1994 cinema law. The screen quotas adopted in 1997 require exhibitors to show one day of EU-produced film for every three days of non-EU-produced film instead of the original ratio of one to two. In July 2001, after lengthy debate about eliminating film screen quotas, the Spanish Parliament adopted new legislation that maintains quotas. The new law calls for revisiting the issue of potential quota elimination in 2006.

**Postal Services**

United States' express and package service providers remain concerned that postal monopolies in many EU Member States restrict their market access and subject them to unequal conditions of competition. In October 2001, EU Member States agreed to open additional postal services to competition beginning in 2003, including all outgoing cross-border mail. Depending upon the results of a European Commission study (scheduled to be completed by the end of 2006), full liberalization of the EU postal market could occur by 2009.

The procurement of postal services will soon be regulated by the new public procurement Directives recently adopted by the Council of Ministers and the European Parliament (See Government Procurement section above).

*Belgium*: American firms continue to be concerned that the Belgian state railroad is using its monopoly power in rail passenger transportation to cross-subsidize the Belgian package delivery service, known as ABX. The Belgian railroads are also exempt from VAT on their mail transport business and reportedly do not pay any of the fines (such as traffic tickets) frequently incurred by private mail operators. The Belgian Postal Group has developed express mail units to compete with private sector operations in this field. This gives rise to additional concerns regarding cross-subsidization. Concerns have also been expressed about a possible joint venture between the Belgian Postal Group and Belgacom on secure Internet communications. The dominant positions held by the two publicly-owned incumbents could limit competition from other Internet Service Providers (ISPs) in the electronic communications market.

*Germany*: In June 2002, the European Commission found, in a case originally brought by a U.S. firm in 1994, that German postal monopoly Deutsche Post had illegally used state aids to cross-subsidize its package delivery services. Deutsche Post paid the imposed fine of 906 million Euro in January 2003, though it has appealed the Commission's decision to the courts.

**Professional Services**

In the area of professional services, there are significant variations in EU Member State requirements for foreign lawyers and accountants intending to practice in the European Union. While many of these are not outright barriers, disparities among EU Member State requirements can complicate access to the European market for U.S. lawyers and accountants.

**Legal Services**

*Austria*: In general, Austria displays a high degree of regulation intensity, including market entry barriers for all services professions, according to a study carried out by the Austrian Institute for Advanced Studies for the European Commission's Competition Directorate General and published in January 2003. To provide legal advice on foreign and international law on other than a temporary basis, requires establishing a commercial presence as well as joining the Austrian Bar Association. Only an Austrian or other EU national can join the Bar Association. Lawyers from elsewhere in the EU or the European Economic Area (EEA) receive equal treatment under the EU's Directive to Facilitate the Practice of the Profession of Lawyer on a Permanent Basis in a Member State. Citizens from other countries cannot practice law in Austria.

*Denmark*: Foreign legal consultants are restricted in their ability to advertise, including restrictions on the use of letterhead or signs on office doors. These restrictions are not applied to attorneys licensed to practice Danish law. There are restrictions on the ability of foreign lawyers to associate with Danish lawyers. Foreign attorneys may hire Danish attorneys in private firms but foreign attorneys who are not members of the Danish bar cannot own a Danish firm. Also foreign attorneys who do not also have appointment as Danish attorneys cannot be partners in a Danish legal firm. To be an attorney in Denmark, a person must be a Danish law school graduate and clerk in a law firm for three years.

*Finland*: Foreigners from non-EU countries cannot become members of the Finnish Bar Association and receive the higher law profession title of Asianajaja. This does not, however, prevent persons from practicing domestic or international law (including EU law) using the lower level title of Lakimies or Jurisiti. A Finn must pass a test and have five years of legal experience before becoming an Asianajaja. The title gives added prestige and helps solicit clients, but is not essential to practice law.

*France*: There is a nationality requirement to qualify as a practicing lawyer avocat. Non-EU firms are not permitted to establish branch offices in France under their own names. Also, non-EU lawyers and firms are not permitted to form partnerships with or hire French lawyers.

*Germany*: Foreign non-EU lawyers from WTO members that have joined the German Bar Association under their home title may practice international law (but not EU law) and the law of their home country, provided these countries are listed in a Justice Ministry directive as having equivalent bar rules. Such countries include the United States, Japan, New Zealand, Turkey, and Brazil. Foreign lawyers from other WTO members and non-WTO countries may only practice the law of their home country. To be admitted to the bar to practice German law, individuals generally complete five years of study and two years of practical training.

*Ireland*: Lawyers with non-Irish qualifications who wish to practice Irish law and appear before Irish courts must either pass transfer examinations or retrain as lawyers under the direction of the Law Society of Ireland. Only lawyers who have either been admitted to the Bar of England, Wales, or Northern Ireland, practiced as an attorney in New York, Pennsylvania (with five years experience required in Pennsylvania), or New Zealand, or have been admitted as lawyers in either an EU or EFTA Member State are entitled to take the transfer examination.

*Italy*: In 2001, Italy passed a law implementing EU Directive 98/5 on EU lawyers' freedom to establish themselves EU-wide and enabling Italian lawyers to practice jointly, including with EU lawyers, through an Italian societa tra avvocati (company of lawyers, a type of limited liability partnership) or through the Italian branch of a partnership formed in another EU Member State, so long as the societa tra avvocati or partnership is composed exclusively of Italian and EU lawyers. The status of non-EU lawyers is not expressly addressed by the law. This omission leaves the status of international law firms with offices in Italy uncertain, insofar as they have Italian and non-EU lawyers as partners.

**Accounting and Auditing Services**

*France*: There is a nationality requirement for establishment of a practice, which can be waived at the discretion of the French authorities. However, an applicant for such a permit must have lived in France for at least five years.

*Greece*: The transition period for de-monopolization of the Greek audit industry officially ended on July 1, 1997. Numerous attempts to reserve a portion of the market for the former state audit monopoly during the transition period (1994-97) were blocked by the European Commission and came under peer review scrutiny in the OECD. In November 1997, the government issued a presidential decree that continues to undermine the competitiveness of multinational auditing firms. The decree establishes a method for fixing minimum fees for audits, and mandates restrictive professional qualifications requirements for different types of audits. It also prohibits auditing firms from doing multiple tasks for a client, thus raising the cost of audit work. The Greek government has defended these regulations as necessary to ensure the quality and objectivity of audits. However, in practice, the decree represents a step back from deregulation of the industry.

**Architectural Services**

*Austria:* Only citizens from EU and EEA Member States are eligible to obtain a license to provide independent architectural services in Austria. Austria's Schedule of Specific Commitments under the GATS does not list any limitations on the supply of architectural services on a cross-border basis or through a commercial presence. This measure appears to be inconsistent with Austria's GATS commitments on market access and national treatment.

**Telecommunications Market Access**

Both the WTO Basic Telecommunications Agreement and the EU's regulatory framework for telecoms services have spurred liberalization and competition in the European telecommunications sector. Under the WTO Agreement, for example, all EU Member States made commitments to provide market access and national treatment for voice telephony and data services. However, liberalization and harmonization have been uneven across the EU's Member States, as reflected below. In many markets significant problems remain with the provisioning and pricing of unbundled local loops, line sharing, co-location, and the provisioning of leased lines. Partial government ownership of some EU Member States' incumbent telecommunications operators also has the potential to raise problems for new entrants.

In 2002, the EU issued a new regulatory framework for electronic communications that includes a framework directive, which defines the role of National Regulatory Authorities, and four specific directives on licensing, access, and interconnection, universal service and user rights, and data protection.

Member States had until July 25, 2003 to implement the new rules with the exception of the data privacy Directive that required transposition into Member State legislation by the end of October 2003.

This new regulatory framework replaces a number of EU Directives that previously covered the sector, and updates and adapts European legislation to developments such as the continuing convergence of technologies, as well as establishing a system that will be responsive to future technological and market developments. The new regulatory framework will apply to all forms of electronic communications networks and associated services, not just traditional fixed telephony networks. The long-term goal is to phase out sector-specific, *ex-ante* regulation (for all but public interest reasons) in favor of reliance on general competition rules. Many Member States failed to meet the implementation deadline, and the European Commission has commenced the first stage of infringement proceedings to pressure them to bring their regulatory regimes in line with the new framework.

**Member State Practices**

Enforcement of existing legislation by National Regulatory Authorities (NRA) appears hampered by unnecessarily lengthy and cumbersome procedures in France, Italy, Austria, Portugal, among others. The European Commission also found that incumbents in Germany, Greece, Spain, Italy, Ireland, Austria, Finland, and Sweden have slowed the arrival of competition by systematically appealing their national regulators' decisions despite the fact that in most cases the appeals are not successful.

*Austria*: The European Commission found that Austria has already transposed into national law the Framework, Authorization, Access, and Universal Services Directive, and has begun to transpose the e-Privacy Directive. Austria's new Telecom Act went into force August 20, 2003. In general, Austria has moved toward a more open and competitive telecommunications market, despite ongoing issues such as mobile phone spectrum allocation and interconnection fees. The National Regulatory Authorities (NRA) provides timely initial decisions, but follow-up on NRA decisions, including the appeals process for such decisions, remains uncertain and slow.

*Belgium*: Telecom operators in Belgium continue to express concern over the country's slow pace in incorporating European Commission directives into national law. Belgium, together with seven other EU Member States, has not yet implemented the Commission's Telecommunications Regulatory Package. With the threat of infringement proceedings by the Commission, Belgium is expected to pass the legislation in the first quarter of 2004.

Belgacom, Belgium's former telecom monopoly incumbent, is one of the few European operators in which the government is still the majority shareholder. The minority shareholders will divest their stake in an initial offering that is slated for 2004. The operator will not sell its share and intends to purchase 10 percent of the minority holdings, thus increasing the government's share in the company to 60 percent.

Belgacom still enjoys dominant market position in both fixed and mobile telephony with a total 75 percent market share. Regarding broadband access, despite the company's strong position, the number of unbundled local loops is growing. Other Licensed Operators (OLOs) can either collocate with Belgacom in the local exchange or purchase wholesale bitstream access from the company. These offers have had a significant effect on the market, with many OLOs now offering DSL services. However, OLOs contend that Belgacom does not offer a consistent cost model. The OLOs demand that BIPT, the now independent national telecommunications regulatory authority, take measures to ensure that Belgacom develop an honest pricing policy that will enable the OLOs sufficient profit margin.

*Finland*: In Finland, traditional operators still hold 80 percent to 90 percent of local loop operations. Amendments to the Telecommunications Market Act passed in March 2001 intend to increase competition in local networks by creating a new right-of-use obligation in network operations under which local operators are obliged to offer for rent their upper band subscriber lines to other telecommunications service providers (local loop unbundling). Customers are allowed to obtain competitive bids from different telecommunications service providers. As of September 1, 2001, Finns have been able to make local calls using the operator of their choice and choose which operator is used when calling from a fixed-line phone to a mobile subscriber.

In July 2003, the second stage of the comprehensive reform of communication legislation (in 2001-2002) implemented the new Communications Market Act. The stated aims are to improve the legislative environment for competition and the development of communications technology and innovations. The Act implements four new Directives on electronic communications. Internet Service Providers are also included in the scope of the Act.

According to the Act, specific requirements will be applied to telecom operators with significant market power. Regulation of smaller operators is less stringent. The Finnish Communications Regulatory Authority will determine if there is not enough competition within a particular market and institute what it sees as remedial requirements. The intent of the regulation is to approach telecom operators on a case-by-case basis. Decisions of the Communications Regulatory Authority can be appealed to the Supreme Administrative Court. For example, a telecom operator can be required to turn over to another telecom operator, at cost-oriented price, an access right to mobile subscription (SIM card) capacity or some other equivalent capacity of a smart card used in managing communications network termination points. The obligation to relinquish the capacity of a SIM card is expected to promote content production in the communications market.

*France*: The independent regulatory agency Autorité de Régulation des Télécommunications (ART) continues to prod the 50 percent government-owned telecom company, to comply with EU Directives and French law. Nevertheless, former monopolist France Telecom still dominates the fixed line market and is a major player in mobile services and Internet services through subsidiaries Orange and Wanadoo. In the fixed line market, FT has 64 percent market share (by volume) for national and international long distance calls and an 80 percent market share for local calls. Meanwhile, FT subsidiary Orange controls 50 percent of the mobile phone market. In mid-2003, the European Commission sanctioned FT subsidiary Wanadoo for expanding its market share to 72 percent at the expense of its competitors by offering internet services well below costs.

France has still not fully implemented the EU Telecom Framework Directive, despite the July 2003 deadline. Where possible, ART has made regulatory changes to ease the transition to the new framework. However, many formal changes to French law are necessary and draft legislation still awaits Parliamentary approval.

Addressing a long-standing complaint from France Telecom competitors, ART promised to make fixed-to-mobile termination rates more cost-oriented, lowering them 40 percent over three years from 2002 to 2004. Following through on these promised rate reductions, in November 2003, ART announced that Orange and SFR (the two mobile operators with significant market power in interconnection) will decrease their call termination charges by 12.5 percent as of January 2004, following a 15 percent reduction in January 2003.

*Germany*: Germany has made slow progress in introducing competition to some sectors of its telecommunications market. However, new entrants continue to face difficulties competing with the partially state-owned incumbent Deutsche Telekom AG (DT), which retains a near-monopoly in a number of key services, including local loop and broadband connections. The Regulatory Authority for Telecommunications and Posts (RegTP) issued some pro-competitive rulings during 2002 and 2003, but the incumbent challenged virtually all of them in court, meaning most of the decisions have never been implemented. Competitors maintained, and some RegTP officials agreed, that the cumbersome German legal system had become a barrier to competition. On the positive side, implementation of carrier selection and pre-selection for local calling was completed in July 2003 and as a result, competitors gained close to 20 percent of the local calling market. Competitors had hoped that the ongoing revision of the German telecommunications law to implement EU directives, which has already missed the EU's deadline of July 2003, would address many of these competitive problems. While the draft which passed the cabinet October 2003 does attempt to speed up court challenges, investors have criticized its provisions which could severely limit the application of regulation that competitors need to prevent market abuses and which limit competitors' ability to petition RegTP when there are abuses of market power.

Throughout 2003, competitors charged that DT continued to engage in a variety of anticompetitive practices. In January 2003, several telecommunications trade associations and private firms filed complaints with the U.S. Government under Section 1377 of the Omnibus Trade and Competitiveness Act of 1988. The submissions asserted, *inter alia,* that: timely interconnection and timely unbundling of the local loop remained serious problems; DT's unbundled rates were not cost-oriented; DT's broadband monopoly remains unchallenged; and DT and other mobile providers charge excessive termination charges when fixed-line users call mobile phones.

*Ireland*: The government privatized the state monopoly, Telecom Eireann, in 1999, but the new company, Eircom, retains either market dominance or significant market power in fixed lines (80 percent share) and leased line services and national interconnection. Thus, while there are currently 42 fixed line licensed operators in the Irish market, 19 of which are active, these new entrants only account for 20 percent of the fixed line market. Competition has significantly reduced prices for international business and residential calls, while the price for local service remains high, discouraging both broadband development and Internet use.

Significant competition is now emerging in the mobile phone market, with three licensed and active operators. The mobile penetration rate in Ireland in 2003 was 81 percent; there are 3.17 million mobile subscribers. Following adoption of EU local loop unbundling legislation, the Irish government committed to full liberalization of access to the last mile of telephone lines on January 1, 2001. However, progress has been slow. The industry regulator, the Commission for Communications Regulation (COMREG), was embroiled in a legal dispute with Eircom over the tariff rate for the last mile. This dispute was settled in April 2002, which resulted in an overall reduction in charges offered by Eircom. The determination of interconnection rates will benefit new entrants and Irish rates now compare more favorably with prices across the EU.

*Italy*: The Italian telecommunications market is almost fully liberalized. Fixed telephony is fully open to competition, with approximately 220 fixed line operators licensed to provide commercial services including Internet access, local and long distance calls, and international service. Three GSM operators are fully operational, and five third generation cellular (UMTS) licenses were awarded in October 1999 of which four are operational. As elsewhere, the start of UMTS in Italy has been delayed by the market slowdown, high licensing costs, and the bureaucracy involved in launching such services. The local loop is now unbundled. One issue of concern is the continued State role in the telecommunications sector.

Despite the progress in liberalizing the overall telecommunications market, and even though it sold off its residual three percent share in the Telecom Italia, the Italian government is still able to influence the firm. The State also exerts its influence in other companies, as well. For example, the government holds a majority interest in ENEL, the national electricity conglomerate that in turn owns a controlling interest in cellular operator WIND and fixed line operator Infostrada. The government also holds interests in other participants in telecommunications consortia also operating at the national level.

*Spain*: Leased lines in Spain remain problematic as rates are not based on actual cost. The Spanish regulator introduced in 2001 a wholesale offer for the provision of leased lines, a significant price reduction in 2002 (around 35-40 percent), and another moderate reduction (around 15 percent) in July 2003. However, wholesale prices are still above the European average and around 100 percent above U.S. prices. This has allowed the incumbent operator Telefónica to offer to final customers discounts on the leased line which eliminate any advantage in the prices of the downstream services which could be offered by alternative operators.

Spanish mobile operators charge excessive prices for their mobile termination services. The Spanish regulator imposed a reduction of 17 percent on these prices in July 2002 and a seven percent reduction in October 2003, but there is still a wide margin between costs and prices. U.S. citizens and companies calling to European mobile numbers are charged an excessive price. American operators active in the European markets are squeezed out from the fixed-to-mobile communications markets, as mobile operators offer retail mobile-to-mobile and fixed-to-mobile calls at prices below the wholesale termination price. A recent investigation by Spain's antitrust authority found that the three dominant mobile providers (Telefónica Mobiles, Auna, and Vodafone) have launched thousands of retail offers at prices below their wholesale rates. The market awaits announcement of penalties and changes that will be required of these providers.

Evolution of the broadband market has been slow and problematic, and many operators have ceased offering these services. Although Telefónica's market share is slowly being reduced, it is still the dominant player and it is difficult for new entrants to operate on a commercially viable basis in Spain. Competitors that have tried to negotiate nondiscriminatory access directly with Telefónica have been met by refusal from the incumbent, and at times disinterest by the regulator.

*Sweden*: Sweden implemented the EU directive on local loop unbundling (LLUB) in January 2001. Interest in last mile access is increasing as new companies emerge to offer services to a broader customer base. There are complaints at times among new players about price levels and terms of delivery. Charges have to be cost-based and the Swedish National Post and Telecom Agency (PTS) is monitoring activities to make sure that prices are correct.

There is some dissatisfaction among new entrants regarding Telia Sonera's ownership of the copper infrastructure. They would prefer that the company sell that part, which is called Skanova. Skanova would act as an independent supplier of capacity in the market. So far, PTS has seen no need to force Telia Sonera to do so as the market is regulated in this respect.

*United Kingdom*: There is little competition in advanced data services over fixed-line incumbent British Telecom's (BT) infrastructure. In a recent OECD study, the UK ranked near the bottom of OECD countries in the use of broadband services. BT has been criticized by potential competitors for blocking access to its network so that alternative broadband services could be offered; at the same time, BT has been slow to offer its own high-speed data services. Competition in high-speed services is emerging, however, with cable television companies offering lower-priced broadband access over their own infrastructure. In 2002, the integration of broadband services increased rapidly in the UK: one million people had purchased the service by October and 30,000 people a week were subscribing in late 2002. The government has stated that it aims to become the leader in broadband services among G-7 countries by 2005, and the government, including the Prime Minister, have recently given the goal high-level attention.

## INVESTMENT BARRIERS

# EUROPEAN UNION

The European Commission's mandate on investment issues is evolving, and it has a growing role in defining the way in which U.S. investments in EU Member States are treated. Still, in many instances Member State practices are of more direct relevance to U.S. firms. Under the 1993 Maastricht Treaty, free movement of capital became an EU responsibility, and capital controls both among EU Member States and between EU members and third countries were lifted. However, a few Member State barriers existing on December 31, 1993 remain in effect, although EU law can now supersede these. Right of establishment issues, particularly regarding third countries, is a shared competence between the EU and the Member States. The division of this shared competence varies from sector to sector, based on whether the EU has legislated regulations in that sector. Direct branches of non-EU financial service institutions remain subject to individual member country authorization and regulation. EU Member States negotiate their own bilateral investment protection and taxation treaties, and generally retain responsibility for their investment regimes, until and unless they are superseded by EU law. The EU supports national treatment for foreign investors in most sectors. Once established, EU law, with a few exceptions, requires that any company established under the laws of one Member State must, as a Community undertaking, receive national treatment in all Member States, regardless of its ultimate ownership. However, some restrictions on U.S. investment do exist under EU law and others have been proposed (see below).

During 2002, the European Commission conveyed to the United States its concern that certain provisions of Bilateral Investment Treaties (BITs) between the United States and several Central and Eastern European countries could conflict with EU law following the entry of these countries into an enlarged EU. The United States and EU engaged in consultations on this issue during 2002 and 2003. The United States stressed the importance of preserving the treaties and the protections they afford to U.S. investors, but expressed a willingness to explore ways to meet EU concerns regarding legal consistency. On September 2, 2003, the United States, the European Commission, and the eight U.S. BIT partners that are expected to join the EU (Czech Republic, Estonia, Latvia, Lithuania, Poland, the Slovak Republic, Bulgaria, and Romania) endorsed a political Understanding that preserves the BITs. The Understanding sets out the steps that the parties will take to remedy actual or potential incompatibilities between the BITs and EU law. These steps include several narrow amendments and joint interpretations of the BITs and a commitment to continued consultation on EU authority to restrict capital movements into and out of U.S. BIT partners and on future EU measures potentially affecting U.S. investments.

**Ownership Restrictions and Reciprocity Provisions**

The right to provide maritime transport services within certain EU Member States is restricted. EU banking, insurance, and investment services Directives include reciprocal national treatment clauses, under which financial services firms from a third country may be denied the right to establish a new business in the EU if the EU determines that the investor's home country denies national treatment to EU service providers. The right of U.S. firms to national treatment in this area was reinforced by the EU's GATS commitments. In the EU Hydrocarbons Directive, the notion of reciprocity may have been taken further to require mirror-image reciprocal treatment, under which an investor may be denied a license if its home country does not permit EU investors to engage in activities under circumstances comparable to those in the EU. It should be noted, however, that so far no U.S.-owned firms have been affected by these reciprocity provisions.

**Member State Practices**

*Austria*: While European Economic Area Member States' banks may operate branches on the basis of their home country license, banks from outside the EEA must obtain an Austrian license to operate in Austria. However, if such a non-EEA bank has already obtained a license in another EEA country for the operation of a subsidiary, it does not need a license to establish branch offices in Austria.

*France*: There are no general screening or prior approval requirements for non-EU foreign investment. Notification requirements apply to foreign investments, EU and non-EU, for acquisition of a stake of more than five percent in the capital of a firm in the national defense, public safety, or public health sector. The government is able to exert influence over privatized firms through golden share provisions. The use of golden shares remains exceptional. France continues to apply reciprocity requirements to non-EU investments in a number of sectors. For the purpose of applying these requirements, the French government generally determines a firm's residency based on the residency of its ultimate owners rather than on the basis of the firm's place of establishment or incorporation.

*Germany*: Germany's new takeover law, which came into effect on January 1, 2002, has reintroduced measures that allow firms to ward off hostile takeover bids: first, at the stockholder level, where management may be given authority at the annual shareholders' meeting to take measures deemed necessary to guard against unwanted interest; and, second, at the management level where the managing board can take protective measures upon approval by the supervisory board bypassing the need for stockholder approval altogether. These provisions may have negative consequences for outside investors and stockholders.

The German government has introduced legislation to create a right of review and approval for planned investments by foreign entities of 25 percent and more in German armament companies. Planned share acquisitions meeting the threshold must be submitted for approval to an inter-ministerial review. The draft bill was approved by the Cabinet in early December 2003 and is expected to be adopted by Parliament in early 2004. If adopted, the legislation could seriously restrain U.S. and other foreign investors.

*Greece*: Greek authorities take into serious consideration local content and export performance when evaluating applications for tax and investment incentives. However, these factors are not mandatory prerequisites for approving investments.

Greece, which restricted foreign and domestic private investment in public utilities (except for cellular telephony and energy from renewable sources, e.g., wind and solar), has recently opened its telecommunications market and has plans to gradually liberalize its energy sector. As of January 1, 2001, the traditional voice telephony market and the market for providing infrastructure for it has been opened to EU firms. The Greek energy market entered a phase of deregulation in February 2001. The electricity market in Greece will have to be fully deregulated by 2005. In addition, the Development Ministry has continually refused to grant licenses to several U.S. renewable energy providers to connect to the Greek transmission grid, hampering attempts by U.S. firms to develop much needed energy production facilities.

United States' and other non-EU investors receive less advantageous treatment than domestic or other EU competitors in the banking, mining, maritime, air transport, and broadcast industries (which were opened to EU citizens due to EU single market rules). Extensive red tape and contract delays also are major impediments to U.S. investments in Greece. There are national security-related restrictions for non-EU investors on land purchases in border regions and on certain islands.

*Italy:* In conformity with EU Treaty Article 43, Italy provides national treatment to foreign investors except in a few instances. The exceptions include limits to access to government subsidies for the film industry, some additional capital requirements for banks from non-EU countries and restrictions on non-EU airlines operating domestic routes. Firms incorporated in EU countries may offer investment services in Italy without establishing a presence. U.S. and other firms from non-EU countries may operate based on authorization from the Italian Companies and Stock Exchange Commission, the security oversight body (CONSOB, Italy's equivalent of SEC). CONSOB may deny authorization to firms from countries that discriminate against Italian firms. Finally, foreign insurance firms must prove that they have been active in life and property insurance for not less than ten years and must appoint a general agent domiciled in Italy.

*Portugal*: Most foreign investments in Portugal are only subject to *post facto* registration. However, Portugal retains the discretion to limit foreign investment, on a case-by-case basis, in state-owned companies that are being privatized. To date, this prerogative has not been exercised.

*United Kingdom*: On December 1, 2001, the Financial Services Authority (FSA) assumed its full powers and responsibilities under the Financial Services and Markets Act of 2000. In its role as the single statutory regulator responsible for deposit-taking, insurance, and investment business, the Authority requires that key staff at regulated firms be approved by the Authority. Although the rules apply to all banks, globally managed banks had noted the rules would pose a large administrative burden on them, and require that hundreds of bankers already working in the UK seek FSA approval. However, firms and individuals that held equivalent status under the old legislation are being grand-fathered, which means that firms can carry on without re-applying for permission or approval.

## ELECTRONIC COMMERCE

The European Union currently maintains no significant barriers to electronic commerce. However, U.S. businesses and the U.S. Government continue to monitor potential problems related to data privacy regulation and taxation of electronic transactions.

### Data Privacy

Data privacy retains a high profile in transatlantic relations. There are three relevant EU Directives: a horizontal Directive on Data Protection that was adopted in 1995 and took effect in October 1998; a telecommunications-specific Data Privacy Directive that was adopted in 1997 and took effect in October 2000; and a Directive on Privacy and Electronic Communications that extends coverage to all electronic communications passed in July 2002 and was to be transposed into Member State laws by October 2003. Based on the Commission First Report of May 2003 on the transposition of the Data Protection Directive of 1995, only four Member States passed national laws implementing the Directive within the October 1998 deadline. France still has not passed legislation necessary to bring its old data protection law of 1978 fully into line with the Directive. Ireland has passed legislation recently, which has yet to be notified to the Commission.

The horizontal Directive seeks to protect individual privacy with regard to the storage, processing, and transmission of personal data, while still permitting the free flow of data within the EU. It allows transmission of data to third countries, if those countries are deemed by the EU to provide an adequate level of protection, if the recipient can provide other forms of guarantee (e.g., a contract) that ensures adequate protection, or if the data transfer falls within the limited exceptions in the Directive.

The United States and the European Commission concluded in July 2000 a Safe Harbor arrangement that bridges the differences between the EU and U.S. approaches to privacy protection and will help ensure that data flows are not interrupted. Under the Safe Harbor arrangement, U.S. companies can voluntarily participate in the Safe Harbor by self-certifying to the Department of Commerce. Currently, only entities whose activities fall under the regulatory authority of the Federal Trade Commission or the Department of Transportation are eligible to participate in the Safe Harbor. Whether or how other sectors, in particular financial services (banks, insurance, credit unions), telecommunications common carriers and not-for-profits, will be considered in relation to Safe Harbor will be determined in the future. The U.S. Department of the Treasury and the EU Commission agreed at the time the safe harbor arrangement was concluded that separate talks should continue on bringing the benefits of an adequacy finding to the financial services industry. Both sides agreed that it was essential to take into account the additional privacy protections applicable to U.S. financial institutions that would be implemented in 2001 under the Gramm-Leach-Bliley Act of 1999. Discussions on this issue are ongoing.

The telecommunications Data Protection Directive addresses issues such as the storage of customer data and gives consumers rights related to unsolicited calls or faxes as well as inclusion in directories. The new draft privacy Directive proposed in July 2000 includes an update that would expand coverage to all kinds of electronic communications networks and associated services (e.g., Internet services would be covered). It also introduces more stringent restrictions on unsolicited commercial mail and directory services. The proposal has raised a number of questions and practical concerns regarding transnational implications of its implementation on both sides of the Atlantic and its ultimate impact on U.S. service providers remains to be seen. The Directive has made it harder for legitimate direct marketing via the Internet, which is expected to have a detrimental effect on e-commerce. In addition, business has concerns with the proposal in that it will increase the amount of data they have to retain and ensure confidentiality of, thereby making it technically and financially more burdensome.

**Taxation of Electronic Commerce**

On May 7, 2002, the European Union (Council) adopted Directive 2002/38/EC setting out the principles of the system to collect Value Added Tax on electronically supplied services (commerce transaction). While EU Member States have agreed that no new or additional taxes should be imposed on electronic commerce, they found that existing taxes should be adapted and applied. In each EU Member State, a domestic value-added tax (VAT), which is a consumption tax, is payable on deliveries of goods and the provision of services. In this regard, the Council agreed that electronic commerce transactions that do not involve the delivery of physical goods are a provision of a service subject to VAT, no matter whether the services are supplied from inside or outside the EU. From July 1, 2003, U.S.-based companies providing these electronically supplied services (ESS) to EU-based final consumers have had to collect VAT. The Directive sets out an indicative list of the types of services covered, which includes digitally downloadable software, web-site hosting, on-line music delivery, and distance teaching. U.S.-based providers of these services to EU based consumers will be able to choose from three options in order to comply with the new rules. They can establish in the EU (in effect become an EU company), register in each Member State where they make supplies of ESS (the standard business registration for non-established businesses) or use a Special Scheme set up by the Directive that allows non-EU based suppliers to choose a single VAT authority with which to conduct their VAT affairs. (The proposed Directive would require that non-EU suppliers register with a VAT authority in a single Member State.) The VAT on digital products supplied from outside the EU would be levied at the rate applicable in the customer's country of residence, and VAT revenue then reallocated from the supplier's country of registration to that of the customer.

U.S.-based businesses have expressed concern about the potentially discriminatory effects of this Directive. Specifically, U.S. businesses are concerned that the proposed Directive treats U.S. suppliers of electronically supplied services (digital products) less favorably than their EU counterparts. For instance, unless the U.S. supplier establishes a permanent base in the EU it would be obliged to collect and remit VAT at 15 different rates depending on the consumer’s Member State of residence. By contrast, EU suppliers would only be obliged to collect and remit VAT at the rate of the single Member State in which that supplier is registered. Moreover, the Directive appears to create more stringent administrative burdens for U.S. suppliers because they need to check their customer’s location prior to each sale a difficult task in a real time online environment (including strict verification and data storage requirements).

**Member State Practices**

*Austria*: Although Austria was among the first EU countries to introduce a comprehensive law on electronic signatures in 1999, private businesses complain that widespread use of the practice is hampered because only government and quasi-government agencies can accredit firms that provide qualified signature certificates.

## OTHER BARRIERS

### Subsidies for Fruit and Canned Fruit

EU shipments of heavily subsidized canned peaches continue to distort world markets to the detriment of U.S. producers. Similarly, EU subsidies for the production of prunes, table grapes, cherries, and clementines affect U.S. exports to the EU and globally. Although a 1985 U.S.-EU Canned Fruit Agreement brought some discipline to processing subsidies, significant fraud and abuse have undermined the discipline imposed by the Agreement. Under the EU's current subsidy regime, a per-ton payment is made directly to producer organizations such as cooperatives. The United States will continue to monitor EU subsidies to this sector, evaluate their trade-distorting effects, and monitor other areas of interest to our agricultural sector, for example, horticulture, grains, pork, and beef.

### Vitamins and Health Food Products

*Spain:* Spain has restrictive practices with respect to the use of vitamins and health food products. Since March 2002, Ministry of Health inspectors have raided health food shops and removed 227 different types of health food products from the market. Although the EU passed a new directive on dietetics, Spain maintains its restrictive policy with regard to limits in vitamin and mineral composition.