

Agriculture and the Transatlantic Trade and Investment Partnership (T-TIP) Negotiations

(name redacted)

Specialist in Agricultural Policy

July 14, 2016

Congressional Research Service

7-.... www.crs.gov R44564

Summary

The Transatlantic Trade and Investment Partnership (T-TIP) is a potential reciprocal free trade agreement being negotiated between the United States and the European Union (EU). Formal negotiations began in July 2013. Through the negotiations, both sides are seeking to liberalize transatlantic trade and investment, set globally relevant rules and disciplines that could boost economic growth, support multilateral trade liberalization through the World Trade Organization (WTO), and address third-country trade policy challenges. Agricultural issues have been an active topic of debate in the negotiations, given the potential market access gains for both sides and the potential to address a series of regulatory and intellectual property rights issues.

The United States is among the world's largest net exporters of agricultural products. The EU is an important export market for U.S. agricultural exports and ranks as the fifth largest market for U.S. food and farm exports. However, in recent years, growth in U.S. agricultural exports to the EU has not kept pace with growth in trade to other U.S. markets, and imports from Europe currently exceed U.S. exports to the EU. In 2015, U.S. exports of agricultural products to the EU totaled \$12 billion, while EU exports of agricultural products to the United States totaled \$20 billion, resulting in a trade deficit of nearly \$8 billion for the United States and reversing the net trade surplus in U.S. agricultural exports to the EU during the 1990s. (These statistics include data for all current 28 EU member states, including the United Kingdom, which voted in June 2016 to leave the EU, a process that could take many years.)

Addressing market access for U.S. agricultural exports to the EU is among the major goals of the T-TIP negotiation. The U.S. Department of Agriculture (USDA) reports that the EU's average agricultural tariff is 30%, well above the average U.S. agricultural tariff of 12%. Restrictive tariff rate quotas (TRQs) on agricultural products are also a concern for U.S. exporters. A USDA study reports that removing tariffs and TRQs could increase U.S. agricultural exports to the EU by an estimated \$5.5 billion (compared to a 2011 base year). EU exports to the United States are estimated to rise by \$0.8 billion. These totals cover all current 28 EU member states.

High tariff barriers are further exacerbated by additional non-tariff barriers that may limit U.S. agricultural exports. Addressing non-tariff barriers is another major goal of the U.S. agricultural sectors in the negotiation, covering certain sanitary and phytosanitary (SPS) concerns. These include delays in reviews of biotech products (limiting U.S. exports of grain and oilseed products), prohibitions on growth hormones in beef production and certain antimicrobial and pathogen reduction treatments (limiting U.S. meat and poultry exports), and burdensome and complex certification requirements (limiting U.S. exports of processed foods, animal products, and dairy products). As such, T-TIP negotiations on agricultural products are conditioned by a number of these long-standing, high-profile transatlantic trade disputes between the United States and EU. Other EU regulations of concern to U.S. exporters include lack of a science-based focus in establishing SPS measures, difficulty meeting food safety standards and obtaining product certification, lack of cohesive labeling requirements, and stringent testing requirements that are often applied inconsistently across EU member nations. USDA reports that removing select nontariff barriers affecting meats, field crops, and fruits and vegetables could raise U.S. exports to the EU by an additional \$4.1 billion over gains estimated from removing tariffs and TRQs (compared to a 2011 base year) across all current 28 EU member states.

Other U.S. concerns involve the EU's use of geographical indications (GIs)—certain protected product names that many U.S. food producers consider to be generic names. Further complicating negotiations regarding GIs are underlying regulatory and administrative differences between the United States and the EU in how each addresses GIs within their respective borders.

Contents

Agricultural Issues in the Negotiation	1
Studies of Potential Trade Gains	3
Potential Impacts of Brexit	5
Tariff Barriers to Trade	<i>6</i>
Market Access Issues	
Goals and Challenges Within Ongoing Negotiations	
Non-Tariff Barriers to Trade	8
SPS/TBT Issues	
Goals and Challenges Within Ongoing Negotiations	
Agricultural Biotechnology	
Goals and Challenges Within Ongoing Negotiations	
Goals and Challenges Within Ongoing Negotiations	
Next Steps	
Figures	
Figure 1. U.SEU Agricultural Trade, 1980-2015	2
Figure 2. U.SUK Agricultural Trade, 1996-2015	5
Figure 3. EU Member States Opting Out of GM Crop Cultivation	20
Tables	
Table 1. USDA Estimates of Potential T-TIP Gains to U.S. and EU Agriculture	4
Table 2. Estimated AVE Cost of NTMs on U.SEU Agricultural Trade	9
Table 3. USTR-Reported Concerns Involving SPS/TBT Measures in the EU, 2014	
Table 4. Bt Corn Area in the EU, by Member State	19
Table 5. Product Name Registrations Under EU's GI Programs	26
Appendixes	
Appendix. EU's Application of the Precautionary Principle	33
Contacts	
Author Contact Information	37

he Transatlantic Trade and Investment Partnership (T-TIP) is a potential reciprocal free trade agreement that the United States and the European Union (EU) are negotiating with each other. Formal negotiations commenced in July 2013. Both sides had initially aimed to conclude the negotiations in two years but have more recently expressed interest in concluding the negotiations by the end of 2016.

Through the negotiation, the United States and EU seek to enhance market access and trade disciplines by addressing remaining transatlantic barriers to trade and investment in goods, services, and agriculture by negotiating a "comprehensive and high-standard" T-TIP. The goals of the negotiation aim to reduce and eliminate tariffs between the United States and EU; further open services and government procurement markets; enhance cooperation, convergence, and transparency in regulations and standards-setting processes; and strengthen and develop new rules in areas such as intellectual property rights (IPR), investment, digital trade, trade facilitation, labor and the environment, localization barriers, and state-owned enterprises. For more background information on the negotiation, see CRS Report R43387, *Transatlantic Trade and Investment Partnership (T-TIP) Negotiations*.

Agricultural issues have been an active topic of debate in the T-TIP negotiation. The EU is an important export market for U.S. agricultural exports; but growth in U.S. agricultural exports to the EU has not kept pace with growth in trade to other U.S. markets. Agricultural imports from Europe currently exceed U.S. exports to the EU. The U.S. Department of Agriculture (USDA) reports that the EU's import tariffs on U.S. agricultural products average well above U.S. tariffs on EU agricultural products. High EU average tariffs on U.S. exports are exacerbated by the EU's non-tariff barriers to U.S. agricultural products.

Agricultural Issues in the Negotiation

The United States is among the world's largest net exporters of agricultural products, averaging more than \$140 billion per year (2010-2015) worldwide. The EU is a leading export market for U.S. agricultural exports—absorbing roughly 10% of exports—and is ranked as the fifth largest market for U.S. food and farm exports. In recent years, however, growth in U.S. agricultural exports to the EU has not kept pace with growth in trade to other U.S. markets, and imports from Europe currently exceed U.S. exports to the EU. In 2015, U.S. exports of agricultural products to the EU totaled \$12 billion, while EU exports of agricultural products totaled \$20 billion, resulting in a substantial trade deficit of nearly \$8 billion for the United States. This reverses the net trade surplus in U.S. agricultural exports during the early 1990s (see **Figure 1**). Overall, compared to the value of all merchandise trade (both agricultural and non-agricultural products) between the United States and EU, agricultural trade accounts for less than 5% of total trade annually.

Major U.S. agricultural exports to the EU include tree nuts, soybeans, forest products, distilled spirits, vegetable oils, wine and beer, planting seeds and tobacco, and processed fruit and wheat. Major EU agricultural exports to the United States include wine and beer, essential oils, snack foods, processed fruits and vegetables, other vegetable oils, cheese, cocoa paste/butter, live animals, nursery products, and red meats.²

¹ USDA, "EU-U.S. Agricultural Trade and the TTIP," GAIN Report E14009, February 5, 2014.

² USDA, "Why Trade Promotion Authority Is Essential for U.S. Agriculture and the Transatlantic Trade and Investment Partnership," April 2014.

These statistics include data for all current 28 EU member states,³ including the United Kingdom (covering England, Scotland, Wales, and Northern Ireland), which voted in June 2016 to exit the EU (referred to as "Brexit").⁴ Separate trade data for the UK is provided in the section titled "Potential Impacts of Brexit."

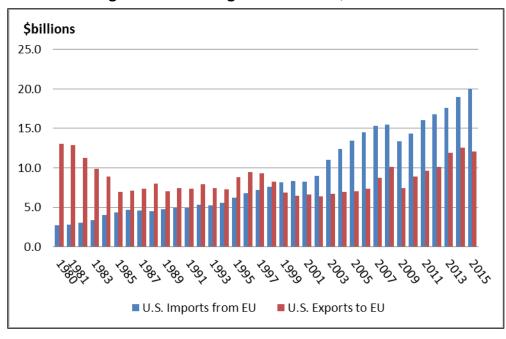


Figure 1. U.S.-EU Agricultural Trade, 1980-2015

Source: CRS from trade data for "Agricultural Products" posted at USDA's Foreign Agricultural Service's Global Agricultural Trade System, http://apps.fas.usda.gov/gats/ExpressQuery I.aspx. Product grouping for "Agricultural Products" is defined by USDA and does not include data for other "Agricultural Related Products" covering distilled spirits, fish and seafood, and forestry and bioenergy products.

Notes: Reflects data for the EU-28 countries over the time period (calendar year), including the UK (England, Scotland, Wales, and Northern Ireland).

Agricultural issues have been actively debated in the T-TIP negotiation in the context of market access for agricultural products through reduced or eliminated agricultural import tariffs but also within regulatory and intellectual property rights discussions by addressing existing non-tariff measures that may be barriers to trade. These goals are generally shared by both U.S. and EU agricultural organizations.⁵

Negotiating agricultural issues regarding regulatory and intellectual property rights issues have focused, in part, on the goals of ensuring greater transparency, harmonization, and coherence to improve cooperation and streamline the regulatory approval process among the trading partners. However, negotiating such issues is often complicated by long-standing differences between the

³ For a listing of the EU member countries, see http://europa.eu/about-eu/countries/member-countries/.

⁴ For more information, see EC fact sheet, "UK Referendum on Membership of the European Union: Questions & Answers," June 24, 2016, and also CRS Insight IN10513, *United Kingdom Votes to Leave the European Union*.

⁵ See, for example, and Copa-Cogeca, "Copa and Cogeca Urge EU Chief Negotiators to Make Progress on Eliminating Red Tape and Non-Tariff Barriers to Trade in Transatlantic Trade (TTIP) Talks When Meet Next Week," press release, October 14, 2015. Copa-Cogeca (European Farmers European Agri-Cooperatives) represents farmers and agri-cooperatives across 70 member organizations from EU member states.

United States and EU in terms of laws and regulations governing food safety and sanitary and phytosanitary (SPS) measures. These include disputes over the use of hormones in beef production and pathogen reduction treatment for poultry, regulations related to bovine spongiform encephalopathy (BSE, commonly known as mad cow disease) and pesticide residues on foods, animal welfare, agricultural biotechnology (genetically modified organisms, or GMOs), and the use of certain product names and brands and so-called Geographical Indications (GIs).

Negotiating documents that were made public in May 2016 were said to suggest that the EU was considering making concessions to its policies and standards regarding SPS and other issues. This interpretation of events has been largely discredited by policymakers in both the United States and EU.

The Office of the United States Trade Representative (USTR) maintains a website that provides a summary of U.S. objectives, negotiating round and public forum information, blog posts, facts sheets, reports, and press releases. The European Commission (EC) maintains the EU's official website, which contains negotiating proposals and fact sheets on T-TIP, covering market access, and regulatory cooperation (including SPS, technical barriers to trade [TBT], and IPR issues), among other sectors and negotiation issues.

Studies of Potential Trade Gains

A USDA study reports that removing tariffs and tariff rate quotas (TRQs) in U.S.-EU trade could have increased U.S. agricultural exports to the EU by an estimated \$5.5 billion, measured against a 2011 base year. Gains would be greatest in the U.S. livestock sectors. EU exports to the United States are also estimated to be higher by \$0.8 billion compared to the study's 2011 base year (Table 1). On a percentage basis, accounting for trade diversions to and from other U.S. trading partners globally, U.S. agricultural exports would have been 2% higher, while U.S. imports would have risen by 1%. By comparison, changes in both EU agricultural exports and imports are estimated to be lower. These results suggest that while agricultural trade between the United States and EU is expected to increase, the overall gains to U.S. agricultural exports could be greater than gains in EU exports, mostly attributable to expected lower overall prices for U.S. products following the removal of EU tariffs and TRQs.

USDA further reports that removing selected non-tariff barriers, in addition to removing tariffs and TRQs in U.S.-EU trade, could increase U.S. agricultural exports to the EU by an additional estimated \$4.1 billion annually (measured against a 2011 base year). Gains would be greatest to the U.S. livestock and produce industries. EU exports to the United States are estimated to rise by an additional \$1.2 billion (**Table 1**). On a percentage basis, U.S. agricultural exports are estimated to increase by 2% while U.S. imports rise by less than 1%. By comparison, changes in both EU agricultural exports and imports are estimated to be lower.

⁶ SPS and related regulatory issues may be included as part of either an agriculture chapter or a chapter on regulatory coherence issues, whereas GIs may likely be included in a discussion of IPR.

⁷ USTR, "Transatlantic Trade and Investment Partnership (T-TIP)," https://ustr.gov/ttip.

⁸ The EC is the EU's executive body and represents the interests of the EU as a whole. It is responsible for proposing legislation, implementing decisions, upholding the EU's treaties, and day-to-day running of the EU.

⁹ EC, "In Focus: Transatlantic Trade and Investment Partnership (TTIP)," http://ec.europa.eu/trade/policy/in-focus/ttip/.

¹⁰ J. Beckman et al., *Agriculture in the Transatlantic Trade and Investment Partnership: Tariffs, Tariff-Rate Quotas, and Non-Tariff Measures*, USDA, ERR-198, November 2015. Estimates compared to a 2011 base year.

Table I. USDA Estimates of Potential T-TIP Gains to U.S. and EU Agriculture

Scenario	Change in trade value compared to 2011 base	Percent change compared to 2011 base
Scenario I (removal of tariffs and TRQs)		
Changes to U.S. exports to EU	+\$5.5 billion	+39.5%
Changes to U.S. exports to other countries	-\$1.7 billion	-1.4%
Changes to EU exports to U.S.	+\$0.8 billion	+3.8%
Changes to EU exports to other countries	+\$0.2 billion	<1%
Scenario 2 (removal of select NTMs, in a	addition to gains from tariffs/TR	Q removals)
Changes to U.S. exports to EU	+\$4.1 billion	+29.7%
Changes to U.S. exports to other countries	-\$1.2 billion	-0.8%
Changes to EU exports to U.S.	+\$1.2 billion	+5.7%
Changes to EU exports to other countries	+\$0.5 billion	<1%

Source: J. Beckman et al., Agriculture in the Transatlantic Trade and Investment Partnership: Tariffs, Tariff-Rate Quotas, and Non-Tariff Measures, USDA, ERR-198, November 2015. NA = Not Available.

Notes: Estimates are compared to a 2011 base year, reported at \$13.9 billion (U.S. agricultural exports to the EU), \$64.0 billion (total U.S. agricultural exports), \$21.2 billion (EU agricultural exports to the United States), and \$498.8 billion (total EU agricultural exports).

An EU-financed a study of the economic impacts of T-TIP—measured in terms of changes in gross domestic product, employment, and production at a sectoral level for most economic sectors, including the agricultural sector—concludes that the expected impact of T-TIP on agricultural output and employment would be low compared to estimated impacts in other sectors. However, some gains are expected in U.S.-EU agricultural trade. According to the study, the estimated percentage change in U.S. exports of cereals/grains and vegetables/fruit is generally expected to be greater than that estimated for the EU, while the change in EU imports of these same product categories is expected to be lower than that for the United States. Other studies also predict an increase in U.S. exports. Other studies have reported estimated effects by economic sector, including agriculture and food sectors, for each of the EU member states. Another study by the European Parliament acknowledges that gains from tariff cuts would be limited unless regulatory and administrative barriers are also addressed.

All available studies of the possible trade gains under T-TIP were completed assuming an EU membership of 28 countries, and to date none have accounted for the possible exclusion of the UK from the agreement.

¹¹ Ecorys, *Trade SIA on the Transatlantic Trade and Investment Partnership (TTIP) Between the EU and the USA*, Draft Interim Technical Report, May 2016. Study scenarios are calculated under both an "ambitious" and "less ambitious" (often times referred to as "TTIP light") scenarios. The Centre for Economic Policy Research conducted a previous study, "Reducing Transatlantic Barriers to Trade and Investment: An Economic Assessment," in March 2013.

¹² Friends of the Earth, "Trading Away EU Farmers the Risks to Europe's Agriculture from the TTIP," April 2016.

¹³ See, for example, World Trade Institute, TTIP and the EU Member States, 2016.

¹⁴ European Parliament, Risks and Opportunities for the EU Agri-Food Sector in a Possible EU-US Trade Agreement, July 2014.

Potential Impacts of Brexit

The potential impact of Brexit on T-TIP remains unclear, and both parties are currently evaluating the effect of Brexit on the negotiations. ¹⁵ Technically, the referendum is only advisory for the European Parliament, and a high degree of uncertainty remains about how the separation might work, which will likely take years. Nevertheless, the exclusion of the UK from the EU could be significant in terms of the reduction of potential trade gains under the T-TIP agreement. The UK is one of the largest among the European economies and accounts for a sizeable share (about 15%) of U.S. agricultural exports to the EU each year.

In 2015, U.S. exports of agricultural products to the UK totaled \$1.8 billion, consisting mostly of wine and beer, fruit products, oilseed and cereal grains, and other miscellaneous edible products. EU agricultural exports to the United States totaled \$0.7 billion in 2015, consisting mostly of cheese and dairy products and also beer (**Figure 2**). These statistics exclude distilled spirits, fish and seafood, and other agricultural products. Including these products yields a very different trade picture, as the U.S. and UK trade heavily in distilled spirits (e.g., whiskey and gin) and fish products. In 2015, U.S. exports of all agricultural, fisheries, and distilled spirits to the UK totaled \$1.9 billion, while UK exports of these products to the United States totaled \$2.3 billion. ¹⁶

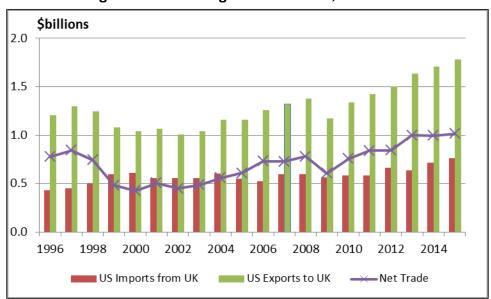


Figure 2. U.S.-UK Agricultural Trade, 1996-2015

Source: CRS from trade data for "Agricultural Products" posted at USDA's Foreign Agricultural Service's Global Agricultural Trade System, http://apps.fas.usda.gov/gats/ExpressQuery I.aspx. Product grouping for "Agricultural Products" is defined by USDA and does not include data for other "Agricultural Related Products" covering distilled spirits, fish and seafood, and forestry and bioenergy products.

Notes: Reflects calendar year data for the UK (England, Scotland, Wales, and Northern Ireland).

¹⁵ See, for example, USTR, "Remarks by Ambassador Michael Froman at the Bretton Woods Committee Annual Meeting," June 27, 2016; and P. Hutchinson, "EU Leaders to Reconsider TTIP Negotiating Mandate," *Food Chemical News*, June 3, 2016.

¹⁶ Compiled by CRS from trade data posted at the U.S. International Trade Commission (USITC) Interactive Tariff and Trade DataWeb database covering harmonized trade schedule codes in chapters 1 through 22. For other information, see USDA, "United Kingdom: Exporter Guide," December 23, 2015.

Among the types of issues cited by proponents of the UK exiting the EU were concerns about EU bureaucracy and regulations emerging out of Brussels¹⁷ as well as concerns about national sovereignty, among other issues. In the food industry, UK food manufacturers had supported remaining in the EU and expressed concern that leaving the EU would affect the food sectors, since most of the workforce is from the EU and much of the UK's food is supplied by other EU countries. Opinion among UK farmers was more mixed: Some worried about the loss of agricultural support under the EU's Common Agricultural Policy (CAP), while others wanted to remove the perceived burden of EU environmental regulations and restrictions on pesticide use. Overall, the UK imports more food than it exports to other EU countries.

Tariff Barriers to Trade

Market Access Issues

Increased market access by reducing or eliminating tariffs and modifying TRQs on agricultural products is a primary goal for U.S. agricultural exporters in negotiating the T-TIP. Some claim that high EU tariffs effectively price U.S. agricultural products out of the EU market and contribute to the U.S. trade deficit in agriculture trade.²¹

The World Trade Organization (WTO) reports that the simple average most-favored-nation (MFN) tariff²² applied to agricultural product imports in the United States was 5.1% in 2014, compared to an average MFN tariff of 12.2% for the EU.²³ Including all products imported under an applied tariff and TRQ, USDA reports that the calculated average rate across all U.S. agricultural imports is roughly 12% overall, well below the EU's average of 30%.²⁴ By commodity group, EU tariffs average more than 40% for imported meat products, grains, and grain products and average at or above 20% for most fruit and vegetable products. For some products EU tariffs are even greater, averaging more than 80% for imported dairy products, more that 50% for sugar cane and sweeteners, and nearly 350% for sugar beets.²⁵ USDA further notes that other EU trading partners benefit from preferential tariff access to the EU, given that the EU has concluded FTAs with more than 30 countries and plans to negotiate agreements with a dozen

¹⁷ Most of the EU's primary institutions are located in Brussels, Belgium, including the EC, the Council of the European Union, the European Council, and also an important seat of the European Parliament.

¹⁸ See, for example, M. Stone, "Food Manufacturers Back EU Membership 'Overwhelmingly," FoodNavigator.com, March 16, 2016; and R. Pendrous, "Brexit Will 'Damage UK Food Manufacturing:' Survey," June 6, 2016.

¹⁹ J. Lawless, "British Farmers Crave Independence but Fear Cost of EU Exit," Associated Press, June 20, 2016. For information on the CAP, see CRS Report R44524, *EU Agricultural Support: Overview and Comparison with the United States*.

²⁰ J. Hopkinson, "U.K. Farmers Ready to Try Brexit Despite Warning Signs," *PoliticoPro Agriculture*, June 22, 2016.

²¹ See, for example, *World Trade Online*, "U.S. Envoy Charges EU Stance on Agriculture Could Endanger TTIP Deal," March 22, 2016.

²² MFN tariffs are normal non-discriminatory tariffs charged on imports (excluding preferential tariffs under free trade agreements [FTAs] and other schemes or tariffs charged inside quotas) applied by countries/customs territories.

²³ WTO, World Tariff Profiles, 2015, https://www.wto.org/english/res_e/booksp_e/tariff_profiles15_e.pdf.

²⁴ USDA, "Why Trade Promotion Authority Is Essential for U.S. Agriculture and T-TIP," February 2015.

²⁵ P. Gibson et al., *Profiles of Tariffs in Global Agricultural Markets*, USDA, AER-796, January 2001. See Table 2. The EU tariff schedule can be accessed at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri= OJ:L:2014:312:FULL&from=EN.

more countries.²⁶ This preferential access provides other U.S. export competitors an advantage over U.S. agricultural exporters.

TRQs on agricultural products are also a concern for U.S. exporters. TRQs allow imports of fixed quantities of a product at a lower tariff. Once the quota is filled, a higher tariff is applied on additional imports. The EU allocates TRQs to importers using import licenses issued by the member states' national authorities. Only companies established in the EU may apply for import licenses. For exports under a U.S.-specific TRQ, a certificate of origin must be supplied. The EU has TRQs on exports of many beef and poultry products, sheep and goat meat, dairy products, cereals, rice, sugar, and fruit and vegetables. Some products are heavily protected by both TRQs and non-tariff SPS measures. Products are heavily protected by both TRQs and non-tariff SPS measures.

Goals and Challenges Within Ongoing Negotiations

Previous exchanges of proposals on market access mostly excluded agricultural products.³⁰ According to press reports, in October 2015, the United States and EU exchanged their initial tariff and market access offers for agricultural and industrial products.³¹ Limited information is available on these proposals and the status of the negotiations. However, negotiating documents leaked in May 2016 suggest that the negotiations are focused on eliminating certain agricultural tariff lines over an undetermined phase-out period that could exceed seven years—a category known as the "T-box."³² For the United States, these include 19 lines for swine and lamb/sheep, 17 lines for dairy and cheese products, 13 lines for chocolate, four lines for olives, and 25 lines for food preparations and miscellaneous products.³³ In addition, within fishery products, another 14 lines are being negotiated for sturgeon roe, sardines, tuna, fish sticks, and caviar.

The EU's T-box tariff lines are roughly split between agricultural and industrial products. The EU's agricultural tariff lines include 23 lines for poultry meat, four lines for hams and swine meat preparations, eight lines for barley/maize/wheat and wheat flour, nine lines for rice, two lines for bakery and food preparations and fertilized eggs other than chicken, and another 51 lines for miscellaneous products. Other more recent information suggests the negotiations have not addressed tariff lines reserved for certain "sensitive" agricultural products, such as beef, pork, poultry, dairy, rice, and fruits and vegetables, many of which are protected by TRQs. The European Council of Young Farmers (CEJA) calls for the protection of certain sensitive sectors even if it involves safeguard clauses, such as import quotas or the "exclusion of some sectors,"

²⁶ For more information on EU FTAs, see EC, "Bilateral Investment Dialogues and Agreements," http://ec.europa.eu/internal_market/capital/third-countries/bilateral_relations/index_en.htm. Information on EU FTAs and trade negotiations is available at http://ec.europa.eu/trade/policy/countries-and-regions/agreements/.

²⁷ USDA, "Tariff Rate Quotas," http://www.usda-eu.org/trade-with-the-eu/tariffs/tariff-rate-quotas/. Council Regulation 717/2008 establishes a procedure for administering quantitative quotas. Rules on the administration of TRQs for agricultural products under a system of import licenses are set out in Council Regulation 1301/2006.

²⁸ M. Normile et al., U.S. and EU Farm Policy—How Similar?, USDA, WRS-04-04, February 2004.

²⁹ See, for example, S. Arita et al., *Sanitary and Phytosanitary Measures and Tariff-Rate Quotas for U.S. Meat Exports to the European Union*, USDA, LDPM-245-01, December 2014.

³⁰ Inside U.S. Trade, "TTIP Stumbles Over U.S.-EU Differences on Regulatory Changes, Tariffs," February 28, 2014.

³¹ EC, "The Transatlantic Trade and Investment Partnership (TTIP) State of Play," April 2016.

³² Previous reports indicate that tariff discussions involve certain timeline baskets for tariff elimination, including immediate and phase-out over different year increments.

³³ World Trade Online, "U.S., EU Remain at Odds Over Maximum Tariff Phaseout Periods in TTIP," May 10, 2016.

³⁴ P. Hutchison and D. Conroy, "TTIP Talks Round 13: GIs Discussed but Stand-Off Remains," *Food Chemical News*, May 2, 2016.

regarding a number of different factors (such as production costs, price, environmental standards, animal welfare, etc.)" especially in sectors "particularly threatened by competition (e.g.: beef)." 35

In April 2016, Senate leadership sent a letter to USTR reiterating that a final agreement with "a strong framework for agriculture," including "tariff elimination on all products—including beef, pork, poultry, rice, and fruits and vegetables" and "liberalization in all sectors of agriculture" remains a priority, if the agreement is to obtain the support of Congress. ³⁶ The letter also addressed the importance of "longstanding regulatory barriers," including import approval of U.S. biotechnology products and addressing concerns about "geographical indication (GI) restrictions promoted by the EU."

Non-Tariff Barriers to Trade

High tariff barriers are further exacerbated by additional non-tariff barriers that may limit U.S. agricultural exports, including SPS measures and other types of non-tariff barriers. *Non-tariff measures* (NTMs) generally refer to policy measures other than tariffs that may have a negative economic effect on international trade.³⁷ NTMs include both technical and nontechnical measures. Technical measures include both SPS and TBTs and pre-shipment formalities and related requirements. Nontechnical measures include quotas, price control measures, rules of origin requirements, and government procurement restrictions.

Non-tariff barriers affect agricultural trade in various ways, including delays in reviews of biotech products (creating barriers to U.S. exports of grain and oilseed products), prohibitions on growth hormones in beef production and certain antimicrobial and pathogen reduction treatments (creating barriers to U.S. meat and poultry exports), and burdensome and complex certification requirements (creating barriers to U.S. processed foods, animal products, and dairy products).³⁸

A report by the U.S. International Trade Commission³⁹ notes that in addition to high EU tariffs, extensive EU regulations and difficulty finding up-to-date information are among the primary concerns of U.S. businesses, particularly for makers of processed foods. U.S. businesses report concerns about the lack of a science-based focus in establishing SPS measures, difficulty meeting food safety standards and obtaining product certification, differences across countries in food labeling requirements, and stringent testing requirements that are often applied inconsistently across EU member nations.

USDA has calculated the *ad valorem equivalent* (AVE)⁴⁰ effects for a range of agricultural commodities based on both U.S. and EU non-tariff barriers to imports. EU non-tariff barriers to U.S. agricultural exports are estimated to range from 23% to 102% for some more heavily protected products, including meat products, fruits and vegetables, and some crops (**Table 2**).

-

³⁵ CEJA, "CEJA Position Paper Transatlantic Trade and Investment Partnership (TTIP)," April 28, 2015. CEJA promotes "a younger and innovative agricultural sector across the EU 28."

³⁶ Letter from Senate leadership to Ambassador Froman, USTR, April 22, 2016.

³⁷ For more information, see U.N. Conference on Trade and Development, *Non-Tariff Measures: Evidence from Selected Developing Countries and Future Research Agenda*, 2010.

³⁸ S. Arita et al., Estimating the Effects of Selected Sanitary and Phytosanitary Measures and Technical Barriers to Trade on U.S.-EU Agricultural Trade, USDA, ERR-199, November 2015.

³⁹ USITC, Trade Barriers that U.S. Small and Medium-sized Enterprises Perceive as Affecting Exports to the European Union, Investigation 332-541, USITC Publication 4455, March 2014.

⁴⁰ AVE refers to import duties or other charges levied on a traded good, expressed as a percentage of the value of the imported item and not based on the weight, size, or quantity of the item.

SPS/TBT Issues

SPS measures are laws, regulations, standards, and procedures that governments employ as "necessary to protect human, animal or plant life or health" from the risks associated with the spread of pests, diseases, or disease-carrying and causing organisms or from additives, toxins, or contaminants in food, beverages, or feedstuffs. Examples include product standards, requirements for products to be produced in disease-free areas, quarantine and inspection procedures, sampling and testing requirements, residue limits for pesticides and drugs in foods, and limits on food additives. TBTs cover both food and non-food traded products. TBTs in agriculture include SPS measures and other types of measures related to health and quality standards, testing, registration, certification requirements, and packaging and labeling regulations. Examples include process and product standards; technical regulations; product environmental regulations; voluntary procedures relating to health, sanitation, and animal welfare; inspection procedures; product specifications; and approval and marketing of biotechnology.

Table 2. Estimated AVE Cost of NTMs on U.S.-EU Agricultural Trade

Sector	Example of Non-Tariff Measures in Sectors	Ad Valouere Equivalent (AVE)		
EU Sectors	with Non-Tariff Concerns Raised by U.S. Exporters	Ad Valorem Equivalent (AVE)		
Beef	Growth hormones, pathogen reduction treatment (PRTs)	23%		
Poultry	PRTs	102%		
Pork	Ractopamine, trichanae, PRTs	81%		
Corn	Biotech restrictions	79%		
Soy	Biotech restrictions	17%		
Fruits	Maximum residue limits	35%		
Vegetables	Maximum residue limits	53%		
U.S. Sectors	s with Non-Tariff Concerns Raised by EU Exporters			
Beef	Bovine spongiform encephalopathy (BSE)	N/A		
Fruits	Import approval process	45%		
Vegetables	Import approval process	37%		

Source: S. Arita et al., Estimating the Effects of Selected Sanitary and Phytosanitary Measures and Technical Barriers to Trade on U.S.-EU Agricultural Trade, USDA, ERR-199, November 2015, Table 5, p. 11. N/A = "Not Available."

SPS/TBT measures regarding food safety and related public health protection are addressed in various multilateral trade agreements and are regularly notified to and debated within the WTO. International trade rules recognize the rights and obligations of governments to adopt and enforce such requirements. These rules are spelled out primarily in two WTO agreements: (1) the Agreement on Sanitary and Phytosanitary Measures, and (2) the Agreement on Technical Barriers to Trade.⁴¹

In general, under the SPS and TBT agreements, WTO members agree to apply such measures, based on scientific evidence and information, only to the extent necessary to protect human, animal, or plant life and health and to not arbitrarily or unjustifiably discriminate between WTO members where identical standards prevail. Member countries are also encouraged to observe

⁴¹ Both agreements were entered into force on January 1, 1995, as part of the establishment of the WTO.

established and recognized international standards. Improper use of SPS and TBT measures can create substantial barriers to trade when they are disguised protectionist barriers, are not supported by scientific evidence, or are otherwise unwarranted. For more background information see CRS Report R43450, *Sanitary and Phytosanitary (SPS) and Related Non-Tariff Barriers to Agricultural Trade.*

Goals and Challenges Within Ongoing Negotiations

Goals of the Negotiation

Among the stated goals of T-TIP regarding SPS and TBT issues are to negotiate provisions that "go beyond" both the WTO SPS and the TBT agreements—referred to as "SPS-Plus" and "TBT-Plus"—as outlined in a report submitted by U.S. and EU trade officials as part of the so-called U.S.-EU High Level Working Group on Jobs and Growth (HLWG). The text box below describes the HLWG's recommendations regarding SPS and TBT issues.

U.S.-EU High Level Working Group (HLWG) Regarding "SPS-Plus" and "TBT-Plus"

SPS measures are laws, regulations, standards, and procedures that governments employ as "necessary to protect human, animal or plant life or health" from the risks associated with the spread of pests, diseases, or disease-carrying and -causing organisms or from additives, toxins, or contaminants in food, beverages, or feedstuffs. TBTs cover both food and non-food traded products.

As part of ongoing trade negotiations, a final report submitted by U.S. and EU trade officials as part of the HLWG to advise T-TIP negotiations recommended that the United States and EU seek to negotiate both an "ambitious 'SPS-plus' chapter" and an "ambitious 'TBT-plus' chapter" to the agreement. Recommendations submitted to the President of the United States and leadership in the European Council and the EC call for:

- an "ambitious 'SPS-plus' chapter, including establishing an ongoing mechanism for improved dialogue and cooperation" to address bilateral SPS issues by building on key principles of WTO SPS agreement, including "requirements that each side's SPS measures be based on science and on international standards or scientific risk assessments, applied only to the extent necessary to protect human, animal, or plant life or health, and developed in a transparent manner, without undue delay," and
- an "ambitious 'TBT-plus' chapter, building on horizontal disciplines in the WTO [TBT Agreement], including establishing an ongoing mechanism for improved dialogue and cooperation for addressing bilateral TBT issues," including the goals of "greater openness, transparency, and convergence in regulatory approaches and requirements and related standards-development processes ..., to reduce redundant and burdensome testing and certification requirements, promote confidence in our respective conformity assessment bodies, and enhance cooperation on conformity assessment and standardization issues globally."

The "SPS Plus" and "TBT Plus" concepts generally mean building on and going beyond the rights and obligations of all WTO members through the WTO's SPS and TBT agreements. For example, this could mean that the EU and United States would provide for greater transparency and more timely SPS and TBT notifications than required by the WTO, along with some form of "rapid response mechanism" for resolving stoppages of agricultural products at the border and adopting enforcement mechanisms or a dispute settlement process—although these negotiations would be more challenging.

Source: HLWG, "Final Report of the U.S.-EU High Level Working Group on Jobs and Growth," February 11, 2013.

In addition, among the goals of the T-TIP negotiation are efforts to address regulatory differences that have plagued U.S.-EU agricultural trade in the past. Major differences exist in how the United States and the EU apply SPS and TBT measures and how each regulates food safety and related public health protection, including various administrative and technical review differences. One major difference is the EU's application of the so-called *precautionary principle*, which remains central to the EU's risk management policy regarding food safety and animal and plant health and is often cited as the rationale behind the EU's practice of taking a generally more risk-averse approach to risk management. The **Appendix** provides a more detailed discussion of

the EU's use of the precautionary principle. (In the EU, the European Food Safety Agency [EFSA] is responsible for providing scientific advice and communication on food-borne risks.)

Regulatory differences between the United States and EU have likely contributed to some long-standing trade disputes regarding SPS and TBT rules between the two trading blocs. The United States has several formal trade disputes regarding SPS/TBT measures with the EU. These include concerns regarding the EU's ban on U.S. meats treated with growth-promoting hormones, ⁴² the EU's restrictions on chemical treatments ("pathogen reduction treatments" or "PRTs") on U.S. poultry, ⁴³ and the EU's approval process of biotechnology products. ⁴⁴ Other SPS concerns involve U.S. concerns over EU BSE-related regulations and other regulations involving plant processing, pesticides, endocrine-disrupting chemicals, and animal welfare requirements. Some of these types of trade concerns have not risen to the level of a formal WTO dispute. **Table 3** provides a list of selected issues based on annual reporting by USTR.

The EU has also reported concerns about certain agricultural policies in the United States, including perceived SPS barriers to EU exports of sheep and goat meat, egg products, and beef, certain dairy products, live bivalve mollusks, apples and pears and also difficulties protecting IPR, such as EU geographical indications on food and drinks. Other EU concerns have involved the use of "Buy American" restrictions in the United States governing public procurement. Some have expressed concern that T-TIP negotiations on public procurement may affect local food procurement, including restricting the use of bidding contract preferences contained in U.S. and EU farm-to-school programs. These types of issues are being addressed in the T-TIP negotiation but are not further addressed in this report.

-

⁴² WTO, "Dispute DS26." See also CRS Report R40449, *The U.S.-EU Beef Hormone Dispute*.

⁴³ WTO, "Dispute DS389." See also CRS Report R40199, U.S.-EU Poultry Dispute on the Use of Pathogen Reduction Treatments (PRTs).

⁴⁴ WTO, "Dispute DS291," See also CRS Report RS21556, Agricultural Biotechnology: The U.S.-EU Dispute.

⁴⁵ EC, "Report from the Commission to the European Council: Trade and Investment Barriers Report 2015," COM(2015) 127, March 17, 2015.

⁴⁶ K. Hansen-Kuhn and S. Suppan, "Promises and Perils of the TTIP: Negotiating a Transatlantic Agricultural Market," Institute for Agriculture and Trade Policy, October 2013.

⁴⁷ For more background information on government procurement and services issues in the negotiations, see CRS Report R43387, *Transatlantic Trade and Investment Partnership (T-TIP) Negotiations*.

Table 3. USTR-Reported Concerns Involving SPS/TBT Measures in the EU, 2014

SPS/TBT	Food Product Category	SPS/TBT Category	U.S. Concerns
SPS	Various Products	Biotechnology	Enforces policies restricting imports of products derived from agricultural biotechnology; requires prior approval for a specific use before a product may be imported or used. Several EU countries also restrict biotech products.
SPS	Beef, Beef Products	Food Safety	Prohibits U.S. beef raised with growth-promoting hormones.
SPS	Beef and Poultry	Food Safety	Restricts use of "pathogen reduction treatments" (PRTs), designed to reduce the amount of microbes on meat.
SPS	Milk and Milk Products	Food Safety	Limits the somatic cell count in milk (below U.S. levels) as part of its public health requirements for dairy imports.
SPS	Maximum Residue Limits	Food Safety	Process for setting import tolerances for pesticides has raised concerns.
SPS	Ractopamine	Food Safety	Prohibits U.S. meat produced with ractopamine.
SPS	Seafood	Food Safety	Prohibits imports of U.Sorigin molluscan shellfish other than scallops.
SPS	Animal Byproducts (tallow)	Animal Health	Prohibits U.S. tallow not intended for human consumption, including tallow-containing products.
SPS	Seeds	Plant Health	Restrictions regarding the re-export to the EU of seeds that were produced in another country.
SPS	Wheat	Plant Health	Many EU countries (especially UK and Greece) have strict sampling requirements to test for certain plant diseases.
SPS	BPA	Packaging	France bans the use of materials produced using Bisphenol-A (BPA).
SPS	Eggs	Food Safety	Romania does not recognize non-EU suppliers of fresh or processed eggs.
SPS	Frozen Bovine Semen	Animal Health	Romania requires samples be collected to test for Bovine Brucellosis.
ТВТ	Wine	Labeling	Imposes detailed rules regarding designations of origin and geographical indication, traditional terms, and labeling.
ТВТ	Distilled Spirits	Aging Requirements	Imposes minimum aging requirements for whiskey.
ТВТ	Agricultural Products	Quality Schemes	Requirements regarding EU quality schemes, marketing standards, and other certification and labeling schemes, such as organics and animal welfare.
ТВТ	Food Products	Food Quality	New food quality scheme requires verified certification procedures and labeling systems subject to official controls.

Source: CRS from information reported in USTR, 2014 Report on Sanitary and Phytosanitary Measures and 2014 Report on Technical Barriers to Trade (http://www.ustr.gov/). Generally excludes non-agricultural products, cosmetics, and body care products.

Some Members of Congress and other stakeholders hope that the T-TIP negotiations will resolve long-standing trade disputes regarding SPS rules between the two trading blocs and address SPS issues and other non-tariff barriers. A letter to USTR from Senate leadership in April 2016 addressed the importance of "longstanding regulatory barriers such as hormone use in U.S. beef, maximum residue limits in fruits and vegetables, and dairy certification requirements." Given such regulatory differences and also existing non-tariff barriers between the United States and the EU, particularly regarding SPS matters, some are concerned about whether T-TIP would be able to address such concerns or whether the agreement might exclude agricultural products altogether, given the range of sensitive agricultural products such as beef, pork, poultry, dairy, rice, and fruits and vegetables. Some in the EU have also expressed such concerns, suggesting that a less ambitious negotiated agreement (e.g., focused only on market access) would also be unacceptable to EU lawmakers.

In the T-TIP negotiations, non-tariff barriers including SPS and TBT issues have been broadly grouped along with other issues related to regulatory coherence. The U.S. Chamber of Commerce defines regulatory coherence as "good regulatory practices, transparency, and stakeholder engagement in a domestic regulatory process" and regulatory cooperation as "the process of interaction between U.S. and EU regulators, founded on the benefits regulators can achieve through closer partnership and greater regulatory interoperability." (Related terminology may refer interchangeably to regulatory convergence, cooperation, and/or harmonization.) They further note that regulatory coherence will not threaten regulatory sovereignty, nor will it guarantee or bind regulatory outcome in either market.

Regulatory coherence and cooperation are inherent to USTR's stated goals and objectives in the negotiation regarding non-tariff barriers and regulatory issues regarding SPS and TBT issues. These goals include to:⁵³

- eliminate or reduce non-tariff barriers that decrease opportunities for U.S. exports, provide a competitive advantage to products of the EU, or otherwise distort trade, such as unwarranted SPS restrictions that are not based on science, unjustified TBT restrictions, and other "behind-the-border" barriers, including the restrictive administration of tariff-rate quotas and permit and licensing barriers, which impose unnecessary costs and limit competitive opportunities for U.S. exports;
- achieve greater compatibility of U.S. and EU regulations and related standards development processes (while maintaining health, safety and environmental

⁴⁸ See, for example, "Chairman Nunes Announces Hearing on Advancing the U.S. Trade Agenda: Benefits of Expanding U.S. Agriculture Trade and Eliminating Barriers to U.S. Exports," hearing advisory, House Ways and Means Trade Subcommittee, June 11, 2014; letter to USDA Secretary Thomas Vilsack and Acting USTR Demetrios Marantis from 26 farm-state U.S. Senators, May 7, 2013; and testimony by Don Shawcroft, Colorado Farm Bureau, before the U.S. House of Representatives, Subcommittee on Agriculture, Energy, and Trade of the Committee on Small Business, May 22, 2014.

⁴⁹ Letter from Senate leadership to Ambassador Froman, USTR, April 22, 2016.

⁵⁰ See, for example, Reuters, "U.S. Senators Worried U.S.-EU Talks Might Not Address Agriculture," January 24, 2013; and letter from several U.S. agriculture and food groups to USTR Ron Kirk, March 4, 2013.

⁵¹ P. Hutchinson, "EU Won't Accept a 'TTIP-Lite'—Farm Commissioner," *Food Chemical News*, February 17, 2016.

⁵² U.S. Chamber of Commerce, "Regulatory Coherence & Cooperation in the Transatlantic Trade and Investment Partnership (TTIP)," February 27, 2015,

⁵³ USTR, "Non-Tariff Barriers and Regulatory Issues," https://ustr.gov/trade-agreements/free-trade-agreements/transatlantic-trade-and-investment-partnership-t-tip/t-tip-2.

protection), with the objective of reducing costs associated with unnecessary regulatory differences and facilitating trade, inter alia by promoting transparency in the development and implementation of regulations and good regulatory practices, establishing mechanisms for future progress, and pursuing regulatory cooperation initiatives where appropriate;

- build on key principles and disciplines of the TBT agreement through strong cross-cutting disciplines and, as appropriate, sectoral approaches to achieve meaningful market access and establish ongoing mechanisms for improved dialogue and cooperation on TBT issues;
- build on key principles and disciplines of the SPS agreement to achieve meaningful market access, including commitments to base SPS measures on science and international standards or scientific risk assessments; apply them only to the extent necessary to protect human, animal, or plant life or health; develop such measures in a transparent manner without undue delay; and establish an ongoing mechanism for improved dialogue and cooperation addressing bilateral SPS issues.

Similarly, the EU's initial goals regarding food safety and animal and plant health in the negotiation include pragmatic and speedy procedures and decisions on regulations related to trade, a single approval process for exports from all EU countries, clear and transparent processes and timelines, a basis for working together—including on animal welfare issues—to avoid differences that hinder trade, and mechanisms for resolving trade disputes.⁵⁴ The stated goals in the EU's March 2016 revised proposal include "achieving more compatible regulations" between the EU and United States through a "commitment to an ambitious outcome on regulatory cooperation," including a "commitment to international regulatory cooperation by regulators" in both markets. 55 The revised proposal emphasizes the need to "enhance or at least maintain the level of protection through regulatory cooperation" while providing for greater transparency and public participation and the possibility of "more compatibility of EU and U.S. regulations in specific areas," among other objectives. The EU's March 2016 draft chapter on agriculture includes provisions regarding geographical indications (for further discussion see "Geographical Indications") but explicitly does not directly address SPS issues, which the EU expects could be addressed in a dedicated SPS chapter in the negotiation.⁵⁶ Previous EU tabled text on SPS issues proposed to establish food safety equivalency on SPS issues.⁵⁷

Challenges in the Negotiation

A number of challenges exist on specific issues. EU industry groups are also urging the T-TIP negotiators to address non-tariff barriers by focusing on regulatory cooperation and coherence, international standards, and trade facilitation, among other concerns. ⁵⁸ Some interest groups

-

⁵⁴ EC, "Food Safety and Animal and Plant Health in TTIP," January 2015.

⁵⁵ EC, "Regulatory Cooperation in TTIP, An Introduction to the EU's Revised Proposal," March 21, 2016 (updates and incorporates aspects of the EU's previous proposal released in January 2015); and EC, "TTIP-EU Proposal for Chapter: Regulatory Cooperation," March 21, 2016. In addition to public health; human, animal, and plant life and health; health and safety; working conditions; and animal welfare, the EU's proposal covers the environment, consumers, social protection and security, personal data and cybersecurity, cultural diversity, and financial stability.

⁵⁶ EC, "TTIP - Draft Chapter on Agriculture," Article X.1, March 21, 2016, http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154371.pdf.

⁵⁷ EC, "Sanitary and Phytosanitary Measures (SPS)," Article 9, tabled text September 29-October 3, 2014.

⁵⁸ See, for example, Joint Statement by Copa and Cogeca, "EU Agri-Food Chain Organizations Call on Negotiators to (continued...)

support maintaining existing "standards that are appropriate for human health and wellbeing, animal welfare and environmental sustainability." Specifically, the EU's proposed chapter on regulatory cooperation explicitly covers animal welfare (among other issues), which could prove to be a contentious point for U.S. negotiators who contend that animal welfare does not constitute an SPS issue. Previous EU tabled text on SPS issues proposed to "build upon and extend the scope" of the Veterinary Equivalency Agreement that the United States and EU signed in 1998 to include additional animal welfare protections. Such protections are generally opposed by some U.S. farm groups. Other types of regulatory coherence talking points involve notice-and-comment procedures, testing requirements, and other compliance issues, such as whether to allow for third-party labs (as in the United States) or self-certification (as in the EU).

Various reports have further indicated that some U.S. and EU stakeholders seek to include a range of related policy issues that may or may not become part of the T-TIP negotiations. These include the use of certain pesticides and chemicals, the use of antibiotics in animal production, and the role of technology in agriculture, among other applications. Some issues have been raised as T-TIP proposals. For example, the EU has submitted a proposal to address anti-microbial resistance (AMR) in the SPS chapter of T-TIP "aimed at strong cooperation within the framework of T-TIP on jointly reducing the use of antibiotics in animal production in order to combat the development of antibiotic resistance." The United States is still actively considering how it will address the use of antibiotics in U.S. animal production, but some in Congress are supporting restrictions similar to those in the EU. Some issues of interest to the Unites States, such as concerns regarding the EU's prohibition on the use of ractopamine and hormones in livestock production—drugs and practices widely used in the United States—may be more difficult to raise as part of the T-TIP negotiation since some issues are already established in EU law.

Other issues of potential concern to U.S. interests are also emerging. For example, in September 2015, the European Parliament voted to ban the cloning of all farm animals and the sale of cloned livestock, their offspring, and products derived from them.⁶⁷ Cloning for research purposes would

(...continued)

Resolve Key Non-Tariff Measures During TTIP Negotiations," September 30, 2013.

-

⁵⁹ CEJA, "CEJA Position Paper Transatlantic Trade and Investment Partnership (TTIP)," April 28, 2015.

⁶⁰ EC, "TTIP-EU Proposal for Chapter: Regulatory Cooperation," March 21, 2016.

⁶¹ J. Hagstrom, "Tips on TTIP from 'E.U. Anonymous," *Hagstrom Report*, November 30, 2015.

⁶² EC, "Sanitary and Phytosanitary Measures (SPS)," tabled text September 29-October 3, 2014. For information on the agreement, see USDA, "The US-EU Veterinary Equivalency Agreement: Content and Comparison," *GAIN Report* E35219, December 2005.

⁶³ See, for example, CRS Report RS22493, *The Animal Welfare Act: Background and Selected Animal Welfare Legislation*; and CRS Report R42534, *Table Egg Production and Hen Welfare: Agreement and Legislative Proposals*.

⁶⁴ World Trade Online, "TTIP Negotiators Create Joint Text on Regulatory Cooperation, Discuss New TBT Proposal," April 24, 2015.

⁶⁵ EC, "EU Proposal to Include an Article on Anti-Microbial Resistance Within the SPS Chapter of TTIP," November 6, 2015, http://trade.ec.europa.eu/doclib/docs/2015/november/tradoc_153936.pdf. Other general information on the EU's AMR activities is available at http://ec.europa.eu/dgs/health_food-safety/amr/index_en.htm.

⁶⁶ See, for example, congressional briefing on T-TIP and antibiotic resistance promoted by Representative Louise Slaughter, May 27, 2014. For other information on this issue, see CRS In Focus IF10190, *Antibiotic Use in Food Animals: FDA's Current Activities*.

⁶⁷ European Parliament, "Cloning of Animals Kept and Reproduced for Farming Purposes," September 8, 2015. Also see G. Vogel, "E.U. Parliament Votes to Ban Cloning of Farm Animals," AAAS *ScienceInsider*, September 8, 2015; and CRS correspondence with BIO representatives, April 22, 2015. An EU-commissioned study (ICF International, *Study on the Labelling of Products from Cloned Animals and their Offspring*, November 2015) reports that tracing and labeling of livestock related to EU proposed cloning requirements could cost nearly \$900 million annually, and costs (continued...)

be permitted. The EU's position on cloning is at odds with that of the United States. The U.S. Food and Drug Administration (FDA) has found no significant differences between healthy clones and non-cloned animals. FDA also regards the products from cloned animals to be as safe as that from non-clones. The United States and Brazil raised concerns about the EU's proposal at a WTO TBT Committee meeting in November 2015. 69

Other broad U.S. concerns may involve the EU's June 2016 temporary renewal of the widely used herbicide glyphosate, while some member states, including Germany and France, are reportedly considering further restrictions on its use. EFSA recently concluded that "glyphosate is unlikely to be genotoxic (i.e., damaging to DNA) or to pose a carcinogenic threat to humans." EU's proposal to restrict use is opposed by some U.S. agrochemical groups. Also in June 2016 the EU released a draft proposal to establish criteria for endocrine (hormone) disrupting chemicals, which are opposed by some U.S. groups. The EU is also considering changes to laws and regulations affecting the use of nanotechnology. CropLife America estimates that the EU's rules affecting endocrine disrupting chemicals could block 4 billion in U.S. agricultural exports annually and expects that the T-TIP talks will help avoid such trade disruption. It is unclear whether these issues will be directly addressed in the negotiation.

In some cases, the U.S. Administration has explicitly pursued certain trade issues by outside the T-TIP negotiations, such as perceived import restrictions on pasteurized milk products by EU dairy producers trying to obtain Grade A certification from the United States.⁷⁸

Agricultural Biotechnology

Issues involving biotechnology broadly fall under category of issues related to SPS and related non-tariff trade measures. Agricultural biotechnology refers primarily to the use of recombinant DNA techniques to genetically modify or bioengineer plants and animals so that they have certain desired characteristics. Most crops developed through recombinant DNA technology have been

(...continued)

would be even greater if DNA verification systems were required.

⁶⁸ FDA, "Animal Cloning and Food Safety," 2008, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm148768.htm.

⁶⁹ WTO, "WTO: 2015 News Items," https://www.wto.org/english/news_e/news15_e/tbt_10nov15_e.htm.

⁷⁰ K. Dixon and E. Livingstone, "Commission to Clear Controversial Weedkiller Glyphosate for 18 Months," *Politico*, June 28, 2016.

⁷¹ EC Statement, "Glyphosate: Commission Proposes the Way Forward," June 1, 2016; and EFSA, "Glyphosate: EFSA Updates Toxicological Profile," November 12, 2015, https://www.efsa.europa.eu/en/efsajournal/pub/4302.

⁷² CropLife America, "Assessment from FAO/WHO Confirms Safety of Glyphosate, Contradicts IARC," May 24, 2016.

⁷³ EC, "Impact Assessment Defining Criteria for Identifying Endocrine Disruptors in the Context of the Implementation of the Plant Protection Products Regulation and Biocidal Products Regulation," SWD(2016) 212 final, June 15, 2016.

⁷⁴ CropLife America, "EC Takes Questionable Approach to Endocrine Disruptor Criteria," June 15, 2016.

⁷⁵ Food Chemical News, "Call for EU Regulatory Overhaul to Cover Nanomaterials," May 2, 2014.

⁷⁶ CropLife America, "CropLife America President Recommends Harmonized Approach to Pollinator Health and Endocrine Policies," March 20, 2014.

⁷⁷ See, for example, *World Trade Online*, "EPA Official Says U.S.-EU Endocrine Disruptor Talks Have No Link to TTIP." November 19, 2015.

⁷⁸ World Trade Online, "FDA Seeks to Sever EU Regulatory Cooperation Efforts from TTIP Talks," July 16, 2014. Other information is at Food and Drink Federation, "Major Non-Tariff Barriers for Food and Drink Exports to US," July 2012, http://trade.ec.europa.eu/doclib/docs/2012/july/tradoc_149679.pdf.

engineered to be tolerant of various herbicides or to be pest resistant by having a pesticide genetically engineered into the plant organism. U.S. soybean, cotton, and corn farmers have rapidly adopted genetically engineered (GE) varieties of these crops since their commercialization starting in 1996. Over the past few decades, GE varieties in the United States have increased. In recent years, USDA reports that U.S. farmers planted roughly 170 million acres of GE crops annually. Worldwide, 28 countries planted GE crops on an estimated 444 million acres in 2015. GE varieties now dominate soybean, cotton, and corn production in the United States, and they continue to expand rapidly in other countries. A 2016 study published by the National Academies of Sciences, Engineering, and Medicine found "no substantiated evidence that foods from GE crops were less safe than foods from non-GE crops" based on a review of the scientific literature.

In general, EU officials have been cautious in allowing GE crops—commonly referred to in Europe as genetically modified organisms (GMOs)—to enter the EU market, and all GE-derived food and feed must be labeled as such. The EU's regulatory framework regarding biotechnology is generally regarded as one of the most stringent systems worldwide.⁸³

This regulatory framework requires all GE food and feed to undergo an authorization (approval) process, be labeled and traceable, and "co-exist" with non-GE (conventional) food and feed. This approach stipulates that "growing GM crops requires authorization based on a rigorous safety assessment (environmental and health impact); food and feed derived from GM crops must be labelled as such, to inform consumers; [and] technical and administrative measures must be taken to ensure GM crops can sustainably coexist with conventional or organic farming (e.g. limiting cross-fertilization of plants in neighboring fields)."

GE crops play a limited role in the EU's agricultural production. Currently, Monsanto's Bt corn (MON 810)⁸⁵ is the only GE plant authorized (approved) for cultivation in the EU⁸⁶ and is grown only in Spain, Portugal, the Czech Republic (Czechia), Slovakia, and Romania (**Table 4**). The EU's Bt corn production peaked at 367,300 acres in 2015, accounting for about 1% of the EU's total corn acreage. Most production (94%) is in Spain, with another 5% in Portugal. Other GE products are authorized for food or feed use in the EU, including certain varieties of corn, cotton, soybean, canola (rapeseed), sugar beet, and microorganisms (bacterial and yeast biomass).⁸⁷ A listing of genetically modified food and feed approved (authorized) in the EU is available through

⁷⁹ J. Fernandez-Cornejo, et al., *Genetically Engineered Crops in the United States*, USDA, ERR-162, February 2014.

⁸⁰ International Service for the Acquisition of Agri-biotech Applications, "Global Status of Commercialized Biotech/GM Crops in 2015."

⁸¹ For information, see CRS Report RL32809, *Agricultural Biotechnology: Background, Regulation, and Policy Issues*. For more direct assistance, contact (name redacted) ([redacted]@crs.loc.go%-...).

⁸² National Academies of Sciences, Engineering, and Medicine, *Genetically Engineered Crops: Past Experience and Future Prospects*, May 2016. Other studies are underway to examine this issue (see, for example, Factor GMO, "World's Largest Ever Study on GMO and Pesticide Safety," press release, November 11, 2014).

⁸³ See, for example, USDA, "EU-27 Agricultural Biotechnology Annual," *GAIN Report* FR9142, July 12, 2013; and Greenpeace, "Tougher European GMO Legislation," July 2, 2003.

⁸⁴ EC, "Citizens' Summary: EU Report—Coexistence of GM Crops with Conventional and Organic Farming."

⁸⁵ Bt corn refers to corn that has been bioengineered to express, in the plant's tissues, insecticidal endotoxins derived from *Bacillus thuringiensis* (a common soil bacterium) to control pest infestations.

⁸⁶ USDA, "EU-28 Agricultural Biotechnology Annual," *GAIN Report* FR9174, July 23, 2015. A GE potato (Amflora potato) was authorized for cultivation and industrial processing in 2010 for use in paper-making, but is no longer authorized in the EU.

⁸⁷ EC, "EU Register of Authorized GMOs," http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

its register. ⁸⁸ As of July 2016, the EU had authorized or is considering renewal of 57 GE varieties. Another 22 registrations are still under review. An authorization permit applies to all EU countries. Soybean meal is the main GE product imported in the EU, mostly from Brazil.

Even if a GE variety is approved, an EU member state is able to ban cultivation. Several EU countries have banned the cultivation of GE crops in their territories or have specific rules on the trade of GE seeds.

A series of regulations, directives, and recommendations govern the EU's handling of food and feed derived from genetic engineering. The text box summarizes key directives and regulations.⁸⁹

"Building Blocks" of the GMO Legislation in the EU

- Directive 2001/18/EC on the deliberate release of GMOs into the environment
- Regulation (EC) 1829/2003 on genetically modified food and feed
- **Directive (EU) 2015/412** amending Directive 2001/18/EC as regards the possibility for the member states to restrict or prohibit the cultivation of GMOs in their territory
- Regulation (EC) 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs
- Directive 2009/41/EC on contained use of genetically modified micro-organisms
- Regulation (EC) 1946/2003 on transboundary movements of GMOs
- Other supplemental rules, recommendations, and guidelines on more specific aspects

Source: EC, "GMO Legislation," http://ec.europa.eu/food/plant/gmo/legislation/index en.htm.

Even though a GE variety has been approved, further authorization is required to allow for the cultivation or "deliberate release into the environment" of a GE variety. EFSA grants authorization by assessing the environmental and health risks according to the EU's deliberate release rules. EU regulations further establish a minimum threshold of "adventitious presence" or "technically unavoidable traces" of authorized GE material, below which these products need not be labeled (Article 21). In the EU, this minimum threshold is set at 0.9%. Although some major U.S. trading partner countries have established certain allowable tolerance levels for GE as part of their labeling laws, the United States does not specify such tolerance levels for GE in any of its laws, policies, or guidance. Moreover, USDA "has not established an official tolerance level for the specific amount of unintended GE material that can be found in organically grown and other non-GE products." Some private processors, retailers, and buyers in countries without regulatory requirements may also set a minimum tolerance level. USDA reports that many U.S. organic and non-GE food manufacturers and retailers adhere to the 0.9% tolerance level, such as

⁸⁸ EC, SANCO, "EU Register of Authorised GMOs," http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

⁸⁹ For more information, see USDA's annual agricultural attaché reports on agricultural biotechnology in the EU and in individual EU countries (USDA, "EU-28 Agricultural Biotechnology Annual," *GAIN Report* FR9174, July 23, 2015). See also CRS Congressional Distribution Memorandum, "Regulation of Biotechnology in the European Union (EU)," by (name redacted) [redacted]@crs.loc.gox/7-....), available upon request.

⁹⁰ Commission of the European Communities, Annex to the Communication from the Commission to the Council and the European Parliament Report on the Implementation of National Measures on the Coexistence of Genetically Modified Crops with Conventional and Organic Farming," Commission Staff Working Document, COM(2006) 104, March 2006.

⁹¹ C. Greene et al., *Economic Issues in the Coexistence of Organic, Genetically Engineered (GE), and Non-GE Crops*, USDA, EIB-149, February 2016, p. 14.

under the Non-GMO Project Verified protocol. 92 Other EU regulations address labeling and traceability of GMOs in the EU market.

Table 4. Bt Corn Area in the EU, by Member State

	2007	2010	2012	2013	2014	2015 Est
Country				(acres)		
Spain	185,694	189,221	287,400	338,440	325,035	296,526
Portugal	10,376	12,032	19,027	20,268	21,108	14,826
Czech Republic (Czechia)	12,355	11,560	7,537	6,326	4,334	4,201
Romania	818	2,031	536	2,061	1,905	6
Slovakia	2,298	3,165	467	247	1,016	988
France	54,697	0	0	0	0	0
Germany	6,635	0	0	0	0	0
Poland	247	8,649	9,884	0	0	0
Total Bt corn area (acres)	273,120	226,657	324,852	367,341	353,397	316,549
Total corn area (1,000 acres)	20,866	19,729	24,019	23,870	23,475	23,846
Share of Bt corn/total corn area	1.31%	1.15%	1.35%	1.54%	1.51%	1.33%

Source: USDA, "EU-28 Agricultural Biotechnology Annual," GAIN Report FR9174, July 23, 2015.

In January 2015, the European Parliament adopted new legislation to allow each EU member state to ban or approve GE crops in its respective country. Proposals to implement these new directives were released in March 2015. Many in the United States believe the EU's proposal lacks a scientific basis 4 and question whether the measures might violate the SPS agreement. Several EU countries have signed a "joint declaration" calling for the development of a GE-free agricultural model in Europe. Other proposed efforts seeking to ban or restrict the *use or sale* of EU-approved GE products in member territories have been rejected by the European Parliament. The new legislation allows member states to ban cultivation of a GE crop even if it has been approved for cultivation. To date, EU countries opting out of GE crop cultivation include Austria, Bulgaria, Croatia, Cyprus, Denmark, France, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, and Slovenia (Figure 3). Belgium and Britain requested opt-out for only part of their countries' respective territories—Wallonia in Belgium and Northern Ireland, Wales, and Scotland in the UK. Germany has requested a partial opt-out to allow research.

⁹² Ibid. Non-GMO Project Verified protocol is an independent verification system launched in 2005.

⁹³ Directive (EU) 2015/412. European Commission Fact Sheet, "Review of the Decision-Making Process on GMOs in the EU: Questions and Answers," April 2015. Information on these proposals is available at http://ec.europa.eu/food/plant/gmo/authorisation/index_en.htm.

⁹⁴ USDA, "EU-28 Agricultural Biotechnology Annual," GAIN Report FR9174, July 23, 2015.

⁹⁵ World Trade Online, "U.S. Says Draft EU Law on Biotech Imports May Violate SPS Agreement," August 26, 2015.

⁹⁶ USDA, "19 European Countries Restrict the Cultivation of GE crops," GAIN Report FR9180, October 13, 2015.

⁹⁷ P. Hutchinson, "EU Member States Claim Benefits of 'GMO-Free' Farming Model," *Food Chemical News*, October 22, 2015. Countries include Austria, Cyprus, Hungary, Italy, Lithuania, Poland, and Slovenia.

⁹⁸ European Parliament, "Parliament Rejects National GMO Bans Proposal," *EP News*, October 28, 2015.

Several EU countries have not opted out of GE crop cultivation. These include Sweden, Finland, Estonia, Ireland, part of the United Kingdom (England), parts of Belgium, the Czech Republic (Czechia), Slovakia, Romania, Portugal, and Spain.

Public opinion remains strongly opposed to GE food and the cultivation of GE crops in most EU member states, although national political leaders are generally considered to be more supportive. A 2010 survey by the EC suggests overall "suspicion" of GE foods among the European public: 70% agree that GE food is "fundamentally unnatural," and 61% agree that GE food "makes them feel uneasy." In addition, roughly 60% of Europeans disagree that the development of GE food should be encouraged. The same number disagree that GE food is safe for their health and that of their families and disagree that GE food is safe for future generations.

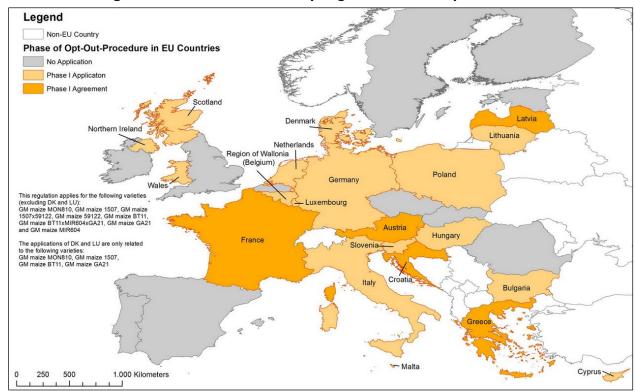


Figure 3. EU Member States Opting Out of GM Crop Cultivation

Source: GMO-Free Europe map, http://www.gmo-free-regions.org/gmo-free-regions/opt-out-monitor.html. **Notes:** EU countries with "no application" to opt-out include Sweden, Finland, Estonia, Ireland, part of the United Kingdom (England), part of Belgium, Czech Republic (Czechia), Slovakia, Romania, Portugal, and Spain.

Goals and Challenges Within Ongoing Negotiations

Concerns regarding agricultural biotechnology issues in T-TIP, among other free trade negotiations, mostly involve the asynchronous approval of GE crops worldwide. According to Biotechnology Innovation Organization (BIO) and European Association for Bioindustries (EuropaBio)—two trade associations representing biotechnology companies and related

⁹⁹ EC, *Biotechnology*, October 2010, http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf.

¹⁰⁰ Ambassador Darci Vetter, USTR Agricultural Negotiator, Agri-Pulse interview, May 10, 2016.

organizations—these concerns include an increasing number of GE product approval requests in the EU, a growing gap between approval timelines in major markets, failure by EU regulators to act as prescribed by EU law, and a growing complexity of approvals from "stacked traits" in biotech products. ¹⁰¹

Many in Congress have highlighted these concerns. In April 2016, Senate leadership sent a letter to USTR complaining that "EU members continue to miss key deadlines for import approvals of biotechnology products" and that "currently there are at least three products that have been awaiting import approval since 2011 and 2012." The Senators further claim that approvals have been delayed despite positive evaluations by EFSA. Previously, in October 2014, Senator Chuck Grassley sent a letter to the EC to press for the completion of the review process for eight pending approvals covering soy, corn, canola, and cotton that had received positive reviews from EFSA. U.S. farm groups sent similar letters to USTR and the EC. In April 2015, the EC authorized imports of 17 GM products, which EuropaBio claims had been pending on average 6.5 years from the time of submission until the final authorization. They further claim that over 40 additional GM applications for import are waiting in the system. The United States continues to reiterate its concerns regarding EU measures affecting the approval and marketing of biotech products within the WTO.

U.S. producer groups have long asserted that U.S. agricultural exports to the EU have been limited by EU labeling and traceability regulations and by lack of timelines and transparency in the administrative process for admitting GE crops. ¹⁰⁷ In a dispute brought by the United States and other WTO members, a dispute settlement panel determined that the EU had maintained a *de facto* moratorium on GE products between 1999 and 2003. ¹⁰⁸ EU regulations released in 2013, providing the basis upon which companies submit applications for authorization and EFSA risk assessment, ¹⁰⁹ were intended to clarify the application for authorization procedures and improve the process. USDA, however, claims that these regulatory changes will "unlikely ... speed up the process, and the flexibility of risk assessors to adapt the approach used on a case-by-case basis will be reduced by imposing mandatory studies." ¹¹⁰ Moreover, U.S. producers continue to assert that continuing EU labeling and traceability regulations ¹¹¹ and lack of timelines and transparency

¹⁰¹ EuropaBio and BIO submission to the HLWG, "EU-U.S. High Level Working Group on Jobs and Growth Response," December 2015. "Stacked traits" refers to combined traits and gene stacking, or the process of combining two or more genes of interest into a single plant.

¹⁰² Letter from Senate leadership to Ambassador Froman, USTR, April 22, 2016.

¹⁰³ Letter from Senator Chuck Grassley to José Manuel Barroso, EC President, October 14, 2014.

¹⁰⁴ Letters to USTR and a member of the EC from 19 U.S. farm and feed groups, August 20, 2014. Signatories included the American Farm Bureau Federation, the American Seed Trade Association, and others.

 $^{^{105}\} Europa Bio, ``The\ State\ of\ Agricultural\ Biotech\ in\ Europe,"\ http://biotechaddress.europabio.org/the-state-of-agricultural-biotech-in-europe/.$

¹⁰⁶ See, for example, World Trade Online, "U.S., EU Square Off on GMOs; Commission Announces Two New Traits," June 23, 2016; and WTO Dispute Settlement news release, January 25, 2016.

¹⁰⁷ See, for example, Steve Wellman, President, American Soybean Association, response to HLWG request for public comment, February 3, 2012; and comments by representative of Dow Chemical Company at a congressional staff briefing, April 27, 2016.

¹⁰⁸ For more information on the WTO dispute, see http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm.

¹⁰⁹ Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006.

¹¹⁰ USDA, "EU-27 Agricultural Biotechnology Annual," GAIN Report FR9142, July 12, 2013.

¹¹¹ EU regulations require that most food, ingredients, and animal feed containing more than 0.9% of a GMO product (continued...)

in the EU process for admitting GMO products have caused U.S. exports of certain crops, such as soybeans, to decline over time. ¹¹² Some in Congress question whether they would approve T-TIP negotiating language that does not address the EU's biotechnology approval process. ¹¹³

BIO expects that the negotiation will help establish "a long-term solution to normalize trade in products derived from agricultural biotechnology" and provide for greater transparency and benchmarking in the EU's regulatory process and the weight of scientific evidence in EU risk assessment, streamline the EU's approval process for stacked GE events, and provide for ways to address low-level GE presence. 114 Other recommendations regarding the EU guidance documentation include aligning risk assessment requirements and adhering to legislated timelines, adopting commercially viable low-level presence policy, and improving accountability with regard to avoiding and resolving disputes, among other regulatory coherence recommendations. 115 Accordingly, U.S. negotiators are seeking more consistent and timely biotech approvals and want the EU to "commit to doing what their law says" to reduce the risk of trade disruption resulting from gaps between the respective approval processes in the United States and EU. 116

Several U.S. farm and feed groups have expressed concerns about the potential effect of the EU's biotechnology policies on feed grains and on Europe's livestock industries due to feed shortages and prices. ¹¹⁷ Several EU trade associations representing feed grain suppliers have also expressed similar concerns. ¹¹⁸

Among the types of factors cited for the EU's hesitation in completing the approvals are opposition to GE crop approvals from a majority of EU member states and support to allow for national bans on GE crop cultivation. Some groups have also expressed concern that T-TIP negotiations could lessen EU standards and also threaten efforts to label GE products in the United States.

However, press reports indicate that EU negotiators have rejected a U.S. proposal intended to speed up the approval process for GE products through certain regulatory changes, such as allowing for trace elements of unauthorized biotechnology traits in otherwise approved shipments, which was reportedly perceived to suggest that the EU has changed its regulatory

(...continued)

be labeled as containing such.

be labeled as containing such.

¹¹² Steve Wellman, President, American Soybean Association, response to HLWG request for public comment, February 3, 2012.

¹¹³ World Trade Online, "Thune Warns Congress Could Reject TTIP over Stalled EU Biotech Approvals," January 29, 2015.

¹¹⁴ K. Batra, "TTIP: Don't Forget about Agriculture," Biotech-Now.org, April 28, 2016.

¹¹⁵ Comments submitted to USTR regarding T-TIP from BIO (Docket Number: USTR-2013-0019), May 17, 2013.

¹¹⁶ Comments from Ambassador Darci Vetter, USTR Agricultural Negotiator, Agri-Pulse interview, May 10, 2016.

¹¹⁷ See, for example, letter to Tonio Berg, Member of the EC, from 19 U.S. farm and feed groups, August 20, 2014.

¹¹⁸ See, for example, European Feed Manufacturers' Federation, "Together with EU Food and Feed Chain, COPA-COGECA Urges EU Commission Not to Delay Authorisation of New Varieties of Genetically Modified Grain, Otherwise Livestock Industry Threatened," press release, October 17, 2014. See also communications from other EU organizations, including COCERAL (representing trade in cereals, rice, feedstuffs oilseeds, olive oil, oils and fats, and agro-supply) and EDIOL (representing the European vegetable oils and protein meal industry).

¹¹⁹ J. Bird, "Another EU Stalemate on a GM Crop Approval," Food Chemical News, February 20, 2015.

¹²⁰ See, for example, letter to USTR from U.S. and international organizations, among other local and regional groups, September 30, 2014. Signatories include the Center for Food Safety, the Consumers Union, and Food & Water Watch.

process to focus more on a cost-benefit approach, among other changes. ¹²¹ EU officials argue that the number of product approval requests is increasing, but some agricultural industry stakeholders assert that the time for processing (close to 3.5 years in the EU, in contrast to an average of 1.5 years in the United States) and the backlog in approvals continue to disrupt trade. ¹²² These stakeholders suggest that legally prescribed timelines, transparency, and risk assessment (among other things) could be established to address these issues.

The United States is actively seeking to speed up the approval process for GE crops, which is viewed by some European and U.S. advocacy groups as the United States using the trade negotiation to weaken the EU's risk assessment procedures and commit the EU to faster approvals of future products made with new agricultural technologies. Some groups that support the EU's more cautious approach to the use of biotechnology contend that U.S. laws do not provide for adequate regulation and testing of GE crops, and they further support the EU's labeling requirements for GE products. Some in the European Parliament further claim that the United States is using the negotiation in an attempt to "water down" EU regulations and risk assessment procedures for GE products.

The United States continues to oppose the EU's directives allowing each EU member state to ban or approve GE crops within its territory. ¹²⁶ Along with other WTO members, the United States has expressed concerns about the EU's opt-out policies and claim that they violate the WTO's SPS agreement. ¹²⁷ In August 2015, the United States submitted comments to the EU, urging that it should notify its policies to the WTO's SPS Committee. ¹²⁸

Geographical Indications

Geographical indications (GIs) are geographical names that act to protect the quality and reputation of a distinctive product originating in a certain region. The term is most often applied to wines, spirits, and agricultural products. Some food producers benefit from the use of GIs by giving certain foods recognition for their distinctiveness, differentiating them from other foods in the marketplace. ¹²⁹ In this manner, GIs can be commercially valuable. GIs may also be eligible for relief from acts of infringement or unfair competition. The use of GIs may also protect

¹²¹ See, for example, *World Trade Online*, "EU Chief Negotiator Rules Out U.S. TTIP Proposals on GMOs, Regulatory Coherence," May 3, 2016.

¹²² Carel du Marchie Savaas, for Europa Bio and the Biotechnology Industry Association, response to HLWG request for public comment, November 30, 2012.

¹²³ World Trade Online, "U.S. Seeks to Speed Up EU Approval of GMOs, Novel Agriculture Products," May 6, 2016; European Free Alliance, "US Using TTIP as Vehicle to Attack European GMO Laws," September 25, 2015; and Greenpeace, "Commission Fails to Regulate New GMOs After Intense U.S. Lobbying," April 21, 2016.

¹²⁴ See, for example, Greenpeace, "Commission Fails to Regulate New GMOs after Intense U.S. Lobbying,"

¹²⁵ See, for example, European Free Alliance, "U.S. Using TTIP as a Vehicle to Attack European GMO Laws.".

¹²⁶ Directive (EU) 2015/412. European Commission Fact Sheet, "Review of the Decision-Making Process on GMOs in the EU: Questions and Answers," April 2015. Information on these proposals is available at http://ec.europa.eu/food/plant/gmo/authorisation/index_en.htm.

¹²⁷ T. Maler, "WTO Members Voice Concern over EU GMO Proposal," Food Chemical News, June 24, 2015.

¹²⁸ World Trade Online, "U.S. Says Draft EU Law on Biotech Imports May Violate SPS Agreement," August 26, 2015.

¹²⁹ Examples of non-agricultural GIs may include handicrafts or products using local natural resources or techniques "embedded in the traditions of local communities," such as Vetro di Murano glass, Scottish tartans, Marmo di Carrara marble, or Meissner Porzellan porcelain. See EC, "Making the Most out of Europe's Traditional Know-How: A Possible Extension of Geographical Indication Protection of the European Union to Non-Agricultural Products," COM(2014) 469, July 15, 2014.

consumers from deceptive or misleading labels. Examples of GIs include Parmesan cheese and Parma ham from the Parma region of Italy, Tuscan olive oil, Roquefort cheese, Champagne from the region of the same name in France, Irish whiskey, Darjeeling tea, Ceylon tea, Florida oranges, Idaho potatoes, Vidalia onions, Washington State apples, and Napa Valley wines.

GIs are an example of IPR, along with other types of intellectual property such as patents, copyrights, trademarks, and trade secrets. The use of GIs has become a contentious international trade issue, particularly for U.S. wine, cheese, and sausage makers. In general, some consider GIs to be protected intellectual property, while others consider them to be generic or semi-generic terms. GIs are included among other IPR issues in the current U.S. trade agenda. In the T-TIP negotiation, GIs have been an active area of debate between the United States and EU. Laws and regulations governing GIs differ markedly between the United States and EU, which further complicates this issue. Within a potential T-TIP agreement, GIs may likely be included as part of either a chapter on IPR or an agriculture chapter in the agreement. The EU's March 2016 draft chapter on agriculture includes its proposal regarding GIs.

GIs are protected by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which sets binding minimum standards for IP protection that are enforceable by the WTO's dispute settlement procedure. Under TRIPS, WTO members must recognize and protect GIs as intellectual property. The United States is a signatory of TRIPS and is subject to its rights and obligations. Accordingly, under TRIPS, the United States and EU have committed to providing a minimum standard of protection for GIs (i.e., protecting GI products to avoid misleading the public and prevent unfair competition) and an "enhanced level of protection" to wines and spirits that carry a GI, subject to certain exceptions. TRIPS builds on treaties administered by the World Intellectual Property Organization (WIPO). WIPO is a specialized agency in the United Nations with the mission to "lead the development of a balanced and effective international intellectual property (IP) system."¹³² WIPO also oversees the "International Register of Appellations of Origin" established in the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration. The agreement's multilateral register covers food products and beverages and related products, as well as non-food products (including Cuban cigars). 133 For other background information, see CRS Report R44556, Geographical Indications in the Transatlantic Trade and Investment Partnership (T-TIP) Negotiations.

Goals and Challenges Within Ongoing Negotiations

Goals of the Negotiation

In the EU, a series of regulations governing GIs was initiated in the early 1990s covering agricultural and food products, wines, and spirits. Legislation adopted in 1992 covered agricultural products (not including wines and spirits), ¹³⁴ but it was changed in 2006 following a WTO panel ruling that found some aspects of the EU's scheme inconsistent with WTO rules. ¹³⁵

-

¹³⁰ For more information, see CRS In Focus IF10033, *Intellectual Property Rights (IPR) and International Trade*.

¹³¹ EC, "TTIP - Draft Chapter on Agriculture," Article X.1, March 21, 2016, http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154371.pdf.

¹³² See WIPO's website, http://www.wipo.int/about-wipo/en/.

¹³³ The registry database is searchable at http://www.wipo.int/ipdl/en/search/lisbon/search-struct.jsp.

¹³⁴ Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs.

 $^{^{135}}$ Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and (continued...)

The new rules came into force in January 2013. ¹³⁶ The EU laws and regulations cover three EU-wide quality labeling schemes: ¹³⁷ (1) Protected Designation of Origin (PDO), (2) Protected Geographical Indication (PGI), and (3) Traditional Specialties Guaranteed (TSG). Product registration markers for these three quality schemes, along with the relevant regulations, are shown in text box below.

The EU regulations establish provisions regarding products from a defined geographical area, given linkages between the characteristics of products and their geographical origin. The EU defines a GI as "a distinctive sign used to identify a product as originating in the territory of a particular country, region or locality where its quality, reputation or other characteristic is linked to its geographical origin." According to the EU, GIs matter "economically and culturally" and "can create value for local communities through products that are deeply rooted in tradition, culture and geography" and "support rural development and promote new job opportunities in production, processing and other related services." ¹³⁹

EU trade policy actively supports better protection of GIs internationally, including as part of its multilateral and bilateral negotiations, given concerns about GI "violations throughout the world" from misuse and imitation. Regarding protection of GIs, the EU is seeking certain "TRIPS-Plus" provisions that would establish a list of EU names to be protected "directly and indefinitely" in countries outside the EU, allow co-existence with prior trademarks (if they are "registered in good faith"), phase out other uses of EU names, ensure a right to use (as opposed to trademark license system), guarantee administrative protections, and create a cooperation mechanism and dialogue. ¹⁴¹

As of May 2016, more than 4,500 product names were registered and protected in the EU for foods, wine, and spirits originating in both EU member states and other countries (**Table 5**). Nearly two-thirds are wine registrations. Overall, about one-fourth of all registrations are for non-EU ("third country") registrations, but they are also overwhelmingly wine registrations. For more information on the EU's protection of GIs, see CRS Report R44556, *Geographical Indications in the Transatlantic Trade and Investment Partnership (T-TIP) Negotiations*.

(...commuca,

designations of origin for agricultural products and foodstuffs.

^{(...}continued)

¹³⁶ Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs. For more information, see A. Matthews, "What Outcome to Expect on Geographical Indications in the TTIP Free Trade Agreement Negotiations with the United States," prepared paper for the European Association of Agricultural Economists (EAAE) seminar, April 2015.

¹³⁷ EC, "Geographical Indications and Traditional Specialities," http://ec.europa.eu/agriculture/quality/schemes/index_en.htm.

 $^{^{138}\} EC, "Geographical-Indications," \ http://ec.europa.eu/trade/policy/accessing-markets/intellectual-property/geographical-indications/.$

¹³⁹ Ibid.

¹⁴⁰ See EC website at http://ec.europa.eu/trade/policy/accessing-markets/intellectual-property/geographical-indications/.

¹⁴¹ Matthews, "What Outcome to Expect," citing Advisory Group International Aspect of Agriculture, "Working Document on International Protection of EU Geographical Indications: Objectives, Outcome and Challenges," June 25, 2012, meeting.

"Quality Schemes" Protecting GIs in the European Union

- Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs.
- Regulation (EU) No 251/2014 of the European Parliament and of the Council of 26 February 2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products and repealing Council Regulation (EEC) No 1601/91.
- Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001, and (EC) No 1234/2007.
- Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling, and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89.

Below are product registration markers for three quality schemes—PGIs, PDOs, and TSGs.



Source: EUR-Lex: Access to European Union Law (http://eur-lex.europa.eu/homepage.html?locale=en); Database of Origin and Registration (http://ec.europa.eu/agriculture/quality/door/list.html); and EC, "Quality Policy in the EU."

Table 5. Product Name Registrations Under EU's GI Programs

Product Category	Total Registrations	EU Registrations	Non-EU Registrations
Food and Agriculture	1,341	1,320	21
Wine	2,885	1,750	1,135ª
Spirits	336	334	2
Total	4,562	3,404	1,158

Source: CRS data compilation from Database of Origin and Registration (agricultural products and foodstuffs); "E-Bacchus" database (wine); and "E-Spirit-Drinks" database (spirits), available at http://ec.europa.eu/agriculture/. Data are as of May 2016.

a. Of these, 697 wine ("Name of Origin") registrations are held by the United States.

In the United States, GIs generally fall under the common law right of possession or "first in time, first in right" as trademarks or collective or certification marks under the purview of the existing trademark regime, administered by the U.S. Patent and Trademark Office (PTO) and

protected under the U.S. Trademark Act. ¹⁴² Trademarks are distinctive signs that companies use to identify themselves and their products or services to consumers and can take the form of a name, word, phrase, logo, symbol, design, image, or a combination of these elements. Trademarks do not refer to generic terms, nor do they refer exclusively to geographical terms. ¹⁴³ Trademarks may refer to geographical names to indicate the specific qualities of goods either as certification marks or as collective marks. ¹⁴⁴ PTO does not have a special database register for GIs in the United States. PTO's trademark register, the U.S. Trademark Electronic Search System, contains GIs registered as trademarks, certification marks, and collective marks. ¹⁴⁵ Statements by USTR claim that EU farm products hold nearly 12,000 trademarks. ¹⁴⁶ These register entries are not designated with any special field (such as "geographical indications") and cannot be readily compiled into a complete list of registered GIs. In addition, the Alcohol and Tobacco Tax and Trade Bureau (TTB) ¹⁴⁷ oversees the labeling resources and guidance for wine, malt beverages, beer, and distilled spirits. ¹⁴⁸ For more information on the protection of GIs in the United States, see CRS Report R44556, *Geographical Indications in the Transatlantic Trade and Investment Partnership (T-TIP) Negotiations*.

U.S. trade policy is actively engaged in addressing concerns in the United States regarding the EU's GI protections to ensure that they "do not undercut U.S. industries' market access" and to defend the use of certain "common food names." ¹⁴⁹ In general, the United States is seeking protection for current U.S. owners of trademarks that overlap with EU-protected GIs, the ability to use U.S. trademarked names in third countries, and the ability to use U.S. trademarked names in the EU.

Challenges in the Negotiation

Many U.S. food manufacturers view the use of common or traditional names as generic terms and the EU's protection of its registered GIs as a way to monopolize the use of certain food and wine terms and as a form of trade protectionism. Specifically, several industry groups have expressed concern that the EU is using GIs to impose restrictions on the use of common names for some foods—such as parmesan, feta, and provolone cheeses and certain wines—and limit U.S. food companies from marketing these foods using these common names. The United States does not protect a geographic term that is considered "generic," being "so widely used that consumers

¹⁴² 15 U.S.C. §1051 et seq. Section 4 provides for the registration of "certification marks including indications of regional origin." For more information, see PTO's website at http://www.uspto.gov/ip/global/geographical/.

¹⁴³ UN, "Legal Protection of Geographical Indications," http://www.fao.org/fileadmin/user_upload/foodquality/fichefiles/en/c6.1.pdf. WIPO identifies another form of protection based on business practices, including administrative product approval schemes.

¹⁴⁴ Comments by presenters at the "American Origin Products and Current Trade Treaties: What Are the Stakes?" webinar, March 5, 2016.

¹⁴⁵ The database is accessible at http://www.uspto.gov/ebc/tess/index.html.

¹⁴⁶ Inside U.S. Trade, "Froman Denies Need for GI Protection in TTIP, Criticizes EU Food Safety Rules," June 15, 2016.

¹⁴⁷ Formerly the Bureau of Alcohol, Tobacco, Firearms and Explosives, TTB is part of the U.S. Treasury.

¹⁴⁸ TTB, https://www.ttb.gov/labeling/labeling-resources.shtml#general.

¹⁴⁹ USTR, 2016 Special 301 Report, April 2016, https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf. Pursuant to the Trade Act of 1974 as amended, the report identifies countries with inadequate IPR regimes on "watch lists."

¹⁵⁰ Ibid. See also B. Babcock, "Common Names or Protected Property? A U.S. Perspective on Strengthening GI Protection," presentation at EAAE seminar, April 2015.

view it as designating a category of all of the goods/services of the same type, rather than as a geographic origin." ¹⁵¹

According to USTR, "The United States continues to have serious concerns with the EU's system for the protection of GIs, including with respect to its negative impact on the protection of trademark and market access for U.S. products that use generic names." Bilateral trade concerns arise when a product name recognized as a protected GI in Europe is considered a generic name in the United States. For example, in the United States, "feta" is considered the generic name for a type of cheese. However, it is protected as a GI in Europe. As such, feta cheese produced in the United States may not be exported for sale in the EU since only feta produced in countries or regions currently holding GI registrations may be sold commercially.

Complicating this issue further are GI protections afforded to registered products in third country markets. This has become a concern for U.S. agricultural exporters following a series of recently concluded trade agreements between the EU and countries such as Canada, South Korea, South Africa, and other countries that are, in many cases, also major trading partners with the United States. Specifically, provisions in these agreements may provide full protection of GIs and not defer to a country's independent assessment of generic status for key product names. For example, separate recent agreements negotiated by the EU with Canada and South Africa could reportedly recognize up to 200 EU GIs for milk and dairy products. Similar types of GI protections are reportedly also in other trade agreements between the EU and other countries, affecting a range of food products and wine. In addition to facing trade restrictions for U.S. products in the EU market, these protections may limit the future sale of U.S. exported products bearing such names to these third countries, regardless of whether the United States may have been exporting such products carrying a generic name for years.

With these concerns in mind, USTR's 2016 Special 301 Report on the status of global IPR protection and enforcement outlines GI-related concerns in both the U.S.-EU trade negotiations and other initiatives with Canada, China, Costa Rica, El Salvador, Japan, Jordan, Morocco, the Philippines, South Africa, and Vietnam, among others. Some Members of Congress have long expressed their concerns about EU protections for GIs, which they claim are being misused to create market and trade barriers. They are also concerned about the implementation of GI protections in other trade agreements that have been or are being negotiated by the EU with other countries. USDA Secretary Tom Vilsack has also expressed concerns that the EU's system of protections for GIs "doesn't fit well into our trademark system" because U.S. law seeks to protect the end agricultural product, not the process through which it is made." Previously, Secretary

¹⁵¹ PTO, "Geographical Indication Protection in the United States," http://www.uspto.gov/web/offices/dcom/olia/globalip/pdf/gi_system.pdf.

¹⁵² USTR, 2014 National Trade Estimate Report on Foreign Trade Barriers, p. 111.

¹⁵³ See, for example, USDA, "South Africa: Proposed Protection of Geographical Indications in South Africa," *GAIN Report*, August 29, 2014; and National Milk Producers Federation, "U.S. Dairy Industry Decries Market Barriers Raised in EU-Canada Trade Deal," September 29, 2014.

¹⁵⁴ See, for example, comments during a House Committee on Ways and Means, "U.S. Trade Policy Agenda," January 27, 2015, and also during a Senate Finance Committee hearing on "President Obama's 2015 Trade Policy Agenda," January 27, 2015. See also numerous letters from Congress to the Administration, including a letter from Senate leadership to Ambassador Froman, USTR, April 22, 2016; a letter from several Members of Congress to USTR and USDA, May 9, 2014; a letter from Senate Finance Committee chairman and ranking Member to USTR, February 12, 2013; and a letter from several Members of Congress to USTR, September 27, 2010. See also letter referenced in Senator Pat Roberts, "Sens. Roberts and Baldwin Fight to Protect U.S. Producers against Ridiculous EU Trade Demands on Names of Meat Products," press release, April 4, 2014.

¹⁵⁵ A. Marshall, "Vilsak: Biotech, Geographical Indications, Cloning Discussed at 'Historic' TTIP Meeting," *Agri*(continued...)

Vilsack indicated that the United States would not agree to EU demands to reserve certain food names for EU producers. Others note that the GI debate in the T-TIP negotiation threatens U.S. commercial interests by blocking current and future U.S. exports of agricultural products (particularly cheese exports), discriminating against U.S. branded products that have greatly expanded the visibility and demand for certain GI products, and creating inconsistency in EU lists of generic terms (for example, through the inclusion of new and expanded protected names, such as feta). 157

Many U.S. food producers are also members of the Consortium for Common Food Names (CCFN), along with producers in other countries including Canada, Mexico, Argentina, Chile, and Costa Rica. This group aims to protect the right to use common food names and protect legitimate food-related GIs. ¹⁵⁸ Among the U.S. agricultural groups that are supporting these efforts are the Wine Institute, the American Farm Bureau Federation, Agri-Mark, the International Dairy Foods Association, the American Cheese Society, the American Meat Institute, and the Northwest Horticultural Council. ¹⁵⁹

Some U.S. agricultural industry groups, however, are trying to create a system similar to the EU GI system for U.S. agricultural producers. Specifically, the American Origin Products Association (AOPA) is seeking to protect American Origin Products (AOPs) in the marketplace from fraud and deceptive labeling, increase the value-added for all AOPs as a distinct food category, and create a national system to recognize AOPs through certification, among other goals. AOPA contends that "GIs respond to new trends in consumer demand, including the growth in a 'foodie' culture; a consumer-driven interest in wine education; the creation of new specialty meats and cheeses; the search for food with a story and a greater demand for regional products." Members include Napa Valley Vintners, California Dried Plum Board, Cuatro Puertas/New Mexico Native Chile Peppers, the Ginseng Board of Wisconsin, the Idaho Potato Commission, the International Maple Syrup Institute, the Kona Coffee Farmers Association, the Maine Lobstermen's Association, Missouri Northern Pecan Growers, and Vermont Maple Sugar Makers.

This divide is particularly evident in the U.S. wine industry, ¹⁶³ which had largely considered some of its concerns regarding the use of traditional and semi-generic names, among other related bilateral trade concerns, to have been partly addressed following bilateral negotiations and the existing agreement on wine in the 2006 U.S.-EU Agreement on Trade in Wine. The 2006 agreement addressed a range of issues regarding wine production, labeling, and import requirements and was intended to establish predictable conditions for bilateral wine trade. Among the key provisions in the 2006 agreement were measures regarding the U.S. industry's use of 16 "semi-generic" names of wine that originate in the EU (including Sherry, Chablis, and Chianti) as well as the use of certain traditional labeling terms (such as Chateau and Vintage). The EU also

(...continued)

Pulse, June 17, 2014.

¹⁵⁶ World Trade Online, "Vilsak Shoots Down EU GI Demands in Meeting with Agriculture Ministers," June 16, 2014.

¹⁵⁷ Babcock, "Common Names or Protected Property?"

¹⁵⁸ CCFN, "Our Mission," http://www.commonfoodnames.com/the-issue/our-mission/.

¹⁵⁹ CCFN, "Supporters," http://www.commonfoodnames.com/about-us/supporters/.

¹⁶⁰ AOPA, "What We Stand For," http://www.aop-us.org/what-we-stand-for.html.

¹⁶¹ N. Potenza Denis, "Industry Speaks Up as GI Talks Continue in DC," Specialty Food News, June 5, 2014.

¹⁶² AOPA, "Current Members," http://www.aop-us.org/current-members.html.

¹⁶³ See, for example, A. Alvarez, "U.S. Vintners Fracture over TTIP Wine Debate," June 13, 2016; and *Inside U.S. Trade*, "TTIP Debate over Semi-Generics Highlights Rift Among U.S. Winemakers," August 14, 2014.

agreed to accept all current U.S. winemaking practices and establish a process to approve new practices. Despite this agreement, ongoing trade concerns include GIs and "semi-generic" terms, market access issues regarding "traditional" terms, new winemaking practices and related technical issues, and issues related to "regulatory coherence" (especially testing and certification). For more information on the agreement, see CRS Report R43658, *The U.S. Wine Industry and Selected Trade Issues with the European Union*.

Not only have EU officials publicly declared their intentions to maintain GI protections as part of the T-TIP negotiations, ¹⁶⁴ but the EU's tabled March 2016 proposals included annex lists with roughly 200 protected food and agricultural products, including meats and cheese, fruits and vegetables, and wines and spirits. ¹⁶⁵ EU member state Greece has also threatened to veto T-TIP unless GIs are protected, ¹⁶⁶ including feta cheese—a name claimed by the Greeks under the EU's GI regime. According to dairy industry representatives, cheese names on the EU's GI list represent about 14% of U.S. cheese production, valued at approximately \$4.2 billion per year. ¹⁶⁷ More recent reports suggest that the EU might consider prioritizing this list to roughly 50 GIs. ¹⁶⁸

The EU's March 2016 proposal further notes the need to include specific GI provisions in T-TIP, given perceived shortcomings in the U.S. system relating to GIs. ¹⁶⁹ Among the types of concerns the EU cites regarding the PTO system are registration and judicial costs, ineffective protection against fraud and infringements, and misleading indications of origin. ¹⁷⁰ USTR continues to maintain that the U.S. trademark system provides adequate protection for European products in the United States. ¹⁷¹

Given concerns voiced primarily by the U.S. dairy industry and the seeming reluctance of either party to compromise on GIs, some have speculated whether this issue would need to be addressed at a higher political level than the T-TIP negotiators. ¹⁷²

For more information, see CRS Report R44556, *Geographical Indications in the Transatlantic Trade and Investment Partnership (T-TIP) Negotiations*.

Next Steps

The T-TIP negotiations present Congress with the challenge of whether the United States and the EU will be able to conclude a final agreement that is "comprehensive and high standard." Such an outcome depends on a number of factors. The United States and the EU, like all economies, have offensive and defensive interests. These include recognition that some sectors are import-

¹⁶⁴ See, for example, Reuters, "EU Says German Sausages Not at Risk in U.S. Trade Deal," January 6, 2015.

¹⁶⁵ EC, "Agriculture and Geographical Indications (GIs) in TTIP: A Guide to the EU's Proposal," March 21, 2016. Text and Annex lists for protected products are available at http://trade.ec.europa.eu/doclib/press/index.cfm?id=1477.

¹⁶⁶ EurActiv, "Greece to Block TTIP Unless Geographical Indications Are Protected," May 17, 2016.

¹⁶⁷ C. Hough, "The EU Is Trying to Grab All the Cheese," *Politico*, June 8, 2016.

¹⁶⁸ World Trade Online, "U.S., EU to Increase Tariffs Subject to Immediate Elimination, but Clash on Eliminating All," April 29, 2016.

¹⁶⁹ EC, "The European Commission Paper on Geographical Indications (GIs) in the EU-U.S. Transatlantic Trade and Investment Partnership," March 21, 2016, http://trade.ec.europa.eu/doclib/press/index.cfm?id=1477.

¹⁷⁰ Ibid. See also presentation by Anna Beatrice Ciorba, General Directorate for Hygiene, Food Safety and Nutrition, EU Ministry of Health, April 28, 2016.

¹⁷¹ I. Kullgren, "GIs or Bust in TTIP Talks," *POLITICO Pro Agriculture*, June 16, 2016.

¹⁷² World Trade Online, "TTIP Round Produces Signs of New Flexibilities on GIs, Services Exceptions," April 29, 2015.

sensitive, including certain agricultural products, which may constrain the level of ambition in the T-TIP negotiations. For more information on the overall status of the negotiations, see CRS Report R43387, *Transatlantic Trade and Investment Partnership (T-TIP) Negotiations*.

Addressing agricultural market access and other non-tariff barriers is an important goal for many on both sides of the negotiation. A study by a European organization identified agri-business and multinational food companies as the leading constituency lobbying European leadership on aspects of the T-TIP negotiation in terms of the number of contacts with government officials. 173 Given a number of sensitive agricultural products—such as beef, pork, poultry, dairy, rice, and fruits and vegetables—along with regulatory differences between the United States and the EU. particularly regarding SPS matters, some have questioned whether the agreement might exclude agricultural products altogether. Officials on both sides have suggested that an agreement that does not include agriculture would not be acceptable. Senate leadership has expressed its expectation that any final T-TIP agreement should have "a strong framework for agriculture." 174 U.S. food and agriculture organizations have also indicated their expectation that a T-TIP deal address agriculture, including EU non-tariff trade barriers. ¹⁷⁵ In addition, USTR is urging completion of the negotiation given that the EU has negotiated agreements with a number of U.S. trading partners—including Canada, Vietnam, and Singapore—and is actively negotiating bilateral agreements with other countries, including Japan, Mexico, Brazil, Argentina, India, and others. 176

The impact of Brexit on the T-TIP negotiation remains unclear. The UK is a close ally of the United States and has been one of the strongest advocates of T-TIP among the EU bloc. Also, in general, the regulatory framework of the UK's food industries and actions taken by its Food Standards Agency is often more aligned with those in the United States. The Were the UK to break with the EU, it could lose its preferential market access under a T-TIP agreement. Previously, USTR had indicated that the United States is "not particularly in the market for free trade agreements with individual countries" when addressing the possibility that the UK might separate from the EU. However, since the Brexit vote, some in Congress have indicated the possibility of the United States negotiating a separate bilateral FTA with the UK. As the UK begins the process of exiting the EU, it will likely remain subject to the same tariffs and trade-related measures as countries outside of the network of U.S. FTAs. The near-term prospects for U.S. agricultural producers, however, are likely to be impacted given the sharp drop in the value of the

¹⁷³ Corporate Europe Observatory, "TTIP: A Lose-Lose Deal for Food and Farming," July 8, 2014, http://corporateeurope.org/international-trade/2014/07/ttip-lose-lose-deal-food-and-farming.

¹⁷⁴ Letter from Senate leadership to Ambassador Froman, USTR, April 22, 2016. Also, *Agri-Pulse*, interview with Ambassador Darci Vetter, USTR Agricultural Negotiator, May 10, 2016.

¹⁷⁵ See, for example, letter to USTR and USDA leadership from leading U.S. food and agricultural trade associations, June 22, 2016; and letters to USTR from a coalition of 60 organizations, including American Farm Bureau Federation, American Meat Institute, Grocery Manufacturers Association, and National Association of State Departments of Agriculture, among others (January 2012 and November 2012).

¹⁷⁶ Ambassador Michael Froman, remarks at the National Council of Farmer Cooperatives' Washington Conference, June 14, 2016.

¹⁷⁷ See, for example, C. Ansell and D. Vogel, *What's the Beef? The Contested Governance of European Food Safety* (Cambridge, MA: MIT Press, 2006); and T. Karst, "Brexit Could Create Trade Shifts," June 30, 2016. The Food Standards Agency was created by the Food Standards Act 1999, which defines its powers and duties in UK law.

¹⁷⁸ L. Cerulus, "Froman Tells UK: No to EU Means No to Trade Deal," *PoliticoPro*, October 28, 2015.

¹⁷⁹ See, for example, M. Cassella, "Ryan Calls for Post-Brexit Trade Deal with U.K.," *Politico*, June 28, 2016; and House Resolutions proposed by Representatives Charles W. Dent and Gregory W. Meeks.

British pound relative to the U.S. dollar following the Brexit vote, effectively making U.S. exports more expensive in the UK.

Stakeholders have expressed concern that the T-TIP negotiations have not advanced as quickly as hoped and that political momentum and public support for the negotiation has waned. Some hope that the successful conclusion of the Trans-Pacific Partnership (TPP) negotiations might inject new momentum into the T-TIP negotiations. At the same time, many in the U.S. agricultural sectors are looking to the TPP for indications on how certain proposals in T-TIP could be negotiated, particularly on issues such a regulatory coherence and GI names. Stakeholders in the United States are also looking to other ongoing separate negotiations between the EU and countries such as Canada, Japan, and Mexico. They are tracking how those negotiations might address certain SPS and GI issues and are concerned about the potential implications for global agricultural trade under these preferential agreements between the EU and its trading partners, as well as establishing precedent on certain issues.

¹⁸⁰ For information on how agricultural issues have been negotiated in the TPP agreement, see CRS Report R44337, *American Agriculture and the Trans-Pacific Partnership (TPP) Agreement*; and also CRS In Focus IF10412, *TPP: Taking the Measure of the Agreement for U.S. Agriculture*.

Appendix. EU's Application of the Precautionary Principle

The precautionary principle remains central to the EU's risk management policy regarding food safety and animal and plant health, among other concerns. It was reportedly referenced as part of the 1992 treaty establishing the EU, and its use was further outlined in a 2000 communication and then formally established in EU food legislation in 2002 (Regulation EC No 178/2002). The EU's regulatory definition (Article 7) states:

In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

The EU's 2000 communication further outlines guidelines for applying the precautionary principle, including implementation, the basis for invoking the principle, and the general standards of application. In international trade, under EU law, application of the precautionary principle provides for "rapid response" to address "possible danger to human, animal, or plant health, or to protect the environment" and can be used to "stop distribution or order withdrawal from the market of products likely to be hazardous." Although its application may not be used as a pretext for protectionist measures, many countries have challenged as "protectionist" some EU actions that have invoked the precautionary principle.

No universally agreed-upon definition of the precautionary principle exists, and many differently worded or conflicting definitions can be found in international law. However, within the context of the WTO and the SPS agreement, the precautionary principle (or precautionary approach) allows a country to set higher standards and methods of inspecting products. It also allows countries to take "protective action"—including restricting trade of products or processes—if they believe that scientific evidence is inconclusive regarding their potential impacts on human health and the environment (provided the action is consistent and not arbitrary). The text box provides more information on the precautionary principle in the context of the WTO and SPS agreement. For more information, see CRS Report R43450, *Sanitary and Phytosanitary (SPS) and Related Non-Tariff Barriers to Agricultural Trade*.

¹⁸¹ Commission of European Communities, "Communication from the Commission on the Precautionary Principle," COM(2000) 1, Brussels, February 2, 2000.

¹⁸² Regulation (EC) No 178/2002 of the European Union Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Other information is at http://eur-lex.europa.eu.

 $^{^{183}}$ EU, "Summaries of EU Legislation," http://europa.eu/legislation_summaries/consumer_safety/ $132042_en.htm.$

The Precautionary Principle, WTO and the SPS Agreement

Within the context of the WTO and the SPS agreement, the precautionary principle (or precautionary approach) allows a country to take "protective action"—including restricting trade of products or processes—if it believes that scientific evidence is inconclusive regarding their potential impacts on human health and the environment.

According to the WTO, applicable rules state:

Member countries are encouraged to use international standards, guidelines and recommendations where they exist. When they do, they are unlikely to be challenged legally in a WTO dispute. However, members may use measures which result in higher standards if there is scientific justification. They can also set higher standards based on appropriate assessment of risks so long as the approach is consistent, not arbitrary. And they can to some extent apply the "precautionary principle", a kind of "safety first" approach to deal with scientific uncertainty.

Provisions allowing countries to use different standards and methods of inspecting products are also contained within the SPS agreement:

- **Paragraph 6 of the Preamble** encourages harmonization of national SPS measures with international standards without requiring countries to change their sovereignly determined appropriate levels of health protection.
- Article 3.3 explicitly permits members to adopt SPS measures that are more stringent than measures based on the relevant international standards.
- Article 5.7 allows a country "to take provisional measures when sufficient scientific evidence does not exist to permit a final decision on the safety of a product or process." If a country imposes a provisional (temporary) SPS measure, it must seek "additional information necessary for a more objective assessment of risk, and must review the SPS measure within a reasonable period of time."

The WTO acknowledges that "the need to take precautionary actions in the face of scientific uncertainty has long been widely accepted," particularly in the fields of food safety and plant and animal health protection. Examples might include a sudden outbreak of an animal disease that is suspected of being linked to imports, which may require a country to impose certain trade restrictions while further information about the source and extent of the outbreak is assessed. Accordingly, some argue that the precautionary principle suggests that if scientific evidence is insufficient or inconclusive regarding potential dangers to human, environmental, animal, or plant health of a product or practice, that product or practice may be prohibited if reasonable grounds for concern exist.

Source: WTO, "Glossary Term: Precautionary Principle;" WTO, "Understanding the WTO Agreement on Sanitary and Phytosanitary Measures;" WTO, "Current Issues, 8.2 The Precautionary Principle;" United Nations, *Trading Precaution: The Precautionary Principle and the WTO*, November 2005.

Application of the precautionary principle by some countries remains an ongoing source of contention in international trade, particularly for the United States, and is often cited as a reason why some countries may restrict imports of some food products and processes. A 2013 paper authored by researchers at several U.S. land grant universities and USDA cites the following criticisms of the precautionary principle: (1) the ambiguity and lack of definition of the precautionary principle; (2) the arbitrariness in how it is used and applied; and (3) bias against new technologies, such as biotechnology and nanotechnology. The authors conclude that the precautionary principle has become "unworkable and counterproductive." 185

Many U.S. agricultural and food organizations contend that the precautionary principle undermines sound science and innovation and results in "unjustifiable restrictions" on U.S. exports. ¹⁸⁶ The stated policy of the U.S. Chamber of Commerce is also to support a "science-

¹⁸⁴ G. Marchant et al., "Impact of the Precautionary Principle on Feeding Current and Future Generations," CAST Issue Paper 52-QC, June 2013.

¹⁸⁵ Ibid.

¹⁸⁶ See, for example, letters from several U.S. agriculture and food groups to Michael Froman, Deputy National Security Advisor for International Economic Affairs, May 20, 2013; and letter from several agro-chemical groups to the presidents of the European Commission, European Council, and European Parliament, October 24, 2013.

based approach to risk management, where risk is assessed based on scientifically sound and technically rigorous standards" and "oppose the domestic and international adoption of the precautionary principle as a basis for regulatory decision making." Its strategy aims to "educate consumers, businesses, and federal policymakers about the implications of the precautionary principle."

Several U.S. agricultural and manufacturing groups continue to oppose the EU's application of the precautionary principle and argue that it allows EU regulations to disregard scientific evidence demonstrating that certain food products and processes are safe, based on evidence from available scientific risk assessments, allowing the EU and other importing countries to engage in disguised protectionism. Some in the U.S. agriculture and food industry are urging that the T-TIP agriculture negotiations address the use and application of the principle, which is central to the EU's risk management policy. Some contend that the EU's use of the precautionary principle contributes to its practice of taking a generally "more risk-averse approach to risk management" allows EU regulators to put in place restrictions on products or processes when they believe that scientific evidence on their potential impact on human health or the environment is inconclusive." Many in the United States claim that "science-based decision making and not the precautionary principle must be the defining principle in setting up mechanisms and systems" to address SPS concerns. Other T-TIP objectives for some U.S. agricultural and food groups include calls for changes to the EU's approach for approving and labeling biotechnology products.

However, some wish to further strengthen the EU's application of the precautionary principle and believe the SPS agreement too severely limits its use. Many in the EU continue to defend the application of the precautionary principle to a range of agricultural issues, and U.S. agriculture and food groups have expressed concern that "a resolution regarding the T-TIP passed by the European Parliament on April 24 [2013] strongly expresses the intent of the EU to maintain the precautionary principle, which would undermine sound science and ultimately the agreement itself."

Some groups have expressed concern that the T-TIP negotiations might cause the EU to relax its food safety laws and standards, which some believe to be superior to laws and standards in the United States. ¹⁹⁵ The EU's proposals on regulatory cooperation, released in March 2016, restate

¹⁸⁷ U.S. Chamber of Commerce, "Precautionary Principle," August 4, 2010.

¹⁸⁸ See, for example, letter from many U.S. agriculture trade associations to Froman, May 20, 2013; and statement from U.S. Chamber of Commerce and Council for Agricultural Science and Technology (CAST), "Impact of the Precautionary Principle on Feeding Current and Future Generations" CAST Issue paper 52, June 2013.

¹⁸⁹ Testimony by James Grueff of Decision Leaders before the House of Representatives, Committee on Ways and Means, Subcommittee on Trade, May 16, 2013.

¹⁹⁰ Inside U.S. Trade, "EU Will Not Change 'Precautionary Principle' Through Trade Talks: Official," May 20, 2013.

¹⁹¹ G. Marchant et al., "Impact of the Precautionary Principle." See also policy statements at the Business Coalition for Transatlantic Trade website.

¹⁹² Friends of the Earth International, *Trade and People's Food Sovereignty*, position paper, April 2003. The document also charged that "the Codex is so heavily influenced by food and chemical corporations that the standards it sets may be lower than those already in place in many nations."

¹⁹³ Food Chemical News, "European Parliament Backs U.S.-EU Trade Deal Talks but Draws 'Red Lines," June 14, 2013; and *Inside U.S. Trade*, "EU Will Not Change 'Precautionary Principle."

¹⁹⁴ Letters from several U.S. agriculture and food groups to Froman, May 20, 2013. See also *World Trade Online*, "U.S. Food, Ag Groups Want 'Precautionary Principle' on Table in EU Talks," May 22, 2013.

¹⁹⁵ Center for Food Safety, "Trade Matters: Transatlantic Trade and Investment Partnership (TTIP) Impacts on Food and Farming," May 2014; Institute for Agriculture and Trade Policy, "How New Free Trade Agreements Would (continued...)

the ability of each party to "apply its fundamental principles governing regulatory measures in its jurisdiction, for example in the areas of risk assessment and risk management," which some broadly interpreted as covering the EU's continued application of the precautionary principle. 197

Recent developments further illustrate this divide. Negotiating documents made public in May 2016 were said to suggest, based on the analysis by environmental advocates who released them, that the EU had made compromises in certain areas, including the "precautionary principle." ¹⁹⁸ Related criticisms suggest that a U.S. proposal regarding the EU's biotechnology approval process would likely commit the EU to faster approvals of GE products and would change EU policies regarding traces of GE product found in otherwise approved GE or conventional shipments. 199 Policymakers in both the United States and EU have discredited this interpretation of events. Press reports indicate that USTR has called these interpretations as "misleading" and "wrong." 200

The EU's trade commissioner, Cecilia Malmström, responded that the EU's proposal for regulatory coherence that was tabled during the February 2016 round and made public "includes references to the precautionary principle, and points out our well-established public consultation procedures that are open to all stakeholders." Specifically, the introduction to the EU's proposal stated: "We stress our commitment to enhance or maintain the levels of protection in public policy areas, to respect the right to regulate and the application of our fundamental principles such as the precautionary principle for the EU side."²

The statement further says: "No EU trade agreement will ever lower our level of protection of consumers, or food safety, or of the environment. Trade agreements will not change our laws on GMOs, or how to produce safe beef, or how to protect the environment." Also in response to press reports, the European Parliament's trade committee chairman, Bernd Lange, said: "The S&D [Socialists and Democrats] Group demands that the EU be equally tough in upholding our own values, including safeguarding the EU's precautionary principle which guarantees high levels of protection for our citizens. We will not accept a T-TIP that includes any lowering of standards."²⁰⁴ The EU's chief negotiator, Ignacio Garcia Bercero, also dismissed media reports about negotiated changes to the EU's precautionary principle and added, "We have made crystal clear that we would not agree on anything that implies changes of our regulatory regime on

(...continued)

Undermine Food Safety," http://www.iatp.org; and D. Sarmadi, "TTIP: The Downfall of EU Agriculture," EurActiv.com, February 18, 2016.

¹⁹⁶ See EU's March 21, 2016, Regulatory Cooperation proposal, http://trade.ec.europa.eu/doclib/docs/2016/march/ tradoc_154377.pdf.

¹⁹⁷ See, for example, World Trade Online, "Greenpeace Blasts Malmstrom Response to Leak over Precautionary Principle," May 2, 2016.

¹⁹⁸ See, for example, "Sierra Club Statement on Leaked Transatlantic Trade Deal Text," press release, May 2, 2016; and Friends of the Earth Europe press statement, May 2, 2016.

¹⁹⁹ World Trade Online, "U.S. Seeks to Speed Up EU Approval of GMOs, Novel Agriculture Products," May 5, 2016. According to these reports, the U.S. proposal is reflected in the bracketed Article X.12 of the SPS chapter and covers "Regulatory Approvals for Products of Modern Agricultural Technology."

²⁰⁰ Reported by World Trade Online, "The Greenpeace TTIP Leak: A Roundup," May 2, 2016.

²⁰¹ EU, "Negotiating TTIP: Comment by Commissioner Malmström," press release, May 2, 2016.

²⁰² Available at http://trade.ec.europa.eu/doclib/press/index.cfm?id=1230#regulatory-cooperation.

²⁰³ EU, "Negotiating TTIP."

²⁰⁴ Group of the Progressive Alliance of Socialist and Democrats in the European Parliament, "TTIP Must Comply with European Values and Standards or It Will Fail, Say S&D Euro MPs," press release, May 2, 2016.

GMOs."²⁰⁵ More recently, another EU official, John Clarke, reiterated that EU "laws are not on the table" and that efforts to harmonize regulations between the United States and EU would not weaken EU food safety standards.²⁰⁶ Previously, in 2015, Garcia Bercero stated that the "EU is not going to change its food safety legislation" because of T-TIP.²⁰⁷ This position dates back even earlier.²⁰⁸

Author Contact Information

(name redacted)
Specialist in Agricultural Policy
[redacted]@crs.loc.goy7-....

²⁰⁵ World Trade Online, "U.S. Seeks to Speed Up EU Approval of GMOs, Novel Agriculture Products," May 5, 2016.

²⁰⁶ I. Kullgren, "EU Won't Budge on Food Safety, Either," *POLITICO Pro Agriculture*, June 16, 2016.

²⁰⁷ J. Vitásek, "Commission Official: The EU Is Not Going to Change Its Food Legislation Because of TTIP," EurActiv.com, January 8, 2015.

²⁰⁸ See, for example, *Food Chemical News*, "Grain Group Seeks Alignment of U.S./EU Food Safety Rules," March 7, 2014; and *Politico Pro Agriculture*, "TTIP Won't Cross 'Red Lines' on Food Safety," June 18, 2014.

EveryCRSReport.com

The Congressional Research Service (CRS) is a federal legislative branch agency, housed inside the Library of Congress, charged with providing the United States Congress non-partisan advice on issues that may come before Congress.

EveryCRSReport.com republishes CRS reports that are available to all Congressional staff. The reports are not classified, and Members of Congress routinely make individual reports available to the public.

Prior to our republication, we redacted names, phone numbers and email addresses of analysts who produced the reports. We also added this page to the report. We have not intentionally made any other changes to any report published on EveryCRSReport.com.

CRS reports, as a work of the United States government, are not subject to copyright protection in the United States. Any CRS report may be reproduced and distributed in its entirety without permission from CRS. However, as a CRS report may include copyrighted images or material from a third party, you may need to obtain permission of the copyright holder if you wish to copy or otherwise use copyrighted material.

Information in a CRS report should not be relied upon for purposes other than public understanding of information that has been provided by CRS to members of Congress in connection with CRS' institutional role.

EveryCRSReport.com is not a government website and is not affiliated with CRS. We do not claim copyright on any CRS report we have republished.