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Questions arising from the EU Commission's proposal on biofuels

On 17 October 2012, the EU Commission presented its 'Proposal for a Directive of the European Parliament and of the Council amending Directive 98/70/EC relating to the quality of petrol and diesel fuels and amending Directive 2009/28/EC on the promotion of the use of energy from renewable sources' (see Trade Perspectives, Issue No. 17 of 21 September 2012). The proposal was transmitted to the EU Parliament on 18 October 2012, where the Committee on Environment, Public Health and Food Safety is competent for discussing it and issuing a report, so that it will be subsequently debated during a plenary session of the EU Parliament, in accordance with the co-decision procedure.

The proposal provides, inter alia, for the inclusion of ILUC (Indirect Land Use Change) as a relevant factor for the calculation of greenhouse gas emissions for purposes of compliance with the 6% target established by the EU Fuel Quality Directive. To that end, the proposal provides for a primary distinction between biofuels, which results in two main categories: 1) biofuels produced from food crops or 'first generation biofuels'; and 2) biofuels produced from feedstocks that do not create an additional demand for land, or 'advanced biofuels'. The former category envisages the attribution of different estimated ILUC emissions to biofuels, resulting in different 'polluting values', depending on which feedstock has been used. In particular, the proposal foresees that: (i) biofuels from cereals and other starch-rich crops be attributed 12 gCO2/MJ (grams of carbon dioxide per megajoule of energy); (ii) biofuels from sugars be attributed 13 gCO2/MJ; and (iii) biofuels from oil crops be attributed 55 gCO2/MJ. Further, the aforementioned distinction within 'first generation biofuels' (i.e., food crop-based biofuels) is not mirrored in the category of 'advanced biofuels', which are all assigned an identical ILUC factor equivalent to 0. According to the EU Commission, such values are the result of a precautionary approach to the best available state of science, inasmuch as a 2010 report from the EU Commission identified a number of 'deficiencies and uncertainties' regarding the modelling employed to estimate the effects of ILUC, the greenhouse gas emissions of which are 'inherently uncertain', since they require projecting the impacts of past data into the future, an operation that can never be entirely authenticated.

Should the proposal eventually be adopted into EU law, it would need to be in compliance with the obligations of the EU under international trade law. As it stands, arguably, the EU Commission proposal may lead to discrimination between: (i) food crop-based biofuels and 'advanced biofuels'; and (ii) among food crop-based biofuels, on the basis of the feedstock used for the production of biofuel. A measure attributing different 'polluting values' to different biofuels might affect the EU's obligations under Articles I and III of the General Agreement on Tariffs and Trade (hereinafter, GATT), which prevent WTO Members from according discriminatory treatment to imported products, vis-à-vis 'like' products of foreign or domestic origin. Such a measure would, in fact, result in discriminatory treatment granted on the basis of process and production methods, a factor not affecting the 'likeness' of products

under WTO case law, unless it impacts on the physical characteristics of the final products in a way that they no longer constitute 'like' products.

The measure envisaged by the proposal may also arguably constitute a technical regulation within the meaning of Annex 1:1 of the WTO Agreement on Technical Barriers to Trade (hereinafter, TBT Agreement), which allows WTO Members to adopt measures directed (inter alia) at the protection of the environment. Reflecting the basic non-discrimination principles under Articles I and III of the GATT, Article 2.1 of the TBT Agreement establishes that technical regulations cannot result in discrimination vis-à-vis 'like' products of national origin, or originating in any other country. In addition, Article 2.2 of the TBT Agreement requires that technical regulations not create unnecessary barriers to trade and be based on scientific evidence. By attributing a higher 'polluting value' to biofuels from food crops, and, within such latter category, to biofuels obtained from oil crops, the EU measure may likely result in import restrictions, which could also be contrary to Article XI of the GATT.

The EU Commission appears to shield its decision to classify biofuels in the aforementioned manner behind the lack of certain scientific evidence regarding greenhouse emissions from ILUC, asserting that the classification described above is the best possible one, in light of the current stage of scientific developments. It is noted that the asymmetric differentiation between 'first generation biofuels' and 'advanced biofuels', as well as the sub-categorisation of biofuels only within the former group, recalls the controversy raised by the EU Commission proposal for an implementing measure under the EU Fuel Quality Directive, aimed at establishing the life-cycle greenhouse gas intensity of fossil fuels (for further background and developments thereon, see Trade Perspectives, Issue No. 9 of 7 May 2010, Issue No. 7 of 8 April 2011, and Issue No. 5 of 9 March 2012). The latest draft of that proposal attributed higher 'polluting values' to fossil fuels obtained through oil sands and shale oil, which would result in discrimination vis-à-vis fossil fuels from certain WTO Members.

In this light, the question of whether the EU proposal concerning ILUC embodies a somewhat arbitrary distinction among biofuels is at least pertinent, and the possible impact on the EU's WTO obligations should certainly be taken into consideration by EU institutions and key stakeholders in the decision-making process leading to the adoption of this proposal.

WTO Members discuss the use of the ad hoc mediation mechanism for SPS disputes

WTO Members agreed to accelerate deliberations in order to strengthen the ad hoc consultations or negotiations mechanism on specific SPS issues, also referred to as the 'good offices' of the Chairperson or 'ad hoc mediation' mechanism. At the meeting of the Committee on Sanitary and Phytosanitary Measures (hereinafter, 'SPS Committee') on 18-19 October 2012, WTO Members confirmed their intention to continue discussing with the objective of settling outstanding issues by March 2013.

The ad hoc mediation mechanism is foreseen in Article 12.2 of the Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter, 'SPS Agreement'), which requires the SPS Committee to encourage and facilitate ad hoc consultations or negotiations among WTO Members on specific SPS issues. Despite offering an opportunity to achieve a solution through consultations on SPS issues, without resorting to dispute settlement procedures, to date this mechanism has only been used on three occasions (i.e., in March 1998, with respect to measures relating to citrus canker taken by the EU; in November 1998, with respect to restrictions on wheat and oilseeds maintained by Poland; and in 2001, with respect to import restrictions on bovine semen maintained by India). On 11 July 2005, during the Second Review of the operation and implementation of the SPS Agreement, WTO

Members agreed to enhance this mechanism as a practical route to facilitate the definition of an accord.

A joint proposal was submitted by Argentina and the US, with a view to implementing a formal procedure for the ad hoc mediation mechanism. This proposal served as the basis for the WTO Secretariat's revised proposal (hereinafter, 'Recommended Procedure for ad hoc consultations'), which was first circulated in 2009 and then again in 2011, following the receipt of comments from WTO Members. The current version of the proposed procedure contemplates, inter alia, that any WTO Member may request consultations in writing at any time, indicating: 1) the SPS measure or technical issue of concern; and 2) the reasons for the request, as well as any preliminary concern regarding such measure or technical issue, including any relevant provisions of the SPS Agreement and/or international standards. In addition, the proposed procedure specifies that WTO Members should raise the issue as a specific trade concern (STC) at a meeting of the SPS Committee prior to the request of the ad hoc mediation mechanism and that Member participation in consultations is voluntary. The consulting Members shall set a date for the consultations within 45 days from the acceptance of the consultations request and it must aim at completing consultations within a reasonable period of time. The general outcome of the consultations will be reported by the Chairperson of the SPS Committee, only with approval from both consulting Members.

During the last SPS Committee meeting in October 2012, WTO Members discussed whether the procedure would result in a compulsory or voluntary mechanism; the timetables for the stages of the procedure, including a possible non-binding target of six months for completing the consultations; the role of the mediator; the transparency and confidentiality in the procedure; and the relationship with other proposals currently tabled within the DDA negotiations to address non-tariff barriers (i.e., under the so-called NAMA negotiations). WTO Members approached consensus on some points, such as the role of the mediator or 'facilitator', which would be limited in order to facilitate communication between the consulting Members. The voluntary or compulsory nature of such system stands as a key issue of these negotiations, especially in light of the possible resort to dispute settlement procedures: the current proposed draft provides that Members' participation in these consultations is voluntary, that the ad hoc mediation procedure does not add or detract from existing rights and obligations under the WTO agreements, and that the decision of whether to participate in consultations, and all positions taken by Members during such consultations, are without prejudice to the rights or obligations under the WTO. WTO Members will need to clarify the relationship between the two remedies, in particular whether the SPS consultations can be conducted simultaneously to the WTO dispute settlement process (for example, the good offices, conciliation and mediation mechanism envisaged under Article 5 of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes may be triggered only after the request for WTO dispute settlement consultations has been filed) or whether one mechanism should be de facto 'exhausted' first.

International trade in agricultural products is increasingly being affected by the adoption and maintenance of regulations, standards and requirements aiming at ensuring food safety and the protection of human, animal and plant life and health. These measures, which are generally aimed at pursuing legitimate objectives, often result in barriers to trade and pose high compliance burdens on exporting countries, particularly developing countries. Considering the difficulties connected to the compliance with SPS regulations and the uncertainties linked to existing tools for solving specific trade concerns arising from the application of SPS measures (i.e., the forum provided by the SPS Committee, where trade concerns may remain on the agenda for years without WTO Members getting any closer to a solution, and the WTO dispute settlement process, which is relatively lengthy for these sorts of disputes and requires governments to devote additional resources), a mechanism that would facilitate a swifter solution of SPS-related disputes is certainly welcome and may be

useful to timely and effectively address SPS issues that are of key commercial relevance to exporting countries.

Substantial amendment of the EU regulatory framework on medical devices and international trade implications

On 26 September 2012, the EU Commission published two proposals for the substantial amendment of the regulatory framework on medical devices: a 'Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009', and a 'Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices' (hereinafter, IVD).

The reasons for the recast of the EU regulatory framework are four-fold: 1) there has been enormous technological and scientific progress in the past 20 years; 2) EU Member States do not always interpret and implement the current rules (set out in Directives) in the same way; 3) it is not always possible to trace medical devices back to their supplier (i.e., rules on traceability are needed), and 4) supervision of the independent conformity assessment bodies (the so-called 'notified bodies') by EU Member States need to be strengthened to ensure that all bodies have the necessary competence to carry out the pre-market assessment of medical devices. In addition, the IVD proposal clarifies the scope in respect to genetic tests, companion diagnostics and diagnostic services offered at a distance.

Medical devices include products such as sticking plasters, contact lenses, dental filling materials, x-ray machines, pacemakers, breast implants or hip replacements. IVDs include products such as devices used to ensure the safety of blood transfusion (inter alia, blood grouping), detect infectious diseases (inter alia, HIV), monitor diseases (inter alia, diabetes) and perform blood chemistry (inter alia, cholesterol measurement). Medical devices should not be mistaken for medicinal products (often referred to as pharmaceuticals), which are subject to a separate regulatory framework. The main difference between medical devices and medicinal products is the principal mode of action, which is typically physical for a medical device (inter alia, mechanical action, physical barrier, replacement of or support to organs or body functions).

Medical devices and IVDs produced in a third country and imported into the EU are subject to the same rules as medical devices produced within the EU. According to the proposed rules, before placing a device on the EU market, importers shall ensure the following: 1) that the appropriate conformity assessment procedure has been carried out by the manufacturer; 2) that an authorised representative has been designated by the manufacturer; 3) that the EU declaration of conformity and the technical documentation has been drawn up by the manufacturer; 4) that the device bears the required CE marking of conformity; 5) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use and EU declaration of conformity; and 6) that, where applicable, a Unique Device Identification (hereinafter, UDI) has been assigned by the manufacturer.

International harmonisation is an objective that the proposals claim to envisage. With a view to converging the regulatory requirements for medical devices in major economies into EU law, the EU Commission proposes to incorporate relevant guidelines developed at international level by the former Global Harmonization Task Force (GHTF) and the new International Medical Device Regulators Forum (IMDRF), established in October 2011 by representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, the EU, Japan and the US, as well as the World Health Organization (WHO).

The proposals set the basis for an European UDI system to allow traceability of medical devices. The proposed rules resemble the 'one step forward and one step back' approach on traceability in the food sector, established in Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law. To ensure identification within the supply chain, for medical devices, other than custom-made or investigational devices, economic operators shall be able to identify the following: 1) any economic operator to whom they have supplied a device; 2) any economic operator that has supplied them with a device; and 3) any health institution or healthcare professional to whom they have supplied a device. Upon request, the economic operator shall inform the competent authorities accordingly. The UDI system shall allow the identification and traceability of devices and shall consist of the following: 1) a device identifier specific to a manufacturer and a device model, providing access to certain information; 2) a production identifier that identifies data related to the unit of device production; 3) placement of the UDI on the label of the device; 4) storage of the UDI by the economic operators and the health institutions through electronic means; and 5) establishment of an electronic system on UDI. The UDI for traceability of medical devices is a further element, which is similar to specific requirements set out in the food sector, in particular, the 'unique identifier for genetically modified organisms' established in Regulation (EC) No. 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and Commission Regulation (EC) No. 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms.

Manufacturers of medical devices in third countries will have to comply with all these requirements in order to access the EU market. Under Article 2.2 of the TBT Agreement, technical regulations shall not create unnecessary obstacles to international trade and shall not be more trade-restrictive than necessary to fulfil a legitimate objective. Such legitimate objectives under the TBT Agreement include, inter alia, the protection of human health or safety. According to Article 5.1(2) of the TBT Agreement, also conformity assessment procedures shall not create unnecessary obstacles to international trade. The question is whether the requirements set out in the proposals, in particular the pre-market assessment of medical devices and the traceability rules, may be considered more burdensome than necessary (de facto, if not de jure) in order to achieve the legitimate objective of protecting human health. This would require a detailed analysis, particularly in light of the specific application and the effects that it may have on trade.

On 23 October 2012, the EU notified both proposals on medical devices to other WTO Members through the WTO Committee on Technical Barriers to Trade, as proposed technical regulations according to Article 2.9(2) of the TBT Agreement and proposed conformity assessment procedures according to Article 5.2(2) of the TBT Agreement. WTO Members have 90 days from date of notification for the submission of comments and observations on the proposed measures. The EU Commission claims that the proposals are not a direct response to the recent serious incidents involving medical implants (inter alia, breast implants, metal-on-metal hip replacements), which have put patient safety at risk and have damaged the confidence of patients, consumers and healthcare professionals in the safety of the devices. The EU Commission states that it has been working on the revision of the medical device legislation for a long time and much before the said incidents. However, these incidents have revealed further shortcomings of the current legislation, especially with regard to post-market controls, and have been analysed in order to ensure that the proposals are solid enough to prevent such problems from occurring again. As to the next steps in the EU legislative procedure, the EU Commission proposals need to be adopted by the EU Parliament and the EU Council in the ordinary legislative procedure, which is expected for 2014. The ensuing Regulations would then gradually come into effect from 2015 to 2019.

The EU Commission Annual Report indicates trends in EU trade defence activities during 2011

The 2011 Report from the EU Commission on the EU's Anti-Dumping, Anti-Subsidy and Safeguard Activities (hereinafter, the 30th Annual Report) was submitted to the EU Parliament on 19 October 2012. The document summarises the number of investigations undertaken in 2011, in addition to describing the recent measures taken in order to ensure consistency with the EU's WTO obligations.

The 30th Annual Report indicates an upswing in the number of investigations initiated in 2011, with an increase to 21 from 18 in the previous year, and an increase in the number of definitive measures imposed (i.e., up from 9 in 2010 to 13 in 2011). In terms of the country of origin of the investigated exports, the trend in this period has continued to mirror the developments of the last number of years, in that most of the newly initiated investigations have related to developing economies, with the bulk of these relating to China. While there was a slight decrease in the trend this year, of the 14 new investigations initiated by the EU Commission, 8 of these involved China. The volume of cases concerning China must be put into perspective, however, taking into account statistics released by DG Trade in September 2012, which have confirmed that the EU's trade defence instruments cover only around 1% of its total imports from China.

The product scope of the anti-dumping and anti-subsidy investigations initiated in 2011 has also generally followed that of previous investigations in the period beginning in 2007, in that while investigations were initiated vis-à-vis a wide range of sectors, there continues to be a heavy concentration of cases relating to the chemicals and metal products sectors, both industrial goods that compete largely on price. Interestingly, during this period were anti-subsidy and anti-dumping investigations concerning US imports of bioethanol, in response to US federal and state subsidy programmes, which are now likely to close without the imposition of further measures (see Trade Perspectives, Issue No. 19 of 19 October 2012).

The 30th Annual Report also refers to two WTO dispute settlement reports concerning EU anti-dumping measures issued in 2011. Both the European Communities – Definitive Anti-Dumping Measures on Certain Iron or Steel Fasteners from China (hereinafter, EC – Fasteners from China) and the European Union – Anti-Dumping Measures on Certain Footwear from China (hereinafter, EU – Footwear from China) cases led to an amendment of Article 9(5) of the EU's Regulation (EC) No. 1225/2009 of 30 November 2009 on protection against dumped imports from countries not members of the European Community (hereinafter, the EU's Basic Anti-dumping Regulation). Article 9(5) of the EU's Basic Anti-Dumping Regulation provides that an anti-dumping duty will normally be determined for each supplier except (i) where it is 'impracticable' to specify a duty for each supplier; and (ii) where the provisions for non-market economy countries (i.e., countries in which domestic prices are controlled by the State) apply. In these cases, the said article permits a single 'country-wide' duty to be applied to all suppliers and imports from that country. However, this article also allows an individual duty to be specified for producers from non-market economy countries, in cases where the producers concerned meet five criteria regarding market-based business practices (i.e., the 'individual treatment test'). The Appellate Body in EC – Fasteners from China found that, with respect to producers based in WTO Member countries with non-market economies, Article 9(5) of the EU's Basic Anti-Dumping Regulation was inconsistent with Articles 6.10 and 9.2 of the WTO Anti-Dumping Agreement in that it conditioned the determination of individual anti-dumping duties on the fulfilment of the 'individual treatment test' contained in that provision (see Trade Perspectives, Issue No. 15 of 29 July 2011). On 3 September 2012, the EU's Official Journal published Regulation 765/2012 of 13 June 2012 amending Council Regulation (EC) No. 1225/2009 on protection against dumped imports from countries not members of the European Community, which

amended the article, clarifying that, as a rule, individual duties shall be calculated for each supplier.

This year's report can be read in the context of the EU's initiative for the Modernisation of Trade Defence Instruments, which aims at examining a set of rules that has remained largely unchanged for the last 16 years. The initiative has been aided by an independent evaluation study of trade defence instruments, which was published on 16 March 2012, and a public consultation on the 'Initiative on Modernisation of Trade Defence Instruments' by DG Trade, which has recently been concluded. The independent study mentioned that the protection given by EU Trade Defence Instruments is moderately greater than what would be required to offset injury and also suggested that the length of the period of investigation prior to the imposition of provisional measures should be shortened. The contributors to the public consultation process supported proposals to improve the EU's protection against retaliatory measures, specifically the ex-officio initiation of investigations, as well as improving transparency in trade defence investigations. While the findings of the 30th Annual Report offer an insight into the application of trade defence instruments within the EU, it remains to be seen whether the EU Commission's ongoing modernisation initiative will lead to a change in these trends in the near future.

Recently Adopted EU Legislation

Trade Remedies

- *Commission Regulation (EU) No. 973/2012 of 22 October 2012 initiating an investigation concerning the possible circumvention of anti-dumping measures imposed by Council Regulation (EC) No. 925/2009 on imports of certain aluminium foil originating in the People's Republic of China by imports of certain aluminium foil in rolls which are not annealed and of a width exceeding 650 mm originating in the People's Republic of China, and making such imports subject to registration*

- *Council Implementing Regulation (EU) No. 986/2012 of 22 October 2012 clarifying the scope of the definitive anti-dumping duties imposed by Regulation (EC) No 383/2009 on imports of certain PSC wires and strands originating in the People's Republic of China*

- *Council Implementing Regulation (EU) No. 987/2012 of 22 October 2012 reimposing a definitive anti-dumping duty on imports of ironing boards originating in the People's Republic of China, manufactured by Zhejiang Harmonic Hardware Products Co. Ltd*

Customs Law

- *Regulation (EU) No. 978/2012 of the European Parliament and of the Council of 25 October 2012 applying a scheme of generalised tariff preferences and repealing Council Regulation (EC) No. 732/2008*

- *Commission Implementing Regulation (EU) No. 927/2012 of 9 October 2012 amending Annex I to Council Regulation (EEC) No. 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff*

Food and Agricultural Law

- *Commission Implementing Directive 2012/31/EU of 25 October 2012 amending Annex IV to Council Directive 2006/88/EC as regards the list of fish species susceptible to Viral haemorrhagic septicaemia and the deletion of the entry for Epizootic ulcerative syndrome*

- *Commission Implementing Regulation (EU) No. 991/2012 of 25 October 2012 concerning the authorisation of zinc chloride hydroxide monohydrate as feed additive for all animal species*

- *Commission Implementing Regulation (EU) No. 990/2012 of 25 October 2012 concerning the authorisation of a preparation of Propionibacterium acidipropionici (CNCM MA 26/4U) as a feed additive for all animal species*

- *Commission Implementing Regulation (EU) No. 988/2012 of 25 October 2012 amending Implementing Regulation (EU) No. 543/2011 as regards the trigger levels for additional duties on mandarins and satsumas, clementines, artichokes, oranges and courgettes*

Other

- *Council Decision of 22 October 2012 establishing the position to be taken by the European Union within the General Council of the World Trade Organisation on the accession of the Lao People's Democratic Republic to the WTO*

- *Commission Implementing Decision of 4 October 2012 on the European Union financial contribution to national programmes of six Member States (Germany, Lithuania, the Netherlands, Poland, Sweden and the United Kingdom) in 2012 for the collection, management and use of data in the fisheries sector (notified under document C(2012) 6838)*

- *Decision of the Council and of the Representatives of the Governments of the Member States, meeting within the Council of 7 June 2012 on the signing, on behalf of the Union, and provisional application of the Common Aviation Area Agreement between the European Union and its Member States and the Republic of Moldova*

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