FRATINIVERGANO
EUROPEAN LAWYERS
TRADE PERSPECTIVES©

Issue No. 10 of 20 May 2011

EU Parliament calls for new cloning regulations, which could affect many beef exporting countries

Debate continues within the EU regarding the adoption of new EU regulations governing food from cloned animals. The EU Parliament's Vice-President, Mr. Gianni Pittella, has issued an urgent call for the EU Commission to present a new legislative proposal to introduce labelling information on food products derived from cloned animals and their offspring, stating that this information is a basic right for consumers. A legislative proposal on cloning will soon be prepared by the EU Commission, after which it will be transmitted to the EU Council and EU Parliament for adoption under the co-decision procedure.

The EU Institutions have discussed the regulation of trade in clones, and trade in products from cloned animals and their offspring, since a draft regulation on novel foods was originally submitted by the EU Commission to the EU Council and EU Parliament on 15 January 2008 (see more background in Trade Perspectives, Issue No. 5 of 10 March 2011). The objective of the proposal was to replace the EU's current novel foods regulation with a new regulatory regime that would encourage the development and placing on the EU market of safe, innovative foods, and ensure food safety and the protection of human health. The proposed novel foods regulation eventually failed at the conciliation stage on 29 March 2011 due to contentions over whether products of the offspring of cloned animals should be considered novel foods. To consider the products of cloned animals to be novel foods under the EU's draft regulation on novel foods was seen as facilitating their authorisation for human consumption within the EU. The President of the EU Council called this failure a '*serious collective fiasco*' by EU Institutions. As a result of this debate, on 13 April 2011, EU Commissioner for Health and Consumer Policy, Mr. John Dalli, confirmed that products from cloned animals and their offspring will be removed from the novel foods procedure and placed in a separate legislative proposal on which work will soon begin.

A legislative proposal on cloning may include a ban on animal cloning in the EU for food production; a ban on food from cloned animals, whatever their origin; and/or a ban on any supply of clones in the EU for food production. These measures might be temporary. In addition, during the conciliation phase for the novel foods regulation, the EU Council proposed the following possible requirements to the EU Parliament: that a traceability system be required for semen and embryos from cloned animals; a traceability system be required for the live offspring of cloned animals; labelling be required for fresh meat from the offspring of cloned cattle; and labelling be required for all other foods from the offspring of cloned animals.

As food (*e.g.*, fresh meat) from the offspring of clones arguably cannot be distinguished from food from other animals, a complete traceability system would be needed. Any such mechanism could be costly and burdensome to put into place, as it would require detailed tracing of all generations of offspring for the species used for food production. Furthermore,

such a strict traceability system may lead to a *de facto* ban on imports of any food of animal origin (*i.e.,* meat, milk and processed products) from third countries where cloning technology exists, or which may have imported reproductive material from clones. These proposed measures could cause significant trade distortions on agricultural exports (*i.e*, beef) from countries such as Argentina, Australia, Botswana, Brazil, Chile, Canada, and the US.

Depending on how they are drafted and applied, EU measures restricting trade in clones and products from cloned animals and their offspring may conflict with a number of WTO obligations, such as the prohibition on quantitative restrictions found in Article XI of the General Agreement on Tariffs and Trade (hereinafter, GATT), and the obligations in Article 2 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter, SPS Agreement) to apply a sanitary measure only to the extent necessary to protect human or animal health, only if based on sufficient scientific evidence, and not in a manner which would constitute a disguised restriction on international trade. The EU measures may also contravene Article 5.1 of the SPS Agreement, which requires that an SPS measure be based on an appropriate assessment of the risks to human or animal life or health. On the other hand, the EU could try to argue that its restrictive measures are necessary on the basis of the precautionary principle in Article 5.7 of the SPS Agreement, and under some of the general exceptions found in Article XX of the GATT, such as the Article XX(a) public morals exception and the Article XX(b) exception for human and animal health. The extent to which WTO law may allow future EU measures to be justified on such grounds will depend on the actual context, design and effect of the EU measures, and may ultimately need to be assessed under the WTO dispute settlement mechanism.

MEPs have raised another issue, arguing that the EU Council's legal experts had concluded in an internal memo that bans on food from cloned animals and food from their offspring could be justified on the basis of consumers' ethical considerations. However, according to the press, a Council spokesman contested the conclusion drawn by MEPs as inaccurate and incomplete, concluding that all measures under discussion (including bans of food from cloned animals and from their offspring) entail risks as far as their compatibility with WTO rules is concerned. WTO law would only permit a ban on food from animal clones and their offspring if these products could not be considered to be '*like products'* to natural ones. Otherwise, the measure would likely violate Article III:4 of the GATT or Article 2.1 of the Agreement on Technical Barriers to Trade (hereinafter, TBT Agreement). However, should the EU not be able to prove that these products are not '*like products*', both GATT and TBT rules would be breached. According to the EU Council's Legal Service, '*the EU might be able to justify the infringement of the GATT under its Article XX, but might face condemnation under the TBT Agreement which, contrary to the GATT, provides for no exception for public morals considerations*'. This speaks volumes to the type of discussions and interpretative divisions that seem to exist among EU Institutions on the possible WTO inconsistency of the envisaged measures.

The commercial consequences of the EU's planned cloning legislation are significant. The complex technical, regulatory and commercial requirements of a cloning traceability and labelling system may impose high costs on commercial parties active in the production and trade of animal products in all major food exporting countries. Moreover, it is clear that the proposed labelling and traceability requirements would affect not only cloned animals, meat and by-products from cloned animals, and products from naturally-conceived offspring of clones, but also producers of '*natural*' or '*organic*' meat products. Interested parties should closely monitor the next steps taken by the EU Institutions, and be prepared to participate in shaping the upcoming EU legislation by interacting with EU Institutions, their own governments, relevant trade associations and affected stakeholders.

Warning labels for sweetener aspartame introduced in the EU Food Information Regulation

Ahead of the July 2011 plenary vote of the EU Parliament in the second reading of the Food Information Regulation (hereinafter, FIR), a new controversy on a well-known subject has emerged. Members of the EU Parliament have introduced a mandatory warning label for the sweetener aspartame. According to this amendment, foods containing aspartame/aspartame-acesulfame salt authorised pursuant to *Regulation (EC) No. 1333/2008 on food additives* would have to include the following specification: '*contains aspartame (a source of phenylalanine)*' and '*might be unsuitable for pregnant women*'.

The first part of this warning message (*i.e.*, '*contains a source of phenylalanine*') is not new to EU food law, and was already included in *Commission Directive 94/54/EC of 18 November 1994 concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Council Directive 79/112/EEC*. This provision aims at protecting sufferers of the rare inherited disease phenylketonuria (PKU), who cannot safely consume aspartame, as they are unable to properly metabolise the amino acid phenylalanine (one of the components of aspartame). Similar to the above provision in EU law, in the US, foods containing aspartame are legally required to state '*Phenylketonurics: Contains Phenylalanine*'.

The phenylalanine warning and other additional labelling particulars for sweeteners, in particular, '*with sweetener(s)*' (for foods containing a sweetener or sweeteners), '*with sugar(s) and sweetener(s)*' (for foods containing both an added sugar or sugars and a sweetener or sweeteners), and '*excessive consumption may produce laxative effects*' (for foods containing more than 10% added polyols), are already part of EU food law and shall be consolidated in the FIR.

However, the proposed warning label '*might be unsuitable for pregnant women*' for aspartame-containing foods is a novelty, and it is likely to have a negative impact on foods containing aspartame. The concerns behind the EU Parliament's initiative seem to stem from two studies: a Danish epidemiological study that found a statistical association between the consumption of soft drinks containing sweeteners and an increased risk of preterm delivery, and a study from Italy reporting an increased incidence of cancer amongst male mice fed with very high doses of aspartame.

In February 2011, however, the European Food Safety Authority (hereinafter, EFSA) concluded that the two studies do not provide adequate reasons to reconsider previous safety assessments of aspartame or of other sweeteners currently authorised in the EU, and that there is no reason to revise the previously established Acceptable Daily Intake (ADI) for aspartame of 40 mg/kg of body weight.

Assessing the proposed warning message under EU food law, it is obvious that measures relating to food safety must be underpinned by strong science. *Regulation No. 178/2002* governing general food law establishes that the three inter-related components of risk analysis (*i.e.*, risk assessment, risk management and risk communication) provide the basis for food law. Scientific assessment of risk must be undertaken in an independent, objective, and transparent manner based on the best available science. The EFSA has repeatedly considered the matter and currently sees no reason to change its opinion with respect to the safety of aspartame sweeteners or of foods containing aspartame.

Insofar as there is an international trade dimension (aspartame is used and traded worldwide, in particular in the US, Canada, Japan and South America), international trade law may also provide for alternative or additional instruments to scrutinise the legality of the

EU Parliament's proposal and address its trade-related aspects, thus minimising the negative commercial impact of the proposed EU measures. The SPS Agreement arguably offers the most relevant international legal framework for this type of scrutiny. If the EU Parliament's proposal were to be adopted as it stands, there would be the potential for EU trading partners to challenge the new aspartame warning label rule at the WTO by primarily arguing under the SPS Agreement that the measure is not based on science, but also that it is disproportionate (vis-à-vis the objectives being sought), overly-burdensome, and more trade-restrictive than necessary (*de facto* if not *de jure*).

On the other side, it appears that some Members of the European Parliament are arguing that the proposed measure, independently of the safety assessment made by EFSA or by industry, would be based on the precautionary principle, since there is a certain degree of uncertainty over the safety of aspartame and its effect on pregnant women. Recourse to the precautionary principle is allowed by Article 5.7 of the SPS Agreement, but the EU would have to argue that the relevant scientific evidence (*i.e.*, the one currently available and on the basis of which EFSA is deeming aspartame sweeteners or foods containing aspartame to be safe) is insufficient. Any such decision by the EU would have to be provisional in nature and the EU would then have to seek to obtain the additional scientific information necessary for a more objective assessment of risk, and review its measure accordingly, within a reasonable period of time.

It is not yet certain whether the warning label on aspartame will finally be included in the new regulation and, if so, what specific language will be used. The next phase of the EU legislative process, before the vote in second reading (scheduled for 5 July 2011), is a series of '*trialogues*' between the EU Parliament, the EU Council and the EU Commission. Since neither the original proposal by the EU Commission, nor the EU Council's first reading position, included the warning message for pregnant women, it is highly likely that the final language will not be that of the current proposal by the EU Parliament. However, interested stakeholders should monitor the legislative developments closely, and be aware that WTO rules and mechanisms (for instance, the technical discussions within the SPS Committee) may provide useful and effective legal arguments which may ensure that the final EU measure is one that is based on science, is not disproportionate vis-à-vis the legitimate objectives being pursued by the EU, and restricts and/or distorts trade as little as possible.

The EU Parliament has voted on an EU Commission draft regulation on transitional arrangements for BITs

On 10 May 2011, the EU Parliament voted on an EU Commission proposal establishing transitional arrangements for bilateral investment treaties (hereinafter, BITs) signed between EU Member States and third countries.

The Treaty on the Functioning of the European Union (hereinafter, the TFEU) established the exclusive competence of the EU regarding foreign direct investment. In accordance with Article 2(1) of the TFEU, only the EU may legislate and adopt legally binding acts in areas in which exclusive competence has been conferred upon it. The resulting challenge has been how to manage the approximately 1,200 BITs signed between EU Member States and third parties prior to the entry into force of the TFEU on 1 December 2009, in light of the newly acquired competence of the EU.

In order to minimise the risk of legal uncertainty among investors and EU Member States, and due to the absence of an explicit transitional regime in the TFEU clarifying the legal status of these BITs, the EU Commission proposed on 7 July 2010 a draft regulation establishing transitional arrangements for BITs between EU Member States and third

countries (see Trade Perspectives, Issue No. 14 of 16 July 2010). The proposed draft regulation would '*grandfather*' EU Member State BITs and set out the conditions and the procedure under which EU Member States are authorised to amend or conclude bilateral agreements with third countries relating to investment, as well as to maintain in force existing BITs with third parties. In particular, under the text proposed by the EU Commission, EU Member States would have to notify the EU Commission of the particular BITs that they wish to maintain. The EU Commission would then have to review and decide whether to authorise them, thus rendering the particular BIT legal under the TFEU framework. The proposed regulation would allow the EU Commission to review these BITs, and withdraw legal authorisation for a particular BIT, if it conflicts with EU law, overlaps with an EU investment agreement with the same country, or conflicts with general EU investment policy. The EU Commission would also retain the power to grant authorisation to EU Members to enter into negotiations to amend existing BITs or conclude new agreements.

One of the most significant amendments adopted by the EU Parliament relates to the EU's proposed procedure for authorising existing BITs. According to the EU Parliament's amendments, the EU Commission would no longer be required to conduct a review of each BIT that EU Member States wish to maintain and that has been notified to that effect. Instead, the authorisation procedure appears to have been '*decoupled*' from BIT reviews. This means that the legality of notified agreements would not depend on mandatory reviews. Whereas this appears to grant greater legal certainty to parties to these agreements, it would also enable the EU Commission to focus its review on those BITs that EU Member States have concluded with perceived strategic partners with which the EU may wish to conclude future agreements. The EU Commission would always retain the power to withdraw authorisation of notified BITs in certain specified cases.

In addition, as amended by the EU Parliament, the draft regulation now provides that authorisation must be withdrawn where the EU has already ratified an agreement with the same third country relating to investment. Although it is not specified, this provision would appear to apply as of the entry into force of the regulation. As the concept of 'agreement relating to investment' is not defined in the proposed amendment (or elsewhere in the proposed regulation), it is not clear to what extent the concept of 'agreement relating to investment' would cover broader investment commitments contained in EU trade agreements (*i.e.*, bilateral and multilateral, such as the GATS). In addition, it is not clear to what extent this provision would be useful where there are no conflicting provisions between an 'agreement relating to investment' concluded by the EU and a third party, on one side, and a previously-concluded BIT between an EU Member State and the same third party, on the other side. For example, in the EU-South Korea Free Trade Agreement, recently ratified by the EU, the scope of the investment obligations covers so far the conditions of market access and investment liberalisation, thus complementing the scope of EU Member States' BITs with South Korea, which mainly cover the treatment of investments '*post-entry*' (*i.e.*, the treatment of investments after they have been made in the host country). Perhaps this provision could benefit from further clarification.

The EU Parliament's adoption at first reading of a report amending the EU Commission's draft regulation sets the stage for the next phases of the co-decision procedure. The draft regulation will now be assessed by the EU Council and voted upon in a qualified majority vote. In light of the EU Parliament's proposed amendments, the EU Council may propose its own amendments to the draft regulation. Ultimately, the EU Parliament and EU Council will have to jointly approve the text of the draft regulation before it can be adopted.

The EU and Japan discuss the launch of FTA negotiations

The EU and Japan continue to discuss the possible launch of formal FTA negotiations this year. Japan has been urging the EU to agree to the start of formal negotiations at a bilateral EU – Japan summit to be held in Brussels on 27-28 May 2011. However, Mr. Karel de Gucht, EU Commissioner for Trade, has announced that the EU will not agree to begin FTA negotiations at the upcoming summit, stating that the bilateral summit will instead be an opportunity to achieve further progress on the outstanding issues that have so far delayed the start of FTA negotiations.

Since 2010, a joint EU – Japan High Level Group has held informal negotiations on removing EU – Japanese trade barriers relating to tariffs, non-tariff measures, services, IP rights, and government procurement. On 11 May 2011, the EU Parliament adopted a non-binding resolution supporting the signing of a FTA with Japan, provided that Japan accords meaningful market access opportunities to EU firms, and that the EU obtains the right to invoke safeguard measures to protect European manufacturers in market areas in which the Japanese have a strong presence, such as electronics, automobiles and machines (along the lines of what the EU achieved in its FTA with South Korea). Japan's desire to conclude a FTA with the EU has increased further following the EU's signing of a FTA with South Korea: Japan fears that some of its firms may lose market share to South Korean rival companies and it is eager to maintain competitive market access to the EU in light of many other FTAs being negotiated by the EU with some of its direct competitors.

EU-Japan trade is worth 120 billion EUR per year, with Japan currently being the EU's sixth-largest export market. The major trade irritants for the EU appear to be Japanese restrictions on access to its government procurement market and Japanese non-tariff trade barriers. EU firms have noted that they have access to a smaller relative proportion of the Japanese government procurement market than do Japanese firms in the EU market: a 22 billion EUR Japanese government procurement market reportedly available to EU firms in 2007 (0.5% of Japan's GDP), compared to an EU one of 312 billion EUR (2.5% of the EU's GDP) available to Japanese firms in 2007. The EU has also insisted that, prior to beginning FTA talks, Japan must reduce certain non-tariff barriers, such as strength and safety certification procedures for construction materials and cars. Finally, the EU has raised concerns about Japan's investment climate, urging Japan to better enforce its *Anti-Monopoly Act* and to open its economy to more foreign direct investment from the EU. Japan, for its part, has insisted that the EU agree to begin FTA talks before Japan addresses these non-tariff trade barriers. Japan has also reportedly requested that the EU reduce import tariffs for Japanese products such as automobiles, digital cameras, and liquid crystal display televisions. Arguably, all these reciprocal requests should be part and parcel of the actual FTA negotiations, rather than apparent posturing exercises which are probably not conducive to an early start of commercial talks.

A FTA between the EU and Japan could bring large gains to both parties: it has been estimated that the removal of tariff and non-tariff barriers in an EU – Japan FTA could result in over 40 billion EUR of additional EU exports to Japan, and more than 50 billion EUR of additional exports from Japan to the EU. However, Japan's recent announcement that it will delay a decision on whether to join the talks on a Trans-Pacific Partnership FTA (hereinafter, TPP) between the US, Australia, Brunei, Chile, Malaysia, New Zealand, Singapore, Peru, and Vietnam could affect the nature of an eventual FTA between the EU and Japan. One commentator has noted that parallel TPP and EU FTA negotiations could allow the EU and US to coordinate positions vis-à-vis Japanese negotiators on certain key issues, such as market access for automobiles or standards for electric vehicles. Japan's delay in joining the TPP talks may thus affect the strength of the EU's '*negotiating hand*' in eventual EU – Japan FTA talks. Business parties with an interest in these major trade markets should monitor closely the developments towards a possible EU – Japan FTA and actively work with their

respective governments and trade negotiators to ensure that the full list of current trade impediments and future commercial objectives are on the negotiating table when FTA talks start.

Recently Adopted EU Legislation

Market Access

- *Commission Implementing Regulation (EU) No 488/2011 of 19 May 2011 withdrawing the suspension of submission of applications for import licences for sugar products under certain tariff quotas*

- *Commission Implementing Regulation (EU) No 489/2011 of 19 May 2011 on the allocation of import rights for applications lodged during the first seven days of May 2011 under the tariff quotas opened by Regulation (EC) No 616/2007 for poultrymeat*

- *Commission Implementing Regulation (EU) No 482/2011 of 18 May 2011 suspending submission of applications for import licences for sugar products under certain tariff quotas*

- *Commission Implementing Regulation (EU) No 439/2011 of 6 May 2011 on a derogation from Regulation (EEC) No 2454/93 in respect of the definition of the concept of originating products used for the purposes of the scheme of generalised tariff preferences to take account of the special situation of Cape Verde regarding exports of certain fisheries products to the European Union*

- *Council Decision of 12 April 2011 on the conclusion of a Protocol to the Partnership and Cooperation Agreement establishing a partnership between the European Communities and their Member States, of the one part, and the Republic of Moldova, of the other part, on a Framework Agreement between the European Union and the Republic of Moldova on the general principles for the participation of the Republic of Moldova in Union programmes*

- *Council Decision of 16 September 2010 on the signing, on behalf of the European Union, and provisional application of the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part*

Trade Remedies

- *Commission Regulation (EU) No 477/2011 of 17 May 2011 initiating an investigation concerning the possible circumvention of anti-dumping measures imposed by Council Implementing Regulation (EU) No 511/2010 on imports of certain molybdenum wires originating in the People's Republic of China by imports of certain molybdenum wires consigned from Malaysia and Switzerland, whether declared as originating in Malaysia and Switzerland or not, and making such imports subject to registration*

- *Council Implementing Regulation (EU) No 475/2011 of 13 May 2011 amending Regulation (EC) No 1425/2006 imposing a definitive anti-dumping duty on*

imports of certain plastic sacks and bags originating in the People's Republic of China and Thailand, and terminating the proceeding on imports of certain plastic sacks and bags originating in Malaysia

- *Council Implementing Regulation (EU) No 469/2011 of 13 May 2011 amending Regulation (EC) No 1292/2007 imposing a definitive anti-dumping duty on imports of polyethylene terephthalate (PET) film originating in India*

- *Commission Decision of 13 May 2011 accepting an undertaking offered in connection with the anti-dumping proceeding concerning imports of zeolite A powder originating in Bosnia and Herzegovina*

- *Council Implementing Regulation (EU) No 464/2011 of 11 May 2011 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of zeolite A powder originating in Bosnia and Herzegovina*

- *Council Implementing Regulation (EU) No 457/2011 of 10 May 2011 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of melamine originating in the People's Republic of China*

- *Commission Regulation (EU) No 446/2011 of 10 May 2011 imposing a provisional anti-dumping duty on imports of certain fatty alcohols and their blends originating in India, Indonesia and Malaysia*

- *Council Implementing Regulation (EU) No 451/2011 of 6 May 2011 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of coated fine paper originating in the People's Republic of China*

- *Council Implementing Regulation (EU) No 452/2011 of 6 May 2011 imposing a definitive anti-subsidy duty on imports of coated fine paper originating in the People's Republic of China*

- *Council Implementing Regulation (EU) No 443/2011 of 5 May 2011 extending the definitive countervailing duty imposed by Regulation (EC) No 598/2009 on imports of biodiesel originating in the United States of America to imports of biodiesel consigned from Canada, whether declared as originating in Canada or not, and extending the definitive countervailing duty imposed by Regulation (EC) No 598/2009 to imports of biodiesel in a blend containing by weight 20 % or less of biodiesel originating in the United States of America, and terminating the investigation in respect of imports consigned from Singapore*

- *Council Implementing Regulation (EU) No 444/2011 of 5 May 2011 extending the definitive anti-dumping duty imposed by Regulation (EC) No 599/2009 on imports of biodiesel originating in the United States of America to imports of biodiesel consigned from Canada, whether declared as originating in Canada or not, and extending the definitive anti-dumping duty imposed by Regulation (EC) No 599/2009 to imports of biodiesel in a blend containing by weight 20 % or less of biodiesel originating in the United States of America, and terminating the investigation in respect of imports consigned from Singapore*

- *Council Implementing Regulation (EU) No 453/2011 of 4 May 2011 imposing a definitive anti-dumping duty on imports of furfuraldehyde originating in the People's Republic of China following an expiry review pursuant to Article 11(2) of Regulation (EC) No 1225/2009*

- *Council Implementing Regulation (EU) No 474/2011 of 3 May 2011 amending Regulation (EC) No 1425/2006 imposing a definitive anti-dumping duty on imports of certain plastic sacks and bags originating, inter alia, in the People's Republic of China*

Food and Agricultural Law

- *Commission Implementing Regulation (EU) No 470/2011 of 16 May 2011 amending Regulation (EC) No 828/2009 laying down detailed rules of application for the marketing years 2009/2010 to 2014/2015 for the import and refining of sugar products of tariff heading 1701 under preferential agreements*

- *Commission Implementing Regulation (EU) No 467/2011 of 13 May 2011 fixing the import duties in the cereals sector applicable from 16 May 2011*

- *Commission Regulation (EU) No 460/2011 of 12 May 2011 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards the maximum residue level for chlorantraniliprole (DPX E-2Y45) in or on carrots*

- *Commission Implementing Regulation (EU) No 463/2011 of 12 May 2011 amending the representative prices and additional import duties for certain products in the sugar sector fixed by Regulation (EU) No 867/2010 for the 2010/11 marketing year*

- *Commission Implementing Regulation (EU) No 456/2011 of 11 May 2011 amending the representative prices and additional import duties for certain products in the sugar sector fixed by Regulation (EU) No 867/2010 for the 2010/11 marketing year*

Other

- *Council Decision of 13 May 2011 establishing the position to be taken by the European Union within the General Council of the World Trade Organization on the accession of the Republic of Vanuatu to the World Trade Organization*

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